DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–H005C–2006–0870]

RIN 1218–AB76

Occupational Exposure to Beryllium

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

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is amending its existing standards for occupational exposure to beryllium and beryllium compounds. OSHA has determined that employees exposed to beryllium at the previous permissible exposure limits face a significant risk of material impairment to their health. The evidence in the record for this rulemaking indicates that workers exposed to beryllium are at increased risk of developing chronic beryllium disease and lung cancer. This final rule establishes new permissible exposure limits of 0.2 micrograms of beryllium per cubic meter of air (0.2 μg/m³) as an 8-hour time-weighted average and 2.0 μg/m³ as a short-term exposure limit determined over a sampling period of 15 minutes. It also includes other provisions to protect employees, such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping.

OSHA is issuing three separate standards—for general industry, for shipyards, and for construction—in order to tailor requirements to the circumstances found in these sectors.

DATES: *Effective date:* The final rule becomes effective on March 10, 2017.

Compliance dates: Compliance dates for specific provisions are set in § 1910.1024(o) for general industry, § 1915.1024(o) for shipyards, and § 1926.1124(o) for construction. There are a number of collections of information contained in this final rule (*see* Section IX, OMB Review under the Paperwork Reduction Act of 1995). Notwithstanding the general date of applicability that applies to all other requirements contained in the final rule, affected parties do not have to comply with the collections of information until the Department of Labor publishes a separate document in the **Federal Register** announcing the Office of Management and Budget has approved them under the Paperwork Reduction Act.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates Ann Rosenthal, Associate Solicitor of Labor for Occupational Safety and Health, Office of the Solicitor of Labor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, to receive petitions for review of the final rule.

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) 693–1950.

SUPPLEMENTARY INFORMATION: The preamble to the rule on occupational exposure to beryllium follows this outline:

Citation Method

In the docket for the beryllium rulemaking, found at *http://www.regulations.gov,* every submission was assigned a document identification (ID) number that consists of the docket number (OSHA–H005C–2006–0870) followed by an additional four-digit number. For example, the document ID number for OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis is OSHA–H005C–2006–0870–0426. Some document ID numbers include one or more attachments, such as the National Institute for Occupational Safety and Health (NIOSH) prehearing submission (*see* Document ID OSHA–H005C–2006–0870–1671).

When citing exhibits in the docket, OSHA includes the term ''Document ID'' followed by the last four digits of the document ID number, the attachment number or other attachment identifier, if applicable, page numbers (designated ''p.'' or ''Tr.'' for pages from a hearing transcript). In a citation that contains two or more document ID numbers, the document ID numbers are separated by semi-colons. In some sections, such as Section V, Health Effects, author names and year of study publication are included before the document ID number in a citation, for example: (Deubner *et al.,* 2011, Document ID 0527). Where multiple exhibits are listed with author names and year of study publication, document ID numbers after the first are in parentheses, for example: (Elder *et al.,* 2005, Document ID 1537; Carter *et al.,* 2006 (1556); Refsnes *et al.,* 2006 (1428)).

I. Executive Summary

This final rule establishes new permissible exposure limits (PELs) for beryllium of 0.2 micrograms of beryllium per cubic meter of air (0.2 μg/m³) as an 8-hour time-weighted average (TWA) and 2.0 μg/m³ as a short-term exposure limit (STEL) determined over a sampling period of 15 minutes. In addition to the PELs, the rule includes provisions to protect employees such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping. OSHA is issuing three separate standards—for general industry, for shipyards, and for construction—in order to tailor requirements to the circumstances found in these sectors. There are, however, numerous common elements in the three standards.

The final rule 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, Pertinent Legal Authority, for a full discussion of OSH Act legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to beryllium. OSHA has also developed estimates of the risk of beryllium-related diseases, assuming exposure over a working lifetime, at the preceding PELs as well as at the revised PELs and action level. Comments received on OSHA's preliminary analysis, and the Agency's final findings, are discussed in Section V, Health Effects, Section VI, Risk Assessment, and Section VII, Significance of Risk. OSHA finds that employees exposed to beryllium at the preceding PELs are at an increased risk of developing chronic beryllium disease (CBD) and lung cancer. As discussed in Section VII, OSHA concludes that exposure to beryllium constitutes a significant risk of material impairment to health and that the final rule will substantially lower that risk. The Agency considers the level of risk remaining at the new TWA PEL to still be significant. However, OSHA did not adopt a lower TWA PEL because the Agency could not demonstrate technological feasibility of a lower TWA PEL. The Agency has adopted the STEL and ancillary provisions of the rule to further reduce the remaining significant risk.

OSHA's examination of the technological and economic feasibility of the rule is presented in the Final Economic Analysis and Regulatory Flexibility Analysis (FEA), and is summarized in Section VIII of this preamble. OSHA concludes that the final PELs are technologically feasible for all affected industries and application groups. Thus, OSHA concludes that engineering and work practice controls will be sufficient to reduce and maintain beryllium exposures to the new PELs 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 PELs cannot be achieved even when employers implement all feasible engineering and work practice controls, use of respirators will be required.

OSHA developed quantitative estimates of the compliance costs of the 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 rule and an evaluation of the 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 finds that compliance with the requirements of the rule is economically feasible in every affected industry sector.

The final rule includes several major changes from the proposed rule as a result of OSHA's analysis of comments and evidence received during the comment periods and public hearings. The major changes are summarized below and are fully discussed in Section XVI, Summary and Explanation of the Standards. OSHA also presented a number of regulatory alternatives in the Notice of Proposed Rulemaking (80 FR 47566, 47729–47748 (8/7/2015). Where the Agency received substantive comments on a regulatory alternative, those comments are also discussed in Section XVI. A full discussion of all regulatory alternatives can be found in Chapter VIII of the Final Economic Analysis (FEA).

Scope. OSHA proposed to cover occupational exposures to beryllium in general industry, with an exemption for articles and an exemption for materials containing less than 0.1% beryllium by weight. OSHA has made a final determination to cover exposures to beryllium in general industry, shipyards, and construction under the final rule, and to issue separate standards for each sector. The final rule also provides an exemption for materials containing less than 0.1% beryllium by weight only where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level of 0.1 $\mu g/m^3$ as an 8-hour TWA under any foreseeable conditions.

Exposure Assessment. The proposed rule would have required periodic exposure monitoring annually where employee exposures are at or above the action level but at or below the TWA PEL; no periodic monitoring would have been required where employee exposures exceeded the TWA PEL. The final rule specifies that exposure monitoring must be repeated within six months where employee exposures are at or above the action level but at or below the TWA PEL, and within three months where employee exposures are above the TWA PEL or STEL. The final rule also includes provisions allowing the employer to discontinue exposure monitoring where employee exposures fall below the action level and STEL. In addition, the final rule includes a new provision that allows employers to assess employee exposures using any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium (*i.e.,* the ''performance option'').

Beryllium Work Areas. The proposed rule would have required the employer to 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. As discussed in the Summary and Explanation section of this preamble, OSHA has narrowed the definition of beryllium work area in the final rule from the proposal. The final rule now limits the requirement to work areas containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level. The final rule expands the exposure requirement to include work areas containing a process or operation where there is potential dermal contact with beryllium based on comments from public health experts that relying solely on airborne exposure omits the potential contribution of dermal exposure to total exposure. See the Summary and Explanation section of this preamble for a full discussion of the relevant comments and reasons for changes from the proposed standard. Beryllium work areas are not required under the standards for shipyards and construction.

Respiratory Protection. OSHA has added a provision in the final rule requiring the employer to provide a powered air-purifying respirator (PAPR) instead of a negative pressure respirator where respiratory protection is required by the rule and the employee requests a PAPR, provided that the PAPR provides adequate protection.

Personal Protective Clothing and Equipment. The proposed rule would have required use of protective clothing and equipment where employee exposure exceeds, or can reasonably be expected to exceed the TWA PEL or STEL; where employees' clothing or skin may become visibly contaminated with beryllium; and where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds. The final rule requires use of protective clothing and equipment where employee exposure exceeds, or can reasonably be expected to exceed the TWA PEL or STEL; or where there is a reasonable expectation of dermal contact with beryllium.

Medical Surveillance. The exposure trigger for medical examinations has been revised from the proposal. The proposed rule would have required that medical examinations be offered to each employee who has worked in a regulated area (*i.e.,* an area where an employee's exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL) for more than 30 days in the last 12 months. The final rule requires that medical examinations be offered to each employee who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year. A trigger to offer periodic medical surveillance when recommended by the most recent written medical opinion was also added the final rule. Under the final rule, the licensed physician recommends continued periodic medical surveillance for employees who are confirmed positive for sensitization or diagnosed with CBD. The proposed rule also would have required that medical examinations be offered annually; the final rule requires that medical examinations be offered at least every two years.

The final medical surveillance provisions have been revised to provide enhanced privacy for employees. The rule requires the employer to obtain a written medical opinion from a licensed physician for medical examinations provided under the rule but limits the information provided to the employer to the date of the examination, a statement that the examination has met the requirements of the standard, any recommended limitations on the employee's use of respirators, protective clothing, and equipment, and a statement that the results of the exam have been explained to the employee. The proposed rule would have required that such opinions contain additional information, without requiring employee authorization, such as the 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, and any recommended limitations upon the employee's exposure to beryllium. In the final rule, the written opinion provided to the employer will only include recommended limitations on the employee's exposure to beryllium, referral to a CBD diagnostic center, a recommendation for continued periodic medical surveillance, or a recommendation for medical removal if the employee provides written authorization. The final rule requires a separate written medical report provided to the employee to include this additional information, as well as detailed information related to the employee's health.

The proposed rule would have required that the licensed physician provide the employer with a written medical opinion within 30 days of the examination. The final rule requires that the licensed physician provide the employee with a written medical report and the employer with a written medical opinion within 45 days of the examination, including any follow-up beryllium lymphocyte proliferation test (BeLPTs).

The final rule also adds requirements for the employer to provide the CBD diagnostic center with the same information provided to the physician or other licensed health care professional who administers the medical examination, and for the CBD diagnostic center to provide the employee with a written medical report and the employer with a written medical opinion. Under the final standard, employees referred to a CBD diagnostic center can choose to have future evaluations performed there. A requirement that laboratories performing BeLPTs be certified was also added to the final rule.

The proposed rule would have required that employers provide low dose computed tomography (LDCT) scans to employees who met certain exposure criteria. The final rule requires LDCT scans when recommended by the physician or other licensed healthcare professional administering the medical exam, after considering the employee's history of exposure to beryllium along with other risk factors.

Dates. OSHA proposed an effective date 60 days after publication of the rule; a date for compliance with all provisions except change rooms and engineering controls of 90 days after the effective date; a date for compliance with change room requirements, which was one year after the effective date; and a date for compliance with engineering control requirements of two years after the effective date.

OSHA has revised the proposed compliance dates. The final rule is effective 60 days after publication. All obligations for compliance commence one year after the effective date, with two exceptions: The obligation for change rooms and showers commences two years after the effective date; and the obligation for engineering controls commences three years after the effective date.[1]

Under the OSH Act's legal standard directing OSHA to set health standards based on findings of significant risk of material impairment and technological and economic feasibility, OSHA does not use cost-benefit analysis to determine the PEL or other aspects of the rule. It does, however, determine and analyze costs and benefits for its own informational purposes and to meet certain Executive Order requirements, as discussed in Section VIII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis and in the FEA. Table I–1—which is derived from material presented in Section VIII of this preamble—provides a summary of OSHA's best estimate of the costs and benefits of the rule using a discount rate of 3 percent. As shown, the rule is estimated to prevent 90 fatalities and 46 new cases of CBD annually once the full effects are realized, and the estimated cost of the rule is $73.9 million annually. Also as shown in Table I–1, the discounted monetized benefits of the rule are estimated to be $560.9 annually, and the rule is estimated to generate net benefits of approximately $487 annually; however, there is a great deal of uncertainty in those benefits due to assumptions made about dental workers' exposures and reductions; see Section VIII of this preamble. As that section shows, benefits significantly exceed costs regardless of how dental workers' exposures are treated.

TABLE I–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S FINAL BERYLLIUM STANDARD

[3 Percent discount rate, 2015 dollars]

Annualized Costs:	
Control Costs	$12,269,190
Rule Familiarization	180,158
Exposure Assessment	13,748,676
Regulated Areas	884,106

[1] Note that the main analysis of costs and benefits presented in this FEA does not take into account the lag in effective dates but, instead, assumes that the rule takes effect in Year 1. To account for the lag in effective dates, OSHA has provided in the sensitivity analysis in Chapter VII of the FEA an estimate of its separate effects on costs and benefits relative to the main analysis. This analysis, which appears in Table VII–16 of the FEA, indicates that if employers delayed implementation of all provisions until legally required, and no benefits occurred until all provisions went into effect, this would decrease the estimated costs by 3.9 percent; the estimated benefits by 8.5 percent, and the estimated net benefits of the standard by 9.2 percent (to $442 million).

TABLE I–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S FINAL BERYLLIUM STANDARD—Continued

[3 Percent discount rate, 2015 dollars]

Beryllium Work Areas	129,648
Medical Surveillance	7,390,958
Medical Removal	1,151,058
Written Exposure Control Plan	2,339,058
Protective Work Clothing & Equipment	1,985,782
Hygiene Areas and Practices	2,420,584
Housekeeping	22,763,595
Training	8,284,531
Respirators	320,885
Total Annualized Costs (Point Estimate)	$73,868,230
Annual Benefits: Number of Cases Prevented:	
Fatal Lung Cancers (Midpoint Estimate)	4
Fatal Chronic Beryllium Disease	86
Beryllium-Related Mortality	90
Beryllium Morbidity	46
Monetized Annual Benefits (Midpoint Estimate)	$560,873,424
Net Benefits:	
Net Benefits	$487,005,194

Sources: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (''the Act'' or ''the OSH 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 set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce'' (29 U.S.C. 651(b)(3); *see* 29 U.S.C. 654(a) (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 primary statutory provision relied upon by the Agency in promulgating health standards is section 6(b)(5) of the Act; other sections of the OSH Act, however, authorize the Occupational Safety and Health Administration (''OSHA'') to require labeling and other appropriate forms of warning, exposure assessment, medical examinations, and recordkeeping in its standards (29 U.S.C. 655(b)(5), 655(b)(7), 657(c)).

The Act provides that in promulgating standards dealing with toxic materials or harmful physical agents, such as 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'' (29 U.S.C. 655(b)(5)). Thus, ''[w]hen Congress passed the Occupational Safety and Health Act in 1970, it chose to place pre-eminent value on assuring employees a safe and healthful working environment, limited only by the feasibility of achieving such an environment'' (*American Textile Mfrs. Institute, Inc.* v. *Donovan,* 452 US 490, 541 (1981) (''*Cotton Dust*'')).

OSHA proposed this new standard for beryllium and beryllium compounds and conducted its rulemaking pursuant to section 6(b)(5) of the Act ((29 U.S.C. 655(b)(5)). The preceding beryllium standard, however, was adopted under the Secretary's authority in section 6(a) of the OSH Act (29 U.S.C. 655(a)), to adopt national consensus and established Federal standards within two years of the Act's enactment (*see* 29 CFR 1910.1000 Table Z–1). Any rule that ''differs substantially from an existing national consensus standard'' must ''better effectuate the purposes of this Act than the national consensus standard'' (29 U.S.C. 655(b)(8)). Several additional legal requirements arise from the statutory language in sections 3(8) and 6(b)(5) of the Act (29 U.S.C. 652(8), 655(b)(5)). The remainder of this section discusses these requirements, which OSHA must consider and meet before it may promulgate this occupational health standard regulating exposure to beryllium and beryllium compounds.

Material Impairment of Health

Subject to the limitations discussed below, when setting standards regulating exposure to toxic materials or harmful physical agents, the Secretary is required to set health standards that ensure that ''no employee will suffer material impairment of health or functional capacity. . .'' (29 U.S.C. 655(b)(5)). ''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 (*AFL–CIO,* 965 F.2d at 975). Thus the Agency has taken the position that ''subclinical'' health effects, which may be precursors to more serious disease, can be material impairments of health that OSHA should address when feasible (43 FR 52952, 52954 (11/14/78) (Lead Preamble)).

Significant Risk

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 its decision on OSHA's benzene standard, interpreted section 3(8) to mean that before promulgating any standard, the Secretary must evaluate whether ''significant risk[ ]'' exists under current conditions and to then determine whether that risk can be ''eliminated or lessened'' through regulation (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 642 (1980) (plurality opinion) (''*Benzene*'')). The Court's holding is consistent with evidence in the legislative record, with regard to section 6(b)(5) of the Act (29 U.S.C. 655(b)(5)), that Congress intended the Agency to regulate unacceptably severe occupational hazards, and not ''to establish a utopia free from any hazards'' or to address risks comparable to those that exist in virtually any occupation or workplace (116 Cong. Rec. 37614 (1970), Leg. Hist. 480–82). It is also consistent with Section 6(g) of the OSH Act, which states that, in determining regulatory priorities, ''the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments'' (29 U.S.C. 655(g)).

The Supreme Court in *Benzene* clarified that ''[i]t is the Agency's responsibility to determine, in the first instance, what it considers to be a 'significant' risk'' (*Benzene,* 448 U.S. at 655), and that it was not the Court's responsibility to ''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'' (*Benzene,* 448 U.S. at 659). The Court stated, however, that the section 6(f) (29 U.S.C. 655(b)(f)) substantial evidence standard applicable to OSHA's significant risk determination does not require the Agency ''to support its finding that a significant risk exists with anything approaching scientific certainty'' (*Benzene,* 448 U.S. at 656). Rather, OSHA may rely on ''a body of reputable scientific thought'' to which ''conservative assumptions in interpreting the data . . . '' may be applied, ''risking error on the side of overprotection'' (*Benzene,* 448 U.S. at 656; *see also United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1248 (D.C. Cir. 1980) (''*Lead I*'') (noting the *Benzene* court's application of this principle to carcinogens and applying it to the lead standard, which was not based on carcinogenic effects)). OSHA may thus act with a ''pronounced bias towards worker safety'' in making its risk determinations (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988) (''*Asbestos II*'').

The Supreme Court further recognized that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' (*Benzene,* 448 U.S. at 655) and will be ''based largely on policy considerations'' (*Benzene,* 448 U.S. at 655 n. 62). The Court gave the following example:

> If . . . 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% benzene will be fatal, a reasonable person might well consider the risk significant . . . (*Benzene,* 448 U.S. at 655).

Following *Benzene,* OSHA has, in many of its health standards, considered the one-in-a-thousand metric when determining whether a significant risk exists. Moreover, as ''a prerequisite to more stringent regulation'' in all subsequent health standards, OSHA has, consistent with the *Benzene* plurality decision, based each standard on a finding of significant risk at the ''then prevailing standard'' of exposure to the relevant hazardous substance (*Asbestos II,* 838 F.2d at 1263). The Agency's final risk assessment is derived from existing scientific and enforcement data and its final conclusions are made only after considering all evidence in the rulemaking record. Courts reviewing the validity of these standards have uniformly held the Secretary to the significant risk standard first articulated by the *Benzene* plurality and have generally upheld the Secretary's significant risk determinations as supported by substantial evidence and ''a reasoned explanation for his policy assumptions and conclusions'' (*Asbestos II,* 838 F.2d at 1266).

Once OSHA makes its significant risk finding, the ''more stringent regulation'' (*Asbestos II,* 838 F.2d at 1263) it promulgates must be ''reasonably necessary or appropriate'' to reduce or eliminate that risk, within the meaning of section 3(8) of the Act (29 U.S.C. 652(8)) and *Benzene* (448 U.S. at 642) (*see Asbestos II,* 838 F.2d at 1269). The courts have interpreted section 6(b)(5) of the OSH Act as requiring OSHA to set the standard that eliminates or reduces risk to the lowest feasible level; as discussed below, the limits of technological and economic feasibility usually determine where the new standard is set (*see UAW* v. *Pendergrass,* 878 F.2d 389, 390 (D.C. Cir. 1989)). In choosing among regulatory alternatives, however, ''[t]he determination that [one standard] is appropriate, as opposed to a marginally [more or less protective] standard, is a technical decision entrusted to the expertise of the agency . . . '' (*Nat'l Mining Ass'n* v. *Mine Safety and Health Admin.,* 116 F.3d 520, 528 (D.C. Cir. 1997)) (analyzing a Mine Safety and Health Administration standard under the *Benzene* significant risk standard). In making its choice, OSHA may incorporate a margin of safety even if it theoretically regulates below the lower limit of significant risk (*Nat'l Mining Ass'n,* 116 F.3d at 528 (citing *American Petroleum Inst.* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1982))).

Working Life Assumption

The OSH Act requires OSHA to set the standard that most adequately protects employees against harmful workplace exposures for the period of their ''working life'' (29 U.S.C. 655(b)(5)). OSHA's longstanding policy is to define ''working life'' as constituting 45 years; thus, it assumes 45 years of exposure when evaluating the risk of material impairment to health caused by a toxic or hazardous substance. This policy is not based on empirical data that most employees are exposed to a particular hazard for 45 years. Instead, OSHA has adopted the practice to be consistent with the statutory directive that ''no employee'' suffer material impairment of health ''even if'' such employee is exposed to the hazard for the period of his or her working life (*see* 74 FR 44796 (8/31/09)). OSHA's policy was given judicial approval in a challenge to an OSHA standard that lowered the permissible exposure limit (PEL) for asbestos (*Asbestos II,* 838 F.2d at 1264–1265). In that case, the petitioners claimed that the median duration of employment in the affected industry sectors was only five years. Therefore, according to petitioners, OSHA erred in assuming a 45-year working life in calculating the risk of health effects caused by asbestos exposure. The D.C. Circuit disagreed, stating ''[e]ven if it is only the rare worker who stays with asbestos-related tasks for 45 years, that worker would face a 64/1000 excess risk of contracting cancer; Congress clearly authorized OSHA to protect such a worker'' (*Asbestos II,* 838 F.2d at 1264–1265). OSHA might calculate the health risks of exposure, and the related benefits of lowering the exposure limit, based on an assumption of a shorter working life, such as 25 years, but such estimates are for informational purposes only.

Best Available Evidence

Section 6(b)(5) of the Act requires OSHA to set standards ''on the basis of the best available evidence'' and to consider the ''latest available scientific data in the field'' (29 U.S.C. 655(b)(5)). As noted above, the Supreme Court, in its *Benzene* decision, explained that OSHA must look to ''a body of reputable scientific thought'' in making its material harm and significant risk determinations, while noting that a reviewing court must ''give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge'' (*Benzene,* 448 U.S. at 656).

The courts of appeals have afforded OSHA similar latitude to issue health standards in the face of scientific uncertainty. The Second Circuit, in upholding the vinyl chloride standard, stated: ''[T]he ultimate facts here in dispute are 'on the frontiers of scientific knowledge', and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient'' (*Society of the Plastics Industry, Inc.* v. *OSHA,* 509 F.2d 1301, 1308 (2d Cir. 1975) (quoting *Indus. Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467, 474 (D.C. Cir. 1974) (''*Asbestos I*''))). The D.C. Circuit, in upholding the cotton dust standard, stated: ''OSHA's mandate necessarily requires it to act even if information is incomplete when the best available evidence indicates a serious threat to the health of workers'' (*Am. Fed'n of Labor & Cong. of Indus. Orgs.* v. *Marshall,* 617 F.2d 636, 651 (D.C. Cir. 1979), *aff'd in part and vacated in part on other grounds, American Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490 (1981)). When there is disputed scientific evidence in the record, OSHA must review the evidence on both sides and ''reasonably resolve'' the dispute (*Pub. Citizen Health Research Grp.* v. *Tyson,* 796 F.2d 1479, 1500 (D.C. Cir. 1986)). The Court in *Public Citizen* further noted that, where ''OSHA has the expertise we lack and it has exercised that expertise by carefully reviewing the scientific data,'' a dispute within the scientific community is not occasion for the reviewing court to take sides about which view is correct (*Pub. Citizen Health Research Grp.,* 796 F.2d at 1500) or for OSHA or the courts to '' 'be paralyzed by debate surrounding diverse medical opinions' '' (*Pub. Citizen Health Research Grp.,* 796 F.2d at 1497 (quoting H.R. Rep. No. 91–1291, 91st Cong., 2d Sess. 18 (1970), reprinted in Legislative History of the Occupational Safety and Health Act of 1970 at 848 (1971))). Provided the Agency gave adequate notice in the proposal's preamble discussion of potential regulatory alternatives that the Secretary would be considering one or more stated options for regulation, OSHA is not required to prefer the option in the text of the proposal over a given regulatory alternative that was addressed in the rulemaking if substantial evidence in the record supports inclusion of the alternative in the final standard. *See Owner-Operator Independent Drivers Ass'n, Inc.* v. *Federal Motor Carrier Safety Admin.,* 494 F.3d 188, 209 (D.C. Cir. 2007) (notice by agency concerning modification of sleeper-berth requirements for truck drivers was sufficient because proposal listed several options and asked a question regarding the details of the one option that ultimately appeared in final rule); *Kooritzky* v. *Reich,* 17 F.3d 1509, 1513 (D.C. Cir. 1994) (noting that a final rule need not match a proposed rule, as long as ''the agency has alerted interested parties to the possibility of the agency's adopting a rule different than the one proposed'' and holding that agency failed to comply with notice and comment requirements when ''preamble in July offered no clues of what was to come in October'').

Feasibility

The OSH Act requires that, in setting a standard, OSHA must eliminate the risk of material health impairment ''to the extent feasible'' (29 U.S.C. 655(b)(5)). The statutory mandate to consider the feasibility of the standard encompasses both technological and economic feasibility; these analyses have been done primarily on an industry-by-industry basis (*Lead I,* 647 F.2d at 1264, 1301). The Agency has also used application groups, defined by common tasks, as the structure for its feasibility analyses (*Pub. Citizen Health Research Grp.* v. *OSHA,* 557 F.3d 165, 177–179 (3d Cir. 2009)). The Supreme Court has broadly defined feasible as ''capable of being done'' (*Cotton Dust,* 452 U.S. at 509–510).

Although OSHA must set the most protective PEL that the Agency finds to be technologically and economically feasible, it retains discretion to set a uniform PEL even when the evidence demonstrates that certain industries or operations could reasonably be expected to meet a lower PEL. OSHA health standards generally set a single PEL for all affected employers; OSHA exercised this discretion most recently in its final rules on occupational exposure to Chromium (VI) (71 FR 10100, 10337–10338 (2/28/2006) and Respirable Crystalline Silica (81 FR 16285, 16576–16575 (3/25/2016); see also 62 FR 1494, 1575 (1/10/97) (methylene chloride)). In its decision upholding the chromium (VI) standard, including the uniform PEL, the Court of Appeals for the Third Circuit addressed this issue as one of deference, stating ''OSHA's decision to select a uniform exposure limit is a legislative policy decision that we will uphold as long as it was reasonably drawn from the record'' (Chromium (VI), 557 F.3d at 183 (3d Cir. 2009)); see also *Am. Iron & Steel Inst.* v. *OSHA*, 577 F.2d 825, 833 (3d Cir. 1978)). OSHA's reasons for choosing one chromium (VI) PEL, rather than imposing different PELs on different application groups or industries, included: Multiple PELs would create enforcement and compliance problems because many workplaces, and even workers, were affected by multiple categories of chromium (VI) exposure; discerning individual PELs for different groups of establishments would impose a huge evidentiary burden on the Agency and unnecessarily delay implementation of the standard; and a uniform PEL would, by eliminating confusion and simplifying compliance, enhance worker protection (Chromium (VI), 557 F.3d at 173, 183–184). The Court held that OSHA's rationale for choosing a uniform PEL, despite evidence that some application groups or industries could meet a lower PEL, was reasonably drawn from the record and that the Agency's decision was within its discretion and supported by past practice (Chromium (VI), 557 F.3d at 183–184).

Technological Feasibility

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed (*Lead I,* 647 F.2d at 1272; *Amer. Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991) (''*Lead II*'')). OSHA's standards may be ''technology forcing,'' *i.e.,* where the Agency gives an industry a reasonable amount of time to develop new technologies, OSHA is not bound by the ''technological status quo'' (*Lead I,* 647 F.2d at 1264). While the test for technological feasibility is normally articulated in terms of the ability of employers to decrease exposures to the PEL, provisions such as exposure measurement requirements must also be technologically feasible (*see Forging Indus. Ass'n* v. *Sec'y of Labor,* 773 F.2d 1436, 1453 (4th Cir. 1985)).

In its *Lead* decisions, the D.C. Circuit described OSHA's obligation to demonstrate the technological feasibility of reducing occupational exposure to a hazardous substance.

> [W]ithin the limits of the best available evidence . . . OSHA must prove a reasonable possibility 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 . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators . . . Insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine this general presumption in favor of feasibility. Rather, in such operations firms will remain responsible for installing engineering and work practice controls to the extent feasible, and for using them to reduce . . . exposure as far as these controls can do so (*Lead I,* 647 F.2d at 1272).

Additionally, the D.C. Circuit explained that ''[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time . . .'' (*Lead II,* 939 F.2d at 990).

Courts have given OSHA significant deference in reviewing its technological feasibility findings. ''So long as we require OSHA to show that any required means of compliance, even if it carries no guarantee of meeting the PEL, will substantially lower . . . exposure, we can uphold OSHA's determination that every firm must exploit all possible means to meet the standard'' (*Lead I,* 647 F.2d at 1273). Even in the face of significant uncertainty about technological feasibility in a given industry, OSHA has been granted broad discretion in making its findings (*Lead I,* 647 F.2d at 1285). ''OSHA cannot let workers suffer while it awaits . . . scientific certainty. It can and must make reasonable [technological feasibility] predictions on the basis of 'credible sources of information,' whether data from existing plants or expert testimony'' (*Lead I,* 647 F.2d at 1266 (quoting *Am. Fed'n of Labor & Cong. of Indus. Orgs.,* 617 F.2d at 658)). For example, in *Lead I,* the D.C. Circuit allowed OSHA to use, as best available evidence, information about new and expensive industrial smelting processes that had not yet been adopted in the U.S. and would require the rebuilding of plants (*Lead I,* 647 F.2d at 1283–1284). Even under circumstances where

OSHA's feasibility findings were less certain and the Agency was relying on its ''legitimate policy of technology forcing,'' the D.C. Circuit approved of OSHA's feasibility findings when the Agency granted lengthy phase-in periods to allow particular industries time to comply (*Lead I,* 647 F.2d at 1279–1281, 1285).

OSHA is permitted to adopt a standard that some employers will not be able to meet some of the time, with employers limited to challenging feasibility at the enforcement stage (*Lead I,* 647 F.2d at 1273 & n. 125; *Asbestos II,* 838 F.2d at 1268). Even when the Agency recognized that it might have to balance its general feasibility findings with flexible enforcement of the standard in individual cases, the courts of appeals have generally upheld OSHA's technological feasibility findings (*Lead II,* 939 F.2d at 980; *see Lead I,* 647 F.2d at 1266–1273; *Asbestos II,* 838 F.2d at 1268). Flexible enforcement policies have been approved where there is variability in measurement of the regulated hazardous substance or where exposures can fluctuate uncontrollably (*Asbestos II,* 838 F.2d at 1267–1268; *Lead II,* 939 F.2d at 991). A common means of dealing with the measurement variability inherent in sampling and analysis is for the Agency to add the standard sampling error to its exposure measurements before determining whether to issue a citation (*e.g.,* 51 FR 22612, 22654 (06/20/86) (Asbestos Preamble)).

Economic Feasibility

In addition to technological feasibility, OSHA is required to demonstrate that its standards are economically feasible. A reviewing court will 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 . . .'' (*Lead I,* 647 F.2d at 1265 (omitting citation)). As articulated by the D.C. Circuit in *Lead I,* ''OSHA must construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms'' (*Lead I,* 647 F.2d at 1272). A reasonable estimate entails assessing ''the likely range of costs and the likely effects of those costs on the industry'' (*Lead I,* 647 F.2d at 1266). As with OSHA's consideration of scientific data and control technology, however, the estimates need not be precise (*Cotton Dust,* 452 U.S. at 528–529 & n. 54) as long as they are adequately explained. Thus, as the D.C. Circuit further explained:

> Standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely. Nor does the concept of economic feasibility necessarily guarantee the continued existence of individual employers. It would appear to be consistent with the purposes of the Act to envisage the economic demise of an employer who has lagged behind the rest of the industry in protecting the health and safety of employees and is consequently financially unable to comply with new standards as quickly as other employers. As the effect becomes more widespread within an industry, the problem of economic feasibility becomes more pressing (*Asbestos I,* 499 F.2d. at 478).

OSHA standards therefore satisfy the economic feasibility criterion even if they impose significant costs on regulated industries so long as they do not cause massive economic dislocations within a particular industry or imperil the very existence of the industry (*Lead II,* 939 F.2d at 980; *Lead I,* 647 F.2d at 1272; *Asbestos I,* 499 F.2d. at 478). As with its other legal findings, OSHA ''is not required to prove economic feasibility with certainty, but is required to use the best available evidence and to support its conclusions with substantial evidence'' ((*Lead II,* 939 F.2d at 980–981) (citing *Lead I,* 647 F.2d at 1267)).

Because section 6(b)(5) of the Act explicitly imposes the ''to the extent feasible'' limitation on the setting of health standards, OSHA is not permitted to use cost-benefit analysis to make its standards-setting decisions (29 U.S.C. 655(b)(5)).

> Congress itself defined the basic relationship between costs and benefits, by placing the ''benefit'' of worker health above all other considerations save those making attainment of this ''benefit'' unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in § 6(b)(5) (*Cotton Dust,* 452 U.S. at 509).

Thus, while OSHA estimates the costs and benefits of its proposed and final rules, these calculations do not form the basis for the Agency's regulatory decisions; rather, they are performed to ensure compliance with requirements such as those in Executive Orders 12866 and 13563.

Structure of OSHA Health Standards

OSHA's health standards traditionally incorporate a comprehensive approach to reducing occupational disease. OSHA substance-specific health standards generally include the ''hierarchy of controls,'' which, as a matter of OSHA's preferred policy, mandates that employers install and implement all feasible engineering and work practice controls before respirators may be used. The Agency's adherence to the hierarchy of controls has been upheld by the courts (*ASARCO, Inc.* v. *OSHA,* 746 F.2d 483, 496–498 (9th Cir. 1984); *Am. Iron & Steel Inst.* v. *OSHA,* 182 F.3d 1261, 1271 (11th Cir. 1999)). In fact, courts view the legal standard for proving technological feasibility as incorporating the hierarchy: ''OSHA must prove a reasonable possibility 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. . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators'' (*Lead I,* 647 F.2d at 1272).

The reasons supporting OSHA's continued reliance on the hierarchy of controls, as well as its reasons for limiting the use of respirators, are numerous and grounded in good industrial hygiene principles (see discussion in Section XVI. Summary and Explanation of the Standards, Methods of Compliance). The hierarchy of controls focuses on removing harmful airborne materials at their source ''to prevent atmospheric contamination'' to which the employee would be exposed, rather than relying on the proper functioning of a respirator as the primary means of protecting the employee (see 29 CFR 1910.134, 1910.1000(e), 1926.55(b)).

In health standards such as this one, the hierarchy of controls is augmented by ancillary provisions. These provisions work with the hierarchy of controls and personal protective equipment requirements to provide comprehensive protection to employees in affected workplaces. Such provisions typically include exposure assessment, medical surveillance, hazard communication, and recordkeeping.

The OSH Act compels OSHA to require all feasible measures for reducing significant health risks (29 U.S.C. 655(b)(5); *Pub. Citizen Health Research Grp.,* 796 F.2d at 1505 (''if in fact a STEL [short-term exposure limit] would further reduce a significant health risk and is feasible to implement, then the OSH Act compels the agency to adopt it (barring alternative avenues to the same result)''). When there is significant risk below the PEL, the D.C. Circuit indicated that OSHA should use its regulatory authority to impose additional requirements on employers when those requirements will result in a greater than de minimis incremental benefit to workers' health (*Asbestos II,* 838 F.2d at 1274). The Supreme Court alluded to a similar issue in *Benzene,* pointing out that ''in setting a permissible exposure level in reliance on less-than-perfect methods, OSHA would have the benefit of a backstop in the form of monitoring and medical testing'' (*Benzene,* 448 U.S. at 657). OSHA concludes that the ancillary provisions in this final standard provide significant benefits to worker health by providing additional layers and types of protection to employees exposed to beryllium and beryllium compounds.

III. Events Leading to the Final 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 (Document ID 1323). 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 1970, ANSI issued a national consensus standard for beryllium and beryllium compounds (ANSI Z37.29–1970). 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 (Document ID 1303).

In 1971, OSHA adopted, under Section 6(a) of the Occupational Safety and Health Act of 1970, and made applicable to general industry, the ANSI standard (Document ID 1303). Section 6(a) provided 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 as well as several from United States of America Standards Institute (USASI) [later the American National Standards Institute (ANSI)].

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 with Recommended Exposure Limits (RELs) of 2 μg/m³ as an 8-hour TWA 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 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 from studies finding that beryllium caused cancer in animals (40 FR 48814 (10/17/75)). 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. Then in 2009, ACGIH adopted a revised TLV for beryllium that lowered the TWA to 0.05 μg/m³ (inhalable) (see Document ID 1755, Tr. 136).

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 (Document ID 1323). 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 (10 CFR 850.22; 64 FR 68873 and 68906, Dec. 8, 1999).

Also in 1999, OSHA was petitioned by the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) (Document ID 0069) and by Dr. Lee Newman and Ms. Margaret Mroz, from the National Jewish Health (NJH) (Document ID 0069), 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 (Document ID 0069). 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) [6(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 ordinary notice and comment [section 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 in preparation for possible section 6(b) rulemaking.

On November 26, 2002, OSHA published a Request for Information (RFI) for ''Occupational Exposure to Beryllium'' (Document ID 1242). 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 chronic beryllium disease (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 on January 15, 2008 which included the SERs' comments. 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.''

OSHA then developed a draft preliminary beryllium health effects evaluation (Document ID 1271) and a draft preliminary beryllium risk assessment (Document ID 1272), and in 2010, OSHA hired a contractor to oversee an independent scientific peer review of these documents. 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 Beryllium Lymphocyte Proliferation Test (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 preliminary 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 (Document ID 1210). 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 (Document ID 1210). 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 $\mu g/m^3$ or higher, and that the greatest reduction in risk was achieved when exposures for all processes were lowered to 0.1 $\mu g/m^3$ or below.

In February 2012, the Agency received for consideration a draft recommended standard for beryllium (Materion and USW, 2012, Document ID 0754). This draft standard 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. They 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 (NPRM) for beryllium. As described in greater detail in the Introduction to the Summary and Explanation of the final rule, there was substantial agreement between the submitted joint standard and the OSHA proposed standard.

On August 7, 2015, OSHA published its NPRM in the **Federal Register** (80 FR 47565 (8/7/15)). In the NPRM, the Agency made a preliminary determination that employees exposed to beryllium and beryllium compounds at the preceding PEL face a significant risk to their health and that promulgating the proposed standard would substantially reduce that risk. The NPRM (Section XVIII) also responded to the SBREFA Panel recommendations, which OSHA carefully considered, and clarified the requirements about which SERs expressed confusion. OSHA also discussed the regulatory alternatives recommended by the SBREFA Panel in NPRM, Section XVIII, and in the PEA (Document ID 0426).

The NPRM invited interested stakeholders to submit comments on a variety of issues and indicated that OSHA would schedule a public hearing upon request. Commenters submitted information and suggestions on a variety of topics. In addition, in response to a request from the Non-Ferrous Founders' Society, OSHA scheduled an informal public hearing on the proposed rule. The Agency invited interested persons to participate by providing oral testimony and documentary evidence at the hearing. OSHA also welcomed presentation of data and documentary evidence that would provide the Agency with the best available evidence to use in determining whether to develop a final rule.

The public hearing was held in Washington, DC on March 21 and 22, 2016. Administrative Law Judge William Colwell presided over the hearing. The Agency heard testimony from several organizations, such as public health groups, the Non-Ferrous Founders' Society, other industry representatives, and labor unions. Following the hearing, participants who had filed notices of intent to appear were allowed 30 days—until April 21, 2016—to submit additional evidence and data, and an additional 15 days—until May 6, 2016—to submit final briefs, arguments, and summations (Document ID 1756, Tr. 326).

In 2016, in an action parallel to OSHA's rulemaking, DOE proposed to update its action level to 0.05 $\mu g/m^3$ (81 FR 36704–36759, June 7, 2016). 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 (Document ID 1323; 10 CFR 850.23(b)). Unlike OSHA's PEL, however, DOE's selection of an action level is not required to meet statutory requirements of technological and economic feasibility.

In all, the OSHA rulemaking record contains over 1,900 documents, including all the studies OSHA relied on in its preliminary health effects and risk assessment analyses, the hearing transcript and submitted testimonies, the joint Materion-USW draft proposed standard, and the pre- and post-hearing comments and briefs. The final rule on occupational exposure to beryllium and beryllium compounds is thus based on consideration of the entire record of this rulemaking proceeding, including materials discussed or relied upon in the proposal, the record of the hearing, and all written comments and exhibits timely received. Based on this comprehensive record, OSHA concludes that employees exposed to beryllium and beryllium compounds are at significant risk of material impairment of health, including chronic beryllium disease and lung cancer. The Agency concludes that the PEL of 0.2 μg/m^3 reduces the significant risks of material impairments of health posed to workers by occupational exposure to beryllium and beryllium compounds to the maximum extent that is technologically and economically feasible. OSHA's substantive determinations with regard to the comments, testimony, and other information in the record, the legal standards governing the decision-making process, and the Agency's analysis of the data resulting in its assessments of risks, benefits, technological and economic feasibility, and compliance costs are discussed elsewhere in this preamble. More technical or complex issues are discussed in greater detail in the background documents referenced in this preamble.

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 (Document ID 0389, p. 1). It occurs naturally in rocks, soil, coal, and volcanic dust (Document ID 1567, p. 1). 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, deliques-cent 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.
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 (Document ID 0389, p. 1). 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 (Document ID 1342, pp. 45, 48).

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 (Document ID 1342, p. 48). Imported beryl is also converted into beryllium hydroxide as the United States has very little beryl that can be economically mined (Document ID 0616, p. 28).

Industrial Uses

Materion Corporation (Materion), 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 (Document ID 0389, p. 1). Beryllium oxide is used in components such as ceramics, electrical insulators, microwave oven components, military vehicle armor, laser structural components, and automotive ignition systems (Document ID 1567, p. 147). 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 (Document ID 0389, p. 2; 1278, p. 182; 1280, pp. 1–2; 1281, pp. 816, 818). Electrical components and conductors are stamped and formed from beryllium alloys. Beryllium-copper alloys are used to make switches in automobiles (Document ID 1280, p. 2; 1281, p. 818) and connectors, relays, and switches in computers, radar, satellite, and telecommunications equipment (Document ID 1278, p. 183). Beryllium-aluminum alloys are used in the construction of aircraft, high resolution medical and industrial X-ray equipment, and mirrors to measure weather patterns (Document ID 1278, p. 183). 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 (Document ID 0385, 0426).

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

Overview of Findings and Supportive Comments

As discussed in detail throughout this section (section V, Final Health Effects) and in Section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA finds, based upon the best available evidence in the record, that exposure to soluble and poorly soluble forms of beryllium are associated with several adverse health outcomes including sensitization, chronic beryllium disease, acute beryllium disease and lung cancer.

The findings and conclusions in this section are consistent with those of the National Academies of Sciences (NAS), the World Health Organization's International Agency for Research on Cancer (IARC), the U.S. Department of Health and Human Services' (HHS) National Toxicology Program (NTP), the National Institute for Occupational Safety and Health (NIOSH), the Agency for Toxic Substance and Disease Registry (ATSDR), the European Commission on Health, Safety and Hygiene at Work, and many other organizations and individuals, as evidenced in the rulemaking record and further discussed below. Other scientific organizations and governments have recognized the strong body of scientific evidence pointing to the health risks of exposure to beryllium and have deemed it necessary to take action to reduce those risks. In 1999, the Department of Energy (DOE) updated its airborne beryllium concentration action level to 0.2 $\mu g/m^3$ (Document ID 1323). In 2009, the American Conference of Governmental Industrial Hygienists (ACGIH), a professional society that has been recommending workplace exposure limits for six decades, revised its Threshold Limit Value (TLV) for beryllium and beryllium-containing compounds to 0.05 $\mu g/m^3$ (Document ID 1304).

In finalizing this Health Effects preamble section for the final rule, OSHA updated the preliminary Health Effects section published in the NPRM based on the stakeholder response received by the Agency during the public comment period and public hearing. OSHA also corrected several non-substantive errors that were published in the NPRM as well as those identified by NIOSH and Materion including several minor organizational changes made to sections V.D.3 and V.E.2.b (Document ID 1671, pp. 10–11; 1662, pp. 3–5). A section titled ''Dermal Effects'' was added to V.F.5 based on comments received by the American Thoracic Society (ATS), National Jewish Health, and the National Supplemental Screening Program (Document ID 1688, p. 2; 1664, p. 5; 1677, p. 3). Additionally, the Agency responded to relevant stakeholder comments contained in specific sections.

In developing its review of the preliminary health effects from beryllium exposure and assessment of risk for the NPRM, OSHA prepared a pair of draft documents, entitled ''Occupation Exposure to Beryllium: Preliminary Health Effects Evaluation'' (OSHA, 2010, Document ID 1271) and ''Preliminary Beryllium Risk Assessment'' (OSHA, 2010, Document ID 1272), that underwent independent scientific peer review in accordance with the Office of Management and Budget's (OMB) Information Quality Bulletin for Peer Review. Eastern Research Group, Inc. (ERG), under contract with OSHA, selected five highly qualified experts with collective expertise in occupational epidemiology, occupational medicine, toxicology, immunology, industrial hygiene, and risk assessment methodology.[2] The peer reviewers responded to 27 questions that covered the accuracy, completeness, and understandability of key studies and adverse health endpoints as well as questions regarding the adequacy, clarity and reasonableness of the risk analysis (ERG, 2010; Document ID 1270).

Overall, the peer reviewers found that the OSHA draft health effects evaluation described the studies in sufficient detail, appropriately addressed their strengths and limitations, and drew scientifically sound conclusions. The peer reviewers were also supportive of the Agency's preliminary risk assessment approach and the major conclusions. OSHA provided detailed responses to reviewer comments in its publication of the NPRM (80 FR 47646–47652, 8/7/2015). Revisions to the draft health effects evaluation and preliminary risk assessment in response to the peer review comments were reflected in sections V and VI of the same publication (80 FR 47581–47646, 8/7/2015). OSHA received public comment and testimony on the Health Effects and Preliminary Risk Assessment sections published in the NPRM, which are discussed in this preamble.

The Agency received a wide variety of stakeholder comments and testimony for this rulemaking on issues related to the health effects and risk of beryllium exposure. Statements supportive of OSHA's Health Effects section include comments from NIOSH, the National Safety Council, the American Thoracic Society (ATS), Representative Robert C. ''Bobby'' Scott, Ranking Member of Committee on Education and the Workforce, the U.S. House of Representatives, national labor organizations (American Federation of Labor—Congress of Industrial Organizations (AFL–CIO), North American Building Trades Unions (NABTU), United Steelworkers (USW), Public Citizen, ORCHSE, experts from National Jewish Health (Lisa Maier, MD and Margaret Mroz, MSPH), the American Association for Justice, and the National Council for Occupational Safety and Health.

For example, NIOSH commented in its prepared written hearing testimony:

> OSHA has appropriately identified and documented all critical health effects associated with occupational exposure to beryllium and has appropriately focused its greatest attention on beryllium sensitization (BeS), chronic beryllium disease (CBD) and lung cancer . . .

NIOSH went on to say that sensitization was more than a test result with little meaning. It relates to a condition in which the immune system is able to recognize and adversely react to beryllium in a way that increases the risk of developing CBD. NIOSH agrees with OSHA that sensitization is a functional change that is necessary in order to proceed along the pathogenesis to serious lung disease.

The National Safety Council, a congressionally chartered nonprofit safety organization, also stated that ''beryllium represents a serious health threat resulting from acute or chronic exposures.'' (Document ID 1612, p. 5). Representative Robert C. ''Bobby'' Scott, Ranking Member of Committee on Education and the Workforce, the U.S. House of Representatives, submitted a statement recognizing that the evidence strongly supports the conclusion that sensitization can occur from exposure to soluble and poorly soluble forms of beryllium (Document ID 1672, p. 3).

OSHA also received supporting statements from ATS and ORCHSE on the inclusion of beryllium sensitization, CBD, skin disease, and lung cancer as major adverse health effects associated with beryllium exposure (Document ID 1688, p. 7; 1691, p. 14). ATS specifically stated:

> . . . the ATS supports the inclusion of beryllium sensitization, CBD, and skin disease as the major adverse health effects associated with exposure to beryllium at or below 0.1 μg/m^3 and acute beryllium disease at higher exposures based on the currently available epidemiologic and experimental studies. (Document ID 1688, p. 2)

In addition, OSHA received supporting comments from labor organizations representing workers exposed to beryllium. The AFL–CIO, NABTU, and USW submitted comments supporting the inclusion of beryllium sensitization, CBD and lung cancer as health effects from beryllium exposure (Document ID 1689, pp. 1, 3; 1679, p. 6; 1681, p. 19). AFL–CIO commented that ''[t]he proposal is based on extensive scientific and medical evidence . . .'' and ''[b]eryllium exposure causes immunological sensitivity, CBD and lung cancer. These health effects are debilitating, progressive and irreversible. Workers are exposed to beryllium through respiratory, dermal and gastrointestinal routes.'' (Document ID 1689, pp. 1, 3). Comments submitted by USW state that ''OSHA has correctly identified, and comprehensively documented the material impairments of health resulting from beryllium exposure.'' (Document ID 1681, p. 19).

Dr. Lisa Maier and Ms. Margaret Mroz of National Jewish Health testified about the health effects of beryllium in support of the beryllium standard:

> We know that chronic beryllium disease often will not manifest clinically until irreversible lung scarring has occurred, often years after exposure, with a latency of 20 to 30 years as discussed yesterday. Much too late to make changes in the work place. We need to look for early markers of health effects, cast the net widely to identify cases of sensitization and disease, and use screening results in concert with exposure sampling to identify areas of increased risk that can be modified in the work place. (Document ID 1756, Tr. 102; 1806).

American Association for Justice noted that:

> Unlike many toxins, there is no threshold below which no worker will become sensitized to beryllium. Worker sensitization to beryllium is a precursor to CBD, but not cancer. The symptoms of chronic beryllium disease (CBD) are part of a continuum of disease that is progressive in nature. Early recognition of and treatment for CBD may lead to a lessening of symptoms and may prevent the disease from progressing further. Symptoms of CBD may occur at exposure levels well below the proposed permissible exposure limit of .2 μg/m^3 and even below the action level of .1 μg/m^3. OSHA has clear authority to regulate health effects across the entire continuum of disease to protect workers. We applaud OSHA for proposing to do so. (Document ID 1683, pp. 1–2).

National Committee for Occupational Safety and Health support OSHA findings of health effects due to beryllium exposure (1690, p. 1). Comments from Public Citizen also support OSHA findings: ''Beryllium is toxic at extremely low levels and exposure can result in BeS, an immune response that eventually can lead to an autoimmune granulomatous lung disease known as CBD. BeS is a necessary prerequisite to the development of CBD, with OSHA's

[2] The five selected peer reviewers were John Balmes, MD, University of California-San Francisco; Patrick Breysse, Ph.D., Johns Hopkins University, Bloomberg School of Public Health; Terry Gordon, Ph.D., New York University School of Medicine; Milton Rossman, MD, University of Pennsylvania School of Medicine; Kyle Steenland, Ph.D., Emory University, Rollins School of Public Health.

NPRM citing studies showing that 31–49 percent of all sensitized workers were diagnosed with CBD after clinical evaluations. Beryllium also is a recognized carcinogen that can cause lung cancer.'' (Document ID 1670, p.2).

In addition to the comments above and those noted throughout this Health Effects section, Materion submitted their correspondence to the National Academies (NAS) regarding the company's assessment of the NAS beryllium studies and their correspondence to NIOSH regarding the Cummings 2009 study (Document 1662, Attachments) to OSHA. For the NAS study, Materion included a series of comments regarding studies included in the NAS report. OSHA has reviewed these comments and found that the comments submitted to the NAS critiquing their review of the health effects of beryllium were considered and incorporated where appropriate. For the NIOSH study Materion included comments regarding 2 cases of acute beryllium disease evaluated in a study published by Cummings *et al.,* 2009. NIOSH also dealt with the comments from Materion as they found appropriate. However, none of the changes recommended by Materion to the NAS or NIOSH altered the overall findings or conclusions from either study. OSHA has taken the Materion comments into account in the review of these documents. OSHA found them not to be sufficient to discount either the findings of the NAS or NIOSH.

Introduction

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, Document ID 1324, 1325, 1326, 1327, 1328; NIOSH, 2011 (0544)).

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—Particle Characterization

1. Particle Physical/Chemical Properties

Beryllium has two oxidative states: Be(0) and $Be(2^{+})$ (Agency for Toxic Substance and Disease Registry (ATSDR) 2002, Document ID 1371). 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) as discussed in more detail in the Beryllium Sensitization section below. Beryllium has a high charge-to-radius ratio, forming various types of ionic bonds. In addition, 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, Document ID 1371; Greene *et al.,* 1998 (1519)). However, it appears that few, if any, toxicity studies exist for the organometallic compounds. Additional physical/chemical properties, such as solubility, for beryllium compounds that may be important in their biological response are summarized in Table 1 below. Solubility (as discussed in biological fluids in Section V.A.2.A below) is an important factor in evaluating the biological response to beryllium. For comparative purposes, water solubility is used in Table 1. The International Chemical Safety Cards lists water solubility as a way to standardize solubility values among particles and fibers. The information contained within Table 1 was obtained from the International Chemical Safety Cards (ICSC) for beryllium metal (ICSC 0226, Document ID 0438), beryllium oxide (ICSC 1325, Document ID 0444), beryllium sulfate (ICSC 1351, Document ID 0443), beryllium nitrate (ICSC 1352, Document ID 0442), beryllium carbonate (ICSC 1353, Document ID 0441), beryllium chloride (ICSC 1354, Document ID 0440), beryllium fluoride (ICSC 1355, Document ID 0439) and from the hazardous substance data bank (HSDB) for beryllium hydroxide (CASRN: 13327–32–7), and beryllium phosphate (CASRN: 13598–15–7, Document ID 0533). 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—BERYLLIUM CHARACTERISTICS AND PROPERTIES

Compound name	Chemical formula	Molecular mass	Acute physical hazards	Solubility in water at 20 °C
Beryllium Metal	Be	9.0	Combustible; Finely dispersed particles—Explosive.	None.
Beryllium Oxide	BeO	25.0	Not combustible or explosive	Very sparingly soluble.
Beryllium Carbonate	$Be_2CO_3(OH)/Be_2CO_5\ H_2$	181.07	Not combustible or explosive	None.
Beryllium Sulfate	$BeSO_4$	105.1	Not combustible or explosive	Slightly soluble.
Beryllium Nitrate	$BeN_2O_6/Be(NO_3)_2$	133.0	Enhances combustion of other substances	Very soluble (1.66×10^6 mg/L).
Beryllium Hydroxide	$Be(OH)_2$	43.0	Not reported	Slightly soluble 0.8 × 10 minus;4 mol/L (3.44 mg/L).
Beryllium Chloride	$BeCl_2$	79.9	Not combustible or explosive	Soluble.
Beryllium Fluoride	BeF_2	47.0	Not combustible or explosive	Very soluble.
Beryllium Phosphate	$Be_3(PO_4)_2$	271.0	Not reported	Soluble.

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 and cause respiratory tract exposure or dermal exposure (also referred to as dermal contact). The physical properties of 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, solubility 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. 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.

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 contact or exposure, the physical characteristics of the particle are also important since they can influence skin absorption and bioavailability. This section addresses certain physical characteristics (*i.e.,* solubility, particle size, particle surface area) that influence the toxicity of beryllium materials in occupational settings.

a. Solubility

Solubility has been shown to 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, Document ID 1560; Mandervelt *et al.,* 1997 (1451)). Similar to inhaled agents, the ability of materials to penetrate the skin is also influenced by solubility because dermal absorption may occur at a greater rate for soluble materials than poorly soluble materials (Kimber *et al.,* 2011, Document ID 0534). In post-hearing comments, NIOSH explained:

> In biological systems, solubility is used to describe the rate at which a material will undergo chemical clearance and dissolve in a fluid (airway lining, inside phagolysomes) relative to the rate of mechanical clearance. For example, in the lung a ''poorly soluble'' material is one that dissolves at a rate slower than the rate of mechanical removal via the mucociliary escalator. Examples of poorly soluble forms of beryllium are beryllium silicates, beryllium oxide, and beryllium metal and alloys (Deubner *et al.* 2011; Huang *et al.* 2011; Duling *et al.* 2012; Stefaniak *et al.* 2006, 201la, 2012). A highly soluble material is one that dissolves at a rate faster than mechanical clearance. Examples of highly soluble forms of beryllium are beryllium fluoride, beryllium sulfate, and beryllium chloride. (Document ID 1660–A2, p. 9).

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 poorly 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, Document ID 1309). According to an EPA report, 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 poorly soluble hydroxides or hydrated complexes within the general physiological range of pH values (between 5 and 8) (EPA, 1998, Document ID 1322). This may be an important factor in the development of CBD since lower-soluble 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, Document ID 1355).

Beryllium oxide (BeO), hydroxide ($Be(OH)_2$), carbonate ($Be_2\ CO_3\ (OH)_2$), and sulfate (anhydrous) ($BeSO_4$) are either insoluble, slightly soluble, or considered to be sparingly or poorly soluble (almost insoluble or having an extremely slow rate of dissolution and most often referred to as poorly soluble in more recent literature). 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, Document 1547). 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, Document ID 1510). 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, Document ID 0527).

Investigators have also attempted to determine how biological fluids can dissolve beryllium materials. In two studies, poorly soluble beryllium, taken up by activated phagocytes, was shown to be ionized by myeloperoxidases (Leonard and Lauwerys, 1987, Document ID 1293; Lansdown, 1995 (1469)). 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, Document ID 1355). 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, Document ID 1398), 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, Document ID 0539) 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, Document ID 0539).

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 smelter 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, Document ID 0537).

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, and rose more 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, Document ID 0531).

In an *in vitro* skin model, Sutton *et al.* (2003) demonstrated the dissolution of beryllium compounds (poorly soluble beryllium hydroxide, soluble beryllium phosphate) in a simulated sweat fluid (Document ID 1393). 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) (Document ID 0539).

In summary, studies have shown that soluble forms of beryllium readily dissolve into ionic components making them biologically available for dermal penetration and activation of immune cells (Stefaniak *et al.,* 2011; Document ID 0537). Soluble forms can also be converted to less soluble forms in the lung (Reeves and Vorwald, 1967, Document ID 1309) making persistence in the lung a possibility and increasing the potential for development of CBD (see section V.D.2). Studies by Stefaniak *et al.* (2003, 2006, 2011, 2012) (Document ID 1347; 1398; 0537; 0469), Huang *et al.* (2011), Duling *et al.* (2012), and Deubner *et al.* (2011) have demonstrated poorly soluble forms can be readily dissolved in biological fluids such as sweat, lung fluid, and cellular fluids. The dissolution of beryllium ions into biological fluids increases the likelihood of beryllium presentation to immune cells, thus increasing the potential for sensitization through dermal contact or lung exposure (Document ID 0531; 0539; 0527) (see section V.D.1).

OSHA received comments from the Non-Ferrous Founders' Society (NFFS) contending that the scientific evidence does not support insoluble beryllium as a causative agent for sensitization and CBD (Document ID 1678, p. 6). The NFFS contends that insoluble beryllium is not carcinogenic or a sensitizer to humans, and argues that based on this information, OSHA should consider a bifurcated standard with separate PELs for soluble and poorly soluble beryllium and beryllium compounds and insoluble beryllium metallics (Document ID 1678, p. 7). As evidence supporting its conclusion, the NFFS cited a 2010 statement written by Dr. Christian Strupp commissioned by the beryllium industry (Document ID 1785, 1814), which reviewed selected studies to evaluate the toxic potential of beryllium metal and alloys (Document ID 1678, pp. 7). The Strupp and Furnes statement (2010) cited by the NFFS is the background material and basis of the Strupp (2011a and 2011b) studies in the docket (Document ID 1794; 1795). In response to Strupp 2011 (a and b), Aleks Stefaniak of NIOSH published a letter to the editor refuting some of the evidence presented by Strupp (2011a and b, Document ID 1794; 1795). The first study by Strupp (2011a) evaluated selected animal studies and concluded that beryllium metal was not a sensitizer. Stefaniak (2011) evaluated the validity of the Strupp (2011a) study of beryllium toxicity and noted numerous deficiencies, including deficiencies in the study design, improper administration of beryllium test compounds, and lack of proper controls (Document ID 1793). In addition, Strupp (2011a) omitted numerous key animal and epidemiological studies demonstrating the potential of poorly soluble beryllium and beryllium metal as a sensitizing agent. One such study, Tinkle *et al.* (2003), demonstrated that topical application of poorly soluble beryllium induced skin sensitization in mice (Document ID 1483). Comments from NIOSH and National Jewish Medical Center state that poorly soluble beryllium materials are capable of dissolving in sweat (Document ID 1755; 1756). After evaluating the scientific evidence from epidemiological and animal studies, OSHA finds, based on the best available evidence, that soluble and poorly soluble forms of beryllium and beryllium compounds are causative agents of sensitization and CBD.

b. Particle Size

The toxicity of beryllium as exemplified by beryllium oxide is dependent, in part, on the particle size, with smaller particles (less than 10 µm in diameter) able to penetrate beyond the larynx (Stefaniak *et al.,* 2008, Document ID 1397). Most inhalation studies and occupational exposures involve quite small (less than 1–2 µm in diameter) beryllium oxide particles that can penetrate to the pulmonary regions of the lung (Stefaniak *et al.,* 2008, Document ID 1397). In inhalation studies with beryllium ores, particle sizes are generally much larger, with deposition occurring in several areas throughout the respiratory tract for particles less than 10 µm in diameter.

The temperature at which beryllium oxide is calcined influences its particle size, surface area, solubility, and ultimately its toxicity (Delic, 1992, Document ID 1547). 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, Document ID 1547).

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 (Document ID 0540). 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 across different operations (Document ID 1314). 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 (Document ID 1053). 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 those smaller particles being 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 (Document ID 1389). Kent *et al.* (2001) measured airborne beryllium using size-selective samplers in five furnace areas at a beryllium processing facility (Document ID 1361). A statistically significant linear trend was reported between the 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 (Document ID 0465). 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 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 poorly soluble forms of beryllium. Analysis of particle size revealed most process areas had particles ranging from 5 to 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 by considering more relevant aspects of exposure such as particle size distribution, chemical form, and solubility could potentially improve exposure assessments (Virji *et al.,* 2011, Document ID 0465).

To summarize, particle size influences deposition of beryllium particles in the lung, thereby influencing toxicity. Studies by Stefaniak *et al.* (2008) demonstrated that the majority of particles generated by beryllium processing operations were in the respirable range (less than 1–2 μm) (Document ID 1397). However, studies by Virji *et al.* (2011) (Document ID 0465), Cohen *et al.* (1983) (Document ID 0540) and Hoover *et al.* (1990) (Document ID 1314) showed that some operations could generate particle sizes ranging from 3 to 16 μm.

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, Document ID 1539; Miller, 1995 (0523); Oberdorster *et al.,* 1996 (1434)). 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, pro- and anti-oxidant defenses and apoptosis, which has been shown to increase the tumorigenic potential of poorly-soluble particles (Elder *et al.,* 2005, Document ID 1537; Carter *et al.,* 2006 (1556); Refsnes *et al.,* 2006 (1428)).

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 (Document ID 1317). 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 (Document ID 1547).

Several studies have investigated the lung toxicity of beryllium oxide calcined at different temperatures and generally have 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, Document ID 1495; Polák *et al.,* 1968 (1431); Haley *et al.,* 1989 (1366); Haley *et al.,* 1992 (1365); Hall *et al.,* 1950 (1494)). 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, Document ID 1495). 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, Document ID 1535).

Stefaniak *et al.* (2003) investigated the particle structure and surface area of beryllium metal, beryllium oxide, and copper-beryllium alloy particles (Document ID 1347). 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.* (2003) found lesser variation in SSA for the alloys or oxides (Document ID 1347). 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 beryllium sensitization 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, absorption through the skin, or ingestion. 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. Disposition (deposition and clearance) of the particle or droplet along the respiratory tract influences the biological response to the toxicant (Schlesinger *et al.,* 1997, Document ID 1290). Inhaled beryllium particles are deposited along the respiratory tract in a size dependent manner as described by the International Commission for radiological Protection (ICRP) model (Figure 1). 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 in particle diameter, 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). However, due to the hygroscopic nature of soluble particles, deposition patterns may be slightly different with an enhanced preference for the tracheobronchial or bronchial region of the lung. Nonetheless, soluble particles are still capable of depositing in the pulmonary region (Schlesinger *et al.,* 1997, Document ID 1290).

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.

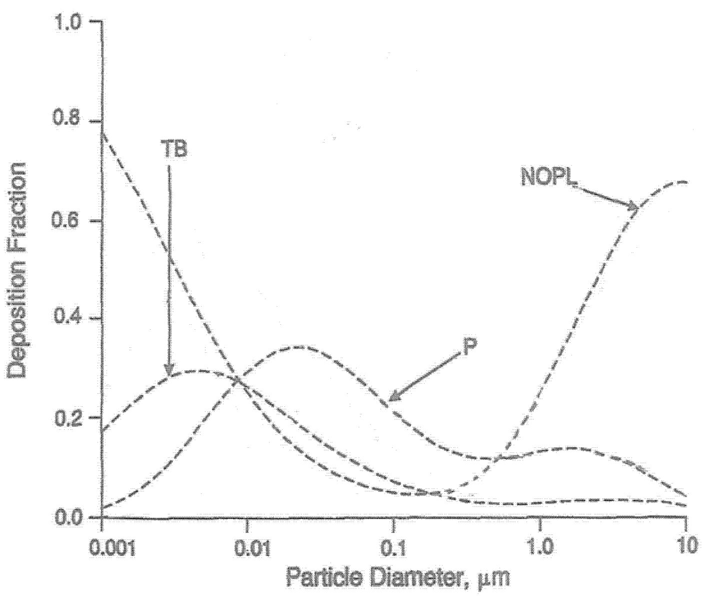


Figure 1, ICRP model: Regional Deposition Model in Humans (Adapted from Yeh et al., 1996, Document ID 0386))

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 or chemical clearance (Schlesinger, 1997, Document ID 1290). Sparingly soluble or poorly soluble beryllium is removed via mechanical mechanisms and may remain in the lungs for many years after exposure, as has been observed in workers (Schepers, 1962, Document ID 1414). Clearance mechanisms for sparingly soluble or poorly soluble 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, Document ID 1290). Mechanical clearance mechanisms may occur slowly in humans, which is consistent with some animal and human 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, Document ID 1405).

Due to physiological differences, clearance rates can vary between humans and animal species (Schlesinger, 1997, Document ID 1290; Miller, 2000 (1831)). However, clearance rates are also dependent upon the solubility, dose, and size of the inhaled beryllium compound. As reviewed in a WHO Report (2001) (Document ID 1282), 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, Document ID 1287; Hart *et al.,* 1980 (1493); Finch *et al.,* 1990 (1318)). Animal inhalation or intratracheal instillation studies administering soluble beryllium salts demonstrated significant absorption of approximately 20 percent of the initial lung burden with rapid dissolution of soluble compounds from the lung (Delic, 1992, Document ID 1547). Absorption of poorly soluble compounds such as beryllium oxide administered via inhalation or intratracheal instillation was slower and less significant (Delic, 1992, Document ID 1547). Additional animal studies have demonstrated that clearance of poorly 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, Document ID 1558; Sanders *et al.,* 1978 (1485); Delic, 1992 (1547); WHO, 2001 (1282)). Confirmatory studies in rats have shown the half-time for the rapid phase to be between 1 and 60 days, while the slow phase ranged from 0.6 to 2.3 years. Studies have also shown that this process was influenced by the solubility of the beryllium compounds: Weeks/months for soluble compounds, months/years for poorly soluble compounds (Reeves and Vorwald, 1967; Reeves *et al.,* 1967; 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 poorly soluble beryllium compounds or metal administered by this exposure route. (WHO, 2001, Document ID 1282; ATSDR, 2002 (1371).)

Evidence from animal studies suggests that greater amounts of beryllium deposited in the lung may result in slower clearance times. Acute inhalation studies performed in rats and mice using a single dose of inhaled aerosolized beryllium metal showed that exposure to beryllium metal can slow particle clearance and induce lung damage in rats and mice (Finch *et al.,* 1998, Document ID 1317; Haley *et al.,* 1990 (1314)). 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 to 380 days for the three concentrations. For mice (Finch *et al.,* 1998, Document ID 1317), 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 was shown to distribute primarily to the tracheobronchial lymph nodes via the lymph system, bloodstream, and skeleton (Stokinger *et al.,* 1953, Document ID 1277; Clary *et al.,* 1975 (1320); Sanders *et al.,* 1975 (1486); Finch *et al.,* 1990 (1318)). Studies in rats demonstrated accumulation of beryllium chloride in the skeletal system following intraperitoneal injection (Crowley *et al.,* 1949, Document ID 1551; Scott *et al.,* 1950 (1413)) and accumulation of beryllium phosphate and beryllium sulfate in both non-parenchymal and parenchymal cells of the liver after intravenous administration in rats (Skilleter and Price, 1978, Document ID 1408). Studies have also demonstrated intracellular accumulation of beryllium oxide in bone marrow throughout the skeletal system after intravenous administration to rabbits (Fodor, 1977, Document ID 1532; WHO, 2001 (1282)). Trace amounts of beryllium have also been shown to be distributed throughout the body (WHO, 2001, Document ID 1282).

Systemic distribution of the more soluble compounds was shown to be greater than that of the poorly soluble compounds (Stokinger *et al.,* 1953, Document ID 1277). 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, Document ID 1342). A half-life of 450 days has been estimated for beryllium in the human skeleton (ICRP, 1960, Document ID 0248). 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 (WHO, 2001, Document ID 1282). In a recent review of the information, the American Conference of Governmental Industrial Hygienists (ACGIH, 2010) was not able to confirm the association between occupational inhalation and urinary excretion (Document ID 1662, p. 4). However, IARC (2012) noted that an accidental exposure of 25 people to beryllium dust reported in a study by Zorn *et al.* (1986) resulted in a mean serum concentration of 3.5 µg/L one day after the exposure, which decreased to 2.4 µg/L by day six. The IARC report concluded that beryllium from beryllium metal was biologically available for systemic distribution from the lung (IARC, 2012, Document ID 0650).

Based on these studies, OSHA finds that the respiratory tract is a primary pathway for beryllium exposure. While particle size and surface area may contribute to the toxicity of beryllium, there is not sufficient evidence for OSHA to regulate based on size and surface area. However, the Agency finds that both soluble and poorly soluble forms of beryllium and beryllium compounds can contribute to exposure via the respiratory system and therefore can be causative agents of sensitization and CBD.

2. Dermal Exposure

Beryllium compounds have been shown to cause skin irritation and sensitization in humans and certain animal models (Van Ordstrand *et al.,* 1945, Document ID 1383; de Nardi *et al.,* 1953 (1545); Nishimura, 1966 (1435); Epstein, 1991 (0526); Belman, 1969 (1562); Tinkle *et al.,* 2003 (1483); Delic, 1992 (1547)). 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, Document ID 1371). However, even minute contact and absorption across the skin may directly elicit an immunological response resulting in sensitization (Deubner *et al.,* 2001, Document ID 1543; Toledo *et al.,* 2011 (0522)). 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 less than or equal to 1μm in diameter, as confirmed by scanning electron microscopy (Document ID 1483). 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, Document ID 1391) suggesting the flexing and stretching motion as a plausible mechanism for dermal penetration of beryllium as well. As earlier summarized, poorly soluble forms of beryllium can be solubilized in biological fluids (*e.g.,* sweat) making them available for absorption through intact skin (Sutton *et al.,* 2003, Document ID 1393; Stefaniak *et al.,* 2011 (0537) and 2014 (0517); Duling *et al.,* 2012 (0539)).

Although its precise role remains to be elucidated, there is evidence 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, Document ID 1383). Further investigation by McCord in 1951 (Document ID 1448) 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 poorly soluble 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, Document ID 1273). 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, Document ID 1383). Contamination of cuts and scrapes with beryllium can result in the beryllium becoming embedded within the skin causing an ulcerating granuloma to develop in the skin (Epstein, 1991, Document ID 0526). Soluble and poorly soluble beryllium-compounds that penetrate the skin as a result of abrasions or cuts have been shown to result in chronic ulcerations and skin granulomas (Van Ordstrand *et al.,* 1945, Document ID 1383; Lederer and Savage, 1954 (1467)). Beryllium absorption through bruises and cuts has been demonstrated as well (Rossman *et al.,* 1991, Document ID 1332).

In a study by Ivannikov *et al.* (1982) (as cited in Deubner *et al.,* 2001, Document ID 0023), beryllium chloride was applied directly to three different types of wounded skin: abrasions (superficial skin trauma), cuts (skin and superficial muscle trauma), and penetration wounds (deep muscle trauma). According to Deubner *et al.* (2001) the percentage of the applied dose systemically absorbed 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 (Deubner *et al.,* 2001, Document ID 0023).

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, Document ID 1543). 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, Document ID 0474), multiplied by a factor of 10 to approximate the workplace concentrations and the very low absorption rate of beryllium into skin of 0.001 percent (taken from EPA estimates). As cited by Deubner *et al.* (2001), the EPA 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 (Deubner *et al.,* 2001, Document ID 1543).

A study conducted by Day *et al.* (2007) evaluated the effectiveness of a dermal protection program implemented in a beryllium alloy facility in 2002 (Document ID 1548). 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 strong correlation between air concentrations determined from sampling data 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) demonstrating the importance of dermal protection measures since sensitization can occur via dermal exposure as well as respiratory exposure. The investigators demonstrated multiple pathways of exposure which could lead to sensitization, increasing risk for developing CBD (Day *et al.,* 2007, Document ID 1548).

The same group of investigators extended their work on investigating multiple exposure pathways contributing to sensitization and CBD (Armstrong *et al.,* 2014, Document ID 0502). 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 and surface concentrations; glove and surface concentrations; and air and glove concentrations at this facility. This work supports findings from Day *et al.* (2007) (Document ID 1548) demonstrating the importance of airborne beryllium concentrations to surface contamination and dermal exposure even at exposures below the preceding OSHA PEL (Armstrong *et al.,* 2014, Document ID 0502).

OSHA received comments regarding the potential for dermal penetration of poorly soluble particles. Materion contended there is no supporting evidence to suggest that insoluble or poorly soluble particles penetrate skin and stated:

> . . . we were aware that, a hypothesis has been put forth which suggests that being sensitized to beryllium either through a skin wound or via penetration of small beryllium particles through intact skin could result in sensitization to beryllium which upon receiving a subsequent inhalation dose of airborne beryllium could result in CBD. However, there are no studies that skin absorption of insoluble beryllium results in a systemic effect. The study by Curtis, the only human study looking for evidence of a beryllium sensitization reaction occurring through intact human skin, found no sensitization reaction using insoluble forms of beryllium. (Document ID 1661, p. 12).

OSHA disagrees with the assertion that no studies are available indicating skin absorption of poorly soluble (insoluble) beryllium. In addition to the study cited by Materion (Curtis, 1951, Document ID 1273), OSHA reviewed numerous studies on the effects of beryllium solubility and dermal penetration (see section V. B. 2) including the Tinkle *et al.* (2003) (Document ID 1483) study which demonstrated the potential for poorly soluble beryllium particles to penetration skin using an ex vivo human skin model. While OSHA believes that these studies demonstrate poorly soluble beryllium can in fact penetrate intact skin, penetration through intact skin is not the only means for a person to become sensitized through skin contact with poorly soluble beryllium. During the informal hearing proceedings, NIOSH was asked about the role of poorly soluble beryllium in sensitizing workers to beryllium. Aleks Stefaniak, Ph.D., NIOSH, stated that ''intact skin naturally has a barrier that prevents moisture from seeping out of the body and things from getting into the body. Very few people actually have fully intact skin, especially in an industrial environment. So the skin barrier is often compromised, which would make penetration of particles much easier.'' (Document ID 1755, Tr. 36).

As summarized above, poorly soluble beryllium particles have been shown to solubilize in biological fluids (*e.g.,* sweat) releasing beryllium ions and making them available for absorption through intact skin (Sutton *et al.,* 2003, Document ID 1393; Stefaniak *et al.* 2014 (0517); Duling *et al.,* 2012 (0539)). Epidemiological studies evaluating the effectiveness of PPE in facilities working with beryllium (with special emphasis on skin protection) have demonstrated a reduced rate of beryllium sensitization after implementation of this type of control (Day *et al.,* 2007, Document ID 1548; Armstrong *et al.,* 2014 (0502)). Dr. Stefaniak confirmed these findings:

> [T]he particles can actually dissolve when they're in contact with liquids on the skin, like sweat. So we've actually done a series of studies, using a simulant of sweat, but it had characteristics that very closely matched human sweat. We see in those studies that, in fact, beryllium particles, beryllium oxide, beryllium metal, beryllium alloys, all these sort of what we call insoluble forms actually do in fact dissolve very readily in analog of human sweat. And once beryllium is in an ionic form on the skin, it's actually very easy for it to cross the skin barrier. And that's been shown many, many times in studies that beryllium ions can cross the skin and induce sensitization. (Document ID 1755, Tr. 36–37).

Based on information from various studies demonstrating that poorly soluble particles have the potential to penetrate skin, that skin as a barrier is rarely intact (especially in industrial settings), and that beryllium particles can readily dissolve in sweat and other biological fluids, OSHA finds that dermal exposure to poorly soluble beryllium can cause sensitization (Rossman, *et al.,* 1991, Document ID 1332; Deubner *et al.,* 2001 (1542); Tinkle *et al.,* 2003 (1483); Sutton *et al.,* 2003 (1393); Stefaniak *et al.,* 2011 (0537) and 2014 (0517); Duling *et al.,* 2012 (0539); Document ID 1755, Tr. 36–37).

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 (Document ID 1282). 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 poorly soluble material deposited in the upper respiratory tract (Schlesinger, 1997, Document ID 1290). Animal studies have shown oral administration of beryllium compounds to result in very limited absorption and storage (as reviewed by U.S. EPA, 1998, Document ID 0661). Oral studies utilizing radio-labeled beryllium chloride in rats, mice, dogs, and monkeys, found the majority of the beryllium was unabsorbed by the gastrointestinal tract and was eliminated in the feces. In most studies, less than 1 percent of the administered radioactivity was absorbed into the bloodstream and subsequently excreted in the urine (Crowley *et al.,* 1949, Document ID 1551; Furchner *et al.,* 1973 (1523); LeFevre and Joel, 1986 (1464)). 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 poorly soluble phosphate and is not absorbed (Reeves, 1965, Document ID 1430; WHO, 2001 (1282)).

Further studies suggested that beryllium absorbed into the bloodstream is primarily excreted via urine (Crowley *et al.,* 1949, Document ID 1551; Furchner *et al.,* 1973 (1523); Scott *et al.,* 1950 (1413); Stiefel *et al.,* 1980 (1288)). Unabsorbed beryllium is primarily excreted via the fecal route (Finch *et al.,* 1990, Document ID 1318; Hart *et al.,* 1980 (1493)). Parenteral administration in a variety of animal species demonstrated that beryllium was eliminated at much higher percentages in the urine than in the feces (Crowley *et al.,* 1949, Document ID 1551; Furchner *et al.,* 1973 (1523); Scott *et al.,* 1950 (1413)). A study using percutaneous administration of soluble beryllium nitrate in rats demonstrated that more than 90 percent of the beryllium in the bloodstream was eliminated via urine (WHO, 2001, Document ID 1282). Greater than 99 percent of ingested beryllium chloride was excreted in the feces (Mullen *et al.,* 1972, Document ID 1442). A study of mice, rats, monkeys, and dogs given intravenously dosed with beryllium chloride determined elimination half-times to be between 890 to 1,770 days (2.4 to 4.8 years) (Furchner *et al.,* 1973, Document ID 1523). In a comparison study, baboons and rats were instilled intratracheally with beryllium metal. Mean daily excretion rates were calculated as 4.6×10^{-5} percent of the dose administered in baboons and 3.1×10^{-5} percent in rats (Andre *et al.,* 1987, Document ID 0351).

In summary, animal studies evaluating the absorption, distribution and excretion of beryllium compounds found that, in general, poorly soluble beryllium compounds were not readily absorbed in the gastrointestinal tract and was mostly excreted via feces (Hart *et al.,* 1980, Document ID 1493; Finch *et al.,* 1990 (1318); Mullen *et al.,* 1972 (1442)). Soluble beryllium compounds orally administered were partially cleared via urine; however, some soluble forms are precipitated in the gastrointestinal tract due to different pH values between the intestine and the stomach (Reeves, 1965, Document ID 1430). Intravenous administration of poorly soluble beryllium compounds were distributed systemically through the lymphatics and stored in the skeleton for potential later release (Furchner *et al.,* 1973, Document ID 1523). Therefore, while intravenous administration can lead to uptake, OSHA does not consider oral and gastrointestinal exposure to be a major route for the uptake of beryllium because poorly soluble beryllium is not readily absorbed in the gastrointestinal tract.

4. Metabolism

Beryllium and its compounds may not be metabolized or biotransformed, but soluble beryllium salts may be converted to less soluble forms in the lung (Reeves and Vorwald, 1967, Document ID 1309). As stated earlier, solubility is an important factor for persistence of beryllium in the lung. Poorly soluble phagocytized beryllium particles can be dissolved into an ionic form by an acidic cellular environment and by myeloperoxidases or macrophage phagolysomal fluids (Leonard and Lauwerys, 1987, Document ID 1293; Lansdown, 1995 (1469); WHO, 2001 (1282); Stefaniak *et al.,* 2006 (1398)). The positive charge of the beryllium ion 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, Document ID 1531).

5. Conclusion For Particle Characterization and Kinetics and Metabolism of Beryllium

The forms and concentrations of beryllium across the workplace vary substantially based upon location, process, production and work task. Many factors may influence the potency of beryllium including concentration, composition, structure, size, solubility 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, Document ID 1355), 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 to release beryllium ions (Sutton *et al.,* 2003, Document ID 1393; Stefaniak *et al.,* 2011(0537) and 2014(0517)). For beryllium to persist in the lung it needs to be poorly soluble. However, soluble beryllium has been shown to precipitate in the lung to form poorly soluble beryllium (Reeves and Vorwald, 1967, Document ID 1309).

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 poorly soluble particles or mist) can deposit in the respiratory tract and interact with immune cells located along the entire respiratory tract (Scheslinger, 1997, Document ID 1290). Interaction and presentation of beryllium (either in ionic or particulate form) is discussed further in Section V.D.1.

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, Document ID 1383) and later reported by Eisenbud (1948) and Aub (1949) (as cited in Document ID 1662, p. 2). Since the Atomic Energy Commission's adoption of a maximum permissible peak occupational exposure limit of 25 $\mu g/m^3$ for beryllium beginning in 1949, cases of ABD have been much rarer. According to the World Health Organization (2001), ABD is generally associated with exposure to beryllium levels at or above 100 $\mu g/m^3$ and may be fatal in 10 percent of cases (Document ID 1282). However, cases of ABD have been reported with beryllium exposures below 100 $\mu g/m^3$ (Cummings *et al.,* 2009, Document ID 1550). The Cummings *et al.* (2009) study examined two cases of workers exposed to soluble and poorly soluble beryllium below 100 $\mu g/m^3$ using data obtained from company records. Cummings *et al.* (2009) also examined the possibility that an immune-mediated mechanism may exist for ABD as well as CBD and that ABD and CBD are on a pathological continuum since some patients would later develop CBD after recovering from ABD (ACCP, 1965, Document ID 1286; Hall, 1950 (1494); Cummings *et al.,* 2009 (1550)).

ABD involves an inflammatory or immune-mediated 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, Document ID 1527).

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, Document ID 1494; DeNardi *et al.,* 1953 (1545); Newman and Kreiss, 1992 (1440)). Evidence of a dose-response relationship to the concentration of beryllium is limited (Eisenbud *et al.,* 1948, Document ID 0490; Stokinger, 1950 (1484); Sterner and Eisenbud, 1951 (1396)). Recovery from either type of ABD is generally complete after a period of several weeks or months (DeNardi *et al.,* 1953, Document ID 1545). However, deaths have been reported in more severe cases (Freiman and Hardy, 1970, Document ID 1527). 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, 1982, Document ID 1254; Middleton, 1998 (1445)). ABD is extremely rare in the workplace today due to more stringent exposure controls implemented following occupational and environmental standards set in 1970–1971 (ACGIH, 1971, Document ID 0543; ANSI, 1970 (1303); OSHA, 1971, see 39 FR 23513; EPA, 1973 (38 FR 8820)).

Materion submitted post-hearing comments regarding ABD (Document ID 1662, p. 2; Attachment A, p. 1). Materion contended that only soluble forms of beryllium have been demonstrated to produce ABD at exposures above 100 $\mu g/m^3$ because cases of ABD were only found in workers exposed to beryllium during beryllium extraction processes which always contain soluble beryllium (Document ID 1662, pp. 2, 3). Citing communications between Marc Kolanz (Materion) and Dr. Eisenbud, Materion noted that when Mr. Kolanz asked Dr. Eisenbud if he ever ''observed an acute reaction to beryllium that did not involve the beryllium extraction process and exposure to soluble salts of beryllium,'' Dr. Eisenbud responded that ''he did not know of a case that was not either directly associated with exposure to soluble compounds or where the work task or operation would have been free from exposure to soluble beryllium compounds from adjacent operations.'' (Document ID 1662, p. 3). OSHA acknowledges that workers with ABD may have been exposed to a combination of soluble and poorly soluble beryllium. This alone, however, cannot completely exclude poorly soluble beryllium as a causative or contributing agent of ABD. The WHO (2001) has concluded that both ABD and CBD results from exposure to both soluble and insoluble forms of beryllium. In addition, the European Commission has classified poorly soluble beryllium and beryllium oxide as acute toxicity categories 2 and 3 (Document ID 1669, p. 2).

Additional comments from Materion regarding ABD criticized the study by Cummings *et al.* (2009), stating that it ''incompletely explained the source of the workers exposures, which resulted in the use of a misleading statement that, 'None of the measured air samples exceeded 100 μg/m^3 and most were less than 10 μg/m^3.' '' (Document ID 1662, p. 3). Materion argues that the Cummings *et al.* study is not valid because workers in that study ''had been involved with high exposures to soluble beryllium salts caused by upsets during the chemical extraction of beryllium.'' (Document ID 1662, pp. 3–4). In response, NIOSH written testimony explained that the measurements in the study ''were collected in areas most likely to be sources of high beryllium exposures in processes, but were not personal breathing zone measurements in the usual sense.'' (Document ID 1725, p. 3). ''Cummings *et al.* (2009) made every effort to overestimate (rather than underestimate) exposure,'' including ''select[ing] the highest time weighted average (TWA) value from the work areas or activities associated with a worker's job and tenure'' and not adjusting for ''potential protective effects of respirators, which were reportedly used for some tasks and during workplace events potentially associated with uncontrolled higher exposures.'' Even so, ''the available TWA data did not exceed 100 μg/m^3 even on days with evacuations.'' (Document ID 1725, p. 3). Furthermore, OSHA notes that, the discussion in Cummings *et al.* (2009) stated, ''we cannot rule out the possibility of unusually elevated airborne concentrations of beryllium that went unmeasured.'' (Document ID 1550, p. 5).

In response to Materion's contention that OSHA should eliminate the section on ABD because this disease is no longer a concern today (Document ID 1661, p. 2), OSHA notes that the discussion on ABD is included for thoroughness in review of the health effects caused by exposure to beryllium. As indicated above, the Agency acknowledges that ABD is extremely rare, but not non-existent, in workplaces today due to the more stringent exposure controls implemented since OSHA's inception (OSHA, 1971, see 39 FR 23513).

D. Beryllium Sensitization and 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 (Document ID 1516). It was proposed as early as 1951 that CBD could be a chronic disease resulting from sensitization to beryllium (Sterner and Eisenbud, 1951, Document ID 1396; Curtis, 1959 (1273); Nishimura, 1966 (1435)). 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, Document ID 1355). 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, Document ID 0436; Rossman *et al.,* 1988 (0476); Saltini *et al.,* 1989 (1351)).

CBD shares many clinical and histopathological features with pulmonary sarcoidosis, a granulomatous lung disease of unknown etiology. These similarities include 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, Document ID 1533; Rossman and Kreider, 2003 (1423)). 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.,* 2005, Document ID 1262; Cherry *et al.,* 2015 (0463)).

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 (Pappas and Newman, 1993, Document ID 1433; Rossman, 1996 (1283); NAS, 2008 (1355)). These symptoms are consistent with the CBD symptoms described during the public hearing by Dr. Kristin Cummings of NIOSH and Dr. Lisa Maier of National Jewish Health (Document ID 1755, Tr. 70–71; 1756, Tr. 105–107).

Besides these listed symptoms from CBD patients, there have been reported cases of CBD that remained asymptomatic (Pappas and Newman, 1993, Document ID 1433; Muller-Querheim, 2005 (1262); NAS, 2008 (1355); NIOSH, 2011 (0544)). Asymptomatic CBD refers to those patients that have physiological changes upon clinical evaluation yet exhibit no outward signs or symptoms (also referred to as subclinical CBD).

Unlike ABD, CBD can result from inhalation exposure to beryllium at levels below the preceding OSHA PEL, can take months to years after initial beryllium exposure before signs and symptoms of CBD occur (Newman 1996, Document ID 1283, 2005 (1437) and 2007 (1335); Henneberger, 2001 (1313); Seidler *et al.,* 2012 (0457); Schuler *et al.,* 2012 (0473)), and may continue to progress following removal from beryllium exposure (Newman, 2005, Document ID 1437; Sawyer *et al.,* 2005 (1415); Seidler *et al.,* 2012 (0457)). 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, Document ID 1425; Newman *et al.,* 2005 (1437)). The National Academy of Sciences (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, Document ID 1355). 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 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, Document ID 1355). A study by Newman (1996) emphasized the need for prospective studies to determine the natural history and time course from beryllium sensitization and asymptomatic CBD to full-blown disease (Newman, 1996, Document ID 1283). Drawing from his own clinical experience, Dr. 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, Document ID 1355; Newman, 1996 (1283)).

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 *et al.,* 2008, Document ID 0370; NAS, 2008 (1355)). 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.

A study by Pappas and Newman (1993) observed that patients with known prior beryllium exposure and identified as confirmed positive for beryllium sensitization through the beryllium lymphocyte proliferation test (BeLPT) screening were evaluated for physiological changes in the lung. Pappas and Newman categorized the patients as being either ''clinically identified,'' meaning they had known physiological abnormalities (*e.g.,* abnormal chest radiogram, respiratory symptoms) or ''surveillance-identified,'' meaning they had BeLPT positive results with no reported symptoms, to differentiate state of disease progression. Physiological changes were identified by three factors: (1) Reduced tolerance to exercise; (2) abnormal pulmonary function test during exercise; (3) abnormal arterial blood gases during exercise. Of the patients identified as ''surveillance identified,'' 52 percent had abnormal exercise physiologies while 87 percent of the ''clinically identified'' patients had abnormal physiologies (Pappas and Newman, 1993, Document ID 1433). During the public hearing, Dr. Newman noted that:

> . . . one of the sometimes overlooked points is that in that study . . . the majority of people who were found to have early stage disease already had physiologic impairment. So before the x-ray or the CAT scan could find it the BeLPT had picked it up, we had made a diagnosis of pathology in those people, and their lung function tests—their measures of gas exchange, were already abnormal. Which put them on our watch list for early and more frequent monitoring so that we could observe their worsening and then jump in with treatment at the earliest appropriate time. So there is advantage of having that early diagnosis in terms of the appropriate tracking and appropriate timing of treatment. (Document ID 1756, p. 112).

OSHA was unable to find any controlled studies to determine the optimal treatment for CBD (see Rossman, 1996, Document ID 1425; NAS 2008 (1355); Sood, 2009 (0456)), and none were added to the record during the public comment period. 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. Document ID 1355; Maier *et al.,* 2012 (0461); Salvator *et al.,* 2013 (0459)) 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, Document ID 1521; Zaki *et al.,* 1987 (1374)). Alternative treatments such as azathioprine and infliximab, while successful at treating symptoms of CBD, have been demonstrated to have side effects as well (Pallavicino *et al.,* 2013, Document ID 0630; Freeman, 2012 (0655)).

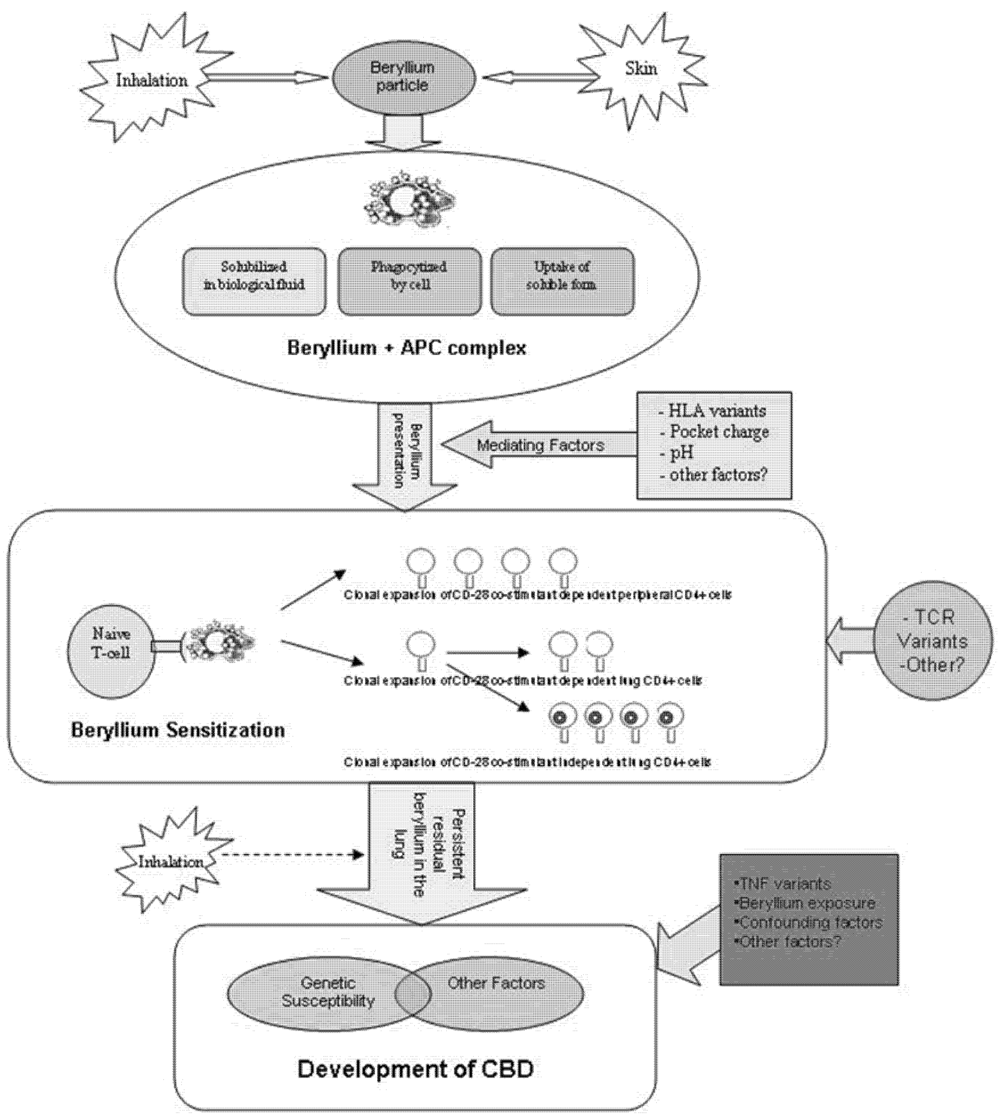
1. Development of Beryllium Sensitization

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, Document ID 1437; NAS, 2008 (1355)), as well as from skin exposure to beryllium (Curtis, 1951, Document ID 1273; Newman *et al.,* 1996 (1439); Tinkle *et al.,* 2003 (1483); Rossman, *et al.,* 1991, (1332); Deubner *et al.,* 2001 (1542); Tinkle *et al.,* 2003 (1483); Sutton *et al.,* 2003 (1393); Stefaniak *et al.,* 2011 (0537) and 2014 (0517); Duling *et al.,* 2012 (0539); Document ID 1755, Tr. 36–37). Representative Robert C. ''Bobby'' Scott, Ranking Member of Committee on Education and the Workforce, the U.S. House of Representatives, provided comments to the record stating that ''studies have demonstrated that beryllium sensitization, an indicator of immune response to beryllium, can occur from both soluble and poorly soluble beryllium particles.'' (Document ID 1672, p. 3).

Sensitization is currently detected using the BeLPT (a laboratory blood test) described in section V.D.5. Although there may be no clinical symptoms associated with beryllium sensitization, 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, Document ID 1477; Newman *et al.,* 1996 (1439); Kreiss *et al.,* 1997 (1360); Kelleher *et al.,* 2001 (1363); Rossman, 2001 (1424); Newman *et al.,* 2005 (1437)). Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of sensitization (NAS, 2008, Document ID 1355). The expert peer reviewers agreed that the scientific evidence supported sensitization as a necessary condition and an early endpoint in the development of CBD (ERG, 2010, Document ID 1270, pp. 19–21). Dr. John Balmes remarked that the ''scientific evidence reviewed in the [Health Effects] document supports consideration of beryllium sensitization as an early endpoint and as a necessary condition in the development of CBD.'' Dr. Patrick Breysee stated that ''there is strong scientific consensus that sensitization is a key first step in the progression of CBD.'' Dr. Terry Gordon stated that ''[a]s discussed in the draft [Health Effects] document, beryllium sensitization should be considered as an early endpoint in the development of CBD.'' Finally, Dr. Milton Rossman agreed ''that sensitization is necessary for someone to develop CBD and should be considered a condition/risk factor for the development of CBD.'' Various factors, including genetic susceptibility, have been shown to influence risk of developing sensitization and CBD (NAS 2008, Document ID 1355) 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, Document ID 1363; Henneberger *et al.,* 2001 (1313)). 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, Document ID 1354; Henneberger *et al.,* 2001 (1313); Rossman, 2001 (1424); Schuler *et al.,* 2005 (0919); Donovan *et al.,* 2007 (0491), Schuler *et al.,* 2012 (0473)) 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, Document ID 1477; Kreiss *et al.,* 1997 (1360)). While only very limited evidence has described humoral changes in certain patients with CBD (Cianciara *et al.,* 1980, Document ID 1553), clear evidence exists for an immune cell-mediated response, specifically the T-cell (NAS, 2008, Document ID 1355). Figure 2 delineates the major steps required for progression from beryllium contact to sensitization to CBD.

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



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, Document ID 1475). Some soluble forms of beryllium are readily presented, since the soluble beryllium form disassociates into its ionic components. However, for poorly soluble 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 (Document ID 1257). Stefaniak *et al.* (2006 and 2012) reported that poorly soluble beryllium particles phagocytized by macrophages were dissolved in phagolysomal fluid (Stefaniak *et al.,* 2006, Document ID 1398; Stefaniak *et al.,* 2012 (0469)) and that the dissolution rate stimulated by phagolysomal fluid was different for various forms of beryllium (Stefaniak *et al.,* 2006, Document ID 1398; Duling *et al.,* 2012 (0539)). 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, Document ID 1417; Sawyer *et al.,* 2004 (1416); Kittle *et al.,* 2002 (0485)). 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, Document ID 1355).

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, Document ID 1355; Yucesoy and Johnson, 2011 (0464); Petukh *et al.,* 2014 (0397)). Several studies have also demonstrated that the electrostatic charge of HLA may be a factor in binding beryllium (Snyder *et al.,* 2003, Document ID 0524; Bill *et al.,* 2005 (0499); Dai *et al.,* 2010 (0494)). 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, Document ID 0471; Dai *et al.,* 2010 (0494); Petukh *et al.,* 2014 (0397)). 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, Document ID 0455). The direct binding of BeO may eliminate the biological requirement for antigen processing or dissolution of beryllium oxide to activate an immune response.

Once the beryllium-MHC-APC complex is established, the complex binds 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, Document ID 1351 and 1990 (1420); Martin *et al.,* 2011 (0483)) 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, Document ID 0489). This may also indicate a pathogenic potential for subsets of T-cell clones expressing this homologous TCR (NAS, 2008, Document ID 1355). Fontenot *et al.* (2006) (Document ID 0487) reported beryllium self-presentation by HLA–DP expressing BAL $CD4^+$ T-cells. According the NAS report, BAL T-cell self-presentation in the lung granuloma may result in cell death, leading to oligoclonality (only a few clones) of the T-cell population characteristic of CBD (NAS, 2008, Document ID 1355).

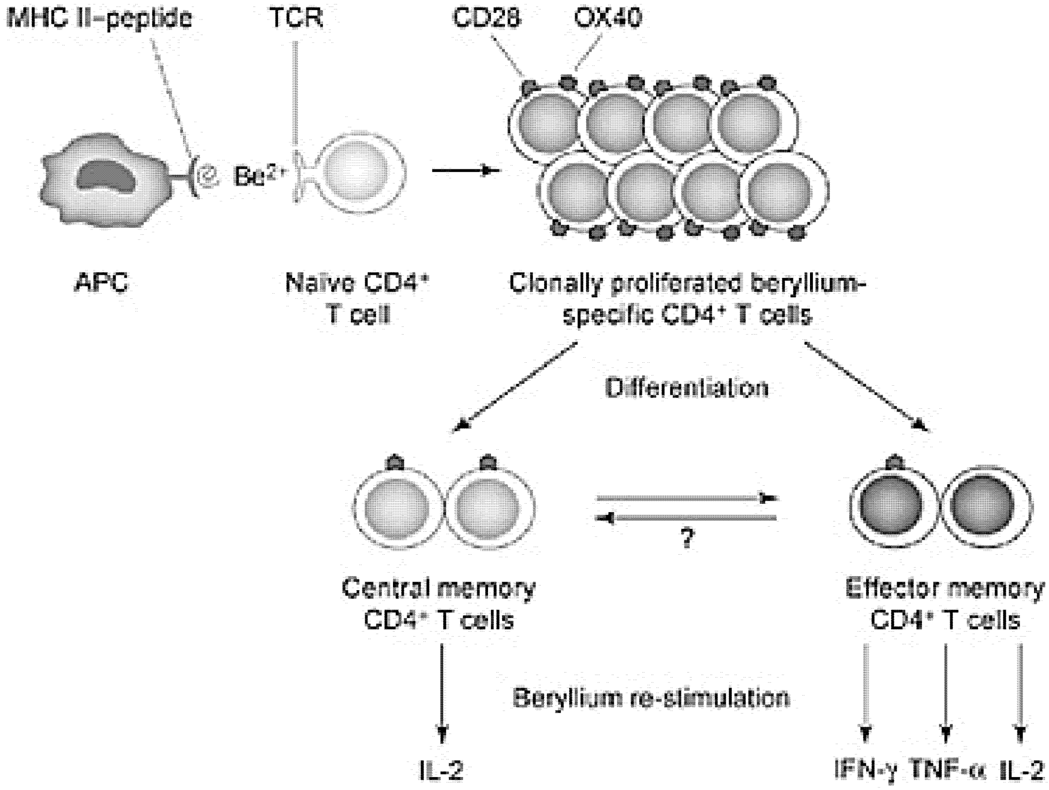


FIGURE 3 - Immune response to beryllium.
Source: Fontenot and Maier 2005. Reprinted with permission; copyright 2005, Trends in Immunology (Document ID 0488).

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, Document ID 1416; Kimber *et al.,* 2011 (0534)).

In summary, OSHA concludes that sensitization is a necessary and early functional change in the immune system that leads to the development of CBD.

2. Development of CBD

The continued presence 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, Document ID 1529). This change in phenotype correlated with lung inflammation (Fontenot *et al.,* 2003, Document ID 1529). While these $CD4^+$ independent cells continued to secrete cytokines necessary for additional recruitment of inflammatory and immunological cells, they were less proliferative and less susceptible to cell death compared to the CD28 dependent cells (Fontenot *et al.,* 2005, Document ID 1528; Mack *et al.,* 2008 (1460)). These beryllium-specific $CD4^+$ independent cells are considered to be mature memory effector cells (Ndejembi *et al.,* 2006, Document ID 0479; Bian *et al.,* 2005 (0500)). 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, Document ID 1528).

$CD4^+$ 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.,* 1997, Document ID 1387; Tinkle *et al.,* 1997 (1388); Fontenot *et al.,* 2002 (1530)) and MIP–1α and GRO–1 (Hong-Geller, 2006, Document ID 1511). This also results in the accumulation of various types of inflammatory cells including mononuclear cells (mostly $CD4^+$ T cells) in the BAL fluid (Saltini *et al.,* 1989, Document ID 1351, 1990 (1420)).

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, Document ID 1355). 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, Document ID 1415; Tinkle *et al.,* 1996 (0468); Hong-Geller *et al.,* 2006 (1511); NAS, 2008 (1355)).

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, Document ID 1351, 1990 (1420)).

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, Document ID 1421). 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, Document ID 1319; ACCP, 1965 (1286); Kriebel *et al.,* 1988, Document ID 1292; Kriebel *et al.,* 1988 (1473)). While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys (ATSDR, 2002, Document ID 1371).

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, Document ID 1417; Kittle *et al.,* 2002 (0485); Sawyer *et al.,* 2004 (1416)). 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, Document ID 0478; Rana, 2008 (0477)). Macrophages and neutrophils can phagocytize beryllium particles in an attempt to remove the beryllium from the lung (Ding, *et al.,* 2009, Document ID 0492)). Multiple studies (Sawyer *et al.,* 2004, Document ID 1416; Kittle *et al.,* 2002 (0485)) 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, Document ID 1299; Dai *et al.,* 1999 (0495)). The stimulation of CBD-derived macrophages by beryllium sulfate 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, Document ID 1417). However, other factors, such as genetic factors and duration or level of exposure leading to a continued presence of beryllium in the lung, may influence the development of CBD and are outlined in the following sections V.D.3 and V.D.4.

In summary, the persistent presence of beryllium in the lung of a sensitized individual creates a progressive inflammatory response that can culminate in the granulomatous lung disease, CBD.

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, Document ID 1396). 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, Document ID 1531; Amicosante *et al.,* 2005 (1564); Tinkle *et al.,* 1996 (0468); Gaede *et al.,* 2005 (0486); Van Dyke *et al.,* 2011 (1696); Silveira *et al.,* 2012 (0472)).

Potential sources of variation associated with genetic susceptibility have been investigated. 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, beryllium sensitization, and CBD (McClesky *et al.,* 2009, as cited in Document ID 1808, p. 3). Specific SNPs have been evaluated as a factor in the Glu69 variant from the HLA–DPB1 locus (Richeldi *et al.,* 1993, Document ID 1353; Cai *et al.,* 2000 (0445); Saltini *et al.,* 2001 (0448); Silviera *et al.,* 2012 (0472); Dai *et al.,* 2013 (0493)). Other SNPs lacking the Glu69 variant, such as HLA–DRPheβ47, have also been evaluated for an association with CBD (Amicosante *et al.,* 2005, Document ID 1564).

HLA–DPB1 (one of 2 subtypes of HLA–DP) with a glutamic acid at amino position 69 (Glu69) has been shown to confer increased risk of beryllium sensitization and CBD (Richeldi *et al.,* 1993, Document ID 1353; Saltini *et al.,* 2001 (0448); Amicosante *et al.,* 2005 (1564); Van Dyke *et al.,* 2011 (1696); Silveira *et al.,* 2012 (0472)). *In vitro* human research has identified genes coding for specific protein molecules on the surface of the immune cells of sensitized individuals from a cohort of beryllium workers (McCanlies *et al.,* 2004, Document ID 1449). The research identified the HLA–DPB1 (Glu69) allele that place carriers at greater risk of becoming sensitized to beryllium and developing CBD than those not carrying this allele (McCanlies *et al.,* 2004, Document ID 1449). Fontenot *et al.* (2000) demonstrated that beryllium presentation by certain alleles of the class II human leukocyte antigen-DP (HLA–DP [3]) to $CD4^+$ T cells is the mechanism underlying the development of CBD (Document ID 1531). Richeldi *et al.* (1993) reported a strong association between the MHC class II allele HLA–DPB 1 and the development of CBD in beryllium-exposed workers from a Tucson, AZ facility (Document ID 1353). 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 alleles of the HLA–DPB 1 containing a variant of Glu69 are negatively charged at this site and could directly interact with the positively charged beryllium ion. Additional studies by Amicosante *et al.* (2005) (Document ID 1564) 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) (Document ID 1394) also found a relationship between the HLA–DP 1 allele and beryllium sensitization. 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 sensitization 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 yielded an approximately 10-fold increase (Weston *et al.,* 2005, Document ID 1345; Snyder *et al.,* 2008 (0471)). Specifically, Snyder *et al.* (2008) found that variants of the Glu69 allele with the greatest negative charge may confer greater risk for developing CBD (Document ID 0471). The study by Weston *et al.* (2005) assigned odds ratios for specific alleles on the basis of previous studies discussed above (Document ID 1345). The researchers found a strong

[3] HLA–DP and HLA DPB1 alleles have been associated with genetic susceptibility for developing CBD. HLA–DP has 2 subtypes, HLA–DPA and HLA–DPB. HLA–DBP1 is involved with the Glu69 allele most associated with genetic susceptibility.

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 (Weston *et al.,* 2005, Document ID 1345). This confirms the importance of beryllium charge as a key factor in its ability to induce an immune response.

In contrast, the HLA–DRB1 allele, which lacks Glu69, has also been shown to increase the risk of developing sensitization and CBD (Amicosante *et al.,* 2005, Document ID 1564; Maier *et al.,* 2003 (0484)). Bill *et al.* (2005) found that HLA–DR has a glutamic acid at position 71 of the β chain, functionally equivalent to the Glu69 of HLA–DP (Bill *et al.,* 2005, Document ID 0499). Associations with BeS and CBD have also been reported with the HLA–DQ markers (Amicosante *et al.,* 2005, Document ID 1564; Maier *et al.,* 2003 (0484)). 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, Document ID 1370). 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, Document ID 0497). 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 non-proliferating BAL CD4 T cells may still contribute to inflammation leading to the progression of CBD (Chou *et al.,* 2005, Document ID 0497).

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 that may be associated with a more progressive form of CBD (NAS, 2008). Beryllium exposure has been shown to upregulate transcription factors AP–1 and NF-κB (Sawyer *et al.,* 2007, as cited in Document ID 1355) 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, Document ID 1456; Saltini *et al.,* 2001 (0448); Dotti *et al.,* 2004 (1540)). While a study by McCanlies *et al.* (2007) (Document ID 0482) of 886 beryllium workers (including 64 sensitized for beryllium and 92 with CBD) found no relationship between TNF-α polymorphism and sensitization or CBD, the National Academies of Sciences noted that ''discrepancies between past studies showing associations and the more recent studies may be due to misclassification, exposure differences, linkage disequilibrium between HLA–DRB1 and TNF-α genes, or statistical power.'' (NAS, 2008, Document ID 1355).

Other genetic variations have been shown to be associated with increased risk of beryllium sensitization and CBD (NAS, 2008, Document ID 1355). These include TGF-β (Gaede *et al.,* 2005, Document ID 0486), angiotensin-1 converting enzyme (ACE) (Newman *et al.,* 1992, Document ID 1440; Maier *et al.,* 1999 (1458)) and an enzyme involved in glutathione synthesis (glutamate cysteine ligase) (Bekris *et al.,* 2006, as cited in Document ID 1355). 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 (Document ID 0481). 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 between those variants and beryllium sensitization.

In addition to the genetic factors which may contribute to the susceptibility and severity of disease, other factors such as smoking and sex may play a role in the development of CBD (NAS, 2008, Document ID 1355). 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, Document ID 1356).

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 BeLTT (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, Document ID 1552; Maier, 2001 (1456)). 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 to 49 percent of them were diagnosed with CBD (Kreiss *et al.,* 1993, Document ID 1479; Newman *et al.,* 1996 (1283), 2005 (1437), 2007 (1335); Mroz, 2009 (1356)), although some estimate that with increased surveillance that percentage could be much higher (Newman, 2005, Document ID 1437; Mroz, 2009 (1356)). 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, Document ID 1437). The study by Newman *et al.* (2005) was the first longitudinal study to assess the progression from beryllium sensitization to CBD in individuals undergoing clinical evaluation at National Jewish Medical and Research Center from 1988 through 1998. Approximately 50 percent of sensitized individuals (as identified by BeLPT) had CBD at their initial clinical evaluation. The remaining 50 percent, or 76 individuals, without evidence of CBD were monitored at approximately two year intervals for indication of disease progression by pulmonary function testing, chest radiography (with International Labour Organization B reading), fiberoptic bronchoscopy with bronchoalveolar lavage, and transbronchial lung biopsy. Fifty-five of the 76 individuals were monitored with a range of two to five clinical evaluations each. The Newman *et al.* (2005) study found that CBD developed in 31 percent of individuals (17 of the 55) in a period ranging from 1.0 to 9.5 years (average 3.8 years). After an average of 4.8 years (range 1.7 to 11.6 years) the remaining individuals showed no signs of progression to CBD. A study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that the sensitization rate in exposed workers increased rapidly over the first 10 years of beryllium exposure and then more gradually in succeeding years. On the other hand, the rate of CBD pathology increased slowly over the first 15 years of exposure and then climbed more steeply following 15 to 30 years of beryllium exposure (Stange *et al.,* 2001, Document ID 1403). The findings from these longitudinal studies of sensitized workers provide evidence of CBD progression over time from asymptomatic to symptomatic disease. One limitation for all these studies is lack of long-term follow-up. Newman suggested that it may be necessary to continue to monitor these workers in order to determine whether all sensitized workers will develop CBD (Newman *et al.,* 2005, Document ID 1437).

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, Document ID 1355). OSHA requested additional information in the NPRM, but no additional studies were added during the public comment period. 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, Document ID 1355). In advanced cases of CBD, corticosteroids are the standard treatment (NAS, 2008, Document ID 1355). No comprehensive studies have been published measuring the overall effect of removal of workers from beryllium exposure on sensitization and CBD (NAS, 2008, Document ID 1355) although this has been suggested as part of an overall treatment regime for CBD (Mapel *et al.,* 2002, as cited in Document ID 1850; Sood *et al.,* 2004 (1331); Sood, 2009 (0456); Maier *et al.,* 2012 (0461)). Expert testimony from Dr. Lee Newman and Dr. Lisa Maier agreed that while no studies exist on the efficacy of removal from beryllium exposure, it is medically prudent to reduce beryllium exposure once someone is sensitized (Document ID 1756, Tr. 142). Sood *et al.* reported that cessation of exposure can sometimes have beneficial effects on lung function (Sood *et al.,* 2004, Document ID 1331). However, this was based on anecdotal evidence from six patients with CBD, while this indicates a benefit of removal of patients from exposure, more research is needed to better determine the relationship between exposure duration and disease progression.

Materion commented that sensitization should be defined as a test result indicating an immunological sensitivity to beryllium without identifiable adverse health effects or other signs of illness or disability. It went on to say that, for these reasons, sensitization is not on a pathological continuum with CBD (Document ID 1661, pp. 4–7). Other commenters disagreed. NIOSH addressed whether sensitization should be considered an adverse health effect and said the following in their written hearing testimony:

> Some have questioned whether BeS should be considered an adverse health effect. NIOSH views it as such, since it is a biological change in people exposed to beryllium that is associated with increased risk for developing CBD. BeS refers to the immune system's ability to recognize and react to beryllium. BeS is an antigen-specific cell mediated immunity to beryllium, in which CD4+ T cells recognize a complex composed of beryllium ion, self-peptide, and major histocompatibility complex (MHC) Class II molecule on an antigen-presenting cell [Falta *et al.* (2013); Fontenot *et al.* (2016)]. BeS necessarily precedes CBD. Pathogenesis depends on the immune system's recognition of and reaction to beryllium in the lung, resulting in granulomatous lung disease. BeS can be detected with tests that assess the immune response, such as the beryllium lymphocyte proliferation test (BeLPT), which measures T cell activity in the presence of beryllium salts [Balmes *et al.* (2014)]. Furthermore, after the presence of BeS has been confirmed, periodic medical evaluation at 1–3 year intervals thereafter is required to assess whether BeS has progressed to CBD [Balmes *et al.* (2014)]. Thus, BeS is not just a test result, but an adverse health effect that poses risk of the irreversible lung disease CBD. (Document ID 1725, p. 2)

The American College of Occupational and Environmental Medicine (ACOEM) also commented that the term pathological ''continuum'' should only refer to signs and symptoms associated with CBD because some sensitized workers never develop CBD (Document ID 1685, p. 6). However, Dr. Newman, testifying on behalf of ACOEM, clarified that not all members of the ACOEM task force agreed:

> So I hope I'm reflecting to you the range and variety of outcomes relating to this. My own view is that it's on a continuum. I do want to reflect back that the divided opinion among people on the ACOEM task force was that we should call it a spectrum because not everybody is necessarily lock step into a continuum that goes from sensitization to fatality. (Document ID 1756, Tr. 133).

Lisa Maier, MD of National Jewish Health agreed with Dr. Newman (Document ID 1756, Tr. 133–134). Additionally, Dr. Weissman of NIOSH testified that sensitization is ''a biological change in people exposed to beryllium that is associated with increased risk for developing CBD'' and should be considered an adverse health effect (Document ID 1755, Tr. 13).

OSHA agrees that not every sensitized worker develops CBD, and that other factors such as extent of exposure, particulate characteristics, and genetic susceptibility influence the development and progression of disease. The mechanisms by which beryllium sensitization leads to CBD are described in earlier sections and are supported by numerous studies (Newman *et al.,* 1996a, Document ID 1439; Newman *et al.,* 2005 (1437); Saltini *et al.,* 1989 (1351); Amicosante *et al.,* 2005a (1564); Amicosante *et al.,* 2006 (1465); Fontenot *et al.,* 1999 (0489); Fontenot *et al.,* 2005 (1528)). OSHA concludes that sensitization is an immunological condition that increases one's likelihood of developing CBD. As such, sensitization is a necessary step along a continuum to clinical lung disease.

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 Supplemental Information for the Beryllium Health Effects Section summarizes the prevalence of beryllium sensitization and CBD, range of exposure measurements, and other salient information from the key epidemiological studies (Document ID 1965).

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 preceding 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, Document ID 1313), case-control studies of workers at the Rocky Flats nuclear weapons facility (Viet *et al.,* 2000, Document ID 1344), and workers from a beryllium machining plant in Cullman, AL (Kelleher *et al.,* 2001, Document ID 1363). 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, Document ID 1368; Johnson *et al.,* 2001 (1505); Schuler *et al.,* 2005 (0919)). 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 (0590); Bailey *et al.,* 2010 (0676); Schuler *et al.,* 2012(0473)).

Some of the epidemiological studies presented in this section 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 preceding PEL of 2 μg/m³. The available literature also indicates that the rate of beryllium sensitization 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) (Document ID 1516). 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, Document ID 1355). 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, Document ID 1514). 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, Document ID 1461). 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, Document ID 1284; Lieben and Metzner, 1959 (1343)). 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, Document ID 1355).

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, Document ID 1515); or any three of the six criteria listed below (Hasan and Kazemi, 1974, Document ID 0451). Patients identified using the above criteria were registered and added to the BCR from 1952 through 1983 (Eisenbud and Lisson, 1983, Document ID 1296).

The BCR listed the following criteria for diagnosing CBD (Eisenbud and Lisson, 1983, Document ID 1296):

(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, Document ID 1296). 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 (Document ID 0447). 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, Document ID 0196; Pappas and Newman, 1993 (1433); Maier *et al.,* 1999 (1458)):

(1) History of beryllium exposure;

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

(3) Positive blood or BAL BeLPT (Newman *et al.,* 1989, Document ID 0196).

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, Document ID 1283). 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 that 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, Document ID 0068; Frome, 2003 (0462)). 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, 0435; Rossman *et al.,* 2001 (1424)). 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, Document ID 1478; Pappas and Newman, 1993 (1433)). 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, Document ID 1478). 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, Document ID 1364).

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, Document ID 1344; Stange *et al.,* 2001 (1403); DOE/HSS Report, 2006 (0664)), a beryllium ceramics plant in Arizona (Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Cummings *et al.,* 2007 (1369)), a beryllium production plant in Ohio (Kreiss *et al.,* 1997, Document ID 1476; Kent *et al.,* 2001 (1112)), a beryllium machining facility in Alabama (Kelleher *et al.,* 2001, Document ID 1363; Madl *et al.,* 2007 (1056)), a beryllium alloy plant (Schuler *et al.,* 2005, Document ID 0473; Thomas *et al.,* 2009 (0590)), and another beryllium processing plant (Rosenman *et al.,* 2005, Document ID 1352) 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.

In order to investigate the reliability and laboratory variability of the BeLPT, Stange *et al.* (2004, Document ID 1402) studied 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, Document ID 1402). Borak *et al.* (2006) contended that the positive predictive value (PPV) [4] is not high enough to meet the criteria of a good screening tool (Document ID 0498). 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, Document ID 0480). 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, Document ID 0480). The three criteria proposed by panel members were Criterion A (one abnormal BeLPT result establishes sensitization); Criterion B (one abnormal and one borderline result establish sensitization); and Criterion C (two abnormal results establish sensitization). 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 2—CHARACTERISTICS OF BELPT ALGORITHMS (ADAPTED FROM MIDDLETON *et al.,* (2008)

[Adapted from Middleton *et al.,* 2008, Document ID 0480]

	Criterion A (1 abnormal)	Criterion B (1 abnormal + 1 borderline)	Criterion 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%

[4] PPV is the portion of patients with positive test result correctly diagnosed.

TABLE 2—CHARACTERISTICS OF BELPT ALGORITHMS (ADAPTED FROM MIDDLETON *et al.,* (2008)—Continued

[Adapted from Middleton *et al.,* 2008, Document ID 0480]

	Criterion A (1 abnormal)	Criterion B (1 abnormal + 1 borderline)	Criterion C (2 abnormal)
False positives per 10,000	111	8	2

The Middleton *et al.* (2008) 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, Document ID 0480).

Still, there has been criticism regarding the reliability and specificity of the BeLPT as a screening tool and that the BeLPT has not been validated appropriately (Cher *et al.,* 2006, as cited in Document ID 1678; Borak *et al.,* 2006 (0498); Donovan *et al.,* 2007 (0491); Document ID 1678, Attachment 1, p. 6). Even when a confirmational second test is performed, an apparent false positive can occur in people not occupationally exposed to beryllium (NAS, 2008, Document ID 1355). 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, Document ID 0491). 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. However, this should not be considered unusual because there have been reported incidences of non-occupational and community-based beryllium sensitization (Eisenbud *et al.,* 1949, Document ID 1284; Leiben and Metzner, 1959 (1343); Newman and Kreiss, 1992 (1440); Maier and Rossman, 2008 (0598); NAS, 2008 (1355); Harber *et al.,* 2014 (0415), Harber *et al.,* 2014 (0421)).

Materion objected to OSHA treating ''two or three uninterpretable or borderline abnormal BeLPT test results as confirmation of BeS for the purposes of the standard'' (Document ID 1808, p. 4). In order to address some criticism regarding the PPV of the BeLPT, Middleton *et al.* (2011) conducted another study to evaluate borderline results from BeLPT testing (Document ID 0399). Utilizing the common clinical algorithm with a criterion that accepted one abnormal result and one borderline result as establishing beryllium sensitization resulted in a PPV of 94.4 percent. This study also found that three 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 the value of borderline results in predicting beryllium sensitization using the BeLPT. OSHA finds that multiple, consistent borderline BeLPT results (as found with three borderline results) recognize a change in a person's immune system to beryllium exposure. In addition, a study by Harber *et al.* (2014) reexamined the algorithms to determine sensitization and CBD data using the BioBank data.[5] The study suggested that changing the algorithm could potentially help distinguish sensitization from progression to CBD (Harber *et al.,* 2014, Document ID 0363).

Materion further contended that ''[w]hile some refer to BeLPT testing as a 'gold' standard for BeS, it is hardly 'golden,' as numerous commentators have noted.'' (Document ID 1808, p. 4). NIOSH submitted testimony to OSHA comparing the use of the BeLPT for determining beryllium sensitization to other common medical screening tools such as mammography for breast cancer, tuberculin skin test for latent tuberculosis infection, prostate-specific antigen (PSA) for prostate cancer, and fecal occult blood testing for colon cancer. NIOSH stated that ''[a]lthough there is no gold standard test to identify beryllium sensitization, BeLPT has been estimated to have a sensitivity of 66–86% and a specificity of >99% for sensitization [Middleton *et al.* (2006)]. These values are comparable or superior to those of other common medical screening tests.'' (Document ID 1725, pp. 32–33). In addition, Dr. Maier of National Jewish Health stated during the public hearing that ''medical surveillance should rely on the BeLPT or a similar test if validated in the future, as it detects early and late beryllium health effects. It has been validated in many population-based studies.'' (Document ID 1756, Tr. 103).

Since there are currently no alternatives to the BeLPT in a beryllium sensitization screening program, many programs rely on a second test to confirm a positive result (NAS, 2008). Various expert organizations support the use of the BeLPT (with a second confirmational test) as a screening tool for beryllium sensitization and CBD. The American Thoracic Society (ATS), based on a systematic review of the literature, noted that ''the BeLPT is the cornerstone of medical surveillance'' (Balmes *et al.,* 2014; Document ID 0364, pp. 1–2). The use of the BeLPT in medical surveillance has been endorsed by the National Academies in their review of beryllium-related diseases and disease prevention programs for the U. S. Air Force (NAS, 2008, Document ID 1355). In 2011, NIOSH issued an alert ''Preventing Sensitization and Disease from Beryllium Exposure'' where the BeLPT is recommended as part of a medical screening and surveillance program (NIOSH, 2011, Document ID 0544). OSHA finds that the BeLPT is a useful and reliable test method that has been utilized in numerous studies and validated and improved through multiple studies.

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, Document ID 1354; Stange *et al.,* 2001 (1403)). Based on the studies above, as well as comments from NIOSH, ATS, and National Jewish Health, OSHA regards

[5] BioBank is a repository of biological specimens and clinical data collected from beryllium-exposed Department of Energy workers and contractors.

the BeLPT as a reliable medical surveillance tool.

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, Document ID 1282). 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, Document ID 1282). Most exposures from mining and extraction come in the form of beryllium ore, beryllium salts, beryllium hydroxide (NAS, 2008, Document ID 1355) or beryllium oxide (Stefaniak *et al.,* 2008, Document ID 1397).

Deubner *et al.* published a study of 75 workers employed at a beryllium mining and extraction facility in Delta, UT (Deubner *et al.,* 2001b, Document ID 1543). 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 concentrations. 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 (Document ID 1397).

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 (Document ID 1360). 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 μg/m³, with 18.5 percent of samples exceeding OSHA's preceding permissible ceiling concentration of 5.0 μg/m³. 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/m³) and furnace rebuild (28.6 percent of short-term BZ samples over the preceding OSHA permissible ceiling concentration of 5 μg/m³). LP samples (n = 179), which were available from 1990 to 1992, had a median value of 1 μg/m³.

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 result upon initial testing and at least one of two subsequent test results for each of those workers confirmed the worker 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 workers 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, Document ID 1360). After including five workers who had been diagnosed prior to the study, a total of 29 (4.6 percent of the 627 workers who underwent BeLPT screening) workers still employed at the time of the study 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, Document ID 1360). Preliminary follow-up investigations of particle size-specific sampling at five furnace sites within the plant determined that the highest respirable (*i.e.,* particles <10 μm in diameter as defined by the authors) and alveolar-deposited (*i.e.,* 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, Document ID 1361; McCawley *et al.,* 2001 (1357)). 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) (Document ID 0610) evaluated the effectiveness of a workplace preventive program in lowering incidences of sensitization at the beryllium metal, oxide, and alloy production plant studied by Kreiss *et al.* (1997) (Document ID 1360). 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 and administrative 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, Document ID 0610).

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 (Document ID 1352). Of 715 former workers located, 577 were screened for beryllium sensitization with the BLPT and 544 underwent chest radiography to identify cases of beryllium sensitization 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 (Document ID 1352). 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 poorly soluble beryllium (metal and oxide), soluble beryllium (fluoride and hydroxide), mixed soluble and poorly soluble 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 preceding 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, Document ID 1352).

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 (Document ID 1352).

Of the 577 workers who were evaluated for CBD, 32 (5.5 percent) with evidence of granulomas were classified as ''definite'' CBD cases (as identified by bronchoscopy). 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 those 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 (Document ID 1352).

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 preceding OSHA PEL of 2 $\mu g/m^3$. Of those, seven (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 (Document ID 1352).

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, Document ID 1352). 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 poorly soluble 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 poorly soluble beryllium than those classified as sensitized without disease, while exposure to soluble beryllium was higher among sensitized individuals than those with CBD (Document ID 1352).

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 (Document ID 1352).

A follow-up was conducted of the cross-sectional study of a population of workers first evaluated by Kreiss *et al.* (1997) (Document ID 1360) and Rosenman *et al.* (2005) (Document ID 1352) by Schuler *et al.* (2012) (Document ID 0473), and in a companion study by Virji *et al.* (2012) (Document ID 0466). 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, Document ID 0473).

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) (Document ID 0466). 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.

e. Beryllium Machining Operations

Newman *et al.* (2001) (Document ID 1354) and Kelleher *et al.* (2001) (Document ID 1363) 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, Document ID 1354; Madl *et al.,* 2007 (1056)). 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 controls, rather than PPE, were primarily used to control beryllium exposures at the plant (Madl *et al.,* 2007, Document ID 1056). 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, Document ID 1056). Throughout the plant's history, respiratory protection was used mainly for ''unusually large, anticipated exposures'' to beryllium (Kelleher *et al.,* 2001, Document ID 1363), and was not routinely used otherwise (Newman *et al.,* 2001, Document ID 1354).

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 BAL and transbronchial lung biopsy, if the repeat test was abnormal. CBD was diagnosed upon evidence of sensitization with granulomas or mononuclear cell infiltrates in the lung tissue (Newman *et al.,* 2001, Document ID 1354). 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, Document ID 1056).

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, Document ID 1363). 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 in diameter, particles less than 1 μm in diameter, and total mass. The great majority of workers' exposures were below the preceding OSHA PEL of 2 μg/m³. However, a few higher exposure 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 included in the study parameters (1981 to 1984, 1995 to 1997, and 1998 to 1999) 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.* Of the 20 workers composing the case group, 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). The other seven were evaluated for CBD and found to be sensitized only. Nine of the remaining 215 workers first identified in original study (Newman *et al.,* 2001, Document ID 1354) 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 less than 6 μm in diameter, and particles less than 1 μm in diameter 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 preceding PEL of 2 μg/m³, and no cases of sensitization or CBD were observed among workers with LTW exposure less than 0.02 μg/m³. Twelve (60 percent) of the 20 sensitized workers had LTW exposures >0.20 μg/m³.

In 2007, Madl *et al.* 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 (Madl *et al.,* 2007, Document ID 1056). 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, Document ID 1056). 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 sensitized workers or workers with CBD were likely to have been exposed to airborne beryllium levels greater than 0.2 μg/m³ as an 8-hour TWA at some point in their history of employment in the plant. Madl *et al.* also concluded that most sensitization and CBD cases were likely to have been exposed to levels greater than 0.4 μg/m³ at some point in their work at the plant. Madl *et al.* did not reconstruct exposures for workers at the plant who were not sensitized and did not develop 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, Document ID 1056). 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, Document ID 1056).

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 (Document ID 1478). 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 of the 9 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 to 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, Document ID 1477), 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/m³, 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/m³, $p = 0.0001$). 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 as a DWA.

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 (Document ID 1477). 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, Document ID 1477). The overall prevalence of sensitization in the plant was 5.9 percent, with a 4.4 percent prevalence of CBD.

Kreiss *et al.* (1996) (Document ID 1477) 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 (Document ID 1478), one case of CBD was diagnosed in a worker who had never been employed in a production job. This worker was employed in office administration, a job with a median DWA of 0.1 μg/m³ (range 0.1–0.3 μg/m³).

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, Document ID 1313). All current plant employees were eligible for the study unless they had previously been diagnosed with CBD. The study tracked two sets of workers in presenting prevalence outcomes and exposure characterization. ''Short-term workers'' were those hired since the last plant survey in 1992. ''Long-term workers'' were those hired before 1992 and had a longer history of beryllium exposures. There were 74 short-term and 77 long-term workers in the survey (Henneberger *et al.,* 2001, Document ID 1313).

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—0.39 μg/m^3; mean—14.9 μg/m^3) than the short-term workers, who were hired after 1992 (median—0.28 μg/m^3, mean—6.1 μg/m^3).

Fifteen cases of sensitization were found in the 151 study participants (15/151; 9.9%), including seven among short-term (7/74; 9.5%) and eight among long-term workers (8/77; 10.4%). There were eight cases of CBD (8/151; 5.3%) identified in the study. One sensitized short-term worker developed CBD (1/74; 1.4%). Seven of the eight sensitized long-term workers developed CBD (7/77; 9.1%). The other sensitized long-term worker declined to participate in the clinical evaluation.

Henneberger *et al.* (2001) 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 (Document ID 1313). No association was observed for average or cumulative exposures. The authors reported higher (but not statistically significant) prevalence of sensitization 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. Document ID 1291). 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 2002–2003. 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, Document ID 1369). 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/m^3 in production, similar to the 1994–1999 samples. However, respiratory protection requirements to control workers' airborne beryllium exposures were instituted prior to the 2000 sample collections, so actual exposure to the production workers may have been lower than the airborne beryllium levels indicate.

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 of 126 workers). 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.* (2007) 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 (Document ID 1369). 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 particle migration control (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 who processed copper-beryllium alloys and small quantities of nickel-beryllium alloys and converted 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, it also performed salt baths, cadmium plating, welding and deburring. Since the late 1980s, rod and wire production processes have been 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, Document ID 0919). 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 the laboratory was experiencing technical problems with the test (Schuler *et al.,* 2005, Document ID 0919). 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.* (2005) 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 (Document ID 0919). Occupational exposures to airborne beryllium were generally low. Ninety-nine percent of all LP measurements were below the preceding OSHA PEL of 2.0 μg/m³ (8-hr TWA); 93 percent were below the new final OSHA PEL 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 preceding OSHA ceiling limit of 5.0 μg/m³. The highest levels of beryllium exposure 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 μg/m³, range 0.01–0.72 μg/m³), in production support jobs (median 0.02 μg/m³, range <0.01–0.33 μg/m³), plant administration (median 0.02 μg/m³, range <0.01–0.11 μg/m³), and office administration jobs (median 0.01 μg/m³, 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 workers who had never worked in strip metal ($p > 0.1$). Based on these results, together with the higher exposure levels reported for the rod and wire production area, Schuler *et al.* (2005) 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.* (2001) among beryllium ceramics workers exposed for one year or less (16 percent) (Henneberger *et al.,* 2001, Document ID 1313). All four workers who were sensitized without disease had been exposed for 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.,* 2005, Table 2, Document ID 0919).

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 as a DWA. 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 preceding 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, Document ID 0919). 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, Document ID 1061). Measures 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 protection 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 2000–2001 samples in areas other than the RAZ. Within the RAZ, required use of powered air-purifying respirators indicates that actual respiratory exposure was negligible (Thomas *et al.,* 2009, Document ID 1061).

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 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.,* 2009, Document ID 1061).

Thomas *et al.* (2009) 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, Document ID 1061). 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, Document ID 1061).

Stanton *et al.* (2006) (Document ID 1070) conducted a study of workers in three different copper-beryllium alloy distribution centers in the United States. The distribution centers, consisting of 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.

Stanton *et al.* (2006) estimated workers' beryllium exposures using IH data from company records and job history information collected through interviews conducted by a company occupational health nurse (Document ID 1090). 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/m^3. The authors reported a median of 0.03 μg/m^3 and an arithmetic mean of 0.05 μg/m^3 for the 393 full-shift LP samples, where samples below the LOD were assigned a value of half the applicable LOD. Median values for specific jobs ranged from 0.01–0.07 μg/m^3 while geometric mean values for specific jobs ranged from 0.02–0.07 μg/m^3. All measurements were below the preceding OSHA PEL of 2.0 μg/m^3 and 97 percent were below the new final OSHA PEL of 0.2 μg/m^3. The study does not report use of respiratory or skin protection.

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 μg/m^3, 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, Document ID 1090).

h. Nuclear Weapons Production Facilities and 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) (Document ID 1480) 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. Six workers had abnormal BeLPT readings, and four were diagnosed with CBD. This study classified workers as sensitized after one abnormal BeLPT reading, so this resulted in an estimated 11.8 percent prevalence of sensitization.

Kreiss *et al.* (1993) expanded the work of Kreiss *et al.* (1989) (Document ID 1480) by performing a cross-sectional study of 895 current and former beryllium workers in the same nuclear weapons plant (Document ID 1479). Participants were placed in qualitative exposure groups (''no exposure,'' ''minimal exposure,'' ''intermittent exposure,'' and ''consistent exposure'') based on questionnaire responses. Eighteen workers had abnormal BeLPT test results, with 12 being diagnosed with CBD. Three additional sensitized workers (those with abnormal BeLPT results) 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 both individual susceptibility to sensitization and exposure circumstance affect the development of beryllium sensitization and CBD.

In 1991, the Beryllium Health Surveillance Program (BHSP) was established at the Rocky Flats Nuclear Weapons Facility to offer BeLPT screening to current and former employees who may have been exposed to beryllium (Stange *et al.,* 1996, Document ID 0206). 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 exposure samples collected between 1970 and 1988 (mean concentration 0.016 μg/m³) and personal samples collected between 1984 and 1987 (mean concentration 1.04 μg/m³). 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 (Document ID 1403). 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 test results. 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, based on a 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. In order to determine beryllium exposure for all participants in the study, personal beryllium air monitoring results were used, when available, from employees with the same job title or similar job. However, no quantitative exposure information was presented in the study. The authors conclude that for some individuals, exposure to beryllium at levels below the preceding OSHA PEL appears to cause sensitization and CBD.

Viet *et al.* (2000) conducted a case-control study of the Rocky Flats worker population studied by Stange *et al.* (1996 and 2001, Document ID 0206 and 1403) 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 fixed airhead samples from Building 444, the beryllium machine shop, where machine operators were considered to have the highest exposures at the Rocky Flats facility. These fixed air samples were collected away from the breathing zone 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.,* 2000, Document ID 1344).

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 but 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 (Document ID 1505). 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 from 1981–1997. The authors estimated that over the 17 years of measurement data analyzed, airborne beryllium concentrations did exceed 2.0 μg/m³, but 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 had not been routinely conducted among any of the workers at this facility.

Arjomandi *et al.* (2010) (Document ID 1275) 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 (Document ID 1275). Of the 1,875 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 and 2005. Arjomandi *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 authors believed beryllium levels were 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 across exposure categories 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 (Arjomandi *et al.,* 2010, Document ID 1275).

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 (Document ID 0621).

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

Eight-hour TWA exposures 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 TWA with an arithmetic mean of 0.25 μg/m³ and geometric mean of 0.06 μg/m³. Based on a survey of published studies, the investigators concluded that exposure levels to beryllium observed in aluminum smelters were 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 low participation rate of 60 percent 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 exposures estimated in this plant were 0.1 μg/m³ to 0.31 μg/m³ (Nilsen *et al.,* 2010, Document ID 0460).

6. Animal Models of CBD

This section reviews the relevant animal studies supporting the biological mechanisms outlined above. In order for an animal model to be useful for investigating the mechanisms underlying the development of CBD, the model should include: The demonstration of a beryllium-specific immune response; the formation of immune granulomas following inhalation exposure to beryllium; and progression of disease as observed in 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 not immune-induced reactions (which would predominantly consist of T-cells or lymphocytes), but were foreign-body-induced reactions, which predominantly consist of macrophages and monocytes, with only a small numbers of lymphocytes. Although no single model has completely mimicked the disease process as it progresses in humans, 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, such as sensitization and CBD. However, there is no dependable animal model that mimics all facets of the human response, and studies thus far have been limited by single dose experiments, too few animals, or abbreviated observation periods. Therefore, the utility of this data is limited. 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 Supplemental Information for the Beryllium Health Effects Section summarizes species, route, chemical form of beryllium, dose levels, and pathological findings of the key studies (Document ID 1965).

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, Document ID 1257). One group of dogs served as an air inhalation control group 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.[6]

[6] As discussed above, calcining temperature affects 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

Continued

BAL content was collected at 30, 60, 90, 180, and 210 days after exposure, and lavage fluid and cellular content was evaluated for neutrophilic and lymphocytic infiltration. In addition, BAL cells were evaluated at the 210 day period to determine activation potential by phytohemagglutinin (PHA) or beryllium sulfate as mitogen. BAL neutrophils were significantly elevated only at 30 days with exposure to either dose of 500 °C beryllium oxide. BAL lymphocytes were significantly elevated at all time points of the high dose of beryllium oxide. 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. Only the BAL lymphocytes from animals exposed to the 500 °C beryllium oxide responded to stimulation by either PHA or beryllium sulfate.

In a series of studies, Haley *et al.* also found that the beagle dog models certain aspects of human CBD (Haley *et al.,* 1989, 1991 and 1992; Document ID 1366, 1315, 1365. Briefly, dogs were exposed by inhalation to a single exposure to beryllium aerosol generated from beryllium oxide calcined at 500 °C or 1,000 °C for initial lung burdens of 17 or 50 μg beryllium/kg body weight (Haley *et al.,* 1989, Document ID 1366; 1991 (1315)). The dogs were monitored for lung pathologic effects, particle clearance, and immune sensitization of peripheral blood leukocytes. Lung retention was higher in the 1,000 °C treated beryllium oxide group (Haley *et al.,* 1989, Document ID 1366).

Haley *et al.* (1989) described the bronchoalveolar lavage (BAL) and histopathological changes in dogs exposed as described above. One group of dogs underwent BAL for lung lymphocyte analysis at 3, 6, 7, 11, 15, 18, and 22 months post exposure. The investigators 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 and 1,000 °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 at 3 and 6 month post exposure. Another group underwent histopathological examination at days 8, 32, 64, 180, and 365 (Haley *et al.,* 1989, Document ID 1366; 1991 (1315)).

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. Although there was considerable inter-animal variation, lesions were generally more severe in the dogs exposed to material calcined at 500 °C. The investigators observed granulomatous lesions and lung lymphocyte responses consistent with those observed in humans with CBD, including perivascular and peribronchiolar infiltrates of lymphocytes and macrophages, progressing to microgranulomas with areas of granulomatous pneumonia and interstitial fibrosis. However, lesions declined in severity after 64 days post-exposure. 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 CBD 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 (cases) for an initial lung burden target of 50 μg beryllium oxide/kg body weight (Haley *et al.,* 1992, Document ID 1365). Immune responses of blood and BAL lymphocytes, as well as 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 in beagle dogs.

In a comparison study of dogs and monkeys, Conradi *et al.* (1971) exposed animals via inhalation to an average aerosol to either 0, 3,300 or 4,380 μg/m³ of beryllium as beryllium oxide calcined at 1,400 °C for 30 minutes, once per month for 3 months (Document ID 1319). Conradi *et al.* found no changes in the histological or ultrastructure of the lung of animals exposed to beryllium versus control animals. This was in contrast to previous findings reported in other studies cited by Conradi *et al.* The investigators speculated that the differences may be due in part to calcination temperature or follow-up time after initial exposure. The findings from Haley *et al.* (1989, Document ID 1366; 1991 (1915); and 1992 (1365)) as well as Harmsen *et al.* (1986, Document ID 1257) suggest that the beagle model for sensitization of CBD is more closely related to the human response that other species such as the monkey (and those reviewed in Table A2 of the Supplemental Information for the Beryllium Health Effects Section).

A 1994 study by Haley *et al.* comparing the potential toxicity of beryllium oxide versus beryllium metal showed that instillation of both beryllium oxide and beryllium metal induced an immune response in monkeys. Briefly, male cynomolgus monkeys were exposed to either beryllium metal or beryllium oxide calcined at 500 °C via intrabronchiolar instillation as a saline suspension. Lymphocyte counts in BAL fluid were observed through bronchoalveolar lavage at 14, 30, 60, 90, and 120 days post exposure, and were found to be significantly increased in monkeys exposed to beryllium metal on post-exposure days 14, 30, 60, and 90, and in monkeys exposed to beryllium oxide on post-exposure day 30 and 60. Histological examination of lung tissue revealed that monkeys exposed to beryllium metal developed interstitial fibrosis, Type II cell hyperplasia with increased lymphocytes infiltration, and lymphocytic mantles accumulating around alveolar macrophages. Similar but much less severe lesions were observed in beryllium-oxide-exposed monkeys. Only monkeys exposed to beryllium metal had positive BAL BeLPT results (Haley *et al.,* 1994, Document ID 1364).

As discussed earlier in this Health Effects section, at the cellular level, beryllium dissolution may be necessary in order for either a dendritic cell or a macrophage to present beryllium as an antigen to induce the cell-mediated CBD immune reactions (NAS, 2008, Document ID 1355). 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 (Stefaniak *et al.,* 2006, Document ID 1398). As discussed previously, Haley *et al.* (1989, Document ID 1366) 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

factors in determining the toxic potential of beryllium compounds or materials.

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.,* 1989, Document ID 1366 and 1991 (1315)).

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, Document ID 1364). A study by Mueller and Adolphson (1979) observed that an oxide layer can develop on beryllium-metal surfaces after exposure to air (Mueller and Adolphson, 1979, Document ID 1260). According to the NAS report, Harmesen *et al* (1994) suggested that the presence of beryllium metal could lead to persistent exposures of small amounts beryllium oxide sufficient for presentation to the immune system (NAS, 2008, Document ID 1355).

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, Document ID 1345; Snyder *et al.,* 2008 (0471)): (1) The HLA–DPB1*0401 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*0201 mice, where the transgene codes for glutamic acid residue at the 69th position of the B-chain 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 but coded for a more negatively charged protein to confer higher risk of CBD (Tarantino-Hutchinson *et al.,* 2009, Document ID 0536).

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, Document ID 1345; Snyder *et al.,* 2008 (0471)). 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. Beryllium Sensitization and CBD Conclusions

There is substantial evidence that skin and inhalation exposure to beryllium may lead to sensitization (section V.D.1) and that inhalation exposure, or skin exposure coupled with inhalation exposure, may lead to the onset and progression of CBD (section V.D.2). These conclusions are supported by extensive human studies (section V.D.5). 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 earlier sections (sections V.D.1–5). Sensitization is considered to be a necessary first step to the onset of CBD (NAS, 2008, Document ID 1355; ERG, 2010 (1270)). 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 can progress to CBD (Rosenman *et al.,* 2005, Document ID 1352; NAS, 2008 (1355); Mroz *et al.,* 2009 (1356)). 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, Document ID 1257; Haley *et al.,* 1989 (1366), 1992 (1365), 1994 (1364)). 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, Document ID 1257; Haley *et al.,* 1992 (1365); Tarantino-Hutchison *et al.,* 2009 (0536)). The evidence supports sensitization as an early functional change that allows the immune system to recognize and adversely react to beryllium. As such, OSHA regards beryllium sensitization as a necessary first step along a continuum that can culminate in clinical lung disease.

The epidemiological evidence presented in section V.D.5 demonstrates that sensitization and CBD are continuing to occur from exposures below OSHA's preceding PEL. The prevalence of sensitization among beryllium-exposed workers, as measured by the BeLPT and reported in 16 surveys of occupationally exposed cohorts reviewed by the Agency, ranged from 0.3 to 14.5 percent (Deubner *et al.,* 2001, Document ID 1543; Kreiss *et al.,* 1997 (1360); Rosenman *et al.,* 2005 (1352); Schuler *et al.,* 2012 (0473); Bailey *et al.,* 2010 (0676); Newman *et al.,* 2001 (1354); OSHA, 2014 (1589); Kreiss *et al.,* 1996 (1477); Henneberger *et al.,* 2001 (0589); Cummings *et al.,* 2007 (1369); Schuler *et al.,* 2005 (0919); Thomas *et al.,* 2009 (1061); Kreiss *et al.,* 1989 (1480); Arjomandi *et al.,* 2010 (1275); Taiwo *et al.,* 2011 (0621); Nilson *et al.,* 2010 (0460)). The lower prevalence estimates (0.3 to 3.7 percent) were from facilities known to have implemented respiratory protection programs and have lower personal exposures (Cummings *et al.,* 2007, Document ID 1369; Thomas *et al.,* 2009 (1061); Bailey *et al.,* 2010 (0676); Taiwo et al, 2011 (0621), Nilson *et al.,* 2010 (0460); Arjomandi *et al.,* 2010 (1275)). Thirteen of the surveys also evaluated workers for CBD and reported prevalences of CBD ranging from 0.1 to 7.8 percent. The cohort studies cover workers across many different industries and processes as discussed in section V.D.5. Several studies show that incidence of sensitization among workers can be reduced by reducing inhalation exposure and that minimizing skin exposure may serve to further reduce sensitization (Cummings *et al.,* 2007, Document ID 1369; Thomas *et al.,* 2009 (1061); Bailey *et al.,* 2010 (0676)). The risk assessment further discusses the effectiveness of interventions to reduce beryllium exposures and the risk of sensitization and CBD (see section VI of this preamble, Risk Assessment).

Longitudinal studies of sensitized workers found early signs of asymptomatic CBD that can progress to clinical disease in some individuals. One study found that 31 percent of beryllium-exposed sensitized employees progressed to CBD with an average follow-up time of 3.8 years (Newman, 2005, Document ID 1437). However, Newman (2005) went on to suggest that if follow-up times were much longer, the rate of progression from sensitization to CBD could be much higher. Mroz *et al.* (2009) (Document ID 1356) conducted a longitudinal study between 1982 and 2002 in which they followed 171 cases of CBD and 229 cases of sensitization initially evaluated through workforce medical surveillance by National Jewish Health. All study subjects had abnormal BeLPTs upon study entry and were then clinically evaluated and treated for CBD. Over the 20-year study period, 22 sensitized individuals went on to develop CBD which was an incidence of 8.8 percent (*i.e.,* 22 cases out of 251 sensitized, calculated by adding those 22 cases to the 229 initially classified as sensitized). The findings from this study indicated that the average span of time from initial beryllium exposure to CBD diagnosis for those 22 workers was 24 years (Mroz *et al.,* 2009, Document ID 1356).

A study of sensitized workers believed to have been exposed to low levels of airborne beryllium metal (*e.g.,* 0.01 μg/m³ or less) at a nuclear weapons research and development facility were clinically evaluated between 1999 and 2005 (Arjomandi *et al.*, 2010, Document ID 1275). Five of 49 sensitized workers (10.2 percent incidence) were found to have pathology consistent with CBD. The CBD was asymptomatic and had not progressed to clinical disease. The mean duration of employment among workers in the study was 18 years with mean latency of 32 years to time of CBD diagnosis (Arjomandi *et al.*, 2010, Document ID 1275). This suggests that some sensitized individuals can develop CBD even from low levels of beryllium exposure. Another study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that sensitization rate among exposed workers was highest over the first 10 years of beryllium exposure while onset of CBD pathology was greatest following 15 to 30 years of exposure (Stange *et al.,* 2001, Document ID 1403). This indicates length of exposure may play a role in further development of the disease. OSHA concludes from the study evidence that the persistent presence of beryllium in the lungs of sensitized workers can lead to a progression of CBD over time from an asymptomatic stage to serious clinical disease.

E. Beryllium Lung Cancer Section

Beryllium exposure is 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, IARC did an extensive evaluation in 1993 (Document ID 1342) and reevaluation in April 2009 (IARC, 2012, Document ID 0650). 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, Document ID 0661), and the National Toxicology Program (NTP) classifies beryllium and its compounds as known carcinogens (NTP, 2014, Document ID 0389). OSHA has conducted an independent evaluation of the carcinogenic potential of beryllium and these compounds. The following is a summary of the studies used to support the Agency's finding 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, Document ID 1355).

Non-mammalian test systems (generally bacterial assays) are often used to identify genotoxicity of a compound. In bacteria studies evaluating beryllium sulfate for mutagenicity, all studies performed utilizing the Ames assay (Simmon, 1979, Document ID 0434; Dunkel *et al.,* 1981 (0432); Arlauskas *et al.,* 1985 (0454); Ashby *et al.,* 1990 (0437)) and other bacterial assays (E. coli *pol A* (Rosenkranz and Poirer, 1979, Document ID 1426); E. coli WP2 *uvrA* (Dunkel *et al.,* 1981, Document ID 0432), as well as those utilizing *Saccharomyces cerevisiae* (Simmon, 1979, Document ID 0434)) were reported as negative, with the exception of results reported for Bacillus *subtilis rec* assay (Kada *et al.,* 1980, Document ID 0433; Kanematsu *et al.,* 1980 (1503)). Beryllium nitrate was also reported as negative in the Ames assay (Tso and Fung, 1981, Document ID 0446; Kuroda *et al.,* 1991 (1471)) but positive in a Bacillus *subtilis rec* assay (Kuroda *et al.,* 1991, Document ID 1471). In addition, beryllium chloride was reported as negative using the Ames assay (Ogawa *et al.,* 1987, as cited in Document ID 1341, p. 112; Kuroda *et al.,* 1991 (1471)) and other bacterial assays (E. coli WP2 *uvrA* (Rossman *et al.,* 1984, Document ID 0431), as well as the Bacillus *subtilis rec* assay (Nishioka, 1975, Document ID 0449)) and failed to induce SOS DNA repair in E. coli (Rossman *et al.,* 1984, Document ID 0431). Positive results for beryllium chloride were reported for Bacillus *subtilis rec* assay using spores (Kuroda *et al.,* 1991, Document ID 1471) as well as increased mutations in the *lacI* gene of E. coli KMBL 3835 (Zakour and Glickman, 1984, Document ID 1373). Beryllium oxide was reported to be negative in the Ames assay and Bacillus *subtilis rec* assays (Kuroda *et al.,* 1991, Document ID 1471; EPA, 1998 (0661)).

Mutations using *in vitro* mammalian systems were also evaluated. Beryllium chloride induced mutations in V79 and CHO cultured cells (Miyaki *et al.,* 1979, Document ID 0450; Hsie *et al.,* 1978 (0427); Vegni-Talluri and Guiggiani, 1967 (1382)), and beryllium sulfate induced clastogenic alterations, producing breakage or disrupting chromosomes in mammalian cells (Brooks *et al.,* 1989, Document ID 0233; Larramendy *et al.,* 1981 (1468); Gordon and Bowser, 2003 (1520)). However, 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). Positive results were found for beryllium chloride when evaluating the *hprt* gene in Chinese hamster lung V79 cells (Miyaki *et al.,* 1979, Document ID 0450).

Data from *in vivo* genotoxicity testing of beryllium are limited. Beryllium metal was found to induce methylation of the p16 gene in the lung tumors of rats exposed to beryllium metal (Swafford *et al.,* 1997, Document ID 1392) (described in more detail in section V.E.3). A study by Nickell-Brady *et al.,* (1994) found that 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 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 (described in more detail in section V. E. 3) (Nickell-Brady *et al.,* 1994, Document ID 1312). On the other hand, beryllium chloride evaluated in a mouse model indicated increased DNA strand breaks and the formation of micronuclei in bone marrow (Attia *et al.,* 2013, Document ID 0501).

In summary, genetic mutations have been observed in mammalian systems (*in vitro* and *in vivo*) with beryllium chloride, beryllium sulfate, and beryllium metal in a number of studies (Miyaki *et al.,* 1979, Document ID 0450; Hsie *et al.,* 1978 (0427); Vegni-Talluri and Guiggiani, 1967 (1382); Brooks *et al.,* 1989 (0233); Larramendy *et al.,* 1981 (1468); Miyaki *et al.,* 1979 (0450); Swafford *et al.,* 1997 (1392); Attia *et al.,* 2013 (0501); EPA, 1998 (0661); Gordon and Bowser, 2003 (1520)). However, most studies utilizing non-mammalian test systems (either with or without metabolic activity) have found that beryllium chloride, beryllium nitrate, beryllium sulfate, and beryllium oxide did not induce gene mutations, with the exception of Kada *et al.* (1980, Document ID 0433) (Kanematsu *et al.,*1980, Document ID 1503; Kuroda *et al.,* 1991 (1471)).

2. Human Epidemiological Studies

This section describes the human epidemiological data supporting the mechanistic overview of beryllium-induced lung cancer in workers. It has been divided into reviews of epidemiological studies by industry and beryllium form. The epidemiological studies utilizing data from the BCR, in general, focus on workers mainly exposed to soluble forms of beryllium. Those studies evaluating the epidemiological evidence by industry or process are, in general, focused on exposures to poorly soluble or mixed (soluble and poorly soluble) compounds. Table A.3 in the Supplemental Information for the Beryllium Health Effects Section summarizes the important features and characteristics of each study discussed herein (Document ID 1965).

a. Beryllium Case Registry (BCR)

Two studies evaluated participants in the BCR (Infante *et al.,* 1980, Document ID 1507; Steenland and Ward, 1991 (1400)). 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 from 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) (Document ID 1400) extended the work of Infante *et al.* (1980) (Document ID 1507) 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 with confirmed beryllium exposure. 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 then diagnosed with beryllium disease (ABD and CBD).

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.

Bayliss *et al.* (1971) (Document ID 1285) performed a nested cohort study of 7,948 former workers from the beryllium processing industry who were employed from 1942–1967. Information for the workers was collected from the personnel files of participating companies. Of the 7,948 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, Document ID 1453; 1979, (0529); 1980 (1452)) and Mancuso and El-Attar (1969) (Document ID 1455) performed a series of occupational cohort studies on a group of workers (primarily white males) employed in the beryllium manufacturing industry during 1937–1948. The cohort identified in Mancuso and El-Attar (1969) was a study of 3,685 workers (primarily white males) while Mancuso (1970, 1976, 1980) continued the study follow-up with 3266 workers due to several limitations in identifying specific causes for mortality as identified in Mancuso and El-Attar (1969). 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 (exposure data was taken from a study by Zielinsky *et al.,* 1961 (as cited in Mancuso, 1970)). 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 initial exposure regardless of the length of employment.

Wagoner *et al.* (1980) (Document ID 1379) expanded the work of Mancuso (1970, Document ID 1453; 1979 (0529); 1980 (1452)) 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 of employment and a ≥25-year interval since the beginning of employment ($p < 0.05$). The study was criticized by two epidemiologists (MacMahon, 1978, Document ID 0107; Roth, 1983 (0538)), by a CDC Review Committee appointed to evaluate the study (as cited in Document ID 0067), and by one of the study's coauthors (Bayliss, 1980, Document ID 0105) 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 (which may underestimate the expected number of lung cancer deaths for the cohort) and inadequate adjustment for smoking.

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, Document ID 1250). 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 exposures. 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 largest and most comprehensive study investigated the mortality experience of 9,225 workers employed in 7 different beryllium processing plants over a 30-year period (Ward *et al.,* 1992, Document ID 1378). 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. The workers at these two plants were believed to have the highest exposure levels to beryllium. 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) (Document ID 1455), Mancuso (1970, Document ID 1453; 1979 (0529); 1980 (1452)), and Wagoner *et al.* (1980) (Document ID 1379). The men were employed for no less than 2 days between January 1940 and December 1969. Medical records were followed through 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.

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-exposed employees (Levy *et al.,* 2002, Document ID 1463). Both cohort studies (Levy *et al.,* 2002, Document ID 1463; Ward *et al.,* 1992 (1378)) are limited by a lack of job history and air monitoring data that would allow investigation of mortality trends with different levels and durations of 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.

Levy *et al.* (2002) (Document ID 1463) questioned the results of Ward *et al.* (1992) (Document ID 1378) 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) (Document ID 1463) 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) (Document ID 1378) for their smoking adjustment, or (2) results from a smoking/lung cancer study of veterans. Second, Levy *et al.* (2002) also examined the 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 (Document ID 1463). Finally, Levy *et al.* (2002) considered a meta-analytical approach to combining the results across beryllium facilities (Document ID 1463). For all of the alternatives Levy *et al.* (2002) (Document ID 1463) considered, except the meta-analysis, the facility-specific and combined SMRs derived were lower than those reported by Ward *et al.* (1992) (Document ID 1378). 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) (Document ID 1463) to conclude that there was little evidence of statistically significant elevated SMRs in those plants. This study was not included in the synthesis of epidemiological studies assessed by IARC due to several methodological limitations (IARC, 2012, Document ID 0650).

The EPA Integrated Risk Information System (IRIS), IARC, and California EPA Office of Environmental Health Hazard Assessment (OEHHA) all based their cancer assessments on the Ward *et al.* 1992 study, with supporting data concerning exposure concentrations from Eisenbud and Lisson (1983) (Document ID 1296) and NIOSH (1972) (Document ID 0560), 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 increase in lung cancer deaths (EPA, 1987, Document ID 1295). Based on its 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'' (EPA, 1998, Document ID 0237). The EPA 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.

Sanderson *et al.* (2001) (Document ID 1419) estimated the cumulative, average, and maximum beryllium exposure concentration for the 142 known lung cancer cases to be 46.06 ± 9.3$\mu g/m^3$-days, 22.8 ± 3.4 $\mu g/m^3$, and 32.4 ± 13.8 $\mu g/m^3$, 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 (Sanderson *et al.,* 2001, Document ID 1419). 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 1940s and 1950s and the shape of the dose-response curve for lung cancer (Sanderson *et al.,* 2001, Document ID 1419). 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 preceding 8-hour OSHA TWA PEL (2 $\mu g/m^3$) 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, Document ID 0650). NIOSH comments in the rulemaking docket support IARC's finding (citing Schubauer-Berigan *et al.,* 2007; Hein *et al.,* 2009, 2011; Langholz and Richardson 2009; Wacholder 2009) (Document ID 1671, Attachment 1, p. 10).

Schubauer-Berigan *et al.* (2008) (Document ID 1350) reanalyzed data from the Sanderson *et al.* (2001) nested case-control study of 142 lung cancer cases in the Reading, PA, beryllium processing plant. 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 (Document ID 1419). 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.

Schubauer-Berigan *et al.* stated that the reanalysis indicated that differences in the hire ages among cases and controls, first noted by Deubner *et al.* (2001) (Document ID 0109) and Levy *et al.* (2007) (Document ID 1462), 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, Document ID 1350). 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) (Document ID 1512) re-examined the weight of evidence of beryllium as a lung carcinogen in a recent publication. 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 was not relevant to today's industrial settings. IARC performed a similar re-evaluation in 2009 (IARC, 2012, Document ID 0650) 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.* (2011) (Document ID 1266) 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 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 this change represents more than an update of the beryllium cohort. Standardized mortality ratios (SMRs) were estimated based on U.S. 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 U.S. 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) (Schubauer-Berigan *et al.,* 2011, Document ID 1266). Mortality rates for most diseases of interest increased with time since hire. For the category including CBD, rates were substantially elevated compared to the U.S. 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 that 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.,* 2011, Document ID 1266).

A study by Boffetta *et al.* (2014, Document ID 0403) and an abstract by Boffetta *et al.,* (2015, Document ID 1661, Attachment 1) were submitted by Materion for Agency consideration (Document ID 1661, p. 3). Briefly, Boffetta *et al.* investigated lung cancer and other diseases in a cohort of 4,950 workers in four beryllium manufacturing facilities. Based on available process information from the facilities, the cohort of workers included only those working with poorly soluble beryllium. Workers having potential for soluble beryllium exposure were excluded from the study. Boffetta *et al.* reported a slight increase in lung cancer rates among workers hired prior to 1960, but the increase was reported as not statistically significant. Bofetta *et al.* (2014) indicated that ''[t]his study confirmed the lack of an increase in mortality from lung cancer and nonmalignant respiratory diseases related to [poorly] soluble beryllium compounds'' (Document ID 0403, p. 587). OSHA disagrees, and a more detailed analysis of the Boffetta *et al.* (2014, Document ID 0403) study is provided in the Risk Assessment section (VI) of this preamble. The Boffetta *et al.* (2015, Document ID 1661, Attachment 1) study cited by Materion was an abstract to the 48th annual Society of Epidemiological Research conference and does not provide sufficient information for OSHA to consider.

To summarize, most of the epidemiological studies reviewed in this section show an elevated lung cancer rate in beryllium-exposed workers compared to control groups. While exposure data was incomplete in many studies inferences can be made based on industry profiles. Specifically, studies reviewing excess lung cancer in workers registered in the BCR found an elevated lung cancer rate in those patients identified as having acute beryllium disease (ABD). ABD patients are most closely associated with exposure to soluble forms of beryllium (Infante *et al.,* 1980, Document ID 1507; Steenland and Ward, 1991 (1348)). Industry profiles in processing and extraction indicate that most exposures would be due to poorly soluble forms of beryllium. Excess lung cancer rates were observed in workers in industries associated with extraction and processing (Schubauer-Berigan *et al.,* 2008, Document ID 1350; Schubauer-Berigan *et al.* 2011 (1266, 1815 Attachment 105); Ward *et al.,* 1992 (1378); Hollins *et al.,* 2009 (1512); Sanderson *et al.,* 2001 (1419); Mancuso *et al.,* 1980 (1452); Wagoner *et al.,* 1980 (1379)). During the public comment period NIOSH noted that:

> . . . in Table 1 of Ward *et al.* (1992), all three of these beryllium plants were engaged in operations associated with both soluble and [poorly soluble] forms of beryllium. Industrial hygienists from NIOSH [Sanderson *et al.* (2001); Couch *et al.* (2011)] and elsewhere [Chen (2001); Rosenman *et al.* (2005)] created job-exposure matrices (JEMs), which estimated the form of beryllium exposure (soluble, consisting of beryllium salts; [poorly soluble], consisting of beryllium metal, alloys, or beryllium oxide; and mixed forms) associated with each job, department and year combination at each plant. Unpublished evaluations of these JEM estimates linked to the employee work histories in the NIOSH risk assessment study [Schubauer-Berigan *et al.,* 2011b, Document ID 0521] show that the vast majority of beryllium work-time at all three of these facilities was due to either [poorly] soluble or mixed chemical forms. In fact, [poorly] soluble beryllium was the largest single contributor to work-time (for beryllium exposure of known solubility class) at the three facilities across most time periods . . . . Therefore, the strong and consistent exposure-response pattern that was observed in the published NIOSH studies was very likely associated with exposure to [poorly] soluble as well as soluble forms of beryllium. (Document ID 1725, p. 9)

Taken collectively, the Agency finds that the epidemiological data presented in the reviewed studies provides sufficient evidence to demonstrate carcinogenicity in humans of both soluble and poorly soluble forms of beryllium.

3. Animal Cancer Studies

This section reviews the animal literature used to support the findings for beryllium-induced lung cancer. Early animal studies revealed that some beryllium compounds are carcinogenic when inhaled (ATSDR, 2002, Document ID 1371). 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 mice. 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, Document ID 1341: IARC, 2012 (0650)). While not completely understood, experimental studies in animals (*in vitro and in vivo*) have found that a number of mechanisms are likely involved in beryllium-induced carcinogenicity, including chronic inflammation, genotoxicity, mitogenicity, oxidative stress, and epigenetic changes.

In an inhalation study assessing the potential tumorigenicity of beryllium, Schepers *et al.* (1957) (Document ID 0458) exposed 115 albino Sherman and Wistar rats (male and female) via inhalation to 0.0357 mg beryllium/m³ (1 γ beryllium/ft³) [7] 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,[8] including adenomas, squamous-cell carcinomas, acinous adenocarcinomas, papillary adenocarcinomas, and alveolar-cell adenocarcinomas, were observed in 52 of the rats exposed to the beryllium sulfate aerosol. Adenocarcinomas 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 3:

TABLE 3—NEOPLASM ANALYSIS, BASED ON SCHEPERS ET AL. (1957)

Neoplasm	Number	Metastases
Adenoma	18	0
Squamous carcinoma	5	1
Acinous adenocarcinoma	24	2
Papillary adenocarcinoma	11	1
Alveolar-cell adenocarcinoma	7	0
Mucigenous tumor	7	1
Endothelioma	1	0
Retesarcoma	3	3
Total	76	8

Schepers (1962) (Document ID 1414) 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. Ten varieties of tumors were observed, with adenocarcinoma being the most common variety.

In another study, Vorwald and Reeves (1959) (Document ID 1482) 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.* (1967) investigated the carcinogenic process in lungs resulting from chronic (up to 72 weeks) beryllium sulfate inhalation (Document ID 1310). 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 were ‘‘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 occurred in females.

In the second article, Reeves *et al.* (1967) (Document ID 1309) described the rate of accumulation and clearance of beryllium sulfate aerosol from the same experiment (Reeves *et al.,* 1967) (Document ID 1310). 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

[7] 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.

[8] 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.

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) (Document ID 1316) 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 4—SUMMARY OF BERYLLIUM DOSE, BASED ON GROTH ET AL. (1980)

[Document ID 1316]

Form of Be	Percent Be	Percent other compounds	Total Number 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. Of 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, Document ID 1316).

Finch *et al.* (1998b) (Document ID 1367) investigated the carcinogenic effects of inhaled beryllium on heterozygous TSG-p53 knockout (*p53* $^{+/-}$) mice and wild-type (*p53*+/+) mice. Knockout mice can be valuable tools in determining the role played by specific genes in 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 5—SUMMARY OF ANIMAL DATA, BASED ON FINCH ET AL. (1998)

[Document ID 1367]

Mouse strain	Mean exposure concentration (µg Be/L)	Target beryllium 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

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 of which 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.,* 1998, Document ID 1367).

During the public comment period Materion submitted correspondence from Dr. Finch speculating on the reason for the less-robust lung cancer response observed in mice (versus that observed in rats) (Document ID 1807, Attachment 11, p. 1). Materion contended that this was support for their assertion of evidence that ''directly contradicts the claims that beryllium metal causes cancer in animals'' (Document ID 1807, p. 6). OSHA reviewed this correspondence and disagrees with Materion's assertion. While Dr. Finch did suggest that the mouse lung cancer response was less robust, it was still present. Dr. Finch went on to suggest that while the rat has a more profound neutrophilic response (typical of a ''foreign body response), the mouse has a lung response more typical of humans (neutrophilic and lymphocytic) (Document ID 1807, Attachment 11, p. 1).

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 (Document ID 1312). 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* or 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) (Document ID 1312) 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 concluded 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 (Document ID 1392). 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) (Document ID 1392), Belinsky *et al.* (2002) (Document ID 1300) 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) (Document ID 1481) 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/m^3, corresponding to 210 μg beryllium/m^3 and 620 μg beryllium/m^3 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 (Document ID 1319). 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/m^3. 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.

To summarize, animal studies show that multiple forms of beryllium, when inhaled or instilled in the respiratory tract of rats, mice, and monkeys, lead to increased incidence of lung tumors. Animal studies have demonstrated a consistent scenario of beryllium exposure resulting in chronic pulmonary inflammation and tumor formation at levels below overload conditions (Groth *et al.,* 1980, Document ID 1316; Finch *et al.,* 1998 (1367); Nickel-Brady *et al.,* 1994 (1312)). The animal studies support the human epidemiological evidence and contributed to the findings of the NTP, IARC, and others that beryllium and beryllium-containing material should be regarded as known human carcinogens. The beryllium compounds found to be carcinogenic in animals include both soluble beryllium compounds, such as beryllium sulfate and beryllium hydroxide, as well as poorly soluble beryllium compounds, such as beryllium oxide and beryllium metal. The doses that produce tumors in experimental animal are fairly large and also lead to chronic pulmonary inflammation. The exact tumorigenic mechanism for beryllium is unclear and a number of mechanisms are likely involved, including chronic inflammation, genotoxicity, mitogenicity, oxidative stress, and epigenetic changes.

4. In Vitro Studies

The exact mechanism by which beryllium induces pulmonary neoplasms in animals remains unknown (NAS 2008, Document ID 1355). Keshava *et al.* (2001) performed studies to determine the carcinogenic potential of beryllium sulfate in cultured mammalian cells (Document ID 1362). Joseph *et al.* (2001) investigated differential gene expression to understand the possible mechanisms of beryllium-induced cell transformation and tumorigenesis (Document ID 1490). 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 (Document ID 1362). 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 after beryllium sulfate exposure in a mouse cell line (Document ID 1490). 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*).

In summary, *in vitro* studies have been used to evaluate the neoplastic potential of beryllium compounds and the possible underlying mechanisms. Both Keshava *et al.* (2001) (Document ID 1362) and Joseph *et al.* (2001) (Document ID 1490) have found that beryllium sulfate induced a number of onco-genes (c-*fos,* c-*jun,* c-*myc,* and R-*ras*) and down-regulated genes responses for normal cellular function and repair (including those involved in DNA synthesis, repair, and recombination).

5. Lung Cancer Conclusions

OSHA has determined that substantial evidence in the record indicates that beryllium compounds should be regarded as occupational lung carcinogens. Many well-respected scientific organizations, including IARC, NTP, EPA, NIOSH, and 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 that an indirect mechanism, such as inflammation or other epigenetic changes, may be responsible for most tumorigenic activity of beryllium in animals and humans (IARC, 2012, Document ID 0650). 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 immunological response, beryllium has been demonstrated to produce an inflammatory response in animal models similar to the response produced by other particles (Reeves *et al.,* 1967, Document ID 1309; Swafford *et al.,* 1997 (1392); Wagner *et al.,* 1969 (1481)), possibly contributing to its carcinogenic potential. Studies conducted in rats have demonstrated that chronic inhalation of materials similar in solubility to beryllium results in increased pulmonary inflammation, fibrosis, epithelial hyperplasia, and, in some cases, pulmonary adenomas and carcinomas (Heinrich *et al.,* 1995, Document ID 1513; NTP, 1993 (1333); Lee *et al.,* 1985 (1466); Warheit *et al.,* 1996 (1377)). This response is generally referred to as an ''overload'' response and is specific to particles of low solubility with a low order of toxicity, which are non-mutagenic and non-genotoxic (*i.e.,* poorly soluble particles like titanium dioxide and non-asbestiform talc); this response is observed only in rats (Carter *et al.,* 2006, Document ID 1556). ''Overload'' is described in ECETOC (2013) as inhalation of high concentrations of low solubility particles resulting in lung burdens that impair particle clearance mechanisms (ECETOC, 2013 as cited in Document ID 1807, Attachment 10, p. 3 (pdf p. 87)). Substantial data indicate that tumor formation in rats after exposure to some poorly 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. Because these specific particles (*i.e.,* titanium dioxide and non-asbestiform talc) exhibit no cytotoxicity or genotoxicity, they are considered to be biologically inert (ECETOC, 2013; see Document ID 1807, Attachment 10, p. 3 (pdf p. 87)). Animal studies, as summarized above, have demonstrated a consistent scenario of beryllium exposure resulting in chronic pulmonary inflammation below an overload scenario. NIOSH submitted comments describing the findings from a low-dose study of beryllium metal among male and female F344 rats (Document ID 1960, p. 11). The study by Finch *et al.* (2000) indicated lung tumor rates of 4, 4, 12, 50, 61, and 91 percent in animals with beryllium metal lung burdens of 0, 0.3, 1, 3, 10, and 50 µg respectively (Finch *et al.,* 2000 as cited in Document ID 1960, p. 11). NIOSH noted the lung burden levels were much lower than those from previous studies, such as a 1998 Finch *et al.* study with initial lung burdens of 15 and 60 µg (Document ID 1960, p. 11). Based on evidence from mammalian studies of the mutagenicity and genotoxicity of beryllium (as described in above in section V.E.1) and the evidence of tumorigenicity at lung burden levels well below overload, OSHA concludes that beryllium particles are not poorly soluble particles like titanium dioxide and non-asbestiform talc.

It has been hypothesized that the recruitment of neutrophils during the inflammatory response and subsequent release of oxidants from these cells play an important role in the pathogenesis of rat lung tumors (Borm *et al.,* 2004, Document ID 1559; Carter and Driscoll, 2001 (1557); Carter *et al.,* 2006 (1556); Johnston *et al.,* 2000 (1504); Knaapen *et al.,* 2004 (1499); Mossman, 2000 (1444)). This is one potential carcinogenic pathway for beryllium particles. Inflammatory mediators, acting at levels below overload doses 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 as well as mitogenic, inducing a proliferative response (Ferriola and Nettesheim, 1994, Document ID 0452; Coussens and Werb, 2002 (0496)). The resultant effect is an environment rich for neoplastic transformations and the progression of fibrosis and tumor formation. This is consistent with findings from the National Cancer Institute, which has estimated that one-third of all cancers may be due to chronic inflammation (NCI, 2010, Document ID 0532). However, an inflammation-driven contribution to the neoplastic transformation does not imply no risk at levels below inflammatory response; rather, the overall weight of evidence suggests 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. As summarized above, animal studies have consistently demonstrated beryllium exposure resulting in chronic pulmonary inflammation below overload conditions in multiple species (Groth *et al.,* 1980, Document ID 1316; Finch *et al.,* 1998 (1367); Nickel-Brady *et al.,* 1994 (1312)). While OSHA recognizes chronic inflammation as one potential pathway to carcinogencity the Agency finds that other carcinogenic pathways such as genotoxicity and epigenetic changes may also contribute to beryllium-induced carcinogenesis.

During the public comment period OSHA received several comments on the carcinogenicity of beryllium. The NFFS agreed with OSHA that ''the science is quite clear in linking these soluble Beryllium compounds'' to lung cancer (Document ID 1678, p. 6). It also, however, contended that there is considerable scientific dispute regarding the carcinogenicity of beryllium metal (*i.e.,* poorly soluble beryllium), citing findings by the EU's REACH Beryllium Commission (later clarified as the EU Beryllium Science and Technology Association) (Document ID 1785, p. 1; Document ID 1814) and a study by Strupp and Furnes (2010) (Document ID 1678, pp. 6–7, and Attachment 1). Materion, similarly, commented that ''[a] report conclusion during the recent review of the European Cancer Directive for the European Commission stated regarding beryllium: 'There was little evidence for any important health impact from current or recent past exposures in the EU' '' (Document ID 1958, p. 4).

The contentions of both Materion and NFFS regarding scientific findings from the EU is directly contradicted by the document submitted to the docket by the European Commission on Health, Safety and Hygiene at Work, discussed above. This document states that the European Chemicals Agency (ECHA) has determined that all forms of beryllium (soluble and poorly soluble) are carcinogenic (Category 1B) with the exception of aluminum beryllium silicates (which have not been allocated a classification) (Document ID 1692, pp. 2–3).

OSHA also disagrees with NFFS's other contention that there is a scientific dispute regarding the carcinogenicity of poorly soluble forms of beryllium. In coming to the conclusion that all forms of beryllium and beryllium compounds are carcinogenic, OSHA independently evaluated the scientific literature, including the findings of authoritative entities such as NIOSH, NTP, EPA, and IARC (see section V.E). The evidence from human, animal, and mechanistic studies together demonstrates that both soluble and poorly soluble beryllium compounds are carcinogenic (see sections V.E.2, V.E.3, V.E.4). The well-respected scientific bodies mentioned above came to the same conclusion: That both soluble and poorly soluble beryllium compounds are carcinogenic to humans.

As supporting documentation the NFFS submitted an ''expert statement'' by Strupp and Furnes (2010), which reviews the toxicological and epidemiological information regarding beryllium carcinogenicity. Based on select information in the scientific literature on lung cancer, the Strupp and Furnes (2010) study concluded that there was insufficient evidence in humans and animals to conclude that insoluble (poorly soluble) beryllium was carcinogenic (Document ID 1678, Attachment 1, pp. 21–23). Strupp and Furnes (2010) asserted that this was based on criteria established under

Annex VI of Directive 67/548/EEC which establishes criteria for classification and labelling of hazardous substances under the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA reviewed the Strupp and Furnes (2010) ''expert statement'' submitted by NFFS and found it to be unpersuasive. Its review of the epidemiological evidence mischaracterized the findings from the NIOSH cohort and the nested case-control studies (Ward *et al.,* 1992; Sanderson *et al.,* 2001; Schubauer-Berigan *et al.,* 2008) and misunderstood the methods commonly used to analyze occupational cohort studies (Document ID 1725, pp. 27–28).

The Strupp and Furnes statement also did not include the more recent studies by Schubauer-Berigan *et al.* (2011, Document ID 1815, Attachment 105, 2011 (0626)), which demonstrated elevated rates for lung cancer (SMR 1.17; 95% CI 1.08 to 1.28) in a study of 7 beryllium processing plants. In addition, Strupp and Furnes did not consider expert criticism from IARC on the studies by Levy *et al.* (2007) and Deubner *et al.,* (2007), which formed the basis of their findings. NIOSH submitted comments that stated:

> The Strupp (2011b) review of the epidemiological evidence for lung carcinogenicity of beryllium contained fundamental mischaracterizations of the findings of the NIOSH cohort and nested case-control studies (Ward *et al.* 1992; Sanderson *et al.* 2001; Schubauer-Berigan *et al.* 2008), as well as an apparent misunderstanding of the methods commonly used to analyze occupational cohort studies (Document ID 1960, Attachment 2, p. 10).

As further noted by NIOSH:

> Strupp's epidemiology summary mentions two papers that were critical of the Sanderson *et al.* (2001) nested case-control study. The first of these, Levy *et al.* (2007a), was a re-analysis that incorporated a nonstandard method of selecting control subjects and the second, Deubner *et al.* (2007), was a simulation study designed to evaluate Sanderson's study design. Both of these papers have themselves been criticized for using faulty methods (Schubauer-Berigan *et al.* 2007; Kriebel, 2008; Langholz and Richardson, 2008); however, Strupp's coverage of this is incomplete. (Document ID 1960, Attachment 2, Appendix, p. 19).

NIOSH went on to state that while the Sanderson *et al.* (2001) used standard accepted methods for selecting the control group, the Deubner *et al.* (2007) study limited control group eligibility and failed to adequately match control and case groups (Document ID 1960, Attachment 2, Appendix, pp. 19–20). NIOSH noted that an independent analysis published by Langholz and Richardson (2009) and Hein *et al.,* (2009) (as cited in Document ID 1960, Attachment 2, Appendix, p. 20) found that Levy *et al.'s* method of eliminating controls from the study had the effect of ''always produc[ing] downwardly biased effect estimates and for many scenarios the bias was substantial.'' (Document ID 1960, Attachment 2, Appendix, p. 20). NIOSH went on to cite numerous errors in the studies cited by Strupp (2011) (Document ID 1794, 1795).[9] OSHA finds NIOSH's criticisms of the Strupp (2011) studies as well as their criticism of studies by Levy *et al.,* 2007 and Deubner *et al.,* 2007 to be reliable and credible.

The Strupp and Furnes (2010) statement provided insufficient information on the extraction of beryllium metal for OSHA to fully evaluate the merit of the studies regarding potential genotoxicity of poorly soluble beryllium (Document ID 1678, Attachment 1, pp. 18–20). In addition, Strupp and Furnes did not consider the peer-reviewed published studies evaluating the genotoxicity of beryllium metal (see section V.E.1 and V.E.2).

In coming to the conclusion that the evidence is insufficient for classification under GHS, Strupp and Furnes failed to consider the full weight of evidence in their evaluation using the criteria set forth under Annex VI of Directive 67/548/EEC which establishes criteria for classification and labelling of hazardous substances under the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (Document ID 1678, attachment 1, pp. 21–23). Thus, the Agency concludes that the Strupp and Furnes statement does not constitute the best available scientific evidence for the evaluation of whether poorly soluble forms of beryllium cause cancer.

Materion also submitted comments indicating there is an ongoing scientific debate regarding the relevance of the rat lung tumor response to humans with respect to poorly soluble beryllium compounds (Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)), Materion contended that the increased lung cancer risk in beryllium-exposed animals is due to a particle overload phenomenon, in which lung clearance of beryllium particles initiates a non-specific neutrophilic response that results in intrapulmonary lung tumors. The materials cited by Materion as supportive of its argument—Obedorster (1995), a 2009 working paper to the UN Subcommittee on the Globally Harmonized System of Classification and Labelling of Chemicals (citing ILSI (2000) as supporting evidence for poorly soluble particles), Snipes (1996), the Health Risk Assessment Guidance for Metals, ICMM (2007), and ECETOC (2013)—discuss the inhalation of high exposure levels of poorly soluble particles in rats and the relevance of these studies to the human carcinogenic response (Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)). Using particles such as titanium dioxide, carbon black, non-asbestiform talc, coal dust, and diesel soot as models, ILSI (2000) and ECETOC (2013) describe studies that have demonstrated that chronic inhalation of poorly soluble particles can result in pulmonary inflammation, fibrosis, epithelial cell hyperplasia, and adenomas and carcinomas in rats at exposure levels that exceed lung clearance mechanisms (the ''overload'' phenomenon) (ILSI (2000)[10], p. 2, as cited in Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)).

However, these expert reports indicate that the ''overload'' phenomenon caused by biologically inert particles (poorly soluble particles of low cytotoxicity for which there is no evidence of genotoxicity) is relevant only to the rat species. (Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)). OSHA finds that this model is not in keeping with the data presented for beryllium for several reasons. First, beryllium has been shown to be a ''biologically active'' particle due to its ability to induce an immune response in multiple species including humans, has been shown to be genotoxic in certain mammalian test systems, and induces epigenetic changes (*e.g.* DNA methylation) (as described in detail in sections V. D. 6, V.E.1, V.E.3 and V.E.4). Second, beryllium has been shown to produce lung tumors after inhalation or instillation in several animal species, including rats, mice, and monkeys (Finch *et al.,* 1998, Document ID 1367; Schepers *et al.,* 1957 (0458) and 1962 (1414); Wagner *et al.,* 1969 (1481); Belinsky *et al.,* 2002 (1300); Groth *et al.,*

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[9] Strupp and Furnes was the background information for the Strupp (2011) publications (Document ID, Attachment 2, Appendix, p. 20).

[10] It is important to note that the ILSI report states that in interpreting data from rat studies alone, ''in the absence of mechanistic data to the contrary it must be assumed that the rat model can identify potential hazards to humans'' (ILSI, 2000, p. 2, as cited in Document ID 1807, Attachment 10, p. 1 (pdf p. 85)). The report by Oberdorster has similar language to the ILSI report (see Document ID 1807, Attachment 10, pp. 1, 3 (pdf pp. 85, 87). It should also be noted that the working paper to the UN Subcommittee on the Globally Harmonized System of Classification and Labelling of Chemicals, which cited ILSI (2000), was not adopted and has not been included in any revision to the GHS (*http://www.unece.org/fileadmin/DAM/trans/doc/2009/ac10c4/ST-SG-AC10-C4-34e.pdf*).

1980 (1316); Vorwald and Reeves, 1957 (1482); Nickell-Brady *et al.,* 1994 (1312); Swafford *et al.,* 1997 (1392); IARC, 2012 (1355)). In addition, poorly soluble beryllium has been demonstrated to produce chronic inflammation at levels below overload (Groth *et al.,* 1980, Document ID 1316; Nickell-Brady *et al.,* 1994 (1312); Finch *et al.,* 1998 (1367); Finch *et al.,* 2000 (as cited in Document ID 1960, p. 11)).

In addition, IARC and NAS performed an extensive review of the available animal studies and their findings were supportive of the OSHA findings of carcinogenicity (IARC, 2012, Document ID 0650; NAS, 2008 (1355)). OSHA performed an independent evaluation as outlined in section V.E.3 and found sufficient evidence of tumor formation in multiple species (rats, mice, and monkeys) after inhalation at levels below overload conditions. The Agency has found evidence supporting the hypothesis that multiple mechanisms may be at work in the development of cancer in experimental animals and humans and cannot dismiss the roles of inflammation (neutrophilic and T-cell mediated), genotoxicity, and epigenetic factors (see section V.E.1, V.E. 3, V.E.4). After evaluating the best scientific evidence available from epidemiological and animal studies (see section V.E) OSHA concludes the weight of evidence supports a mechanistic finding that both soluble and poorly soluble forms of beryllium and beryllium-containing compounds are carcinogenic.

F. Other Health Effects

Past studies on other health effects have been thoroughly reviewed by several scientific organizations (NTP, 1999, Document ID 1341; EPA, 1998 (0661); ATSDR, 2002 (1371); WHO, 2001 (1282); HSDB, 2010 (0533)). 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 on humans mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 OSHA, 1971, see 39 FR 23513; EPA, 1973 (38 FR 8820)). (OSHA, 1971, see 39 FR 23513; ACGIH, 1971 (0543); ANSI, 1970 (1303)) and EPA, 1973 (38 FR 8820) 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. During the public comment period OSHA received comments suggesting that OSHA add dermal effects to this section. Therefore, dermal effects have been added, below, and are also discussed in the section on kinetics and metabolism (section V.B.2).

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, in one study, beryllium phosphate accumulated almost exclusively within sinusoidal (Kupffer) cells of the liver, while beryllium sulfate was found mainly in parenchymal cells. Conversely, beryllium sulphosalicylic acid complexes were rapidly excreted (Skilleter and Paine, 1979, Document ID 1410).

According to a few autopsies, beryllium-laden livers had central necrosis, mild focal necrosis and inflammation, as well as, occasionally, beryllium granuloma (Sprince *et al.,* 1975, Document ID 1405).

2. Cardiovascular Effects

Severe cases of CBD 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, Document ID 1516). 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, Document ID 1378). Additionally, a study by Schubauer-Berigan *et al.* (2011) found an increase in mortality due to cor pulmonale in a follow-up study of workers at seven beryllium processing plants who were exposed to beryllium levels near the preceding OSHA PEL of 2.0 μg/m^3 (Schubauer-Berigan *et al.,* 2011, Document ID 1266).

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, 1957, Document ID 0458). Decreased arterial oxygen tension was observed in dogs exposed to 30 mg beryllium/m^3 as beryllium oxide for 15 days (HSDB, 2010, Document ID 0533), 3.6 mg beryllium/m^3 as beryllium oxide for 40 days (Hall *et al.,* 1950, Document ID 1494), and 0.04 mg beryllium/m^3 as beryllium sulfate for 100 days (Stokinger *et al.,* 1950, Document ID 1484). These are thought 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 or kidney stones have been found in severe cases of CBD 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, Document ID 0453). The ATSDR reported that 10 percent of the CBD cases found in the BCR reported kidney stones. In addition, an excess of calcium in the blood and urine was frequently found in patients with CBD (ATSDR, 2002, Document ID 1371).

4. Ocular and Mucosal Effects

Soluble and poorly soluble beryllium compounds have been shown to cause ocular irritation in humans (VanOrdstrand *et al.,* 1945, Document ID 1383; De Nardi *et al.,* 1953 (1545); Nishimura, 1966 (1435); Epstein, 1991 (0526); NIOSH, 1994 (1261). In addition, soluble and poorly soluble beryllium has been shown to induce acute conjunctivitis with corneal maculae and diffuse erythema (HSDB, 2010, Document ID 0533).

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, Document ID 0533).

5. Dermal Effects

Several commenters suggested OSHA add dermal effects to this Health Effects section. National Jewish Health noted that rash and granulomatous reactions of the skin still occur in occupational settings (Document ID 1664, p. 5). The National Supplemental Screening Program also recommended including skin conditions such as dermatitis and nodules (Document ID 1677, p. 3). The American Thoracic Society also recommended including ‘‘beryllium sensitization, CBD, and skin disease as the major adverse health effects associated with exposure to beryllium at or below 0.1 μg/m^3 and acute beryllium disease at higher exposures based on the currently available epidemiologic and experimental studies'' (Document ID 1688, p. 2). OSHA agrees and has included dermal effects in this section of the final preamble.

As summarized in Epstein (1991), skin exposure to soluble beryllium compounds (mainly beryllium fluoride but also beryllium metal which may contain beryllium fluoride) resulted in irritant dermatitis with inflammation, and local edema. Beryllium oxide, beryllium alloys and nearly pure beryllium metal did not produce such responses in the skin of workers (Epstein, 1991, Document ID 0526). Skin lacerations or abrasions contaminated with soluble beryllium can lead to skin ulcerations (Epstein, 1991, Document ID 0526). Soluble and poorly soluble beryllium-compounds that penetrate the skin as a result of abrasions or cuts have been shown to result in chronic ulcerations and skin granulomas (VanOrdstrand *et al.,* 1945, Document ID 1383; Lederer and Savage, 1954 (1467)). However, ulcerating granulomatous formation of the skin is generally associated with poorly soluble forms of beryllium (Epstein, 1991, Document ID 0526). Beryllium, beryllium oxide and other soluble and poorly soluble forms of beryllium have been classified as a skin irritant (category 2) in accordance with the EU Classification, Labelling and Packaging Regulation (Document ID 1669, p. 2). Contact dermatitis (skin hypersensitivity) was observed in some individuals exposed via skin to soluble forms of beryllium, especially individuals with a dermal irritant response (Epstein, 1991, Document ID 0526). Contact allergy has been observed in workers exposed to beryllium chloride (Document ID 0522).

G. Summary of Conclusions Regarding Health Effects

Through careful analysis of the best available scientific information outlined in this section, OSHA has determined that beryllium and beryllium-containing compounds can cause sensitization, CBD, and lung cancer. The Agency has determined through its review and evaluation of 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's review and evaluation of the studies outlined in section V.E. of this health effects section led to a finding that inhalation exposure to beryllium and beryllium-containing materials can cause lung cancer.

1. OSHA's Evaluation of the Evidence Finds That Beryllium Causes Sensitization Below the Preceding 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 has concluded that the scientific evidence supports the following mechanisms for the development of sensitization and CBD.

- Inhaled beryllium and beryllium-containing materials able to be retained and solubilized in the lungs have the ability to initiate sensitization and facilitate CBD development (section V.B.5). Genetic susceptibility may play a role in the development of sensitization and progression to CBD in certain individuals.
- 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 the capacity to dissolve beryllium compounds in the lung (section V.A.2a).
- Sensitization occurs through a T-cell mediated process with both soluble and poorly soluble beryllium and beryllium-containing compounds through direct antigen presentation or through further antigen processing 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 (section V.D.1).
- 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).
- Particle characteristics such as size, solubility, surface area, and other properties may play a role in the rate of development of beryllium sensitization and CBD. However, there is currently not sufficient information to delineate the biological role these characteristics may play.
- Animal studies have provided supporting evidence for T-cell proliferation in the development of granulomatous lung lesions after beryllium exposure (sections 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 (section V.D.1). While no clinical symptoms are associated with sensitization, a sensitized worker is at risk of developing CBD when inhalation exposure to beryllium has occurred. Epidemiological evidence that covers a wide variety of beryllium compounds and industrial processes demonstrates that sensitization and CBD are continuing to occur at present-day exposures below OSHA's preceding PEL (sections V.D.4; V.D.5 and section VI of this preamble).
- 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 appear to 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. OSHA's Evaluation of the Evidence Has Determined Beryllium To Be a Human Carcinogen

OSHA conducted an evaluation of the available scientific information regarding the carcinogenic potential of beryllium and beryllium-containing compounds (section V.E). Based on the 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 determined that beryllium and beryllium-containing materials are properly regarded as human carcinogens. This information is in accordance with findings from IARC, NTP, EPA, NIOSH, and ACGIH (section V.E). Key points from this analysis are summarized briefly here.

- 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 in multiple species of laboratory 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 (section V.E).

While OSHA has determined there is sufficient evidence of beryllium carcinogenicity, the Agency acknowledges that the exact tumorigenic mechanism for beryllium has yet to be determined. A number of mechanisms are likely 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 animals after inhalation exposure to poorly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicity of the particles (section V.E.5).

• A review conducted by the NAS (2008) (Document ID 1355) 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 are discussed 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 1970–1973 (ACGIH, 1971, Document ID 0543; ANSI, 1970 (1303); OSHA, 1971, see 39 FR 23513; EPA, 1973 (38 FR 8820)) and therefore are less relevant.

VI. Risk Assessment

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.'' Section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b). 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. Section II, Pertinent Legal Authority, of this preamble addresses the statutory bases for these requirements and how they have been construed by the Supreme Court and federal courts of appeals.

It is OSHA's practice to evaluate risk to workers and determine the significance of that risk based on the best available evidence. Using that evidence, OSHA identifies material health impairments associated with potentially hazardous occupational exposures, assesses whether exposed workers' risks are significant, and determines whether a new or revised rule will substantially reduce these risks. As discussed in Section II, Pertinent Legal Authority, when determining whether a significant risk exists OSHA considers whether there is a risk of at least one-in-a-thousand of developing amaterial health impairment from a working lifetime of exposure at the prevailing OSHA standard (referred to as the ''preceding standard'' or ''preceding TWA PEL'' in this preamble). For this purpose, OSHA generally assumes that a term of 45 years constitutes a working life. The Supreme Court has found that OSHA is not required to support its finding of significant risk with scientific certainty, but may instead rely on a body of reputable scientific thought and may make conservative assumptions (*i.e.,* err on the side of protecting the worker) in its interpretation of the evidence (see Section II, Pertinent Legal Authority).

For single-substance standards governed by section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5), OSHA sets a permissible exposure limit (PEL) based on its risk assessment as well as feasibility considerations. These health and risk determinations are made in the context of a rulemaking record in which the body of evidence used to establish material impairment, assess risks, and identify affected worker population, as well as the Agency's preliminary risk assessment, are placed in a public rulemaking record and subject to public comment. Final determinations regarding the standard, including final determinations of material impairment and risk, are thus based on consideration of the entire rulemaking record.

OSHA's approach for the risk assessment for beryllium incorporates both: (1) A review of the literature on populations of workers exposed to beryllium at and below the preceding time-weighted average permissible exposure limit (TWA PEL) of 2 μg/m^3; and (2) OSHA's own analysis of a data set of beryllium-exposed machinists. The Preliminary Risk Assessment included in the NPRM evaluated risk at several alternate TWA PELs that the Agency was considering (1 μg/m^3, 0.5 μg/m^3, 0.2 μg/m^3, and 0.1 μg/m^3), as well as OSHA's preceding TWA PEL of 2 μg/m^3. OSHA's risk assessment relied on available epidemiological studies to evaluate the risk of sensitization and CBD for workers exposed to beryllium at and below the preceding TWA 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 preceding PEL and alternate PELs the Agency was considering. For this analysis, OSHA used data provided by National Jewish Health (NJH), a leading medical center specializing in the research and treatment of CBD, 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 both show significant risk of sensitization and CBD among workers exposed at and below the preceding TWA PEL of 2 μg/m^3. They also show substantial reduction in risk where employers implemented a combination of controls, including stringent control of airborne beryllium levels and additional measures, such as respirators and dermal personal protective equipment (PPE) to further protect workers against dermal contact and airborne beryllium exposure.

To evaluate lung cancer risk, OSHA relied on a quantitative risk assessment published in 2011 by Schubauer-Berigan *et al.* (Document ID 1265). Schubauer-Berigan *et al.* found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure; the authors predicted significant risk of lung cancer at the preceding TWA PEL, and substantial reductions in risk at the alternate PELs OSHA considered in the proposed rule, including the final TWA PEL of 0.2 μg/m^3 (Schubauer-Berigan *et al.,* 2011).

OSHA requested input on the preliminary risk assessment presented in the NPRM, and received comments from a variety of public health experts and organizations, unions, industrial organizations, individual employers, and private citizens. While many comments supported OSHA's general approach to the risk assessment and the conclusions of the risk assessment, some commenters raised specific concerns with OSHA's analytical methods or recommended additional studies for OSHA's consideration. Comments about the risk assessment as a whole are reviewed here, while comments on specific aspects of the risk assessment are addressed in the relevant sections throughout the remainder of this chapter and in the background document, Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization (OSHA, 2016), which can be found in the rulemaking docket (docket number OSHA–H005C–2006–0870) at *www.regulations.gov.* Following OSHA's review of all the comments submitted on the preliminary risk assessment, and its incorporation of suggested changes to the risk assessment, where appropriate, the Agency reaffirms its conclusion that workers' risk of material impairment of health from beryllium exposure at the preceding PEL of 2 μg/m³ is significant, and is substantially reduced but still significant at the new PEL of 0.2 μg/m³ (see this preamble at Section VII, Significance of Risk).

The comments OSHA received on its preliminary risk analysis generally supported OSHA's overall approach and conclusions. NIOSH indicated that OSHA relied on the best available evidence in its risk assessment and concurred with ''OSHA's careful review of the available literature on [beryllium sensitization] and CBD, OSHA's recognition of dermal exposure as a potential pathway for sensitization, and OSHA's careful approach to assessing risk for [beryllium sensitization] and CBD'' (Document ID 1725, p. 3). NIOSH agreed with OSHA's approach to the preliminary lung cancer risk assessment (Document ID 1725, p. 7) and the selection of a 2011 analysis (Schubauer-Berigan *et al.,* 2011, Document ID 1265) as the basis of that risk assessment (Document ID 1725, p. 7). NIOSH further supported OSHA's preliminary conclusions regarding the significance of risk of material health impairment at the preceding TWA PEL of 2 μg/m³, and the substantial reduction of such risk at the new TWA PEL of 0.2 μg/m³ (Document ID 1725, p. 3). Finally, NIOSH agreed with OSHA's preliminary conclusion that compliance with the new PEL would lessen but not eliminate risk to exposed workers, noting that OSHA likely underestimated the risks of beryllium sensitization and CBD (Document ID 1725, pp. 3–4).

Other commenters also agreed with the general approach and conclusions of OSHA's preliminary risk assessment. NJH, for example, determined that ''OSHA performed a thorough assessment of risk for [beryllium sensitization], CBD and lung cancer using all available studies and literature'' (Document ID 1664, p. 5). Dr. Kenny Crump and Ms. Deborah Proctor commented, on behalf of beryllium producer Materion, that they ''agree with OSHA's conclusion that there is a significant risk (>1/1000 risk of CBD) at the [then] current PEL, and that risk is reduced at the proposed PEL (0.2 μg/m³) in combination with stringent measures (ancillary provisions) to reduce worker's exposures'' (Document ID 1660, p. 2). They further stated that OSHA's ''finding is evident based on the available literature . . . and the prevalence data [OSHA] presented for the Cullman facility'' (Document ID 1660, p. 2).

OSHA also received comments objecting to OSHA's conclusions regarding risk of lung cancer from beryllium exposure and suggesting additional published analyses for OSHA's consideration (*e.g.,* Document ID 1659; 1661, pp. 1–3). One comment critiqued the statistical exposure-response model OSHA presented as one part of its preliminary risk analysis for sensitization and CBD (Document ID 1660). These comments are discussed and addressed in the remainder of this chapter.

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

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 preceding PEL of 2 μg/m³ (*e.g.,* Kreiss *et al.,* 1993, Document ID 1478; Henneberger *et al.,* 2001 (1313); Schuler *et al.,* 2005 (0919); Schuler *et al.,* 2012 (0473)). In the mid-1990s, some facilities using beryllium began to aggressively monitor and reduce workplace exposures. In the NPRM, OSHA reviewed studies of workers at four plants where several rounds of BeLPT screening were conducted before and after implementation of new exposure control methods. These studies provide the best 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 ceramics facility in Tucson, AZ, a beryllium processing facility in Elmore, OH, and a machining facility in Cullman, AL—show that comprehensive exposure control programs that used engineering controls to reduce airborne exposure to beryllium, required the use of 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. In contrast, efforts to prevent sensitization and CBD by using engineering controls to reduce workers' beryllium exposures to median levels around 0.2 μg/m³, with no corresponding emphasis on PPE, were less effective than comprehensive exposure control programs implemented more recently. OSHA also reviewed additional, but more limited, information on the occurrence of sensitization and CBD among workers with low-level beryllium exposures at nuclear facilities and aluminum smelting plants. A summary discussion of the experiences at all of these facilities is provided in this section. Additional discussion of studies on these facilities and several other studies of sensitization and CBD among beryllium-exposed workers is provided in Section V, Health Effects.

The Health Effects section also discusses OSHA's findings and the supporting evidence concerning the role of particle characteristics and beryllium compound solubility in the development of sensitization and CBD among beryllium-exposed workers. First, it finds that 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. Second, it finds that both soluble and poorly soluble forms of beryllium are able to induce sensitization and CBD. Poorly soluble 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 particle size and solubility may influence the toxicity of beryllium, the available data are too limited to reliably account for these factors in the Agency's estimates of risk.

1. Reading, PA, Plant

Schuler *et al.* (2005, Document ID 0919) and Thomas *et al.* (2009, Document ID 0590) conducted studies of workers at a copper-beryllium processing facility in Reading, PA. Exposures at this plant were believed to be low throughout its history due to both 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) (Schuler *et al.,* 2005). Ninety-nine percent of personal lapel sample measurements were below the preceding OSHA TWA PEL of 2 μg/m³; 93 percent were below the new TWA

PEL of 0.2 μg/m³ (Schuler *et al.,* 2005). Schuler *et al.* (2005) screened 152 workers at the facility with the BeLPT in 2000. 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 both the preceding and final TWA PELs.[11] 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 (Schuler *et al.,* 2005).

After the initial BeLPT screening was conducted in 2000, the company began implementing new measures to further reduce workers' exposure to beryllium (Thomas *et al.* 2009, Document ID 0590). Requirements designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000–2002. In 2001, the company installed local exhaust ventilation (LEV) in die grinding and polishing operations (Thomas *et al.,* 2009, Figure 1). Personal lapel samples collected between June 2000 and December 2001, showed reduced exposures plant-wide (98 percent were below 0.2 μg/m³). Median, arithmetic mean, and geometric mean values less than or equal to 0.03 μg/m³ were reported in this period for all processes except one, a 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) (Thomas *et al.,* 2009, Table 3). In January 2002, the company enclosed the wire annealing and pickling process in a restricted access zone (RAZ). Beginning in 2002, the company required use of powered air-purifying respirators (PAPRs) in the RAZ, and implemented stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone, such as requiring RAZ workers to shower before leaving the zone (Thomas *et al.,* 2009, Figure 1). While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–2001 samples in areas other than the RAZ (Thomas *et al.,* 2009, Table 3). The authors 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 (Thomas *et al.,* 2009, Document ID 0590). 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, which had been releasing beryllium into the surrounding area, 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 built was confirmed as sensitized. From these early results comparing the screening conducted on workers hired before 2000 and those hired in 2000 and later, especially following the enclosure of the RAZ, it appears that the greatest reduction in sensitization risk (to one sensitized worker, or 2.2 percent) was achieved after workers' exposures were reduced to below 0.1 μg/m³ and PPE to prevent dermal contact was instituted (Thomas *et al.,* 2009).

2. Tucson, AZ, Plant

Kreiss *et al.* (1996, Document ID 1477), Cummings *et al.* (2007, Document ID 1369), and Henneberger *et al.* (2001, Document ID 1313) conducted studies of workers at a beryllia ceramics plant in Tucson, Arizona. Kreiss *et al.* (1996) screened 136 workers at this plant with the BeLPT in 1992. Full-shift area samples collected between 1983 and 1992 showed primarily low airborne beryllium levels at this facility (76 percent of area samples were at or below 0.1 μg/m³ and less than 1 percent exceeded 2 μg/m³). 4,133 short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 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).

Kreiss *et al.* reported that eight (5.9 percent) of the 136 workers tested in 1992 were sensitized, six (4.4 percent) of whom were diagnosed with CBD. 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. Personal lapel samples taken on administrative workers during the 1990s were below the detection limit at the time, 0.2 μg/m³ (Cummings *et al.,* 2007, Document ID 1369).

Following the 1992 screening, the facility reduced exposures in machining areas (for example, by enclosing additional machines and installing additional exhaust ventilation), resulting in median exposures of 0.2 μg/m³ in production jobs and 0.1 μg/m³ in production support jobs (Cummings *et al.,* 2007). In 1998, a second screening found that 7 out of 74 tested workers hired after the 1992 screening (9.5 percent) were sensitized, one of whom was diagnosed with CBD. All seven of these sensitized workers had been employed at the plant for less than two years (Henneberger *et al.,* 2001, Document ID 1313, Table 3). Of 77 Tucson workers hired prior to 1992 who were tested in 1998, 8 (10.4 percent) were sensitized and 7 of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001).

Following the 1998 screening, the company continued efforts to reduce exposures, along with risk of sensitization and CBD, by implementing additional engineering and administrative controls and a comprehensive PPE program which included the use of respiratory protection (1999) and latex gloves (2000) (Cummings *et al.,* 2007, Document ID 1369). Enclosures were installed for various beryllium-releasing processes by 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. 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 97 workers hired between 2000 and 2004, one case of sensitization was identified (1 percent) (Cummings *et al.,* 2007).

3. Elmore, OH, Plant

Kreiss *et al.* (1997, Document ID 1360), Bailey *et al.* (2010, Document ID 0676), and Schuler *et al.* (2012, Document ID 0473) conducted studies of workers at a beryllium metal, alloy, and oxide production plant in Elmore, Ohio. Workers participated in several plant-wide BeLPT surveys beginning in 1993–1994 (Kreiss *et al.,* 1997; Schuler *et al.,* 2012) and in a series of screenings

[11] Although OSHA reports percentages to indicate the risks of sensitization and CBD in this section, the benchmark OSHA typically uses to demonstrate significant risk, as discussed in Pertinent Legal Authority, is greater than or equal to 1 in 1,000 workers. One in 1,000 workers is equivalent to 0.1 percent. Therefore, any value of 0.1 percent or higher when reporting occurrence of a health effect is considered by OSHA to indicate a significant risk.

for workers hired in 2000 and later, conducted beginning in 2000 (Bailey *et al.,* 2010).

Exposure levels at the plant between 1984 and 1993 were characterized using a mixture of general area, short-term breathing zone, and personal lapel samples (Kreiss *et al.,* 1997, Document ID 1360). Kreiss *et al.* reported that the median area samples for various work areas ranged from 0.1 to 0.7 μg/m^3, with the highest values in the alloy arc furnace and alloy melting-casting areas. Personal lapel samples were available from 1990–1992, and showed high exposures overall (median value of 1.0 μg/m^3), with very high exposures for some processes. Kreiss *et al.* reported median sample values from the personal lapel samples of 3.8 μg/m^3 for beryllium oxide production, 1.75 μg/m^3 for alloy melting and casting, and 1.75 μg/m^3 for the arc furnace. The authors reported that 43 (6.9 percent) of 627 workers tested in 1993–1994 were sensitized. 29 workers (including 5 previously identified) were diagnosed with CBD (29/632, or 4.6 percent) (Kreiss *et al.,* 1997).

In 1996–1999, the company took further steps to reduce workers' beryllium exposures, including enclosure of some beryllium-releasing processes, establishment of restricted-access zones, and installation or updating of certain engineering controls (Bailey *et al.,* 2010, Document ID 0676, Tables 1–2). Beginning in 1999, all new employees were required to wear loose-fitting PAPRs in manufacturing buildings. 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. By 2001, either half-mask respirators or PAPRs were required throughout 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).

Beginning in 2000, newly hired workers were offered periodic BeLPT testing to evaluate the effectiveness of the new exposure control program implemented by the company (Bailey *et al.,* 2010). Bailey *et al.* 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'') with that of 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. This four-fold reduction in sensitization suggests that beryllium-exposed workers' risk of sensitization (and therefore of CBD, which develops only following sensitization) can be much reduced by the combination of process controls, respiratory protection requirements, and PPE requirements applied in this facility. Because most of the workers in the study had been employed at the facility for less than two years, and CBD typically develops over a longer period of time (see section V, Health Effects), Bailey *et al.* did not report the incidence of CBD among the sensitized workers (Bailey *et al.,* 2010). Schuler *et al.* (2012, Document ID 0473) 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, Document ID 0466). The study population included 264 workers employed in 1999 with up to 6 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. A set of 1999 exposure surveys and employee work histories was used to estimate employees' long-term lifetime weighted (LTW) average, cumulative, and highest-job-worked exposures for total, respirable, and submicron beryllium mass concentrations (Schuler *et al.,* 2012; Virji *et al.,* 2012).

As reported by Schuler *et al.* (2012), 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. Although follow-up time was too short (at most 6 years) to fully evaluate CBD in this group, 6 of those sensitized were diagnosed with CBD (2.3 percent, 6/264). Schuler *et al.* (2012) found 17 cases of sensitization (8.6%) within the first 3 quartiles of LTW average exposure (198 workers with LTW average total mass exposures lower than 1.1 μg/m^3) and 4 cases of CBD (2.2%) within those first 3 quartiles (183 workers with LTW average total mass exposures lower than 1.07 μg/m^3)[12] The authors found 3 cases (4.6%) of sensitization among 66 workers with total mass LTW average exposures below 0.1 μg/m^3, and no cases of sensitization among workers with total mass LTW average exposures below 0.09 μg/m^3, suggesting that beryllium-exposed workers' risk can be much reduced or eliminated by reducing airborne exposures to average levels below 0.1 μg/m^3.

Schuler *et al.* (2012, Document ID 0473) then used logistic regression to explore the relationship between estimated beryllium exposure and sensitization and CBD. For beryllium sensitization, the logistic models by Schuler *et al.* showed elevated odds ratios (OR) for LTW 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).[13] Relationships between sensitization and respirable exposure estimates were similarly elevated for LTW average (OR 1.37) and highest job (OR 1.32) exposures. 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. Average and highest job exposures were predictive of risk for sensitization, while cumulative exposure was predictive of risk for CBD (Schuler *et al.,* 2012).

Materion submitted comments supporting OSHA's use of the Schuler *et al.* (2012) study as a basis for the final TWA PEL of 0.2 μg/m^3. Materion stated that ''the best available evidence to establish a risk-based OEL [occupational exposure limit] is the study conducted by NIOSH and presented in Schuler 2012. The exposure assessment in

[12] The total number of workers Schuler *et al.* reported in their table of LTW average quartiles for sensitization differs from the total number of workers reported in their table of LTW average quartiles for CBD. The table for CBD appeared to exclude 20 workers with sensitization and no CBD.

[13] An odds ratio (OR) is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure.

Schuler *et al.* was based on a highly robust workplace monitoring dataset and the study provides improved data for determining OELs'' (Document ID 1661, pp. 9–10). Materion also submitted an unpublished manuscript documenting an analysis it commissioned, entitled ''Derived No-Effect Levels for Occupational Beryllium Exposure Using Cluster Analysis and Benchmark Dose Modeling'' (Proctor *et al.,* Document ID 1661, Attachment 5). In this document, Proctor *et al.* used data from Schuler *et al.* 2012 to develop a Derived No-Effect Level (DNEL) for beryllium measured as respirable beryllium, total mass of beryllium, and inhalable beryllium.[14] OSHA's beryllium standard measures beryllium as total mass; thus, the results for total mass are most relevant to OSHA's risk analysis for the beryllium standard. The assessment reported a DNEL of 0.14 μg/m³ for total mass beryllium (Document ID 1661, Attachment 5, p. 16). Materion commented that this finding ''add[s] to the body of evidence that supports the fact that OSHA is justified in lowering the existing PEL to 0.2 μg/m³'' (Document ID 1661, p. 11).

Proctor *et al.* characterized the DNEL of 0.14 μg/m³ as ''inherently conservative because average exposure metrics were used to determine DNELs, which are limits not [to] be exceeded on a daily basis'' (Document ID 1661, Attachment 5, p. 22). Materion referred to the DNELs derived by Proctor *et al.* as providing an ''additional margin of safety'' for similar reasons (Document ID 1661, p. 11).

Consistent with NIOSH comments discussed in the next paragraph, OSHA disagrees with this characterization of the DNEL as representing a ''no effect level'' for CBD or as providing a margin of safety for several reasons. The DNEL from Proctor *et al.* is based on CBD findings among a short-term worker population and thus cannot represent the risk presented to workers who are exposed over a working lifetime. Proctor *et al.* noted that it is ''important to consider that these data are from relatively short-term exposures [median tenure 20.9 months] and are being used to support DNELs for lifetime occupational exposures,'' but considered the duration of exposure to be sufficient because ''CBD can develop with latency as short as 3 months of exposure, and . . . the risk of CBD declines over time'' (Document ID 1661, Attachment 5, p. 19). In stating this, Procter *et al.* cite studies by Newman *et al.* (2001, Document ID 1354) and Harber *et al.* (2009, as cited in Document ID 1661). Newman *et al.* (2001) studied a group of workers in a machining plant with job tenures averaging 11.7 years, considerably longer than the worker cohort from the study used by Procter *et al.,* and identified new cases of CBD from health screenings conducted up to 4 years after an initial screening. Harber *et al.,* (2009) developed an analytic model of disease progression from beryllium exposure and found that, although the rate at which new cases of CBD declined over time, the overall proportion of individuals with CBD increased over time from initial exposure (see Figure 2 of Haber *et al.,* 2009). Furthermore, the study used by Proctor *et al.* to derive the DNEL, Schuler *et al.* (2012), did report finding that the risk of CBD increased with cumulative exposure to beryllium, as summarized above. Therefore, OSHA is not convinced that a ''no effect level'' for beryllium that is based on the health experience of workers with a median job tenure of 20.9 months can represent a ''no-effect level'' for workers exposed to beryllium for as long as 45 years.

NIOSH commented on the results of Proctor *et al.*'s analysis and the underlying data set, noting several features of the dataset that are common to the beryllium literature, such as uncertain date of sensitization or onset of CBD and no ''background'' rate of beryllium sensitization or CBD, that make statistical analyses of the data difficult and add uncertainty to the derivation of a DNEL (Document ID 1725, p. 5). NIOSH also noted that risk of CBD may be underestimated in the underlying data set if workers with CBD were leaving employment due, in part, to adverse health effects (''unmeasured survivor bias'') and estimated that as much as 30 percent of the cohort could have been lost over the 6-year testing period (Document ID 1725, p. 5). NIOSH concluded that Proctor *et al.*'s analysis ''does not contribute to the risk assessment for beryllium workers'' (Document ID 1725, p. 5). OSHA agrees with NIOSH that the DNEL identified by Proctor *et al.* cannot be considered a reliable estimate of a no-effect level for beryllium.

4. Cullman, AL, Plant

Newman *et al.* (2001, Document ID 1354), Kelleher *et al.* (2001, Document ID 1363), and Madl *et al.* (2007, Document ID 1056) studied beryllium workers at a precision machining facility in Cullman, Alabama. After a case of CBD was diagnosed at the plant in 1995, the company began BeLPT screenings to identify workers at risk of CBD and implemented engineering and administrative controls designed to reduce workers' beryllium exposures in machining operations. Newman *et al.* (2001) conducted a series of BeLPT screenings of workers at the facility between 1995 and 1999. The authors reported 22 (9.4 percent) sensitized workers among 235 tested, 13 of whom were diagnosed with CBD within the study period. Personal lapel samples collected between 1980 and 1999 indicate that median exposures were generally well below the preceding PEL (≤0.35 μg/m³ in all job titles except maintenance (median 3.1 μg/m³ during 1980–1995) and gas bearings (1.05 μg/m³ during 1980–1995)).

Between 1995 and 1999, the company built enclosures around several beryllium-releasing operations; installed or updated LEV for several machining departments; replaced pressurized air hoses and dry sweeping with wet methods and vacuum systems for cleaning; changed the layout of the plant to keep beryllium-releasing processes close together; limited access to the production area of the plant; and required the use of company uniforms. Madl *et al.* (2007, Document ID 1056) reported that engineering and work process controls, rather than personal protective equipment, were used to limit workers' exposure to beryllium. 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 and non-machining jobs had medians of 0.16 μg/m³ and 0.08 μg/m³, respectively (Madl *et al.,* 2007, Table IV). 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 and had therefore benefitted to some extent from the controls described above. 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, Document ID 1354). The later study by Madl. *et al.* reported seven sensitized workers who had been hired between 1995 and 1999, of whom four had developed CBD as of 2005 (2007, Table II) (total number of workers hired between 1995 and 1999 not reported).

Beginning in 2000 (after the implementation of controls between 1997 and 1999), exposures in all jobs at the machining facility were reduced to

[14] Derived No-Effect Level (DNEL) is used in REACH quantitative risk characterizations to mean the level of exposure above which humans should not be exposed. It is intended to represent a safe level of exposure for humans., REACH is the European Union's regulation on Registration, Evaluation, Authorization and Restriction of Chemicals.

extremely low levels (Madl *et al.,* 2007, Document ID 1056). Personal lapel samples collected between 2000 and 2005 had a median of 0.12 μg/m³ or less in all machining and non-machining processes (Madl. *et al.,* 2007, Table IV). Only one worker hired after 1999 became sensitized (Madl *et al.* 2007, Table II). The worker had been employed for 2.7 years in chemical finishing, which had the highest median exposure of 0.12 μg/m³ (medians for other processes ranged from 0.02 to 0.11 μg/m³); Madl *et al.* 2007, Table II). This result from Madl *et al.* (2007) suggests that beryllium-exposed workers' risk of sensitization can be much reduced by steps taken to reduce workers' airborne exposures in this facility, including enclosure of beryllium-releasing processes, LEV, wet methods and vacuum systems for cleaning, and limiting worker access to production areas.

The Cullman, AL facility was also the subject of a case-control study published by Kelleher *et al.* in 2001 (Document ID 1363). After the diagnosis of a case of CBD at the plant in 1995, NJH researchers, including Kelleher, worked with the plant to conduct the medical surveillance program mentioned above, using the BeLPT to screen workers biennially for beryllium sensitization and offering sensitized workers further evaluation for CBD (Kelleher *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, Document ID 1358). Kelleher *et al.* used the dataset of 100 personal lapel samples collected by Martyny *et al.* and other NJH researchers to characterize exposures for each job in the plant. 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 average exposure estimates based on the total mass of beryllium reported in their exposure samples, Kelleher *et al.* calculated cumulative and LTW average 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 results, however, were inconclusive, probably due to the relatively small size of the dataset (Kelleher *et al.,* 2001).

5. Aluminum Smelting Plants

Taiwo *et al.* (2008, Document ID 0621; 2010 (0583) and Nilsen *et al.* (2010, Document ID 0460) studied the relationship between beryllium exposure and adverse health effects among workers at aluminum smelting plants. Taiwo *et al.* (2008) studied a population of 734 employees at 4 aluminum smelters located in Canada (2), Italy (1), and the United States (1). In 2000, a company-wide beryllium exposure limit of 0.2 μg/m³ and an action level of 0.1 μg/m³, expressed as 8-hour TWAs, 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 four 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 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
US smelter	346	0.03	0.26	0.04

Adapted from Taiwo *et al.,* 2008, Document ID 0621, 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). 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
US smelter	270	268	2	0

Adapted from Taiwo *et al.,* 2008, Document ID 0621, 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 pulmonary function tests, respiratory symptoms, and radiographic evidence in the other.

In 2010, Taiwo *et al.* (Document ID 0583) published a study of beryllium-exposed workers from four companies, with a total of nine smelting operations. These workers included some of the workers from the 2008 study. 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, and the criteria appeared to vary considerably (Taiwo *et al.,* 2010); thus, it is difficult to compare rates of sensitization across companies in this study. 1932 workers, about 60 percent of invited workers, participated in the program between 2000 and 2006, of whom 9 were determined to be sensitized (.4 percent). The authors stated that all nine workers were referred to a respiratory physician for further evaluation for CBD. Two were diagnosed with CBD (.1 percent), as described above (*see* Taiwo *et al.,* 2008).

In general, there appeared to be a low level of sensitization and CBD among employees at the aluminum smelters studied by Taiwo *et al.* (2008; 2010). 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 noted that respiratory and dermal protection had been used at these plants to protect workers from other hazards (Taiwo *et al.,* 2008).

A study by Nilsen *et al.* (2010, Document ID 0460) of aluminum workers in Norway also found a low rate of sensitization. In the study, 362 workers and 31 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 exposure measurements 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 was the case in the smelters studied by Taiwo *et al.* (2008; 2010).

6. Nuclear Weapons Facilities

Viet *et al.* (2000, Document ID 1344) and Arjomandi *et al.* (2010, Document ID 1275) evaluated beryllium-exposed nuclear weapons workers. 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. The program, which the authors reported had tested over 5,000 current and former Rocky Flats employees for sensitization, had identified a total of 127 sensitized individuals as of 1994 when Viet *et al.* initiated their study; 51 of these sensitized individuals had been diagnosed with CBD.

Using subjects from the BHSP, Viet *et al.* (2000) matched a total of 50 CBD cases to 50 controls who tested negative for beryllium sensitization 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 matched to 74 control individuals from the BHSP database who tested negative for beryllium sensitization.

Viet *et al.* (2000) developed exposure estimates for the cases and controls based on daily fixed airhead (FAH) beryllium air samples collected in one of 36 buildings at Rocky Flats where beryllium was used, the Building 444 Beryllium Machine Shop. Annual mean FAH samples in Building 444 collected between 1960 and 1988 ranged from a low of 0.096 μg/m³ (1988) to a high of 0.622 μg/m³ (1964) (Viet *et al.,* 2000, Table II). Because exposures in this shop were better characterized than in other buildings, the authors developed estimates of exposures for all workers based on samples from Building 444. The authors' statistical analysis of the resulting data set included conditional logistic regression analysis, modeling the relationship between risk of each health outcome and individuals' log-transformed cumulative exposure estimate (CEE) and mean exposure estimate (MEE). These coefficients corresponded 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). Viet *et al.* 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.

Arjomandi *et al.* (2010) published a study of 50 sensitized workers from a nuclear weapons research and development facility who were evaluated for CBD. Quantitative exposure estimates for the workers were not presented; however, the authors characterized their likely exposures as low (possibly below 0.1 μg/m³ for most jobs). 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).

Five of the 50 evaluated 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. OSHA notes that this prevalence of CBD among sensitized workers is lower than the prevalence of CBD that has been observed in some other worker groups known to have exposures exceeding the action level of 0.1 μg/m³. For example, as discussed above, Newman *et al.* (2001, Document ID 1354) reported 22 sensitized workers, 13 of whom (59 percent) were diagnosed with CBD within the study period. Comparison of these results suggests that controlling respiratory exposure to beryllium may reduce risk of CBD among already-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 then develop CBD.

7. Conclusions

The published literature on beryllium sensitization and CBD discussed above shows that risk of both health effects can be significant in workplaces in compliance with OSHA's preceding PEL (*e.g.,* Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Newman *et al.,* 2001 (1354); Schuler *et al.,* 2005 (0919), 2012 (0473); Madl *et al.,* 2007 (1056)). For example, in the Tucson beryllia ceramics plant discussed above, Kreiss *et al.* (1996) reported that 8 (5.9 percent) of the 136 workers tested in 1992 were sensitized, 6 (4.4 percent) of whom were diagnosed with CBD. In addition, of 77 Tucson workers hired prior to 1992 who were tested in 1998, 8 (10.4 percent) were sensitized and 7 of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001, Document ID 1313). Full-shift area samples showed airborne beryllium levels below the preceding PEL (76 percent of area samples collected between 1983 and 1992 were at or below 0.1 μg/m³ and less than 1 percent exceeded 2 μg/m³; short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 μg/m³; personal lapel samples collected at the plant beginning in 1991 had a median of 0.2 μg/m³) (Kreiss *et al.,* 1996).

Results from the Elmore, OH beryllium metal, alloy, and oxide production plant and Cullman, AL machining facility also showed significant risk of sensitization and CBD among workers with exposures below the preceding TWA PEL. Schuler *et al.* (2012, Document ID 0473) found 17 cases of sensitization (8.6%) among Elmore, OH workers within the first three quartiles of LTW average exposure (198 workers with LTW average total mass exposures lower than 1.1 μg/m³) and 4 cases of CBD (2.2%) within the first three quartiles of LTW average exposure (183 workers with LTW average total mass exposures lower than 1.07 μg/m³; note that follow-up time of up to 6 years for all study participants was very short for development of CBD). At the Cullman, AL machining facility, Newman *et al.* (2001, Document ID 1354) reported 22 (9.4 percent) sensitized workers among 235 tested in 1995–1999, 13 of whom were diagnosed with CBD. Personal lapel samples collected between 1980 and 1999 indicate that median exposures were generally well below the preceding PEL (≤0.35 μg/m³ in all job titles except maintenance (median 3.1 μg/m³ during 1980–1995) and gas bearings (1.05 μg/m³ during 1980–1995)).

There is evidence in the literature that although risk will be reduced by compliance with the new TWA PEL, significant risk of sensitization and CBD will remain in workplaces in compliance with OSHA's new TWA PEL of 0.2 μg/m³ and could extend down to the new action level of 0.1 μg/m³, although there is less information and therefore greater uncertainty with respect to significant risk from airborne beryllium exposures at and below the action level. For example, Schuler *et al.* (2005, Document ID 0919) reported substantial prevalences of sensitization (6.5 percent) and CBD (3.9 percent) among 152 workers at the Reading, PA facility who had BeLPT screening in 2000. These results showed significant risk at this facility, even though airborne exposures were primarily below both the preceding and final TWA PELs due to the low percentage of beryllium in the metal alloys used (median general area samples ≤0.1 μg/m³, 97% ≤0.5 μg/m³); 93% of personal lapel samples were below the new TWA PEL of 0.2 μg/m³). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with exposures below the new action level of 0.1 μg/m³ (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³ (Schuler *et al.,* 2005). The Schuler *et al.* (2012, Document ID 0473) study of short-term workers in the Elmore, OH facility found 3 cases (4.6%) of sensitization among 66 workers with total mass LTW average exposures below 0.1 μg/m³; 3 of these workers had LTW average exposures of approximately 0.09 μg/m³.

Furthermore, cases of sensitization and CBD continued to arise in the Cullman, AL machining plant after control measures implemented beginning in 1995 brought median airborne exposures below 0.2 μg/m³ (personal lapel samples between 1996 and 1999 in machining jobs had a median of 0.16 μg/m³ and 0.08 μg/m³ in non-machining jobs) (Madl *et al.,* 2007, Document ID 1056, Table IV). At the time that Newman *et al.* (2001, Document ID 1354) 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 and had therefore benefitted to some extent from the exposure reductions. Four (6.7 percent) of these workers were found to be sensitized, two of whom were diagnosed with CBD and one with probable CBD (Newman *et al.,* 2001). A later study by Madl. *et al.* (2007, Document ID 1056) reported seven sensitized workers who had been hired between 1995 and 1999, of whom four had developed CBD as of 2005 (Table II; total number of workers hired between 1995 and 1999 not reported).

The experiences of several facilities in developing effective industrial hygiene programs have shown the importance of minimizing both airborne exposure and dermal contact to effectively reduce risk of sensitization and CBD. Exposure control programs that have used a combination of engineering controls and PPE to reduce workers' airborne exposure and dermal contact have substantially lowered risk of sensitization among newly hired workers.[15] Of 97 workers hired between 2000 and 2004 in the Tucson, AZ plant after the introduction of mandatory respirator use in production areas beginning in 1999 and mandatory use of latex gloves beginning in 2000, one case of sensitization was identified (1 percent) (Cummings *et al.,* 2007, Document ID 1369). In Elmore, OH, 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 percent (Bailey *et al.,* 2010, Document ID 0676). In the Reading, PA facility, only one (2.2 percent) of 45 workers hired after workers' exposures were reduced to below 0.1 μg/m³ and PPE to prevent dermal contact was instituted was sensitized (Thomas *et al.,* 2009, Document ID 0590). And, in the aluminum smelters discussed by Taiwo *et al.* (2008, Document ID 0621), where available exposure samples from four plants 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).

OSHA recognizes that 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 adequately 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 studies examining the post-2000, very low-exposed worker cohorts in Tucson, Reading, and Elmore (Cummings *et al.* 2007, Document ID 1369; Thomas *et al.* 2009 (0590); Bailey *et al.* 2010 (0676)). 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) (Madl *et al.,* 2007, Document ID 1056, Table III). 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, Document ID 1070), and workers employed only in administration at a beryllium ceramics facility (Kreiss *et al.,* 1996, Document ID 1477). Therefore, there is some evidence that cases of CBD can occur in work environments where beryllium exposures are quite low.

8. Community-Acquired CBD

In the NPRM, OSHA discussed an additional source of information on low-level beryllium exposure and CBD: Studies of community-acquired chronic beryllium disease (CA–CBD) in residential areas surrounding beryllium

[15] As discussed in Section V, Health Effects, beryllium sensitization can occur from dermal contact with beryllium. Studies conducted in the 1950s by Curtis *et al.* showed that soluble beryllium particles could cause beryllium hypersensitivity (Curtis, 1951, Document ID 1273; NAS, 2008, Document ID 1355). 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, Document ID 1483). 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.

production facilities. The literature on CA–CBD, including the Eisenbud (1949, Document ID 1284), Leiben and Metzner (1959, Document ID 1343), and Maier *et al.* (2008, Document ID 0598) studies, documents cases of CBD among individuals exposed to airborne beryllium at concentrations below the new PEL. OSHA included a review of these studies in the NPRM as a secondary source of information on risk of CBD from low-level beryllium exposure. However, the available studies of CA–CBD have important limitations. These case studies do not provide information on how frequently individuals exposed to very low airborne levels develop CBD. In addition, the reconstructed exposure estimates for CA–CBD cases are less reliable than the exposure estimates for working populations reviewed in the previous sections. The literature on CA–CBD therefore was not used by OSHA as a basis for its quantitative risk assessment for CBD, and the Agency did not receive any comments or testimony on this literature. Nevertheless, these case reports and the broader CA–CBD literature indicate that individuals exposed to airborne beryllium below the final TWA PEL can develop CBD (*e.g.,* Leiben and Metzner, 1959; Maier *et al.,* 2008).

B. OSHA's Prevalence Analysis for Sensitization and CBD

OSHA evaluated exposure and health outcome data on a population of workers employed at the Cullman machining facility as one part of the Agency's Preliminary Risk Analysis presented in the NPRM. A summary of OSHA's preliminary analyses of these data, a discussion of comments received on the analyses and OSHA's responses to these comments, as well as a summary OSHA's final quantitative analyses, are presented in the remainder of this section. A more detailed discussion of the data, background information on the facility, and OSHA's analyses appears in the background document OSHA has placed in the record (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016).

NJH researchers, with consent and information provided by the Cullman 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 about work operations and conditions at the plant, developed exposure estimates for individual workers in the dataset, and helped to conduct quantitative analyses of the data to inform OSHA's risk assessment (Document ID tbd).

1. Worker Exposure Reconstruction

The work history database contains job history records for 348 workers. ERG calculated cumulative and average exposure estimates for each worker in the database. Cumulative exposure was calculated as,

$$\sum_i e_i t_i ,$$

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.[16] 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. However, individuals' beryllium exposure levels and sensitization status are not continuously monitored, so 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 attempted to represent workers' highest exposures by constructing 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 presented below.

2. Prevalence of Sensitization and CBD

In the database provided to OSHA, 7 workers were reported as sensitized only (that is, sensitized with no known development of CBD). 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–3, VI–4, and VI–5 below present the prevalence of sensitization and CBD cases across several categories of LTW average, cumulative, and HEJ exposure. Exposure values were grouped by quartile. For this analysis, OSHA excluded 8 workers with no job title listed in the data set (because their exposures could not be estimated); 7 workers whose date of hire was before 1969 (because this indicates they worked in the company's previous plant, for which no exposure measurements were available); and 14 workers who had zero exposure time in the data set, perhaps indicating that they had been hired but had not come to work at Cullman. After these exclusions, a total of 319 workers remained. None of the excluded workers were identified as having beryllium sensitization or CBD.

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–3—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJH DATA SET

LTW 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

[16] Each worker's exposure was calculated at each time that BeLPT testing was conducted.

TABLE VI–3—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJH DATA SET—Continued

LTW average exposure ($\mu g/m^3$)	Group size	Sensitized only	CBD	Total sensitized	Total (%)	CBD (%)
Total	319	7	19	26	8.2	6.0

TABLE VI–4—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE IN NJH DATA SET

Cumulative exposure ($\mu g/m^3$-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–5—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE IN NJH DATA SET

HEJ exposure ($\mu g/m^3$)	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–3 shows increasing prevalence of total sensitization and CBD with increasing LTW average exposure. The lowest prevalence of sensitization and CBD was observed among workers with average exposure levels less than or equal to 0.08 $\mu g/m^3$, 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 $\mu g/m^3$. This worker was diagnosed with CBD in 1997.

The second quartile of LTW average exposure (0.081–0.18 $\mu g/m^3$) shows a marked rise in overall prevalence of beryllium-related health effects, with 6 workers sensitized (8.2 percent), of whom 4 (5.5 percent) were diagnosed with CBD. Among 6 sensitized workers in the third quartile (0.19–0.51 $\mu g/m^3$), 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–4, the lowest prevalences of CBD and sensitization are in the first two quartiles of cumulative exposure (0.0–0.147 $\mu g/m^3$-yrs, 0.148–1.467 $\mu g/m^3$-yrs). The upper bound on this cumulative exposure range, 1.467 $\mu g/m^3$-yrs, is the cumulative exposure that a worker would have if exposed to beryllium at a level of 0.03 $\mu g/m^3$ for a working lifetime of 45 years; 0.15 $\mu g/m^3$ for ten years; or 0.3 $\mu g/m^3$ for five years. These exposure levels are in the range of those OSHA was interested in evaluating for purposes of this rulemaking.

A sharp increase in prevalence of sensitization and CBD occurs in the third quartile (1.468–7.008 $\mu g/m^3$-yrs), with roughly similar levels of both in the highest group (7.009–61.86 $\mu g/m^3$-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 $\mu g/m^3$, for 10 years to levels between 0.15 and 0.7 $\mu g/m^3$, or for 5 years to levels between 0.3 and 1.4 $\mu g/m^3$.

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. In Table VI–5, the lowest prevalence is observed in the first quartile (0.0–0.086 $\mu g/m^3$), 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 $\mu g/m^3$) 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 other highly-exposed workers from early periods may have developed CBD and left the plant before sensitization testing began in 1995 (*i.e.,* the healthy worker survivor effect).

The results of this prevalence analysis support OSHA's conclusion that maintaining exposure levels below the new TWA PEL will help to reduce risk of beryllium sensitization and CBD, and that maintaining exposure levels below the action level can further reduce risk of beryllium sensitization and CBD. However, risk of both sensitization and CBD remains even among the workers with the lowest airborne exposures in this data set.

C. OSHA's Statistical Modeling for Sensitization and CBD

1. OSHA's Preliminary Analysis of the NJH Data Set

In the course of OSHA's development of the proposed rule, OSHA's contractor (ERG) also developed a statistical analysis using the NJH data set and a discrete time proportional hazards analysis (DTPHA). This preliminary analysis predicted significant risks of both sensitization (96–394 cases per 1,000, or 9.6–39.4 percent) and CBD (44–313 cases per 1,000, or 4.4–31.3 percent) at the preceding TWA PEL of 2 μg/m^3 for an exposure duration of 45 years (90 μg/m^3-yr). The predicted risks of 8.2–39.9 cases of sensitization per 1,000 (0.8–3.9 percent) and 3.6 to 30.0 cases of CBD per 1,000 (0.4–3 percent) were approximately 10-fold less, but still significant, for a 45-year exposure at the new TWA PEL of 0.2 μg/m^3 (9 μg/m^3-yr).

In interpreting the risk estimates, OSHA took into consideration limitations in the preliminary statistical analysis, primarily study size-related constraints. Consequently, as discussed in the NPRM, OSHA did not rely on the preliminary statistical analysis for its significance of risk determination or to develop its benefits analysis. The Agency relied primarily on the previously-presented analysis of the epidemiological literature and the prevalence analysis of the Cullman data for its preliminary significance of risk determination, and on the prevalence analysis for its preliminary estimate of benefits. Although OSHA did not rely on the results of the preliminary statistical analysis for its findings, the Agency presented the DTPHA in order to inform the public of its results, explain its limitations, and solicit public comment on the Agency's approach.

Dr. Kenny Crump and Ms. Deborah Proctor submitted comments on OSHA's preliminary risk assessment (Document ID 1660). Crump and Proctor agreed with OSHA's review of the epidemiological literature and the prevalence analysis presented previously in this section. They stated, ''we agree with OSHA's conclusion that there is a significant risk (>1/1000 risk of CBD) at the [then] current PEL, and that risk is reduced at the [then] proposed PEL (0.2 μg/m^3) in combination with stringent measures (ancillary provisions) to reduce worker's exposures. This finding is evident based on the available literature, as described by OSHA, and the prevalence data presented for the Cullman facility'' (Document ID 1660, p. 2). They also presented a detailed evaluation of the statistical analysis of the Cullman data presented in the NPRM, including a critique of OSHA's modeling approach and interpretation and suggestions for alternate analyses. However, they emphasized that the new beryllium rule should not be altered or delayed due to their comments regarding the statistical model (Document ID 1660, p. 2).

After considering comments on this preliminary model, OSHA instructed its contractor to change the statistical analysis to address technical concerns and to incorporate suggestions from Crump and Proctor, as well as NIOSH (Document ID 1660; 1725). OSHA reviews and addresses these comments on the preliminary statistical analysis and provides a presentation of the final statistical analysis in the background document (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016). The results of the final statistical analysis are summarized here.

2. OSHA's Final Statistical Analysis of the NJH Data Set

As noted above, Dr. Roslyn Stone of University of Pittsburgh School of Public Health reanalyzed for OSHA the Cullman data set in order to address concerns raised by Crump and Proctor (Document ID 1660). The reanalysis uses a Cox proportional hazards model instead of the DTPHA. The Cox model, a regression method for survival data, provides an estimate of the hazard ratio (HR) and its confidence interval.[17] Like the DTPHA, the Cox model can accommodate time-dependent data; however, the Cox model has an advantage over the DTPHA for OSHA's purpose of estimating risk to beryllium-exposed workers in that it does not estimate different ''baseline'' rates of sensitization and CBD for different years. Time-specific risk sets were constructed to accommodate the time-dependent exposures. P-values were based on likelihood ratio tests (LRTs), with p-values <0.05 considered to be statistically significant.

[17] The hazard ratio is an estimate of the ratio of the hazard rate in the exposed group to that of the control group.

As in the preliminary statistical analysis, Dr. Stone used fractional polynomials [18] to check for possible nonlinearities in the exposure-response models, and checked the effects of age and smoking habits using data on birth year and smoking (current, former, never) provided in the Cullman data set. Data on workers' estimated exposures and health outcomes through 2005 were included in the reanalysis.[19] The 1995 risk set (*e.g.,* analysis of cases of sensitization and CBD identified in 1995) was excluded from all models in the reanalysis so as not to analyze long-standing (prevalent) cases of sensitization and CBD together with newly arising (incident) cases of sensitization and CBD. Finally, Dr. Stone used the testing protocols provided in the literature on the Cullman study population to determine the years in which each employee was scheduled to be tested, and excluded employees from the analysis for years in which they were not scheduled to be tested (Newman *et al.,* 2001, Document ID 1354).

In the reanalysis of the NJH data set, the HR for sensitization increased significantly with increasing LTW average exposure (HR = 2.92, 95% CI = 1.51–5.66, p = 0.001; note that HRs are rounded to the second decimal place). Cumulative exposure was also a statistically significant predictor for beryllium sensitization, although it was not as strongly related to sensitization as LTW average exposure (HR = 1.04, 95% CI 1.00–1.07, p = 0.03). The HR for CBD increased significantly with increasing cumulative exposure (HR = 1.04, 95% CI = 1.01–1.08, p = 0.02). The HR for CBD increased somewhat with increasing LTW average exposure, but this increase was not significant at the 0.05 level (HR = 2.25, 95% CI = 0.94–5.35, p = 0.07).

None of the analyses Dr. Stone performed to check for nonlinearities in exposure-response or the effects of smoking or age substantially impacted the results of the analyses for beryllium sensitization or CBD. The sensitivity analysis recommended by Crump and Proctor, excluding workers hired prior to 1980 (see Document ID 1660, p. 11), did not substantially impact the results

[18] Fractional polynomials are linear combinations of polynomials that provide flexible shapes of exposure response.

[19] Data from 2003 to 2005 were excluded in some previous analyses due to uncertainty in some employees' work histories. OSHA accepted the.Crump and Proctor recommendation that these data should be included, so as to treat uncertain exposure estimates consistently in the reanalysis (data prior to the start of sampling in 1980 were included in the previous analysis and most models in the reanalysis).

of the analyses for beryllium sensitization, but did affect the results for CBD. The HR for CBD using cumulative exposure dropped to slightly below 1 and was not statistically significant following exclusion of workers hired before 1980 (HR 0.96, 95% CI 0.81–1.13, p = 0.6). OSHA discusses this result further in the background document, concluding that the reduced follow-up time for CBD in the subcohort hired in 1980 or later, in combination with genetic risk factors that may attenuate both exposure-response and disease latency in some people, may explain the lack of significant exposure-response observed in this sensitivity analysis.

Because LTW average exposure was most strongly associated with beryllium sensitization, OSHA used the final model for LTW average exposure to estimate risk of sensitization at the preceding TWA PEL, the final TWA PEL, and several alternate TWA PELs it considered. Similarly, because cumulative exposure was most strongly associated with CBD, OSHA used the final model for cumulative exposure to estimate risk of CBD at the preceding, final, and alternate TWA PELs. In calculating these risks, OSHA used a small, fixed estimate of ''baseline'' risk (*i.e.,* risk of sensitization or CBD among persons with no known exposure to beryllium), as suggested by Crump and Proctor (Document ID 1660) and NIOSH (Document ID 1725). Table VI–6 presents the risk estimates for sensitization and the corresponding 95 percent confidence intervals using two different fixed ''background'' rates of sensitization, 1 percent and 0.5 percent. Table VI–7 presents the risk estimates for sensitization and the corresponding 95 percent confidence intervals using a fixed ''background'' rate of CBD of 0.5 percent. 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). Since the Cox proportional hazards model does not estimate a baseline risk, this 95 percent interval fully represents statistical uncertainty in the risk estimates.

TABLE VI–6—PREDICTED CASES OF SENSITIZATION PER 1,000 WORKERS EXPOSED AT THE PRECEDING AND ALTERNATE PELS BASED ON COX PROPORTIONAL HAZARDS MODEL, LTW AVERAGE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT.

[1 Percent and 0.5 percent baselines]

Exposure level (μg/m³)	Estimated cases/1000, .5% baseline	95% CI	Estimated cases/1000, 1% baseline	95% CI
2.0	42.75	11.4–160.34	85.49	22.79–320.69
1.0	14.62	7.55–28.31	29.24	15.10–56.63
0.5	8.55	6.14–11.90	17.10	12.29–23.80
0.2	6.20	5.43–7.07	12.39	10.86–14.15
0.1	5.57	5.21–5.95	11.13	10.42–11.89

TABLE VI–7—PREDICTED CASES OF CBD PER 1,000 WORKERS EXPOSED AT THE PRECEDING AND ALTERNATIVE PELS BASED ON COX PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[0.5 percent baseline]

Exposure level (μg/m³)	Exposure Duration							
	5 years		10 years		20 years		45 years	
	Cumulative (μg/m³-yrs)	Estimated cases/1000 95% CI	μg/m³-yrs	Estimated cases/1000 95% CI	μg/m³-yrs	Estimated cases/1000 95% CI	μg/m³-yrs	Estimated cases/1000 95% CI
2.0	10.0	7.55 5.34–10.67	20.0	11.39 5.70–22.78	40.0	25.97 6.5–103.76	90.0	203.60 9.02–4595.67
1.0	5.0	6.14 5.17–7.30	10.0	7.55 5.34–10.67	20.0	11.39 5.70–22.78	45.0	31.91 6.72–151.59
0.5	2.5	5.54 5.08–6.04	5.0	6.14 5.17–7.30	10.0	7.55 5.34–10.67	22.5	12.63 5.79–27.53
0.2	1.0	5.21 5.03–5.39	2.0	5.43 5.07–5.82	4.0	5.9 5.13–6.77	9.0	7.24 5.30–9.89
0.1	0.5	5.1 5.02–5.19	1.0	5.21 5.03–5.39	2.0	5.43 5.07–5.82	4.5	6.02 5.15–7.03

The Cox proportional hazards model, used with the fixed ''baseline'' rates of 0.5 percent and 1 percent, predicted risks of sensitization totaling 43 and 86 cases per 1,000 workers, respectively, or 4.3 and 8.6 percent, at the preceding PEL of 2 μg/m³. The predicted risk of CBD is 203 cases per 1,000 workers, or 20.3 percent, at the preceding PEL of 2 μg/m³, assuming 45 years of exposure (cumulative exposure of 90 μg/m³-yr).[20] The predicted risks of sensitization at the new PEL of 0.2 μg/m³ are substantially lower, at 6 and 12 cases per 1,000 for the baselines of 0.5% and 1.0%, respectively. The predicted risk of CBD is also much lower at the new TWA PEL of 0.2 μg/m³ (9 μg/m³-year), at 7 cases per 1,000 assuming 45 years of exposure.

Due to limitations in the Cox analysis, including the small 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, limited follow-

[20] The predictions for each model represent the estimated probability of being sensitized or having CBD at one point in time, rather than the cumulative risk over a lifetime of exposure, which would be higher. Lifetime risks are presented in the FEA, Benefits Analysis.

up time on many workers, and sensitivity of the results to the ''baseline'' values assumed for sensitization and CBD, OSHA must interpret the model-based risk estimates presented in Tables VI–6 and VI–7 with caution. Uncertainties in these risk estimates are discussed in the background document (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016). However, these uncertainties do not alter OSHA's conclusions with regard to the significance of risk at the preceding PEL and alternate PELs that OSHA considered, which are based primarily on the Agency's review of the literature and the prevalence analysis presented earlier in this section (also see Section VII, Significance of Risk).

D. Lung Cancer

As discussed more fully in the Health Effects section of the preamble, OSHA has determined beryllium to be a carcinogen based on an extensive review of the scientific literature regarding beryllium and cancer (see Section V.E). This review included an evaluation of the human epidemiological, animal cancer, and mechanistic studies described in the Health Effects section of this preamble. OSHA's conclusion is supported by the findings of public health organizations such as the International Agency for Research on Cancer (IARC), which has determined beryllium and its compounds to be carcinogenic to humans (Group 1 category) (IARC 2012, Document ID 0650); the National Toxicology Program (NTP), which classifies beryllium and its compounds as known carcinogens (NTP 2014, Document ID 0389); and the Environmental Protection Agency (EPA), which considers beryllium to be a probable human carcinogen (EPA 1998, Document ID 0661).

The Sanderson *et al.* study previously discussed in Health Effects evaluated the association between beryllium exposure and lung cancer mortality based on data from a beryllium processing plant in Reading, PA (Sanderson *et al.,* 2001, Document ID 1419). Specifically, this case-control study evaluated lung cancer mortality in a cohort of 3,569 male 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 identified lung cancer cases and 710 controls.

A conditional logistic regression analysis showed an increased risk of death from lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years (Sanderson *et al.,* 2001, Document ID 1419). This lag was incorporated in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer. The authors noted that there was considerable uncertainty in the estimation of exposure levels for the 1940s and 1950s and in the shape of the dose-response curve for lung cancer. In a 2008 study, Schubauer-Berigan *et al.* reanalyzed the data, adjusting for potential confounders of hire age and birth year (Schubauer-Berigan *et al.,* 2008, Document ID 1350). The study reported a significant increasing trend ($p < 0.05$) in lung cancer mortality when average (log transformed) exposure was lagged by 10 years. However, it did not find a significant trend when cumulative (log transformed) exposure was lagged by 0, 10, or 20 years (Schubauer-Berigan *et al.,* 2008, Table 3).

In formulating the final rule, OSHA was particularly interested in lung cancer risk estimates from a 45-year (*i.e.,* working lifetime) exposure to beryllium levels between 0.1 μg/m^3 and 2 μg/m^3. The majority of case and control workers in the Sanderson *et al.* (2001, Document ID 1419) case-control analysis were first hired during the 1940s and 50s when exposures were extremely high (estimated daily weighted averages (DWAs) >20 μg/m^3 for most jobs) in comparison to the exposure range of interest to OSHA (Sanderson *et al.* 2001, Document ID 1419, Table II). 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 have needed to extrapolate from very high to 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 high exposures would have created substantial uncertainty in a risk assessment based on this particular study population.

In addition, the relatively high exposures of the least-exposed workers in the study population might have created 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 this study population, workers in the lowest quartile were exposed well above the preceding OSHA TWA PEL (average exposure <11.2 μg/m^3) and may have had a significant lung cancer risk. This issue would have introduced further uncertainty into the lung cancer risks.

In 2011, Schubauer-Berigan *et al.* published a quantitative risk assessment that addressed several of OSHA's concerns regarding the Sanderson *et al.* analysis. This new 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, Document ID 1265). This study population was exposed, on average, to lower levels of beryllium and had fewer short-term workers than the previous cohort analyzed by Sanderson *et al.* (2001, Document ID 1250) and Schubauer-Berigan *et al.* (2008, Document ID 1350). Schubauer-Berigan *et al.* (2011) followed the study population through 2005 where possible, increasing the length of follow-up time overall by an additional 17 years of observation compared to the previous analyses. For these reasons, OSHA considered the Schubauer-Berigan (2011) analysis more appropriate than Sanderson *et al.* (2001) and Schubauer-Berigan (2008) for its risk assessment. OSHA therefore based its preliminary QRA for lung cancer on the results from Schubauer-Berigan *et al.* (2011).

OSHA received several comments about its choice of Schubauer-Berigan *et al.* (2011) as the basis for its preliminary QRA for lung cancer. NIOSH commented that OSHA's choice of Schubauer-Berigan *et al.* for its preliminary analysis was appropriate because ''[n]o other study is available that presents quantitative dose-response information for lung cancer, across a range of beryllium processing facilities'' (Document ID 1725, p. 7). In supporting OSHA's use of this study, NIOSH emphasized in particular the study's inclusion of relatively low-exposed workers from two facilities that began operations in the 1950s (after employer awareness of acute beryllium disease (ABD) and CBD led to efforts to minimize worker exposures to beryllium), as well as the presence of both soluble and poorly soluble forms of beryllium in the facilities studied (Document ID 1725, p. 7).

According to Dr. Paolo Boffetta, who submitted comments on this study, Schubauer-Berigan *et al.* (2011) is not the most relevant study available to OSHA for its lung cancer risk analysis. Dr. Boffetta argued that the most informative study of lung cancer risk in the beryllium industry after 1965 is one that he developed in 2015 (Boffetta *et al.,* 2015), which he described as a pooled analysis of 11 plants and 4 distribution centers (Document ID 1659, p. 1). However, Dr. Boffetta did not provide OSHA with the manuscript of his study, which he stated was under review for publication. Instead, he reported some results of the study and directed OSHA to an abstract of the study in the 2015 Annual Conference of the Society for Epidemiologic Research (Document ID 1659; Document ID 1661, Attachment 1).

Because only an abstract of Boffetta *et al.'*s 2015 study was available to OSHA (*see* Document ID 1661, Attachment 1), OSHA could not properly evaluate it or use it as the basis of a quantitative risk assessment for lung cancer. Nevertheless, OSHA has addressed comments Dr. Boffetta submitted based on his analyses in the relevant sections of the final QRA for lung cancer below. Because it was not possible to use this study for its lung cancer QRA and OSHA is not aware of other studies appropriate for use in its lung cancer QRA (nor did commenters besides Dr. Boffetta suggest that OSHA use any additional studies for this purpose), OSHA finds that the body of available evidence has not changed since the Agency conducted its preliminary QRA based on Schubauer-Berigan *et al.* (2011, Document ID 1265). Therefore, OSHA concludes that Schubauer-Berigan *et al.* (2011) is the most appropriate study for its final lung cancer QRA, presented below.

1. QRA for Lung Cancer Based on Schubauer-Berigan *et al.* (2011)

The cohort studied by Schubauer-Berigan *et al.* (2011, Document ID 1265) included 5,436 male workers who had worked for at least 2 days at the Reading facility or at the beryllium processing plants in 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 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.* (2001, Document ID 1250), Chen *et al.* (2001, Document ID 1593), and Couch *et al.* (2010, Document ID 0880).

Workers' cumulative exposures (μg/m^3-days) were estimated by summing daily average exposures (assuming five workdays per week) (Schubauer-Berigan *et al.,* 2011). To estimate mean exposure (μg/m^3), cumulative exposure was divided by exposure time (in days), accounting where appropriate for lag time. Maximum exposure (μg/m^3) was calculated as the highest annual DWA on record for a worker from the first exposure until the study cutoff date of December 31, 2005, again 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–8 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 (Schubauer-Berigan *et al.,* 2011). Whereas the median worker from Hazleton had a mean exposure across his tenure of less than 1.5 μg/m^3 and the median worker from Elmore had a mean exposure of less than 1 μg/m^3, the median worker from Reading had a mean exposure of 25 μg/m^3. 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–8—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/m^3) among cases	*10-year lag*	15.15	25	1.443	0.972
Median value for cumulative exposure	*No lag*	2843	2895	3968	1654
(μg/m^3-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/m^3) 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, Document ID 1265, Table 1.

Schubauer-Berigan *et al.* analyzed the data set using a variety of exposure-response modeling approaches, including categorical analyses, continuous-variable piecewise log-linear models, and power models (2011, Document ID 1265). All models adjusted for birth cohort and plant. Because 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/m^3 for mean and maximum exposure, 0.05 μg/m^3-days for cumulative exposure). The authors used restricted cubic spline models to assess the shape of the exposure-response curves 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 (those employed in 1968), smoking could not be controlled for directly in the models. Schubauer-Berigan *et al.* reported that within the subset with smoking information, there was little difference in smoking by cumulative or maximum exposure category, 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 (ten percent of cases) and workers believed to have asbestos exposure (one-third of cases). These models were intended to mitigate the potential impact of smoking and asbestos as confounders.[21]

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, Document ID 1265). They selected the best-fitting categorical, power, and monotonic piecewise log-linear (PWL) models with a 10-year lag to generate HRs for male workers with a mean exposure of 0.5 μg/m³ (the current NIOSH Recommended Exposure Limit for beryllium).[22] In addition, they estimated the daily weighted average exposure that would be associated with an excess lung cancer mortality risk of one in one thousand (.005 μg/m³ to .07 μg/m³ depending on model choice). To estimate excess risk of cancer, they multiplied these hazard ratios by the 2004 to 2006 background lifetime lung cancer rate among U.S. males who had survived, cancer-free, to age 30. At OSHA's request, Dr. Schubauer-Berigan also estimated excess lung cancer risks for workers with mean exposures at the preceding PEL of 2 μg/m³ and at each of the other alternate PELs that were under consideration: 1 μg/m³, 0.2 μg/m³, and 0.1 μg/m³ (Document ID 0521). The resulting risk estimates are presented in Table VI–9 below.

TABLE VI–9—EXCESS LUNG CANCER RISK PER 1,000 [95% CONFIDENCE INTERVAL] FOR MALE WORKERS AT ALTERNATE PELS

[Based on Schubauer-Berigan *et al.,* 2011]

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]	140 [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]

SOURCE: Schubauer-Berigan, Document ID 0521, pp. 6–10.

Schubauer-Berigan *et al.* (2011, Document ID 1265) discuss several strengths, weaknesses, and uncertainties of their analysis. Strengths include a long (>30 years) follow-up time and the extensive exposure and work history data available for the development of exposure estimates for workers in the cohort. Weaknesses and uncertainties of the study include the limited information available on workers' smoking habits: As mentioned above, smoking information was available only for workers employed in 1968, about 25 percent of the cohort. Another potential weakness was that 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. This could cause the relationship between exposure level and lung cancer risk to appear weaker than it would in the absence of this source of error in the estimation of workers' beryllium exposures.

Schubauer-Berigan *et al.* (2011) did not discuss the reasons for basing risk estimates on mean exposure rather than cumulative exposure, which is more commonly used for lung cancer risk analysis. OSHA believes the decision may involve the non-monotonic relationship the authors 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 have been at high risk of lung cancer due to the tendency of beryllium to persist in the lung for long periods. This could lead to the appearance of a non-monotonic 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 authors' use of the mean exposure metric to be appropriate and scientifically defensible for this particular dataset.

Dr. Boffetta's comment, mentioned above, addressed the relevance of the Schubauer-Berigan *et al.* (2011) cohort to determining whether workers currently employed in the beryllium industry experience an increased lung cancer hazard (Document ID 1659, pp. 1–2). His comment also analyzed the methods and findings in Schubauer-Berigan *et al.* (2011) (Document ID 1659, pp. 2–3). Notably, he stated that his own study, Boffetta *et al.* (2015) provides better information for risk assessment than does Schubauer-Berigan *et al.* (2011) (Document ID 1659, pp. 1–2). As discussed above, OSHA cannot rely on a study for its QRA (Boffetta *et al.,* 2015) that has not been submitted to the record and is not otherwise available to OSHA. However, in the discussion below, OSHA addresses Dr. Boffetta's study to the extent it can given the

[21] The authors appeared to reason that 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, 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.

[22] Here, ''monotonic PWL model'' means a model producing a monotonic exposure-response curve in the 0 to 2 μg/m³ range.

limited information available to the Agency. OSHA also responds to Dr. Boffetta's comments on Schubauer-Berigan *et al.* (2011, Document ID 1265) and Boffetta *et al.* (2014, Document ID 0403), which Dr. Boffetta asserts provides evidence that poorly soluble beryllium compounds are not associated with lung cancer (Document ID 1659, p. 1).

Boffetta argued that the most informative study in the modern (post-1965) beryllium industry is Boffetta *et al.* (2015, Document ID 1661, Attachment 1). According to Boffetta's comment, the study found an SMR of 1.02 (95% CI 0.94–1.10, based on 672 deaths) for the overall cohort and an SMR for lung cancer among workers exposed only to insoluble beryllium of 0.93 (95% CI 0.79–1.08, based on 157 deaths). Boffetta noted that his study was based on 23 percent more overall deaths than the Schubauer-Berigan *et al.* cohort (Document ID 1659, pp. 1–2). As stated earlier, this study is unpublished and was not provided to OSHA. The abstract provided by Materion (Document ID 1661, Attachment 1) included very little information beyond the SMRs reported; for example, it provided no information about the manufacturing plants and distribution centers included, workers' beryllium exposure levels, how the cohorts were defined, or how the authors determined the solubility of the beryllium to which workers were exposed. OSHA is therefore unable to evaluate the quality or conclusions of this study.

Dr. Boffetta also commented that there is a lack of evidence of increased lung cancer risk among workers exposed only to poorly soluble beryllium compounds (Document ID 1659, p. 1). To support this statement, he cited a study he published in 2014 of workers at four ''insoluble facilities'' (Boffetta *et al.,* 2014) and Schubauer-Berigan *et al.*'s 2011 study, arguing that increased cancer risk in beryllium-exposed workers in those two studies was only observed in workers employed in Reading and Lorain prior to 1955. Workers employed at the other plants and workers who were first employed in Reading and Lorain after 1955, according to Dr. Boffetta, were exposed primarily to poorly soluble forms of beryllium and did not experience an increased risk of lung cancer. Dr. Boffetta further stated that his unpublished paper (Boffetta *et al.,* 2015) shows a similar result (Document ID 1659, p. 1).

OSHA carefully considered Dr. Boffetta's argument regarding the status of poorly soluble beryllium compounds, and did not find persuasive evidence showing that the solubility of the beryllium to which the workers in the studies he cited were exposed accounts for the lack of statistically significantly elevated risk in the Boffetta *et al.* (2014) cohort or the Schubauer-Berigan *et al.* (2011) subcohort. While it is true that the SMR for lung cancer was not statistically significantly elevated in the Schubauer-Berigan *et al.* (2011) study when workers hired before 1955 in the Reading and Lorain plants were excluded from the study population, or in the study of four facilities published by Boffetta *et al.* in 2014, there are various possible reasons for these results that Dr. Boffetta did not consider in his comment. As discussed below, OSHA finds that the type of beryllium compounds to which these workers were exposed is not likely to explain Dr. Boffetta's observations.

As discussed in Section V, Health Effects and in comments submitted by NIOSH, animal toxicology evidence shows that poorly soluble beryllium compounds can cause cancer. IARC determined that poorly soluble forms of beryllium are carcinogenic to humans in its 2012 review of Group I carcinogens (see section V.E.5 of this preamble; Document ID 1725, p. 9; IARC, 2012, Document ID 0650). NIOSH noted that poorly soluble forms of beryllium remain in the lung for longer time periods than soluble forms, and can therefore create prolonged exposure of lung tissue to beryllium (Document ID 1725, p. 9). This prolonged exposure may lead to the sustained tissue inflammation that causes many forms of cancer and is believed to be one pathway for carcinogenesis due to beryllium exposure (see Section V, Health Effects).

The comments from NIOSH also demonstrate that the available information cannot distinguish between the effects of soluble and poorly soluble beryllium. NIOSH submitted information on the solubility of beryllium in the Schubauer-Berigan *et al.* (2011) cohort, stating that operations typically involving both soluble and poorly soluble beryllium were performed at all three of the beryllium plants included in the study (Document ID 1725, p. 9; Ward *et al.,* 1992, Document ID 1378). Based on evaluations of the JEMs and work histories of employees in the cohort (which were not published in the 2011 Schubauer-Berigan *et al.* paper), NIOSH stated that ''the vast majority of beryllium work-time at all three of these facilities was due to either insoluble or mixed chemical forms. In fact, insoluble beryllium was the largest single contributor to work-time (for beryllium exposure of known solubility class) at the three facilities across most time periods'' (Document ID 1725, p. 9). NIOSH also provided figures showing the contribution of insoluble beryllium to exposure over time in the Schubauer-Berigan *et al.* (2011) study, as well as the relatively small proportion of work years during which workers in the study were exposed exclusively to either soluble or poorly soluble forms (Document ID 1725, pp. 10–11).

Boffetta *et al.* (2014, Document ID 0403) examined a population of workers allegedly exposed exclusively to poorly soluble beryllium compounds, in which overall SMR for lung cancer was not statistically significantly elevated (SMR 96.0, 95% CI 80.0–114.3). Boffetta *et al.* concluded, ''[a]lthough a small risk for lung cancer is compatible with our results, we can confidently exclude an excess greater than 20%'' in the study population (Boffetta *et al.,* 2014, p. 592). Limitations of the study include a lack of information on many workers' job titles, a lack of any beryllium exposure measurements, and the very short-term employment of most cohort members at the study facilities (less than 5 years for 72 percent of the workers) (Boffetta *et al.,* 2014).

OSHA reviewed this study, and finds that it does not contradict the findings of the Schubauer-Berigan *et al.* (2011) lung cancer risk analysis for several reasons. First, as shown in Table VI–9 above, none of the predictions of excess risk in the risk analysis exceed 20 percent (200 per 1,000 workers); most are well below this level, and thus are well within the range that Boffetta *et al.* (2014) state they cannot confidently exclude. Thus, the statement by Boffetta *et al.* that the risk of excess lung cancer is no higher than 20 percent is actually consistent with the risk findings from Schubauer-Berigan *et al.* (2011) presented above. Second, the fact that most workers in the cohort were employed for less than five years suggests that most workers' cumulative exposures to beryllium were likely to be quite low, which would explain the non-elevated SMR for lung cancer in the study population regardless of the type of beryllium to which workers were exposed. The SMR for workers employed in the study facilities for at least 20 years was elevated (112.7, CI 66.8–178.1) (Boffetta *et al.,* 2014, Document ID 0403, Table 3),[23] supporting OSHA's observation that the lack of elevated SMR in the cohort overall may be due to short-term

[23] This SMR was not statistically significantly elevated, probably due to the small size of this subcohort (153 total deaths, 18 lung cancer deaths).

employment and low cumulative exposures.

Finally, the approach of Boffetta *et al.* (2014), which relies on SMR analyses, does not account for the healthy worker effect. SMRs are calculated by comparing disease levels in the study population to disease levels in the general population, using regional or national reported disease rates. However, because working populations tend to have lower disease rates than the overall population, SMRs can underestimate excess risk of disease in those populations. The SMR in Boffetta *et al.* (2014) for overall mortality in the study population was statistically significantly reduced (94.7, 95 percent CI 89.9–99.7), suggesting a possible healthy worker effect. The SMR for overall mortality was even further reduced in the category of workers with at least 20 years of employment (87.7, 95 percent CI 74.3–102.7), in which an elevated SMR for lung cancer was observed. NIOSH commented that ''[i]n a modern industrial population, the expected SMR for lung cancer would be approximately 0.93 [Park *et al.* (1991)]'' (Document ID 1725, p. 8). This is lower than the SMR for lung cancer (96) observed in Boffetta *et al.* (2014) and much lower than the SMR for lung cancer in the category of workers employed for at least 20 years (112.7), which is the group most likely to have had sufficient exposure and latency to show excess lung cancer (Boffetta *et al.,* 2014, Document ID 0403, Tables 2 and 3). Thus, it appears that the healthy worker effect is another factor (in addition to low cumulative exposures) that may account for the findings of Boffetta *et al.'*s 2014 study.

Taken together, OSHA finds that the animal toxicology evidence on the carcinogenicity of poorly soluble beryllium forms, the long residence of poorly soluble beryllium in the lung, the likelihood that most workers in Schubauer-Berigan *et al.* (2011) were exposed to a mixture of soluble and poorly soluble beryllium forms, and the points raised above regarding Boffetta *et al.* (2014) rebut Boffetta's claim that low solubility of beryllium compounds is the most likely explanation for the lack of statistically significantly elevated SMR results.

Dr. Boffetta's comment also raised technical questions regarding the Schubauer-Berigan *et al.* (2011, Document ID 1265) risk analysis. He noted that risk estimates at low exposures are dependent on choice of model in their analysis; the authors' choice of a single ''best'' model was based on purely statistical criteria, and the results of the statistics used (AIC) were similar between the models'' (Document ID 1659, p. 2). Therefore, according to Dr. Boffetta, ''there is ample uncertainty about the shape of the dose-response function in the low-dose range'' (Document ID 1659, p. 3).

OSHA agrees that it is difficult to distinguish a single ''best'' model from the set of models presented by Schubauer-Berigan *et al.* (2011), and that risk estimates at low exposure levels vary depending on choice of model. That is one reason OSHA presented results from all of the models (see Table VI–9). OSHA further agrees that there is uncertainty in the lung cancer risk estimates, the estimation of which (unlike for CBD) required extrapolation below beryllium exposure levels experienced by workers in the Schubauer-Berigan *et al.* (2011) study. However, the Schubauer-Berigan risk assessment's six best-fitting models all support OSHA's significant risk determination, as they all predict a significant risk of lung cancer at the preceding TWA PEL of 2 μg/m³ (estimates ranging from 33 to 170 excess lung cancers per 1,000 workers) and a substantially reduced, though still significant, risk of lung cancer at the new TWA PEL of 0.2 μg/m³ (estimates ranging from 3 to 30 excess lung cancers per 1,000 workers) (see Table VI–9).

Dr. Boffetta also noted that the risk estimates provided by Schubauer-Berigan *et al.* (2011, Document ID 1265) for OSHA's lung cancer risk assessment depend on the background lung cancer rate used in excess risk calculations, and that industrial workers may have a different background lung cancer risk than the U.S. population as a whole (Document ID 1659, p. 2). OSHA agrees that choice of background risk could influence the number of excess lung cancers predicted by the models the Agency relied on for its lung cancer risk estimates. However, choice of background risk did not influence OSHA's finding that excess lung cancer risks would be substantially reduced by a decrease in exposure from the preceding TWA PEL to the final TWA PEL, because the same background risk was factored into estimates of risk at both levels. Furthermore, the Schubauer-Berigan *et al.* (2011) estimates of excess lung cancer from exposure at the preceding PEL of 2 μg/m³ (ranging from 33 to 170 excess lung cancers per 1,000 workers, depending on the model) are much higher than the level of 1 per 1,000 that OSHA finds to be clearly significant. Even at the final TWA PEL of 0.2 μg/m³, the models demonstrate a range of risks of excess lung cancers of 3 to 30 per 1,000 workers, estimates well above the threshold for significant risk (see Section II, Pertinent Legal Authority). Small variations in background risk across different populations are highly unlikely to influence excess lung cancer risk estimates sufficiently to influence OSHA's finding of significant risk at the preceding TWA PEL, which is the finding OSHA relies on to support the need for a new standard.

Finally, Dr. Boffetta noted that the models that exclude professional and asbestos workers (the groups that Schubauer-Berigan *et al.* believed could be affected by confounding from tobacco and asbestos exposure) showed non-significant increases in lung cancer with increasing beryllium exposure. According to Dr. Boffetta, this suggests that confounding may contribute to the results of the models based on the full population. He speculates that if more precise information on confounding exposures were available, excess risk estimates might be further reduced (Document ID 1659, p. 2).

OSHA agrees with Dr. Boffetta that there is uncertainty in the Schubauer-Berigan *et al.* (2011) lung cancer risk estimates, including uncertainty due to limited information on possible confounding from associations between beryllium exposure level and workers' smoking habits or occupational co-exposures. However, in the absence of detailed smoking and co-exposure information, the models excluding professional and asbestos workers are a reasonable approach to addressing the possible effects of unmeasured confounding. OSHA's decision to include these models in its preliminary and final QRAs therefore represents the Agency's best available means of dealing with this uncertainty.

E. Risk Assessment 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 data set provided by NJH. OSHA has a high level of confidence in its finding that the risks of sensitization and CBD are above the benchmark of 1 in 1,000 at the preceding PEL, and the Agency believes that a comprehensive 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 and tightly controlled both respiratory exposure and dermal contact have substantially reduced risk of sensitization within the first years of exposure. These conclusions are supported by the results of several studies conducted in facilities dealing with a variety of production activities and physical forms of beryllium that have reduced workers' exposures substantially by implementing stringent exposure controls and PPE requirements since approximately 2000. In addition, these conclusions are supported by OSHA's analyses of the NJH data set, which contains highly-detailed exposure and work history information on several hundred beryllium workers.

Furthermore, OSHA believes that more stringent control of airborne beryllium exposures will reduce beryllium-exposed workers' significant risk of lung cancer. The risk estimates from the lung cancer study by Schubauer-Berigan *et al.* (2011, Document ID 1265; 0521), described above, range from 33 to 170 excess lung cancers per 1,000 workers exposed at the preceding PEL of 2 μg/m³, based on the study's six best-fitting models. These models each predict substantial reductions in risk with reduced exposure, ranging from 3 to 30 excess lung cancers per 1,000 workers exposed at the final PEL of 0.2 μg/m³. The evidence of lung cancer risk from the Schubauer-Berigan *et al.* (2011) risk assessment provides additional support for OSHA's conclusions regarding the significance of risk of adverse health effects for workers exposed to beryllium levels at and below the preceding PEL. However, the lung cancer risks required a sizable low dose extrapolation below beryllium exposure levels experienced by workers in the Schubauer-Berigan *et al.* (2011) study. As a result, there is greater uncertainty regarding the lung cancer risk estimates than there is for the risk estimates for beryllium sensitization and CBD. The conclusions with regard to significance of risk are presented and further discussed in section VII of the preamble.

VII. Significance of Risk

In this section, OSHA discusses its findings that workers exposed to beryllium at and below the preceding TWA PEL face a significant risk of material impairment of health or functional capacity within the meaning of the OSH Act, and that the new standards will substantially reduce this risk. To make the significance of risk determination for a new final 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 assuming exposure over a working lifetime. As discussed in section II, Pertinent Legal Authority, courts have stated that OSHA should consider all forms and degrees of material impairment—not just death or serious physical harm. To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on 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 (generally 45 years) at levels of exposure reflecting compliance with the preceding standard and compliance with the new standards (see Section II, Pertinent Legal Authority). When determining whether a significant risk exists OSHA considers whether there is a risk of at least one-in-a-thousand of developing a material health impairment from a working lifetime of exposure. The Supreme Court has found that OSHA is not required to support its finding of significant risk with scientific certainty, but may instead rely on a body of reputable scientific thought and may make conservative assumptions (*i.e.,* err on the side of protecting the worker) in its interpretation of the evidence (Section II, Pertinent Legal Authority).

OSHA's findings in this section follow in part from the conclusions of the preceding sections V, Health Effects, and VI, Risk Assessment. In this preamble at section V, Health Effects, OSHA reviewed the scientific evidence linking occupational beryllium exposure to a variety of adverse health effects and determined that beryllium exposure causes sensitization, CBD, and lung cancer, and is associated with various other adverse health effects (see section V.D, V.E, and V.F). In this preamble at section VI, Risk Assessment, OSHA found that the available epidemiological data are sufficient to evaluate risk for beryllium sensitization, CBD, and lung cancer among beryllium-exposed workers. OSHA evaluated the risk of sensitization, CBD, and lung cancer from levels of airborne beryllium exposure that were allowed under the previous standard, as well as the expected impact of the new standards on risk of these conditions. In this section of the preamble, OSHA explains its determination that the risk of material impairments of health, particularly CBD and lung cancer, from occupational exposures allowable under the preceding TWA PEL of 2 μg/m³ is significant, and is substantially reduced but still significant at the new TWA PEL of 0.2 μg/m³. Furthermore, evidence reviewed in section VI, Risk Assessment, shows that significant risk of CBD and lung cancer could remain in workplaces with exposures as low as the new action level of 0.1 μg/m³. OSHA also explains here that the new standards will reduce the occurrence of sensitization.

In the NPRM, OSHA preliminarily determined that both CBD and lung cancer are material impairments of health. OSHA also preliminarily determined that a working lifetime (45 years) of exposure to airborne beryllium at the preceding time-weighted average permissible exposure limit (TWA PEL) of 2 μg/m³ would pose a significant risk of both CBD and lung cancer, and that this risk is substantially reduced but still significant at the new TWA PEL of 0.2 μg/m³. OSHA did not make a preliminary determination as to whether beryllium sensitization is a material impairment of health because, as the Agency explained in the NPRM, it was not necessary to make such a determination. The Agency's preliminary findings on CBD and lung cancer were sufficient to support the promulgation of new beryllium standards.

Upon consideration of the entire rulemaking record, including the comments and information submitted to the record in response to the preliminary Health Effects, Risk Assessment, and Significance of Risk analyses (NPRM Sections V, VI, and VIII), OSHA reaffirms its preliminary findings that long-term exposure at the preceding TWA PEL of 2 μg/m³ poses a significant risk of material impairment of workers' health, and that adoption of the new TWA PEL of 0.2 μg/m³ and other provisions of the final standards will substantially reduce this risk.

Material Impairment of Health

As discussed in Section V, Health Effects, CBD is a respiratory disease caused by exposure to beryllium. CBD develops when 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 (Document ID 1319); ACCP, 1965 (1286); Kriebel *et al.,* 1988a (1292) and b (1473)).

In early, asymptomatic stages of CBD, small granulomatous lesions and mild inflammation occur in the lungs. 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, Document ID 1421). 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 (Conradi *et al.,* 1971, Document ID 1319; ACCP, 1965 (1286); Kriebel *et al.*, 1988 (1292); Kriebel *et al.,* 1988 (1473)).

Dr. Lee Newman, speaking at the public hearing on behalf of the American College of Occupational and Environmental Medicine (ACOEM), testified on his experiences treating patients with CBD: ''as a physician who has spent most of my [practicing] career seeing patients with exposure to beryllium, with beryllium sensitization, and with chronic beryllium disease including those who have gone on to require treatment and to die prematurely of this disease . . . [I've seen] hundreds and hundreds, probably over a thousand individuals during my career who have suffered from this condition'' (Document ID 1756, Tr. 79). Dr. Newman further testified about his 30 years of experience treating CBD in patients at various stages of the disease:

> . . . some of them will go from being sensitized to developing subclinical disease, meaning that they have no symptoms. As I mentioned earlier, most of those will, if we actually do the tests of their lung function and their oxygen levels in their blood, those people are already demonstrating physiologic abnormality. They already have disease affecting their health. They go on to develop symptomatic disease and progress to the point where they require treatment. And sometimes to the extent of even requiring a [lung] transplant (Document ID 1756, Tr. 131).

Dr. Newman described one example of a patient who developed CBD from his occupational beryllium exposure and ''who went on to die prematurely with a great deal of suffering along the way due to the condition chronic beryllium disease'' (Document ID 1756, Tr. 80).

During her testimony at the public hearing, Dr. Lisa Maier of National Jewish Health (NJH) provided an example from her experience with treating CBD patients. ''This gentleman started to have a cough, a dry cough in 2011 . . . His symptoms progressed and he developed shortness of breath, wheezing, chills, night sweats, and fatigue. These were so severe that he was eventually hospitalized'' (Document ID 1756, Tr. 105). Dr. Maier noted that this patient had no beryllium exposure prior to 2006, and that his CBD had developed from beryllium exposure in his job melting an aluminum alloy in a foundry casting airplane parts (Document ID 1756, Tr. 105–106). She described how her patient could no longer work because of his condition. ''He requires oxygen and systemic therapy . . . despite aggressive treatment [his] test findings continue to demonstrate worsening of his disease and increased needs for oxygen and medications as well as severe side effects from medications. This patient may well need a lung transplant if this disease continues to progress . . . '' (Document ID 1756, Tr. 106–107).

The likelihood, speed, and severity of individuals' transition from asymptomatic to symptomatic CBD is understood to vary widely, with some individuals responding differently to exposure cessation and treatment than others (Sood, 2009, Document ID 0456; Mroz *et al.,* 2009 (1443)). In the public hearing, Dr. Newman testified that the great majority of individuals with very early stage CBD in a cross-sectional study he published (Pappas and Newman, 1993) had physiologic impairment. Thus, even before x-rays or CAT scans found evidence of CBD, the lung functions of those individuals were abnormal (Document ID 1756, Tr. 112). Materion commented that the best available evidence on the transition from asymptomatic to more severe CBD is a recent longitudinal study by Mroz *et al.* (2009, Document ID 1443), which found that 19.3 percent of individuals with CBD developed clinical abnormalities requiring oral immunosuppressive therapy (Document ID 1661, pp. 5–6). The authors' overall conclusions in that study include a finding that adverse physiological changes among initially asymptomatic CBD patients progress over time, requiring many individuals to be treated with corticosteroids, and that the patients' levels of beryllium exposure may affect progression (Mroz *et al.,* 2009). Dr. Maier, a co-author of the study, testified that studies ''indicate that higher levels of exposure not only are risk factors for [developing CBD in general] but also for more severe [CBD] (Document ID 1756, Tr. 111).[24]

Treatment of CBD using inhaled and systemic steroid therapy has been shown to ease symptoms and slow or prevent some aspects of disease progression. As explained below, these treatments can be most effectively applied when CBD is diagnosed prior to development of symptoms. In addition, the forms of treatment that can be used to manage early-stage CBD have relatively minor side effects on patients, while systemic steroid treatments required to treat later-stage CBD often cause severe side effects.

In the public hearing, Dr. Newman and Dr. Maier testified about their experiences treating patients with CBD at various stages of the disease. Dr. Newman stated that patients' outcomes depend greatly on how early they are diagnosed. ''So there are those people who are diagnosed very late in the course of disease where there's little that we can do to intervene and they are going to die prematurely. There are those people who may be detected with milder disease where there are opportunities to intervene'' (Document ID 1756, Tr. 132). Both Dr. Maier and Dr. Newman emphasized the importance of early detection and diagnosis, stating that removing the patient from exposure and providing treatment early in the course of the disease can slow or even halt progression of the disease (Document ID 1756, Tr. 111, 132).

Dr. Maier testified that inhaled steroids can be used to treat relatively mild symptoms that may occur in early stages of the disease, such as a cough during exercise (Document ID 1756, Tr. 139). Inhaled steroids, she stated, are commonly used to treat other health conditions and have fewer and milder side effects than forms of steroid treatment that are used to treat more severe forms of CBD (Document ID 1756, Tr. 140). Early detection of CBD helps physicians to properly treat early-onset symptoms, since appropriate forms of treatment for early stage CBD can differ from treatments for conditions it is commonly mistaken for, such as chronic obstructive pulmonary disease

[24] The study by Mroz *et al.* (2009, Document ID 1443) included all individuals who were clinically evaluated at NJH between 1982 and 2002 and were found to have CBD on baseline clinical evaluation. All cohort members were identified by abnormal BeLPTs before identification of symptoms, physiologic abnormalities, or radiographic changes. All members were offered evaluation for clinical abnormalities every 2 years through 2002, including pulmonary function testing, exercise testing, chest radiograph with International Labor Organization (ILO) B-reading, fiberoptic bronchoscopy with bronchoalveolar lavage (BAL), and transbronchial lung biopsies. Of 171 CBD cases, 33 (19.3%) developed clinical abnormalities requiring oral immunosuppressive therapy, at an average of 1.4 years after the initial diagnosis of CBD. To examine the effect of beryllium exposure level on the progression of CBD, Mroz *et al.* compared clinical manifestations of CBD among machinists (the group of patients likely to have had the highest beryllium exposures) to non- machinists, including only CBD patients who had never smoked. Longitudinal analyses showed significant declines in some clinical indicators over time since first exposure for machinists (p <0.01) as well as faster development of illness ($p < 0.05$), compared to a control group of non-machinists.

(COPD) and asthma (Document ID 1756, Tr. 140–141).

CBD in later stages is often managed using systemic steroid treatments such as corticosteroids. In workers with CBD whose beryllium exposure has ceased, corticosteroid therapy 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, Document ID 0370). Thus, although there is no cure for CBD, properly-timed treatment can lead to CBD regression in some patients (Sood, 2004, Document ID 1331). Other patients have shown short-term improvements from corticosteroid treatment, but then developed serious fibrotic lesions (Marchand-Adam *et al.,* 2008). Ms. Peggy Mroz, of NJH, discussed the results of the Marchand-Adam *et al.* study in the hearing, stating that treatment of CBD using steroids has been most successful when treatment begins prior to the development of lung fibrosis (Document ID 1756, Tr. 113). Once fibrosis has developed in the lungs, corticosteroid treatment cannot reverse the damage (Sood, 2009, Document ID 0456). Persons with late-stage CBD experience severe respiratory insufficiency and may require supplemental oxygen (Rossman, 1991, Document 1332). Historically, late-stage CBD often ended in death (NAS, 2008, Document ID 1355). While the use of steroid treatments can help to reduce the effects of CBD, OSHA is not aware of any studies showing the effect of these treatments on the frequency of premature death among patients with CBD.

Treatment with corticosteroids has severe side effects (Trikudanathan and McMahon, 2008, Document ID 0366; Lipworth, 1999 (0371); Gibson *et al.,* 1996 (1521); Zaki *et al.,* 1987 (1374)). Adverse effects associated with long-term corticosteroid use include, but are not limited to: increased risk of opportunistic infections (Lionakis and Kontoyiannis, 2003, Document ID 0372; Trikudanathan and McMahon, 2008 (0366)); accelerated bone loss or osteoporosis leading to increased risk of fractures or breaks (Hamida *et al.,* 2011, Document ID 0374; Lehouck *et al.,* 2011 (0355); Silva *et al.,* 2011 (0388); Sweiss *et al.,* 2011 (0367); Langhammer *et al.,* 2009 (0373)); psychiatric effects including depression, sleep disturbances, and psychosis (Warrington and Bostwick, 2006, Document ID 0365; Brown, 2009 (0377)); adrenal suppression (Lipworth, 1999, Document ID 0371; Frauman, 1996 (0356)); ocular effects including cataracts, ocular hypertension, and glaucoma (Ballonzoli and Bourcier, 2010, Document ID 0391; Trikudanathan and McMahon, 2008 (0366); Lipworth, 1999 (0371)); an increase in glucose intolerance (Trikudanathan and McMahon, 2008, Document ID 0366); excessive weight gain (McDonough *et al.,* 2008, Document ID 0369; Torres and Nowson, 2007 (0387); Dallman *et al.,* 2007 (0357); Wolf, 2002 (0354); Cheskin *et al.,* 1999 (0358)); increased risk of atherosclerosis and other cardiovascular syndromes (Franchimont *et al.,* 2002, Document ID 0376); skin fragility (Lipworth, 1999, Document ID 0371); and poor wound healing (de Silva and Fellows, 2010, Document ID 0390).

Based on the above, 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 that can cause severe and lasting side effects, and may in some cases cause premature death.

Furthermore, OSHA has determined that early-stage CBD, an asymptomatic period during which small lesions and inflammation appear in the lungs, is also a material impairment of health. OSHA bases this conclusion on evidence and expert testimony that early-stage CBD is a measurable change in an individual's state of health that, with and sometimes without continued exposure, can progress to symptomatic disease (*e.g.,* Mroz *et al.,* 2009 (1443); 1756, Tr. 131). Thus, prevention of the earliest stages of CBD will prevent development of more serious disease. In OSHA's Lead standard, promulgated in 1978, the Agency stated its 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 the 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 (43 FR 52952, 52954).

Since the Lead rulemaking, OSHA has also found other non-symptomatic (or sub-clinical) health conditions to be material impairments of health. In the Bloodborne Pathogens 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). OSHA stated: ''Becoming a carrier [of HBV] 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 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 and Bloodborne Pathogens standards. Early stage CBD involves lung tissue inflammation without symptoms 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 determined 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 finds all stages of CBD to be material impairments of health within the meaning of section 6(b)(5) of the OSH Act (29 U.S.C. 655(b)(5)).

In reviewing OSHA's Lead standard in *United Steelworkers of America, AFL–CIO* v. *Marshall,* 647 F.2d 1189, 1252 (D.C. Cir. 1980) (*Lead I*), the D.C. Circuit affirmed that the OSH Act ''empowers OSHA to set a PEL that prevents the subclinical effects of lead that lie on a continuum shared with overt lead disease.'' *See also AFL–CIO* v. *Marshall,* 617 F.2d 636, 654 n.83 (D.C. Cir. 1979) (upholding OSHA's authority to prevent early symptoms of a disease, even if the effects of the disease are, at that point, reversible). According to the Court, OSHA only had to demonstrate, on the basis of substantial evidence, that preventing the subclinical effects would help prevent the clinical phase of disease (*United Steelworkers of America, AFL–CIO,* 647 F.2d at 1252). Thus, OSHA has the authority to regulate to prevent asymptomatic CBD whether or not it is properly labeled as a material impairment of health.

OSHA has also determined that exposure to beryllium can cause beryllium sensitization. Sensitization is a precursor to development of CBD and an essential step for development of the disease. As discussed in Section V, Health Effects, only sensitized individuals can develop CBD (NAS, 2008, Document ID 1355).[25] As explained above, OSHA has the authority to promulgate regulations designed to prevent precursors to material impairments of health. Therefore, OSHA's new beryllium standards aim to prevent sensitization as well as the development of CBD and lung cancer. OSHA's risk assessment for sensitization, presented in section VI, informs the Agency's understanding of what exposure control measures have been successful in preventing sensitization, which in turn prevents development of CBD. Therefore, OSHA addresses sensitization in this section on significance of risk.

Risk Assessment

As discussed in Section VI, Risk Assessment, the risk assessment for beryllium sensitization and CBD relied on two approaches: (1) OSHA's review of epidemiological studies of sensitization and CBD that contain information on exposures in the range of interest to OSHA (2 μg/m³ and below), and (2) OSHA's analysis of a NJH data set on sensitization and CBD in a group of beryllium-exposed machinists in Cullman, AL.

OSHA's review of the literature includes studies of beryllium-exposed workers at a Tucson, AZ ceramics plant (Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Cummings *et al.,* 2007 (1369)); a Reading, PA copper-beryllium processing plant (Schuler *et al.,* 2005, Document ID 0919; Thomas *et al.,* 2009 (0590)); a Cullman, AL beryllium machining plant (Newman *et al.,* 2001, Document ID 1354; Kelleher *et al.,* 2001 (1363); Madl *et al.,* 2007 (1056)); an Elmore, OH metal, alloy, and oxide production plant (Kreiss *et al.,* 1993 Document ID 1478; Bailey *et al.,* 2010 (0676); Schuler *et al.,* 2012 (0473)); aluminum smelting facilities (Taiwo *et al.* 2008, Document ID 0621; 2010 (0583); Nilsen *et al.,* 2010 (0460)); and nuclear facilities (Viet *et al.,* 2000, Document ID 1344; Arjomandi *et al.,* 2010 (1275)).

The published literature on beryllium sensitization and CBD discussed in section VI shows that the risk of both can be significant in workplaces where exposures are at or below OSHA's preceding PEL of 2 μg/m³ (*e.g.,* Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Newman *et al.,* 2001 (1354); Schuler *et al.,* 2005 (0919), 2012 (0473); Madl *et al.,* 2007 (1056)). For example, in the Tucson ceramics plant mentioned above, Kreiss *et al.* (1996) reported that eight (5.9 percent)[26] of the 136 workers tested in 1992 were sensitized, six (4.4 percent) of whom were diagnosed with CBD. In addition, of 77 Tucson workers hired prior to 1992 who were tested in 1998, eight (10.4 percent) were sensitized and seven of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001, Document ID 1313). Full-shift area samples showed most airborne beryllium levels below the preceding PEL: 76 percent of area samples collected between 1983 and 1992 were at or below 0.1 μg/m³ and less than 1 percent exceeded 2 μg/m³; short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 μg/m³; and personal lapel samples collected at the plant beginning in 1991 had a median of 0.2 μg/m³ (Kreiss *et al.,* 1996).

Results from the Elmore, OH beryllium metal, alloy, and oxide production plant and the Cullman, AL machining facility also showed significant risk of sensitization and CBD among workers with exposures below the preceding TWA PEL. Schuler *et al.* (2012, Document ID 0473) found 17 cases of sensitization (8.6 percent) among Elmore, OH workers within the first three quartiles of LTW average exposure (198 workers with LTW average total mass exposures lower than 1.1 μg/m³) and 4 cases of CBD (2.2 percent) within those quartiles of LTW average exposure (183 workers with LTW average total mass exposures lower than 1.07 μg/m³; note that follow-up time of up to 6 years for all study participants was very short for development of CBD). At the Cullman, AL machining facility, Newman *et al.* (2001, Document ID 1354) reported 22 (9.4 percent) sensitized workers among 235 tested in 1995–1999, 13 of whom were diagnosed with CBD within the study period. Personal lapel samples collected between 1980 and 1999 indicate that median exposures were generally well below the preceding PEL (≤0.35 μg/m³ in all job titles except maintenance (median 3.1 μg/m³ during 1980–1995) and gas bearings (1.05 μg/m³ during 1980–1995)).

Although risk will be reduced by compliance with the new TWA PEL, evidence in the epidemiological studies reviewed in section VI, Risk Assessment, shows that significant risk of sensitization and CBD could remain in workplaces with exposures as low as the new action level of 0.1 μg/m³. For example, Schuler *et al.* (2005, Document ID 0919) reported substantial prevalences of sensitization (6.5 percent) and CBD (3.9 percent) among 152 workers at the Reading, PA facility screened with the BeLPT in 2000. These results showed significant risk at this facility, even though airborne exposures were primarily below both the preceding and final TWA PELs due to the low percentage of beryllium in the metal alloys used (median general area samples ≤0.1 μg/m³, 97% < 0.5 μg/m³; 93% of personal lapel samples below the new TWA PEL of 0.2 μg/m³). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with exposures below the new action level of 0.1 μg/m³ (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³) (Schuler *et al.,* 2005). The Schuler *et al.* (2012, Document ID 0473) study of short-term workers in the Elmore, OH facility found three cases (4.6%) of sensitization among 66 workers with total mass LTW average exposures below 0.1 μg/m³. All three of these sensitized workers had LTW average exposures of approximately 0.09 μg/m³.

Furthermore, cases of sensitization and CBD continued to arise in the Cullman, AL machining plant after control measures implemented beginning in 1995 brought median airborne exposures below 0.2 μg/m³ (personal lapel samples between 1996 and 1999 in machining jobs had a median of 0.16 μg/m³ and the median was 0.08 μg/m³ in non-machining jobs)

[25] In the NPRM, OSHA took no position on whether beryllium sensitization by itself is a material impairment of health, stating it was unnecessary to do so as part of this rulemaking. The only comment on this issue came from Materion, which argued that ''BeS does not constitute a material impairment of health or functional capacity'' (document ID 1958). Because BeS is also a precursor to CBD, OSHA finds it unnecessary to resolve this issue here.

[26] Although OSHA reports percentages to indicate the risks of sensitization and CBD in this section, the benchmark OSHA typically uses to demonstrate significant risk, as discussed earlier, is greater than or equal to 1 in 1,000 workers. One in 1,000 workers is equivalent to 0.1 percent. Therefore, any value of 0.1 percent or higher when reporting occurrence of a health effect is considered by OSHA to indicate a significant risk.

(Madl *et al.,* 2007, Document ID 1056, Table IV). At the time that Newman *et al.* (2001, Document ID 1354) 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 and had therefore benefitted to some extent from the exposure reductions. 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). A later study by Madl. *et al.* (2007, Document ID 1056) reported seven sensitized workers who had been hired between 1995 and 1999, of whom four had developed CBD as of 2005 (Table II; total number of workers hired between 1995 and 1999 not reported).

The enhanced industrial hygiene programs that have proven effective in several facilities demonstrate the importance of minimizing both airborne exposure and dermal contact to effectively reduce risk of sensitization and CBD. Exposure control programs that have used a combination of engineering controls, PPE, and stringent housekeeping measures to reduce workers' airborne exposure and dermal contact have substantially lowered risk of sensitization among newly-hired workers.[27] Of 97 workers hired between 2000 and 2004 in the Tucson, AZ plant after the introduction of a comprehensive program which included the use of respiratory protection (1999) and latex gloves (2000), one case of sensitization was identified (1 percent) (Cummings *et al.,* 2007, Document ID 1369). In Elmore, OH, 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 percent (Bailey *et al.,* 2010, Document ID 0676). In the Reading, PA facility, after workers' exposures were reduced to below 0.1 μg/m³ and PPE to prevent dermal contact was instituted, only one (2.2 percent) of 45 workers hired was sensitized (Thomas *et al.* 2009, Document ID 0590). And, in the aluminum smelters discussed by Taiwo *et al.* (2008, Document ID 0621), where available exposure samples from four plants 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).

OSHA notes that 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 adequately 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 studies examining the post-2000 worker cohorts with very low exposures in Tucson, Reading, and Elmore (Cummings *et al.* 2007, Document ID 1369; Thomas *et al.* 2009, (0590); Bailey *et al.* 2010, (0676)). 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) (Madl *et al.,* 2007, Document ID 1056, Table III). 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, Document ID 1070), and workers employed only in administration at a beryllium ceramics facility (Kreiss *et al.,* 1996, Document ID 1477). Therefore, there is some evidence that cases of CBD can occur in work environments where beryllium exposures are quite low.

In summary, the epidemiological literature on beryllium sensitization and CBD that OSHA's risk assessment relied on show sufficient occurrence of sensitization and CBD to be considered significant within the meaning of the OSH Act. These demonstrated risks are far in excess of 1 in 1,000 among workers who had full-shift exposures well below the preceding TWA PEL of 2 μg/m³ and workers who had median full-shift exposures down to the new action level of 0.1 μg/m³. These health effects occurred among populations of workers whose follow-up time was much less than 45 years. As stated 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 of occupational exposure to airborne beryllium is likely to be higher than the prevalence of CBD observed among these workers.[28] In either case, based on these studies, the risks to workers from long-term exposure at the preceding TWA PEL and below are clearly significant. OSHA's review of epidemiological studies further showed that worker protection programs that effectively reduced the risk of beryllium sensitization and CBD incorporated engineering controls, work practice controls, and personal protective equipment (PPE) that reduce workers' airborne beryllium exposure and dermal contact with beryllium. OSHA has therefore determined that an effective worker protection program should incorporate both airborne exposure reduction and dermal protection provisions.

OSHA's conclusions on significance of risk at the final PEL and action level are further supported by its analysis of the data set provided to OSHA by NJH from which OSHA derived additional information on sensitization and CBD at exposure levels of interest. 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 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 (0.9 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 new TWA PEL of 0.2 μg/m³, and extensive exposure data collected in workers' breathing zones, as is preferred by OSHA. Unlike the Tucson, Reading, and Elmore facilities after 2000, 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 estimating exposure accounting for respirators. Also unlike the Tucson, Elmore, and Reading facilities, glove use was not reported to be mandatory in the Cullman facility. Therefore, 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 used at other facilities.

OSHA analyzed the prevalence of beryllium sensitization and CBD among

[27] As discussed in Section V, Health Effects, beryllium sensitization can occur from dermal contact with beryllium.

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

workers at the Cullman facility who were exposed to airborne beryllium levels at and below the preceding TWA PEL of 2 μg/m³. In addition, a statistical modeling analysis of the NJH 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 section VI, Risk Assessment and in the background document (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016).

Tables VII–1 and VII–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 data set, including workers with and without a diagnosis of CBD.

TABLE VII–1—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJH DATA SET

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, Risk Assessment.

TABLE VII–2—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE IN NJH DATA SET

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, Risk Assessment.

The preceding 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 μg/m³) exposure levels. In the highest quartile of LTW average exposure, there were 12 cases of sensitization (15.4 percent), including eight (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).[29]

The new TWA 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 six (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 8–9 percent. OSHA considers these rates to be evidence that the risks of developing sensitization and CBD are significant among workers exposed at and below the preceding TWA PEL, and even below the new TWA PEL. These risks are much higher than the benchmark for significant risk of 1 in 1,000. Much lower prevalences of sensitization and CBD were found among workers with exposure levels less than or equal to about 0.08 μg/m³, although these risks are still significant. Two sensitized workers (2.2 percent), including one case of CBD (1.0 percent), were found among workers with LTW average exposure levels less than or equal to 0.08 μg/m³. One case of sensitization (1.2 percent) and no cases of CBD were found among workers with HEJ exposures of at most 0.086 μg/m³. Strict control of airborne exposure to levels below 0.1 μg/m³ using engineering and work practice controls can, therefore, substantially 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 VIII, Summary of the Economic Analysis and Regulatory Flexibility Analysis), the Agency finds that workers in facilities that meet the action level of 0.1 μg/m³ will face lower risks of sensitization and CBD than workers in facilities that cannot meet the action level.

Table VII–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 or her employment.

[29] This exposure-response pattern, wherein higher rates of response are seen in workers with lower exposures, is sometimes attributed to a ''healthy worker effect'' or to exposure misclassification, as discussed in this preamble at section VI, Risk Assessment.

TABLE VII–3—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE IN NJH DATA SET

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, Risk Assessment.

A 45-year working lifetime of occupational exposure at the preceding PEL would result in 90 μg/m³-years of exposure, 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 previous PEL. Workers with 45 years of exposure to the new TWA PEL of 0.2 μg/m³ 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 the higher exposure levels (<1.467 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 preceding PEL of 2 μg/m³, or 7.34–35.04 years of exposure at the new TWA 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 new TWA PEL of 0.2 μg/m³, or 1.5 to 15 years at the action level of 0.1 μg/m³. Risks at all levels of cumulative exposure presented in Table 3 are significant. These findings support OSHA's determination that maintaining exposure levels below the new TWA PEL will help to protect workers against risk of beryllium sensitization and CBD. Moreover, while OSHA finds that significant risk remains at the PEL, OSHA's analysis shows that further reductions of risk will ensue if employers are able to reduce exposure to the action level or even below.

Lung Cancer

Lung cancer, a frequently fatal disease, is a well-recognized material impairment of health. OSHA has determined that beryllium causes lung cancer based on an extensive review of the scientific literature regarding beryllium and cancer. This review included an evaluation of the human epidemiological, animal cancer, and mechanistic studies described in section V, Health Effects. OSHA's conclusion that beryllium is carcinogenic is supported by the findings of expert public health and governmental organizations such as the International Agency for Research on Cancer (IARC), which has determined beryllium and its compounds to be carcinogenic to humans (Group 1 category) (IARC, 2012, Document ID 0650); the National Toxicology Program (NTP), which classifies beryllium and its compounds as known carcinogens (NTP, 2014, Document ID 0389); and the Environmental Protection Agency (EPA), which considers beryllium to be a probable human carcinogen (EPA, 1998, Document ID 0661).

OSHA's review of epidemiological studies of lung cancer mortality among beryllium workers found that most of them did not characterize exposure levels sufficiently to evaluate the risk of lung cancer at the preceding and new TWA PELs. However, as discussed in this preamble at section V, Health Effects and section VI, Risk Assessment, Schubauer-Berigan *et al.* published a quantitative risk assessment based on beryllium exposure and lung cancer mortality among 5,436 male workers first employed at beryllium processing plants in Reading, PA, Elmore, OH, and Hazleton, PA, prior to 1970 (Schubauer-Berigan *et al.,* 2011, Document ID 1265). This 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 LTW average exposure of less than 1.5 μg/m³, while the median worker from Elmore had a LTW average 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 the preliminary risk assessment for lung cancer on the Schubauer-Berigan risk analysis.

Schubauer-Berigan *et al.* (2011, Document ID 1265) analyzed the data set using a variety of exposure-response modeling approaches, described in this preamble at section VI, Risk Assessment. The authors found that lung cancer mortality risk was strongly and significantly correlated with mean, cumulative, and maximum measures of workers' exposure to beryllium (all of the models reported in the study). 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 daily weighted average exposure that would be associated with an excess lung cancer mortality risk of one in one thousand (.005 μg/m³ to .07 μg/m³ depending on model choice). At OSHA's request, the authors also estimated excess lifetime risks for workers with mean exposures at the preceding TWA PEL of 2 μg/m³ as well as at each of the alternate TWA PELs that were under consideration: 1 μg/m³, 0.2 μg/m³, and 0.1 μg/m³. Table VII–4 presents the estimated excess risk of lung cancer mortality associated with various levels of beryllium exposure, based on the final models presented in Schubauer-Berigan *et al*'s risk assessment.[30]

[30] The estimates for lung cancer represent ''excess'' risks in the sense that they reflect the risk of dying from lung cancer over and above the risk of dying from lung cancer faced by those who are not occupationally exposed to beryllium.

TABLE VII–4—EXCESS RISK OF LUNG CANCER MORTALITY PER 1,000 MALE WORKERS AT ALTERNATE PELS (BASED ON SCHUBAUER-BERIGAN *et al.,* 2011)

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	140
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: Schubauer-Berigan, Document ID 0521, pp. 6–10.

The lowest estimate of excess lung cancer deaths from the six final models presented by Schubauer-Berigan *et al.* is 33 per 1,000 workers exposed at a mean level of 2 μg/m³, the preceding TWA PEL. Risk estimates as high as 170 lung cancer deaths per 1,000 result from the other five models presented. Regardless of the model chosen, the excess risk of about 33 to 170 per 1,000 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 new PEL of 0.2 μg/m³ is expected to reduce these risks significantly, to somewhere between 2.7 and 30 excess lung cancer deaths per 1,000 workers. At the new action level of 0.1 μg/m³, risk falls within the range of 1.4 to 19 excess lung cancer deaths. These risk estimates still fall above the threshold of 1 in 1,000 that OSHA considers clearly significant. However, the Agency believes the lung cancer risks should be regarded as less certain than the risk estimates for CBD and sensitization discussed previously. While the risk estimates for CBD and sensitization at the preceding and new TWA PELs were determined from exposure levels observed in occupational studies, the lung cancer risks were extrapolated from much higher exposure levels.

Conclusions

As discussed throughout this section, 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, CBD, and beryllium sensitization, and has evaluated the risk of these effects from exposures allowed under the preceding and new TWA PELs. The Agency has, additionally, reviewed the medical literature, as well as previous policy determinations and case law regarding material impairment of health, and has determined that CBD, at all stages, and lung cancer constitute material health impairments.

OSHA has determined that long-term exposure to beryllium at the preceding TWA PEL would pose a risk of CBD and lung cancer greater than the risk of 1 per 1,000 exposed workers the Agency considers clearly significant, and that adoption of the new TWA PEL, action level, and dermal protection requirements of the final standards will substantially reduce this risk. OSHA believes substantial evidence supports its determinations, including its choices of the best available published studies on which to base its risk assessment, its examination of the prevalence of sensitization and CBD among workers with exposure levels comparable to the preceding TWA PEL and new TWA PEL in the NJH data set, and its selection of the Schubauer-Berigan QRA to form the basis for its lung cancer risk estimates. The previously-described analyses demonstrate that workers with occupational exposure to airborne beryllium at the preceding PEL face risks of developing CBD and dying from lung cancer that far exceed the value of 1 in 1,000 used by OSHA as a benchmark of clearly significant risk. Furthermore, OSHA's risk assessment indicates that risk of CBD and lung cancer can be significantly reduced by reduction of airborne exposure levels, and that dermal protection measures will additionally help reduce risk of sensitization and, therefore, of CBD.

OSHA's risk assessment also indicates that, despite the reduction in risk expected with the new PEL, the risks of CBD and lung cancer to workers with average exposure levels of 0.2 μg/m³ are still significant and could extend down to 0.1 μg/m³, although there is greater uncertainty in this finding for 0.1 μg/m³ since there is less information available on populations exposed at and below this level. Although significant risk remains at the new TWA PEL, OSHA is also required to consider the technological and economic feasibility of the standard in determining exposure limits. As explained in Section VIII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis, OSHA determined that the new TWA PEL of 0.2 μg/m³ is both technologically and economically feasible in the general industry, construction, and shipyard sectors. OSHA was unable to demonstrate, however, that a lower TWA PEL of 0.1 μg/m³ would be technologically feasible. Therefore, OSHA concludes that, in setting a TWA PEL of 0.2 μg/m³, the Agency is reducing the risk to the extent feasible, as required by the OSH Act (see section II, Pertinent Legal Authority). In this context, the Agency finds that the action level of 0.1 μg/m³, dermal protection requirements, and other ancillary provisions of the final rule are critically important in reducing the risk of sensitization, CBD, and lung cancer among workers exposed to beryllium. Together, these provisions, along with the new TWA PEL of 0.2 μg/m³, will substantially reduce workers' risk of material impairment of health from occupational beryllium exposure.

VIII. Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis

A. Introduction

OSHA's Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this final beryllium rule and evaluates regulatory alternatives to the final 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). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The full FEA 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 FEA is to:

- Identify the establishments and industries potentially affected by the final rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits resulting from employers coming into compliance with the final rule in terms of reductions in cases of lung cancer, chronic beryllium disease;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the final rule;
- Assess the economic feasibility of the final rule for affected industries; and
- Assess the impact of the final rule on small entities through a Final Regulatory Flexibility Analysis (FRFA), to include an evaluation of significant regulatory alternatives to the final rule that OSHA has considered.

Significant Changes to the FEA Between the Proposed Standards and the Final Standards

OSHA made changes to the Preliminary Economic Analysis (PEA) for several reasons:

- Changes to the rule, summarized in Section I of the preamble and discussed in detail in the Summary and Explanation;
- Comments on the PEA;
- Updates of economic data; and
- Recognition of errors in the PEA.

OSHA revised its technological and economic analysis in response to these changes and to comments received on the NPRM. The FEA contains some costs that were not included in the PEA and updates data to use more recent data sources and, in some cases, revised methodologies. Detailed discussions of these changes are included in the relevant sections throughout the FEA.

The Final Economic Analysis contains the following chapters:

Chapter I. Introduction
Chapter II. Market Failure and 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. Final Regulatory Flexibility Analysis

Table VIII–1 provides a summary of OSHA's best estimate of the costs and benefits of the final rule using a discount rate of 3 percent. As shown, the final rule is estimated to prevent 90 fatalities and 46 beryllium-related illnesses annually once it is fully effective, and the estimated cost of the rule is $74 million annually. Also as shown in Table VIII–1, the discounted monetized benefits of the final rule are estimated to be $561 million annually, and the final rule is estimated to generate net benefits of $487 million annually. Table VIII–1 also presents the estimated costs and benefits of the final rule using a discount rate of 7 percent.

TABLE VIII–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S FINAL BERYLLIUM STANDARD

[3 Percent Discount Rate, 2015 dollars]

Annualized Costs:	
Control Costs	$12,269,190
Rule Familiarization	180,158
Exposure Assessment	13,748,676
Regulated Areas	884,106
Beryllium Work Areas	129,648
Medical Surveillance	7,390,958
Medical Removal	1,151,058
Written Exposure Control Plan	2,339,058
Protective Work Clothing & Equipment	1,985,782
Hygiene Areas and Practices	2,420,584
Housekeeping	22,763,595
Training	8,284,531
Respirators	320,885
Total Annualized Costs (Point Estimate)	73,868,230
Annual Benefits: Number of Cases Prevented:	
Fatal Lung Cancers (Midpoint Estimate)	4
Fatal Chronic Beryllium Disease	86
Beryllium-Related Mortality	90
Beryllium Morbidity	46
Monetized Annual Benefits (Midpoint Estimate)	$560,873,424
Net Benefits:	
Net Benefits	$487,005,194

Sources: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

The remainder of this section (Section VIII) of the preamble is organized as follows:

B. Market Failure and the Need for Regulation
C. Profile of Affected Industries
D. Technological Feasibility
E. Costs of Compliance
F. Economic Feasibility Analysis and Regulatory Flexibility Determination
G. Benefits and Net Benefits
H. Regulatory Alternatives
I. Final Regulatory Flexibility Analysis.

B. Market Failure and the Need for Regulation

Employees in work environments addressed by the final 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 FEA in support of the final rule, OSHA concludes there is a demonstrable failure of private markets to protect workers from exposure to unnecessarily high levels beryllium and that private markets, as well as information dissemination programs, workers' compensation systems, and tort liability options, each may fail to protect workers from beryllium exposure, resulting in the need for a more protective OSHA beryllium rule.

After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA concludes that, in the case of beryllium exposure, the final mandatory standards represent the best choice for reducing the risks to employees.

C. Profile of Affected Industries

Chapter III of the FEA presents profile data for industries potentially affected by the final beryllium rule. This Chapter provides the background data used throughout the remainder of the FEA including estimates of what industries are affected, and their economic and beryllium exposure characteristics. OSHA identified the following application groups as affected by the standard:

- Beryllium Production
- Beryllium Oxide Ceramics and Composites
- Nonferrous Foundries
- Secondary Smelting, Refining, and Alloying
- Precision Turned Products
- Copper Rolling, Drawing, and Extruding
- Fabrication of Beryllium Alloy Products
- Welding
- Dental Laboratories
- Aluminum Production
- Coal-Fired Electric Power Generation

- Abrasive Blasting

Table VIII–3 shows the affected industries by application group and selected economic characteristics of these affected industries. Table VIII–4 provides industry-by-industry estimates of current exposure.

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Beryllium Production											
Beryllium Production	331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	163	186	10,773	1	1	616	$15,853,340	$97,259,754	$85,233,010
Beryllium Oxide Ceramics and Composites											
Be Oxide - Primary	327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	636	655	13,096	2	2	83	$2,224,322	$3,497,362	$3,395,911
Be Oxide - Secondary	334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	748	830	66,833	9	10	120	$29,075,882	$38,871,500	$35,031,183
Be Oxide - Secondary	334310	Audio and Video Equipment Manufacturing	459	463	8,767	5	5	60	$2,944,276	$6,414,545	$6,359,128
Be Oxide - Secondary	334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	376	418	19,796	11	12	144	$3,829,332	$10,184,393	$9,161,081

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Be Oxide - Secondary	334419	Other Electronic Component Manufacturing	1,162	1,259	54,693	28	30	360	$11,749,377	$10,111,340	$9,332,309
Be Oxide - Secondary	334510	Electrometrical and Electrotherapeutic Apparatus Manufacturing	674	749	64,271	8	9	108	$29,145,680	$43,242,849	$38,912,791
Be Oxide - Secondary	327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	636	655	13,096	14	14	168	$2,224,322	$3,497,362	$3,395,911
Be Oxide - Secondary	336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	9	10	120	$21,336,550	$34,525,161	$31,469,837
Nonferrous Foundries											
Non Sand Foundries	331523	Nonferrous Metal Die-Casting Foundries	396	434	31,010	45	50	822	$8,177,926	$20,651,328	$18,843,147
Non Sand Foundries	331524	Aluminum Foundries (except Die-Casting)	383	406	15,446	7	7	120	$2,953,370	$7,711,149	$7,274,311

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Non Sand Foundries	331529a	Other Nonferrous Metal Foundries (except Die-Casting)	293	300	9,522	18	18	304	$2,517,475	$8,592,063	$8,391,582
Sand Foundries	331529b	Other Nonferrous Metal Foundries (except Die-Casting)	293	300	9,522	22	23	430	$2,517,475	$8,592,063	$8,391,582
Secondary Smelting, Refining, and Alloying											
Smelting - Be Alloys	331314	Secondary Smelting and Alloying of Aluminum	92	114	5,415	1	1	9	$5,866,913	$63,770,798	$51,464,153
Smelting - Be Alloys	331420b	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	3	4	36	$24,370,147	$136,146,071	$97,872,075
Smelting - Precious metals	331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	228	261	10,913	26	30	270	$15,183,933	$66,596,198	$58,175,989

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Precision Machining											
Machining (high)	332721a	Precision turned product manufacturing (high beryllium content)	3,601	3,688	103,546	21	22	289	$18,818,245	$5,225,839	$5,102,561
Machining (low)	332721b	Precision turned product manufacturing (low beryllium content)	3,601	3,688	103,546	339	347	4,607	$18,818,245	$5,225,839	$5,102,561
Copper Rolling, Drawing and Extruding											
Rolling	331420a	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	8	11	1,086	$24,370,147	$136,146,071	$97,872,075
Drawing	331420c	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	32	45	3,597	$24,370,147	$136,146,071	$97,872,075
Stamping, Spring, and Connector Manufacturing											
Springs	332613	Spring Manufacturing	334	392	14,829	252	296	2,166	$3,751,288	$11,231,400	$9,569,611

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Stamping	332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	1,417	1,499	53,018	68	72	508	$12,329,183	$8,700,906	$8,224,939
Stamping	334417	Electronic Connector Manufacturing	195	234	21,132	39	47	328	$5,940,257	$30,462,858	$25,385,715
Stamping	336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	135	148	1,037	$21,336,550	$34,525,161	$31,469,837
Dental Laboratories											
Dental Labs – Substituting *	339116a	Dental Laboratories	4,900	5,114	33,073	1,225	1,278	5,954	$3,604,997	$735,751	$704,996
Dental Labs – Substituting *	621210a	Offices of Dentists	93,863	99,830	654,879	172	183	851	$81,961,314	$873,199	$821,007
Dental Labs – Non-Substituting **	339116b	Dental Laboratories	1,633	1,705	11,024	408	426	1,985	$1,201,666	$735,751	$704,996

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Dental Labs – Non-Substituting **	621210b	Offices of Dentists	31,288	33,277	218,293	57	61	284	$27,320,438	$873,199	$821,007
Arc and Gas Welding											
Welding GI	331110a	Iron and Steel Mills and Ferroalloy Manufacturing	414	562	105,309	5	6	24	$118,135,862	$285,352,323	$210,206,160
Welding GI	331221	Rolled Steel Shape Manufacturing	150	167	7,836	1	2	6	$6,250,961	$41,673,076	$37,430,907
Welding GI	331513	Steel Foundries (except Investment)	194	208	18,236	1	1	5	$4,733,402	$24,398,978	$22,756,739
Welding GI	332117	Powder Metallurgy Part Manufacturing	121	133	8,160	1	1	3	$2,111,591	$17,451,166	$15,876,625
Welding GI	332216	Saw Blade and Handtool Manufacturing	935	1,012	27,852	3	3	13	$7,043,067	$7,532,692	$6,959,553
Welding GI	332312	Fabricated Structural Metal Manufacturing	2,823	3,099	87,722	49	54	216	$27,839,554	$9,861,691	$8,983,399
Welding GI	332313	Plate Work Manufacturing	1,211	1,245	34,225	21	22	87	$7,461,246	$6,161,227	$5,992,968

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Welding GI	332322	Sheet Metal Work Manufacturing	3,830	4,099	98,201	67	71	286	$20,892,732	$5,455,021	$5,097,031
Welding GI	332323	Ornamental and Architectural Metal Work Manufacturing	2,175	2,214	29,694	38	39	154	$6,058,633	$2,785,578	$2,736,510
Welding GI	332439	Other Metal Container Manufacturing	298	346	11,749	5	6	24	$3,885,743	$13,039,407	$11,230,472
Welding GI	332919	Other Metal Valve and Pipe Fitting Manufacturing	224	243	14,260	3	3	12	$5,062,721	$22,601,434	$20,834,244
Welding GI	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	3,483	3,553	70,118	38	38	153	$15,415,053	$4,425,798	$4,338,602
Welding GI	333111a	Farm Machinery and Equipment Manufacturing	1,048	1,124	65,302	19	20	82	$42,075,186	$40,148,079	$37,433,440
Welding GI	333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	441	472	17,959	4	4	18	$5,535,698	$12,552,603	$11,728,174

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Welding GI	333911	Pump and Pumping Equipment Manufacturing	441	539	33,772	6	7	27	$15,903,209	$36,061,699	$29,505,027
Welding GI	333922	Conveyor and Conveying Equipment Manufacturing	751	799	31,725	10	10	41	$8,945,712	$11,911,734	$11,196,135
Welding GI	333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	340	360	22,389	4	5	18	$11,772,772	$34,625,801	$32,702,145
Welding GI	333999	All Other Miscellaneous General Purpose Machinery Manufacturing	1,590	1,654	51,495	20	21	84	$15,726,526	$9,890,897	$9,508,178
Welding GI	336211	Motor Vehicle Body Manufacturing	656	741	40,544	13	15	60	$11,773,922	$17,948,052	$15,889,234
Welding GI	336214	Travel Trailer and Camper Manufacturing	571	663	39,267	12	13	54	$10,544,247	$18,466,282	$15,903,842
Welding GI	336390a	Other Motor Vehicle Parts Manufacturing	1,302	1,508	122,041	5	6	25	$60,628,177	$46,565,420	$40,204,361

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Welding GI	336510a	Railroad Rolling Stock Manufacturing	164	234	29,173	2	3	13	$17,944,334	$109,416,67 1	$76,685,188
Welding GI	336999	All Other Transportation Equipment Manufacturing	387	397	13,327	3	3	12	$7,731,109	$19,977,027	$19,473,827
Welding GI	337215	Showcase, Partition, Shelving, and Locker Manufacturing	1,042	1,097	33,437	2	2	10	$6,809,534	$6,535,062	$6,207,415
Welding GI	811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	19,661	21,347	193,427	136	147	589	$34,529,038	$1,756,220	$1,617,512
Resistance Welding											

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Resistance Welding	333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	414	491	24,138	17	20	428	$6,278,849	$15,166,303	$12,787,881
Resistance Welding	333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	729	878	84,823	29	35	766	$31,852,834	$43,693,874	$36,278,855
Resistance Welding	335210	Small Electrical Appliance Manufacturing	119	127	8,216	6	6	138	$3,560,517	$29,920,308	$28,035,564
Resistance Welding	335221	Household Cooking Appliance Manufacturing	95	98	10,408	5	5	107	$4,674,297	$49,203,131	$47,696,913

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Resistance Welding	335222	Household Refrigerator and Home Freezer Manufacturing	23	30	9,374	1	2	33	$3,686,247	$160,271,594	$122,874,888
Resistance Welding	335224	Household Laundry Equipment Manufacturing	8	9	1,994	0	0	10	$951,577	$118,947,187	$105,730,833
Resistance Welding	335228	Other Major Household Appliance Manufacturing	30	36	9,059	2	2	39	$4,710,323	$157,010,751	$130,842,293
Resistance Welding	336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	788	849	52,752	39	42	925	$33,235,797	$42,177,407	$39,146,993
Resistance Welding	336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	31	34	739	$21,336,550	$34,525,161	$31,469,837
Resistance Welding	336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	210	245	28,663	11	12	267	$12,290,261	$58,525,051	$50,164,329

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Resistance Welding	336340	Motor Vehicle Brake System Manufacturing	156	195	21,859	8	10	213	$10,467,412	$67,098,794	$53,679,036
Resistance Welding	336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	424	503	58,248	21	25	548	$35,792,318	$84,415,844	$71,157,690
Resistance Welding	336360	Motor Vehicle Seating and Interior Trim Manufacturing	302	398	47,010	15	20	434	$23,631,348	$78,249,498	$59,375,247
Resistance Welding	336370	Motor Vehicle Metal Stamping	645	773	81,018	32	39	843	$32,802,040	$50,855,876	$42,434,722
Resistance Welding	333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	441	472	17,959	18	19	412	$5,535,698	$12,552,603	$11,728,174
Resistance Welding	336390b	Other Motor Vehicle Parts Manufacturing	1,302	1,508	122,041	65	75	1,644	$60,628,177	$46,565,420	$40,204,361
Aluminum Production											
Aluminum Production	331313	Alumina Refining and Primary Aluminum Production	3	8	5,433	2	6	859	$370,719	$123,573,107	$46,339,915
Coal Fired Utilities											

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Coal Fired Utilities	221112	Fossil Fuel Electric Power Generation	456	2,716	142,164	70	418	10,534	$167,481,521	$367,284,037	$61,664,772
Coal Fired Utilities	311221	Wet Corn Milling	31	63	6,687	6	12	338	$12,894,946	$415,965,994	$204,681,680
Coal Fired Utilities	311313	Beet Sugar Manufacturing	15	31	5,790	7	14	395	$4,822,174	$321,478,252	$155,553,993
Coal Fired Utilities	311942	Spice and Extract Manufacturing	344	383	17,101	2	2	56	$9,644,849	$28,037,353	$25,182,374
Coal Fired Utilities	312120	Breweries	843	880	27,740	2	2	56	$29,912,097	$35,482,914	$33,991,019
Coal Fired Utilities	321219	Reconstituted Wood Product Manufacturing	149	219	13,423	1	1	28	$6,708,744	$45,025,125	$30,633,533
Coal Fired Utilities	322110	Pulp Mills	33	42	8,678	1	1	28	$6,842,997	$207,363,540	$162,928,496
Coal Fired Utilities	322121	Paper (except Newsprint) Mills	125	209	60,053	7	11	310	$45,144,793	$361,158,345	$216,003,795
Coal Fired Utilities	322122	Newsprint Mills	17	20	4,398	20	24	677	$3,218,103	$189,300,167	$160,905,142
Coal Fired Utilities	322130	Paperboard Mills	82	177	35,545	7	16	451	$29,706,665	$362,276,407	$167,834,268
Coal Fired Utilities	325211	Plastics Material and Resin Manufacturing	899	1,161	69,352	3	4	113	$97,687,597	$108,662,511	$84,140,910

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Coal Fired Utilities	325611	Soap and Other Detergent Manufacturing	615	664	23,229	1	1	28	$28,371,519	$46,132,552	$42,728,192
Coal Fired Utilities	327310	Cement Manufacturing	122	240	12,617	1	2	56	$6,246,422	$51,200,178	$26,026,757
Coal Fired Utilities	333111b	Farm Machinery and Equipment Manufacturing	1,048	1,124	65,302	1	1	28	$42,075,186	$40,148,079	$37,433,440
Coal Fired Utilities	336510b	Railroad Rolling Stock Manufacturing	164	234	29,173	1	1	28	$17,944,334	$109,416,67 1	$76,685,188
Coal Fired Utilities	611310	Colleges, Universities, and Professional Schools	2,282	4,329	1,805,199	5	9	254	$232,517,218	$101,891,85 7	$53,711,531
Abrasive Blasting - Construction											
Abrasive Blasting - Constructio n	238320	Painting and Wall Covering Contractors	31,317	31,376	163,073	1,088	1,090	4,360	$19,595,278	$625,707	$624,531
Abrasive Blasting - Constructio n	238990	All Other Specialty Trade Contractors	28,734	29,072	193,631	998	1,010	4,040	$39,396,242	$1,371,067	$1,355,127
Abrasive Blasting Shipyards***											

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Abrasive Blasting - Shipyards	336611a	Ship Building and Repairing	604	689	108,311	604	689	3,825	$26,136,187	$43,271,832	$37,933,508
Welding in Shipyards****											
Welding in Shipyards	336611b	Ship Building and Repairing	604	689	108,311	6	7	26	$26,136,187	$43,271,832	$37,933,508
Total											
General Industry Subtotal			206,928	226,165	5,877,434	3,869	4,538	50,261	$1,931,626,954	$9,334,778	$8,540,786
Construction Subtotal			60,051	60,448	356,704	2,086	2,100	8,400	$58,991,519	$982,357	$975,905
Maritime Subtotal			1,208	1,378	216,622	610	696	3,086	$52,272,373	$43,271,832	$37,933,508
Total, All Industries			268,187	287,991	6,450,760	6,565	7,333	61,747	$2,042,890,847	$7,617,412	$7,093,593

[a] US Census Bureau, Statistics of US Businesses: 2012.

[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. Within each NAICS industry, the number of affected entities was calculated as the product of total number of entities for that industry and the ratio of the number of affected establishments to the number of total establishments.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

*** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

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

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (µg/m³)										
Application Group/ NAICS	Industry	Exposure Level (µg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
Beryllium Oxide - Primary										
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	9	9	15	6	32	7	3	2	83
Beryllium Oxide - Secondary										
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	41	41	16	2	11	5	2	1	120
334310	Audio and Video Equipment Manufacturing	21	21	8	1	6	3	1	1	60
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	50	50	19	3	13	7	2	1	144
334419	Other Electronic Component Manufacturing	124	124	47	7	34	16	5	4	360
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	37	37	14	2	10	5	1	1	108

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)										
Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	58	58	22	3	16	8	2	2	168
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	41	41	16	2	11	5	2	1	120
Beryllium Production										
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	183	183	85	12	62	39	25	28	616
Dental Labs Substituting*										
339116a	Dental Laboratories	216	216	1,726	173	863	1,381	345	1,035	5,954
621210a	Offices of Dentists	31	31	247	25	123	197	49	148	851
Dental Labs – Non-Substituting**										
339116a	Dental Laboratories	992	992	0	0	0	0	0	0	1,985
621210a	Offices of Dentists	142	142	0	0	0	0	0	0	284
Drawing										
331420c	Copper Rolling, Drawing, Extruding, and Alloying	1,447	1,447	327	40	201	41	41	52	3,597
Machining - High										

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)										
Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
332721a	Precision Turned Product Manufacturing	20	20	34	21	106	44	20	24	289
Machining - Low										
332721b	Precision Turned Product Manufacturing	1,699	1,699	518	58	288	115	58	173	4,607
Non Sand Foundries										
331523	Nonferrous Metal Die-Casting Foundries	17	17	183	45	224	159	49	128	822
331524	Aluminum Foundries (except Die-Casting)	2	2	27	7	33	23	7	19	120
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	6	6	68	17	83	59	18	47	304
Rolling										
331420a	Copper Rolling, Drawing, Extruding, and Alloying	512	512	42	3	14	4	0	0	1,086
Sand Foundries										
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	8	8	85	21	104	74	72	59	430
Smelting - Beryllium Alloys										

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (µg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (µg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
331314	Secondary Smelting and Alloying of Aluminum	0	0	2	0	0	0	2	5	9
331420b	Copper Rolling, Drawing, Extruding, and Alloying	2	2	9	0	0	0	6	18	36
Smelting - Precious Metals										
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	60	60	60	15	75	0	0	0	270
Springs										
332613	Spring Manufacturing	986	986	117	13	64	0	0	0	2,166
Stamping										
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	224	224	13	8	39	0	0	0	508
334417	Electronic Connector Manufacturing	145	145	9	5	25	0	0	0	328
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	457	457	27	16	79	0	0	0	1,037

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range ($\mu g/m^3$) (continued)										
Application Group/ NAICS	Industry	Exposure Level ($\mu g/m^3$)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
Welding - Arc and Gas										
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	7	7	3	1	3	3	0	1	24
331221	Rolled Steel Shape Manufacturing	2	2	1	0	1	1	0	0	6
331513	Steel Foundries (except Investment)	1	1	1	0	1	1	0	0	5
332117	Powder Metallurgy Part Manufacturing	1	1	0	0	0	0	0	0	3
332216	Saw Blade and Handtool Manufacturing	4	4	2	0	2	1	0	0	13
332312	Fabricated Structural Metal Manufacturing	61	61	29	6	29	23	0	6	216
332313	Plate Work Manufacturing	25	25	12	2	12	9	0	2	87
332322	Sheet Metal Work Manufacturing	81	81	39	8	39	31	0	8	286
332323	Ornamental and Architectural Metal Work Manufacturing	44	44	21	4	21	17	0	4	154
332439	Other Metal Container Manufacturing	7	7	3	1	3	3	0	1	24

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (µg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (µg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
332919	Other Metal Valve and Pipe Fitting Manufacturing	3	3	2	0	2	1	0	0	12
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	44	44	21	4	21	17	0	4	153
333111a	Farm Machinery and Equipment Manufacturing	23	23	11	2	11	9	0	2	82
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	5	5	2	0	2	2	0	0	18
333911	Pump and Pumping Equipment Manufacturing	8	8	4	1	4	3	0	1	27
333922	Conveyor and Conveying Equipment Manufacturing	12	12	5	1	5	4	0	1	41
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	5	5	2	0	2	2	0	0	18

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m^3) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m^3)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	24	24	11	2	11	9	0	2	84
336211	Motor Vehicle Body Manufacturing	17	17	8	2	8	7	0	2	60
336214	Travel Trailer and Camper Manufacturing	15	15	7	1	7	6	0	1	54
336390a	Other Motor Vehicle Parts Manufacturing	7	7	3	1	3	3	0	1	25
336510a	Railroad Rolling Stock Manufacturing	4	4	2	0	2	1	0	0	13
336999	All Other Transportation Equipment Manufacturing	3	3	2	0	2	1	0	0	12
337215	Showcase, Partition, Shelving, and Locker Manufacturing	3	3	1	0	1	1	0	0	10

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)										
Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	167	167	80	16	80	64	0	16	589
Welding - Resistance Welding										
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	214	214	0	0	0	0	0	0	428
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	383	383	0	0	0	0	0	0	766
335210	Small Electrical Appliance Manufacturing	69	69	0	0	0	0	0	0	138
335221	Household Cooking Appliance Manufacturing	53	53	0	0	0	0	0	0	107

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range ($\mu g/m^3$) (continued)										
Application Group/ NAICS	Industry	Exposure Level ($\mu g/m^3$)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
335222	Household Refrigerator and Home Freezer Manufacturing	16	16	0	0	0	0	0	0	33
335224	Household Laundry Equipment Manufacturing	5	5	0	0	0	0	0	0	10
335228	Other Major Household Appliance Manufacturing	20	20	0	0	0	0	0	0	39
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	463	463	0	0	0	0	0	0	925
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	370	370	0	0	0	0	0	0	739
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	134	134	0	0	0	0	0	0	267
336340	Motor Vehicle Brake System Manufacturing	106	106	0	0	0	0	0	0	213

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)										
Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	274	274	0	0	0	0	0	0	548
336360	Motor Vehicle Seating and Interior Trim Manufacturing	217	217	0	0	0	0	0	0	434
336370	Motor Vehicle Metal Stamping	421	421	0	0	0	0	0	0	843
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	206	206	0	0	0	0	0	0	412
336390b	Other Motor Vehicle Parts Manufacturing	822	822	0	0	0	0	0	0	1,644
Aluminum Production										
331313	Alumina Refining and Primary Aluminum Production	322	322	77	9	43	34	34	17	859
Coal Fired Utilities										
221112	Fossil Fuel Electric Power Generation w/o Objective Data	3,950	3,950	2,633	0	0	0	0	0	10,534
311221	Wet Corn Milling	127	127	85	0	0	0	0	0	338
311313	Beet Sugar Manufacturing	148	148	99	0	0	0	0	0	395

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
311942	Spice and Extract Manufacturing	21	21	14	0	0	0	0	0	56
312120	Breweries	21	21	14	0	0	0	0	0	56
321219	Reconstituted Wood Product Manufacturing	11	11	7	0	0	0	0	0	28
322110	Pulp Mills	11	11	7	0	0	0	0	0	28
322121	Paper (except Newsprint) Mills	116	116	78	0	0	0	0	0	310
322122	Newsprint Mills	254	254	169	0	0	0	0	0	677
322130	Paperboard Mills	169	169	113	0	0	0	0	0	451
325211	Plastics Material and Resin Manufacturing	42	42	28	0	0	0	0	0	113
325611	Soap and Other Detergent Manufacturing	11	11	7	0	0	0	0	0	28
327310	Cement Manufacturing	21	21	14	0	0	0	0	0	56
333111b	Farm Machinery and Equipment Manufacturing	11	11	7	0	0	0	0	0	28
336510b	Railroad Rolling Stock Manufacturing	11	11	7	0	0	0	0	0	28
611310	Colleges, Universities, and Professional Schools	95	95	63	0	0	0	0	0	254
Abrasive Blasting - Construction										

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
238320	Painting and Wall Covering Contractors	1,046	1,046	1,443	43	216	82	123	359	4,360
238990	All Other Specialty Trade Contractors	970	970	1,337	40	200	76	114	333	4,040
Abrasive Blasting Shipyards***										
336611a	Ship Building and Repairing	734	734	1,013	30	152	58	87	252	3,060
Welding in Shipyards****										
336611b	Ship Building and Repairing	7	7	4	1	4	3	0	1	26
Total										
General Industry Subtotal		**17,222**	**17,222**	**7,428**	**568**	**2,842**	**2,445**	**736**	**1,798**	**50,261**
Construction Subtotal		**2,016**	**2,016**	**2,781**	**83**	**416**	**159**	**238**	**692**	**8,400**
Maritime Subtotal		**742**	**742**	**1,017**	**31**	**155**	**61**	**87**	**253**	**3,086**
Total, All Industries		**19,979**	**19,979**	**11,225**	**683**	**3,413**	**2,665**	**1,060**	**2,742**	**61,747**

Note: Data may not sum to totals due to rounding.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Sources: US DOL OSHA, Directorate of Standards and Guidance, Office of Technological Feasibility.

D. Technological Feasibility of the Final Standard on Occupational Exposure to Beryllium

The OSH Act requires OSHA to demonstrate that a proposed health standard is technologically feasible (29 U.S.C. 655(b)(5)). As described in the preamble to the final rule (see Section II, Pertinent Legal Authority), technological feasibility has been interpreted broadly to mean ''capable of being done'' (*Am. Textile Mfrs. Inst.* v. *Donovan*, 452 U.S. 490, 509–510 (1981) (''Cotton Dust'')). A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed, *i.e.,* technology that ''looms on today's horizon'' (*United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1980) (''Lead I''); *Amer. Iron & Steel Inst.* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) (''Lead II''); *AFL–CIO* v. *Brennan*, 530 F.2 109, 121 (3rd Cir. 1975)). Courts have also interpreted technological feasibility to mean that, for health standards, a typical firm in each affected industry will reasonably be able to implement engineering and work practice controls that can reduce workers' exposures to meet the permissible exposure limit in most operations most of the time, without reliance on respiratory protection (see Lead I, 647 F.2d at 1272; Lead II, 939 F.2d at 990).

OSHA's technological feasibility analysis is presented in Chapter IV of the FEA. The technological feasibility analysis identifies the affected industries and application groups in which employees can reasonably be expected to be exposed to beryllium, summarizes the available air sampling data used to develop employee exposure profiles, and provides descriptions of engineering controls and other measures employers can take to reduce their employees' exposures to beryllium. For each affected industry sector or application group, OSHA provides an assessment of the technological feasibility of compliance with the final permissible exposure limit (PEL) of 0.2 μg/m^3 as an 8-hour TWA and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m^3.

The technological feasibility analysis covers twelve application groups that correspond to specific industries or production processes that involve the potential for occupational exposures to materials containing beryllium and that OSHA has determined fall within the scope of this final beryllium standard. Within each of these application groups, exposure profiles have been developed to characterize the distribution of the available exposure measurements by job title or group of jobs. Each section includes descriptions of existing, or baseline, engineering controls for operations that generate beryllium exposure. For those job groups in which current exposures were found to exceed the final PEL, OSHA identifies and describes additional engineering and work practice controls that can be implemented to reduce exposure and achieve compliance with the final PEL. For each application group or industry, a final determination is made regarding the technological feasibility of achieving the proposed permissible exposure limits based on the use of engineering and work practice controls and without reliance on the use of respiratory protection. The determination is made based on the legal standard of whether the PEL can be achieved for most operations most of the time using such controls. In a separate chapter on short-term exposures, OSHA also analyzes the feasibility of achieving compliance with the Short-Term Exposure Limit (STEL).

The analysis is based on the best evidence currently available to OSHA, 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)), and inspection data from OSHA's Integrated Management Information System (IMIS) and OSHA's Information System (OIS). OSHA also obtained information on beryllium production processes, worker exposures, and the effectiveness of existing control measures from Materion Corporation, the primary beryllium producer in the United States, interviews with industry experts, and comments submitted to the rulemaking docket in response to the Notice of Proposed Rulemaking and informal public hearings. All of this evidence is in the rulemaking record.

The twelve application groups are:

- Primary Beryllium Production,
- Beryllium Oxide Ceramics and Composites,
- Nonferrous Foundries,
- Secondary Smelting, Refining, and Alloying, Including Handling of Scrap and Recycled Materials,
- Precision Turned Products,
- Copper Rolling, Drawing, and Extruding,
- Fabrication of Beryllium Alloy Products,
- Welding,
- Dental Laboratories,
- Abrasive Blasting,
- Coal-Fired Electric Power Generation,
- Aluminum Production

For discussion purposes, the twelve application groups are divided into four general categories based on the distribution of exposures in the exposure profiles: (1) Application groups in which baseline exposures for most jobs are already at or below the final PEL of 0.2 μg/m^3; (2) application groups in which baseline exposures for one or more jobs exceed the final PEL of 0.2 μg/m^3, but additional controls have been identified that could achieve exposures at or below the final PEL for most of the operations most of the time; (3) application groups in which exposures in one or more jobs routinely exceed the preceding PEL of 2.0 μg/m^3, and therefore substantial reductions in exposure would be required to achieve the final PEL; and (4) application groups in which exposure to beryllium occurs due to trace levels of beryllium found in dust or fumes that nonetheless can result in exposures that exceed 0.1 μg/m^3 as an 8-hour TWA under foreseeable conditions.

The application groups in category 1, where exposures for most jobs are already at or below the final PEL of 0.2 μg/m^3, typically handle beryllium alloys containing a low percentage of beryllium (<2 percent) using processes that do not result in significant airborne exposures. These four application groups are (1) copper rolling, drawing, and extruding; (2) fabrication of beryllium alloy products; (3) welding; and (4) aluminum production. The handling of beryllium alloys in solid form is not expected to result in exposures of concern. For example, beryllium alloys used in copper rolling, drawing, and extruding typically contain 2 percent beryllium by weight or less (Document ID 0081, Attachment 1). One facility noted that the copper-beryllium alloys it used contained as little as 0.1 percent beryllium (Document ID 0081, Attachment 1). These processes, such as rolling operations that consist of passing beryllium alloys through a rolling press to conform to a desired thickness, tend to produce less particulate and fume than high energy processes. Exposures can be controlled using containment, exhaust ventilation, and work practices that include rigorous housekeeping. In addition, the heating of metal during welding operations results in the release of fume, but the beryllium in the welding fume accounts for a relatively small percentage of the beryllium exposure. Worker exposure to beryllium during welding activities is largely attributable to flaking oxide scale on the base metal, which can be reduced through chemically stripping or pickling the beryllium alloy piece prior to welding on it, and/or enhancing exhaust ventilation (Corbett, 2006; Kent, 2005; Materion Information Meeting, 2012).

For application groups in category 2, where baseline exposures for one or more jobs exceed the final PEL of 0.2 μg/m^3, but additional controls have been identified that could achieve exposures at or below the final PEL for most of the operations most of the time, workers may encounter higher content beryllium (20 percent or more by weight), or higher temperature processes (Document ID 1662, p. 4.) The application groups in the second category are: (1) Precision turned products and (2) secondary smelting, refining, and alloying. While the median exposures for most jobs in these groups are below the preceding PEL of 2.0 μg/m^3, the median exposures for some jobs in these application groups exceed the final PEL of 0.2 μg/m^3 when not adequately controlled. For these application groups, additional exposure controls and work practices will be required to reduce exposures to or below the final PEL for most operations most of the time. For example, personal samples collected at a precision turned products facility that machined pure beryllium metal and high beryllium content materials (40–60 percent) measured exposures on two machinists of 2.9 and 6.6 μg/m3 (ERG Beryllium Site 4, 2003). A second survey at this same facility conducted after an upgrade to the ventilation systems in the mill and lathe departments measured PBZ exposures for these machinists of 1.1 and 2.3 μg/m^3 (ERG Beryllium Site 9, 2004), and it was noted that not all ventilation was optimally positioned, indicating that further reduction in exposure could be achieved. In 2007, the company reported that after the installation of enclosures on milling machines and additional exhaust, average exposures to mill and lathe operators were reduced to below 0.2 μg/m^3 (ICBD, 2007). For secondary smelting operations, several surveys conducted at electronic recycling and precious metal recovery operations indicate that exposures for mechanical processing operators can be controlled to or below 0.2 μg/m^3. However, for furnace operations in secondary smelting, the median value in the exposure profile exceeds the preceding PEL. Furnace operations involve high temperatures that produce significant amounts of fumes and particulate that can be difficult to contain. Therefore, the reduction of 8-hour average exposures to or below the final PEL may not be achievable for most furnace operations involved with secondary smelting of beryllium alloys. In these cases, the supplemental use of respiratory protection for specific job tasks will be needed to adequately protect furnace workers for operations where exposures are found to exceed 0.2 μg/m^3 despite the implementation of all feasible engineering and work practice controls.

The application groups in category 3 include application groups for which the exposure profiles indicate that exposures in one or more jobs routinely exceed the preceding PEL of 2.0 μg/m^3. The three application groups in this category are: (1) Beryllium production, (2) beryllium oxide ceramics production, and (3) nonferrous foundries. For the job groups in which exposures have been found to routinely exceed the preceding PEL, OSHA identifies additional exposure controls and work practices that the Agency has determined can reduce exposures to or below the final PEL, most of the time. For example, OSHA concluded that exposures to beryllium resulting from material transfer, loading, and spray drying of beryllium oxide powders can be reduced to or below 0.2 μg/m3 with process enclosures, ventilation hoods, and diligent housekeeping for material preparation operators working in beryllium oxide ceramics and composites facilities (FEA, Chapter IV–04). However, for furnace operations in primary beryllium production and nonferrous foundries, and shakeout operations at nonferrous foundries, OSHA recognizes that even after installation of feasible controls, supplemental use of respiratory protection may be needed to protect workers adequately (FEA, Chapter IV–03 and IV–05). The evidence in the rulemaking record is insufficient to conclude that these operations would be able to reduce the majority of the exposure to levels below 0.2 μg/m^3 most of the time, and therefore some increased supplemental use of respiratory protection may be required for certain tasks in these jobs.

Category 4 includes application groups that encounter exposure to beryllium due to trace levels found in dust or fumes that nonetheless can exceed 0.1 μg/m^3 as an 8-hour TWA under foreseeable conditions. The application groups in this category are (1) coal-fired power plants in which exposure to beryllium can occur due to trace levels of beryllium in the fly ash during very dusty maintenance operations, such as cleaning the air pollution control devices; (2) aluminum production in which exposure to beryllium can occur due to naturally occurring trace levels of beryllium found in bauxite ores used to make aluminum; and (3) abrasive blasting using coal and copper slag that can contain trace levels of beryllium. Workers who perform abrasive blasting using either coal or copper slag abrasives are potentially exposed to beryllium due to the high total exposure to the blasting media. Due to the very small amounts of beryllium in these materials, the final PEL for beryllium will be exceeded only during operations that generate excessive amount of visible airborne dust, for which engineering controls and respiratory protection are already required. However, the other workers in the general vicinity do not experience these high exposures if proper engineering controls and work practices, such as temporary enclosures and maintaining appropriate distance during the blasting or maintenance activities, are implemented.

During the rulemaking process, OSHA requested and received comments regarding the feasibility of the PEL of 0.2 μg/m^3, as well as the proposed alternative PEL of 0.1 μg/m^3 (80 FR 47565, 47780 (Aug. 7, 2015)). OSHA did this because it recognizes that significant risk of beryllium disease is not eliminated at an exposure level of 0.2 μg/m^3. As discussed below, OSHA finds that the proposed PEL of 0.2 μg/m^3 can be achieved through engineering and work practice controls in most operations most of the time in all the affected industry sectors and application groups, and therefore is feasible for these industries and application groups under the OSH Act. OSHA could not find, however, that the proposed alternative PEL of 0.1 μg/m^3 is also feasible for all of the affected industry sectors and application groups.

The majority of commenters, including stakeholders in labor and industry, public health experts, and the general public, explicitly supported the proposed PEL of 0.2 μg/m^3 (NIOSH, Document ID 1671, Attachment 1, p. 2; National Safety Council, 1612, p. 3; Beryllium Health and Safety Committee Task Group, 1655, p. 2; Newport News Shipbuilding, 1657, p. 1; National Jewish Health (NJH), 1664, p. 2; the Aluminum Association, 1666, p. 1; the Boeing Company, 1667, p. 1; American Industrial Hygiene Association, 1686, p. 2; United Steelworkers (USW), 1681, p. 7; Andrew Brown, 1636, p. 6; Department of Defense, 1684, p. 1). In addition, Materion Corporation, the sole primary beryllium production company in the U.S., and USW, jointly submitted a draft proposed rule that included an exposure limit of 0.2 μg/m³ (Document ID 0754, p. 4). In its written comments, Materion explained that it is feasible to control exposure to levels below 0.2 μg/m³ through the use of engineering controls and work practices in most, but not all, operations:

> Based on many years' experience in controlling beryllium exposures, its vigorous product stewardship program in affected operations, and the judgment of its professional industrial hygiene staff, Materion Brush believes that the 0.2 μg/m³ PEL for beryllium, based on median exposures, can be achieved in most operations, most of the time. Materion Brush does recognize that it is not feasible to reduce exposures to below the PEL in some operations, and in particular, certain beryllium production operations, solely through the use of engineering and work practice controls (Document ID 1052).

On the other hand, the Nonferrous Founders' Society (NFFS) asserted that OSHA had not demonstrated that the final PEL of 0.2 μg/m³ was feasible for the nonferrous foundry industry (Document ID 1678, pp. 2–3). NFFS asserted that ''OSHA has failed to meet its burden of proof that a ten-fold reduction to the current two micrograms per cubic meter limit is technologically or economically feasible in the non-ferrous foundry industry'' (Document ID 1678, pp. 2–3; 1756, Tr. 18). In written testimony submitted as a hearing exhibit, NFFS claimed that OSHA's supporting documentation in the PEA had no ''concrete assurance on technologic feasibility either by demonstration or technical documentation'' (Document ID 1732, Appendix A, p. 4).

However, contrary to the NFFS comments, which are addressed at greater length in Section IV–5 of the FEA, OSHA's exposure profile is based on the best available evidence for nonferrous foundries; the exposure data are taken from NIOSH surveys, an ERG site visit, and the California Cast Metals Association (Document ID 1217; 1185; 0341, Attachment 6; 0899). Materion also submitted substantial amounts of monitoring data, process descriptions and information of engineering controls that have been implemented in its facilities to control beryllium exposure effectively, including operations that involve the production of beryllium alloys using the same types of furnace and casting operations as those conducted at nonferrous foundries producing beryllium alloys (Document ID 0719; 0720; 0723). Furthermore, Materion submitted the above-referenced letter to the docket stating that, based on its many years of experience controlling beryllium exposures, a PEL of 0.2 μg/m³ can be achieved in most operations, most of the time (Document ID 1052). Materion's letter is consistent with the monitoring data Materion submitted, and OSHA considers its statement regarding feasibility at the final PEL relevant to nonferrous foundries because Materion has similar operations in its facilities, such as beryllium alloy production. As stated in Section IV–5 of the FEA, the size and configuration of nonferrous foundries may vary, but they all use similar processes; they melt and pour molten metal into the prepared molds to produce a casting, and remove excess metal and blemishes from the castings (NIOSH 85–116, 1985). While the design may vary, the basic operations and worker job tasks are similar regardless of whether the casting metal contains beryllium.

In the NPRM, OSHA requested that affected industries submit to the record any available exposure monitoring data and comments regarding the effectiveness of currently implemented control measures to inform the Agency's final feasibility determinations. During the informal public hearings, OSHA asked the NFFS panel to provide information on current engineering controls or the personal protective equipment used in foundries claiming to have difficulty complying with the preceding PEL, but no additional information was provided (Document ID 1756; Tr. 24–25; 1785, p. 1). Thus, the NFFS did not provide any sampling data or other evidence regarding current exposure levels or existing control measures to support its assertion that a PEL of 0.2 μg/m³ is not feasible, and did not show that the data in the record are insufficient to demonstrate technological feasibility for nonferrous foundry industry.

In sum, while OSHA agrees that two of the operations in the nonferrous foundry industry, furnace and shakeout operations, employing a relatively small percentage of workers in the industry, may not be able to achieve the final PEL of 0.2 μg/m³ most of the time, evidence in the record indicates that the final PEL is achievable in the other six job categories in this industry. Therefore, in the FEA, OSHA finds the PEL of 0.2 μg/m³ is technologically feasible for the nonferrous foundry industry.

OSHA also recognizes that engineering and work practice controls may not be able to consistently reduce and maintain exposures to the final PEL of 0.2 μg/m³ in some job categories in other application groups, due to the processing of materials containing high concentrations of beryllium, which can result in the generation of substantial amounts of fumes and particulate. For example, the final PEL of 0.2 μg/m³ cannot be achieved most of the time for furnace operations in primary beryllium production and for some furnace operation activities in secondary smelting, refining, and alloying facilities engaged in beryllium recovery and alloying. Workers may need supplementary respiratory protection during these high exposure activities where exposures exceed the final PEL of 0.2 μg/m³ or STEL of 2.0 μg/m³ with engineering and work practice controls. In addition, OSHA has determined that workers who perform open-air abrasive blasting using mineral grit (*i.e.,* coal slag) will routinely be exposed to levels above the final PEL (even after the installation of feasible engineering and work practice controls), and therefore, these workers will also be required to wear respiratory protection.

Overall, however, based on the information discussed above and the other evidence in the record and described in Chapter IV of the FEA, OSHA has determined that for the majority of the job groups evaluated exposures are either already at or below the final PEL, or can be adequately controlled to levels below the final PEL through the implementation of additional engineering and work practice controls for most operations most of the time. Therefore, OSHA concludes that the final PEL of 0.2 μg/m³ is technologically feasible.

In contrast, the record evidence does not show that it is feasible for most operations in all affected industries and application groups to achieve the alternative PEL of 0.1 μg/m³ most of the time. As discussed below, although a number of operations can achieve this level, they may be interspersed with operations that cannot, and OSHA sees value in having a uniform PEL that can be enforced consistently for all operations, rather than enforcing different PELs for the same contaminant in different operations.

Several commenters supported a PEL of 0.1 μg/m³. Specifically, Public Citizen; the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO); the International Union, United Automobile, Aerospace, and Agriculture Implement Workers of America (UAW); North America's Building Trades Unions (NABTU); and the American College of Occupational and Environmental Medicine contended that OSHA should adopt this lower level because of the residual risk at 0.2 μg/m³

(Document ID 1689, p. 7; 1693, p. 3; 1670, p. 1; 1679, pp. 6–7; 1685, p. 1; 1756, Tr. 167). Two of these commenters, Public Citizen and the AFL–CIO, also contended that a TWA PEL of 0.1 μg/m3 is feasible (Document ID 1756, Tr. 168–169, 197–198). Neither of those commenters, however, submitted any additional evidence to the record that OSHA could rely on to conclude that a PEL of 0.1 μg/m³ is achievable.

On the other hand, the Beryllium Health and Safety Committee and NJH specifically rejected a PEL of 0.1 μg/m³ in their comments. They explained that they believed the proposed PEL of 0.2 μg/m³ and the ancillary provisions would reduce the prevalence of beryllium sensitization and chronic beryllium disease (CBD) and be the best overall combination for protecting workers when taking into consideration the analytical chemistry capabilities and economic considerations (Document ID 1655, p. 16; 1664, p. 2).

Based on the record evidence, OSHA cannot conclude that the alternative PEL of 0.1 μg/m³ is achievable most of the time for at least one job category in 8 of the 12 application groups or industries included in this analysis: Primary beryllium production; beryllium oxide ceramics and composites; nonferrous foundries; secondary smelting, refining, and alloying, including handling of scrap and recycled materials; precision turned products; dental laboratories; abrasive blasting; and coal-fired electric power generation. In general, OSHA's review of the available sampling data indicates that the alternative PEL of 0.1 μg/m³ cannot be consistently achieved with engineering and work practice controls in application groups that use materials containing high percentages of beryllium or that involve processes that result in the generation of substantial amounts of fumes and particulate. Variability in processes and materials for operations involving the heating or machining of beryllium alloys or beryllium oxide ceramics also makes it difficult to conclude that exposures can be routinely reduced to below 0.1 μg/m³. For example, in the precision turned products industry, OSHA has concluded that exposures for machinists machining pure beryllium or high beryllium alloys can be reduced to or below 0.2 μg/m³, but not 0.1 μg/m³. Additionally, OSHA has determined that job categories that involve high-energy operations will not be able to consistently achieve 0.1 μg/m³ (*e.g.,* abrasive blasting with coal slag in open-air). These operations can cause workers to have elevated exposures even when available engineering and work practice controls are used.

In other cases, paucity of data or other data issues prevent OSHA from determining whether engineering and work practice controls can reduce exposures to or below 0.1 μg/m³ most of the time (see Chapter IV of the FEA). A large portion of the sample results obtained by OSHA for the dental laboratories industry and for two of the job categories in the coal-fired electric power generation industry (operations workers and routine maintenance workers) were below the reported limit of detection (LOD). Because the LODs for many of these samples were higher than 0.1 μg/m³, OSHA could not assess whether exposures were below 0.1 μg/m³. For example, studies of dental laboratories showed that use of well-controlled ventilation can consistently reduce exposures to below the LOD of 0.2 μg/m³. However, without additional information, OSHA cannot conclude that exposures can be reduced to or below 0.1 μg/m³ most of the time. Therefore, OSHA cannot determine if a PEL of 0.1 μg/m³ would be feasible for the dental laboratory industry.

The lack of available data has also prevented OSHA from determining whether exposures at or below of 0.1 μg/m³ can be consistently achieved for machining operators in the beryllium oxide ceramics and composites industry. As discussed in Section IV–4 of the FEA, the exposure profile for dry (green) machining and lapping and plate polishing (two tasks within the machining operator job category) is based on 240 full-shift PBZ samples obtained over a 10-year period (1994 to 2003). The median exposure levels in the exposure profile for green machining and lapping and polishing are 0.16 μg/m³ and 0.29 μg/m³, respectively. While the record indicates that improvements in exposure controls were implemented over time (Frigon, 2005, Document ID 0825; Frigon, 2004 (Document ID 0826)), data showing to what extent exposures have been reduced are not available. Nonetheless, because the median exposures for green machining are already below 0.2 μg/m³, and the median exposures for lapping and polishing are only slightly above the PEL of 0.2 μg/m³, OSHA concluded that the controls that have been implemented are sufficient to reduce exposures to at or below 0.2 μg/m³ most of the time. However, without additional information, OSHA cannot conclude that exposures could be reduced to or below 0.1 μg/m³ most of the time for these tasks.

Most importantly for this analysis, the available evidence demonstrates that the alternative PEL of 0.1 μg/m³ is not achievable in five out of the eight job categories in the nonferrous foundries industry: Furnace operator, shakeout operator, pouring operator, material handler, and molder. As noted above, the first two of these job categories, furnace operator and shakeout operator, which together employ only a small fraction of the workers in this industry, cannot achieve the final PEL of 0.2 μg/m³ either, but evidence in the record demonstrates that nonferrous foundries can reduce the exposures of most of the rest of the workers in the other six job categories to or below the final PEL of 0.2 μg/m³, most of the time. However, OSHA's feasibility determination for the pouring operator, material handler, and molder job categories, which together employ more than half the workers at these foundries, does not allow the Agency to conclude that exposures for those jobs can be consistently lowered to the alternative PEL of 0.1 μg/m³. See Section IV–5 of the FEA. Thus, OSHA cannot conclude that most operations in the nonferrous foundries industry can achieve a PEL of 0.1 μg/m³, most of the time. Accordingly, OSHA finds that the alternative PEL of 0.1 μg/m³ is not feasible for the nonferrous foundries industry.

OSHA has also determined either that information in the rulemaking record demonstrates that 0.1 μg/m³ is not consistently achievable in a number of operations in other affected industries or that the information is insufficient to establish that engineering and work practice controls can consistently reduce exposures to or below 0.1 μg/m³. Therefore, OSHA finds that the proposed alternative PEL of 0.1 μg/m³ is not appropriate, and the rule's final PEL of 0.2 μg/m³ is the lowest exposure limit that can be found to be technologically feasible through engineering and work practice controls in all of the affected industries and application groups included in this analysis.

Because of this inability to achieve 0.1 μg/m³ in many operations, if OSHA were to adopt a PEL of 0.1 μg/m³, a substantial number of employees would be required to wear respirators. As discussed in the Summary and Explanation for paragraph (f), Methods of Compliance, use of respirators in the workplace presents a number of independent safety and health concerns. Workers wearing respirators may experience diminished vision, and respirators can impair the ability of employees to communicate with one another. Respirators can impose physiological burdens on employees due to the weight of the respirator and increased breathing resistance experienced during operation. The level of physical work effort required, the use of protective clothing, and environmental factors such as temperature extremes and high humidity can interact with respirator use to increase the physiological strain on employees. Inability to cope with this strain as a result of medical conditions such as cardiovascular and respiratory diseases, reduced pulmonary function, neurological or musculoskeletal disorders, impaired sensory function, or psychological conditions can place employees at increased risk of illness, injury, and even death. The widespread, routine use of respirators for extended periods of time that may be required by a PEL of 0.1 μg/m³ creates more significant concerns than the less frequent respirator usage that is required by a PEL of 0.2 μg/m³.

Furthermore, OSHA concludes that it would complicate both compliance and enforcement of the rule if it were to set a PEL of 0.1 μg/m³ for some industries or operations and a PEL of 0.2 μg/m³ for the remaining industries and operations where technological feasibility at the lower PEL is either unattainable or unknown. OSHA may exercise discretion to issue a uniform PEL if it determines that the PEL is technologically feasible for all affected industries (if not for all affected operations) and that a uniform PEL would constitute better public policy. See Pertinent Legal Authority (discussing the Chromium decision). In declining to lower the PEL to 0.1 μg/m³ for any segment of the affected industries, OSHA has made that determination here. Therefore, OSHA has determined that the proposed alternative PEL of 0.1 μg/m³ is not appropriate.

OSHA also evaluated the technological feasibility of the final STEL of 2.0 μg/m³ and the alternative STEL of 1.0 μg/m³. An analysis of the available short-term exposure measurements presented in Chapter IV, Section 15 of the FEA 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 exposures can also occur during the transfer and handling of beryllium oxide powders. OSHA finds that in many cases, the control of peak short-term exposures associated with these intermittent tasks will be necessary to reduce workers' TWA exposures to or below the final PEL. The short-term exposure data presented in the FEA show that the majority (79%) of these exposures are already below 2.0 μg/m³.

A number of stakeholders submitted comments related to the proposed and alternative STELs. Some of these stakeholders supported a STEL of 2.0 μg/m³. Materion stated that a STEL of 2.0 μg/m³ for controlling the upper range of worker short term exposures is sufficient to prevent CBD (Document ID 1661, p. 3). Other commenters recommended a STEL of 1.0 μg/m³ (Document ID 1661, p. 19; 1681, p. 7). However, no additional engineering controls capable of reducing short term exposures to at or below 1.0 μg/m³ were identified by these commenters. OSHA provides a full discussion of the public comments in the Summary and Explanation section of this preamble. OSHA has determined that the implementation of engineering and work practice controls required to maintain full shift exposures at or below a PEL of 0.2 μg/m³ will reduce short term exposures to 2.0 μg/m³ or below, and that a STEL of 1.0 μg/m³ would require additional respirator use. Furthermore, OSHA notes that the combination of a PEL of 0.2 μg/m³ and a STEL of 2.0 μg/m³ would, in most cases, keep workers from being exposed to 15 minute intervals of 1.0 μg/m³. See Table IV.78 of Chapter IV of the FEA.

Therefore, OSHA concludes that the STEL of 2.0 μg/m³ can be achieved for most operations most of the time, given that most short-term exposures are already below 2.0 μg/m³. OSHA recognizes that for a small number of tasks, short-term exposures may exceed the final STEL, even after feasible control measures to reduce TWA exposure to or below the final PEL have been implemented, and therefore, some limited use of respiratory protection will continue to be required for short-term tasks in which peak exposures cannot be reduced to less than 2.0 μg/m³ through use of engineering controls.

After careful consideration of the record, including all available data and stakeholder comments in the record, OSHA has determined that a STEL of 2.0 μg/m³ is technologically feasible. Thus, as explained in the Summary and Explanation for paragraph (c), OSHA has retained the proposed value of 2.0 μg/m³ as the final STEL.

E. Costs of Compliance

In Chapter V, Costs of Compliance, OSHA assesses the costs to general industry, maritime, and construction 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 final short-term exposure limit (STEL) of 2.0 μg/m³, as well as of complying with the final standard's ancillary provisions. These ancillary provisions encompass the following requirements: Exposure monitoring, regulated areas (and competent person in construction), a written exposure control plan, protective work clothing, hygiene areas and practices, housekeeping, medical surveillance, medical removal, familiarization, and worker training. This final cost assessment is based in part on OSHA's technological feasibility analysis presented in Chapter IV of the FEA; analyses of the costs of the final 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) as part of the Small Business Regulatory Enforcement Fairness Act (SBREFA) process, comments submitted to the docket in response to the PEA, comments during the hearings conducted in March 2016, and comments submitted to the docket after the hearings concluded.

Table VIII–4 presents summary of the annualized costs. All costs in this chapter are expressed in 2015 dollars and were annualized using a discount rate of 3 percent. (Costs at other discount rates are presented in the chapter itself). Annualization periods for expenditures on equipment are based on equipment life, and one-time costs are annualized over a 10-year period. Chapter V provides detailed explanation of the basis for these cost estimates.

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
Beryllium Oxide – Primary				
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$315,959	$117,793	-
Beryllium Oxide – Secondary				
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	$232,556	$105,595	-
334310	Audio and Video Equipment Manufacturing	$118,084	$99,209	-
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	$278,998	$199,642	-
334419	Other Electronic Component Manufacturing	$697,514	$482,652	-
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	$209,703	$35,369	-
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$325,494	$218,758	-
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$232,562	$140,444	-
Beryllium Production				
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	$2,013,397	-	-
Dental Labs – Substituting*				
339116a	Dental Laboratories	$1,253,495	$1,017,075	$631,145
621210a	Offices of Dentists	$178,968	$168,032	$144,738
Dental Labs - Non-Substituting**				
339116b	Dental Laboratories	$2,167,822	$1,757,907	$1,090,462
621210b	Offices of Dentists	$309,649	$290,706	$250,457
Drawing				
331420c	Copper Rolling, Drawing, Extruding, and Alloying	$4,426,834	$2,252,945	$109,260
Machining – High				
332721a	Precision Turned Product Manufacturing	$729,198	$640,150	$137,756
Machining – Low				
332721b	Precision Turned Product Manufacturing	$8,049,765	$7,072,180	$1,542,921
Non Sand Foundries				
331523	Nonferrous Metal Die-Casting Foundries	$3,576,462	$2,153,997	$534,414
331524	Aluminum Foundries (except Die-Casting)	$521,441	$419,706	$106,565
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	$1,323,804	$955,352	$336,613
Rolling				
331420a	Copper Rolling, Drawing, Extruding, and Alloying	$1,177,254	$599,439	$29,407
Sand Foundries				
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	$1,802,392	$1,307,125	$468,335

Smelting - Beryllium Alloys				
331314	Secondary Smelting and Alloying of Aluminum	$41,736	$34,100	$26,479
331420b	Copper Rolling, Drawing, Extruding, and Alloying	$114,295	$67,494	$14,331

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars) (continued)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
Smelting - Precious Metals				
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$805,282	$527,762	$184,943
Springs				
332613	Spring Manufacturing	$3,702,257	$2,602,479	$666,079
Stamping				
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$904,241	$736,071	$177,472
334417	Electronic Connector Manufacturing	$584,177	$277,415	$74,764
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$1,846,653	$1,070,556	$325,146
Welding - Arc and Gas				
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	$67,570	$17,445	$6,384
331221	Rolled Steel Shape Manufacturing	$19,960	$16,860	$5,201
331513	Steel Foundries (except Investment)	$16,788	$9,628	$5,852
332117	Powder Metallurgy Part Manufacturing	$12,314	$8,617	$6,564
332216	Saw Blade and Handtool Manufacturing	$38,399	$26,832	$8,395
332312	Fabricated Structural Metal Manufacturing	$581,440	$394,214	$100,387
332313	Plate Work Manufacturing	$233,595	$206,246	$41,748
332322	Sheet Metal Work Manufacturing	$769,001	$629,529	$153,221
332323	Ornamental and Architectural Metal Work Manufacturing	$415,257	$342,102	$133,212
332439	Other Metal Container Manufacturing	$66,574	$38,415	$10,537
332919	Other Metal Valve and Pipe Fitting Manufacturing	$35,290	$19,690	$4,906
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$412,635	$359,345	$92,112
333111a	Farm Machinery and Equipment Manufacturing	$219,739	$119,863	$37,334
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$50,310	$34,014	$9,120
333911	Pump and Pumping Equipment Manufacturing	$75,055	$29,195	$10,276
333922	Conveyor and Conveying Equipment Manufacturing	$109,339	$83,855	$14,647
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$51,556	$24,921	$8,516
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$226,282	$138,069	$39,972
336211	Motor Vehicle Body Manufacturing	$162,264	$104,321	$22,757
336214	Travel Trailer and Camper Manufacturing	$145,158	$61,005	$23,374

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars) (continued)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
336390a	Other Motor Vehicle Parts Manufacturing	$68,384	$33,840	$10,605
336510a	Railroad Rolling Stock Manufacturing	$36,795	$12,111	$4,009
336999	All Other Transportation Equipment Manufacturing	$35,556	$16,540	$9,603
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$28,978	$21,921	$6,522
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$1,584,633	$932,053	$611,277
Welding - Resistance Welding				
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$526,305	$256,015	$33,706
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	$941,303	$328,435	$32,255
335210	Small Electrical Appliance Manufacturing	$170,175	$125,024	$8,227
335221	Household Cooking Appliance Manufacturing	$131,328	$60,983	$4,126
335222	Household Refrigerator and Home Freezer Manufacturing	$40,241	$7,346	$1,310
335224	Household Laundry Equipment Manufacturing	$12,166	$1,369	$1,310
335228	Other Major Household Appliance Manufacturing	$48,304	$7,091	$1,310
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$1,137,535	$398,286	$57,392
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$908,472	$455,773	$39,843
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$328,342	$107,290	$8,454
336340	Motor Vehicle Brake System Manufacturing	$261,342	$112,290	$5,042
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$674,120	$241,333	$16,175
336360	Motor Vehicle Seating and Interior Trim Manufacturing	$533,438	$189,394	$12,131
336370	Motor Vehicle Metal Stamping	$1,036,026	$617,330	$25,234
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$505,883	$332,174	$46,775
336390b	Other Motor Vehicle Parts Manufacturing	$2,020,751	$953,614	$75,178
Aluminum Production				
331313	Alumina Refining and Primary Aluminum Production	$1,448,385	$1,448,385	-
Coal Fired Utilities				
221112	Fossil Fuel Electric Power Generation	$6,174,423	$989,185	$27,884
311221	Wet Corn Milling	$198,450	$32,970	-
311313	Beet Sugar Manufacturing	$231,570	$42,324	-
311942	Spice and Extract Manufacturing	$33,064	$19,954	-
312120	Breweries	$33,089	$18,534	-
321219	Reconstituted Wood Product Manufacturing	$16,530	$7,274	-

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars) (continued)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
322110	Pulp Mills	$16,553	$2,995	-
322121	Paper (except Newsprint) Mills	$182,256	$39,535	-
322122	Newsprint Mills	$397,171	$173,886	-
322130	Paperboard Mills	$264,737	$37,754	-
325211	Plastics Material and Resin Manufacturing	$66,132	$33,457	-
325611	Soap and Other Detergent Manufacturing	$16,537	$7,446	-
327310	Cement Manufacturing	$33,060	$10,073	-
333111b	Farm Machinery and Equipment Manufacturing	$16,538	$8,747	-
336510b	Railroad Rolling Stock Manufacturing	$16,542	$4,748	-
611310	Colleges, Universities, and Professional Schools	$149,175	$11,694	-
Abrasive Blasting – Construction				
238320	Painting and Wall Covering Contractors	$4,416,714	$3,719,871	$2,605,987
238990	All Other Specialty Trade Contractors	$4,092,952	$3,147,411	$2,149,166
Abrasive Blasting – Shipyards* **				
336611a	Ship Building and Repairing	$3,316,687	$1,063,477	$557,570
Welding in Shipyards****				
336611b	Ship Building and Repairing	$69,071	$20,244	$11,326
Total				
General Industry Subtotal		**$61,972,805**	**$36,113,291**	**$8,624,173**
Construction Subtotal		**$8,509,666**	**$6,867,282**	**$4,755,152**
Maritime Subtotal		**$3,385,759**	**$1,083,721**	**$568,896**
Total, All Industries		**$73,868,230**	**$44,064,294**	**$13,948,222**

Notes:

Figures in rows may not add to totals due to rounding.

"-" denotes industries where OSHA has preliminarily determined that there are no affected small or very small establishments.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

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

F. Economic Feasibility and Regulatory Flexibility Determination

In Chapter VI, OSHA investigates the economic impacts of its final beryllium rule on affected employers. This impact investigation has two overriding objectives: (1) To establish whether the final rule is economically feasible for all affected application groups/industries,[31] and (2) to determine if the Agency can certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Table VIII–5 presents OSHA's screening analysis, which shows costs as percentage of revenues and as a percentage of profits. The chapter explains why these screening analysis

[31] As noted in the FEA, OSHA uses the umbrella term ''application group'' to refer either to an industrial sector or to a cross-industry group with a common process. In the industrial profile chapter, because some of the discussion being presented has historically been framed in the context of the economic feasibility for an ''industry,'' the Agency uses the term ''application group'' and ''industry'' interchangeably.

results can reasonably be viewed as economically feasible. Section VIII.j shows similar results for small and very small entities.

Table VIII-5

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		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 Oxide – Primary										
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	655	2	$2,224,322	--	--	--	$157,979	--	--
Beryllium Oxide – Secondary										
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	830	10	$29,075,882	$35,031,183	0.72%	$250,797	$23,256	0.07%	9.27%
334310	Audio and Video Equipment Manufacturing	463	5	$2,944,276	$6,359,128	-0.24%	-$15,180	$23,617	0.37%	-155.58%
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	418	12	$3,829,332	$9,161,081	3.95%	$361,417	$23,250	0.25%	6.43%
334419	Other Electronic Component Manufacturing	1,259	30	$11,749,377	$9,332,309	3.95%	$368,172	$23,250	0.25%	6.32%
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	749	9	$29,145,680	$38,912,791	4.74%	$1,842,824	$23,300	0.06%	1.26%
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	655	14	$2,224,322	$3,395,911	1.57%	$53,418	$23,250	0.68%	43.52%
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	10	$21,336,550	$31,469,837	1.51%	$475,965	$23,256	0.07%	4.89%
Beryllium Production										
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	186	1	$15,853,340	--	--	--	$2,013,397	--	--
Dental Labs – Substituting*										
339116a	Dental Laboratories	5,114	1,278	$3,604,997	$704,996	7.33%	$51,693	$981	0.14%	1.90%
621210a	Offices of Dentists	99,830	183	$81,961,314	$821,007	7.24%	$59,424	$980	0.12%	1.65%
Dental Labs - Non-Substituting**										
339116b	Dental Laboratories	1,705	426	$1,201,666	$704,996	7.33%	$51,693	$5,087	0.72%	9.84%
621210b	Offices of Dentists	33,277	61	$27,320,438	$821,007	7.24%	$59,424	$5,087	0.62%	8.56%
Drawing										
331420c	Copper Rolling, Drawing, Extruding, and Alloying	249	45	$24,370,147	$97,872,075	2.08%	$2,037,366	$99,439	0.10%	4.88%
Machining – High										
332721a	Precision Turned Product Manufacturing	3,688	22	$18,818,245	$5,102,561	4.73%	$241,533	$33,512	0.66%	13.87%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		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
Machining – Low										
332721b	Precision Turned Product Manufacturing	3,688	347	$18,036,209	$4,890,512	4.73%	$231,495	$22,015	0.45%	9.51%
Non-Sand Foundries										
331523	Nonferrous Metal Die-Casting Foundries	434	50	$7,838,073	$18,060,076	4.72%	$853,009	$70,398	0.39%	8.25%
331524	Aluminum Foundries (except Die-Casting)	406	7	$2,830,636	$6,972,010	4.72%	$329,300	$70,535	1.01%	21.42%
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	300	18	$2,412,855	$8,042,850	4.72%	$379,878	$70,394	0.88%	18.53%
Rolling										
331420a	Copper Rolling, Drawing, Extruding, and Alloying	249	11	$23,357,388	$93,804,771	2.08%	$1,952,698	$95,071	0.10%	4.87%
Sand Foundries										
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	300	23	$2,412,855	$8,042,850	4.72%	$379,878	$76,605	0.95%	20.17%
Smelting - Beryllium Alloys										
331314	Secondary Smelting and Alloying of Aluminum	114	1	$5,623,100	$49,325,439	2.47%	$1,217,849	$40,853	0.08%	3.35%
331420b	Copper Rolling, Drawing, Extruding, and Alloying	249	4	$23,357,388	$93,804,771	2.08%	$1,952,698	$27,690	0.03%	1.42%
Smelting - Precious Metals										
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	261	30	$14,552,929	$55,758,349	2.08%	$1,160,700	$25,959	0.05%	2.24%
Springs										
332613	Spring Manufacturing	392	296	$3,595,394	$9,171,923	4.73%	$434,159	$11,590	0.13%	2.67%
Stamping										
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	1,499	72	$11,816,815	$7,883,132	3.99%	$314,432	$11,597	0.15%	3.69%
334417	Electronic Connector Manufacturing	234	47	$5,693,396	$24,330,752	3.95%	$959,882	$11,591	0.05%	1.21%
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	148	$20,449,859	$30,162,034	1.51%	$456,185	$11,596	0.04%	2.54%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

NAICS Code	Industry	Total Establishments	Total Affected Establishments	Revenues: Total ($1,000)	Revenues: Per Establishment	Profits: Rate	Profits: Per Establishment	Compliance Costs: Per Establishment	Compliance Costs: As a Percent of Revenues	Compliance Costs: As a Percent of Profits
Welding - Arc and Gas										
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	562	6	$113,226,448	$201,470,548	1.24%	$2,500,783	$10,496	0.01%	0.42%
331221	Rolled Steel Shape Manufacturing	167	2	$5,991,188	$35,875,377	2.08%	$746,804	$12,618	0.04%	1.69%
331513	Steel Foundries (except Investment)	208	1	$4,536,694	$21,811,029	4.72%	$1,030,173	$13,345	0.06%	1.30%
332117	Powder Metallurgy Part Manufacturing	133	1	$2,023,839	$15,216,835	3.99%	$606,949	$11,887	0.08%	1.96%
332216	Saw Blade and Handtool Manufacturing	1,012	3	$7,043,067	$6,959,553	4.20%	$292,270	$11,630	0.17%	3.98%
332312	Fabricated Structural Metal Manufacturing	3,099	54	$27,839,554	$8,983,399	2.72%	$244,507	$10,768	0.12%	4.40%
332313	Plate Work Manufacturing	1,245	22	$7,461,246	$5,992,968	2.72%	$163,115	$10,769	0.18%	6.60%
332322	Sheet Metal Work Manufacturing	4,099	71	$20,892,732	$5,097,031	2.72%	$138,729	$10,768	0.21%	7.76%
332323	Ornamental and Architectural Metal Work Manufacturing	2,214	39	$6,058,633	$2,736,510	2.72%	$74,481	$10,765	0.39%	14.45%
332439	Other Metal Container Manufacturing	346	6	$3,885,743	$11,230,472	3.04%	$341,463	$11,043	0.10%	3.23%
332919	Other Metal Valve and Pipe Fitting Manufacturing	243	3	$5,062,721	$20,834,244	6.09%	$1,268,082	$11,767	0.06%	0.93%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	3,553	38	$15,415,053	$4,338,602	6.09%	$264,070	$10,766	0.25%	4.08%
333111a	Farm Machinery and Equipment Manufacturing	1,124	20	$42,075,186	$37,433,440	5.86%	$2,193,945	$10,772	0.03%	0.49%
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	472	4	$5,535,698	$11,728,174	3.21%	$376,991	$11,294	0.10%	3.00%
333911	Pump and Pumping Equipment Manufacturing	539	7	$15,903,209	$29,505,027	3.99%	$1,176,661	$10,961	0.04%	0.93%
333922	Conveyor and Conveying Equipment Manufacturing	799	10	$8,945,712	$11,196,135	3.99%	$446,502	$10,771	0.10%	2.41%
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	360	5	$11,772,772	$32,702,145	3.99%	$1,304,162	$11,272	0.03%	0.86%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	1,654	21	$15,726,526	$9,508,178	3.99%	$379,186	$10,769	0.11%	2.84%
336211	Motor Vehicle Body Manufacturing	741	15	$11,773,922	$15,889,234	1.51%	$240,317	$10,773	0.07%	4.48%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		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
336214	Travel Trailer and Camper Manufacturing	663	13	$10,544,247	$15,903,842	1.51%	$240,538	$10,771	0.07%	4.48%
336390a	Other Motor Vehicle Parts Manufacturing	1,508	6	$60,628,177	$40,204,361	1.51%	$608,070	$11,028	0.03%	1.81%
336510a	Railroad Rolling Stock Manufacturing	234	3	$17,944,334	$76,685,188	1.51%	$1,159,824	$11,708	0.02%	1.01%
336999	All Other Transportation Equipment Manufacturing	397	3	$7,731,109	$19,473,827	4.36%	$848,139	$11,749	0.06%	1.39%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	1,097	2	$6,809,534	$6,207,415	2.91%	$180,835	$12,129	0.20%	6.71%
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	21,347	147	$34,529,038	$1,617,512	2.81%	$45,395	$10,763	0.67%	23.71%
Welding - Resistance Welding										
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	491	20	$6,278,849	$12,787,881	3.21%	$411,054	$26,798	0.21%	6.52%
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	878	35	$31,852,834	$36,278,855	3.21%	$1,166,148	$26,802	0.07%	2.30%
335210	Small Electrical Appliance Manufacturing	127	6	$3,560,517	$28,035,564	4.28%	$1,200,467	$26,799	0.10%	2.23%
335221	Household Cooking Appliance Manufacturing	98	5	$4,674,297	$47,696,913	4.28%	$2,042,354	$26,802	0.06%	1.31%
335222	Household Refrigerator and Home Freezer Manufacturing	30	2	$3,686,247	$122,874,888	4.28%	$5,261,431	$26,827	0.02%	0.51%
335224	Household Laundry Equipment Manufacturing	9	1	$951,577	$105,730,833	4.28%	$4,527,333	$12,166	0.01%	0.27%
335228	Other Major Household Appliance Manufacturing	36	2	$4,710,323	$130,842,293	4.28%	$5,602,591	$26,836	0.02%	0.48%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	849	42	$33,235,797	$39,146,993	1.51%	$592,078	$26,797	0.07%	4.53%
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	34	$21,336,550	$31,469,837	1.51%	$475,965	$26,799	0.09%	5.63%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	245	12	$12,290,261	$50,164,329	1.51%	$758,710	$26,803	0.05%	3.53%
336340	Motor Vehicle Brake System Manufacturing	195	10	$10,467,412	$53,679,036	1.51%	$811,868	$26,804	0.05%	3.30%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

NAICS Code	Industry	Total Establishments	Total Affected Establishments	Revenues: Total ($1,000)	Revenues: Per Establishment	Profits: Rate	Profits: Per Establishment	Compliance Costs: Per Establishment	Compliance Costs: As a Percent of Revenues	Compliance Costs: As a Percent of Profits
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	503	25	$35,792,318	$71,157,690	1.51%	$1,076,224	$26,804	0.04%	2.49%
336360	Motor Vehicle Seating and Interior Trim Manufacturing	398	20	$23,631,348	$59,375,247	1.51%	$898,020	$26,806	0.05%	2.98%
336370	Motor Vehicle Metal Stamping	773	39	$32,802,040	$42,434,722	1.51%	$641,804	$26,805	0.06%	4.18%
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	472	19	$5,535,698	$11,728,174	3.21%	$376,991	$26,795	0.23%	7.11%
336390b	Other Motor Vehicle Parts Manufacturing	1,508	75	$60,628,177	$40,204,361	1.51%	$608,070	$26,800	0.07%	4.41%
Aluminum Production										
331313	Alumina Refining and Primary Aluminum Production	8	6	$370,719	$46,339,915	2.47%	$1,144,136	$224,939	0.49%	19.66%
Coal Fired Utilities										
221112	Fossil Fuel Electric Power Generation	2,716	418	$167,481,521	$123,329,544	0.90%	$553,734	$29,543	0.02%	5.34%
311221	Wet Corn Milling	63	12	$12,894,946	$204,681,680	4.62%	$9,466,006	$16,537	0.01%	0.17%
311313	Beet Sugar Manufacturing	31	14	$4,822,174	$155,553,993	8.23%	$12,796,838	$16,541	0.01%	0.13%
311942	Spice and Extract Manufacturing	383	2	$9,644,849	$25,182,374	4.61%	$1,159,747	$16,532	0.07%	1.43%
312120	Breweries	880	2	$29,912,097	$33,991,019	10.78%	$3,665,509	$16,544	0.05%	0.45%
321219	Reconstituted Wood Product Manufacturing	219	1	$6,708,744	$30,633,533	1.37%	$420,171	$16,530	0.05%	3.93%
322110	Pulp Mills	42	1	$6,842,997	$162,928,496	1.43%	$2,328,331	$16,553	0.01%	0.71%
322121	Paper (except Newsprint) Mills	209	11	$45,144,793	$216,003,795	1.43%	$3,086,804	$16,569	0.01%	0.54%
322122	Newsprint Mills	20	24	$3,218,103	$160,905,142	1.43%	$2,299,416	$16,549	0.01%	0.72%
322130	Paperboard Mills	177	16	$29,706,665	$167,834,268	1.43%	$2,398,437	$16,546	0.01%	0.69%
325211	Plastics Material and Resin Manufacturing	1,161	4	$97,687,597	$84,140,910	5.94%	$4,998,379	$16,533	0.02%	0.33%
325611	Soap and Other Detergent Manufacturing	664	1	$28,371,519	$42,728,192	12.34%	$5,274,306	$16,537	0.04%	0.31%
327310	Cement Manufacturing	240	2	$6,246,422	$26,026,757	1.47%	$382,683	$16,530	0.06%	4.32%
333111b	Farm Machinery and Equipment Manufacturing	1,124	1	$42,075,186	$37,433,440	5.86%	$2,193,945	$16,538	0.04%	0.75%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		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
336510b	Railroad Rolling Stock Manufacturing	234	1	$17,944,334	$76,685,188	1.51%	$1,159,824	$16,542	0.02%	1.43%
611310	Colleges, Universities, and Professional Schools	4,329	9	$232,517,218	$53,711,531	6.07%	$3,259,004	$16,575	0.03%	0.51%
Abrasive Blasting – Construction										
238320	Painting and Wall Covering Contractors	31,376	1,090	$19,595,278	$624,531	3.47%	$21,663	$4,052	0.65%	18.71%
238990	All Other Specialty Trade Contractors	29,072	1,010	$39,396,242	$1,355,127	3.47%	$46,957	$4,052	0.30%	8.63%
Abrasive Blasting – Shipyards* **										
336611a	Ship Building and Repairing	689	689	$26,136,187	$37,933,508	6.13%	$2,324,545	$4,814	0.01%	0.21%
Welding – Shipyards****										
336611b	Ship Building and Repairing	689	7	$26,136,187	$37,933,508	6.13%	$2,324,545	$10,467	0.03%	0.45%
Total										
General Industry Subtotal		226,165	4,538	$1,931,626,954	$8,540,786	3.55%	$303,168	$13,657	0.16%	4.50%
Construction Subtotal		60,448	2,100	$58,991,519	$975,905	3.47%	$33,828	$4,052	0.42%	11.98%
Maritime Subtotal		1,378	696	$52,272,373	$37,933,508	6.13%	$2,324,545	$4,867	0.01%	0.21%
Total, All Industries		**287,991**	**7,333**	**$2,042,890,847**	**$7,617,412**	**3.61%**	**$2,661,541**	**$10,073**	**0.02%**	**0.38%**

Notes:

Figures in rows may not add to totals due to rounding.

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 327110a) and Beryllium Oxide (NAICS 331410a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

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

In Chapter VII, OSHA estimates the benefits and net benefits of the final beryllium rule. The methodology for these estimates largely remains the same as in the PEA. OSHA did not receive many comments challenging any aspect of the benefits analysis presented in the PEA. There are, however, a few significant alterations, such as: Using an empirical turnover rate as part of the estimation of exposure response functions, full analysis of the population model with varying turnover (a model only briefly presented in the PEA), and presentation of a statistical proportional hazard model in response to comment. The other large change to the benefits analysis is the result of the increase in the scope of the rule to protect workers in the construction and ship-building industries. In the proposed rule, coverage of these latter industries was only presented as an alternative and therefore were not included in the benefits in the PEA, but they are covered by the final rule.

This chapter 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 final PEL is adopted in a final standard, and in which employees are exposed throughout their working lives to either the baseline or the final PEL. The second step also assumes that the final PEL is adopted, but uses the results from the first step to estimate what would happen under a realistic scenario in which new employees will not be exposed above the final PEL, while employees already at work will experience a combination of exposures below the final PEL and baseline exposures that exceed the final PEL over their working lifetime. The comparison of these steps is given in Table VIII–6. OSHA also presents in Chapter VII similar kinds of results for a variety of other risk assessment and population models.

Table VIII-6

Prevented Mortality and Morbidity by PEL Option at Midpoint Effectiveness (45-Year Working Life Case) (Quartile Model)

Midpoint Estimates

	Baseline Total Cases	PEL Option (μg/m^3) Total Number of Avoided Cases			Baseline Annual Cases	PEL Option (μg/m^3) Annual Number of Avoided Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
Total Cases								
Be S - Total	22,644	9,008	8,742	7,235	503	200.2	194.3	160.8
CBD	15,115	6,122	5,924	3,899	336	136.1	131.6	86.6
Mortality								
Lung Cancer	535	201	187	167	12	4.5	4.2	3.7
CBD-Related	9,863	4,018	3,851	2,534	219	89.3	85.6	56.3
Total Mortality	10,398	4,219	4,038	2,701	231	93.8	89.7	60.0
Morbidity	5,251	2,104	2,073	1,365	117	46.8	46.1	30.3

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

The third step covers the monetization of benefits. Table VIII–7 presents the monetization of benefits at various interest rates and monetization values.

Table VIII-7

Annual Monetized Benefits Resulting from a Reduction in Exposure to Beryllium to Final PEL of 0.2 μg/m³ and Alternative PELS of 0.1 μg/m³ and 0.5 μg/m³

Lifetime Risk Model — PEL Option (μg/m³)	0.1	0.2	0.5
Discount Rate			
Low Estimates			
Undiscounted (0%)	$280.7	$247.6	$233.7
Discounted at 3%	$152.8	$134.8	$127.2
Discounted at 7%	$58.6	$51.8	$48.8
High Estimates			
Undiscounted (0%)	$2,126.6	$2,100.2	$1,273.9
Discounted at 3%	$1,273.5	$1,257.8	$762.7
Discounted at 7%	$605.2	$597.8	$362.1
Midpoint Estimates			
Undiscounted (0%)	$1,003.4	$968.8	$650.2
Discounted at 3%	$580.9	$560.9	$376.5
Discounted at 7%	$258.0	$249.1	$167.2
Population Model with Varying Tenure — PEL Option (μg/m³)	**0.1**	**0.2**	**0.5**
Discount Rate			
Low Estimates			
Undiscounted (0%)	$502.7	$455.6	$404.5
Discounted at 3%	$271.9	$246.2	$218.8
Discounted at 7%	$102.8	$93.0	$82.8
High Estimates			
Undiscounted (0%)	$2,954.5	$2,918.3	$1,852.5
Discounted at 3%	$1,769.8	$1,748.1	$1,109.4
Discounted at 7%	$841.7	$831.4	$527.3
Midpoint Estimates			
Undiscounted (0%)	$1,480.4	$1,431.6	$995.4
Discounted at 3%	$856.8	$828.5	$576.2
Discounted at 7%	$380.5	$367.9	$255.9

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

In the fourth step, OSHA estimates the net benefits of the final rule by comparing the monetized benefits to the costs presented in Chapter V of the FEA. These values are presented in Table VIII–8. The table shows that benefits exceed costs for all situations except for the low estimate of benefits using a 7 percent discount rate. The low estimate of benefits reflects the assumption that the ancillary provisions have no independent effect in reducing cases of CBD. OSHA considers this assumption to be very unlikely, based on the available evidence.

Table VIII-8

Annual Monetized Net Benefits Resulting from a Reduction in Exposure to Beryllium to Final PEL of 0.2 μg/m^3 and Alternative PELS of 0.1 μg/m^3 and 0.5 μg/m^3 ($Millions)

Lifetime Risk Model				
PEL		**0.1**	**0.2**	**0.5**
Discount Rate	**Range**			
Undiscounted (0%)	Low	$178.6	$175.1	$176.2
	Midpoint	$901.3	$896.3	$592.8
	High	$2,024.5	$2,027.7	$1,216.5
Discounted at 3%	Low	$49.1	$61.0	$68.6
	Midpoint	$477.2	$487.0	$317.9
	High	$1,169.9	$1,183.9	$704.1
Discounted at 7%	Low	($48.7)	($24.9)	($11.9)
	Midpoint	$150.7	$172.4	$106.5
	High	$497.9	$521.2	$301.4
Population Model with Varying Tenure Model				
Undiscounted (0%)	Low	$421.9	$402.8	$364.6
	Midpoint	$1,443.1	$1,422.2	$982.0
	High	$2,983.4	$2,975.6	$1,877.6
Discounted at 3%	Low	$179.3	$182.8	$169.6
	Midpoint	$790.3	$791.0	$543.0
	High	$1,744.2	$1,751.8	$1,100.2
Discounted at 7%	Low	($0.9)	$20.0	$25.5
	Midpoint	$289.2	$307.2	$206.3
	High	$771.0	$791.5	$489.9
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis				

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. This is done because the models underlying each step inevitably need to make a variety of assumptions based on limited data. OSHA invited comments on each aspect of the data and methods used in this chapter, and received none specifically on the sensitivity analysis. Because dental laboratories constituted a significant source of both costs and benefits to the proposal, the PEA indicated that OSHA was particularly interested in comments regarding the appropriateness of the model, assumptions, and data for estimating the benefits to workers in that industry. Although the Agency did not receive any comments on this question directly, the American Dental Association's comments relevant to the underlying use of beryllium alloys in dental labs are addressed in Chapter III of the FEA. The Agency has not altered its main estimates of the exposure profile for dental laboratory workers, but provides sensitivity analyses in the FEA to examine the outcome if a lower percentage of dental laboratories were to substitute materials that do not contain beryllium for beryllium-containing materials. OSHA also estimates net benefits with a variety of scenarios in which dental laboratories are not included. All of these results are presented in Chapter VII of the FEA.

H. Regulatory Alternatives

Chapter VIII presents the costs, benefits and net benefits of a variety of regulatory alternatives.

I. Final Regulatory Flexibility 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 final rulemaking will have on small entities. The RFA states that whenever an agency promulgates a final rule that is required to conform to the notice-and-comment rulemaking requirements of section 553 of the Administrative Procedure Act (APA), the agency shall prepare a final regulatory flexibility analysis (FRFA). 5 U.S.C. 604(a).

However, 5 U.S.C. 605(b) of the RFA states that Section 604 shall not apply to any final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. As discussed in Chapter VI of the FEA, OSHA was unable to so certify for the final beryllium rule.

For OSHA rulemakings, as required by 5 U.S.C. 604(a), the FRFA must contain:

1. A statement of the need for, and objectives of, the rule;
2. a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
5. a description of the projected reporting, recordkeeping and other

compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

6. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected; and for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

The Regulatory Flexibility Act further states that the required elements of the FRFA 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 FRFA. 5 U.S.C. 605(a).

In addition to these elements, OSHA also includes in this section the recommendations from the Small Business Advocacy Review (SBAR) Panel and OSHA's responses to those recommendations.

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 FEA and its supporting materials, this FRFA will summarize the key aspects of OSHA's analysis as they affect small entities.

• The Need for, and Objective of, the Rule

The objective of the final 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 necessary 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 the preamble for a more detailed discussion.

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 final 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 final risk assessment, presented in Section VI of the 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 $\mu g/m^3$. 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 $\mu g/m^3$. The final standard, with a lower PEL of 0.2 $\mu g/m^3$, will help to address these health concerns. See the Health Effects and Risk Assessment sections of the preamble for further discussion.

• Summary of Significant Issues Raised by Comments on the Initial Regulatory Flexibility Analysis (IRFA) and OSHA's Assessment of, and Response to, Those Issues

This section of the FRFA focuses only on public comments concerning significant issues raised on the Initial Regulatory Flexibility Analysis (IRFA). OSHA received only one such comment.

The Non-Ferrous Founders' Society claimed that the costs of the rule will disproportionately affect small employers and result in job losses to foreign competition (Document ID 1678, p. 3). This comment is addressed in the FEA in the section on International Trade Effects in Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination. The summary of OSHA's response is that, in general, metalcasters in the U.S. have shortened lead times, improved productivity through computer design and logistics management, expanded design and development services to customers, and provided a higher quality product than foundries in China and other nations where labor costs are low (Document ID 1780, p. 3–12). All of these measures, particularly the higher quality of many U.S. metalcasting products and the ability of domestic foundries to fulfill orders quickly, are substantial advantages for U.S. metalcasters that may outweigh the very modest price increases that might occur due to the final rule. For a more detailed response please see the section on International Trade Effects in Chapter VI of the FEA.

Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration and OSHA'S Response to Those Comments

The Chief Counsel for Advocacy of the Small Business Administration (''Advocacy'') did not provide OSHA with comments on this rule.

• A Description of, and an Estimate of, the Number of Small Entities To Which the Rule Will Apply

OSHA has analyzed the impacts associated with this final rule, including the type and number of small entities to which the standard will 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.

OSHA estimates that approximately 6.600 small business entities would be affected by the beryllium standard. Within these small entities, 33,800 workers are exposed to beryllium and would be protected by this final standard. A breakdown, by industry, of the number of affected small entities is provided in Table III–14 in Chapter III of the FEA.

OSHA estimates that approximately 5,280 very small entities—those with fewer than 20 employees—would be affected by the beryllium standard. Within these very small entities, 11,800 workers are exposed to beryllium and would be protected by the standard. A breakdown, by industry, of the number of affected very small entities is provided in Table III–15 in Chapter III of the FEA.

A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

Tables VIII–9 and VIII–10 show the average costs of the beryllium standard and the costs of compliance as a percentage of profits and revenues by NAICS code for, respectively, small entities (classified as small by SBA) and very small entities (those with fewer than 20 employees). The full derivation of these costs is presented in Chapter V. The cost for SBA-defined small entities ranges from a low of $832 per entity for entities in NAICS 339116a: Dental Laboratories, to a high of about $599,836 for NAICS 331313: Alumina Refining and Primary Aluminum Production.

The annualized cost for very small entities ranges from a low of $542 for entities in NAICS 339116a: Dental Laboratories, to a high of about $34,222 for entities in NAICS 331529b: Other Nonferrous Metal Foundries (except Die-Casting).[32]

[32] The cost of $542 for NAICS 339116a is the sum of a $524 cost to substitute for a non-hazard material and $19 for cost of ancillary provisions. The total cost of $34,222 for NAICS 331529b is the sum of $22,601 for engineering controls, $186 for respirator costs, and $11,435 for ancillary provisions.

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Beryllium Oxide - Primary				
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$118,743	--	--
Beryllium Oxide - Secondary				
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	$12,538	0.1%	18.1%
334310	Audio and Video Equipment Manufacturing	$20,325	0.4%	-173.4%
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	$19,317	0.3%	8.3%
334419	Other Electronic Component Manufacturing	$18,331	0.3%	7.8%
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	$7,414	0.5%	10.3%
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$16,508	1.0%	63.6%
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$16,333	0.1%	7.1%
Beryllium Production				
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	$0	--	--
Dental Labs Substituting*				
339116a	Dental Laboratories	$832	0.2%	2.1%
621210a	Offices of Dentists	$981	0.1%	1.7%
Dental Labs - Non-Substituting**				
339116b	Dental Laboratories	$4,315	0.8%	11.0%
621210b	Offices of Dentists	$5,090	0.6%	8.6%
Drawing				
331420c	Copper Rolling, Drawing, Extruding, and Alloying	$79,253	0.1%	6.9%
Machining - High				
332721a	Precision Turned Product Manufacturing	$30,658	0.7%	14.5%
Machining - Low				
332721b	Precision Turned Product Manufacturing	$21,237	0.5%	10.0%
Non-Sand Foundries				
331523	Nonferrous Metal Die-Casting Foundries	$52,387	0.6%	12.1%
331524	Aluminum Foundries (except Die-Casting)	$63,675	1.3%	27.1%
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	$56,187	1.0%	21.8%
Rolling				
331420a	Copper Rolling, Drawing, Extruding, and Alloying	$82,941	0.1%	7.2%
Sand Foundries				
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	$61,501	1.1%	23.8%
Smelting - Beryllium Alloys				
331314	Secondary Smelting and Alloying of Aluminum	$36,757	0.1%	5.0%
331420b	Copper Rolling, Drawing, Extruding, and Alloying	$26,425	0.0%	2.3%
Smelting - Precious Metals				
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$22,398	0.0%	2.2%

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Springs				
332613	Spring Manufacturing	$10,777	0.2%	3.4%
Stamping				
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$11,131	0.2%	4.4%
334417	Electronic Connector Manufacturing	$7,926	0.1%	1.5%
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$8,419	0.1%	3.7%
Welding - Arc and Gas				
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	$4,380	0.0%	0.6%
331221	Rolled Steel Shape Manufacturing	$13,662	0.0%	1.8%
331513	Steel Foundries (except Investment)	$9,473	0.1%	1.9%
332117	Powder Metallurgy Part Manufacturing	$8,783	0.1%	2.4%
332216	Saw Blade and Handtool Manufacturing	$9,018	0.2%	5.5%
332312	Fabricated Structural Metal Manufacturing	$8,243	0.1%	5.1%
332313	Plate Work Manufacturing	$9,998	0.2%	7.1%
332322	Sheet Metal Work Manufacturing	$9,650	0.2%	8.9%
332323	Ornamental and Architectural Metal Work Manufacturing	$9,132	0.4%	15.7%
332439	Other Metal Container Manufacturing	$7,874	0.1%	4.5%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$8,224	0.1%	1.1%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$9,726	0.3%	4.4%
333111a	Farm Machinery and Equipment Manufacturing	$6,431	0.1%	1.1%
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$8,622	0.1%	3.4%
333911	Pump and Pumping Equipment Manufacturing	$5,759	0.1%	1.3%
333922	Conveyor and Conveying Equipment Manufacturing	$9,180	0.1%	2.7%
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$6,208	0.1%	1.5%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$7,212	0.1%	3.6%
336211	Motor Vehicle Body Manufacturing	$8,159	0.1%	5.1%
336214	Travel Trailer and Camper Manufacturing	$5,388	0.1%	5.7%
336390a	Other Motor Vehicle Parts Manufacturing	$6,784	0.0%	2.3%
336510a	Railroad Rolling Stock Manufacturing	$6,219	0.0%	1.9%
336999	All Other Transportation Equipment Manufacturing	$5,817	0.1%	3.1%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$9,887	0.2%	7.4%
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$7,050	0.7%	25.1%
Welding - Resistance Welding				
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$16,755	0.2%	7.2%
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	$11,917	0.1%	2.9%
335210	Small Electrical Appliance Manufacturing	$21,934	0.1%	2.9%
335221	Household Cooking Appliance Manufacturing	$13,257	0.1%	1.5%
335222	Household Refrigerator and Home Freezer Manufacturing	$7,733	0.0%	0.5%

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
335224	Household Laundry Equipment Manufacturing	$1,369	0.0%	0.6%
335228	Other Major Household Appliance Manufacturing	$6,753	0.0%	0.7%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$10,707	0.1%	8.5%
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$15,635	0.1%	6.8%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$11,414	0.1%	3.4%
336340	Motor Vehicle Brake System Manufacturing	$16,760	0.1%	4.5%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$12,376	0.1%	3.6%
336360	Motor Vehicle Seating and Interior Trim Manufacturing	$13,577	0.1%	4.3%
336370	Motor Vehicle Metal Stamping	$20,274	0.1%	5.4%
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$19,867	0.2%	7.7%
336390b	Other Motor Vehicle Parts Manufacturing	$15,723	0.1%	5.3%
Aluminum Production				
331313	Alumina Refining and Primary Aluminum Production	$599,836	0.5%	19.7%
Coal Fired Utilities				
221112	Fossil Fuel Electric Power Generation	$41,467	0.0%	3.8%
311221	Wet Corn Milling	$6,657	0.0%	0.3%
311313	Beet Sugar Manufacturing	$10,413	0.0%	0.1%
311942	Spice and Extract Manufacturing	$12,092	0.1%	1.9%
312120	Breweries	$9,720	0.2%	1.5%
321219	Reconstituted Wood Product Manufacturing	$8,314	0.0%	3.4%
322110	Pulp Mills	$3,137	0.0%	0.5%
322121	Paper (except Newsprint) Mills	$7,437	0.0%	0.8%
322122	Newsprint Mills	$11,147	0.0%	0.7%
322130	Paperboard Mills	$7,201	0.0%	1.0%
325211	Plastics Material and Resin Manufacturing	$11,843	0.0%	0.6%
325611	Soap and Other Detergent Manufacturing	$7,622	0.1%	0.9%
327310	Cement Manufacturing	$11,512	0.1%	4.9%
333111b	Farm Machinery and Equipment Manufacturing	$9,096	0.1%	1.5%
336510b	Railroad Rolling Stock Manufacturing	$5,305	0.0%	1.6%
611310	Colleges, Universities, and Professional Schools	$3,773	0.0%	0.6%
Abrasive Blasting - Construction				
238320	Painting and Wall Covering Contractors	$3,430	0.6%	18.7%
238990	All Other Specialty Trade Contractors	$3,175	0.3%	8.8%
Abrasive Blasting Shipyards* **				
336611a	Ship Building and Repairing	$1,818	0.0%	0.3%
Welding Shipyards******				
336611b	Ship Building and Repairing	$3,613	0.0%	0.6%
Total				
General Industry Subtotal		**$9,651**	**0.3%**	**8.1%**
Construction Subtotal		**$3,308**	**0.4%**	**12.3%**
Maritime Subtotal		**$1,835**	**0.0%**	**0.3%**
Weighted Average, All Industries		**$6,876**	**0.0%**	**0.9%**

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit

Notes:

Figures in rows may not add to totals due to rounding.

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 327110a) and Beryllium Oxide (NAICS 331410a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

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

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Beryllium Oxide - Primary				
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$0	--	--
Beryllium Oxide - Secondary				
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	$0	0.00%	0.00%
334310	Audio and Video Equipment Manufacturing	$0	0.00%	0.00%
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	$0	0.00%	0.00%
334419	Other Electronic Component Manufacturing	$0	0.00%	0.00%
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	$0	0.00%	0.00%
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$0	0.00%	0.00%
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$0	0.00%	0.00%
Beryllium Production				
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	$0	--	--
Dental Labs Substituting*				
339116a	Dental Laboratories	$542	0.18%	2.42%
621210a	Offices of Dentists	$872	0.12%	1.67%
Dental Labs - Non-Substituting**				
339116b	Dental Laboratories	$2,812	0.92%	12.54%
621210b	Offices of Dentists	$4,526	0.63%	8.67%
Drawing				
331420c	Copper Rolling, Drawing, Extruding, and Alloying	$9,121	0.26%	12.66%
Machining - High				
332721a	Precision Turned Product Manufacturing	$10,396	0.83%	17.64%
Machining - Low				
332721b	Precision Turned Product Manufacturing	$7,300	0.59%	12.39%
Non-Sand Foundries				
331523	Nonferrous Metal Die-Casting Foundries	$23,395	1.85%	39.11%
331524	Aluminum Foundries (except Die-Casting)	$26,897	3.36%	71.13%
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	$30,747	2.47%	52.38%
Rolling				
331420a	Copper Rolling, Drawing, Extruding, and Alloying	$9,656	0.28%	13.41%
Sand Foundries				
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	$34,222	2.75%	58.30%
Smelting - Beryllium Alloys				
331314	Secondary Smelting and Alloying of Aluminum	$26,479	0.69%	28.12%
331420b	Copper Rolling, Drawing, Extruding, and Alloying	$13,315	0.38%	18.48%
Smelting - Precious Metals				
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$13,081	0.27%	13.12%

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Springs				
332613	Spring Manufacturing	$4,458	0.37%	7.84%
Stamping				
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$4,587	0.33%	8.19%
334417	Electronic Connector Manufacturing	$3,854	0.34%	8.72%
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$3,882	0.33%	21.75%
Welding - Arc and Gas				
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	$3,277	0.12%	9.87%
331221	Rolled Steel Shape Manufacturing	$5,201	0.13%	6.14%
331513	Steel Foundries (except Investment)	$5,852	0.48%	10.10%
332117	Powder Metallurgy Part Manufacturing	$6,564	0.31%	7.82%
332216	Saw Blade and Handtool Manufacturing	$3,829	0.51%	12.17%
332312	Fabricated Structural Metal Manufacturing	$3,039	0.21%	7.67%
332313	Plate Work Manufacturing	$3,212	0.28%	10.14%
332322	Sheet Metal Work Manufacturing	$3,372	0.30%	11.06%
332323	Ornamental and Architectural Metal Work Manufacturing	$4,217	0.59%	21.53%
332439	Other Metal Container Manufacturing	$3,287	0.28%	9.33%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$3,936	0.16%	2.70%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$3,249	0.38%	6.26%
333111a	Farm Machinery and Equipment Manufacturing	$3,043	0.25%	4.19%
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$3,514	0.23%	7.22%
333911	Pump and Pumping Equipment Manufacturing	$3,210	0.12%	3.09%
333922	Conveyor and Conveying Equipment Manufacturing	$3,034	0.18%	4.57%
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$3,491	0.26%	6.50%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$3,040	0.22%	5.49%
336211	Motor Vehicle Body Manufacturing	$3,034	0.20%	13.43%
336214	Travel Trailer and Camper Manufacturing	$3,034	0.25%	16.59%
336390a	Other Motor Vehicle Parts Manufacturing	$3,269	0.19%	12.35%
336510a	Railroad Rolling Stock Manufacturing	$3,877	0.17%	11.02%
336999	All Other Transportation Equipment Manufacturing	$3,924	0.28%	6.47%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$4,266	0.52%	17.84%
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$4,938	0.76%	27.08%
Welding - Resistance Welding				
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$3,830	0.25%	7.90%
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	$1,952	0.10%	3.25%
335210	Small Electrical Appliance Manufacturing	$2,165	0.12%	2.70%
335221	Household Cooking Appliance Manufacturing	$1,310	0.11%	2.68%
335222	Household Refrigerator and Home Freezer Manufacturing	$1,310	0.08%	1.82%

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
335224	Household Laundry Equipment Manufacturing	$1,310	0.09%	2.08%
335228	Other Major Household Appliance Manufacturing	$1,310	0.06%	1.41%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$1,923	0.20%	13.52%
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$2,075	0.18%	11.63%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$1,470	0.07%	4.62%
336340	Motor Vehicle Brake System Manufacturing	$1,310	0.11%	7.60%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$1,315	0.08%	4.98%
336360	Motor Vehicle Seating and Interior Trim Manufacturing	$1,488	0.09%	6.26%
336370	Motor Vehicle Metal Stamping	$2,214	0.10%	6.85%
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$4,252	0.28%	8.73%
336390b	Other Motor Vehicle Parts Manufacturing	$1,906	0.11%	7.20%
Aluminum Production				
331313	Alumina Refining and Primary Aluminum Production	$0	0.00%	0.00%
Coal Fired Utilities				
221112	Fossil Fuel Electric Power Generation	$2,626	0.01%	2.39%
311221	Wet Corn Milling	$0	0.00%	0.00%
311313	Beet Sugar Manufacturing	$0	0.00%	0.00%
311942	Spice and Extract Manufacturing	$0	0.00%	0.00%
312120	Breweries	$0	0.00%	0.00%
321219	Reconstituted Wood Product Manufacturing	$0	0.00%	0.00%
322110	Pulp Mills	$0	0.00%	0.00%
322121	Paper (except Newsprint) Mills	$0	0.00%	0.00%
322122	Newsprint Mills	$0	0.00%	0.00%
322130	Paperboard Mills	$0	0.00%	0.00%
325211	Plastics Material and Resin Manufacturing	$0	0.00%	0.00%
325611	Soap and Other Detergent Manufacturing	$0	0.00%	0.00%
327310	Cement Manufacturing	$0	0.00%	0.00%
333111b	Farm Machinery and Equipment Manufacturing	$0	0.00%	0.00%
336510b	Railroad Rolling Stock Manufacturing	$0	0.00%	0.00%
611310	Colleges, Universities, and Professional Schools	$0	0.00%	0.00%
Abrasive Blasting - Construction				
238320	Painting and Wall Covering Contractors	$2,504	0.71%	20.34%
238990	All Other Specialty Trade Contractors	$2,289	0.32%	9.28%
Abrasive Blasting Shipyards* **				
336611a	Ship Building and Repairing	$1,467	0.10%	1.66%
Welding Shipyards** **				
336611b	Ship Building and Repairing	$3,112	0.22%	3.52%
Total				
General Industry Subtotal		**$2,956**	**0.34%**	**6.06%**
Construction Subtotal		**$2,402**	**0.46%**	**13.22%**
Maritime Subtotal		**$1,483**	**0.10%**	**1.68%**

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Total, All Industries		**$2,641**	**0.09%**	**1.70%**

Notes:

Figures in rows may not add to totals due to rounding.

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 327110a) and Beryllium Oxide (NAICS 331410a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

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

Description of the Steps OSHA Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes and Statement of the Reasons For Selecting the Alternative Adopted in the Final Rule

OSHA has made a number of changes in the final beryllium rule that will serve to minimize significant impacts on small entities consistent with the objectives of the OSH Act. These changes are explained in more detail in Section XVI: Summary and Explanation in this preamble.

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 final rule, the Agency has removed skin contact as a trigger for medical surveillance. OSHA has also reduced the frequency of medical surveillance from annually (in the proposed rule) to biennially in the final rule.

In the final rule, OSHA has added a performance option, as an alternative to scheduled monitoring, to allow employers to comply with exposure assessment requirements. This performance option should allow employers more flexibility, and often lower cost, in complying with the exposure assessment requirements.

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 final rule, OSHA has concluded that all affected employers currently have hand washing facilities. OSHA has also concluded that no affected employers will be required to install showers. OSHA noted in the PEA that some facilities already have showers. There were no comments challenging the Agency's preliminary determinations regarding the existing availability of shower facilities or the means of preventing contamination, so the Agency concludes that all employers have showers where needed. Therefore, employers will not need to provide any new shower facilities to comply with the standard.[33]

Similarly, in the PEA the Agency included no additional costs for readily accessible washing facilities, under the expectation that employers already have such facilities in place (PEA p. IX–19). Although the abrasive blasters exposed to beryllium in maritime and construction work may not have been expressly addressed in the PEA, OSHA notes that their employers are typically already required to provide readily accessible washing facilities to comply with other OSHA standards such as its sanitation standard at 29 CFR 1926.51(f)(1).[34] In the absence of additional comment, OSHA is not including any costs for washing facilities in the FEA.

OSHA's shipyard standard at 29 CFR 1915.58(e) requires handwashing facilities ''at or adjacent to each toilet facility'' and ''equipped with . . . running water and soap, or with waterless skin-cleansing agents that are capable of . . . neutralizing the contaminants to which the employee may be exposed.'' OSHA's construction standard at 29 CFR 1926.51(f)(1) requires ''adequate washing facilities for employees engaged in . . . operations where contaminants may be harmful to the employees. Such facilities shall be in near proximity to the worksite and shall be so equipped as to enable employees to remove such substances.''

[33] OSHA reached the same conclusion in the PEA (p. V–118). For information purposes, OSHA estimated the initial cost of installing portable showers at $39,687, with an annualized cost of $4,653 per facility (Id.) and did not receive any comments suggesting that shower costs should be included or regarding the cost of installing them. The annual cost per employee for shower supplies, towels, and time required for showering was estimated to be $1,519. However, as indicated above in the text, the Agency believed that employers would be able to comply with the standard by less costly means than the installation of shower facilities.

[34] OSHA's shipyard standard at 29 CFR 1915.58(e) requires handwashing facilities ''at or adjacent to each toilet facility'' and ''equipped with . . . running water and soap, or with waterless skin-cleansing agents that are capable of . . . neutralizing the contaminants to which the employee may be exposed.'' OSHA's construction standard at 29 CFR 1926.51(f)(1) requires ''adequate washing facilities for employees engaged in . . . operations where contaminants may be harmful to the employees. Such facilities shall be in near proximity to the worksite and shall be so equipped as to enable employees to remove such substances.''

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.

Finally, in the final rule, OSHA has extended the compliance deadlines for change rooms from one year to two years and for engineering controls from two years to three years.

• Regulatory Alternatives

For the convenience of those persons interested only in OSHA's regulatory flexibility analysis, this section repeats the discussion presented in Chapter VIII of the FEA, but only for the regulatory alternatives to the final OSHA beryllium standard that would have lowered costs.

Each regulatory alternative presented here is described and analyzed relative to the final rule. Where appropriate, the Agency notes whether the regulatory alternative, to have been a legitimate candidate for OSHA consideration, required evidence contrary to the Agency's final findings of significant risk and feasibility. For this chapter on the Final Regulatory Flexibility Analysis, the Agency is only presenting regulatory alternatives that would have reduced costs for small entities. (See Chapter VIII for the full list of all alternatives analyzed.) There are 14 alternatives that would have reduced costs for small entities (and for all businesses in total). Using the numbering scheme from Chapter VIII of the FEA, these are Regulatory Alternatives #1a, #2a, #2b, #5, #6, #7, #8, #9, #10, #11, #12, #13, #15, #16, #18, and #22. OSHA has organized these 16 cost-reducing alternatives (and a general discussion of considered phase-ins of the rule) into four categories: (1) Scope; (2) exposure limits; (3) methods of compliance; and (4) ancillary provisions.

(1) Scope Alternatives

The scope of the beryllium final rule applies to general industry work, construction and maritime activities. In addition, the final rule provides an exemption for those working with materials containing only trace amounts of beryllium (less than 0.1% by weight) when the employer has objective data that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

The first set of regulatory alternatives would alter the scope of the final standard by differing in coverage of groups of employees and employers. Regulatory Alternatives #1a, #2a, and #2b would decrease the scope of the final standard.

Regulatory Alternative #1a would exclude all operations where beryllium exists only as a trace contaminant; that is, where the materials used contain less than 0.1% beryllium by weight, with no other conditions. OSHA has identified two industries with workers engaged in general industry work that would be excluded under Regulatory Alternative #1a: Primary aluminum production and coal-fired power generation.

Table VIII–11 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 final rule. Table VIII–11 also breaks out costs by provision, and benefits by type of disease and by morbidity/mortality prevented. (Note: ''morbidity'' cases are cases where health effects are limited to non-fatal illness; in these cases there is no further disease progression to fatality).

As shown in Table VIII–11, Regulatory Alternative #1a would decrease the annualized cost of the rule from $73.9 million to $64.6 million using a 3 percent discount rate and from $76.6 million to $67.0 million using a 7 percent discount rate. Annualized benefits in monetized terms would decrease from $560.9 million to $515.7 million, using a 3 percent discount rate, and from $249.1 million to $229.0 million using a 7 percent discount rate. Net benefits would decrease from $487.0 million to $451.1 million using a 3 percent discount rate and from $172.4 million to $162.0 million using a 7 percent discount rate.

Table VIII-11 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of Alternative Scope (Regulatory Alternative #1a) (2015 Million Dollars)									
	Rule (PEL = 0.2 μg/m³, AL = 0.10 μg/m³)			Alternative 1a (Remove trace contaminants)			Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$11.6	$12.5		-$0.7	-$0.7
Respirators		$0.3	$0.3		$0.3	$0.3		$0.0	$0.0
Rule Familiarization		$0.2	$0.2		$0.2	$0.2		$0.0	$0.0
Exposure Assessment		$13.7	$14.4		$10.7	$11.1		-$3.1	-$3.2
Regulated Areas		$0.9	$0.9		$0.9	$0.9		$0.0	$0.0
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.1		$0.0	$0.0
Medical Surveillance		$7.4	$7.7		$6.4	$6.6		-$1.0	-$1.1
Medical Removal		$1.2	$1.3		$1.0	$1.1		-$0.2	-$0.2
Exposure Control Plan		$2.3	$2.4		$2.1	$2.2		-$0.2	-$0.2
Protective Clothing and Equipment		$2.0	$2.0		$1.8	$1.8		-$0.2	-$0.2
Hygiene Areas and Practices		$2.4	$2.4		$2.4	$2.4		$0.0	$0.0
Housekeeping		$22.8	$23.2		$20.0	$20.4		-$2.8	-$2.9
Training		$8.3	$8.3		$7.3	$7.3		-$1.0	-$1.0
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$64.6**	**$67.0**		**-$9.3**	**-$9.7**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			79			-7		
Beryllium-Related Mortality	90	$558.0	$247.5	83	$513.1	$227.5	-7	-$44.9	-$19.9
Beryllium Morbidity	46	$2.9	$1.6	42	$2.6	$1.5	-4	-$0.2	-$0.1
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$515.7**	**$229.0**		**-$45.2**	**-$20.1**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$451.1**	**$162.0**		**-$35.9**	**-$10.4**
Notes:									
Figures in rows may not add to totals due to rounding.									
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis									

Regulatory Alternative #2a would exclude construction and maritime work from the scope of the final standard. For example, this alternative would exclude 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.

Table VIII–12 presents the estimated costs, benefits, and net benefits of Regulatory Alternative #2a 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 these alternatives relative to the final rule. Table VIII–12 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

As shown in Table VIII–12, Regulatory Alternative #2a would decrease costs from $73.9 million to $62.0 million, using a 3 percent discount rate, and from $76.6 million to $64.4 million using a 7 percent discount rate. Annualized benefits would decrease from $560.9 million to $533.3 million, using a 3 percent discount rate, and from $249.1 million to $236.8 million using a 7 percent discount rate. Net benefits would change from $487.0 million to $471.3 million, using a 3 percent discount rate, and is essentially unchanged at a discount rate of 7 percent, with the final rule having net benefits of $172.4 million while the alternative has $172.5 million. Thus, at a 7 percent discount rate, the costs exceed the benefits for this alternative by $0.1 million per year. However, OSHA believes that for these industries, the cost estimate is severely overestimated because 45 percent of the costs are for exposure monitoring assuming that employers use the periodic monitoring option. Employers in this sector are far more likely to use the performance based monitoring options at considerably reduced costs. If this is the case, benefits would exceed costs even at a 7 percent discount rate.

Regulatory Alternative #2b would eliminate the ancillary provisions in the final rule for the shipyard and construction sectors and for any operations where beryllium exists only as a trace contaminant. Accordingly, only the final TWA PEL and STEL would apply to employers in these sectors and operations (through 29 CFR 1910.1000 Tables Z–1 and Z–2, 1915.1000 Table Z, and 1926.55 Appendix A). Operations in general industry where the ancillary provisions would be eliminated under Regulatory Alternative #2b include aluminum smelting and production and coal-powered utility facilities and any other operations where beryllium is present only as a trace contaminant (in addition to all operations in construction and shipyards).

As shown in Table VIII–13, Regulatory Alternative #2b would decrease the annualized cost of the rule from $73.9 million to $53.5 million using a 3 percent discount rate, and from $76.6 to $55.6 million using a 7 percent discount rate. Annualized benefits would decrease from $560.9 million to $493.3 million, using a 3 percent discount rate, and from $249.1 million to $219.1 million, using a 7 percent discount rate. Net benefits would decrease from $487.0 million to $439.8 million, using a 3 percent discount rate, and from $172.4 million to $163.5 million, using a 7 percent discount rate.

Table VIII-12 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of Alternative Scope Excluding Maritime and Construction (Regulatory Alternative #2a) (2015 Million Dollars)

	Rule (PEL = 0.2 μg/m^3, AL = 0.10 μg/m^3)			Alternative 2a (Remove Maritime and Construction Sectors)			Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$12.2	$13.2		$0.0	$0.0
Respirators		$0.3	$0.3		$0.3	$0.3		$0.0	$0.0
Rule Familiarization		$0.2	$0.2		$0.1	$0.1		-$0.1	-$0.1
Exposure Assessment		$13.7	$14.4		$8.5	$8.9		-$5.3	-$5.4
Regulated Areas		$0.9	$0.9		$0.6	$0.6		-$0.3	-$0.3
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.2		$0.0	$0.0
Medical Surveillance		$7.4	$7.7		$6.0	$6.2		-$1.4	-$1.5
Medical Removal		$1.2	$1.3		$0.7	$0.7		-$0.5	-$0.6
Exposure Control Plan		$2.3	$2.4		$2.1	$2.2		-$0.2	-$0.2
Protective Clothing and Equipment		$2.0	$2.0		$1.8	$1.8		-$0.2	-$0.2
Hygiene Areas and Practices		$2.4	$2.4		$0.9	$0.9		-$1.5	-$1.6
Housekeeping		$22.8	$23.2		$21.1	$21.6		-$1.6	-$1.7
Training		$8.3	$8.3		$7.5	$7.6		-$0.8	-$0.8
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$62.0**	**$64.4**		**-$11.9**	**-$12.3**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			81			-4		
Beryllium-Related Mortality	90	$558.0	$247.5	85	$530.6	$235.3	-4	-$27.4	-$12.2
Beryllium Morbidity	46	$2.9	$1.6	44	$2.7	$1.5	-2	-$0.1	-$0.1
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$533.3**	**$236.8**		**-$27.6**	**-$12.3**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$471.3**	**$172.5**		**-$15.7**	**$0.0**

Notes:

Figures in rows may not add to totals due to rounding.

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

Table VIII-13 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of Updating Z Tables 1910.1000, 1915.1000, and 1926.55 and Requiring Control Costs for Industries with Trace Contaminants (Regulatory Alternative #2b) (2015 Million Dollars)

	Rule (PEL = 0.2 μg/m³, AL = 0.1 μg/m³)			Alternative 2b (Update Z Tables 1910.1000, 1915.1000, and 1926.55 and Require Control Costs for Industries with Trace Contaminants)			Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$12.3	$13.3		$0.0	$0.0
Respirators		$0.3	$0.3		$0.3	$0.3		-$0.1	-$0.1
Rule Familiarization		$0.2	$0.2		$0.2	$0.2		$0.0	$0.0
Exposure Assessment		$13.7	$14.4		$5.4	$5.7		-$8.3	-$8.7
Regulated Areas		$0.9	$0.9		$0.6	$0.6		-$0.3	-$0.3
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.1		$0.0	$0.0
Medical Surveillance		$7.4	$7.7		$5.0	$5.1		-$2.4	-$2.6
Medical Removal		$1.2	$1.3		$0.5	$0.5		-$0.7	-$0.8
Exposure Control Plan		$2.3	$2.4		$1.9	$1.9		-$0.5	-$0.5
Protective Clothing and Equipment		$2.0	$2.0		$1.6	$1.6		-$0.4	-$0.4
Hygiene Areas and Practices		$2.4	$2.4		$0.9	$0.9		-$1.6	-$1.6
Housekeeping		$22.8	$23.2		$18.3	$18.7		-$4.4	-$4.5
Training		$8.3	$8.3		$6.5	$6.6		-$1.8	-$1.8
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$53.5**	**$55.6**		**-$20.4**	**-$21.1**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			75			-11		
Beryllium-Related Mortality	90	$558.0	$247.5	79	$490.8	$217.7	-11	-$67.2	-$29.8
Beryllium Morbidity	46	$2.9	$1.6	40	$2.5	$1.4	-6	-$0.4	-$0.2
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$493.3**	**$219.1**		**-$67.5**	**-$30.0**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$439.8**	**$163.5**		**-$47.2**	**-$8.9**

Notes:

Figures in rows may not add to totals due to rounding.

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

(2) Exposure Limit (TWA PEL, STEL, and Action Level) Alternatives

Paragraph (c) of the three final standards establishes two PELs for beryllium in all forms, compounds, and mixtures: An 8-hour TWA PEL of 0.2 μg/m³ (paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m³ (paragraph (c)(2)). OSHA has defined the action level for the final standard as an airborne concentration of beryllium of 0.1 μg/m³ calculated as an eight-hour TWA (paragraph (b)). In this final rule, as in other standards, the action level has been set at one half of the TWA PEL.

Regulatory Alternative #5 would set a higher TWA PEL at 0.5 μg/m³ and an action level at 0.25 μg/m³. This alternative 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 final PELs (see Chapter VI of the FEA), and Regulatory Alternative #5 was considered in response to the second half of that recommendation. However, the higher 0.5 μg/m³ TWA PEL is not 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 VIII–14 below indicate that the final TWA PEL would prevent additional fatalities and non-fatal illnesses relative to Regulatory Alternative #5.

Table VIII–14 below presents, for informational purposes, the estimated costs, benefits, and net benefits of the final rule under the final TWA PEL of 0.2 μg/m³ and for the regulatory alternative TWA PEL of 0.5 μg/m³ (Regulatory Alternative #5), 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 final TWA PEL of 0.2 μg/m³. Table VIII–14 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

As Table VIII–14 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 30 beryllium-related fatalities and an additional 16 non-fatal illnesses. This is consistent with OSHA's final risk assessment, which indicates significant risk to workers exposed at a TWA PEL of 0.5 μg/m³; furthermore, OSHA's final feasibility analysis indicates that a lower TWA PEL than 0.5 μg/m³ is feasible. Net benefits of this regulatory alternative versus the final TWA PEL of 0.2 μg/m³ would decrease from $487.0 million to $376.5 million using a 3 percent discount rate and from $172.4 million to $167.2 million using 7 percent discount rate.

Table VIII-14 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of 0.1 µg/m3 and 0.5 µg/m3 PEL Alternative (Regulatory Alternatives #4 and #5) (2015 Million Dollars)

	Rule (PEL = 0.2 µg/m3, AL = 0.10 µg/m3)			Alternative 5 (PEL = 0.5 µg/m3, AL = 0.25 µg/m3)			Alternative 5 Incremental Costs/Benefits		
	Cases	**3%**	**7%**	**Cases**	**3%**	**7%**	**Cases**	**3%**	**7%**
Annualized Costs									
Control Costs		$12.3	$13.3		$7.6	$8.2		**$4.7**	**$5.1**
Respirators		$0.3	$0.3		$0.2	$0.2		**$0.1**	**$0.1**
Rule Familiarization		$0.2	$0.2		$0.2	$0.2		**$0.0**	**$0.0**
Exposure Assessment		$13.7	$14.4		$7.8	$8.4		**$5.9**	**$5.9**
Regulated Areas		$0.9	$0.9		$0.5	$0.5		**$0.4**	**$0.4**
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.2		**$0.0**	**$0.0**
Medical Surveillance		$7.4	$7.7		$4.9	$5.1		**$2.5**	**$2.6**
Medical Removal		$1.2	$1.3		$0.3	$0.4		**$0.8**	**$0.9**
Exposure Control Plan		$2.3	$2.4		$2.3	$2.4		**$0.0**	**$0.0**
Protective Clothing and Equipment		$2.0	$2.0		$2.0	$2.0		**$0.0**	**$0.0**
Hygiene Areas and Practices		$2.4	$2.4		$1.6	$1.6		**$0.8**	**$0.8**
Housekeeping		$22.8	$23.2		$22.8	$23.2		**$0.0**	**$0.0**
Training		$8.3	$8.3		$8.3	$8.3		**$0.0**	**$0.0**
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$58.6**	**$60.7**		**$15.3**	**$15.9**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			56			29		
Beryllium-Related Mortality	90	$558.0	$247.5	60	$374.6	$166.2	30	**$183.4**	**$81.3**
Beryllium Morbidity	46	$2.9	$1.6	30	$1.9	$1.1	16	**$1.0**	**$0.5**
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$376.5**	**$167.2**		**$184.4**	**$81.9**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$376.5**	**$167.2**		**$110.5**	**$5.2**

Notes:

Figures in rows may not add to totals due to rounding.

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

Regulatory Alternative With Unchanged PEL But Full Ancillary Provisions

An Informational Analysis: This final regulation has the somewhat unusual feature for an OSHA substance-specific health standard that most of the quantified benefits that OSHA estimated would come from the ancillary provisions rather than from meeting the PEL solely with engineering controls (see Chapter VII of the FEA for a more detailed discussion). OSHA decided to analyze for informational purposes the effect of retaining the preceding 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 final provisions (including respiratory protection) would be required with their triggers remaining the same as in the final 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. The absence of engineering controls would not be consistent with OSHA's application of the hierarchy of controls, in which engineering controls are applied to eliminate or control hazards, before administrative controls and personal protective equipment are applied to address remaining exposures. Section 6(b)(5) of the OSH Act 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. Also, OSHA estimates the costs would be about the same (or slightly lower, depending on certain assumptions) under that approach as under the traditional final approach.

When examined on an industry-by-industry basis, OSHA found that some industries would have lower costs if they could adopt the ancillary-provision-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 employer-by-employer of when the ancillary-provisions-only approach might be cheaper. In the majority of affected industries, the Agency estimates there are no cost savings to the ancillary-provisions-only approach. However, OSHA estimates an annualized total cost saving of $2.7 million per year 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 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 and medical surveillance.

If respirators were as effective as engineering controls, the ancillary-provisions-only approach would have benefits comparable to the benefits of the final rule. However, in this alternative most exposed individuals would be required to use respirators, which OSHA considers less effective than engineering controls in preventing employee exposure to beryllium. OSHA also examined what the benefits would be if respirators were not required, were not worn, or were ineffective. OSHA found that, if all of the other aspects of the benefits analysis remained the same, the annualized benefits would be reduced by from $33.2 million using a discount rate of 3 percent, and $22.4 using a discount rate of 7 percent, largely as a result of failing to reduce deaths from lung cancer, which are unaffected by the ancillary provisions. However, there are also other reasons to believe that benefits may be even lower:

(1) As noted above, in the final rule 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.

(2) OSHA judges that the benefits of the ancillary provisions (a midpoint estimate of eliminating 45 percent of all remaining cases of CBD for all sectors except for abrasive blasting and coal-fired power plants, and an estimate of 11.25 percent, or one fourth of the percentage for other sectors, for abrasive blasting and coal-fired power plants) would be partially or wholly negated in the absence of engineering controls that would reduce both airborne and surface dust levels. The Agency's high estimate (90 percent for all sectors except abrasive blasting and coal fired power plants, 22.5 percent for abrasive blasting and coal-fired power plants) of the proportion of remaining CBD cases eliminable by ancillary provisions is based on data from a facility with average exposure levels of less than 0.2 μg/m³.

Based on these considerations, OSHA finds that the ancillary-provisions-only approach is not one that is likely to maximize net benefits. The cost savings, 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)(i) of the final standards contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in general industry, maritime, and construction. For each operation in a beryllium work area in general industry or where exposures are or can reasonably be expected to be above the action level in shipyards or construction, employers must ensure that one or more of the following are in place to minimize employee exposure: Material and/or process substitution; isolation, such as ventilated partial or full enclosures; local exhaust ventilation; or process controls, such as wet methods and automation. Employers are exempt from using these methods only when they can show that such methods are not feasible or where exposures are below the action level based on two exposure samples taken at least seven days apart.

OSHA believes that the methods 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 therefore also considered Regulatory Alternative #6, which would drop the provisions of (f)(2)(i) from the final 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 final 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 VIII–15, Regulatory Alternative #6 would decrease the annualized cost of the final rule by $606,706 using a discount rate of 3 percent and by $638,100 using a discount rate of 7 percent.

In the PEA, OSHA had been unable to estimate the benefits of this alternative and invited public comment. The Agency did not receive public comment and therefore has not estimated the change in benefits resulting from Regulatory Alternative #6.

Table VIII-15 Cost of Regulatory Alternative #6 (Eliminate provision (f)(2)) (2015 dollars)

	Total Cost	Increment Relative to Rule
3% Discount Rate		
Rule	$73,868,230	-
Alternative 6: Eliminate (f)(2) controls	$73,261,523	-$606,706
7% Discount Rate		
Rule	$76,637,363	-
Alternative 6: Eliminate (f)(2) controls	$75,999,263	-$638,100
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis		

(4) Regulatory Alternatives That Affect Ancillary Provisions

The final standard contains several ancillary provisions (provisions other than the exposure limits), including requirements for exposure assessment, medical surveillance, medical removal, training, competent person, and regulated areas or access control. As reported in Chapter V of the FEA, these ancillary provisions account for $61.3 million (about 83 percent) of the total annualized costs of the rule ($73.4 million) using a 3 percent discount rate. The most expensive of the ancillary provisions are the requirements for housekeeping and exposure monitoring, with annualized costs of $22.8 million and $13.7 million, respectively, at a 3 percent discount rate.

OSHA's reasons for including each of the final ancillary provisions are explained in Section XVI of the preamble, Summary and Explanation of the Standards.

OSHA has examined a variety of regulatory alternatives involving changes to one or more of the final ancillary provisions. The incremental cost of each of these regulatory alternatives and its impact on the total costs of the final rule are summarized in Table VIII–16 at the end of this section. OSHA has determined that several of these ancillary provisions will increase the benefits of the final 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 final 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 #20), and for medical removal protection (#22).

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 final TWA PEL of 0.2 μg/m³ or the final STEL of 2.0 μg/m³.

Regulatory Alternative #7 would only update 1910.1000 Tables Z–1 and Z–2, so that the final TWA PEL and STEL would apply to all workers in general industry, construction, and maritime. This alternative would eliminate all of the ancillary provisions of the final rule, including exposure assessment, medical surveillance, medical removal protection, PPE, housekeeping, training, competent person, and regulated areas or access control. Under this regulatory alternative, OSHA estimates that the costs for the final ancillary provisions of the rule (estimated at $61.4 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 United Steelworkers, 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 final rule. The total costs for this alternative are $12.5 million at a 3% discount rate and $13.5 million at a 7% discount rate.

OSHA has also estimated the effect of this regulatory alternative on the benefits of the rule, presented in Table VIII–16. As a result of eliminating all of the ancillary provisions, annualized benefits are estimated to decrease 71 percent, relative to the final rule, from $560.9 million to $211.9 million, using a 3 percent discount rate, and from $249.1 million to $94.0 million using a 7 percent discount rate. This estimate follows from OSHA's analysis of benefits in Chapter VII of the FEA, which found that about 68 percent of the benefits of the final 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 final rule will not be fully achieved if employers do not implement the ancillary provisions of the final 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 Materion, the primary beryllium producer, 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 United Steelworkers, 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 final TWA PEL alone could achieve.

Under Regulatory Alternative #8, several ancillary provisions that the current final rule 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 final standard:

—*Exposure monitoring:* Whereas the scheduled monitoring option of the final standards requires monitoring every six months when exposure levels are at or above the action level and at or below the TWA PEL and every three months when exposure levels exceed the TWA PEL, Regulatory Alternative #8 would require annual exposure monitoring where exposure levels exceed the TWA PEL or STEL;

○ *Written exposure control plan:* Whereas the final standards require 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;

○ *PPE:* Whereas the final standards require PPE when airborne exposure to beryllium exceeds, or can reasonably be expected to exceed, the PEL or STEL, and where there is a reasonable expectation of dermal contact with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;

○ *Medical Surveillance:* Whereas the final standard's medical surveillance provisions require employers to offer medical surveillance to employees exposed above the action level for 30 days per year, showing signs or symptoms of CBD, exposed to beryllium in an emergency, or when recommended by a medical opinion, 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, with results presented in Table VIII–16. Combining these various adjustments along with associated unit costs, OSHA estimates that, under this regulatory alternative, the costs for the final rule would decline from $73.9 million to $35.8 million, using a 3 percent discount rate, and from $76.6 million to $37.9 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 final 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 final TWA PEL and STEL could achieve.

The remainder of this chapter discusses additional regulatory alternatives that apply to individual ancillary provisions.

Exposure Monitoring

Paragraph (d) of the final standard, Exposure Assessment, allows employers to choose either the performance option or scheduled monitoring. The scheduled monitoring option requires semi-annual monitoring for those workers exposed at or above the action level but at or below the PEL and quarterly exposure monitoring for those workers exposed above the PEL. The rationale for this provision is provided in the preamble discussion of paragraph (a) in Section XVI, Summary and Explanation of the Standards.

OSHA has examined three regulatory alternatives that would modify the requirements of periodic monitoring in the final rule. Under Regulatory Alternative #9, employers would be required to perform periodic exposure monitoring annually when exposures are at or above the action level or above the STEL, but at or below the TWA PEL. As shown in Table VIII–16, Regulatory Alternative #9 would decrease the annualized cost of the final rule by about $4.3 million using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #10, employers would be required to perform periodic exposure monitoring annually when exposures are at or above the action level. As shown in Table VIII–16, Regulatory Alternative #10 would decrease the annualized cost of the final rule by about $4.9 million using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #11, employers would be required to perform annual exposure monitoring where exposures are at or above the action level but at or below the TWA PEL and STEL. When exposures are above the TWA PEL, no periodic monitoring would be required. As shown in Table VIII–16, Regulatory Alternative #11 would decrease the annualized cost of the final rule by about $5.0 million using either a 3 percent or 7 percent discount rate. OSHA is unable to quantify the effect of this change on benefits but has judged the alternative adopted necessary and protective.

Regulated Areas

Final paragraph (e) for General Industry requires employers to establish and maintain beryllium work areas in any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium, and regulated areas wherever airborne concentrations of beryllium exceed, or can reasonably be expected to exceed, the TWA PEL or STEL. The Shipyards standard also requires regulated areas. The Construction standard has a comparable competent person requirement. Employers in General Industry and Shipyards are required to demarcate 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 in the General Industry and Maritime standards, and eliminate the competent person requirement in the Construction standard. This alternative would not eliminate the final requirement to establish beryllium work areas, where required. As shown in Table VIII–16, Regulatory Alternative #12 would decrease the annualized cost of the final rule by about $1.0 million using either a 3 or 7 percent discount rate.

Personal Protective Clothing and Equipment

Regulatory Alternative #13 would modify the requirements for personal protective equipment (PPE) by eliminating the requirement for appropriate PPE whenever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. This alternative would be narrower, and thus less protective, than the PPE requirement in the final standards, which require PPE to be used where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL, or where there is a reasonable expectation of dermal contact with beryllium.

The economic analysis for the final standard already contains costs for protective clothing, namely gloves, for all employees who can reasonably be expected to be have dermal contact with beryllium; thus OSHA estimated the cost of this alternative as the cost reduction from not providing gloves under these circumstances. As shown in Table VIII–16, Regulatory Alternative #13 would decrease the annualized cost of the final rule by about $481,000 using either a 3 percent or 7 percent discount rate.

• Medical Surveillance

The final requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are or are reasonably expected to be exposed to beryllium at or above the action level for more than 30 days per year, who show signs or symptoms of CBD or other beryllium-related health effects, are exposed to beryllium in an emergency, or whose more recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends such surveillance, and (2) low dose CT scans for employees when recommended by the PLCHP. The final standards require biennial medical exams to be provided for eligible employees. The standards also require tests for beryllium sensitization to be provided to eligible employees biennially.

OSHA estimated in Chapter V of the FEA that the medical surveillance requirements would apply to 4,528 workers in general industry, of whom 387 already receive medical surveillance.[35] In Chapter V of the FEA, OSHA estimated the costs of medical surveillance for the remaining 4,141 workers who would now have such protection due to the final standard. The Agency's final analysis indicates that 4 workers with beryllium sensitization and 6 workers with CBD will be referred to a CBD diagnostic center 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 final PELs, are at significant risk of illness.[36]

OSHA has examined four regulatory alternatives (#15, #16, #18, and #22) that would modify the final 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 final rule, which was modified since the SBAR Panel was convened (see the preamble at Section XVI, Summary and Explanation of the Standards, for more detailed discussion). Regulatory Alternative #16 also responds to recommendations by the SBAR Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements.

OSHA has determined that a significant risk of beryllium sensitization, CBD, and lung cancer exists at exposure levels below the final TWA PEL and that there is evidence that beryllium sensitization can occur even from short-term exposures (see the preamble at Section V, Health Effects, and Section VII, 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 section XVI of this preamble, the Summary and Explanation for paragraph (k)).

Regulatory Alternative #15 would decrease eligibility for medical surveillance to employees who are exposed to beryllium above the final PEL

To estimate the cost of Regulatory Alternative #15, OSHA assumed that all workers exposed above the PEL before the final rule would continue to be exposed after the standard is promulgated. Thus, this alternative eliminates costs for medical exams for the number of workers exposed between the action level and the TWA PEL. As shown in Table VIII–16, Regulatory Alternative #15 would decrease the annualized cost of the final rule by about $4.5 million using a discount rate of 3 percent, and by about $4.8 million using a discount rate of 7 percent.

In response to concerns raised during the SBAR Panel process about testing requirements, OSHA considered 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 VIII–16, this alternative would decrease the annualized cost of the final rule by about $2.4 million using either a 3 percent or 7 percent discount rate.

Regulatory Alternative #18 would eliminate the CT scan requirement from the final rule. This alternative would decrease the annualized cost of the final rule by about $613,000 using a discount rate of 3 percent, and by about $643,000 using a discount rate of 7 percent.

• Medical Removal

Under paragraph (l) of the final standard, Medical Removal, employees in jobs with exposure at or above the action level become eligible for medical removal when they provide their employers with a written medical report indicating they are diagnosed with CBD or confirmed positive for beryllium sensitization, or if a written medical opinion recommends medical removal

[35] See baseline compliance rates for medical surveillance in Chapter III of the FEA, Table III–20.

[36] OSHA did not estimate, and the benefits analysis does not include, monetized benefits resulting from early discovery of illness.

in accordance with the medical surveillance paragraph of the standards. 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, the employer must 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, in which case the employer would have to provide, and the employee would have to use, a respirator.

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 final requirement that employers offer MRP. As shown in Table VIII–16, this alternative would decrease the annualized cost of the final rule by about $1.2 million using a discount rate of 3 percent, and by about $1.3 million using a discount rate of 7 percent.

Table VIII-16 Cost of Regulatory Alternatives Affecting Ancillary Provisions (2015 dollars)

	Total Cost	Incremental Cost Relative to Rule	Benefits	Incremental Benefits Relative to Rule
3% Discount Rate				
Rule	$73,868,230	-	$560,873,424	-
Alternative 7: Update Z table 1910.1000 only (No ancillary provisions)	$12,516,905	-$61,351,325	$211,870,162	-$349,003,262
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$35,794,047	-$38,074,183		
Alternative 9: Annual periodic monitoring between AL/STEL and PEL	$69,544,910	-$4,323,319		
Alternative 10: Annual periodic monitoring AL/STEL to PEL and > PEL.	$69,021,502	-$4,846,728		
Alternative 11: Annual periodic monitoring when exposure above AL/STEL, biannual monitoring when exposure above PEL	$68,847,033	-$5,021,197		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$72,854,475	-$1,013,754		
Alternative 13: No PPE wherever there is contact with beryllium or beryllium contaminated surfaces	$73,387,012	-$481,217		
Alternative 15: Medical surveillance applies to workers above the PEL post-rule	$69,405,421	-$4,462,809		
Alternative 16: No BeLPTs in medical surveillance	$71,492,837	-$2,375,392		
Alternative 17: BeLPTs part of annual exam, rather than biennially.	$76,666,395	$2,798,166		
Alternative 18: No CT Scans	$73,236,886	-$631,343		
Alternative 22: No medical removal protection	$72,717,171	-$1,151,058		
7% Discount Rate				
Rule	$76,637,363	-	$249,078,679	-
Alternative 7: Update Z table 1910.1000 only (No ancillary provisions)	$13,541,714	-$63,095,649	$94,023,516	-$155,055,163
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$37,894,318	-$38,743,045		
Alternative 9: Annual periodic monitoring between AL/STEL and PEL	$72,314,044	-$4,323,319		
Alternative 10: Annual periodic monitoring AL/STEL to PEL and > PEL.	$71,790,636	-$4,846,728		
Alternative 11: Annual periodic monitoring when exposure above AL/STEL, biannual monitoring when exposure above PEL	$71,616,166	-$5,021,197		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$75,594,292	-$1,043,071		
Alternative 13: No PPE wherever there is contact with beryllium or beryllium contaminated surfaces	$76,156,146	-$481,217		
Alternative 15: Medical surveillance applies to workers above the PEL post-rule	$71,882,838	-$4,754,525		
Alternative 16: No BeLPTs in medical surveillance	$74,214,979	-$2,422,384		
Alternative 17: BeLPTs part of annual exam, rather than biennially.	$79,356,557	$2,719,194		
Alternative 18: No CT Scans	$75,994,175	-$643,188		
Alternative 22: No medical removal protection	$75,338,041	-$1,299,322		
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis				

SBAR Panel

Table VIII–17 lists all of the SBAR Panel recommendations and OSHA's response to those recommendations.

• Table VIII–17: 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.
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 final standard, in line with OSHA's normal practice, requires exposure monitoring every three months for levels above the PEL or STEL and every six months for exposures between the action level and the PEL. In the preamble to the final standard, OSHA provides further explanation on the use of objective data, which would exempt employers from the requirements of the final rule. These issues are discussed in the preamble at Section XVI, Summary and Explanation of the Standards, (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 the preamble to the final standards, OSHA discusses the issue of objective data. While OSHA recognizes that some establishments will have objective data, for purposes of estimating the cost of this rule, the Agency is assuming that no establishments will use objective data. The Agency recognizes that this will overestimate costs. The use of objective data is discussed in the preamble at Section XVI, Summary and Explanation of the Standards, (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 final PEL of 0.2 $\mu g/m^3$. The final standards for general industry and maritime require 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 the PEL of 0.2 $\mu g/m^3$. There is no regulated area requirement in Construction.
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.	In General industry employers must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In General Industry, although there is a shower requirement, OSHA has determined that establishments required to have showers will already have them, and employers will not have to install showers to comply with the beryllium standard (Please see the Hygiene Areas and Practices section in Chapter V of the FEA). In Construction and Maritime, for each employee required to use personal protective clothing or equipment, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. For Construction and Maritime, language involving showers has been removed but employers are still required to provide change rooms. Where personal protective clothing or equipment must be used, the employer must provide washing facilities. The standards do not require that eating and drinking areas be provided, but impose requirements when the employer chooses to have eating and drinking areas. Change rooms have been costed in general industry for employees who work in a beryllium work area and in construction and maritime for employees who required to use personal protective clothing or equipment. The Agency has determined that the long-term rental of modular units is 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.

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-analyze 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 the preamble to the final rule, OSHA has clarified the purpose of the housekeeping provision. However, due to the variety of work settings in which beryllium is used, OSHA has concluded that a highly specific directive in the preamble 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 final standards include a more flexible requirement for employers to develop a written exposure control plan specific to their facilities. In general industry, the employer must establish procedures to maintain all surfaces in beryllium work areas as free as practicable of beryllium as required by the written exposure control plan. Other than requirements pertaining to eating and drinking areas, there are no requirements to maintain surface cleanliness in construction or maritime. These issues are discussed in the preamble at Section XVI, Summary and Explanation of the Standards, (f) Methods of Compliance and (j) Housekeeping. The adoption of Regulatory Alternative #20 in the PEA reduced the frequency of physical examinations from annual to biennial, matching the frequency of BeLPT testing in the final rule. These alternatives for medical surveillance are discussed in the Regulatory Alternatives Chapter, Chapter VIII and in the preamble at section XVI, Summary and Explanation of the Standards, (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 medical removal protection (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 final standards, skin exposure is not a trigger for medical removal (unlike the draft version used for the SBAR Panel). Employees are only eligible for medical removal if they are in a job with airborne exposure at or above the action level and provide the employer with a written medical report confirming that they are sensitized or have been diagnosed with CBD, or that the physician recommends removal, or if the employer receives a written medical opinion recommending removal of the employee. 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 employer provides and 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, whichever comes first. OSHA discusses the basis of the provision in the preamble at Section XVI, Summary and Explanation of the Standards, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the FEA in Chapter V and Chapter VI, 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 final 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 final standard ties medical surveillance to exposures at or above the action level for more than 30 days per year (or signs or symptoms of beryllium-related health effects, emergency exposure, or a medical opinion recommending medical surveillance on the basis of a CBD or sensitization diagnosis). Thus, small businesses with exposures below the final action level 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 the preamble at section XVI, Summary and Explanation of the Standards, (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 test.	OSHA has reviewed the possible effects of the final 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 FEA (entitled Economic Feasibility Analysis and Regulatory Flexibility Determination).

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 final 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 final 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 final standard (1) does not apply to beryllium-containing articles that the employer does not process; and (2) does not apply to materials that contain less than 0.1% beryllium by weight if the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. In the preamble to the final standard, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (Section XVI, Summary and Explanation of the Standards, (d) Exposure Monitoring). OSHA also considered 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 VIII of the FEA.
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 the preamble to the final standard at Section V, Health Effects, and Section VI, Risk Assessment. They are also reviewed in the preamble to the final standard at Section VII, Significance of Risk, and the Benefits Chapter of the FEA. As discussed above, OSHA considered Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in Chapter VIII of the FEA.
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 the final standard, including Exposure Assessment and Medical Surveillance. For each employee working in a beryllium work area in general industry, and for each employee required to use personal protective clothing or equipment in construction and maritime, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In addition, the potential for dermal contact with beryllium triggers requirements related to beryllium work areas, the written exposure control plan, washing facilities, housekeeping and training: For some ancillary provisions, including PPE and Housekeeping, the requirements are triggered by visible contamination with beryllium or dermal contact with beryllium. In Construction and Maritime, for each employee required to use personal protective clothing or equipment, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. For Construction and Maritime, language involving showers has been removed and employers are required to provide change rooms for employees required to use personal protective clothing or equipment and required to remove their personal clothing. Where dermal contact occurs, employers must provide washing facilities. These requirements are discussed in the preamble at Section XVI, Summary and Explanation of the Standards. The Agency has also explained the basis and need for compliance with ancillary provisions in the preamble at Section XVI, Summary and Explanation of the Standards.

Panel recommendation	OSHA response
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 FEA, OSHA has described the baseline exposure levels in each industry or application group. In the preamble to the final standards, OSHA discusses the issue of objective data. While OSHA recognizes that some establishments will have objective data, for purposes of the economic analysis, the Agency is choosing to assume that no establishments will use objective data. The Agency recognizes that this will overestimate costs.
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 the preamble to the final rule at section V, Health Effects; and in the preamble at section XVI, Summary and Explanation of the Standards, (b) Definitions and (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. As stated above, the triggers for medical surveillance in the final 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—the final standard ties medical surveillance to exposures above the final action level of 0.1 μg/m^3 (or signs or symptoms of beryllium-related health effects, emergency exposure, or a medical opinion recommending medical surveillance on the basis of a CBD or sensitization diagnosis). The triggers for medical surveillance are discussed in the preamble at section XVI, Summary and Explanation of the Standards, (k) Medical Surveillance. OSHA has considered Regulatory Alternative #16, where employers would not be required to offer employees a BeLPT that tests for beryllium sensitization. from the final standard. This alternative is discussed in the Regulatory Alternatives Chapter and in in the preamble at Section XVI, Summary and Explanation of the Final 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 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 final standards require PPE when there is a reasonable expectation of dermal contact with beryllium. The employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. OSHA uses an exposure profile to determine which workers will be affected by the standards. As a result, in General Industry and Maritime, the final standards require regulated areas where exposures can exceed the PEL or STEL. In General Industry, beryllium work areas must be established in areas that contain a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. In Construction, the written exposure control plan must contain procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, and the competent person must implement the plan. In addition, the scope of the final standards 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 final standard (1) does not apply to beryllium-containing articles that the employer does not process; and (2) does not apply to materials that contain less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. In the preamble to the final standards, OSHA discusses the issue of objective data. While OSHA recognizes that some establishments will have objective data, for purposes of this rule, the Agency is choosing to assume that no establishments will use objective data. The Agency recognizes that this will overestimate costs.

Panel recommendation	OSHA response
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 considered Regulatory Alternative #7, a PEL-only standard. This alternative is discussed in Chapter VIII of the FEA.
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 the final standard, including Exposure Monitoring and Medical Surveillance. In General Industry, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In Construction and Maritime, for each employee required to use personal protective clothing or equipment, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In addition, the language of the final 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 beryllium compounds. These requirements are discussed in the preamble at Section XVI, Summary and Explanation of the Standards. OSHA has explained the scientific basis for minimizing skin exposure to beryllium in the preamble to the final rule at Section V, Health Effects, and explains the basis for specific ancillary provisions related to skin exposure in the preamble at Section XVI, Summary and Explanation of the Standards. In the final standards, 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 considered Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in Chapter VIII of the FEA.
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.	After considering 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 the preamble to the final rule at section V, Health Effects; and in the preamble at section XVI, Summary and Explanation of the Standards, (b) Definitions and (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. The frequency of periodic BeLPT testing in the final 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 biennial to annual, matching the frequency of BeLPT testing in the final rule. In response to the suggestion to allow performance-based medical surveillance, OSHA considered 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 the final standard. Regulatory Alternative #18 would eliminate the CT scan requirement from the final standard. These alternatives are discussed in the Regulatory Alternatives Chapter and in the preamble at Section XVI, Summary and Explanation of the Standards, (k) Medical Surveillance.

Panel recommendation	OSHA response
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.	The final standard includes an MRP provision. OSHA discusses the basis of the provision in the preamble at Section XVI, Summary and Explanation of the Standards, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the FEA in Chapter V and Chapter VI, respectively. The Agency considered Alternative #22, which would eliminate the MRP requirement from the standard. This alternative is discussed in the Regulatory Alternatives Chapter and in the preamble at section XVI, Summary and Explanation of the Standards, (l) Medical Removal Protection.

IX. OMB Review Under the Paperwork Reduction Act of 1995

Introduction

The three final beryllium standards (collectively ''the standards'') for occupational exposure to beryllium—general industry (29 CFR 1910.1024), construction (29 CFR 1926.1124), and shipyard (29 CFR 1915.1024)—contain 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), 44 U.S.C. 3501 *et seq,* and OMB's regulations at 5 CFR part 1320. The PRA requires that agencies obtain approval from OMB before conducting any collection of information (44 U.S.C. 3507). The PRA 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)).

In accordance with the PRA (44 U.S.C. 3506(c)(2)), OSHA solicited public comments on the Beryllium Standard for General Industry (29 CFR 1910.1024*),* Information Collection Request (ICR) (paperwork burden hour and cost analysis) for the proposed rule (80 FR 47555). The Department submitted this ICR to OMB for review in accordance with 44 U.S.C. 3507(d) on August 7, 2015. A copy of this ICR is available to the public at *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=1218-0267*).

On October 21, 2015, OMB issued a Notice of Action (NOA) assigning Beryllium Standard for General Industry new OMB Control Number 1218–0267 to use in future paperwork submissions involving this rulemaking. OMB requested that, ''Prior to publication of the final rule, the agency should provide a summary of any comments related to the information collection and their response, including any changes made to the ICR as a result of comments. In addition, the agency must enter the correct burden estimates.''

The proposed rule invited the public to submit comments to OMB, in addition to OSHA, on the proposed collections of information with regard to the following:

- Whether the proposed collections of information 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 collections of information, 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 (78 FR 56438).

No public comments were received specifically in response to the proposed ICR submitted to OMB for review. However, several public comments submitted in response to the Notice of Proposed Rulemaking (NPRM), described earlier in this preamble, substantively addressed provisions containing collections of information and contained information relevant to the burden hour and costs analysis. These comments are addressed in the preamble, and OSHA considered them when it developed the revised ICR associated with these final standards.

The Department of Labor submitted the final ICR January 9, 2017 containing a full analysis and description of the burden hours and costs associated with the collections of information of the standards to OMB for approval. A copy of the ICR is available to the public at *http://www.reginfo.gov.* OSHA will publish a separate notice in the **Federal Register** that will announce the results of OMB's review. That notice will also include a list of OMB approved collections of information and total burden hours and costs imposed by the new standards.

Under the PRA, Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and the collection of information notice displays a currently valid OMB control number (44 U.S.C. 3507(a)(3)). Also, notwithstanding any other provision of law, no employer 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 (44 U.S.C. 3512). The major collections of information found in the standards are listed below.

Summary of Information Collection Requirements

The Beryllium standards contain collection of information requirements which are essential components of the occupational safety and health standards 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. In the final ICR, OSHA has expanded its coverage to include the construction and shipyard industries—in order to tailor the collection of information requirements to the circumstances found in these sectors. The decision to include standards for construction and shipyards is based on information and comment submitted in response to the NPRM request for comment, and during the informal public hearing.

1. *Title:* Beryllium (29 CFR 1910.1024; 29 CFR 1915.1024; 29 CFR 1926. 1124).

2. *Type of Review:* New.

3. *OMB Control Number:* 1218–0267.

4. *Affected Public:* Business or other for-profit. This standard applies to employers in general industry, shipyard, and construction 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 Final standard.

5. *Number of Respondents:* 5,872 affected employers.

6. *Frequency of Responses:* On occasion; quarterly, semi-annually, annual; biannual.

7. *Number of Responses:* 246,433.

8. *Average Time per Response:* Varies from 5 minutes (.08 hours) for a clerical worker to generate and maintain an employee medical record, to more than 8 hours for a human resource manager to develop and implement a written exposure control plan.

9. *Estimated Total Burden Hours:* 196,894.

10. *Estimated Cost* (capital-operation and maintenance): $46,158,266.

Discussion of Significant Changes in the Collections of Information Requirements

Below is a summary of the collection of information requirements contained in the final rule, and a brief description of the most significant changes between the proposal and the final rule portions of the regulatory text containing collection of information requirements. One of the most significant changes between the NPRM and this final rule is that OSHA extended the scope of the rule so that the most of the provisions now also apply to construction and shipyard work. As a result, while most of the provisions are identical across all three standards (general industry, construction, and shipyards), there are technically more collections of information. However, for purposes of the review and explanation that follows, OSHA has focused on the changes to the general industry provisions and has not separately identified the additions to the construction and shipyard standard unless they deviate from the requirements in the general industry standard. A more detailed discussion of all the changes made to the proposed rule, including the requirements that include identified collection of information, is in Section XVIII: *Summary and Explanation.* The impact on information collections is also discussed in more detail in Item 8 of the ICR.

Exposure Assessment

Paragraph (d) sets forth requirements for assessing employee exposures to beryllium. Consistent with the definition of ''airborne exposure'' in paragraph (b) of these standards, exposure monitoring results must reflect the exposure to airborne beryllium that would occur if the employee were not using a respirator.

Proposed paragraph (d) used the term ''Exposure monitoring.'' In the final rule, this term was changed to ''Exposure assessment'' throughout the paragraph. This change in the final standards was made to align the provision's purpose with the broader concept of exposure assessment beyond conducting air monitoring, including the use of objective data.

OSHA added a paragraph (d)(2) as an alternative exposure assessment method to the scheduled monitoring requirements in the proposed rule. Under this option employers must assess 8-hour TWA exposure and the 15-minute short term exposure for each employee using any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

Proposed paragraph (d)(3), *Periodic Exposure Monitoring,* would have required employers whose initial monitoring results indicated that employee's exposures results are at or above the action level and at or below the TWA PEL to conduct periodic exposure monitoring at least annually. Final paragraph (d)(3), *Scheduled Monitoring Option,* increased the frequency schedule for periodic monitoring and added a requirement to perform periodic exposure monitoring when exposures are above the PEL, paragraph (d)(3)(vi) and when exposures are above the STEL in paragraph (d)(3)(viii).

Proposed paragraph (d)(4) would have required employers to conduct exposure monitoring within 30 days after a change in production processes, equipment, materials, personnel, work practices, or control methods that could reasonably be expected to result in new or additional exposures. OSHA changed the proposed requirement to require that employers perform reassessment of exposures when there is a change in ''production, process, control equipment, personnel, or work practices'' that may reasonably be expected to result in new or additional exposures at or above the action level or STEL. In addition, OSHA added ''at or above the action level or STEL'' to final paragraph (d)(4). In summary, the final rule requires that employers must perform reassessment of exposures when there is a change in production, process, control equipment, personnel, or work practices that may reasonably be expected to result in new or additional exposures at or above the action level or STEL.

Proposed paragraph (d)(5)(i), Employee Notification of Monitoring Results, would have required employers in general industry to inform their employees of results within 15 working days after receiving the results of any exposure monitoring completed under this standard. Final paragraph (d)(6), *Employee Notification of Assessment Results,* requires that employers in general industry, construction and shipyards inform their employees of results within 15 working days after completing an exposure assessment.

Proposed paragraph (d)(5)(ii) (paragraph (d)(6)(ii) of the final standards) would have required that whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must include in the written notification the 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. Final paragraph (d)(6)(ii) removes the requirement that employers include suspected or known sources of exposure in the written notification.

Methods of Compliance

Proposed paragraph (f)(1)(i) would have required employers to establish, implement and maintain a written control plan for beryllium work areas. OSHA has retained the requirement for a written exposure control plan and incorporated most provisions of the proposed paragraph (f)(1)(i) into the final standards for construction and shipyards, with certain modifications due to the work processes and worksites particular to these sectors.

Paragraph (f)(1)(i) differs from the proposal in that it requires a written exposure control plan for each facility, whereas the proposal would have required a written exposure control plan for beryllium work areas within each facility. OSHA has modified the requirement of a list of operations and job titles reasonably expected to have exposure to include those operations and job titles that are reasonably expected to have dermal contact with beryllium. Finally, OSHA modified the proposed requirement to inventory engineering and work practice controls required by paragraph (f)(2) of this standard to include respiratory protection.

Paragraph (f)(1)(ii) of the final standards requires the employer to review and evaluate the effectiveness of each written exposure control plan at least annually and update it when: (A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in additional or new airborne exposure to beryllium; (B) the employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD Diagnostic Center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or (C) the employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

OSHA made several changes to that paragraph. First, OSHA added a requirement to review and evaluate the effectiveness of each written exposure control plan at least annually. Second, OSHA changed the proposed language of (f)(1)(ii)(B) to reflect other changes in the standard, including a change to ensure that employers are not automatically notified of cases of sensitization or CBD among their employees. Third, OSHA modified (f)(1)(ii)(B) to clarify the Agency's understanding that signs and symptoms of beryllium exposure may be related to inhalation or dermal exposure. Finally, OSHA modified the wording of (f)(1)(ii) to require the employer to update ''each'' written exposure control plan rather than ''the'' written exposure control plan, since an employer who operates multiple facilities is required to establish, implement and maintain a written exposure control plan for each facility.

Paragraph (f)(1)(iii) of the proposed rule would have required the employer 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)). OSHA did not receive comments specific to this provision, and has retained it in the final standard for general industry and included the paragraph in the final standards for construction and shipyards.

Respiratory Protection

Proposed Paragraph (g) of the standard would have established the requirements for the use of respiratory protection. OSHA added language to paragraph (g) to clarify that both the selection and use of respiratory protection must be in accordance with the Respiratory Protection standard 29 CFR 1910.134, which is cross-referenced, and to provide a powered air-purifying respirator (PAPR) when requested by an employee. The Respiratory protection standard contains collection of information requirements, include a written respiratory protection program and fit-testing records (29 CFR 1910.134(c)). The collection of information requirements contained in the Respiratory Protection Program standard are approved under OMB Control Number 1218–0099.

Personal Protective Equipment

Final paragraph (h)(3)(iii), like proposed paragraph (h)(3), requires 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.

Housekeeping

Paragraph (j)(3) requires warning labels in accordance with the requirements in paragraph (m) when employer transfer materials containing beryllium. *Medical Surveillance* Final paragraph (k) sets forth requirements for the medical surveillance provisions. The paragraph specifies which employees must be offered medical surveillance, as well as the frequency and content of medical examinations. It also sets forth the information that the licensed physician and CBD diagnostic center is to provide to the employee and employer.

In paragraphs (k)(1)(i)(A)–(D) of the proposal, OSHA specified that employers must make medical surveillance required by this paragraph available for each employee: (1) Who has worked in a regulated area for more than 30 days in the last 12 months; (2) showing symptoms or signs of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue; or (3) exposed to beryllium during an emergency; and (4) who was exposed to airborne beryllium above .2 μg/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. OSHA revised the first proposed medical surveillance trigger to require the offering of medical surveillance based on exposures at or above the action level, rather than the PEL. In addition, OSHA revised the proposed trigger to require employers to make medical surveillance available to each employee who is or is reasonably expected to be exposed at or above the action level for more than 30 days a year, rather than waiting for the 30th day of exposure to occur.

Paragraph (k)(1)(i)(B) has been revised to include signs or symptoms of other beryllium-related health effects.

Proposed paragraph (k)(1)(i)(C) required employers to offer medical surveillance to employees exposed during an emergency. No revisions were made to this paragraph.

OSHA added final paragraph (k)(1)(i)(D), which requires that medical surveillance be made available when the most recent written medical opinion to the employer recommends continued medical surveillance. Under final paragraphs (k)(6) and (k)(7), the written opinion must contain a recommendation for continued periodic medical surveillance if the employee is confirmed positive or diagnosed with CBD, and the employee provides written authorization.

Frequency: Proposed paragraph (k)(2) specified when and how frequently medical examinations were to be offered to those employees covered by the medical surveillance program. Under proposed paragraph (k)(2)(i)(A), employers would have been required to provide each employee with a medical examination within 30 days after making a determination that the employee had worked in a regulated area for more than 30 days in the past 12 months, unless the employee had received a medical examination provided in accordance with this standard within the previous 12 months. OSHA made several changes to this requirement. First, OSHA revised the medical surveillance trigger of employees working in a regulated area to a determination that employee is or is reasonably expected to be exposed at or above the action level for more than 30 days of year; or who shows signs or symptoms of CBD or other beryllium-related health effects. Second, the Agency changed the extended the length of time from within the last 12 months to within the last two years.

Proposed paragraph (k)(2)(ii) required employers to provide an examination annually (after the first examination is made available) to employees who continue to meet the criteria of proposed paragraph (k)(1)(i)(A) or (B). OSHA revised the paragraph to specify that medical examinations were to be made available ''at least'' every two years and to include employees who continue to meet the criteria of final paragraph (k)(1)(i)(D), *i.e.,* each employee whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance. Under the final standards, employees exposed in an emergency, who are covered by paragraph (k)(1)(i)(C), are not included in the biennial examination requirement unless they also meet the criteria of paragraphs (k)(1)(i)(A) or (B) or (D). Final paragraph (k)(2)(i)(A) also differs from the proposal in that in the proposed paragraph the employer did not have to offer an examination if the employee had received an equivalent examination within the last 12 months. In the final rule, this was increased to within two years to align that provision with the frequency of periodic examinations, which is every two years in the final rule.

Proposed paragraph (k)(2)(iii) required the employer to offer a medical examination at the termination of employment, if the departing employee met any of the criteria of proposed paragraphs (k)(1) at the termination of employment for each employee who met the criteria of paragraphs (k)(1)(i)(A), (B), or (C), unless an examination has been provided in accordance with the standard during the 6 months prior to the date of termination.

Final paragraph (k)(2)(iii) requires the employer to make a medical examination available to each employee who meets the criteria of final paragraph (k)(1)(i) at the termination of employment, unless the employee received an exam meeting the requirements of the standards within the last 6 months. OSHA extended the requirement to employees who meet the criteria of final paragraph (k)(1)(i)(D).

Contents of Examination. Paragraph (k)(3) details the contents of the examination. Paragraph (k)(3)(i) requires the employer to ensure that the PLHCP advised 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.

Paragraphs (k)(3)(ii)(A)–(D) detail the content of the medical examination. The final rule made several changes to the content of the employee medical examination including, but not limited to, revising paragraphs: (k)(3)(ii)(A), to include emphasis on past and present airborne exposure to or dermal contact with beryllium; (k)(3)(ii)(C) to require a physical examination for skin rashes, rather than an examination for breaks and wounds; (k)(3)(ii)(E) to require the BeLPT test to be offered ''at least'' every two years, rather than every two years; (k)(3)(ii)(F) to include an LDCT scan when recommended by the PLHCP. With these changes, final paragraphs (k)(3)(ii)(A)–(D) require the medical examination to include: (1) Medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, any history of respiratory dysfunction and smoking history, and; (2) a physical examination with emphasis on the respiratory system; (3) a physical examination for skin rashes; and (4) a pulmonary function test, performed in accordance with guidelines established by the ATS including forced vital capacity (FVC) and a forced expiratory volume in one second (FEV1). A more detailed discussion regarding all of the changes to the content of the Medical examinations may be found in section XVI, *Summary and Explanation of the Standards,* under (k) *Medical Surveillance.*

Information Provided to the PLHCP

Proposed paragraph (k)(4) detailed which information must be provided to the PHLCP. Specifically, the proposed standard required the employer to provide to the examining PLHCP the following information, if known to the employer: A description of the employee's former and current duties that relate to the employee's occupational exposure ((k)(4)(i)); the employee's former and current levels of occupational exposure ((k)(4)(ii)); a description of any personal protective clothing and equipment, including respirators, 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, if the employee provides a medical release of the information ((k)(4)(iv)). OSHA made several changes to this paragraph. First, OSHA updated paragraph (k)(4)(i) to require the employer to provide a description of the employee's former and current duties that relate to both the employee's airborne exposure to and dermal contact with beryllium, instead of merely requiring the provision of information related to occupational exposure. Second, OSHA changed the requirement that the employer obtain a ''medical release'' from the employee to ''written consent'' before providing the PLHCP with information from records of employment-related medical examinations. Third, OSHA revised the provision to require that the employer ensure that the same information provided to the PLHCP is also provided to the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of the standard.

Licensed Physician's Written Medical Opinion

Paragraph (k)(5) of the proposed standard provided for the licensed physician to give a written medical opinion to the employer, but relied on the employer to give the employee a copy of that opinion; thus, there was no difference between information the employer and employee received. The final standards differentiate the types of information the employer and employee receive by including two separate paragraphs within the medical surveillance section that require a written medical report to go to the employee, and a more limited written medical opinion to go to the employer. The requirement to provide the medical opinion to the employee is in paragraph (k)(5) of the final standards; the requirement for providing documentation to the employer is in paragraph (k)(6) of the final standards. Most significantly, OSHA removed the requirement that the medical opinion pass through the employer to the employee.

Licensed Physician's Written Medical Report for the Employee

Final paragraphs (k)(5)(i)–(v) provide the contents of the licensed physician's written medical report for the employee. They include: The results of the medical examination, including any medical condition(s), such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as is defined in paragraph (b) of the standard), that may place the employee at increased risk from further airborne exposure; any medical conditions related to airborne exposure that require further evaluation or treatment (this requirement was not expressly included in the proposal); any recommendations on the employee's use of respirators, protective clothing, or equipment; and any recommended limitations on airborne beryllium exposure.

Paragraph (k)(5) also provides that if the employee is confirmed positive or diagnosed with CBD, or if the physician otherwise deems it appropriate, the written medical report must also contain a referral to a CBD diagnostic center, a recommendation for continued medical surveillance, and a recommendation for medical removal from airborne beryllium exposures above the action level, as described in paragraph (l) of the standard. Proposed paragraph (k)(6) also addressed information provided to employees who were confirmed positive or diagnosed with CBD, but simply required a consultation with the physician.

Licensed Physician's Written Medical Opinion for the Employer

Paragraph (k)(6)(i) requires employers to obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under (k)(3)(ii)(E)). In proposed (k)(5), the physician would have been required to share most of the information identified now provided directly to the employee per final (k)(5) with the employer, but in the final rule OSHA limited the information that could be shared with the employer. In final (k)(6) the written medical opinion for the employer must contain only the date of the examination, a statement that the examination has met the requirements of this standard, and any recommended limitations on the employee's use of respirators, protective clothing, and equipment; and a statement that the PLHCP explained the results of the examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment.

Paragraph (k)(6)(ii) states that if the employee provides written authorization, the written medical opinion for the employer must also contain any recommended limitations on the employee's airborne exposure to beryllium. The requirement for written authorization was not in the proposal. Paragraphs (k)(6)(iii)–(v) state that if an employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a referral for evaluation at a CBD diagnostic center and recommendations for continued medical surveillance and medical removal from airborne exposure to beryllium as described in paragraph (l).

Paragraph (k)(6)(vi) requires the employer to ensure that employees receive a copy of the written medical opinion for the employer within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee. A similar requirement was included in proposed (k)(5)(iii), but the time period was two weeks.

Beryllium Sensitization Test Results Research (Removed)

Proposed paragraph (k)(7) would have required employers to convey the results of beryllium sensitization tests to OSHA for evaluation and analysis at the request of OSHA. Based on comments received during the comment period, OSHA decided not to include the proposed paragraph (k)(7) in the final standard.

Referral to a Diagnostic Center

Final paragraph (k)(7) requires that if the employee wants a clinical evaluation at a CBD diagnostic center, the employer must provide the examination at no cost to the employee. OSHA made several changes to final paragraph (k)(7) as compared to similar provisions in paragraph (k)(6) of the proposal. First, OSHA changed the trigger for referral to a CBD diagnostic center to include both confirmed positive and a CBD diagnosis for consistency with final paragraphs (k)(5)(iii) and (k)(6)(iii). Second, OSHA removed the requirement for a consultation between the physician and employee. However, final paragraph (k)(7)(i) requires that employers provide a no-cost evaluation at a CBD-diagnostic center that is mutually agreed upon by the employee and employer.

Final paragraph (k)(7) requires the employer to ensure that the employee receives a written medical report form the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv) and (v) and that the PLHCP explains the results of the examination of the employee within 30 days of the examination.

Communication of Hazards

Proposed paragraph (m)(1)(i) required chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the HCS (29 CFR 1910.1200) for beryllium. No substantive changes were made to this paragraph.

Proposed paragraph (m)(1)(ii) would have required employers to address at least the following, in classifying the hazards of beryllium: Cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation. 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)). OSHA revised the language to bring it into conformity with other substance specific standards so it is clear that chemical manufacturers, importers, and distributors are among the entities required to classify the hazards of beryllium. OSHA has chosen not to include an equivalent requirement in the final standards for construction and shipyards since employers in construction and shipyards are generally downstream users of beryllium products (blasting media) and would not therefore be classifying chemicals.

Proposed paragraph (m)(1)(iii) would have required 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 and is trained in accordance with the HCS and the training paragraph of the standard. The final paragraph (m)(1)(iii) applies to the general industry, shipyards, and construction. The final provisions are substantively unchanged from the proposal.

Recordkeeping

Paragraph (n) of the final standards sets forth the employer's obligation to comply with requirements to maintain records of air monitoring data, objective data, medical surveillance, and training.

Proposed paragraph (n)(1)(i) required employers to maintain records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of the standard. OSHA made one minor modification in the final standard: OSHA added the words ''make and'' prior to ''maintain'' in order to clarify that the employer's obligation is to create and preserve such records.

Proposed paragraph (n)(1)(ii) required that records of all measurements taken to monitor employee exposure include at least the following information: The date of measurement for each sample taken; the operation being monitored; the sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored. OSHA has made one editorial modification to paragraph (n)(1)(ii)(B), which is to change ''operation'' to ''task.'' Proposed paragraph (n)(1)(iii) required employers to maintain employee exposure monitoring records in accordance with 29 CFR 1910.1020(d)(1)(ii). OSHA has changed the requirement that the employer ''maintain this record as required by'' OSHA's Records Access standard to ''ensure that exposure records are maintained and made available in accordance with'' that standard.

Proposed Paragraph (n)(2) Historical Monitoring Data (Removed)

Proposed paragraph (n)(2) contained the requirement to retain records of any historical monitoring data used to satisfy the proposed standard's the initial monitoring requirements. OSHA deleted the separate recordkeeping requirement for historical data.

Final (n)(2)(i), (ii), and (iii) Objective Data

As a result of deleting paragraph (n)(2) Historical Data, OSHA has included proposed paragraph (n)(3) as paragraph (n)(2) in the final standards, with minor alterations. Paragraph (n)(2) contains the requirements to keep accurate records of objective data. Paragraph (n)(2)(i) requires employers to establish and maintain accurate records of the objective data relied upon to satisfy the requirement for initial monitoring in paragraph (d)(2). Under paragraph (n)(2)(ii), the record is required to contain at least the following information: (A) The data relied upon; (B) the beryllium-containing material in question; (C) source of the data; (D) description of the process, task, or activity on which the objective data were based; (E) other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based. These requirements included minor changes in the description of the last two changes, but were not substantively different.

Paragraph (n)(2)(iii) of the final standard (paragraph (n)(3)(iii) in the proposal) requires the employer to maintain a record of objective data relied upon as required by the Records Access standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(1)(ii)).

Paragraph (n)(3)(i), (ii), & (iii) Medical Surveillance Records

Paragraph (n)(3) of the final standards (paragraph (n)(4) in the proposal), addresses medical surveillance records. Employers must establish and maintain medical surveillance records for each employee covered by the medical surveillance requirements in paragraph (k). Paragraph (n)(3)(ii) lists the categories of information that an employer was required to record: The employee's name, social security number, and job classification; a copy of all licensed physicians' written medical opinions; and a copy of the information provided to the PLHCP. OSHA has moved the requirement that the record include copies of all licensed physicians' written opinions from proposed paragraph (n)(4)(ii)(B) to paragraph (n)(3)(ii)(B) of the final standards.

Proposed paragraph (n)(4)(iii) required the employer to maintain employee medical records in accordance with OSHA's Records Access Standard at 29 CFR 1910.1020. OSHA has added ''and made available'' after ''maintained'' in final paragraph (n)(3)(iii) of the standards, but the requirement is otherwise unchanged.

Paragraph (n)(4)(i) and (ii) Training Records

Paragraph (n)(4) of the final standards (paragraph (n)(5) of the proposal) requires employers to preserve training records, including records of annual retraining or additional training, for a period of three years after the completion of the training. At the completion of training, the employer is required to prepare a record that includes 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 also applied to records of annual retraining or additional training as described in paragraph (m)(4). This paragraph is substantively unchanged from the proposal.

Paragraph (n)(5) Access to Records

Paragraph (n)(5) of the final standards (paragraph (n)(6) of the proposal), requires employers to make all records mandated by these standards 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). This paragraph is substantively unchanged from the proposal.

Paragraph (n)(6) Training Records

Paragraph (n)(6) of the final standards (paragraph (n)(6) in the proposal), requires that employers comply with the Records Access standard regarding the transfer of records, 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. This paragraph is substantively unchanged from the proposal.

X. Federalism

OSHA reviewed the final beryllium rule according to the most recent Executive Order (''E.O.'') on Federalism, E.O. 13132, 64 FR 43255 (Aug. 10, 1999). The E.O. 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. OSHA refers to States that obtain Federal approval for such plans 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. Subject to these requirements, State-Plan States are free to develop and enforce their own occupational safety and health standards.

While OSHA wrote this final rule to protect employees in every State, Section 18(c)(2) of the OSH Act permits State-Plan States to develop and enforce their own standards, provided those standards require workplaces to be at least as safe and healthful as this final rule requires. Additionally, standards promulgated under the OSH Act do not apply to any worker whose employer is a state or local government. 29 U.S.C. 652(5).

This final 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 to adopt stricter standards.

XI. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the States 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). Currently, there are 28 State-Plan States.

A State-Plan State may demonstrate that a standard change is not necessary because the State standard is already the same as or at least as effective as the new or amended Federal standard. 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 28 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 remaining six states and territories cover only public-sector employees: Connecticut, Illinois, New Jersey, Maine, New York, and the Virgin Islands.

This beryllium rule applies to general industry, construction, and shipyards. This rule requires that all State-Plan States revise their standards appropriately within six months of the date of this notice.

XII. 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 (adjusted annually for inflation)'' in any one year before promulgating a final rule. OSHA's rule 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. 29 U.S.C. 652(5). Under voluntary agreement with OSHA, some States require public sector entities to comply with State standards, and these agreements specify that these State standards must be at least as protective as OSHA standards. The OSH Act does not cover tribal governments in the performance of traditional governmental functions, though it does cover tribal governments when they engage in commercial activity. However, the final rule will not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. Thus, the final rule does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Final Economic Analysis (see Section VIII above), OSHA concludes that the rule would not impose a Federal mandate on the private sector in excess of $100 million (adjusted annually for inflation) in expenditures in any one year. As noted below, OSHA also reviewed this final rule in accordance with E.O. 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (Nov. 9, 2000), and determined that it does not have ''tribal implications'' as defined in that Order.

XIII. 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, or product use).

The final beryllium rule is economically significant under E.O. 12866 (see Section IX of this preamble). However, after reviewing the rule, OSHA has determined that it will not impose environmental health or safety risks to children as set forth in E.O. 13045. The final rule will 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 in workplaces disproportionately affects children, who typically are not allowed in workplaces where such exposure exists. OSHA is also not aware that there are a significant number of employees under 18 years of age who may be exposed to beryllium, or that employees of that age are disproportionately affected by such exposure. One commenter, Kimberly-Clark Professional, noted that children may be subject to secondary beryllium exposure due to beryllium particles being carried home on their parents' work clothing, shoes, and hair (Document ID 1962, p. 2). Commenter Evan Shoemaker also noted that ''beryllium can collect on surfaces such as shoes, clothing, and hair as well as vehicles leading to contamination of the family and friends of workers exposed to beryllium'' (Document ID 1658, p. 3). However, OSHA does not believe beryllium exposure disproportionately affects children or that beryllium particles brought home on work clothing, shoes, and hair result in exposures at or near the action level. Furthermore, Kimberly-Clark Professional also noted that potential secondary exposures can be controlled through the use of personal protective equipment in the workplace (Document ID 1676, p. 2). The final standards contain ancillary provisions, such as personal protective clothing and hygiene areas, which are specifically designed to minimize the amount of beryllium leaving the workplace. Therefore, OSHA believes that the final beryllium rule does not constitute a covered regulatory action as defined by E.O. 13045.

XIV. Environmental Impacts

OSHA has reviewed the final beryllium rule 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). OSHA made a preliminary determination that the proposed standard would have no significant impact on air, water, or soil quality; plant or animal life; the use of land or aspects of the external environment. No comments to the record questioned this determination, nor has the Agency found other evidence to invalidate it. Therefore, OSHA concludes that the final beryllium standard will have no significant environmental impacts.

XV. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this final rule in accordance with E.O. 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (Nov. 9, 2000), and determined that it does not have ''tribal implications'' as defined in that order. The OSH Act does not cover tribal governments in the performance of traditional governmental functions, so the rule will not have substantial direct effects on one or more Indian tribes in their sovereign capacity, 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. On the other hand, employees in commercial businesses owned by tribes or tribal members will receive the same protections and benefits of the standard as all other covered employees.

XVI. Summary and Explanation of the Standards

OSHA proposed a standard for occupational exposure to beryllium and beryllium compounds in general industry and proposed regulatory alternatives to address beryllium exposures in the construction and maritime industries. The proposed standard for general industry was structured according to OSHA's traditional approach, with permissible exposure limits, and ancillary provisions such as exposure assessment, methods of compliance, and medical surveillance. As discussed below, OSHA based the proposal substantively on a joint industry and labor stakeholders' draft occupational health standard developed and submitted to OSHA by Materion Corporation (Materion) and the United Steelworkers (USW). The final rule, however, is based on the entirety of the rulemaking record.

In the final rule, OSHA is expanding coverage to include the construction and shipyard industries and establishing separate final standards for occupational exposure to beryllium in general industry, construction, and shipyards. In the NPRM, OSHA discussed Regulatory Alternative 2a to include both the construction and shipyard industries in the final rule (80 FR 47732–47734), presented estimated costs and benefits associated with extending the scope of the final rule, and requested comment on the alternative. The decision to include standards for construction and shipyards is based on information and comment submitted in response to this request for comment and evaluated by OSHA during the public comment periods and the informal public hearing. OSHA decided to issue three separate standards because there are some variations in the standards for each industry, although the structure of the final standards for general industry, construction, and shipyards remains generally consistent with other OSHA health standards. The most significant change is in the standard for construction where paragraph (e) Competent person, replaces paragraph (e) Beryllium work areas and regulated areas in general industry and paragraph (e) Regulated areas in shipyards.

All three final standards have a provision for methods of compliance, although in the standard for construction this provision has an additional requirement to describe procedures used by the designated competent person to restrict access to work areas, when necessary, to minimize the number of employees exposed to airborne beryllium above the PEL or STEL. This requirement allows the competent person to perform essentially the same role as the requirement governing regulated areas in general industry and shipyards, which is to regulate and minimize the number of workers exposed to hazardous levels of beryllium. OSHA decided to include a competent person provision in the final standard for construction because of the industry's familiarity with this concept and its past successful use in many OSHA construction standards and documents. ''Competent person'' is defined in OSHA's Safety and Health Regulations for Construction (29 CFR 1926.32(f)) as being a person who is capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them. This generally applicable definition corresponds well with the definition for ''competent person'' in the standard for construction: In this context, ''competent person'' means an individual who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of this standard.

OSHA has retained, in modified form, the scope exemption from the proposed standard for materials containing less than 0.1 percent beryllium by weight in the standard for general industry and included it in the standards for construction and shipyards. The scope exemption has been modified in the final standards with the additional requirement that the employer must have objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. The 0.1 percent exemption was generally supported by commenters from general industry and shipyards; construction employers did not comment. Other commenters, especially those representing workers or public health organizations, expressed concern that these materials, in some cases, could expose workers to hazardous levels of beryllium. As discussed in more detail in the summary and explanation for Scope and application, the objective data requirement addresses these concerns and ensures the protection of workers who experience significant exposures from materials containing trace amounts of beryllium. Employers who have objective data showing that employees will not be exposed at or above the action level under any foreseeable conditions when processing materials containing less than 0.1 percent beryllium by weight are exempt from the standard.

OSHA decided to add a performance option in paragraph (d), Exposure assessment, as an alternative exposure assessment method to the scheduled monitoring requirements in the proposed rule, based on public comment received from industry and labor. OSHA believes the performance option, which encompasses either exposure monitoring or assessments based on objective data, gives employers flexibility in determining employee exposure to beryllium based on to their unique workplace circumstances. OSHA has provided this performance option in recent health standards such as respirable crystalline silica (29 CFR 1910.1053(d)(2)) and chromium VI (29 CFR 1910.1026(d)(3)).

OSHA also received comments about other provisions in the proposed standard, and in some cases, OSHA responded with changes from the proposed rule that were based on the evidence provided in the record. Any changes made to the provisions in the final standards are described in detail in their specific summary and explanation sections.

Although details of the final standards for general industry, construction, and shipyards differ slightly, most of the requirements are the same or similar in all three standards. Therefore, the summary and explanation is organized according to the main requirements of the standards, but includes paragraph references to the standards for general industry, construction, and shipyards. The summary and explanation uses the term ''standards'' or ''final standards'' when referring to all three standards. Generally, when the summary and explanation refers to the term ''standards,'' it is referring to the final standards. To avoid confusion, the term ''final rule'' is sometimes used when making a comparison to or clarifying a change from the proposed rule.

The proposed rule applied to occupational exposure to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by proposed paragraphs (a)(2) and (a)(3) of the proposed standard. The final standards are identical in their application to occupational exposures to beryllium. In the summary and explanation sections, OSHA has changed ''beryllium and beryllium compounds'' or anything specifying soluble beryllium to just ''beryllium.'' OSHA intends the term ''beryllium'' to cover all forms of beryllium, including compounds and mixtures, both soluble and poorly soluble, throughout the summary and explanation sections. Other global changes in the regulatory text include changing ''shall'' to ''must'' to make it clear when a provision is a requirement and adding ''personal'' to ''protective clothing or equipment'' and ''protective clothing and equipment'' consistently. OSHA has changed ''exposure'' to ''airborne exposure'' to make it clear when referring to just airborne exposure, and specifically noting when OSHA intends to cover dermal contact.

As noted above, OSHA's proposed rule was based, in part, upon a draft occupational health standard submitted to the Agency by Materion, the leading producer of beryllium and beryllium products in the United States, and USW, an international labor union representing workers who manufacture beryllium alloys and beryllium-containing products in a number of industries (Document ID 0754). Materion and USW worked together to craft a model beryllium standard that OSHA could adopt and that would have support from both labor and industry. They submitted their joint draft standard to OSHA in February 2012.

Like the proposal, many of the provisions in the final rules are identical or substantively similar to those contained in Materion and USW's draft standard. For example, the final rule for general industry and the Materion/USW draft standard both include an exclusion for materials containing less than 0.1 percent beryllium; both contain many similar definitions; both contain a time weighted average (TWA) PEL of 0.2 μg/m^3; both include exposure monitoring provisions, including provisions for scheduled monitoring, employee notification of results, methods of sample analysis, and observation of monitoring; both contain similar requirements for beryllium work areas and regulated areas; both mandate a written exposure control plan and engineering and work practice controls that follow OSHA's traditional hierarchy of controls; and both include similar provisions related to respiratory protection, protective clothing and equipment, hygiene areas and practices, housekeeping, medical surveillance, medical removal protection, training and communication of hazards, recordkeeping, and compliance dates.

(a) Scope and Application

Separate standards for general industry, construction, and shipyards. OSHA proposed a standard addressing occupational exposure to beryllium in general industry and regulatory alternatives to address exposures in the construction and maritime industries.[37] The proposal was modeled on a suggested rule that was crafted by two major stakeholders in general industry, Materion Corporation (Materion) and the United Steelworkers (USW) (Document ID 0754). Materion and USW provided OSHA with data on exposure and control measures and information on their experiences with handling beryllium in general industry settings (80 FR 47774). At the time, the information available to OSHA on beryllium exposures outside of general industry was limited. Therefore, the Agency preliminarily decided to limit the scope of its beryllium rule proposal to general industry but propose regulatory alternatives that would expand the scope of the proposed standard to also include employers in construction and maritime if it turned out the record evidence warranted it. Specifically, OSHA requested comment on Regulatory Alternative #2a, which would expand the scope of the proposed standard to also include employers in construction and maritime, and Regulatory Alternative #2b, which 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. OSHA also requested stakeholder comment and data on employees in construction or maritime, or in general industry, not covered in the scope of the proposed standard, who deal with beryllium only as a trace contaminant, who may be at significant risk from occupational beryllium exposures.

OSHA did not receive any additional exposure data for construction or shipyards in response to OSHA's request in the NPRM. However, since the proposal, OSHA reviewed its OIS compliance exposure database and identified personal exposure sample results on beryllium for abrasive blasting workers in construction, general industry and maritime, which can be found broken out by sector in FEA Table IV.68.

The vast majority of stakeholders who submitted comments on this issue supported extending the scope of the proposed rule to cover workers in the construction and maritime industries who are exposed to beryllium (*e.g.,* Document ID 1592; 1625, p. 3; 1655, p. 15; 1658, p. 5; 1664, pp. 1–2; 1670, p. 7; 1671, Attachment 1, p. 5; 1672, p. 1; 1675, p. 2; 1676, p. 1; 1677, p. 1; 1679, p. 2; 1681, pp. 5, 16; 1683, p. 2; 1684, Attachment 2, p. 3; 1685, p. 2; 1686, p. 2; 1689, p. 6; 1690, p. 2; 1693, p. 3; 1703, p. 2; 1705, p. 1). For example, the National Council for Occupational Safety and Health (National COSH) urged that OSHA should ensure greater

[37] The proposed rule did not cover agricultural employers because OSHA had not found any evidence indicating that beryllium is used or handled in agriculture in a way that might result in beryllium exposure. OSHA's authority is also restricted in this area; since 1976, an annual rider in the Agency's Congressional appropriations bill has limited OSHA's use of funds with respect to farming operations that employ fewer than ten employees (Consolidated Appropriations Act, 1976, 94, 90 Stat. 1420, 1421 (1976) (and subsequent appropriations acts)). In the Notice of Proposed Rulemaking (NPRM), the Agency requested information on whether employees in the agricultural sector are exposed to beryllium in any form and, if so, their levels of exposure and what types of exposure controls are currently in place (80 FR 47565, 47775). OSHA did not receive comment on beryllium and the agriculture industry or information that would support coverage of agricultural operations. Therefore, agriculture employers and operations are not covered by the rule.

protections to beryllium exposed workers by extending the scope of the proposed standard to workers in the construction and maritime industries. National COSH explained: ''In the proposed preamble, OSHA recognizes that these workers are exposed to beryllium during abrasive blasting and clean-up of spent material. The risks that construction and maritime workers face when exposed to beryllium particulate is the same as the risk faced at similar exposures by general industry workers'' (Document ID 1690, p. 2). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) agreed, adding that ''[a]vailable data in the construction and maritime sector shows that there is a significant risk of sensitization and CBD among these workers'' (Document ID 1689, p. 6). Similarly, the American Industrial Hygiene Association (AIHA) warned that the ''[p]otential for exposure, especially in the construction industry, is very high'' (Document ID 1686, p. 2).

OSHA also heard testimony during the public hearing from Dr. Lee Newman of the American College of Occupational and Environmental Medicine (ACOEM), Peggy Mroz of National Jewish Health (NJH), Emily Gardner of Public Citizen, Mary Kathryn Fletcher of AFL–CIO, and Mike Wright of the USW that supported covering workers in the construction and maritime industries (Document ID 1756, Tr. 81; 1756, Tr. 97–98; 1756, Tr. 172–175; 1756, Tr. 198–199; 1755, Tr. 181). Peggy Mroz of NJH testified that ''[b]ased on the data presented, [NJH] support[s] expanding the scope of the proposed standard to include . . . employers in construction and maritime'' (Document ID 1756, Tr. 98). Emily Gardner of Public Citizen argued that ''the updated standard cannot leave construction and shipyard workers vulnerable to the devastating effects of beryllium'' (Document ID 1756, Tr. 175). She added that ''Public Citizen urges OSHA to revise the proposed rule to cover these workers'' (Document ID 1756, Tr. 175).

Several commenters specifically supported Regulatory Alternative #2a. For example, the International Union, United Automobile, Aerospace, and Agriculture Implement Workers of America (UAW) indicated its support for this alternative (Document ID 1693, p. 3 (pdf)). UAW added that Alternative #2a 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 (Document ID 1693, p. 3 (pdf)). Kimberly-Clark Professional (KCP) similarly indicated that it favored the adoption of this alternative (Document ID 1676, p. 1). KCP explained that ''[h]azardous exposures are equally dangerous to workers regardless of whether the worker is in a factory or on a construction site, and the worker protection provided by OSHA regulations should also be equal'' (Document ID 1676, p. 1). In addition, 3M Company also observed that Regulatory Alternative #2a is a more protective alternative (Document ID 1625, p. 3 (pdf)).

However, other commenters argued in favor of keeping the proposed scope unchanged (*e.g.,* Document ID 1583; 1661, Attachment 2, pp. 6–7; 1673, pp. 12–23). Some of these stakeholders contended that adding construction and maritime was not necessary (*e.g.,* Document ID 1673, pp. 20–22). For example, Materion opined that ''the requirements of [29 CFR] 1910.94 provide sufficient protections for the construction and maritime industries and accordingly, [Materion and USW] did not include construction and maritime within [their] assessment of technological feasibility or the scope of the standard'' (Document ID 1661, Attachment 2, p. 7). Materion added that ''it is [its] understanding that in the absence of a specific maritime standard, OSHA applies general industry standards to the maritime industries'' (Document ID 1661, Attachment 2, p. 7). While this may be the general practice of the industry, OSHA does not enforce general industry standards where the shipyard standards apply unless they are specifically cross referenced in the shipyard standards.

Some of these commenters offered specific concerns with covering the construction and maritime industries, or with covering abrasive blasting in general. For instance, Jack Allen, Inc. argued against extending the proposed rule to cover the use of coal slag in the sandblasting industry because the industry already has processes and controls in place to prevent exposures to all dusts during operations (Document ID 1582). The Abrasive Blasting Manufacturers Alliance (ABMA) presented a number of arguments against the coverage of abrasive blasting. ABMA argued that regulating the trace amounts of beryllium in abrasive blasting will increase the use of silica-based blasting agents ''despite OSHA's longstanding recommendation of substitution for silica-based materials'' (Document ID 1673, p. 14). ABMA added that scoping in abrasive blasting would increase the amount of coal slag materials ''going to landfills rather than being used for beneficial purpose'' (Document ID 1673, p. 14). ABMA also cited to technological feasibility issues in sampling and analysis, noted that the proposed standard was not appropriately tailored to construction and maritime worksites, and argued that it is not appropriate to regulate abrasive blasting on a chemical-by-chemical basis (Document ID 1673, pp. 8, 21–23).

After careful consideration of these comments and those relating to Regulatory #2b discussed below, OSHA has decided to adopt Regulatory Alternative #2a to expand the proposal's scope to cover construction and shipyards. As noted by commenters like the AFL–CIO, record evidence shows that exposures above the new action level and PEL, primarily from abrasive blasting operations, occur in both the construction and shipyard industries (*see* Chapter IV of the Final Economic Analysis and Regulatory Flexibility Analysis (FEA)). As discussed in Section V, Health Effects, and Section VII, Significance of Risk, employees exposed to airborne beryllium at these levels are at significant risk of developing adverse health effects, primarily chronic beryllium disease (CBD) and lung cancer. And under the OSH Act, and specifically section 6(b)(5), the Agency is required to set health standards which most adequately assure, to the extent feasible, 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 standards for the period of his working life. Therefore, OSHA finds it would be inappropriate to exclude construction and shipyard employers from coverage under this rule.

OSHA disagrees with Materion's assertion that existing standards render it unnecessary to have this standard cover construction and shipyard employers whose employees are exposed to beryllium during abrasive blasting operations. The OSHA Ventilation standard referenced by Materion (29 CFR 1910.94) applies only to general industry and does not cover construction and shipyard workers. The OSHA Ventilation standard in construction (1926.57) and Mechanical paint removers standard in shipyards (1915.34) provide some general protections for abrasive blasting workers but do not provide the level of protection provided by the ancillary provisions contained in the final standards such as medical surveillance, personal protective clothing and equipment, and beryllium-specific training.

OSHA also disagreed with Jack Allen, Inc.'s assertion that the employers conducting abrasive blasting already have sufficient processes and controls in place to prevent exposures to all dusts during operations. OSHA's examination of the record identifies data on beryllium exposure in the abrasive blasting industry showing beryllium exposure above the action level and TWA PEL when beryllium-containing slags are used (*e,g.,* Document ID 1166; 1815, Attachment 35; 1880). And even in abrasive blasting operations where all available controls and work processes to reduce beryllium exposure are used, additional ancillary provisions are still as necessary to protect workers from the harmful effects of exposure to beryllium as in general industry. OSHA also finds unsubstantiated ABMA's assertion that regulating the trace amounts of beryllium in abrasive blasting will increase the use of silica-based blasting agents and result in an increase in the amount of coal slag materials going to landfills. OSHA has identified several controls for abrasive blasting in its technological feasibility analysis (see Chapter IV of the FEA). OSHA also noted that substitution is not always feasible and employers should be cautious to not introduce additional hazards when switching to an alternate media. The Agency is certainly not encouraging employers to increase the use of silica sand as a blasting media. However, workers using silica-based blasting materials are protected under a new comprehensive silica standard (29 CFR 1910.1053, 29 CFR 1926.1153). Employers are in the best position to determine which blasting material to use and how to weigh the costs of compliance with the two rules. A 1998 NIOSH-funded study on substitute materials for silica sand in abrasive blasting provides comprehensive information on alternative media and can be used by employers seeking to identify appropriate abrasive blasting media alternatives (Document ID 1815, Attachment 85–87). In fact, exploring the use of alternative media for safer abrasive blasting media is already underway (Document ID 1741, p. 2). OSHA anticipates that the amount of slag material being deposited in landfills will remain constant regardless of its use prior to disposal, as the spent slag material used in abrasive blasting will still need to be disposed of. OSHA is also not persuaded by ABMA's technological feasibility argument that regulating trace amounts of beryllium would require testing below the limit of detection and that it is not technologically feasible to measure beryllium exposures in abrasive blasting. As explained in sections 2 and 12 of Chapter IV of the Final Economic Analysis, there are a number of available sampling and analytical methods that are capable of detecting beryllium at air concentrations below the action level of 0.1 μg/m³, as well as existing exposure data for beryllium in abrasive blasting operations. And finally, OSHA disagrees with ABMA's assertion that regulating abrasive blasting on a chemical-by-chemical basis is inappropriate. The beryllium rule is typical of OSHA substance-specific health standards that have been promulgated for the construction and shipyard industries and include abrasive blasting operations, such as the Lead standard for construction (1926.62) and the Lead standard for general industry (1910.1025), which applies to the shipyard industry.

However, OSHA does agree with ABMA's observation that many of the conditions in the construction and shipyard industries are distinct from those in general industry, and agrees that the standard as proposed was not tailored to construction and shipyard worksites. The Agency has long recognized a distinction between the construction and general industry sectors and has issued standards specifically applicable to construction and shipyard work under 29 CFR part 1926 and 29 CFR part 1915, respectively. OSHA's understanding of the differences between these industries is why OSHA specifically asked stakeholders with experience and knowledge of the construction or shipyard industries to opine on whether coverage of those industries is appropriate and, if so, how the proposal should be revised to best protect workers in those industries. As discussed throughout the rest of this Summary and Explanation section, many stakeholders responded to OSHA's request.

After careful consideration of the record, OSHA finds that the unique needs of, conditions in, and challenges posed by the construction and maritime sectors, particularly concerning abrasive blasting operations at construction sites and shipyards, warrant different requirements from general industry. Therefore, OSHA is issuing three separate standards—one for each of these sectors. OSHA judges that the primary source of beryllium exposure at construction worksites and in shipyards is from abrasive blasting operations when using abrasives that contain trace amounts beryllium.

Abrasive blasters and their helpers are exposed to beryllium from coal slag and other abrasive blasting material like copper slag that may contain beryllium as a trace contaminant. The most commonly used abrasives in the construction industry include coal slag and steel grit, which are used to remove old coatings and etch the surfaces of outdoor structures, such as bridges, prior to painting (Document ID 1815, Attachment 93, p. 80). Shipyards are large users of mineral slag abrasives. In a recent survey conducted for the Navy, the use of coal slag abrasives accounted for 68 percent and copper slag accounted for 20 percent of abrasive media usage as reported by 26 U.S. shipyards and boatyards (Document ID 0767). The use of coal and copper slag abrasives has increased in recent years as industries have sought substitutes for silica sand blasting abrasives to avoid health risks associated with respirable crystalline silica (Document ID 1671, Attachment 3; 1681, Attachment 1, pp. 1–2).

OSHA's exposure profile for abrasive blasters, pot tenders/helpers, and abrasive material cleanup workers is found in Section 12 of Chapter IV in the FEA. The exposure profile for abrasive blasters shows a median of 0.2 μg/m³, a mean of 2.18 μg/m³, and a range from 0.004 μg/m³ to 66.5 μg/m³. The mean level of 2.18 μg/m³ is above the preceding PEL for beryllium. For pot tenders/helpers, the exposure profile shows a median of 0.09 μg/m³, a mean of 0.10 μg/m³, and a range from 0.04 to 0.20 μg/m³. Beryllium exposure for workers engaged in abrasive material cleanup shows a median of 0.18 μg/m³, a mean of 1.76 μg/m³, and a range from 0.04 μg/m³ to 7.4 μg/m³ (*see* Section 12 of Chapter IV in the FEA). OSHA concludes that abrasive blasters, pot tenders/helpers, and cleanup workers have the potential for significant airborne beryllium exposure during abrasive blasting operations and during cleanup of spent abrasive material. Accordingly, these workers require protection under the beryllium standards. To address high concentrations of various hazardous chemicals in abrasive blasting, employers are already required to use engineering and work practice controls to limit workers' exposures and supplement 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)), 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)). For the shipyard industry, paragraph (c) of the Mechanical paint removers standard (29 CFR 1915.34) also has respiratory protection requirements for abrasive blasting operations. Because of these requirements, OSHA believes that employers already have those controls in place and provide respiratory protection during abrasive blasting operations. Nonetheless, the construction and shipyard standards' new ancillary provisions such as medical surveillance, personal protective clothing and equipment, housekeeping, and beryllium-specific training will provide increased protections to workers in these industries.

OSHA also received comment and heard testimony on potential beryllium exposure from other sources. NIOSH commented that construction workers may be exposed to beryllium when demolishing buildings or building equipment, based on a study of workers demolishing oil-fired boilers (Document ID 1671, Attachment 1, pp. 5, 15; 1671, Attachment 21). Peggy Mroz of NJH testified that ''[n]umerous studies have documented beryllium exposure sensitization and chronic beryllium disease in construction industries, demolition and decommissioning, and among workers who use non-sparking tools'' (Document ID 1756, Tr. 98). Many such cases were discovered among trade workers at Department of Energy sites from the National Supplemental Screening Program (Document ID 1756, Tr. 81–82). Ashlee Fitch from the USW testified that in addition to abrasive blasting using beryllium-contaminated slags, workers in the maritime industry use non-sparking tools that are composed of beryllium alloys. Ms. Fitch stated that these tools can create beryllium particulate when they are dressed (*e.g.,* sharpening, grinding, straightening). She also noted that shipyards may use beryllium for other tasks in the future. Ms. Fitch alluded to a 2000 Navy survey of potential exposure to beryllium in shipyards which identified potential beryllium sources in welding, abrasive blasting, and metal machining (Document ID 1756, Tr. 242–243). Mr. Wright of the USW testified that shipyard management told a USW representative ''that most of the beryllium that they're aware of comes in in the form of articles . . . . That is to say, it might be part of some assembly . . . [a]nd it comes in and it's sealed and closed'' (Document ID 1756, Tr. 270). However, Mr. Wright stated that beryllium is a high-tech material and that ''there is nothing more high-tech than an aircraft carrier or a nuclear submarine'' so exposure from beryllium-containing alloys cannot be ruled out in these operations (Document ID 1756, Tr. 270).

Despite requesting information both in the NPRM and during the public hearing, OSHA does not have sufficient data on beryllium exposures in the construction and shipyard industries to characterize exposures of workers in application groups other than abrasive blasting with beryllium-containing slags. OSHA could not develop exposure profiles for construction and shipyard workers engaged in activities involving non-sparking tools, demolition of beryllium-contaminated buildings or equipment, and working with beryllium-containing alloys. However, OSHA acknowledges the USW's concerns about future beryllium use and recognizes that there is potential for exposure to beryllium in construction and shipyard operations other than abrasive blasting. As such, workers engaged in such operations are exposed to the same hazard of developing CBD and other beryllium-related disease, and therefore deserve the same level of protection as do workers who are engaged in abrasive blasting or covered in the general industry final rule. Therefore, although at this time OSHA cannot specifically quantify exposures in construction or shipyard operations outside of abrasive blasting, OSHA has determined that it is necessary for the final standards for construction and maritime to cover all occupational exposures to beryllium in those industries in order to ensure that the standard is broadly effective and addresses all potential harmful exposures.

Three commenters representing the maritime industry supported Regulatory Alternative #2b—adopting the new PELs for construction and maritime by updating the existing Z tables to incorporate them, but not applying the other ancillary provisions of this standard to construction and maritime (Document ID 1595, p. 2; 1618, p. 2; 1657. p. 1). The Shipbuilders Council of America (SCA) supported lowering the PEL for beryllium from 2.0 μ/m^3 to 0.2 μ/m^3 in 29 CFR 1915.1000 Table Z, but argued that a new beryllium standard would prove to be redundant. SCA contended that many shipyards maintain a comprehensive industrial hygiene program focused on exposure assessments and protective measures for a variety of metals in shipyard tasks, and that shipyards encounter beryllium only at trace contaminant levels in materials involved in the welding and abrasive blasting processes. SCA stated that the potential hazards inherent in and unique to abrasive blasting in shipyards are already effectively controlled through existing regulations (Document ID 1618, pp. 2–4). General Dynamics' Bath Iron Works expressed similar views in their comments on this issue, as did Newport News Shipbuilding (Document 1595, p. 2; 1657, p. 1).

In addition to the commenters representing the maritime industry, Ameren, an electric and natural gas public utility, also supported applying the proposed TWA PEL and STEL to all employers in general industry, construction, and maritime even where beryllium exists only as a trace contaminant (Document ID 1675, p. 3). However, not all commenters endorsed Alternative #2b. The Department of Energy's National Supplemental Screening Program (NSSP) did not support this alternative because the other provisions of the standard would only cover employers and employees within the scope of the proposed general industry rule (Document ID 1677, p. 2). Furthermore, many commenters supported extending the full protections of the standard to the construction and maritime industries as set forth in Regulatory Alternative #2a, discussed earlier, which implicitly rejects Regulatory Alternative #2b (see, *e.g.,* Document ID 1756, Tr. 81; 1756, Tr. 97–98; 1756, Tr. 172–175; 1756, Tr. 198–199; 1755, Tr. 181).

OSHA is not persuaded by the maritime industry commenters' assertions that the ancillary provisions of the beryllium standard would be redundant. While OSHA acknowledges that shipyards encounter beryllium only at trace levels in materials involved in the welding and abrasive blasting processes, OSHA disagrees with their contention that updating the PEL and STEL will provide adequate protection to shipyard workers. OSHA agrees with NSSP and all the commenters supporting Regulatory Alternative #2a that a comprehensive standard specific to beryllium will provide the important protection of ancillary provisions, such as medical surveillance and medical removal protection. OSHA intends to ensure that workers exposed to beryllium in the construction and shipyard industries are provided with protection that is comparable to the protection afforded workers in general industry. Therefore, OSHA has set an identical PEL and STEL and, where no meaningful distinctions are identified in the record, included substantially the same or approximately equivalent ancillary provisions in all three standards. For further discussion of the differences among the standards, see the provision-specific sections included in this Summary and Explanation.

Therefore, OSHA declines to adopt Regulatory Alternative #2b, which, as noted above, would have updated 29 CFR 1910.1000 Tables Z–1 and Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A so that the new TWA PEL and STEL, but not the standard's ancillary provisions, would apply to all employers and employees in general industry, shipyards, and construction, including occupations where beryllium exists only as a trace contaminant. The Agency intends for employers that are exempt from the scope of these comprehensive standards in accordance with paragraph (a) to comply with the preceding TWA PEL and STEL in 29 CFR 1910.1000 Table Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A, as applicable. Given that the Agency is issuing separate beryllium standards for the construction and shipyard industries, OSHA is also adding to these tables a cross-reference to the new standards and clarifying that if the new standards are stayed or otherwise not in effect, the preceding PEL and short-term ceiling limit apply.

Paragraph (a)(1). Proposed paragraph (a)(1) applied the standard 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 (a)(3) of the standards. As OSHA explained in the proposal, the Agency preliminarily chose to treat beryllium generally, instead of individually addressing specific compounds, forms, and mixtures. This decision was based on the Agency's preliminary determination that the toxicological effects of beryllium exposure on the human body are similar regardless of the form of beryllium (80 FR 47774).

Several commenters offered opinions on this approach. The Non-Ferrous Founders' Society (NFFS) expressed concern that beryllium metal was being treated the same as soluble beryllium compounds, such as salts, even though NFFS believes these soluble compounds are more hazardous and suggested that OSHA establish a bifurcated standard for insoluble beryllium versus soluble beryllium compounds (Document ID 1732, p. 3; 1678, p. 2; 1756, Tr. 18). In related testimony, NIOSH's Dr. Aleks Stefaniak discussed the dermal exposure mechanisms of poorly soluble beryllium through particle penetration and particle dissolving (Document ID 1755, pp. 35–39). Dr. Stefaniak testified that while ''intact skin naturally has a barrier . . . [v]ery few people actually have fully intact skin, especially in an industrial environment'' (Document ID 1755, p. 36). He added:

> in fact, beryllium particles, beryllium oxide, beryllium metal, beryllium alloys, all these sort of what we call insoluble forms actually do in fact dissolve very readily in analog of human sweat. And once beryllium is in an ionic form on the skin, it's actually very easy for it to cross the skin barrier (Document ID 1755, pp. 36–37).

NIOSH also provided additional information on beryllium solubility and the development of CBD in its post-hearing brief, labeling as untrue NFFS's assertion that insoluble beryllium does not cause CBD (Document ID 1960, Attachment 2, pp. 8–10), citing studies showing that workers exposed to insoluble forms of beryllium have developed sensitization and CBD (Kreiss, *et al.,* 1997, Document ID 1360; Schuler *et al.,* 2005 (1349); Schuler *et al.,* 2008 (1291); Wegner *et al.,* 2000, (1960, Attachment 7)).

After careful consideration of the various comments on this issue, OSHA is not persuaded that there are differences in workers' health risks that justify treating poorly soluble beryllium differently than soluble compounds. The Agency is persuaded by NIOSH that poorly soluble beryllium presents a significant risk of beryllium-related disease to workers and discusses this topic further in Section V of this preamble, Health Effects. OSHA has determined that the toxicological effects of beryllium exposure on the human body are similar regardless of the form of beryllium. Therefore, the Agency concludes that the record supports issuing standards that apply to beryllium in all forms, compounds, and mixtures. Final paragraph (a)(1) is therefore substantively unchanged from the proposal in all three standards.

Paragraph (a)(2). Proposed paragraph (a)(2) excluded from the standard's scope articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process. As OSHA explained in the proposal (80 FR 47775), 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 . . ., and does not pose a physical hazard or health risk to employees.

OSHA preliminarily found that items or parts containing beryllium that employers assemble where the physical integrity of the item is not compromised are unlikely to release beryllium that would pose a physical or health hazard for workers. Therefore, OSHA proposed to exempt such articles from the scope of the standard. This proposed provision was intended to ease the burden on employers by exempting items from coverage where they are unlikely to pose a risk to employees.

Commenters generally supported this proposed exemption. For example, NFFS stated that the exemption was ''important and practical'' (Document ID 1678, p. 2; Document ID 1756, Tr. 35–36)). However, two commenters requested minor amendments to the exemption. First, ORCHSE Strategies (ORCHSE) asked OSHA to ''clarify'' that proposed paragraph (a)(2) ''exempts 'articles' even if they are processed, unless the processing releases beryllium to an extent that negates the definition of an 'article' '' (Document ID 1691, Attachment 1, p. 16). ORCHSE asserted that the standard should not apply in a workplace when ''the item actually meets OSHA's definition of an article'' and that OSHA should change the regulation's language accordingly (Document ID 1691, Attachment 1, pp. 16–17). Second, the American Dental Association (ADA) asked that OSHA clarify the article exemption, specifically that employers who use but do not process articles are fully exempt from all requirements of the proposed rule, including those established for recordkeeping (Document ID 1597, p. 1).

In contrast, Public Citizen objected to the inclusion of this exemption because exempting articles that are not processed does not take into consideration dermal exposure from handling articles containing beryllium (Document ID 1670, p. 7). Public Citizen pointed to OSHA's proposed rule in which OSHA acknowledged that beryllium absorbed through the skin can induce a sensitization response that is a necessary first step toward CBD and that there is evidence that the risk is not limited to soluble forms. However, during follow-up questioning at the beryllium public hearings, Dr. Almashat of Public Citizen was unable to provide any examples of dermal exposure from articles through their handling, as opposed to when processing beryllium materials (Document ID 1756, Tr. 178–180). And, in its post-hearing comments, Public Citizen did not provide evidence of dermal exposure to workers handling beryllium materials that would fall under the definition of article (Document ID 1964). In the final standard, OSHA has decided not to alter the proposed exemption of articles. OSHA is not persuaded by ORCHSE's argument that OSHA should change the regulation's language to exempt articles even if they are processed, unless the processing releases beryllium to an extent that negates the definition of an article. 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. (29 CFR 1910.1200(c)).

Whether a particular item is an ''article'' under the HCS depends on the physical properties and intended use of that item. However, employers may use and process beryllium-containing items in ways not necessarily intended by the manufacturer. Therefore, OSHA has decided not to link the processing limitation to the definition of an ''article'' and is retaining the language of proposed (a)(2) to comport with the intention of the exemption.

In response to the ADA's request for clarification that employers who use but do not process articles are fully exempt from all requirements of the rule, OSHA notes that paragraph (a)(2) of the final standards states that the ''standard does not apply'' to those articles. Furthermore, the recordkeeping requirement for objective data in paragraph (n)(2) of the standards states that it applies to objective data used to satisfy exposure assessment requirements, but does not mention any data used to determine coverage under paragraph (a). Therefore, OSHA has determined that no further clarification in the regulatory text is necessary.

In response to the comment from Public Citizen, OSHA did not receive any evidence on the issue of beryllium exposure through dermal contact with unprocessed articles. Therefore, OSHA cannot find that such contact poses a risk.

Paragraph (a)(2) of the final standards therefore remains unchanged from the proposed standard. The final standards do 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.

Paragraph (a)(3). Proposed paragraph (a)(3) exempted from coverage materials containing less than 0.1 percent beryllium by weight. Requesting comment on this exemption (80 FR 47776), OSHA presented Regulatory Alternative #1a, which would have eliminated the proposal's exemption for materials containing less than 0.1 percent beryllium by weight, and #1b, which would have exempted operations where the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. The Agency asked whether it is appropriate to include an exemption for operations where beryllium exists only as a trace contaminant, but some workers can nevertheless be significantly exposed. And the Agency asked whether it should consider dropping the exemption, or limiting it to operations where exposures are below the proposed action level and STEL. In addition, OSHA requested additional data describing the levels of airborne beryllium in workplaces that fall under this exemption. Some stakeholders supported keeping the 0.1 percent exemption as proposed (Document ID 1661, p. 6; 1666, p. 2; 1668, p. 2; 1673, p. 8; 1674, p. 3; 1687, Attachment 2, p. 8; 1691, Attachment 1, p. 3; 1756, Tr. 35–36, 63). For example, the Edison Electric Institute (EEI) strongly supported the exemption and asserted ''that abandoning the exemption would result in no additional benefits from a reduction in the beryllium permissible exposure limit (PEL) or from ancillary provisions similar to those already in place for the arsenic and other standards'' (Document ID 1674, p. 3). Mr. Weaver of NFFS also opposed eliminating the exemption, testifying that without the 0.1 percent exemption, 900 to 1,100 foundries would come under the scope of the rule (Document ID 1756, Tr. 55–56).

ABMA also supported the proposed 0.1 percent exemption, suggesting that there is a lack of evidence of significant risk from working with material containing beryllium in trace amounts and that OSHA needs substantial evidence that it is ''at least more likely than not'' that exposure to beryllium in trace amounts presents significant risk of harm, under court decisions concerning the Benzene rule (Document ID 1673, pp. 8–9). ABMA further argued that significant risk does not exist even below the previous PEL of 2.0 μg/m³ (Document ID 1673, pp. 8–9, 11). ABMA added that its members collectively have over 200 years of experience producing coal and/or copper slag abrasive material and have employed thousands of employees in this production process. ABMA explained:

Through the years, Alliance members have worked with and put to beneficial use over 100 million tons of slag material that would otherwise have been landfilled. Despite this extensive history, the Alliance members have no history of employees with beryllium sensitization or beryllium-related illnesses. Indeed, the Alliance members are not aware of a single documented case of beryllium sensitization or beryllium-related illness associated with coal or copper slag abrasive production among their employees, or their customers' employees working with the products of Alliance members (Document ID 1673, p. 9).

OSHA is not persuaded by these arguments. The lack of anecdotal evidence of sensitization or beryllium-related illness does not mean these workers are not at risk. As noted by Representative Robert C. ''Bobby'' Scott, Ranking Member of the U.S. House of Representatives Committee on Education and the Workforce the U.S. House of Representatives, ''medical surveillance has not been required for beryllium-exposed workers outside of the U.S. Department of Energy. The absence of evidence is not evidence of absence'' (Document ID 1672). As discussed in Section II of this preamble, Pertinent Legal Authority, courts have not required OSHA ''to support its finding that a significant risk exists with anything approaching scientific certainty'' (*Benzene,* 448 U.S. 607, 656 (1980)). Rather, OSHA may rely on ''a body of reputable scientific thought'' to which ''conservative assumptions in interpreting the data . . .'' may be applied, ''risking error on the side of overprotection'' (*Benzene,* 448 U.S. at 656). OSHA may thus act with a ''pronounced bias towards worker safety'' in making its risk determinations (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988). Where, as here, the Agency has evidence indicating that a certain operation can result in exposure levels that the Agency knows can pose a significant risk—such as evidence that workers that have been exposed to beryllium at the final PEL of 0.2 μg/m³ in primary beryllium production and beryllium machining operations have developed CBD (see this preamble at section V, Risk assessment)—OSHA need not wait until it has specific evidence that employees in that particular industry are suffering. A number of commenters supported Regulatory Alternative #1a, proposing to eliminate the proposal's exemption for materials containing less than 0.1 percent beryllium by weight (Document ID 1655, p. 15; 1664, p. 2; 1670, p. 7; 1671, Attachment 1, p. 5; 1672, pp. 4–5; 1683, p. 2; 1686, p. 2; 1689, pp. 6–7; 1690, p. 3; 1693, p. 3; 1720, pp. 1, 4). Public Citizen expressed concern with the proposed exemption and pointed out that OSHA identified studies in its proposal unequivocally demonstrating that beryllium sensitization and CBD occur in multiple industries utilizing products containing trace amounts of beryllium and that such an exemption would expose workers in such industries to the risks of beryllium toxicity (Document ID 1670, p. 7). The American Association for Justice, the AFL–CIO, and the UAW were all concerned that the proposed standard's 0.1 percent exemption would result in workers being exposed to significant amounts of beryllium from abrasive blasting (Document ID 1683, p. 2; 1689, pp. 6–7, 10–11; 1693, p. 3). Both Dr. Sammy Almashat and Emily Gardner of Public Citizen testified that they support inclusion of work processes that involve materials containing less than 0.1 percent of beryllium because the beryllium can become concentrated in air, even when using materials with only trace amounts (Document ID 1756, Tr. 174, 177–178, 185–186). Similarly, the AFL–CIO stated that ''there are known over-exposures among industries that use materials with less than 0.1% beryllium by weight, including an estimated 1,665 workers in primary aluminum production and 14,859 coal-fired electric power generation workers'' (Document ID 1689, p. 7). Mary Kathryn Fletcher of the AFL–CIO further explained that the AFL–CIO supported eliminating the exemption because these employees are at significant risk for developing sensitization, chronic beryllium disease (CBD), and lung cancer (Document ID 1756, Tr. 198–199). The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) recommended that OSHA remove the exemption (Document ID 1655, p. 15). AIHA also recommended eliminating or reducing the percentage content exemption until data is available to demonstrate that materials with very low beryllium content will not result in potential exposure above the proposed PEL (Document ID 1686, p. 2).

Both NIOSH and North America's Building Trades Unions (NABTU) expressed concern that the 0.1 percent exemption would expose construction and shipyard workers conducting abrasive blasting with coal slags to beryllium in concentrations above the final PEL. NIOSH and NABTU cited a study by the Center for Construction Research and Training, and NIOSH also cited one of its exposure assessment studies of a coal slag blaster showing beryllium air concentrations exceeding the preceding OSHA PEL (Document ID 1671, Attachment 1, p. 5; 1679, pp. 3–4). In addition, NIOSH points out that although the abrasive blasting workers may use personal protective equipment that limits exposure, supervisors and other bystanders may be exposed. NIOSH gave other examples where the 0.1 percent exemption could result in workers being exposed to beryllium, such as building or building equipment demolition and work in dental offices that fabricate or modify beryllium-containing dental alloys, but did not provide reference material or exposure data for these examples (Document ID 1671, pp. 5–6). In its post-hearing brief, NIOSH also specifically disagreed with EEI's contention that compliance with the arsenic and asbestos standards satisfies the proposed regulatory requirements of the beryllium rule. NIOSH argued that, unlike arsenic and lead, beryllium is a sensitizer, and as such, necessary and sufficient controls are required to protect workers from life-long risk of beryllium sensitization and disease (Document ID 1960, Attachment 2, p. 6).

OSHA also received comment and heard testimony from Dr. Weissman of NIOSH recommending that the scope of the standard be based on employee exposures and not the concentration of beryllium in the material (Document ID 1671, pp. 5–6; Document ID 1755, Tr. 17–18). NIOSH identified coal-fired electric power generation and primary aluminum production as industries that could fall under the 0.1 percent exemption (Document ID 1671, Attachment 1, p. 6). Stating it was not aware of any medical screening of utility workers exposed to fly ash, NIOSH recommended that OSHA include coal-fired electric power generation in the scope of the standard unless and until available data can demonstrate that there is no risk of sensitization to those workers (Document ID 1671, p. 6). NIOSH did not offer specifics on the magnitude of beryllium exposure in the aluminum production industry. In its post-hearing brief, NIOSH recommended that OSHA remove the 0.1 percent exemption from the rule, allowing the rule to cover a broad range of construction, shipyard, and electric utility power generation activities that are associated with beryllium exposure, such as abrasive blasting with coal or copper slag, repairing and maintaining structures contaminated with fly ash, and remediation or demolition (Document ID 1960, Attachment 2, p. 2). And Peggy Mroz of NJH testified that beryllium sensitization and CBD have been reported in the aluminum industry and that NJH has continued to see cases of severe CBD in workers exposed to beryllium through medical recycling and metal reclamation (Document ID 1756, Tr. 98–99).

Other commenters suggested limiting the exemption, as OSHA proposed in Regulatory Alternative #1b, to require employers to demonstrate, using objective data, that the materials, when processed or handled, cannot release beryllium in concentrations at or above the action level as an 8-hour TWA under any foreseeable conditions (Document ID 1597, p. 1; 1681, pp. 5–6). For example, the Materion-USW proposed standard included the 0.1 percent exemption unless objective data or initial monitoring showed exposures could exceed the action level or STEL. USW asserted that not including this requirement in the rule would be a mistake (Document ID 1681, pp. 5–6). The AFL–CIO also supported the joint USW-Materion scope provision (Document ID 1756, Tr. 212). Mike Wright of the USW asserted that maintaining the 0.1 percent exemption would leave thousands of workers unprotected, including those performing abrasive blasting operations in general industry, ship building, and construction (Document ID 1755, Tr. 111–114). Mr. Wright argued that in the 1,3 Butadiene standard OSHA recognized that the 0.1 percent exemption would not protect some workers and therefore included additional language limiting the exemption where objective data showed ''that airborne concentrations generated by such mixtures can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release'' (Document ID 1755, Tr. 113; 29 CFR 1910.1051(a)(2)(ii)). Mr. Wright urged OSHA to include similar language in the beryllium standard (Document ID 1755, Tr. 113–114).

Some commenters endorsed a modified version of Alternative #1b. For example, the Department of Defense (DOD) supported Alternative #1b, but also suggested limiting the exemption if exposures ''could present a health risk to employees'' (Document ID 1684, Attachment 2, pp. 1, 3). Boeing suggested adding a different exemption to the scope of the standard:

where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release dusts, fumes, or mists of beryllium in concentrations at or above 0.02 μg/m³ as an 8-hour time-weighted average (TWA) or at or above 0.2 μg/m³ as determined over a sampling period of 15 minutes under any expected conditions of use (Document ID 1667, p. 12).

Other commenters, like ABMA, criticized Regulatory Alternative #1b, insisting that the rulemaking record contained no evidence to support expanding the scope, but that if the scope was expanded to cover trace beryllium, a significant exemption would be needed. ABMA argued that such an exemption would need to go considerably beyond that of using the action level or STEL because of the substantial costs, particularly on small businesses, that would be incurred where there is no evidence of benefit. However, ABMA did not specify what such an exemption would look like (Document ID 1673, p. 11). Similarly, the National Rural Electric Cooperative Association (NRECA) objected to Regulatory Alternative #1b as being unnecessary to protect employees from CBD in coal fired power plants (Document ID 1687, p. 2).

Ameren did not agree with the objective data requirement in Regulatory Alternative #1b because it would be difficult to perform sampling in a timely manner for the many different maintenance operations that occur infrequently. This would include in the scope of the rule activities for which exposures are difficult to measure, but are less likely to cause exposure than other operations (Document ID 1675, p. 2). The NSSP also does not support Regulatory Alternative #1b because without first expanding the scope of the rule to cover the construction and maritime sectors, employers in construction and maritime would still be excluded (Document ID 1677, p. 1).

OSHA agrees with the many commenters and testimony expressing concern that materials containing trace amounts of beryllium (less than 0.1 percent by weight) can result in hazardous exposures to beryllium. We disagree, however, with those who supported completely eliminating the exemption because this could have unintended consequences of expanding the scope to cover minute amounts of naturally occurring beryllium (Ex 1756 Tr. 55). Instead, we believe that alternative #1b—essentially as proposed by Materion and USW and acknowledging that workers can have significant beryllium exposures even with materials containing less than 0.1%—is the most appropriate approach. Therefore, in the final standard, it is exempting from the standard's application materials containing less than 0.1% beryllium by weight only where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

As noted by NIOSH, NABTU, and the AFL–CIO, and discussed in Chapter IV of the FEA, workers in abrasive blasting operations using materials that contain less than 0.1 percent beryllium still have the potential for significant airborne beryllium exposure during abrasive blasting operations and during cleanup of spent abrasive material. NIOSH and the AFL–CIO also identified coal-fired electric power generation and primary aluminum production as industries that could fall under the 0.1 percent exemption but still have significant worker exposure to beryllium. Furthermore, OSHA agrees with NIOSH that the Agency should regulate based on the potential for employee exposures and not the concentration of beryllium in the material being handled. However, OSHA acknowledges the concerns expressed by ABMA and EEI that processing materials with trace amounts of beryllium may not necessarily cause significant exposures to beryllium. OSHA does not have evidence that all materials containing less than 0.1 percent beryllium by weight can result in significant exposure to beryllium, but the record contains ample evidence that there are significant exposures in operations using materials with trace amounts of beryllium, such as abrasive blasting, coal-fired power generation, and primary aluminum production. As discussed in Section VII of this preamble, Significance of Risk, preventing airborne exposures at or above the action level reduces the risk of beryllium-related health effects to workers. OSHA is also not persuaded by comments that claim obtaining this exposure data is too difficult for infrequent or short-term tasks because employers must be able to establish their eligibility for the exemption before being able to take advantage of it. If an employer cannot establish by objective data, including actual monitoring data, that exposures will not exceed the action level, then the beryllium standards apply to protect that employer's workers.

As pointed out by commenters such as the USW, similar exemptions are included in other OSHA 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 because workers in the exempted industries or workplaces were not exposed to the subject chemical substances at levels of significant risk. 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). The exemption in the BD standard does not apply where airborne concentrations generated by mixtures containing less than 0.1 percent BD by volume can exceed the action level or STEL (29 CFR 1910.1051(a)(2)(ii)). 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 determination that the exemption would encourage employers to reduce the concentration of benzene in certain substances (43 FR 27962, 27968).

OSHA's decision to maintain the 0.1 percent exemption and require employers to demonstrate, using objective data, that the materials, when processed or handled, cannot release beryllium in concentrations at or above the action level as an 8-hour TWA under any foreseeable conditions, is a change from proposed paragraph (a)(3) that specified only that the standard did not apply to materials containing less than 0.1 percent beryllium by weight. This is also a change from Regulatory Alternative #1b in another respect, insofar as it proposed requiring objective data demonstrating that employee exposure to beryllium will remain below both the proposed action level and STEL. OSHA removed the STEL requirement as largely redundant because if exposures exceed the STEL of 2.0 μg/m³ for more than one 15-minute period per 8-hour shift, even if exposures are non-detectable for the remainder of the shift, the 8-hour TWA would exceed the action level of 0.1 μg/m³.

Further, OSHA added the phrase ''under any foreseeable conditions'' to paragraph (a)(3) of the final standards to make clear that limited sampling results indicating exposures are below the action level would be insufficient to take advantage of this exemption. When using the phrase ''any foreseeable conditions,'' OSHA is referring to situations that can reasonably be anticipated. For example, annual maintenance of equipment during which exposures could exceed the action level would be a situation that is generally foreseeable.

In sum, the proposed standard covered occupational exposures to beryllium in all forms, compounds, and mixtures in general industry. It did not apply to articles, as defined by the HCS, or to materials containing less than 0.1 percent beryllium by weight. After a thorough review of the record, OSHA has decided to adopt Regulatory Alternative #2a and include the construction and shipyard sectors within the scope of the final rule. This decision was in response to the majority of comments recommending that OSHA protect workers in these sectors under the final rule and the exposure data in these sectors contained in the record. OSHA has also decided to adopt a modified version of Regulatory Alternative #1b and limit the 0.1 percent exemption to those employers who have objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

Therefore, the final rule contains three standards—one each for general industry, construction, and shipyard. The article exemption has remained unchanged, and the 0.1 percent exemption has been limited to protect workers with significant exposures despite working with materials with trace amounts of beryllium.

(b) Definitions

Paragraph (b) includes definitions of key terms used in the standard. To the extent possible, OSHA uses the same terms and definitions in the 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 and enforcement.

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air (μg/m^3) calculated as an 8-hour time-weighted average (TWA). Exposures at or above the action level trigger requirements for periodic exposure monitoring when the employer is following the scheduled monitoring option (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) requires employers to ensure that at least one of the controls listed in paragraph (f)(2)(i) is in place unless employers can demonstrate for each operation or process either that such controls are not feasible, or that employee exposures are below the action level based on at least two representative personal breathing zone samples taken at least seven days apart. In addition, under paragraph (k)(1)(i)(A), employee exposure at or above the action level for more than 30 days per year triggers requirements for medical surveillance. The medical surveillance provision triggered by the action level allows employees to receive exams at least every two years at no cost to the employee. The action level is also relevant to the medical removal requirements. Employees eligible for removal can choose to remain in environments with exposures at or 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 (if comparable work is not available, the employer must maintain the employee's earnings and benefits for six months or until comparable work becomes available (paragraph (l)(3)).

OSHA's risk assessment indicates that significant risk remains at and below the TWA PEL (see this preamble at section VII, Significance of Risk). When there is significant risk remaining 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 concludes 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 to set an action level involves the variable nature of employee exposures to beryllium. Because of this fact, OSHA concludes 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 paragraph (d)(3).

The United Steelworkers (USW) commented in support of the action level, noting that it is typical in OSHA standards to have an action level at one half of the PEL (Document ID 1681, p. 11). The USW also commented that the ''action level will further reduce exposure to beryllium by workers and will incentivize employers to implement best practice controls keeping exposures at a minimum as well as reducing costs of monitoring and assessments'' (Document ID 1681, p. 11). National Jewish Health (NJH) also supported OSHA's proposal for a more comprehensive standard and noted that the action level in the Department of Energy's beryllium standard has been ''very effective at reducing exposures and rates of beryllium sensitization and chronic beryllium disease in those facilities'' (Document ID 1756, p. 90).

As noted by the commenters, OSHA's decision to set 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), methylene chloride (29 CFR 1910.1052), and respirable crystalline silica (29 CFR 1910.1053).

The definition of ''action level'' is therefore unchanged from the proposal. Some of the ancillary provisions triggered by the action level have changed since the proposal. Those changes are discussed in more detail in the Summary and Explanation sections for those provisions.

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

OSHA included a definition for the terms ''exposure'' and ''exposure to beryllium'' in the proposed rule, and defined the terms to mean ''the exposure to airborne beryllium that would occur if the employee were not using a respirator.'' In the final rule, the word ''airborne'' is added to the terms to make clear that they refer only to airborne beryllium, and not to dermal contact with beryllium. The modified terms replace ''exposure'' and ''exposure to beryllium'' in the rule, and the terms ''exposure'' and ''exposure to beryllium'' are no longer defined.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee. OSHA received no comments on this definition, and it is unchanged from the proposal.

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. For additional explanation of the BeLPT, see the Health Effects section of this preamble (section V). Under paragraph (f)(1)(ii)(B), an employer must review and evaluate its written 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 standard). Paragraph (k)(3)(ii)(E) requires the BeLPT unless a more reliable and accurate test becomes available.

NJH supported OSHA's definition of the BeLPT in the NPRM (Document ID 1664, p. 5). However, OSHA has made one change from the proposed definition of the BeLPT in the NPRM to the final definition to provide greater clarity. The Agency has moved the characterization of a confirmed positive result from the BeLPT definition to the ''confirmed positive'' definition because it was more appropriate there.

Beryllium work area means any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is potential for dermal contact with beryllium. The definition of ''beryllium work area'' has been changed from the proposed definition to reflect stakeholder concerns regarding the overlap between a beryllium work area and regulated area, and to include the potential for dermal exposure. The definition only appears in the general industry standard because the requirement for a beryllium work area only applies to the general industry standard. 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; the regulated area, therefore, is either a subset of the beryllium work area or, less likely, identical to it, depending on the configuration and circumstances of the worksite. Dermal exposure has also been included in the final definition to address the potential for sensitization from dermal contact. Therefore, while not all beryllium work areas are regulated areas, all regulated areas are beryllium work areas because they are areas with employee 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. For further discussion, see this section of the preamble regarding paragraph (e), Beryllium work areas and regulated areas.

The presence of a beryllium work area triggers a number of the requirements in the general industry standard. Under paragraph (d)(3)(i), employers must determine exposures for each beryllium work area. 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)(D), employers must minimize cross-contamination by preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within a beryllium work area. Paragraph (f)(1)(i)(F) states that employers must minimize migration of beryllium from the beryllium work area to other locations within and outside the workplace. Paragraph (f)(2) requires employers to implement at least one of the controls listed in (f)(2)(i)(A) through (D) for each operation in a beryllium work area unless one of the exemptions in (f)(2)(ii) applies. Paragraph (i)(1) requires employers to provide readily accessible washing facilities to employees working in a beryllium work area, and to ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In addition employers must ensure 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. Under paragraph (m)(4)(ii)(B), employers must ensure workers demonstrate knowledge of the written exposure control plan with emphasis on the location(s) of beryllium work areas.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results. For purposes of these standards, 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 standard for CBD diagnostic centers, the hospital would be considered a CBD diagnostic center for purposes of these standards.

OSHA received comments from NJH and ORCHSE Strategies (ORCHSE) regarding the definition of the ''CBD diagnostic center.'' NJH commented that CBD diagnostic centers do not need to be able to perform the BeLPT but should be able to process the BAL appropriately and ship samples within 24 hours to a facility that can perform the BeLPT. NJH also indicated that CBD diagnostic centers should be able to perform CT scans, pulmonary function tests with DLCO (diffusing capacity of the lungs for carbon monoxide), and measure gas exchange abnormalities. NJH further indicated that CBD diagnostic centers should have a medical doctor who has experience and expertise, or is willing to obtain such expertise, in the diagnosis and treatment of chronic beryllium disease (Document ID 1664, pp. 5–6). ORCHSE argued that CBD diagnostic centers should be allowed to rely on off-site interpretation of transbronchial biopsy pathology, reasoning that this change would broaden the accessibility of CBD diagnostic centers to more affected employees (Document ID 1691, p. 3).

OSHA evaluated these recommendations and included the language regarding sample processing and removed the proposal's requirement that BeLPTs be performed on-site. The Agency also changed the requirement that pulmonary specialist perform testing as outlined in the proposal to the final definition which requires that a pulmonary specialist be on-site. This requirement addresses the concerns ORCHSE raised about accessibility of CBD diagnostic centers by increasing the number of facilities that would qualify as centers. This also preserves the expertise required to diagnose and treat CBD as stated by NJH (Document 1664, p. 6).

Paragraph (k)(7) includes provisions providing for an employee who has been confirmed positive to receive an initial clinical evaluation and subsequent medical examinations at a CBD diagnostic center.

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 standard. 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 include a physical examination with emphasis on the respiratory system, in order to identify respiratory conditions such as CBD. Under paragraph (k)(5)(i)(A), the licensed physician's report 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 hazard communication standard (HCS) (29 CFR 1910.1200). Employers must also train employees on the signs and symptoms of CBD (see paragraph (m)(4)(ii)(A) of the general industry and shipyard standards and paragraph (m)(3)(ii)(A) of the construction standard).

Competent person means an individual on a construction site who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the standard for construction. This definition appears only in the standard for construction.

The competent person concept has been broadly used in OSHA construction standards (*e.g.,* 29 CFR 1926.32(f) and 1926.20(b)(2)), including in the recent health standard for respirable crystalline silica (29 CFR 1926.1153). Under 29 CFR 1926.32(f), competent person is defined as ''one capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees and who is authorized to take prompt corrective measures to eliminate them.'' OSHA has adapted this definition for the beryllium construction standard by specifying ''foreseeable beryllium hazards in the workplace'' instead of ''predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees.'' The Agency also replaced the word ''one'' with ''an individual.'' The Agency revised the phrase ''to eliminate them'' to read ''to eliminate or minimize them'' to denote there may be cases where complete elimination would not be feasible. The definition of competent person also indicates that the competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the construction standard, in order to ensure that the competent has appropriate training, education, or experience. See the discussion of ''competent person'' in the summary and explanation of paragraphs (e), Beryllium work areas and regulated areas, and (f), Methods of compliance, in this section.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two (either consecutive or non-consecutive) abnormal BeLPT test results, an abnormal and borderline test result, or three borderline test results. The definition of ''confirmed positive'' also includes a single result of a more reliable and accurate test indicating that a person has been identified as sensitized to beryllium if the test has been validated by repeat testing to have more accurate and precise diagnostic capabilities within a single test result than the BeLPT. OSHA recognizes that diagnostic tests for beryllium sensitization could eventually be developed that would not require a second test to confirm sensitization. Alternative test results would need to have comparable or increased sensitivity, specificity and positive predictive value (PPV) in order to replace the BeLPT as an acceptable test to evaluate beryllium sensitization (see section V.D.5.b of this preamble).

OSHA received comments from NJH, the American Thoracic Society (ATS) and ORCHSE regarding the requirement for consecutive test results within a two year time frame, and the inclusion of borderline test results (Document ID 1664, p.5; 1668, p. 2; 1691, p. 20). NJH and ATS submitted similar comments regarding the requirement of two abnormal BeLPT test results to be consecutive and within two years. According to NJH, ''the definition of 'confirmed positive' [should] include two abnormals, an abnormal and a borderline test result, and/or three borderline tests. This recommendation is based on studies of Middleton *et al.* (2008, and 2011), which showed that these other two combinations result in a PPV similar to two abnormal test results and are an equal predictor of CBD.'' (Document ID 1664, p. 5). In addition, the ATS stated:

> These test results need not be from consecutive BeLPTs or from a second abnormal BeLPT result within a two-year period of the first abnormal result. These recommendations are based on the many studies cited in the docket, as well as those of Middleton, *et al.* (2006, 2008, and 2011), which showed that an abnormal and a borderline result provide a positive predictive value (PPV) similar to that of two abnormal test results for the identification of both beryllium sensitization and for CBD (Document ID 1668, p. 2).

Materion Corporation (Materion) opposed changing the requirement for two abnormal BeLPT results and opposed allowing two or three borderline results to determine sensitization (Document ID 1808, p. 4). Without providing scientific studies or other bases for its position, Materion argued that ''[m]aking a positive BeS determination for an individual without any confirmed abnormal test result is not warranted and clearly is not justifiable from a scientific, policy or legal perspective'' (Document ID 1808, p. 4).

OSHA evaluated these comments and modified the definition of ''confirmed positive'' accordingly for reasons described more fully within the Health Effects section of this preamble, V.D.5.b, including reliance on the Middleton studies (2008, 2011). The original definition for ''confirmed positive'' in the proposed standard was adapted from the model standard submitted to OSHA by Materion and the USW in 2012. Having carefully considered all these comments and their supporting evidence, where provided, the Agency finds the arguments from NJH, ATS, and ORCHSE persuasive. In particular ATS points out the Middleton *et al.* studies ''. . . showed that an abnormal and a borderline result provide a positive predictive value (PPV) similar to that of two abnormal test results for the identification of both beryllium sensitization and for CBD.'' (Document ID. 1688 p. 3). Therefore, the Agency recognizes that a borderline BeLPT test result when accompanied by an abnormal test result, or three separate borderline test results, should also be considered ''confirmed positive.''

In addition, ORCHSE commented on the use of a single test result from a more reliable and accurate test (Document ID 1691, p. 20). Specifically, ORCHSE recommended revising the language to include ''the result of a more reliable and accurate test such that beryllium sensitization can be confirmed after one test, indicating a person has been identified as having beryllium sensitization'' (Document ID 1691, p. 20). In response to the comment from ORCHSE, the Agency has included additional language regarding the results from an alternative test (Document ID 1691, p. 20). OSHA inserted additional language clarifying that the alternative test has to be validated by repeat testing indicating that it has comparable or increased sensitivity, specificity and PPV than the BeLPT. The Agency finds that this language provides more precise direction for acceptance of an alternative test.

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 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. OSHA received no comments on this definition, and it is unchanged from the proposal.

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.

An emergency triggers several requirements of this 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) of the standards for general industry and shipyards and paragraph (m)(3)(ii)(D) of the standard for construction, employers must train employees in applicable emergency procedures.

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 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)). OSHA received no comments on this definition, and it is unchanged from the proposal.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

OSHA did not include a definition of ''objective data'' in the proposed rule. Use of objective data was limited in the proposed rule, and applied only to an exception from initial monitoring requirements in proposed paragraph (d)(2). Proposed paragraph (d)(2)(ii) included criteria for objective data.

The final rule allows for expanded use of objective data. Paragraph (a)(3) allows for use of objective data to support an exception from the scope of the standards. Paragraph (d)(2) allows for use of objective data as part of the performance option for exposure assessment. OSHA is therefore including a definition of ''objective data'' in paragraph (b) of the standards. The definition is generally consistent with the criteria included in proposed paragraph (d)(2)(ii), and with the use of this term in other OSHA substance-specific health standards such as the standards addressing exposure to cadmium (29 CFR 1910.1027), chromium (VI) (29 CFR 1010.1026), and respirable crystalline silica (29 CFR 1910.1053).

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 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 definition of PLHCP, not all PLHCPs must be physicians.

Under paragraph (k)(5) of the standards, the written medical report for the employee must be completed by a licensed physician. Under paragraph (k)(6) of the standard, the written medical opinion for the employer must also 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)(F), (k)(3)(ii)(G), and (k)(5)(iii)). The standard also identifies what information the employer must give to the PLHCP providing the services listed in this standard, and requires that employers maintain a record of this information for each employee (*see* paragraphs (k)(4) and (n)(3)(ii)(C), and the summary and explanation of paragraphs (k), Medical surveillance, in this section).

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), methylene chloride (29 CFR 1910.1052), and respirable crystalline silica (29 CFR 1910.1053). OSHA received no comments on this definition, and it is unchanged from the proposal.

Regulated area means an area, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's airborne exposure exceeds, or can reasonably be expected to exceed, either the TWA PEL or STEL. For an explanation of the distinction and overlap between beryllium work areas and regulated areas, see the definition of ''beryllium work area'' earlier in this section of the preamble and the summary and explanation for paragraph (e), Beryllium work areas and regulated areas. Regulated areas appear only in the general industry and shipyard standards, and they trigger several other requirements.

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 paragraph (m)(2) of the standards for general industry and shipyards). 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. Paragraph (i)(5)(i) prohibits employers from allowing employees to eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas. Paragraph (m)(2) requires warning signs associated with regulated areas to meet certain specifications. Paragraph (m)(4)(ii)(B) requires employers to train employees on the written exposure control plan required by paragraph (f)(1), including the location of regulated areas and the specific nature of operations that could result in airborne exposure.

In the proposed rule, OSHA included in the definition of the term ''regulated area'' that it was ''an area that the employer must demarcate.'' Because the requirement to demarcate regulated areas is presented elsewhere in the standards, the reference in the definition to ''an area that the employer must demarcate'' is redundant, and has been removed from the final definition of the term.

This definition of regulated areas is consistent with other substance-specific health standards that apply to general industry and shipyards, such as the standards addressing occupational exposure to cadmium (29 CFR 1910.1027 and 29 CFR 1915.1027), benzene (29 CFR 1910.1028 and 29 CFR 1915.1028), and methylene chloride (29 CFR 1910.1052 and 29 CFR 1915.1052).

This standard means the beryllium standard in which it appears. In the general industry standard, it refers to 29 CFR 1910.1024. In the shipyard standard, it refers to 29 CFR 1915.1024. In the construction standard, it refers to 29 CFR 1926.1124. This definition elicited no comments and differs from the proposal only in that it appears in the three separate standards.

(c) Permissible Exposure Limits (PELs)

Paragraph (c) of the standards 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/m³ (paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m³ (paragraph (c)(2)). The TWA PEL section of the standards requires employers to ensure that no employee's exposure to beryllium, averaged over the course of an 8-hour work shift, exceeds 0.2 μg/m³. The STEL section of the standards requires employers to ensure that no employee's exposure, sampled over any 15-minute period during the work shift, exceeds 2.0 μg/m³. While the proposed rule contained slightly different language in paragraph (c), *i.e.* requiring that ''each employee's airborne exposure does not exceed'' the TWA PEL and STEL, the final language was chosen by OSHA to remain consistent with prior OSHA health standards and to clarify that OSHA did not intend a different interpretation of the PELs in this standard. The same PELs apply to general industry, construction, and shipyards.

TWA PEL. OSHA proposed a new TWA PEL of 0.2 μg/m³ of beryllium—one-tenth the preceding TWA PEL of 2 μg/m³—because OSHA preliminarily found that occupational exposure to beryllium at and below the preceding TWA PEL of 2 μg/m³ poses a significant risk of material impairment of health to exposed workers. As with several other provisions of these standards, OSHA's proposed TWA PEL followed the draft recommended standard submitted to the Agency by Materion Corporation (Materion) and the United Steelworkers (USW) (see this preamble at section III, Events Leading to the Standards).

After evaluating the record, including published studies and more recent exposure data from industrial facilities involved in beryllium work, OSHA is adopting the proposed TWA PEL of 0.2 μg/m³. OSHA has made a final determination that occupational exposure to a variety of beryllium compounds at levels below the preceding PELs poses a significant risk to workers (see this preamble at section VII, Significance of Risk). OSHA's risk assessment, presented in section VI of this preamble, indicates that there is significant risk of beryllium sensitization,[38] CBD, and lung cancer from a 45-year (working life) exposure to beryllium at the preceding TWA PEL of 2 μg/m³. The risk assessment further indicates that, although the risk is much reduced, significant risk remains at the new TWA PEL of 0.2 μg/m³.

OSHA has determined that the new TWA PEL is feasible across all affected industry sectors (see section VIII.D of this preamble, Technological Feasibility) and that compliance with the new PEL will substantially reduce employees' risks of beryllium sensitization, Chronic Beryllium Disease (CBD), and lung cancer (see section VI of this preamble, Risk Assessment). OSHA's conclusion about feasibility is supported both by the results of the Agency's feasibility analysis and by the recommendation of the PEL of 0.2 μg/m³ by Materion and the USW.

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. Although OSHA also found that there is significant risk at the proposed alternative TWA PEL of 0.1 μg/m³, OSHA did not adopt that alternative because the Agency could not demonstrate technological feasibility at that level (see section VIII.D of this preamble, Technological Feasibility).

The TWA PEL was the subject of numerous comments in the rulemaking record. Comments from stakeholders in labor and industry, public health experts, and the general public supported OSHA's selection of 0.2 μg/m³ as the final PEL (NIOSH, Document ID 1671, Attachment 1, p. 2; National Safety Council, 1612, p. 3; The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee of the Department of Energy's National Nuclear Security Administration Lawrence Livermore National Lab (BHSC Task Group), 1655, p. 2; Newport News Shipbuilding, 1657, p. 1; National Jewish Health (NJH),1664, p. 2; The Aluminum Association, 1666, p. 1; The Boeing Company (Boeing), 1667, p. 1; American Industrial Hygiene Association (AIHA), 1686, p. 2; United Steelworkers (USW), 1681, p. 7; Andrew Brown, 1636, p. 6; Department of Defense, 1684, p. 1). Materion stated that the record does not support the feasibility of any limit lower than 0.2 μg/m³ (Document ID 1808, p. 2). OSHA also received comments supporting selection of a lower TWA PEL of 0.1 μg/m³ from Public Citizen, the AFL–CIO, the United Automobile, Aerospace & Agricultural Implement Workers of America (UAW), North America's Building Trades Unions (NABTU), and the American College of Occupational and Environmental Medicine (ACOEM) (Document ID 1689, p. 7; 1693, p. 3; 1670, p. 1; 1679, pp. 6–7; 1685, p. 1; 1756, Tr. 167). These commenters based their recommendations on the significant risk of material health impairment from exposure at the TWA PEL of 0.2 μg/m³ and below, which OSHA acknowledges.

In addition to their concerns about risk, Public Citizen and the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) argued that a TWA PEL of 0.1 μg/m³ is feasible (Document ID 1756, Tr. 168–169, 197–198). As discussed further below, however, OSHA's selection of the TWA PEL in this case was limited by the findings of its technological feasibility analysis. No commenter provided information that would permit OSHA to show the feasibility of a TWA PEL of 0.1 μg/m³ in industries where OSHA did not have sufficient information to make this determination at the proposal stage. Public Citizen instead argued that insufficient evidence that engineering and work practice controls can maintain exposures at or below a TWA PEL of 0.1

[38] As discussed in section VII of this preamble, Significance of Risk, beryllium sensitization is a necessary precursor to developing CBD.

μg/m³ should not preclude OSHA from establishing such a PEL; and that workplaces unable to achieve a TWA PEL of 0.1 μg/m³ should be required to reduce airborne exposures as much as possible using engineering and work practice controls, supplemented with a respiratory protection program (Document ID 1670, p. 5).

OSHA has determined that Public Citizen's claim that the Agency should find a PEL of 0.1 μg/m³ technologically feasible is inconsistent with the test for feasibility as described by the courts as well as the evidence in the rulemaking record. OSHA bears the evidentiary burden of establishing feasibility in a rulemaking challenge. The D.C. Circuit, in its decision on OSHA's Lead standard (*United Steelworkers of America* v. *Marshall,* 647 F.2d 1189 (D.C. Cir. 1981) (''*Lead*'')), explained that in order to establish that a standard is technologically feasible, ''OSHA must prove a reasonable possibility 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'' (*Lead,* 647 F.2d at 1272). ''The effect of such proof,'' the court continued, ''is to establish a presumption that industry can meet the PEL without relying on respirators'' (*Lead,* 647 F.2d at 1272). The court's definition of technological feasibility thus recognizes that, for a standard based on a hierarchy of controls prioritizing engineering and work practice controls over respirators, a particular PEL is not technologically feasible simply because it can be achieved through the widespread use of respirators (*see Lead,* 647 F.2d at 1272). OSHA's long-held policy of avoiding requirements that will result in extensive respirator use is consistent with this legal standard.

In considering an alternative TWA PEL of 0.1 μg/m³ that would reduce risks to workers further than would the TWA PEL of 0.2 μg/m³, OSHA was unable to determine that this level was technologically feasible. For some work operations, the evidence is insufficient for OSHA to demonstrate that a TWA PEL of 0.1 μg/m³ could be achieved most of the time. In other operations, a TWA PEL of 0.1 μg/m³ appears to be impossible to achieve without resort to respirators (see section VIII.D of this preamble, Technological Feasibility, for a detailed discussion of OSHA's feasibility findings). Thus, OSHA was unable to meet its legal burden to demonstrate the technological feasibility of the alternative TWA PEL of 0.1 μg/m³ (*see Lead,* 647 F.2d at 1272; *Amer. Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 990 (D.C. Cir. 1991)) and has adopted the proposed PEL of 0.2 μg/m³, for which there is substantial evidence demonstrating technological feasibility.

OSHA also invited comment on and considered an alternative TWA PEL of 0.5 μg/m³—two-and-a-half times greater than the proposed PEL that it is adopting. As noted above, OSHA determined that significant risk to worker health exists at the preceding PEL of 2.0 μg/m³ as well as at the new TWA PEL of 0.2 μg/m³. Because OSHA found that a TWA PEL of 0.2 μg/m³ is technologically and economically feasible, the Agency concludes that setting the TWA PEL at 0.5 μg/m³—a level that would leave workers exposed to even greater health risks than they will face at the new PEL of 0.2 μg/m³—would be contrary to the OSH Act, which requires OSHA to eliminate the risk of material health impairment ''to the extent feasible'' (29 U.S.C. 655(b)(5)). Thus, the Agency is not adopting the proposed alternative TWA PEL of 0.5 μg/m³.

Because significant risks of sensitization, CBD, and lung cancer remain at the new TWA PEL of 0.2 μg/m³, the final standards include a variety of ancillary provisions to further 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 has determined that these provisions will reduce the risk beyond that which the TWA PEL alone could achieve. These provisions are discussed later in this Summary and Explanation section of the preamble.

STEL. OSHA is also promulgating a STEL of 2.0 μg/m³, as determined over a sampling period of 15 minutes. The new STEL of 2 μg/m³ was suggested by the joint Materion-USW proposed rule and proposed in the NPRM. As discussed in section VII of this preamble, significant risks of sensitization, CBD, and lung cancer remain at the TWA PEL of 0.2 μg/m³. Where a significant risk of material impairment of health remains at the TWA PEL, OSHA must 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*''); *see also Building and Construction Trades Department, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1271 (D.C. Cir. 1988)). In this case, the evidence in the record demonstrates that the STEL is feasible and that it will further reduce the risk remaining at the TWA PEL. 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 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, a worker's 15-minute exposure in the absence of a STEL could be as high as 6.4 μg/m³ (32 × 0.2 μg/m³) if that worker's 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 8-hour 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 who 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 also been shown to contribute to the development of lung disease in laboratory animals (see this preamble at section V, Health Effects). These study findings indicate that adverse effects to the lung may occur from beryllium exposures of relatively short duration. Thus OSHA expects a STEL to add further protection from the demonstrated significant risk of harm than that afforded by the new 0.2 μg/m³ TWA PEL alone.

STEL exposures are typically associated with, and need to be measured by the employer during, the highest-exposure operations that an employee performs (see paragraph (d)(3)(ii)). OSHA has determined that the STEL of 2.0 μg/m³ can be measured for this brief period of time using OSHA's available sampling and analytical methodology, and that feasible means exist to maintain 15-minute short-term exposures at or below the proposed STEL (see section VIII.D of this preamble, Technological Feasibility). Comments on the STEL were generally supportive of OSHA's decision to include a beryllium STEL, but differed on the appropriate level. NIOSH recommended a STEL of at most 1 μg/m³, noting that available exposure assessment methods are sensitive enough to support a STEL of 1 μg/m³ and that it is likely to be more protective than the proposed STEL of 2 μg/m³ (Document ID 1960, Attachment 2, p. 4; 1725, p. 35; 1755, Tr. 22). NJH's comments also supported a STEL of 1 μg/m³ as the best option (Document ID 1664, p. 3). Public Citizen and the AFL–CIO advocated for a STEL of 1 μg/m³, stating that it would be more protective than the proposed STEL of 2 μg/m³ (Document ID 1670, p. 6; 1689, p. 7–8). The AFL–CIO and Public Citizen both stated that a STEL of 1 μg/m³ is supported in the record, including by exposure data from OSHA workplace inspections (Document ID 1670, p. 6; 1756, Tr. 171). However, no additional engineering controls capable of reducing short term exposures to or below 1.0 μg/m³ were identified by commenters. Public commenters did not provide any empirical data to suggest that those exposed to working conditions associated with a STEL of 2.0 μg/m³ would be more likely to be sensitized than those exposed to working conditions associated with a STEL of 1.0 μg/m³. However, OSHA notes that the available epidemiological literature on beryllium-related disease does not address the question of whether those exposed to working conditions associated with a STEL of 2.0 μg/m³ would be more likely to be sensitized than those exposed to working conditions associated with a STEL of 1.0 μg/m³. Detailed documentation of workers' short-term exposures is typically not available to researchers. Therefore, OSHA cannot exclusively rely on evidence relating health effects to specific short-term exposure levels to set a STEL. In setting a STEL, OSHA also examines the likelihood that a given STEL will help to reduce excursions above the TWA PEL and the feasibility of meeting a given STEL using engineering controls. The UAW emphasized that ''OSHA must include the STEL in the standard to ensure that peak exposures are characterized and controlled'' (Document ID 1693, p. 3). The UAW argued, specifically, for a STEL of five times the PEL (recommending a STEL of 0.5 μg/m³ based on a TWA PEL of 0.1 μg/m³), noting that single short-term, high-level beryllium exposures can lead to sensitization, and that UAW members in industries such as nonferrous foundries and scrap metal reclamation may experience such exposures even when not exposed above the 8 hour TWA PEL (Document ID 1693, p. 3). Ameren Services Company, a public utility that includes electric power generation companies, expressed support for the proposed PEL and STEL, but also expressed support for selecting a STEL of five times the PEL in order to maintain consistency with OSHA's typical approach to setting STELs (Document ID 1675, p. 3).

In contrast, NGK Metals Corporation (NGK) supported the proposed STEL of 2 μg/m³, and specifically argued against a STEL of 0.5 μg/m³ on the basis that a reduced STEL would not be feasible or offer significantly more protection than the proposed STEL (Document ID 1663, p. 4). Materion emphasized the need for ''proactive operational control'' of tasks that could generate high, short-term beryllium exposures, and supported the STEL of 2 μg/m³ contained in OSHA's proposed rule (Document ID 1661, pp. 3, 5). Materion indicated in its comments that the proposed STEL of 2.0 μg/m³ was based on controlling the upper range of worker short term exposures (Document ID 1661). Materion used data provided in the Johnson study of the United Kingdom Atomic Weapons Establishment (AWE) in Cardiff, Wales, as supporting evidence for the proposed STEL (Document ID 1505). However, Dr. Christine Schuler from NIOSH commented that the AWE study was not an appropriate basis for an OSHA STEL because the AWE study was based on workers showing physical signs of CBD (''If somebody became really apparently ill, then they would have identified them.'') (Document ID 1755, Tr. 35). Dr. Schuler additionally commented that the studies performed in the United States are more appropriate since they are based on identified cases of CBD at an earlier stage where there are generally very few symptoms (called asymptomatic or subclinical) (Document ID 1755, Tr. 34–35). OSHA agrees with Dr. Schuler's assessment and that the AWE study should not be used as scientific evidence to support a STEL of 2.0 μg/m³.

After careful consideration of the record, including all available data and stakeholder comments, OSHA has reaffirmed its preliminary determinations that a STEL of 2.0 μg/m³ (ten times the final PEL of 0.2 μg/m³) is technologically feasible and will help reduce the risk of beryllium-related health effects in exposed employees. As discussed in section VIII.D of this preamble, Technological Feasibility, OSHA has determined that the implementation of engineering and work practice controls required to maintain full shift exposures at or below a PEL of 0.2 μg/m³ will reduce short term exposures to 2.0 μg/m³ or below. However, adopting a STEL of 1.0 μg/m³ or lower would likely require additional respirator use in some situations. Thus, OSHA has retained the proposed value of 2.0 μg/m³ as the final STEL.

OSHA also received a comment from Paul Wambach, (an independent commenter) stating that a STEL should not be included in the final rule, arguing that the diseases associated with beryllium exposure are chronic in nature and therefore are not affected by brief excursions above the TWA PEL (Document ID 1591, p. 1). However, as discussed above, OSHA has determined that there is sufficient evidence that brief, high-level exposures to beryllium contribute to the development of beryllium sensitization and CBD to support inclusion of a STEL in the final rule (see this preamble at section V, Health Effects). This comment also discussed the statistical relationship between a 15-minute STEL and 8-hour TWA PEL and issues of sampling strategy, discussed in section VIII.D of this preamble, Technological Feasibility.

CFR Entries. OSHA's preceding PELs for ''beryllium and beryllium compounds,'' were contained in 29 CFR 1910.1000 Table Z–2 for general industry. Table Z–2 contained two PELs: (1) A 2 μg/m³ TWA PEL, and (2) a ceiling concentration of 5 μg/m³ that employers must ensure is not exceeded during the 8-hour work shift, except for a maximum peak of 25 μg/m³ over a 30-minute period in an 8-hour work shift. The preceding PELs for beryllium and beryllium compounds in shipyards (29 CFR 1915.1000 Table Z) and construction (29 CFR 1926.55 Appendix A) were also 2 μg/m³, but did not include ceiling or peak exposure limits. OSHA adopted the preceding PELs in 1972 pursuant to section 6(a) of the OSH Act (29 U.S.C. 655(a)). The 1972 PELs were based on the 1970 American National Standards Institute (ANSI) Beryllium and Beryllium Compounds standard (Document ID 1303), 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 (Document ID 0543).

OSHA is revising the entry for beryllium and beryllium compounds in 29 CFR 1910.1000 Table Z–1 to cross-reference the new general industry standard, 1910.1024. A comparable revision to 29 CFR 1915.1000 Table Z cross-references the shipyard standard, 1915.1024, and 29 CFR 1926.55 Appendix A is revised to cross-reference the construction standard, 1926.1124. A footnote is added to 29 CFR 1910.1000 Table Z–1, which refers to 29 CFR 1910.1000 Table Z–2 for situations when the new exposure limits in 1910.1024 are stayed or otherwise not in effect. The preceding PELs for beryllium are retained in 29 CFR 1910.1000 Table Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A. Footnotes are added to these tables to make clear that the preceding PELs apply to any sectors or operations where the new TWA PEL of 0.2 μg/m³ and STEL of 2.0 μg/m³ are not in effect. The preceding PELs are also applicable during the time between publication of the beryllium rule and the dates established for compliance with the rule, as well as in the event of regulatory delay, a stay, or partial or full invalidation by the Court.

(d) Exposure Assessment

Paragraph (d) of the final standards for general industry, construction, and shipyards sets forth requirements for assessing employee exposures to beryllium. The requirements are issued pursuant to section 6(b)(7) of the OSH Act, 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.'' 29 U.S.C. 655(b)(7). Consistent with the definition of ''airborne exposure'' in paragraph (b) of these standards, exposure monitoring results must reflect the exposure to airborne beryllium that would occur if the employee were not using a respirator. Exposures must be assessed using the new performance option (*i.e.,* use of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures) or by following the scheduled monitoring option (with the frequency of monitoring determined by the results of the initial and subsequent monitoring). The performance option provides flexibility for employers who are able to accurately characterize employee exposures through alternative methods like objective data and has been successfully applied in the Chromium (VI) standard and recently included in the respirable crystalline silica standard. The scheduled monitoring option provides a framework that is familiar to many employers, having been a customary practice in past substance-specific OSHA health standards. Under either option, employers must assess the exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium.

In the proposed exposure monitoring provision, OSHA required employers to assess the exposure of employees who are, or may reasonably be expected to be, exposed to airborne beryllium. This obligation consisted of an initial exposure assessment, unless the employer relied on objective data to demonstrate that exposures would be below the action level or the short term exposure level (STEL) under any expected conditions; periodic exposure monitoring (at least annually if initial exposure monitoring indicates that exposures are at or above the action level and at or below the time-weighted average (TWA) PEL); and additional monitoring if changes in the workplace could reasonably be expected to result in new or additional exposures to beryllium. In the proposed rule, monitoring to determine employee TWA exposures had to represent the employee's average exposure to airborne beryllium over an eight-hour workday. STEL exposures had to be characterized by sampling periods of 15 minutes for each operation likely to produce exposures above the STEL. Samples taken had to reflect the exposure of employees on each work shift, for each job classification, in each beryllium work area. Samples had to be taken within an employee's breathing zone. The proposed rule also included provisions for employee notification of monitoring results and observation of monitoring.

OSHA received comments on a variety of issues pertaining to the proposal's exposure monitoring provision. In hearing testimony, Dr. Lisa Maier from National Jewish Health (NJH) expressed general support for exposure monitoring in the workplace ''to target areas that are at or above the action level and to regulate these areas to trigger administrative controls'' (Document ID 1756, Tr. 108). All other comments regarding the exposure monitoring requirements focused on specific areas of those requirements and are discussed in the appropriate subject section below.

OSHA has retained the provisions related to exposure assessment in the final standards. These provisions are important because assessing employee exposure to toxic substances is a well-recognized and accepted risk management tool. As the Agency noted in the proposal, 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. Assessment enables employers to meet their legal obligation to ensure that their employees are not exposed in excess of the permissible exposure limit (PEL) or short-term exposure limit (STEL) and to ensure employees have access to accurate information about their exposure levels, as required by section 8(c)(3) of the Act, 29 U.S.C. 657(c)(3). In addition, exposure data enable physicians or other licensed health care professionals (PLHCPs) performing medical examinations to be informed of the extent of the worker's exposure to beryllium.

In the final standards, paragraph (d) is now titled ''Exposure assessment.'' This change from ''exposure monitoring'' in the proposal to ''exposure assessment'' in the final standards was made to align the provision's purpose with the broader concept of exposure assessment beyond conducting air monitoring, including the use of objective data.

General Requirements. Proposed paragraph (d)(1)(i) contained the general requirement that the exposure assessment provisions would apply when employees ''are, or may reasonably be expected to be, exposed to airborne beryllium.'' OSHA did not receive comment on this specific provision. However, in paragraph (d)(1) of the final standards for general industry, construction, and shipyards, the Agency has changed the proposed requirement that ''These exposure monitoring requirements apply when employees are, or may reasonably be expected to be, exposed to airborne beryllium'' to ''The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium.'' This change aligns the language to other OSHA standards such as respirable crystalline silica (29 CFR 1910.1053) and hexavalent chromium (δ1910.1026) as well as clarifies the employer's obligation to assess each employee's beryllium exposure. Additionally, for reasons discussed below, paragraph (d)(1) of the final standards now requires the employer to assess employee exposure in accordance with either the new performance option, added at paragraph (d)(2), or the scheduled monitoring option, moved to paragraph (d)(3) of this section. Changes from the proposed exposure monitoring provision also include an increased frequency schedule for periodic monitoring and a requirement to perform periodic exposure monitoring when exposures are above the PEL in the scheduled monitoring option in paragraph (d)(3)(vi) and when exposures are above the STEL in the scheduled monitoring option in paragraph (d)(3)(viii).

Proposed paragraphs (d)(1)(ii)–(v) have been moved to different paragraphs in the final standards and will be discussed in the appropriate sections below.

The performance option. Proposed paragraph (d)(2) set forth initial exposure monitoring requirements and the circumstances under which employers do not need to conduct initial exposure monitoring. In the proposal, employers did not have to conduct initial exposure monitoring if they relied on historical data or objective data. The proposal also set forth requirements for the sufficiency of any historical data or objective data used to satisfy proposed paragraph (d)(2). OSHA has decided to remove this provision from the final standards as part of the change to allow employers to choose between the scheduled monitoring option and the performance option for all exposure assessment. Paragraph (d)(2) of the final standards for general industry, construction, and shipyards describes the exposure assessment performance option. OSHA has included this option because it provides employers flexibility to assess the 8-hour TWA and STEL exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to beryllium. OSHA recognizes that exposure monitoring may present challenges in certain instances, particularly when tasks are of short duration or performed under varying environmental conditions. The performance option is intended to allow employers flexibility in assessing the beryllium exposures of their employees. The performance option for exposure assessment is consistent with other OSHA standards, such as those for exposure to respirable crystalline silica (29 CFR 1910.1053) and chromium (VI) (29 CFR 1910.1026).

When the employer elects the performance option, the employer must initially conduct the exposure assessment and must demonstrate that employee exposures have been accurately characterized. As evident in final paragraph (d)(3), OSHA considers exposures to be accurately characterized when they reflect the exposures of employees on each shift, for each job classification, in each work area. However, under this option, the employer has flexibility to determine how to achieve this. For example, under this option an employer could determine that there are no differences between the exposure of an employee in a certain job classification who performs a task in a particular work area on one shift and the exposure of another employee in the same job classification who performs the same task in the same work area on another shift. In that case, the employer could characterize the exposure of the second employee based on the first employee's exposure.

Accurately characterizing employee exposures under the performance option is also an ongoing duty. In order for exposures to continue to be accurately characterized, the employer is required to reassess exposures whenever a change in production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level or STEL, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred (see discussion below of paragraph (d)(4) of the final standards for general industry, construction, and shipyards).

When using the performance option, the burden is on the employer to demonstrate that the data accurately characterize employee exposure. However, the employer can characterize employee exposure within a range, in order to account for variability in exposures. For example, an employer could use the performance option and determine that an employee's exposure is above the action level but below the PEL. Based on this exposure assessment, the employer would be required under paragraph (k)(1)(i)(A) to provide medical surveillance if the employee is exposed for more than 30 days per year.

OSHA has not included specific criteria for implementing the performance option in the final standards. Because the goal of the performance option is to give employers flexibility to accurately characterize employee exposures using whatever combination of air monitoring data and objective data is most appropriate for their circumstances, OSHA concludes it would be inconsistent to specify in the standards exactly how and when data should be collected. When an employer wants a more structured approach for meeting their exposure assessment obligations, it may opt for the scheduled monitoring option.

OSHA does, however, offer two clarifying points. First, the Agency clarifies that when using the term ''air monitoring data'' in this paragraph, OSHA refers to any monitoring conducted by the employer to comply with the requirements of these standards, including the prescribed accuracy and confidence requirements in paragraph (d)(5). Second, objective data can include historic air monitoring data, but that data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Additional discussion of the types of data and exposure assessment strategies that may be used by employers as ''objective data'' to accurately characterize employee exposures to beryllium can be found in the summary and explanation of ''objective data'' in paragraph (b) (''Definitions'').

Where employers rely on objective data generated by others as an alternative to developing their own air monitoring data, they will be responsible for ensuring that the data relied upon from other sources are accurate measures of their employees' exposures. Thus, the burden is on the employer to show that the exposure assessment is sufficient to accurately characterize employee exposures to beryllium.

As with the Chromium (VI) standard, 29 CFR 1910.1026, OSHA does not limit when objective data can be used to characterize exposure. OSHA permits employers to rely on objective data for meeting their exposure assessment obligations, even where exposures may exceed the action level or PEL. OSHA's intent is to allow employers flexibility to assess employee exposures to beryllium, but to ensure that the data used are accurate in characterizing employee exposures. For example, where an employer has a substantial body of data (from previous monitoring, industry-wide surveys, or other sources) indicating that employee exposures in a given task are between the action level and PEL, the employer may choose to rely on those data to determine his or her compliance obligations (*e.g.,* medical surveillance).

OSHA has also not established time limitations for air monitoring results used to characterize employee exposures under the performance option. The burden is on the employer to show that the data accurately characterize employee exposure to beryllium. This burden applies to the age of the data as well as to the source of the data. For example, monitoring results obtained 18 months prior to the effective date of the standards could be used to determine employee exposures, but only if the employer could show that the data were obtained during work operations conducted under conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Regardless of when they were collected, the data must accurately reflect current conditions.

Any air monitoring data relied upon by employers must be maintained and made available in accordance with the recordkeeping requirements in paragraph (n)(1) of the final standards for general industry, construction, and shipyards. Any objective data relied upon must be maintained and made available in accordance with the recordkeeping requirements in paragraph (n)(2) of the standards.

The scheduled monitoring option. Paragraph (d)(3) of the final standards for general industry, construction, and shipyards describes the scheduled monitoring option. Parts of the scheduled monitoring option in the final standards come from proposed paragraphs (d)(1)(ii)–(iv), which set out the general exposure monitoring requirements. Proposed paragraph (d)(1)(ii) required the employer to determine the 8-hour TWA exposure for each employee, and proposed paragraph (d)(1)(iii) required the employer to determine the 15-minute short-term exposure for each employee. Both proposed paragraph (d)(1)(ii) and (d)(1)(iii) required breathing zone samples to represent the employee's exposure on each work shift, for each job classification, in each beryllium work area.

Some commenters disagreed with the requirement to perform exposure monitoring on each work shift. NGK stated that sampling on each shift is overly burdensome and unnecessary since samples are collected from those employees who are expected to have the highest exposure (Document ID 1663, p. 1). Materion and the United Steelworkers (USW) recommended representative sampling instead of sampling all employees, and sampling from the shift expected to have the highest exposures (Document ID 1680, p. 3). Materion separately commented that monitoring on all three shifts is not warranted, would be burdensome to small businesses, and does not align well with other standards (Document ID 1661, p. 14 (pdf)). In post-hearing comments, Materion submitted an analysis of exposure variation by shift at one of their facilities and argued that the data are the best available evidence that monitoring on all three shifts is not justifiable or necessary to fulfill the requirements of the OSH Act (Document ID 1807, Attachment 1, p. 5, Attachment 7, p. 82; 1958, pp. 5–6). In an individual submission, the USW also stated that three-shift monitoring would add unnecessary compliance costs. Additionally, it commented that if the operations are identical, the shift chosen will not matter, while if they are not identical, then monitoring on the highest exposed shift will overestimate exposures on the other shifts (Document ID 1681, Attachment 1, p. 8). Conversely, the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) noted in post-hearing comments that widely accepted industrial hygiene practice includes exposure monitoring during different shifts, tasks, and times of the year and that monitoring is specifically designed this way to characterize exposure under different conditions (Document ID 1809, p. 1). During the hearings, Dr. Virji from NIOSH testified that because exposure is variable and ''different things happen at different shifts,'' including maintenance activities, ''it is hard to . . . gauge . . . which shift [has] the highest exposure,'' so ''it is important that multiple shifts get representative sampling'' (Document ID 1755, Tr. 50–51).

OSHA agrees with the AFL–CIO and Dr. Virji and has retained the requirement in proposed paragraphs (d)(1)(ii) and (iii) that samples reflect exposures on each shift, for each job classification, and in each work area. This requirement is included in final paragraphs (d)(3)(i) and (ii). However, in response to the comments from Materion and the USW, OSHA restructured the exposure assessment requirements in order to provide employers with greater flexibility to meet their exposure assessment obligations by using either the performance option or the scheduled monitoring option depending on the operation and information available. OSHA believes that conducting exposure assessment on a specific schedule provides employers with a workable structure to properly assess their employees' exposure to beryllium and provides sufficient information for employers to make informed decisions regarding exposure prevention measures. Alternatively, the performance option provides employers with flexibility in accurately characterizing employee exposures to beryllium on the bases of any combination of air monitoring and objective data.

Comments submitted from Mr. Paul Wambach, a private citizen, stated that the proposed short-term exposure limit (STEL) of 2 $\mu g/m^3$ has the potential for being misinterpreted as requiring the use of impractical exposure monitoring methods that would require collecting 32 consecutive 15-minute samples while providing no real health protection benefit and should be dropped from the final rule (Document ID 1591, p. 3). OSHA's intent, however, is that compliance with the STEL can be assessed using a task specific monitoring strategy, during which representative 15-minute samples can be taken to evaluate peak exposures. OSHA maintains that consistent with the comments from Materion, the identification and control of short-term exposures is critical to the protection of worker health from exposure to beryllium.

OSHA has decided to include the scheduled monitoring option in the final standards because it provides employers with a clearly defined, structured approach to assessing employee exposures. Under paragraph (d)(3)(i) of the final standards, employers who select the scheduled monitoring option must conduct initial monitoring to determine employee exposure to beryllium. Air monitoring to determine employee exposures must represent the employee's 8-hour TWA exposure to beryllium. Final paragraph (d)(3)(ii) requires the employer to perform initial monitoring to assess the employee's 15-minute short-term exposure. Under both paragraphs (d)(3)(i) and (d)(3)(ii), samples must be taken within the employee's personal breathing zone, and must represent the employee's airborne exposure on each shift, for each job classification, in each work area. In the final standards, OSHA has changed ''in each beryllium work area'' to ''in each work area'' to avoid confusion with the beryllium work areas defined in paragraphs (b) and (e) of the final standard for general industry. In other OSHA standards, the term ''work area'' is used to describe the general worksite where employees are present and performing tasks or where work processes and operations are being carried out. Employers following the scheduled monitoring option should conduct initial monitoring as soon as work on a task or project involving beryllium exposure begins so they can identify situations where control measures are needed.

Representative sampling. Paragraph (d)(3)(iii) of the final standards, like proposed paragraph (d)(1)(iv), describes the circumstances under which employers may use representative sampling. Proposed paragraphs (d)(1)(iv)(A)–(C) permitted the use of representative sampling to characterize exposures of non-sampled employees, provided that the employer performed such sampling where several employees performed the same job tasks, in the same job classification, on the same work shift, and in the same work area, and had similar duration and frequency of exposure; took breathing zone samples sufficient to accurately characterize exposure on each work shift, for each job classification, in each work area; and sampled the employees expected to have the highest exposure.

The USW and AFL–CIO supported the representative sampling provision in OSHA's proposed exposure monitoring requirements (Document ID 1681, p. 8; 1689, p. 11). OSHA has decided to retain the representative sampling provision in the final standards to provide employers with greater flexibility in meeting their exposure assessment obligations. Under the scheduled monitoring option, just as under the performance option, employers must accurately characterize the exposure of each employee to beryllium. In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of ''representative'' employees is sufficient. As in the proposal, representative exposure sampling is permitted under the final standards when several employees perform the same tasks on the same shift and in the same work area. However, OSHA has not included the requirement in proposed paragraph (d)(1)(iv)(A) that employees ''have similar duration and frequency of exposure'' in final paragraph (d)(3)(iii). This provision is unnecessary because final paragraph (d)(3)(iii), like proposed paragraph (d)(1)(iv)(C), requires the employer to sample the employee(s) expected to have the highest exposures to beryllium. Additionally, the requirement in proposed paragraph (d)(1)(iv)(B) that employers take ''sufficient breathing zone samples to accurately characterize exposure on each work shift, for each job classification, in each work area'' has been removed because when performing exposure monitoring under final paragraphs (d)(3)(i) or (d)(3)(ii), employers already must assess exposures based on personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area. Under these conditions, OSHA expects that exposures will be accurately characterized.

Finally, the proposed requirement in paragraph (d)(1)(iv)(C) that employers must monitor the employee(s) expected to have the highest exposures has been retained in the final standards. For example, this could involve monitoring the beryllium exposure of the employee closest to an exposure source. The exposure result may then be attributed to other employees who perform the same tasks on the same shift and in the same work area. Exposure assessment should include, at a minimum, one full-shift sample and one 15 minute sample taken for each job classification, in each work area, for each shift.

Where employees are not performing the same tasks on the same shift and in the same work area, representative sampling will not adequately characterize actual exposures of those employees, and individual monitoring is necessary.

Frequency of monitoring under scheduled monitoring option. Paragraph (d)(3) of the proposed standard required periodic monitoring at least annually if initial exposure monitoring indicated that exposures were at or above the action level and at or below the TWA PEL. The proposal did not require periodic exposure monitoring if initial monitoring indicated that exposures were below the action level.

In the NPRM, OSHA solicited comment on the reasonableness of discontinuing monitoring based on one sample below the action level. In response, many commenters discussed the importance of taking multiple samples to evaluate a worker's exposure even if initial results are below the action level. NJH emphasized that ''[i]t is NOT reasonable to discontinue monitoring after one sample result below the action level'' because ''a single sample result does not reflect the random variation in sampling and analytical methods'' (Document ID 1664, p. 6). NIOSH commented that, because occupational exposure distributions are right-skewed (*i.e.,* the mean is higher than the median so most sample results will be below the average exposure level), collecting fewer samples leads to a higher likelihood of showing compliance when it may not be warranted (Document ID 1671, Attachment 1, p. 6). Also during the hearings, Marc Kolanz of Materion stated that one sample does not provide ''a good understanding of what's out there,'' and there is ''value in trying to collect at least a few samples'' (Document ID 1755, Tr. 140). The Department of Defense (DOD) commented that it is not appropriate to discontinue monitoring based on one sample below the action level (Document ID 1684, Attachment 2, p. 3). The American College of Occupational and Environmental Medicine (ACOEM) commented that ''[t]here is significant uncertainty associated with limited sample numbers'' (Document 1685, p. 3). Ameren Corporation (Ameren), an electric utility company, stated that the number of samples needed ''depend[s] on how well the sample characterizes the work performed'' (Document ID 1675, p. 10). The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group), a non-profit organization promoting the understanding and prevention of beryllium-induced conditions and illnesses, commented that it would not consider a single sample to be a reasonable determination of exposures (Document ID 1665, p. 6). North America's Building Trades Unions (NABTU) commented that it was unreasonable to allow discontinuation of monitoring based on one sample below the action level, because that sample could be a statistical aberration, and ''the assumption that if a workplace is in compliance at one time it will stay in compliance in the future is a fallacy, particularly on an active, dynamic construction site'' (Document ID 1679, p. 8). The USW and Materion stated that exposure characterization often requires more than one sample (Document ID 1680, p. 3). Southern Company suggested that ''language regarding initial and periodic monitoring, and the discontinuation of both, [should] be consistent with existing substance specific standards'' (Document ID 1668, p. 3).

OSHA has considered these comments and has determined that if initial monitoring indicates that employee exposures are below the action level and at or below the STEL, no further monitoring is required. Paragraph (d)(3)(iv) of the final standards permits employers to discontinue monitoring of employees whose exposure is represented by such monitoring where initial monitoring indicates that exposure is below the action level and at or below the STEL. However, a single sample below the action level and at or below the STEL does not necessarily warrant discontinuation of exposure monitoring. OSHA has clarified in final paragraphs (d)(3)(i) and (d)(3)(ii) that any initial monitoring conducted under the scheduled monitoring option must reflect exposures on each shift, for each job classification, and in each work area. Therefore, where there is more than one shift or work area for a particular task, there will be more than one sample; accordingly, it is unlikely that an employer would be able to sufficiently characterize and assess employee exposure for a given job classification under the scheduled monitoring option using a single sample.

In paragraph (d)(3) of the proposed rule, periodic exposure monitoring was required at least annually if initial exposure monitoring found exposures at or above the action level and at or below the TWA PEL. In the NPRM, OSHA asked a question about the frequency of monitoring and the reasoning behind that frequency. During the hearings, Peggy Mroz with NJH testified that periodic monitoring conducted at least every 180 days when exposures are at or above the action level is ''the most protective for workers'' (Document ID 1756, Tr. 99–100). Ms. Mroz further stated that exposure monitoring should also be conducted at least annually for all other processes and jobs where initial monitoring shows levels below the action level since changes in working conditions can affect monitoring results, and ''[i]t has already been shown that beryllium sensitization and CBD occur at measured exposures below the proposed action level'' (Document ID 1756, Tr. 100). Both NIOSH and NJH recommended more frequent monitoring for employers to fully understand levels of exposure that may vary over time and to assess whether proper controls are in place after a high exposure level is documented (Document ID 1725, p. 29; 1720, p. 5). The BHSC Task Group stated that annual monitoring is inadequate, and recommended sampling more frequently than every 180 days (Document ID 1665, pp. 15, 17). And, the AFL–CIO commented that annual exposure monitoring is inadequate and does not provide the employer with enough information to make appropriate changes to prevent and minimize exposure. The AFL–CIO cited various OSHA health standards that required more frequent periodic exposure monitoring, including cadmium, asbestos, vinyl chloride, arsenic, lead, and respirable crystalline silica (Document ID 1809, pp. 1–2). In contrast, Ameren agreed with the proposal's requirement to conduct monitoring annually if exposures are at or above the action level, because the proposal already requires additional monitoring when work conditions change (Document ID 1675, p. 4). And, the Edison Electric Institute (EEI) commented that beryllium exposure in the electric utility industry occurs during maintenance outages, ''which more closely align with the annual re-sampling requirements than the 180 [day] provisions in these alternatives'' (Document ID 1674, p. 14).

OSHA is persuaded by the commenters recommending more frequent periodic monitoring and has changed the frequency required for exposures between the action level and the TWA PEL in the scheduled monitoring option in the final standards. Paragraph (d)(3)(v) of the final standards requires monitoring every six months if initial exposure monitoring indicates that exposures are at or above the action level but at or below the TWA PEL, which is the typical frequency in other health standards for carcinogens such as respirable crystalline silica, cadmium, vinyl chloride, and asbestos for this level of exposure. Alternatively, employers in general industry, construction, and shipyards can use the performance option in paragraph (d)(2), which provides employers greater flexibility to meet their exposure assessment obligations.

In the proposal, OSHA did not require periodic exposure monitoring if initial exposure monitoring indicated that exposures were above the TWA PEL or STEL. In response to a question in the NPRM about monitoring above the PEL, Materion commented that there is no benefit to expending time and money monitoring exposures that exceed the PEL, because it is more important that activities be directed toward the exposure control plan. Based on their experience, Materion believes that employers will conduct monitoring as often as necessary to demonstrate that exposures have been reduce to below the PEL (Document ID 1661, p. 24 (pdf)). Other commenters disagreed with OSHA's proposal not to require periodic exposure monitoring above the PEL. The DOD commented that periodic monitoring should also be performed when levels are above the PEL to ensure respiratory protection is adequate and to test the effectiveness of engineering controls (Document ID 1684, Attachment 2, p. 9). In response to a question during the hearings on the benefits of monitoring above the PEL, NIOSH's Dr. Virji testified that exposure can vary within a job and that even though an employer may know exposures are high in a particular area, the information is ''useful because then it allows an understanding of what level of engineering controls that would be required to bring down the exposures to acceptable levels'' (Document ID 1755, Tr. 49–50). In her testimony, Mary Kathryn Fletcher with the AFL–CIO expressed support for monitoring above the PEL, stating that ''exposure monitoring is important to reevaluate control measures in cases of over-exposure,'' and ''[it is] important to characterize the job to know the exposures if you're going to try to reduce those exposures'' (Document ID 1756, Tr. 236). Also during the hearings, Ashlee Fitch with the Health, Safety, and Environment Department of the USW responded to a similar question on the benefits of air monitoring in cases where exposures are believed to exceed the PEL. She stated, ''You see oftentimes that employers used exposure rates to measure how well ventilation systems are working or what the exposure is, and after they implement engineering controls, what that exposure goes to'' (Document ID 1756, Tr. 282). In her testimony, Peggy Mroz with NJH expressed support for periodic exposure monitoring every 90 days where exposures exceed the TWA PEL or STEL as ''routine and regular sampling and repeated sampling should be done to assess whether proper controls are in place after a high sample is documented as we know that beryllium sensitization and chronic beryllium disease can occur within a few weeks of exposure'' (Document ID 1756, Tr. 100).

Based on these comments received in the record and testimony obtained from the public hearing, OSHA's final standards require periodic exposure monitoring every three months when exposures are above the TWA PEL or STEL under the scheduled monitoring option in paragraphs (d)(3)(vi) and (d)(3)(viii). Alternatively, employers in general industry, construction, and shipyards can use the performance option in paragraph (d)(2) which provides employers with greater flexibility to meet their exposure assessment obligations.

Proposed paragraph (d) did not include a separate provision to allow employers to discontinue monitoring if exposures were subsequently reduced to below the action level, as demonstrated by periodic monitoring. In the NPRM, OSHA solicited comment on the reasonableness of discontinuing monitoring based on one sample below the action level. As discussed more fully in the explanation of final paragraph (d)(3)(iv), many commenters discussed the importance of taking multiple samples to confirm exposures are below the action level before allowing the discontinuation of monitoring. For example, ORCHSE Strategies (ORCHSE) commented that allowing discontinuation of monitoring based on one sample is not appropriate and that two consecutive samples taken at least seven days apart, that show exposure below the action level, should be required to allow monitoring to be discontinued (Document ID 1691, Attachment 1, p. 3).

As stated in the explanation of final paragraph (d)(3)(iv), OSHA has carefully considered these comments and agrees that a single sample is not sufficient to allow employers to discontinue monitoring. OSHA has therefore decided to add paragraph (d)(3)(vii) to the final standards. This provision requires that, where the most recent exposure monitoring indicates that employee exposure is below the action level, the employer must repeat exposure monitoring within six months of the most recent monitoring. The employer may discontinue TWA monitoring, for those employees whose exposure is represented by such monitoring, only when two consecutive measurements, taken seven or more days apart, are below the action level, except as otherwise provided in the reassessment of exposures requirements in paragraph (d)(4) of the final standards. Additionally, OSHA has added paragraph (d)(3)(viii) to the final standards. This provision requires that, where the most recent exposure monitoring indicates that employee exposure is above the STEL, the employer must repeat exposure monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken seven or more days apart, are below the STEL. At this point, the employer may discontinue monitoring for those employees whose exposure is represented by such monitoring. As discussed below, reassessment is always required whenever a change in the workplace may be reasonably expected to result in new or additional exposures at or above the action level or above the STEL or the employer has any reason to believe that new or additional exposures at or above the action level or above the STEL have occurred, regardless of whether the employer has ceased monitoring because exposures are below the action level or at or below the STEL under paragraphs (d)(3)(iv), (d)(3)(vii), or (d)(3)(viii) of the final standards.

Exposure assessment in construction and shipyard *industries.* Beryllium exposure occurs in the construction and shipyard industries primarily during abrasive blasting operations that use coal and copper slags containing trace amounts of beryllium (Document ID 1815, Attachment 85, pp. 70–72; 0767, p. 6).

During the public hearing, testimony was heard about abrasive blasting operations using slags at a shipyard facility. Mike Wright, with the USW, testified that the use of enclosure (containment) is important to prevent the escape of beryllium dust during abrasive blasting operations and that exposure monitoring could help determine the integrity of the enclosure along with establishing a perimeter where beryllium contamination is controlled (Document ID 1756, Tr. 274–275). Ashlee Fitch, also representing the USW, testified about monitoring worker exposure to beryllium in the maritime industry. Ms. Fitch stated that abrasive blasting using beryllium-containing abrasive materials should be done in full containment and that exposures outside the containment should not exceed the PEL or STEL (Document ID 1756, Tr. 244–245). Ms. Fitch recommended that in cases where full containment is used, ''the employer shall do an initial monitoring for each configuration of the containment'' and ''if the initial monitoring shows exposures above the action level, monitoring shall be performed for every blasting operation.'' She also recommended air monitoring of exposed workers outside of the containment or through monitoring of the positions where exposure is likely to be the highest, or if full containment is not used, ''around any abrasive blasting operation'' (Document ID 1756, Tr. 245). Representative Robert Scott, the ranking minority member on the Committee on Education and the Workforce of the U.S. House of Representatives (Representative Scott), commented that when workers are engaged in abrasive blasting and the abrasive blasting area is contained, exposure monitoring should be routinely performed when levels exceed the action level (Document ID 1672, p.4).

Substantially agreeing with these comments, in paragraph (d)(3) of the final standards, OSHA is requiring monitoring on each work shift, for each job classification, and in each work area when employers are following the scheduled monitoring option. OSHA also agrees that monitoring should be of the positions where exposure is likely to be the highest, so when employers engage in representative sampling under the scheduled monitoring option, final paragraph (d)(3)(iii) requires that they must sample the employee(s) expected to have the highest airborne exposure to beryllium. OSHA also agrees with Representative Scott that exposure monitoring should be routinely performed for abrasive blasting and all other operations exposing workers to beryllium when exposures exceed the action level. If exposures exceed the action level or STEL, the employer is required to monitor exposures at frequencies indicated in the scheduled monitoring option or using the performance option to accurately assess the beryllium exposure of their employees. However, OSHA does not consider monitoring to be necessary each time there is an abrasive blasting or other operation that fits within the profile of a previously taken representative sample.

Reassessment of exposures. Paragraph (d)(4) of the final standards, like paragraph (d)(4) of the proposal, describes the employer's obligation to reassess employee exposures under certain circumstances. Proposed paragraphs (d)(4)(i) and (d)(4)(ii) required the employer to conduct exposure monitoring within 30 days after a change in production processes, equipment, materials, personnel, work practices, or control methods that could reasonably be expected to result in new or additional exposure, or if the employer had any other reason to believe that new or additional exposure was occurring.

Commenters generally advocated for monitoring to assess any new exposures. For example, in her testimony, Mary Kathryn Fletcher with the AFL–CIO expressed support for exposure monitoring even if exposure is reduced as far as feasible, because exposures can change, so ''it's important to monitor as tasks change and over time, there are different procedures, different workers in the area, doing different things'' (Document ID 1756, Tr. 236). Also, NJH commented that ''periodic sampling, even of low exposure potential tasks, ensures that despite changes in processes, personnel, exhaust systems, and other control measures, the exposure remains low and workers remain safe'' (Document ID 1664, p. 6). Therefore, the Agency has decided to retain the requirement of proposed paragraph (d)(4) that employers reassess exposures, but has made minor changes to the regulatory text. OSHA has changed the title ''Additional Monitoring'' in proposed paragraph (d)(4) to ''Reassessment of exposures'' in paragraph (d)(4) of the final standards to be consistent with the change in paragraph (d) terminology from ''exposure monitoring'' to ''exposure assessment.'' OSHA has also changed the proposed requirement that employers conduct exposure monitoring within 30 days after a change in ''production processes, equipment, materials, personnel, work practices, or control methods'' that could reasonably be expected to result in new or additional exposures to the requirement in the final standards that employers must perform reassessment of exposures when there is a change in ''production, process, control equipment, personnel, or work practices'' that may reasonably be expected to result in new or additional exposures at or above the action level or STEL. OSHA made these changes to provide clarity and consistency with other OSHA health standards.

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 has retained the requirement in proposed paragraph (d)(4)(ii) that the employer must reassess exposures whenever the employer has any reason to believe that a change has occurred that may result in new or additional exposures, and has added ''at or above the action level or STEL'' to final paragraph (d)(4). Under this provision, for example, an employer is required to reassess exposures 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 a reassessment of exposures to ascertain if airborne exposures contributed to the beryllium-related health effects. Additionally, reassessment of exposures would be required following a process modification that increases the amount of beryllium-containing material used, thereby possibly increasing employee exposure. Reassessment of exposures will also be required when a shipyard or construction employer introduces a new beryllium-containing slag for use in an abrasive blasting operation. Once reassessment of exposures is performed and if exposures are above the action level, TWA PEL, or STEL, the employer can take appropriate action to protect exposed employees and must perform periodic monitoring as discussed above.

Methods of sample analysis. Paragraph (d)(5) of the final standards, like proposed paragraph (d)(1)(v), addresses methods for evaluating air monitoring samples. Proposed paragraph (d)(1)(v) required employers to use a method of exposure monitoring and analysis that could 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. This provision is largely unchanged in the final standards. OSHA has changed the title ''Accuracy of measurement'' in the proposal's paragraph (d)(1)(v) to ''Methods of sample analysis'' in paragraph (d)(5) of the final standards. OSHA made this change to more accurately describe the purpose of this requirement. Additionally, OSHA changed the requirement that employers ''use a method of exposure monitoring and analysis'' in the proposed rule to require that employers ''ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) are evaluated by a laboratory'' to clarify that employers may send samples to a laboratory for analysis, and OSHA does not intend to require employers to have a laboratory to analyze samples at the worksite.

Under final paragraph (d)(5), the employer is required to make sure that all samples taken to satisfy the monitoring requirements of paragraph (d) are evaluated by a laboratory that can measure airborne levels of 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. The following methods 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. However, not all of these methods are appropriate for measuring beryllium oxide, so employers must verify that the analytical method used is appropriate for measuring the form(s) of beryllium present in the workplace.

In the NPRM, OSHA requested comment on whether these methods would satisfy the requirements of this paragraph, and if there were other methods that would also meet these criteria. The BHSC Task Group commented that OSHA's accuracy criteria could be met for full shift samples using available analytical methods. The BHSC Task Group agreed with the guidance in OSHA's NPRM to use ICP–MS or fluorescence to assure adequate sensitivity and analytical precision (Document ID 1655, p. 2). In response to a question on whether the current methods were sufficiently sensitive, Kevin Ashley with NIOSH testified that both the fluorescence method (NIOSH method 7704) and the inductively coupled plasma mass spectrometry (ASTM method D7439) were adequately sensitive to measure at the proposed PEL and STEL (Document ID 1755, Tr. 58). The DOD commented that the current limit of quantification (LOQ) of 0.05 μg for beryllium using the NIOSH 7300 and OSHA 125G methods would be adequate to detect exposures below the proposed action level of 0.1 μg/m^3 and the proposed STEL of 2 μg/m^3 (Document ID 1684, Attachment 2, p. 9). OSHA has identified several sampling and analysis methods for beryllium that are capable of detecting beryllium at air concentrations below the final action level of 0.1 μg/m^3 and the final STEL of 2.0 μg/m^3 for a 15-minute sampling period (see Chapter IV of the Final Economic Analysis, Technological Feasibility). Therefore, OSHA has determined that the sampling and analytical methods currently available to employers are sufficient to measure beryllium as required in paragraph (d) of the final standards.

Rather than specifying a particular method that must be used, the final standards allow for a performance-oriented approach that allows the employer to use the method and analytical laboratory of its choosing as long as that method meets the accuracy specifications in paragraph (d)(5) and the reported results represent the total airborne concentration of beryllium for the worker being characterized. Other methods, such as a respirable fraction sample or size selective sample, would not provide results directly comparable to either PEL, and therefore would not be considered valid.

Employee Notification of Assessment Results. Paragraph (d)(6) of the final standards, like proposed paragraph (d)(5), addresses employee notification requirements. OSHA did not receive comment specifically on this provision, but several commenters supported the exposure monitoring provisions as a whole, and after reviewing the record, OSHA has decided to retain the employee notification requirements in the final standards. OSHA has changed the title ''Employee Notification of Monitoring Results'' in proposed paragraph (d)(5) to ''Employee Notification of Assessment Results'' in final paragraph (d)(6) to reflect the change in the title of paragraph (d). This requirement is consistent with other OSHA standards, such as those for respirable crystalline silica (29 CFR 1910.1053), methylenedianiline (29 CFR 1910.1050), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

Proposed paragraph (d)(5)(i) required employers to notify each employee of his or her monitoring results within 15 working days after receiving the results of any exposure monitoring. Both the employees whose exposures were measured directly and those whose exposures were represented by the monitoring had to be notified. The employer had to notify each employee individually in writing or post the monitoring results in an appropriate location accessible to all employees required to be notified. Proposed paragraph (d)(5)(i) is now paragraph (d)(6)(i) in the final standards, and has been edited to reflect the change in language from ''exposure monitoring'' to ''exposure assessment,'' discussed earlier. This can be in print or electronically as long as the affected employees have access to the information and have been informed of the posting location. Final paragraph (d)(6)(i) for general industry, construction, and shipyards is substantively unchanged from the proposal. However, due to the transient nature of construction work and the need to receive exposure assessment results while the work is still occurring, OSHA recommends that employers in the construction industry make every effort to notify employees of their monitoring results as soon as possible.

Proposed paragraph (d)(5)(ii) required that, whenever exposures exceeded the TWA PEL or STEL, the written notification required by proposed paragraph (d)(5)(i) include (1) suspected or known sources of exposure and (2) a description of the corrective action(s) that have been taken or will be taken by the employer to reduce the employee's exposure to or below the TWA PEL or STEL where feasible corrective action exists but was not implemented at the time of the monitoring. OSHA did not receive comment on this specific provision, and after reviewing the record, including comments supporting paragraph (d) generally, OSHA has decided to retain a notification requirement focused on individual exposure assessments and the corrective actions being taken for exposures above the PEL or STEL. It is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and to provide employees with information about their exposures. Furthermore, notification to employees of exposures above a prescribed PEL and the corrective actions being taken is required under section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)). In order to provide consistency with other OSHA health standards, OSHA has removed the requirement in proposed paragraph (d)(5)(ii) that employers include suspected or known sources of exposure in the written notification. Proposed paragraph (d)(5)(ii), as revised, is now paragraph (d)(6)(ii) in the final standards.

Observation of monitoring. Paragraph (d)(7) of the final standards, like proposed paragraph (d)(6), requires employers to provide for observation of exposure monitoring. OSHA did not receive comment on this specific provision, and after reviewing the record, including comments supporting paragraph (d) generally, OSHA has decided to retain it in the final standards because it promotes occupational safety and health and is required by 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.

Proposed paragraph (d)(6)(i) required the employer to provide an opportunity to observe any exposure monitoring required by the standards to each employee whose airborne exposure was measured or represented by the monitoring and to each employee's representative(s). Proposed paragraph (d)(6)(i) is now paragraph (d)(7)(i) in the final standards, and is substantively unchanged from the proposal. When observation of monitoring required entry into an area where the use of protective clothing or equipment was required, proposed paragraph (d)(6)(ii) required the employer to provide the observer with that personal protective clothing or equipment, at no cost. The employer was also required to ensure that the observer used such clothing or equipment appropriately. Proposed paragraph (d)(6)(ii) is now paragraph (d)(7)(ii) in the final standards, and is substantively unchanged from the proposal. Paragraph (d)(6)(iii) of the proposal required employers to ensure that each observer complied with all applicable OSHA requirements and the employer's workplace safety and health procedures. Proposed paragraph (d)(6)(iii) is now paragraph (d)(7)(iii) in the final standards. OSHA has changed the proposed language to require that employers ensure that each observer follows all other applicable safety and health procedures to clarify that the burden to comply with OSHA requirements remains on the employer, not the observer.

(e) Beryllium Work Areas and Regulated Areas (General Industry); Regulated Areas (Shipyards); and Competent Person (Construction)

Paragraph (e) of the standards for general industry and shipyards sets forth the requirements for establishing, maintaining, demarcating, and limiting access to certain areas of the workplace to aid in minimizing employee exposure to beryllium. As discussed below, the general industry standard includes requirements for both ''work areas'' and ''regulated areas,'' which are subsets of work areas. The shipyard standard includes requirements for regulated areas, but not work areas. Paragraph (e) of the construction standard does not require either work areas or regulated areas, but instead includes requirements for a ''competent person,'' who has responsibility for demarcating certain areas of beryllium exposure for similar purposes.

Specifically, paragraph (e)(1)(i) and (e)(2)(i) of the standard for general industry requires employers to establish, maintain, and demarcate one or more ''beryllium work area,'' which is defined as a work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. OSHA intends these beryllium work area provisions to apply to the area surrounding the process, operation, or task where airborne beryllium is released or the potential for dermal contact is created. Beryllium work areas are also referenced in the general industry standard in paragraphs (f)(1) (the written exposure control plan), (f)(2) (engineering and work practice controls), and (j) (housekeeping). Under paragraphs (e)(1)(ii) and (e)(1) of the standards for general industry and shipyards, respectively, employers are also required to establish and maintain regulated areas wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. As indicated and discussed in more detail below, the final standards for shipyards and construction do not contain provisions for beryllium work areas and the standard for construction does not require employers to establish regulated areas. In lieu of regulated areas, paragraph (e) of the final standard for construction, Competent Person, consists of a set of requirements designed to provide most of the same protections as regulated areas in general industry and shipyards, using a competent person instead of demarcated areas to achieve these ends.

The requirements to establish beryllium work areas and regulated areas or designate competent persons serve several important purposes. First, requiring employers to establish and demarcate beryllium work areas in general industry ensures that workers and other persons are aware of the potential for work processes to release airborne beryllium or cause dermal contact with beryllium. Second, the required demarcation of regulated areas in general industry and shipyards in accordance with the paragraph (m) requirements for warning signs ensures that all persons entering regulated areas will be aware of the serious health effects associated with exposure to beryllium. Similarly, assignment of a competent person to carry out the provisions of paragraph (e) in the construction standard where exposures may exceed the TWA PEL or STEL provides employees in construction with a knowledgeable on-site authority to convey information about the hazards of beryllium exposure. Third, limiting access to regulated areas (general industry and shipyards) or areas where exposures may exceed the TWA PEL or STEL (construction) restricts the number of workers potentially exposed to beryllium at levels above the TWA PEL or STEL. Finally, provisions for respiratory protection and PPE ensure that those who must enter regulated areas (general industry and shipyards) or areas where exposures may exceed the TWA PEL or STEL (construction) are properly protected, thereby reducing the risk of serious health effects associated with airborne beryllium exposure and dermal contact with beryllium.

The remainder of this section provides detailed discussion of each provision in paragraph (e) of the final standards for general industry, shipyards, and construction, as well as comments OSHA received on paragraph (e) of the proposed standard, OSHA's response to these comments, and the reasons for OSHA's decisions regarding the provisions of paragraph (e) in each final standard.

Beryllium Work Areas (General Industry). Provisions for the establishment of beryllium work areas were included in the proposed standard for general industry in paragraph (e)(1)(i). This proposed provision required employers to establish and maintain beryllium work areas where employees are, or can reasonably be expected to be, exposed to airborne beryllium. OSHA explained that it intended the 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 Agency further explained that—unlike the requirements for regulated areas—the proposed requirements were not tied to a particular level of exposure, but rather were triggered by the presence of airborne beryllium at any exposure level. The provision was based on a provision recommended by Materion Corporation (Materion) and the United Steelworkers (USW) in their joint submission, (see previous discussion in the Introduction to this Summary and Explanation section).

A number of stakeholders commented on the proposed definition of a beryllium work area. Some commenters, such as NGK Metals Corporation (NGK) and ORCHSE Strategies (ORCHSE), argued that the definition of a beryllium work area is vague and requested that OSHA trigger the requirement to establish and maintain beryllium work areas at a measureable threshold, such as the action level (*e.g.,* Document ID 1663, p. 1; 1691, Attachment 1, p. 15). Edison Electric Institute (EEI), an industry association representing electric utility companies, also did not agree with the beryllium work area definition (Document ID 1674, p. 13). Like NGK and ORCHSE, EEI recommended that OSHA tie the beryllium work area requirements to a quantifiable exposure level, like the action level or the PEL (Document ID 1674, p. 13). The Boeing Company (Boeing) also recommended the use of a quantifiable trigger, but suggested a much lower trigger of 0.02 $\mu g/m^3$ (Document ID 1667, p. 3). Boeing explained that not including a specific threshold can lead to inconsistent results because it depends on the sensitivity of the measurement method (Document ID 1667, p. 3).

Other commenters supported the proposed standard's establishment of beryllium work areas at any level of airborne beryllium exposure. For example, AWE commented that its ''supervised beryllium workspaces'' align with the proposal's beryllium work areas (Document ID 1615, p. 1). NIOSH observed that the proposed approach is feasible and appropriate for beryllium work settings where work such as production, processing, handling, and manufacturing of beryllium products is performed and areas where needed preventive controls can be relatively easily demarcated (Document ID 1725, pp. 29–30). Materion and USW reiterated their support for provisions related to beryllium work areas ''where operations generate airborne beryllium particulate'', which were included in the recommended model standard they submitted to OSHA (Document ID 1680, p. 3).

The purpose of a beryllium work area is to establish a demarcated area in which workers and other persons authorized to be in the area are made aware of the potential for beryllium exposure and must take certain precautions accordingly. OSHA finds that establishing beryllium work areas where exposures are at the action level or above the PEL would not adequately protect exposed workers operating outside demarcated regulated areas, for which the applicable trigger is the TWA PEL or STEL. Because, as discussed in Section V, Health Effects, there is still a potential health risk to workers exposed to beryllium below the action level, the establishment and demarcation of beryllium work areas at any level of airborne exposure will provide additional protection for these workers by ensuring that they are aware of the presence of processes that release beryllium. OSHA similarly finds that Boeing's suggested trigger of 0.02 $\mu g/m^3$ is not suitable because OSHA has not established a level of exposure at which beryllium does not pose a risk to workers (see this preamble at Section VI, Risk Assessment). Therefore, OSHA finds that establishing and demarcating beryllium work areas wherever processes or operations release beryllium is more protective. OSHA also does not agree with those commenters who find the trigger for establishing beryllium work areas vague. As explained previously, OSHA has modified the beryllium work areas provision in the final standard for general industry to specify that the source of the airborne beryllium exposure and potential for dermal contact triggering the requirement for a beryllium work area must be generated from a process or operation within that area, not just the fact that an employee may be handling an article containing beryllium. An employer can (but is not required to) use air monitoring to determine the presence of airborne beryllium in the area surrounding the process, operation, or task that may be releasing beryllium or wipe sampling to determine the presence of beryllium on surfaces that workers may come into contact with. Affording the employer such flexibility to comply with this performance-based provision does not make it impermissibly vague. Accordingly, OSHA has decided to retain, as modified, the requirement that beryllium work areas must be established and maintained where there is a process or operation that can release beryllium and employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level. However, as discussed below, OSHA has somewhat modified the definition of beryllium work areas in response to comments from other stakeholders and NIOSH.

Two electric utility companies, Southern Company and Ameren Corporation (Ameren), argued that a work area requirement defined by any level of airborne beryllium exposure was subjective and would result in their entire facility falling under this requirement (Document ID 1668, pp. 3–4; 1675 p. 5). The Aluminum Association stated that there may be areas where airborne beryllium exposures are present but have been found through exposure assessments and monitoring to be insignificant; therefore, beryllium work areas are overly broad as defined in the proposal and should be dropped from the final standard (Document ID 1666, p. 2). The American College of Occupational and Environmental Medicine (ACOEM) also did not agree with the proposed definition of beryllium work areas because it is not specific to workplaces where beryllium is used or processed (Document ID 1685, p. 2). ACOEM argued that airborne beryllium is essentially ubiquitous at very low levels, and that the proposed definition of beryllium work areas could be interpreted to apply to most worksites regardless of work activity. Therefore, ACOEM suggested clarifying the requirement using language that specifies ''worksites in which any beryllium or beryllium-containing materials are or have been processed using methods capable of generating dust or fume'' (Document ID 1685, p. 2).

OSHA did not intend a scenario where an entire facility becomes a beryllium work area from environmental or other non-occupational sources of beryllium. Nor did the Agency intend to cause the entirety of any worksite covered by the rule to become a beryllium work area, even where the amount of airborne beryllium is insignificant in the sense that it is residually present at very low levels in areas of a facility where work processes that release airborne beryllium do not occur. (Note that the best available scientific evidence has not identified a medically insignificant level of beryllium exposure; as discussed in Section VI, Risk Assessment, beryllium sensitization has been found among individuals whose exposures are below the action level.) Such a situation might occur in a coal-fired electric generating plant or a foundry where a very small amount of beryllium may be detectable far away from the processes that released it. To avoid these unintended consequences, OSHA has modified the beryllium work areas provision in the final standard for general industry to specify that the source of the airborne beryllium exposure and potential for dermal contact triggering the requirement for a beryllium work area must be generated from a process or operation within that area. This modification is similar to ACOEM's suggestion to define beryllium work areas as areas where beryllium or beryllium-containing materials are or have been processed (Document ID 1685, p. 2). While the trigger for beryllium work area is based on whether the beryllium is processed by controlling the release of airborne beryllium from the particular process, operation, or task, the employer can limit the size of the beryllium work area and eliminate the likelihood of an entire facility becoming a beryllium work area. OSHA believes this modified definition of beryllium work areas addresses the concerns raised by employers and ACOEM, while also maintaining the protective benefits associated with beryllium work areas for beryllium-exposed employees.

In addition to commenting on the level of exposure that should trigger the establishment and maintenance of a beryllium work area, NIOSH offered an opinion on the type of exposure that should trigger beryllium work areas. Specifically, NIOSH argued that limiting the definition of beryllium work area to employee exposure to airborne beryllium omits the potential contribution of dermal exposure to total exposure (Document ID 1725, p. 30). To support its point, NIOSH cited to Armstrong *et al.* (2014), which reported that work processes associated with elevated risk for beryllium sensitization had high air/high dermal exposure, high air/low dermal exposure, or low air/high dermal exposure indicating that dermal exposures should be considered as relevant pathways (Document ID 1725, p. 30). OSHA agrees with NIOSH and has modified the beryllium work areas section of the final standard for general industry to include potential dermal exposure.

OSHA also made two other minor, nonsubstantive changes to the proposed provision to help streamline the final general industry standard. First, instead of restating the definition of beryllium work area in paragraph (e)(1)(i) (as in the proposal), OSHA has modified final paragraph (e)(1)(i) in the proposal to merely refer to the term as defined in paragraph (b) of the standard for general industry. Second, the definition of beryllium work area in the final general industry standard includes the qualifier ''where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level.'' This is a modification from the proposed beryllium work area definition wording ''where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure.'' Both of these changes were intended only to simplify the language of the regulatory text and should not be read to suggest a change in substantive requirements or the Agency's intent.

The construction and shipyard sectors were not included in the proposed standard. However, OSHA requested comments on Regulatory Alternative #2a in the NPRM, which would apply all provisions of the proposed standard to facilities in construction and shipyards, including provisions pertaining to the establishment of beryllium work areas. Following careful consideration of the comments OSHA received from a variety of stakeholders and from NIOSH on this topic, OSHA has concluded that the requirement to establish and maintain beryllium work areas are not appropriate for construction or shipyards. The work processes (primarily abrasive blasting), worksites, and conditions in construction and shipyards differ substantially from those typically found in general industry; as discussed further below, establishment of beryllium work areas in these sectors is likely to be impractical. However, OSHA has modified the standards so that most of the protective measures related to beryllium work areas in the general industry standard apply to operations in construction and shipyards, using triggers more suitable for these sectors. Thus, OSHA believes the final standards for construction and shipyards provide employees protection similar to employees in general industry, but avoid the difficulties associated with establishment of beryllium work areas in the context of abrasive blasting operations in these sectors.

NIOSH commented that while it supported triggering the requirement to establish beryllium work areas at any level of airborne exposures, it is not clear how such a requirement would work in an outdoor environment (Document ID 1725, p. 30). It explained that it is possible that even ambient conditions could cause an outdoor work environment to qualify as a ''beryllium work area'' (Document ID 1725, p. 30). NIOSH also noted that it was unclear how to delineate beryllium work areas in an outdoor setting when abrasive blasting the outer hull of a large ship and questioned how the beryllium work area trigger of any level of airborne exposure to beryllium could be applied only to that specified area (Document 1755, Tr. 21). NIOSH further explained that establishing a beryllium work area for abrasive blasting in an outdoor environment is difficult because outdoor blasting operations often involve large structures and constant moving of the operation (Document ID 1755, Tr. 55).

Newport News Shipbuilding (NNS) similarly commented that since beryllium is primarily encountered in shipyards as a trace element in coal slag blasting media, the requirement to establish and maintain beryllium work areas is not appropriate for shipyards. NNS stated, ''[i]t is relatively easy to control a work area to a stated number such as a permissible exposure limit or an action level, but controlling 'regardless of level of exposure' for a trace contaminant in dust is impractical'' (Document ID 1657, pp. 1–2).

Recognizing the difficulties described by NIOSH and NNS, the Agency decided not to require employers in construction and shipyards to establish and maintain beryllium work areas. However, OSHA has modified provisions associated with beryllium work areas in paragraph (f)(1) and paragraph (h) of the proposed standard so as to provide employees in all sectors with largely equivalent protective measures. For example, employers in all sectors are required to create, implement, and maintain a written exposure control plan that lists jobs and operations where beryllium exposure may occur, and that documents procedures for limiting cross-contamination and migration of beryllium (see Summary and Explanation of paragraph (f)(1)). Similarly, whereas employers in general industry are required under paragraph (f)(2) to take certain steps to reduce airborne beryllium in beryllium work areas where exposures meet or exceed the action level, employers in construction and shipyards have a nearly identical requirement to take steps to reduce exposures where exposures meet or exceed the action level. Thus, the only provisions related to beryllium work areas that apply in general industry but not in construction and shipyards are those OSHA is persuaded add protective value in general industry but would be unworkable or ineffective in the construction and shipyard contexts of abrasive blasting and outdoor operations, *e.g.,* certain housekeeping provisions related to surface contamination (see Summary and Explanation, paragraph (j), Housekeeping, for further discussion).

Regulated Areas. Paragraph (e)(1)(ii) of the proposed standard required employers to establish and maintain 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. OSHA explained that the requirement to establish and maintain regulated areas would apply if any exposure monitoring 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 would be required to designate 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. In the proposed standard, work in regulated areas triggered additional requirements for medical surveillance (see Summary and Explanation for paragraph (k)), PPE (see Summary and Explanation for paragraph (h)), and hazard communication (see Summary and Explanation for paragraph (m)). The construction and shipyard sectors were not included in the proposed standard, but were included in Regulatory Alternative #2a in the NPRM, which would extend all provisions of the proposed standard for general industry to construction and shipyards, including provisions pertaining to regulated areas. OSHA requested comments on this proposed regulatory alternative.

OSHA received relatively few comments on the proposed provisions for regulated areas, which were largely similar to the regulated areas provisions included in previous substance-specific standards. In general, commenters did not oppose the concept of regulated areas. Clive LeGresly with AWE noted that their organization establishes ''Controlled'' beryllium workspaces that align with the final standards' regulated areas (Document ID 1615, p. 4). However, some commenters suggested modifications to OSHA's proposed definition of regulated areas. In their comments, the Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) and National Jewish Health (NJH) both supported the concept of regulated areas but recommended they be established when exposures are at or above the action level (Document ID 1655, p. 7; 1664, p. 3). Finally, the Department of Defense (DoD) argued that having both beryllium work areas and regulated areas was confusing and burdensome, and suggested that the final standard should include only areas with airborne beryllium above the TWA PEL or STEL, which they described as better defined and more enforceable than the provisions for beryllium work areas in the proposed standard (Document ID 1684, Attachment 2, p. 2). After carefully considering the record on regulated areas, OSHA has decided to modify some of the provisions associated with regulated areas to address commenters' concerns where appropriate, but to retain paragraph (e)(1)(ii) as proposed in the final standard for general industry. Thus, final paragraph (e)(1)(ii) in general industry requires employers to 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. A detailed discussion of OSHA's decisions and reasoning follows.

As applied to general industry, OSHA has not accepted the DoD's suggestion that only work areas where exposures exceed the TWA PEL or STEL need to be demarcated as limited-access or regulated areas. Because employees who are exposed to airborne beryllium below the TWA PEL and STEL and who have dermal contact with beryllium are at risk of adverse health effects, OSHA finds that it is appropriate to establish and demarcate beryllium work areas wherever work processes create such exposures and are primarily located in indoor settings, as OSHA finds is typical of operations in general industry. As discussed above, the requirement for the establishment and maintenance of beryllium work areas is necessary to alert workers to the presence of beryllium and to trigger basic exposure prevention methods, such as hygiene facilities and housekeeping. However, it is also appropriate to establish regulated areas with more stringent requirements, such as respiratory protection, limited access, and warning signs, where exposures may exceed the TWA PEL or STEL. OSHA concludes that beryllium work areas and regulated areas serve distinct purposes, and each provides important protections to employees. Therefore, OSHA has decided to retain both beryllium work areas and regulated areas in the final standard for the general industry standard. As explained elsewhere in this section, OSHA finds that requirements to establish and demarcate beryllium work areas are not appropriate to operations in construction and shipyards, and that the objectives of regulated areas are better achieved through the use of a competent person in construction.

OSHA has also carefully considered the recommendation by the BHSC Task Group and NJH to use the action level rather than the TWA PEL or STEL to trigger the provisions of the proposed standard associated with regulated areas, and finds that it has some merit. For example, in the proposed standard, employees who work in regulated areas for more than 30 days in a 12-month period would be eligible for medical surveillance. Because employees exposed to beryllium at levels below the TWA PEL are at significant risk of material impairment of health as a result of their exposure (Section VII, Significance of Risk), OSHA is persuaded that the action level is a more appropriate trigger for the provision of medical surveillance. Eligibility for medical surveillance at the action level is also consistent with previous OSHA standards where significant risk remains at the TWA PEL, such as the recently published respirable crystalline silica standard. In addition, because beryllium sensitization can occur from dermal contact with beryllium regardless of whether airborne exposures are above or below the TWA PEL or STEL, OSHA believes it is appropriate to apply PPE requirements much more broadly than the proposed standard, which relied heavily on work in regulated areas as a trigger for PPE.

However, OSHA does not believe that all provisions associated with regulated areas should apply at exposure levels below the TWA PEL and STEL. Employers are required to restrict access to regulated areas, thereby limiting the number of employees potentially exposed to beryllium at levels above the TWA PEL or STEL and limiting others' risk of serious health effects associated with such exposure. OSHA finds that lowering the exposure trigger for regulated areas could lead to the creation of large restricted areas, and therefore large numbers of employees with access to restricted areas where exposures may range anywhere between the action level and high above the final PEL. And, as discussed previously, establishing and demarcating regulated areas ensures that workers and other persons are aware of the potential presence of airborne beryllium at levels above the TWA PEL or STEL and ensures that all persons entering regulated areas are made aware of the dangers of exposure to beryllium at these levels. Moreover, in general industry, the requirement to demarcate beryllium work areas triggered by any level of beryllium exposure resulting from a process or operation, provides awareness for the potential hazard of beryllium contact or exposure at levels below the action level. For these reasons, OSHA believes that it is appropriate to retain the proposed standard's definition of regulated areas and related provisions for restricted access and demarcation.

In addition, OSHA finds that it is inappropriate to extend mandatory provision and use of respirators (triggered by work in regulated areas in the proposed standard) to all workers whose exposures meet or exceed the action level. As discussed elsewhere in this Summary and Explanation, OSHA's longstanding policy is to avoid issuing standards that result in widespread use of respiratory protection due to issues of health, safety, and effectiveness that can occur with employees' regular use of respirators (see Summary and Explanation for paragraph (f), Methods of Compliance, and paragraph (g), Respiratory Protection).

For the reasons described above, OSHA has decided to adopt more protective triggers for some of the provisions associated with regulated areas in the proposed standard. OSHA has expanded eligibility for medical surveillance to employees who work for at least 30 days in a 12-month period in operations where airborne beryllium exposures meet or exceed the action level (previously, employees who work for at least 30 days in a 12-month period in a regulated area; see Summary and Explanation for paragraph (k), Medical Surveillance). OSHA has also expanded PPE requirements to all employees whose work involves dermal contact with beryllium (see Summary and Explanation for paragraph (h), PPE). These expanded PPE requirements in recognition of the dermal risk posed by beryllium also are responsive to a request from Public Citizen that beryllium work areas and regulated areas be broadly defined in order to ensure ''appropriate protections against dermal exposure to beryllium, and dermal sensitization'' (Document ID 1756, Tr. 176–77).

As discussed in the Summary and Explanation of paragraph (a), Scope and application, OSHA received comments from a variety of stakeholders on Regulatory Alternative #2a presented in the NPRM, which extends all provisions of the proposed standard to the construction and shipyard sectors. Following careful consideration of these comments, OSHA determined that it is appropriate to extend all provisions of the proposed standard to cover facilities in construction and shipyards, except where some provisions of the general industry standard may be inappropriate due to the nature of workplaces or work processes in construction or shipyards. OSHA has additionally reviewed comments received on the topic of regulated areas in construction and shipyards, to determine whether it is appropriate to modify the requirements for regulated areas in these sectors. Based on its review, as well as OSHA's previous experience regulating chemical exposures in these sectors, the Agency has concluded that provisions for regulated areas (as opposed to the larger beryllium work areas) are appropriate to include in the final standard for shipyards. In construction, OSHA does not find regulated area requirements to be appropriate but has decided instead to require employers to meet the goals of the regulated areas provisions using a competent person approach, which the Agency believes will be more effective in construction work settings. OSHA's review of the record and reasons for these decisions follow.

In the NPRM, OSHA requested comment on whether the provisions of the abrasive blasting substandard in the Ventilation standard for construction (29 CFR 1926.57, paragraph (f)) and the standard for Mechanical paint removers in shipyards (29 CFR 1915.34(c)) provide adequate protection to employees exposed to beryllium from abrasive blasting operations in these sectors. As discussed previously in the Summary and Explanation for paragraph (a), Scope and application, commenters argued persuasively that these abrasive blasting standards do not adequately protect beryllium-exposed construction and shipyard employees, and that OSHA should extend all provisions of the general industry standard to these sectors (*e.g.,* Document ID 1679; 1963). However, the Abrasive Blasting Manufacturers Alliance (ABMA) stated that the proposed provisions for regulated areas in general industry would be inconsistent with regulations for abrasive blasting in shipyards, which do not always require such designated areas (Document ID 1673, p. 22). A similar concern could apply to requirements for regulated areas in construction.

In OSHA's view, the provisions of the abrasive blasting standards in shipyards and in construction provide important baseline requirements appropriate to any situation where abrasive blasting is conducted in these sectors. However, the abrasive blasting standards are not intended to provide comprehensive requirements for all abrasive blasting operations, because some operations may involve hazards unique to the particular process or blast media in use.

Operations that use beryllium-containing blast media present unique risks of beryllium sensitization and CBD to exposed employees (see Section V, Health Effects), and thus require protective measures beyond those of the abrasive blasting standards. As discussed above, regulated areas and related provisions include requirements that are key to protecting employees from the effects of beryllium exposure, such as restricted access, respiratory protection, and warning signs. OSHA concludes that provisions similar to the requirements for regulated areas in the final standard for general industry will provide shipyard employees necessary protection complementing that found in the shipyard mechanical paint remover standard, and is not in conflict with the provisions or intent of that standard.

OSHA has similarly concluded that the beryllium standard should apply to construction because it will better protect employees exposed to beryllium while abrasive blasting than application of the Ventilation standard alone. However, comments in the record and OSHA's experience regulating chemical exposures in construction indicate that the establishment of regulated areas is not the most effective way to ensure that construction employees receive the protections associated with regulated areas in the general industry standard. This decision is chiefly based on the Agency's recognition that conditions at construction worksites present challenges to establishing regulated areas due to the varied and changing nature of construction work. Some of these challenges were noted in the preamble to the recent respirable crystalline silica standard (81 FR 16285) and also apply here. For example, construction tasks, and specifically abrasive blasting, are commonly performed outdoors. Exposure-generating tasks could be short or long in duration and are typically performed at non-fixed workstations or worksites. Moreover, construction tasks may move to different locations during the workday. Such conditions could make it difficult to establish and maintain regulated areas as required by the general industry and shipyard standards.

At the same time, OSHA finds that construction workers, like their counterparts in general industry and shipyards, need to be made aware of those locations in their workplace where airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL. Therefore, OSHA has decided to adopt the method that was recently included in the recent respirable crystalline silica standard for construction, as well as in some prior construction standards. There, in lieu of establishing regulated areas, the Agency included a requirement for a designated competent person to implement procedures in the written exposure control plan to restrict access to work areas, where necessary, to limit exposures to respirable crystalline silica to achieve the primary objectives of a regulated area. OSHA has concluded that a similar approach is appropriate in this rulemaking. The Agency finds that this flexible approach balances the unique conditions of the construction industry with the need to protect construction employees.

In summary, OSHA has decided to include regulated area requirements in the final standards for general industry and shipyards. The requirements to 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, can be found in paragraph (e)(1)(ii) of the standard for general industry and (e)(1) of the standard for shipyards. Other requirements related to regulated areas, *e.g.,* the requirements to identify and limit access to regulated areas, are discussed in more detail below. In addition, OSHA has decided not to include requirements for regulated areas in the final construction standard, but has provided analogous protections for construction employees through the competent person provisions in paragraph (e) of the final construction standard. The competent person requirements are also discussed in detail below.

In addition, NIOSH suggested that since demarcated areas may be difficult to establish and maintain in some construction or maritime settings, OSHA could consider alternative ways to provide the protections associated with such areas to employees in these sectors. For example, respiratory protection could be triggered by exposure to a threshold airborne level, or dermal protections could be triggered based on performance of tasks involving dermal contact with beryllium (Document ID 1755, Tr. 21–22). OSHA has adopted NIOSH's suggestion to tie certain protective measures to employee inhalation exposures or dermal contact rather than using the intermediary step of establishing demarcated areas where such areas are not required in the construction or maritime sectors. For example, as explained below in the discussion of competent person requirements, respiratory protection requirements apply to employees in construction who have or may reasonably be expected to have airborne exposure above the TWA PEL or STEL. In addition, requirements for provision and use of PPE are triggered based on the potential for dermal contact with beryllium in all three standards (see the Summary and Explanation for paragraph (h), Personal protective clothing and equipment). Thus, PPE is available to all employees whose work may involve dermal contact with beryllium, irrespective of whether they work in an industry where demarcated areas are required.

Demarcation of regulated areas. Proposed paragraph (e)(2) included the requirements for the demarcation of beryllium work areas and regulated areas. Under proposed paragraph (e)(2)(i), employers were required 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. OSHA explained that the demarcation must effectively alert workers and other persons that airborne beryllium may be present. Proposed paragraph (e)(2)(ii) required employers to demarcate each regulated area in accordance with the paragraph (m)(2) hazard communication provisions of this standard. OSHA did not further specify requirements for demarcation, proposing instead to offer employers flexibility in determining the best means to demarcate beryllium work areas and regulated areas. The Agency requested comment on each of these proposed provisions, including whether the standard should specify what types of demarcation employers must use or take a more performance-oriented approach. See 80 FR 47786.

OSHA received several comments on demarcation in general industry and maritime settings. First, NIOSH advocated the need for more specification on how to demarcate regulated areas (Document ID 1671, Attachment 1, p. 6). OSHA believes, however, that allowing employers to choose how to best demarcate regulated areas (as well as beryllium work areas) is consistent with its preference for performance-based approaches where, as here, the Agency has determined that employers, based on their knowledge of the specific conditions of their workplace, are in the best position to make such determinations. For example, if an employer knows that exposures in a particular work area might exceed the PEL on one particular day only, that employer might choose a temporary method of demarcation. Conversely, an employer might choose to use a more permanent method of demarcation for a beryllium work area that contains a potentially beryllium-releasing operation that occurs daily. In some workplaces employers might choose to use barricades, in others textured flooring, roped-off areas, ''No entry''/''No access'' signs, or painted boundary lines. OSHA generally approves of each of these methods, provided that the particular method or methods the employer selects are 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 a particular workforce with limited English reading skills.

OSHA has identified several factors that it considers to be appropriate considerations for employers when they are determining how to demarcate beryllium work areas and regulated areas. These factors include the configuration of the beryllium work area or regulated area; whether the beryllium work area or regulated area is permanent; 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 also notes that the use of a performance-oriented approached to the demarcation of regulated areas is consistent with previous health standards, such as respirable crystalline silica (29 CFR 1910.1053) and chromium (VI) (29 CFR 1910.1026).

Moreover, although proposed paragraph (e)(2)(ii) allowed employers to demarcate regulated areas in a variety of ways, it also contained specific requirements for the posting and wording of a warning sign in accordance with proposed paragraph (m)(2). OSHA included this requirement in the proposal because it preliminarily found that employees must recognize when they are entering a regulated area, and understand the hazards associated with the area, as well as the need for respiratory protection. Signs are an effective means of accomplishing these objectives. Therefore, OSHA included a proposed requirement for employers to post all entrances to regulated areas with signs that bear the following legend:

DANGER
BERYLLIUM
BERYLLIUM MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

Ameren, an electric power utility, objected to the proposal's demarcation requirement. Specifically, Ameren stated that ''[c]onfined space areas such as a boiler penthouse during abrasive blasting activities would be hard to demarcate since the entrance to the regulated area is small and would block access to the area for personnel and equipment. It would also be difficult to establish areas for activities such as cleaning fly ash off of plant piping or structural steel.'' Ameren suggested alternate, training-based means of informing employees of beryllium exposures, such as job planning and job safety briefings (Document ID 1675, p. 11). OSHA disagrees that its performance-oriented approach does not accommodate these circumstances. As discussed above, demarcation requirements for beryllium work areas and regulated areas allow employers maximum flexibility in designing forms of demarcation that best fit the nature of their facilities and processes. Forms of demarcation, such as tape, that do not block access to areas and can be applied in areas where fly ash is cleaned are not difficult to design or implement. Furthermore, training to inform employees of the location of beryllium exposures is a valuable complement to, but should not replace, demarcation in the final standards. The reinforcement of training with demarcation is an important protection to ensure that employees, who may work frequently in beryllium work areas and regulated areas, are continually aware of the location of beryllium exposures in their workplace. See summary and Explanation for paragraph (m), discussing employee training requirements. Also, requirements for demarcation ensure that persons other than employees, who may enter the worksite but may not receive training, are adequately informed of the presence of beryllium.

Commenters also opined on the signage requirement in proposed paragraph (e)(2)(ii). Specifically, the ABMA argued that the beryllium specific signs required in the proposed standard for general industry are not appropriate for use in shipyard abrasive blasting, since this operation involves potential exposure to a number of hazardous chemicals (Document ID 1673, p. 22). OSHA disagrees and is maintaining the sign requirement in the final standards (with slightly altered language, noted below). Beryllium specific signs are appropriate and necessary to inform employees and others of the specific health hazards associated with beryllium exposure. Although employees should also be made aware of other hazardous chemicals they may be occupationally exposed to, training and signage regarding these other chemicals must necessarily be addressed elsewhere, and these concerns should not preclude OSHA from requiring appropriate warning signs for beryllium exposure. OSHA notes that in comments from the U.S. House of Representatives Committee on Education and the Workforce, the committee urged OSHA to implement ''demarcation (through postings of warnings) if there is abrasive blasting with beryllium containing materials'' by shipyard workers (Document ID 1672, p. 4).

After carefully reviewing the record, OSHA finds that the proposed approach for the demarcation of beryllium work areas and regulated areas strikes a reasonable balance between the difficulties of establishing and maintaining these areas with the need to alert those exposed of the risks involved, to reduce the number of employees exposed to beryllium, and to protect those employees exposed to high levels of airborne beryllium. In particular, OSHA finds that the general performance-oriented approach in the proposed requirements, when coupled with the specificity of the signage requirements for regulated areas, provides employers with a good balance of direction and flexibility. The final standards do not require employers to establish and demarcate beryllium work areas or regulated areas by permanently segregating and isolating processes generating airborne beryllium. Instead, the standards allow employers to use temporary or flexible methods to demarcate beryllium work areas and regulated areas. In sum, OSHA finds that these flexible, performance-based requirements will accommodate open work spaces, changeable plant layouts, and sporadic or occasional beryllium use without imposing undue costs or burdens. Therefore, OSHA has decided to include paragraphs (e)(2)(i) and (e)(2)(ii), as proposed, in the final standard for general industry and to include regulated areas demarcation requirements in paragraph (e)(2) of the shipyard standard identical to those of paragraph (e)(2)(ii) of the general industry standard. However, OSHA notes that the required legend for the signage has been amended slightly to include the words ''REGULATED AREA,'' as discussed in the Summary and Explanation for paragraph (m), Communication of hazards, in this preamble. (OSHA is not including the proposed demarcation provisions in the final standard for construction because, as discussed above, the construction standard does not require the establishment or maintenance of either beryllium work areas or regulated areas.)

Paragraph (e)(3) of the proposed standard required employers to limit access to regulated areas. Because of the serious health effects of exposure to beryllium and the need for persons entering the regulated area to be properly protected, OSHA proposed that the number of persons allowed to access regulated areas should be limited 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 encompasses persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring under paragraph (d)(7). As explained in the summary and explanation section on paragraph (d) for exposure assessment, 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 respirable crystalline silica (29 CFR 1910.1053), cadmium (29 CFR 1910.1027), and methylene chloride (29 CFR 1910.1052).

The third group 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.

As discussed in the NPRM, limiting access to regulated areas restricts the number of persons potentially exposed to beryllium at levels above the TWA PEL or STEL, and thus reduces the risk of beryllium-related health effects for employees and others who do not need access to regulated areas. As explained previously in the Summary and Explanation for paragraph (a), Scope and application, OSHA has decided to extend all provisions of the general industry standard to construction and shipyards except where the Agency finds that they are not appropriate to construction and shipyard settings. OSHA did not receive comments on this provision in the proposed standard, and did not receive comments or evidence indicating that restricted access areas are not appropriate in construction and shipyards. However, as discussed previously, OSHA has determined that protections associated with regulated areas in general industry will be more effectively accomplished with a competent person provision in construction.

OSHA has therefore decided to retain paragraph (e)(3) as proposed in the final standard for general industry, and to add an identical provision to the shipyard standard and an analogous provision to the construction standard. Thus, final paragraph (e)(3) requires employers in general industry and shipyards 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. And paragraph (e) of the construction standard requires the designation of a competent person, who, among other things, will implement the written exposure control plan under paragraph (f) of this standard. As discussed in more detail below, paragraph (f)(1)(i)(H) of the construction standard requires employers to establish and implement procedures to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors.

Proposed paragraph (e)(4) required 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 the proposed standard. As discussed in the NPRM, provisions for respiratory protection and PPE ensure that those who must enter regulated areas are properly protected, thereby reducing the risk of serious health effects associated with airborne beryllium exposure and dermal contact with beryllium. As explained previously in the Summary and Explanation for paragraph (a), Scope and application, OSHA has decided to extend all provisions of the general industry standard to construction and shipyards except where the Agency finds that they are not appropriate to construction and shipyard settings. OSHA did not receive comments on this provision in the proposed standard for general industry, and did not receive comments or evidence indicating that restricted access areas are not appropriate in construction and shipyards. However, as discussed previously in this section, OSHA has determined that protections associated with regulated areas in general industry will be more effectively accomplished with a competent person provision in construction.

OSHA has therefore decided to retain paragraph (e)(4) as proposed in the final standard for general industry, and to add an identical provision to the shipyard standard and an analogous provision to the construction standard. Thus, final paragraph (e)(4) of the general industry and shipyard standards requires employers to provide and ensure that each employee entering a regulated area uses respiratory protection in accordance with paragraph (g) and personal protective clothing and equipment in accordance with paragraphs (h) of the final standard for general industry. Wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL in construction settings, paragraph (e) of the construction standard requires the employer to designate a competent person to ensure that all employees use respiratory protection and PPE in accordance with paragraphs (g) and (h) of the standard.

Competent Person (Construction). To balance the unique conditions present in the construction industry with the need to protect construction industry employees from high airborne exposures, OSHA has chosen to adopt an approach in the construction standard for restricting access to high-exposure areas similar to that used in the recent respirable crystalline silica standard for construction. This approach requires the employer to designate a competent person or persons, who will, among other things, implement the written exposure control plan, including procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL; ensure that all employees use respiratory protection in accordance with paragraph (g) of this standard; and ensure that all employees use personal protective clothing and equipment in accordance with paragraph (h) of this standard. OSHA finds this approach offers construction employers a flexible means of providing protection to their employees.

The competent person requirement is a well-known and accepted concept in OSHA standards; competent person provisions are included in at least 20 of OSHA's construction standards, including OSHA substance-specific standards for construction, such as lead (29 CFR 1926.62), asbestos (29 CFR 1926.1101), cadmium (29 CFR 1926.1127), and respirable crystalline silica (29 CFR 1926.1153). In addition, OSHA's general safety and health provisions for construction require the employer to initiate and maintain programs for accident prevention, as may be necessary, and such programs require frequent and regular inspections of job sites, materials, and equipment by a designated competent person (29 CFR 1926.20(b)(1) and (2)).

Competent person provisions are also commonly included in American National Standard Institute (ANSI) standards for construction. NIOSH and its state partners also routinely recommend the need for, and role of, designated competent persons in investigation reports conducted under NIOSH's Fatality Assessment and Control Evaluation program. Thus, OSHA finds that the use of a competent person is consistent with current industry practices in that many construction employers are already using a designated competent person.

Moreover, although OSHA did not include a competent person requirement in the proposed rule, stakeholders indicated that such a requirement would be appropriate if the Agency chose to include the construction industry within the scope of this rulemaking. For example, North America's Building Trades Unions (NABTU) testified that beryllium construction work should be done under the supervision of a competent person (Document ID 1756, Tr. 231–232). NABTU added that the most important point of having a competent person designated in the standard is to ensure there is an agent of the employer on site who has the appropriate authority to correct hazards (Document ID 1805, Attachment 1, p. 4).

Based on these comments and the reasons described above, OSHA has decided to include competent person requirements in the final rule for construction, instead of requiring regulated areas. In paragraph (b) of the construction standard, OSHA defines competent person as an individual who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The definition also specifies that the competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the construction standard.

In order to craft an appropriate definition for this term, OSHA considered stakeholder comments, including NABTU's above comments on the need for a competent person in the construction standard, and the definition of competent person in the safety and health regulations for construction (29 CFR 1926.32(f)). Under 29 CFR 1926.32(f), competent person is defined as a person capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees and who is authorized to take prompt corrective measures to eliminate them. OSHA's definition for competent person in the construction standard is consistent with the 1926.32(f) definition with several minor changes. For example, the Agency tailored this definition to beryllium by specifying ''beryllium hazards'' instead of ''unsanitary, hazardous, or dangerous'' conditions. In addition, OSHA replaced the word ''one'' with ''individual,'' which is merely an editorial change. The Agency also removed the phrase ''in the surroundings or working conditions'' and changed it to ''in the workplace'' to make it specific to the workplace. And the Agency removed the phrase ''to eliminate them'' and changed it to ''to eliminate or minimize them'' to denote there may be cases where complete elimination would not be feasible. Finally, OSHA changed ''predictable'' to ''foreseeable'' to make the wording consistent with the scope of this construction standard (paragraph (a)).

OSHA also decided that it was important to detail the necessary characteristics and authority of a competent person in the standard to ensure that he or she is truly competent to carry out the tasks designated under paragraph (e). Thus, under paragraph (b) of the construction standard, the competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the construction standard. However, OSHA has chosen not to specify particular training requirements for competent persons. The Agency finds that it is not practical to specify in the rule the elements and level of training required for a competent person. And the Agency does not find it appropriate to mandate a ''one size fits all'' set of training requirements to establish the competency of competent persons in every conceivable construction setting. Therefore, the training requirement for a competent person is performance-oriented. This approach is consistent with most OSHA construction standards, such as cadmium (29 CFR 1926.1127), lead (29 CFR 1926.62) and respirable crystalline silica (1926.1153), which include a performance-based approach by not specifying training or qualifications required for a competent person.

Like the regulated area provisions in general industry and shipyards, paragraph (e)(1) of the construction standard applies wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. As discussed in more detail above with regard to the establishment and maintenance of regulated areas in general industry and shipyards, OSHA finds that this exposure level trigger is appropriate for provisions such as this one.

Paragraph (e) of the standard for construction further specifies that wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL, the employer shall designate a competent person to: (1) Make frequent and regular inspections of job sites, materials, and equipment; (2) implement the written exposure control plan under paragraph (f) of this standard; (3) ensure that all employees use respiratory protection in accordance with paragraph (g) of this standard; and (4) ensure that all employees use personal protective clothing and equipment in accordance with paragraph (h) of this standard. OSHA finds that these responsibilities, together, offer construction employees similar protection to those afforded to general industry and shipyard employees while offering construction employers more flexibility to suit their workplaces.

Under paragraph (e)(1) of the construction standard, the competent person must make frequent and regular inspections of job sites, materials, and equipment. OSHA included this requirement in order to ensure that the competent person has the necessary information to carry out the rest of his or her duties. For example, the competent person's second responsibility (as discussed below) is to implement the written exposure control plan under paragraph (f) of this standard. Among other things, the written exposure control plan includes procedures for minimizing cross-contamination (paragraph (f)(1)(i)(D)). In order to implement these procedures on a construction worksite, the competent person may need to know about the unique characteristics of the jobsite and the materials and equipment used therein. Similarly, in order to carry out his or her duty to implement the procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, and to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors, as required by paragraph (f)(1)(i)(I), the competent person will equally need to be familiar with the jobsite, materials, and equipment in order to know where high exposures might occur.

Under paragraph (e)(2) of the construction standard, OSHA is requiring that the competent person implement the written exposure control plan because the plan specifies what must be done to consistently identify and control beryllium hazards on a job site. See Summary and Explanation for paragraph (f), Written exposure control plan. In construction, a competent person is needed to ensure that the requirements of the written exposure control plan are being met under variable conditions. The subjects that must be included in the written exposure control plan for construction are consistent with the duties of a competent person in past OSHA standards. Therefore, this requirement should be familiar to construction employers covered by this standard.

In addition, under paragraph (f)(1)(i)(I) the written exposure control plan must contain procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors. By requiring the competent person to implement these procedures, OSHA is offering similar protection to construction employees as given to general industry and shipyard employees through the regulated area provisions in the general industry and shipyard standards.

OSHA is cognizant that the written exposure control plan requirement regarding the exposures generated by other employers or sole proprietors is important in construction because at multi-employer worksites, the actions of one employer may expose employees of other employers to hazards. A competent person can help communicate hazards to other employers. OSHA expects that the employers or their competent persons will work with general contractors at construction sites to avoid high exposures of employees working alongside others by implementing administrative procedures such as scheduling high-exposure tasks when others will not be in the area. However, if this does not occur, the competent person has authority to implement other administrative procedures that would be effective for protecting employees in situations where an employer was not made aware that another employer or sole proprietor would be conducting abrasive blasting operations on the worksite. Upon encountering such situations on a worksite, the competent person is expected to remind employees to stay away from the abrasive blasting site and make sure that employees he or she oversees are positioned at a safe distance from the abrasive blasting activity

In addition to limiting access to high exposure areas, the standard for construction requires the competent person to ensure that employees use respiratory protection and personal protective clothing and equipment while in high exposure areas (paragraph (e)(3)–(4)). This is an important requirement because without demarcated regulated areas, employees would not have signs to remind them of the need to use such protective equipment. It is therefore the competent person's responsibility to provide the necessary warnings.

OSHA is not requiring a competent person for the general industry and shipyard standards. OSHA has determined that in most cases, general industry scenarios are not as variable as those in construction. For example, most work is performed indoors and therefore, not subject to variables such as wind shifts and moving exposure sources that could significantly affect exposures or complicate establishment of regulated areas. Employers covered under the general industry and shipyard standards are more likely to have health and safety professionals on staff who could assist with implementation of the standard. Finally, competent persons have not been included in other OSHA substance-specific standards for general industry. For example, a competent person requirement was included in the construction standard for cadmium because of environmental variability and the presence of multiple employers on the job site, but a competent person requirement was not included in the general industry standard for cadmium (29 CFR 1910.1027; 29 CFR 1926.1127; 57 FR 42101, 42382 (9/14/1992)). A competent person requirement was included in the construction standard for respirable crystalline silica for similar reasons (81 FR 16811). These factors explain and support OSHA's conclusion that there is no regulatory need for including a competent person requirement in the beryllium standards for general industry and shipyards.

(f) Methods of Compliance

Paragraph (f) of the standards establishes methods for reducing employee exposure to beryllium through the use of a written exposure control plan and engineering and work practice controls. Paragraph (f)(1)(i) of each of the standards requires employers to establish, implement, and maintain a written exposure control plan and specifies the information that must be included in the plan. Paragraph (f)(1)(ii) establishes requirements for employers to review their plan(s) at least annually and update it under specified circumstances. Finally, paragraph (f)(1)(iii) requires employers to make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium.

Paragraph (f)(2) of the final standards requires employers to implement engineering and work practice controls to reduce beryllium exposures to employees. Where airborne exposure exceeds the TWA PEL or STEL, the employer must implement engineering and work practice controls to reduce airborne exposure to or below the exceeded exposure limit(s). Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by engineering and work practice controls, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard. In addition, paragraph (f)(2) includes limited requirements for implementation of exposure controls where operations release airborne beryllium exceeding the action level. Finally, paragraph (f)(3) prohibits the employer from rotating employees to different jobs to achieve compliance with the TWA PEL and STEL.

Paragraph (f)(1)(i) of the proposed rule would have required employers to establish, implement, and maintain a written exposure control plan for beryllium work areas, containing an inventory of operations and job titles reasonably expected to have exposure at or above the action level; an inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL; procedures for minimizing cross-contamination, 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; and an inventory of engineering and work practice controls required by paragraph (f)(2) of the proposed standard.

Several commenters offered broad support for the inclusion of paragraph (f)(1)'s provisions in the final rule (*e.g.,* Document ID 1681, Attachment 1, p. 9; 1689, p. 11; 1690, p. 1). For example, United Steelworkers (USW) stated: ''[a] written plan will help to ensure that exposure controls and safety practices are continually followed. This will also provide workers and other stakeholders with information necessary in evaluating the health and safety protections and provisions provided by the employer'' (Document ID 1681, p. 9). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) also supported the inclusion of written exposure control plan requirements (Document ID 1689, p. 11). It argued that ''[r]equiring employers to properly make use of a written plan is an essential tool for continuously controlling exposures and using proper safety practices'' (Document ID 1689, p. 11). The National Council for Occupational Safety and Health (National COSH) agreed, stating that ''[a] comprehensive program to protect workers from these exposures, that includes a requirement for a written beryllium control plan, regular exposure monitoring, medical surveillance, medical removal protection benefits, and training would provide much needed protection for beryllium exposed workers'' (Document ID 1690, p. 1). Written exposure control plan requirements were also included in the draft proposed rule submitted to the Agency by Materion Corporation (Materion) and United Steelworkers (USW) (Document ID 0754, p. 6).

OSHA agrees with the opinions expressed by these commenters. Requiring employers to articulate where exposures occur and how those exposures will be controlled will help to ensure that they have a complete understanding of the controls needed to comply with the rule. Thus, OSHA expects a written exposure control plan will be instrumental in ensuring that employers comprehensively and consistently protect their employees. Consequently, the Agency has decided to include written exposure control plan requirements in paragraph (f)(1) of the final standards.

In the preamble to the proposal, OSHA explained 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 (80 FR 47787). Because skin contact and airborne exposure can occur in any workplace within the scope of the standard, OSHA preliminarily decided to require a written exposure control plan for all employers within the scope of the standard.

OSHA received comments regarding the proposed trigger for written exposure control plan requirements. For example, NGK Metals Corporation (NGK) argued that requiring employers to develop and maintain a written exposure control plan for facilities where exposures are below the action level is burdensome, and recommended that the written plan be required only where exposures exceed the action level (Document ID 1663, p. 2). EEI asserted that a requirement for a written exposure control plan should apply to areas where exposures meet or exceed the action level or PEL, so as to be consistent with other health standards (Document ID 1674, p. 13).

OSHA has re-examined the provisions of (f)(1) in light of these comments and reaffirms its preliminary decision to require all employers within the scope of the standard to establish, implement, and maintain a written exposure control plan. The Agency finds that the requirements that apply where exposures are below the action level (*e.g.,* a list of operations and job titles reasonably expected to involve airborne exposure or dermal contact with beryllium; descriptions of procedures for handling beryllium-contaminated PPE and respirators; and descriptions of procedures for minimizing cross-contamination and migration of beryllium) are important to preventing beryllium sensitization and CBD, and are not overly burdensome. Moreover, many of the requirements in the plan are intended to complement the housekeeping and hygiene requirements that all facilities in the scope of the standard must already meet, and do not create significant burdens for employers beyond documentation of their procedures for meeting the requirements of other paragraphs in the standards, such as (h) Personal protective clothing and equipment, (i) Hygiene areas and practices, and (j) Housekeeping.

Proposed paragraph (f)(1)(i)(A)–(H) set forth the required contents of the written exposure control plan. Under the proposal, the employer's written exposure control plan was required to include: (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 limiting beryllium contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within the beryllium work area; (5) procedures for keeping surfaces in the beryllium work area as 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 used by the employer to comply with paragraph (f)(2) of this standard; and (8) procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

Stakeholders offered comments on the proposed written control plan contents. For example, the Boeing Company suggested that OSHA should revise the proposed provision requiring ''procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium'' to define specific surface contaminant levels (Document ID 1667, p. 4). The apparent advantage of providing a target surface contaminant level is that employers could use surface sampling to determine whether they are in compliance with the standard's requirements for surface cleaning. However, as OSHA explained in the Summary and Explanation for paragraph (j), Housekeeping, the relationship between a precise amount of surface contamination and health risk is unknown. Therefore, OSHA cannot find that a particular level of contamination is safe. Rather, OSHA has determined that keeping surfaces as clean as practicable is appropriate because promptly removing beryllium deposits prevents them from becoming airborne, thus reducing employees' inhalation exposure, and helps to minimize the likelihood of skin contact with beryllium. Moreover, the term ''free as practicable'' is accepted language and has been used in previous standards, such as standards addressing exposure to lead and chromium (VI). Consequently, OSHA has decided to retain the ''free as practicable'' language in the final rule for general industry. (As discussed in more detail below, the final standards for construction and shipyards do not include this requirement.)

After careful consideration of the record, OSHA reaffirms the need for the written exposure control plan to contain each of the provisions included in the proposal. This written record of which operations and job titles are likely to have exposures at certain levels and which housekeeping provisions and engineering and work practice controls the company has selected to control exposures required in paragraph (f) will make it easier for employers to implement monitoring, hygiene practices, housekeeping, engineering and work practice controls, and other measures. The provisions contained in (f)(1)(i)(D), (E), (F), and (H) of the proposed rule will work to minimize the spread of beryllium throughout and outside the workplace and to reduce the likelihood of skin contact and re-entrainment of beryllium particulate.

Therefore, OSHA has decided to retain the proposed contents of the written exposure control plan in the standard for general industry, with the following revisions. First, OSHA has modified the proposed requirement to include an inventory of operations and job titles reasonably expected to have exposure, including by dermal contact. As discussed in detail in the Summary and Explanation for paragraph (h), Personal protective clothing and equipment (PPE), OSHA finds that it is important to protect employees from dermal contact with beryllium. OSHA therefore finds that the written exposure control plan should inform employees and others of jobs and operations where dermal contact with beryllium is reasonably expected, and has added dermal contact with beryllium to paragraph (f)(1)(i)(A) of the final standards. Thus, the final standard for general industry requires the employer to include a list of operations and job titles reasonably expected to involve airborne exposure to beryllium or dermal contact with beryllium in their written exposure control plan(s).

Second, OSHA modified the language of proposed paragraphs (f)(1)(i)(A), (B), (C), and (G) by replacing the term ''inventory'' with the term ''list''. This change in wording does not imply a change in the intent of the provision. Rather, OSHA made this change to clarify the Agency's intent to require employers to simply identify jobs, operations and controls that match the criteria of these provisions, and that employers are not required to provide more extensive description of such jobs and operations. Third, OSHA modified (f)(1)(i)(D) by deleting ''but not limited to'' from the phrase ''including but not limited to preventing the transfer of beryllium'', because the term ''including'' implies that the examples to follow are not intended to be exhaustive. This change in wording does not imply a change in the intent of the provision.

Fourth, OSHA has edited the proposed text, which required an ''inventory'' of operations and job titles reasonably expected to ''have'' exposure; exposure at or above the action level; and exposure above the TWA PEL or STEL. The final text requires a ''list'' of operations and job titles reasonably expected to ''involve'' airborne exposure to or dermal contact with beryllium; airborne exposure at or above the action level; and airborne exposure above the TWA PEL or STEL. This is an editorial change to provide greater clarity to better describe the actual requirement, and does not change the intent of the provision. Fifth, OSHA modified the proposed requirement to inventory engineering and work practice controls required by paragraph (f)(2) of this standard to include respiratory protection. This change ensures that the respiratory protection requirement, which is included in (f)(2)(iv) of the final standards, is treated in the same manner as the engineering and work practices control requirements in (f)(2)(i) and (f)(2)(iii).

Finally, OSHA has included one additional provision in the final rule for general industry that was not contained in the proposal. Specifically, paragraph (f)(1)(i)(H) of the final rule requires employers to include within their written exposure control plan a list of personal protective clothing and equipment required by paragraph (h) of this standard. This provision is added in recognition of the importance of personal protective clothing and equipment in protecting exposed employees, particularly those employees who may have dermal contact with beryllium. With the addition of this new provision, proposed paragraph (f)(1)(i)(H) (regarding procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators) has been redesignated as paragraph (f)(1)(i)(I) of the final rule for general industry.

OSHA has incorporated most provisions of the proposed paragraph (f)(1)(i) into the final standards for construction and shipyards, with certain modifications due to the work processes and worksites particular to these sectors. As explained in the Summary and Explanation for paragraph (j), Housekeeping, OSHA has determined that abrasive blasting operations are the primary source of beryllium exposure in the construction and shipyard sectors and has chosen not to include provisions related to surface cleaning in the final standards for these sectors due to the extreme difficulty of maintaining clean surfaces during blasting operations. OSHA has therefore decided to exclude the provision regarding procedures for keeping surfaces as free as practicable of beryllium (proposed paragraph (f)(1)(i)(E)) from the construction and shipyard standards. And due to the difficulty of controlling contamination during blasting operations, OSHA has decided to include a more performance-oriented provision on cross-contamination in the standards for construction and shipyards than in paragraph (f)(1)(i)(D) of the general industry standard. Employers are still required to establish and implement procedures for minimizing cross-contamination of beryllium in construction and shipyard industries. However, the written exposure control plan provision on cross-contamination simply requires ''procedures for minimizing cross-contamination''; it does not specify ''procedures for minimizing cross-contamination, including preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas'' as in general industry. OSHA has included the proposed provision for minimizing the migration of beryllium in the standards for construction and shipyards, but has removed the reference to beryllium work areas since these are not established in construction and shipyards. The written exposure control plan provision on migration in these sectors requires the plan to include ''procedures for minimizing the migration of beryllium within or to locations outside the workplace.''

Because the requirements pertaining to surfaces contained in final paragraph (f)(1)(i)(E) of the general industry standard do not appear in the construction and shipyard standards, the numbering of the provisions differs from that of the general industry standard. For the construction and shipyard standards, requirements pertaining to the migration of beryllium appear in paragraphs (f)(1)(i)(E); requirements for a list of engineering controls, work practices, and respiratory protection are in paragraphs (f)(1)(i)(F); requirements for a list of personal protective clothing and equipment are in paragraphs (f)(1)(i)(G); and requirements pertaining to removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators, appear in paragraph (f)(1)(i)(H). 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.

OSHA has also included paragraph (f)(1)(i)(I) in the construction standard only, requiring employers in the construction sector to establish, implement and maintain procedures to restrict access where airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL. This addition is related to OSHA's decision, explained in the Summary and Explanation of paragraph (e), not to include a requirement to establish regulated areas in the construction standard, and to achieve the protective benefits associated with regulated areas by other means. In the general industry and shipyard standards, the employer must limit access to regulated areas to persons who are authorized or required to be in a regulated area to perform work duties, observation, or other limited circumstances. OSHA has determined that restricting access to areas where airborne exposures exceed or may reasonably be expected to exceed the TWA PEL or STEL is appropriate to reduce employees' and others' risk of adverse health effects associated with airborne beryllium exposure. OSHA has therefore established alternative methods to ensure that construction employees do not enter such areas unnecessarily. To this end, the final standard for construction includes paragraph (f)(1)(i)(I), which requires employers to establish, implement and maintain procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, in order to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors. Significantly, the construction standard additionally includes paragraph (e), Competent Person, which requires employers to designate a competent person to implement the written exposure control plan. The competent person is therefore responsible for ensuring that the procedures to restrict access are followed in the workplace.

National Jewish Health (NJH) submitted a comment to OSHA regarding the importance of training, labeling, housekeeping measures, restricted entry to beryllium-contaminated areas, and technologies such as sticky mats and boot scrubbers in controlling employees' exposure to beryllium. NJH requested that OSHA emphasize the importance of such measures in paragraph (f) of these standards (Document ID 1664, p. 6). OSHA agrees with NJH that all of these approaches are helpful, and in some cases essential, to reducing employees' exposure. Training and some forms of labeling and access restriction are specifically required in other paragraphs of the standards. Specific tools such as sticky mats and boot scrubbers are not required in the standards, but are approaches employers should consider as part of their control procedures. All of the methods mentioned by NJH are ways to limit migration of beryllium and cross-contamination, and are therefore appropriate for inclusion in an employer's written exposure control plan(s).

The final standards' paragraph (f)(1)(i) differs from the proposal in that it requires a written exposure control plan for each facility, whereas the proposal would have required a written exposure control plan for beryllium work areas within each facility. In addition, OSHA has removed the phrase ''in the beryllium work area'' from provision (f)(1)(i)(E) of the final standard for general industry, so that it now reads: ''Procedures for keeping surfaces as free as practicable of beryllium''. OSHA made these changes because it changed the definition of a ''beryllium work area'' in the proposed standard for general industry. The proposed standard defined a beryllium work area to include any area where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure. As discussed previously in the Summary and Explanation for paragraph (e), the final standard for general industry defines a beryllium work area to include only those areas containing a process or operation that releases beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. Accordingly, OSHA made these changes to the wording of (f)(1)(i) and (f)(1)(i)(E) to maintain the intent of proposed paragraph (f)(1)(i)(A), to require employers to list all jobs and operations throughout their facilities involving beryllium exposure, and paragraph (f)(1)(i)(E) to control dermal contact with beryllium wherever airborne beryllium may settle on surfaces in their facilities. If employers' procedures to prevent migration of beryllium from work areas to other areas of the facility are fully effective (paragraph (f)(1)(i)(F)), further steps to keep surfaces as free as practicable of beryllium will not be necessary. However, if the employer is unable to consistently prevent transfer of beryllium from work areas to other areas of the facility, the employer must develop and implement additional procedures to keep surfaces outside of the beryllium work areas as free as practicable of beryllium.

Paragraph (f)(1)(ii) of the proposed rule would have required the employer to 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. OSHA did not receive any comments on this provision. However, as noted in the proposal, 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 (Document ID 0634; 0473; 0599). OSHA found that this 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 these standards. Thus, after considering the record on this issue, OSHA has decided to retain proposed paragraph (f)(1)(ii) in the final rule, with the modifications discussed below, to ensure that the employer's plan reflects the current conditions in the workplace.

The first modification is that OSHA added a requirement to review and evaluate the effectiveness of each written exposure control plan at least annually. OSHA finds that an annual review is appropriate because workplace conditions can change. In addition, by requiring employers to check the effectiveness of their plans annually, the standards offer employers the opportunity to better protect their employees by reflecting on any lessons learned throughout the previous year. The final annual review requirement is consistent with previous OSHA standards, such as the standards addressing bloodborne pathogens (29 CFR 1910.1030) and respirable crystalline silica (29 CFR 1910.1053).

Second, OSHA changed the proposed language of (f)(1)(ii)(B), which would have required employers to update their written exposure control plans when an employee is confirmed positive for beryllium sensitization, is diagnosed with CBD, or shows signs or symptoms associated with exposure. This change is related to another change from the proposed standard, which would have required notification of employers whenever an employee is confirmed positive for beryllium sensitization. As explained in the Summary and Explanation for paragraph (k), Medical Surveillance, OSHA has modified this provision so that employers are not automatically notified of cases of sensitization or CBD among their employees. However, employers will receive a written medical opinion from the licensed physician that may include a referral for an evaluation at a CBD Diagnostic Center (*see* (k)(6)(iii)) or a recommendation for medical removal from exposure to beryllium (*see* (k)(6)(v)). An employee may also provide the employer with a written medical report indicating a confirmed positive finding or CBD diagnosis. Final paragraph (f)(1)(ii)(B) has been revised from the proposal to reflect the circumstances under the final standards where an employer will be notified that an employee has, or may have, a beryllium-related health effect. This includes when the employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of the standard (*i.e.,* when the employee provides the employer with a written medical report indicating a confirmed positive finding or CBD diagnosis, or the employer receives a written medical opinion recommending removal from exposure to beryllium); when the employer is notified that an employee is referred for evaluation at a CBD Diagnostic Center, or when an employee shows signs and symptoms associated with exposure. Third, OSHA further modified (f)(1)(ii)(B) to clarify the Agency's understanding that signs and symptoms may be related to inhalation or dermal exposure, as discussed in Section V, Health Effects. Final paragraph (f)(1)(ii)(B) therefore refers to signs and symptoms of ''airborne exposure to or dermal contact with beryllium''. Fourth, OSHA modified the wording of (f)(1)(ii) to require the employer to update ''each'' written exposure control plan rather than ''the'' written exposure control plan, since an employer who operates multiple facilities is required to establish, implement and maintain a written exposure control plan for each facility.

Paragraph (f)(1)(ii) of the final standards thus requires the employer to review and evaluate the effectiveness of each written exposure control plan at least annually and update it 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 airborne exposure to beryllium; (B) the employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD Diagnostic Center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or (C) the employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

Paragraph (f)(1)(iii) of the proposed rule would have required the employer 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)). As discussed above and in the NPRM, access to the exposure control plan will enable employees to partner with their employers in keeping the workplace safe. OSHA did not receive comments specific to this provision, and has decided to retain it in the final standard for general industry and include it in the final standards for construction and shipyards.

Proposed paragraph (f)(2) established a hierarchy of controls that employers must use to reduce beryllium exposures. This paragraph required employers to rely on engineering and work practice controls as the primary means to reduce exposures. As a general matter, where airborne exposure exceeded the TWA PEL or STEL, proposed paragraph (f)(2) required employers to implement engineering and work practice controls to reduce airborne exposure to or below the PELs. Wherever the employer demonstrated that it is not feasible to reduce airborne exposure to or below the PELs through the use of engineering and work practice controls, the employer would have been required to implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard. In addition, proposed paragraph (f)(2) included limited requirements for implementation of exposure controls for each operation in a beryllium work area.

OSHA's long-standing hierarchy of controls policy was supported by a number of commenters, including USW; the Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group); AWE; AFL–CIO; 3M; and National Jewish Health (*e.g.,* Document ID 1963, p. 12; 1655, pp. 8, 16; 1618, p. 8 (pdf); 1689, p. 11; 1625, p. 6 (pdf); 1664, p. 6). For example, the BHSC Task Group stated that OSHA's mandate ''to assure safe and healthy workplaces requires it to reinforce fundamental industrial hygiene tenets. Prime among these is application of a hierarchy of controls'' (Document ID 1655, p. 16). Similarly, 3M indicated that it ''agree[d] with OSHA that the hierarchy of controls—effective engineering and work practice controls—should be the primary means to help reduce employee exposures to beryllium and its compounds'' (Document ID 1625, p. 6 (pdf)). 3M added that ''when engineering controls and work practices cannot reduce employee exposure to beryllium to below the PEL, then the employer must protect employees' respiratory health through the use of respirators'' (Document ID 1625, p. 6 (pdf)). NJH added that

> . . . engineering and/or work practice controls are critical in reducing beryllium exposure and we have consulted with clients on this issue. In identifying controls, using the hierarchy of industrial controls to start with elimination or substitution . . . followed by engineering controls and process

controls such as enclosures, local exhaust ventilation, and wet methods . . . is crucial (Document ID 1664, p. 6).

After a careful review of the record, OSHA concludes that requiring primary reliance on engineering and work practice controls is necessary and appropriate 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. The Agency finds 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.

OSHA has identified several key methods of reducing exposures: (1) Substitution; (2) isolation (*e.g.,* enclosures); (3) ventilation; and (4) process controls (*e.g.* wet methods, automation). Substitution refers to the replacement of a toxic material with another material that reduces or eliminates the harmful exposure. When available, substitution can replace a toxic material in the work environment with a non-toxic material, thus eliminating the risk of adverse health effects.

Isolation, *i.e.,* separating workers from the source of the hazard, is another effective engineering control employed to reduce exposures to beryllium. Isolation can be accomplished by either containing the hazard or isolating workers from the source of the hazard. For example, to contain the hazard, an employer might install a physical barrier around the source of exposure to contain a toxic substance within the barrier. Isolating the source of a hazard within an enclosure restricts respirable dust from spreading throughout a workplace and exposing employees who are not directly involved in exposure-generating operations. Or, alternatively, an employer might isolate employees from the hazard source by placing them in a properly ventilated space or at some distance from the source of the beryllium exposure.

Ventilation is another engineering control method used to minimize airborne concentrations of a contaminant by supplying or exhausting air. The primary type of ventilation system used to control beryllium exposure is local exhaust ventilation (LEV). LEV is used to remove an air contaminant by capturing it at or near the source of emission, before the contaminant spreads throughout the workplace. If designed properly, LEV systems efficiently remove contaminants and provide for cleaner and safer work environments.

Work practice controls involve adjustments in the way a task is performed. In many cases, work practice controls complement engineering controls in providing worker protection. For example, periodic inspection and maintenance of process equipment and control equipment such as ventilation systems is an important work practice control. Frequently, equipment which is in disrepair or near failure will not perform normally. Regular inspections can detect abnormal conditions so that timely maintenance can then be performed. If equipment is routinely inspected, maintained, and repaired or replaced before failure is likely, there is less chance that hazardous exposures will occur.

Workers must know the proper way to perform their job tasks in order to minimize their exposure to beryllium and to maximize the effectiveness of control measures. For example, if an exhaust hood is designed to provide local ventilation and a worker performs a task that generates a contaminant away from the exhaust hood, the control measure will be of no use. Workers can be informed of proper operating procedures through information and training. Good supervision further ensures that proper work practices are carried out by workers. By persuading a worker to follow proper procedures, such as positioning the exhaust hood in the correct location to capture the contaminant, a supervisor can do much to minimize unnecessary exposure. Employees' exposures can also be controlled by scheduling operations with the highest exposures at a time when the fewest employees are present.

Under the hierarchy of controls, respirators can be another means of providing employees effective protection from exposure to air contaminants. However, to be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. In many workplaces, these conditions for effective respirator use are difficult to achieve. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides to some or all of the employees. For example, certain types of respirators require the user to be clean shaven to achieve an effective seal where the respirator contacts the employee's skin. Failure to ensure a tight seal due to the presence of facial hair compromises the effectiveness of the respirator.

Respirator effectiveness ultimately relies on employers educating employees on the necessary good work practices and ensuring that employees adopt those practices. In contrast, the effectiveness of engineering controls does not rely so heavily on actions of individual employees. Engineering and work practice controls are capable of reducing or eliminating a hazard from a worksite, while respirators protect only the employees who are wearing them correctly. Furthermore, engineering and work practice controls permit the employer to evaluate their effectiveness directly through air monitoring and other means. It is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. OSHA therefore continues to consider the use of respirators to be the least satisfactory approach to exposure control.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators can impose substantial physiological burdens on employees, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment. Job and workplace factors such as the level of physical work effort, the use of protective clothing, and temperature extremes or high humidity can also impose physiological burdens on employees wearing respirators. These stressors may interact with respirator use to increase the physiological strain experienced by employees.

Certain medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee wearing the respirator at an increased risk of illness, injury, and even death. These medical conditions include cardiovascular and respiratory diseases (*e.g.,* a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic bronchitis, emphysema), and reduced pulmonary function caused by other factors (*e.g.,* smoking or prior exposure to respiratory hazards), neurological or musculoskeletal disorders (*e.g.,* epilepsy, lower back pain), and impaired sensory function (*e.g.,* a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease (*see* 63 FR 1152, 1208–1209 (1/8/98)).

In addition, safety problems created by respirators that limit vision and communication must always be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult, annoying, and fatiguing. In addition, movement of the jaw in speaking can cause leakage, thereby reducing the efficiency of the respirator and decreasing the protection afforded the employee. Skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress to employees and can cause employees to refrain from wearing the respirator, thereby rendering it ineffective.

These potential burdens placed on employees by the use of respirators were acknowledged in OSHA's revision of its respiratory protection standard, and are the basis for the requirement (29 CFR 1910.134(e)) that employers provide a medical evaluation to determine the employee's ability to wear a respirator before the employee is fit tested or required to use a respirator in the workplace (*see* 63 FR at 1152). Although experience in industry shows that most healthy employees do not have physiological problems wearing properly chosen and fitted respirators, nonetheless common health problems can cause difficulty in breathing while an employee is wearing a respirator.

For these reasons, all OSHA substance-specific health standards have recognized and required employers to observe the hierarchy of controls, favoring engineering and work practice controls over respirators. And the Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see* Section II, Pertinent Legal Authority for further discussion of these cases).

Therefore, OSHA has decided to require the use of the long-established hierarchy of controls in this standard. Because engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace, while respirators protect only the employees who are wearing them and depend on the selection and maintenance of the respirator and the actions of employees, OSHA holds to the view that engineering and work practice controls offer more reliable and consistent protection to a greater number of employees, and are therefore preferable to respiratory protection. Thus, the Agency continues to conclude that engineering and work practice controls provide a more protective first line of defense than respirators and must be used first when feasible.

The provisions related to engineering and work practice controls begin in paragraph (f)(2)(i). Paragraph (f)(2)(i)(A) of the proposed rule stated that, for each operation in a beryllium work area (*i.e.,* any work area involving airborne beryllium exposure), 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. Under proposed paragraph (f)(2)(i)(B), an employer would be 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.

Because OSHA recognized that these proposed provisions are not typical for OSHA standards, which usually require engineering controls only where exposures exceed the PEL(s), the Agency asked for comments on the potential benefits of including such provisions in the beryllium standard, the potential costs and burdens associated with them, and whether OSHA should include these provisions in the final standard (80 FR 47789). In addition, the Agency examined and asked for comment on Regulatory Alternative #6, which would exclude the provisions of proposed paragraph (f)(2)(i) from the final standard.

Comments on these provisions focused mainly on the trigger for proposed paragraph (f)(2)(i) or the action level exemption in proposed paragraph (f)(2)(i)(B)(*2*) and fell into one of two categories. The first group of stakeholders argued that the engineering and work practice controls requirement in proposed paragraph (f)(2)(i) was too broad. Specifically, they objected to the inclusion of a requirement for controls where exposures do not exceed the TWA PEL or STEL. For example, NGK argued that ''this provision essentially halves the PEL by requiring engineering controls above the action level'' (Document ID 1663, p. 2). NGK asserted that engineering controls should only be required where exposures exceed the TWA PEL or STEL, concluding that the ''mandatory use of certain engineering controls'' should be removed (Document ID 1663, p. 4). Similarly, Ameren disagreed with the proposed requirement to use at least one engineering control in areas where, it stated, there may be only minimal exposures and thus no benefit to be gained from installing additional controls (Document ID 1675, p. 5).

The second set of commenters argued that the engineering and work practice controls requirement in proposed paragraph (f)(2)(i) was too narrow. These commenters objected to the exemption in proposed paragraph (f)(2)(i)(B)(2), which exempted employers from using one of the controls listed in (f)(2)(i) to the extent that the employer could 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. USW commented that the only legitimate reasons not to require engineering controls below the action level are if such a requirement is technologically or economically infeasible (Document ID 1681, p. 10). The AFL–CIO and National COSH similarly recommended that the final standard require engineering and work practice controls wherever airborne beryllium is present (Document ID 1689, p. 11; 1690, p. 3). The AFL–CIO based their recommendation on the capacity of beryllium at very low concentrations to cause beryllium sensitization and its carcinogenicity (Document ID 1689, p. 12).

OSHA has carefully reviewed the opinions and arguments of these commenters, and has concluded that the requirement to implement at least one form of exposure control on beryllium-releasing processes will serve to reduce the significant risk of both CBD and lung cancer remaining at the TWA PEL (*see* Section VII, Significance of Risk), and will also reduce the likelihood of exposures exceeding the PEL in the absence of any engineering or work practice control. OSHA therefore disagrees with Ameren's argument that the requirements of (f)(2)(i) will not benefit workers, and with NGK's position that engineering controls should not be required below the TWA

PEL and STEL. OSHA also disagrees with NGK's characterization of the list of controls provided in (f)(2)(i) as a ''mandatory use of certain engineering controls'' (Document ID 1663, p. 4). Rather, the list includes a broad range of possible approaches to eliminate, capture or control beryllium emissions at the source so as to reduce employees' exposure to airborne beryllium, and provides employers great flexibility in selection of at least one such approach where required by the standards.

However, while the Agency upholds the importance of requiring at least one engineering or work practice control where operations release beryllium, it disagrees with comments that such controls should be required wherever there is airborne beryllium at any level. OSHA recognizes that a significant risk of developing beryllium-related adverse health effects remains at the action level. But the Agency finds that an exemption from the requirement to implement at least one of the controls listed in proposed paragraph (f)(2)(i)(A) when exposures are demonstrably below the action level strikes a reasonable balance between providing additional protection for employees who are at risk and the burdens associated with implementing controls that may provide little or no benefit (*i.e.,* where airborne exposures are minimal). The action level serves as a reasonable and administratively convenient benchmark for a number of provisions in the standards (*e.g.,* periodic exposure monitoring, medical surveillance); OSHA finds that the action level serves a comparable purpose with regard to the requirement to implement at least one of the controls listed in proposed paragraph (f)(2)(i)(A) as well.

Moreover, as discussed in the NPRM, the inclusion of the engineering and work practice control provision in proposed paragraph (f)(2)(i)(A) addresses a concern regarding the proposed PEL. OSHA expects that day-to-day changes in workplace conditions might 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. Substitution or controls such as those outlined in proposed paragraph (f)(2)(i)(A) provide the most reliable means to control variability in exposure levels. And, as noted above, they have the added benefit of further reducing beryllium exposures to employees where such means are feasible, and so reducing the significant risk of beryllium-related adverse health effects associated with airborne exposures at the TWA PEL and the action level (*see* Section VII, Significance of Risk). In addition, OSHA finds that the exemption in proposed paragraph (f)(2)(i)(B)(*2*) will reduce the cost burden on 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. OSHA notes that 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. Therefore, OSHA has retained the proposed provisions of paragraph (f)(2)(i) and the proposed exemptions. The Agency also revised the enumeration of the paragraphs for clarity in the final standards.

OSHA has made a number of clarifying changes to the language of proposed paragraph (f)(2)(i), none of which is meant to change the meaning of the proposed language. First, OSHA revised the proposed language of (f)(2)(i)(A) (paragraph (f)(2)(i) in the final standards) by specifying that this provision applies to each operation in a beryllium work area ''that releases airborne beryllium.'' The proposed language could have been interpreted to require controls on operations that do not release airborne beryllium, if such operations happened to be performed in a beryllium work area; it was not OSHA's intent to require employers to apply controls to any operations that do not release beryllium. Second, OSHA added the term ''airborne'' preceding ''exposure'' in proposed (f)(2)(i)(A) and (f)(2)(i)(B)(*2*) (paragraphs (f)(2)(i) and (f)(2)(ii)(B) in the final standards) to clarify the type of exposure addressed by these provisions. Third, OSHA removed the phrase ''engineering and work practice controls'' preceding the list of controls provided in proposed paragraph (f)(2)(i)(A) (paragraph (f)(2)(i) in the final standards) for brevity. Fourth, OSHA modified the language of proposed paragraph (f)(2)(i)(A) (paragraph (f)(2)(i) in the final standards) to require employers to ''reduce'', rather than ''minimize'' airborne exposure because ''reduce'' is more consistent with the requirement; employers are not required to implement more than one such control unless exposures exceed the TWA PEL or STEL. 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) (*see* Appendix A).

The fifth and sixth clarifying changes to proposed paragraph (f)(2)(i) address the types of control measures that are acceptable for complying with the provision. The Southern Company suggested that isolation/containment should be considered for inclusion in the listed controls in proposed paragraph (f)(2)(i)(A) (Document ID 1668, p. 5). OSHA agrees that isolation is an appropriate method of exposure control, and proposed paragraph (f)(2)(i)(A)(*2*) listed ''ventilated partial or full enclosures'', which are forms of isolation. Paragraph (f)(2)(i)(B) of the final standards indicates ''isolation, such as ventilated partial or full enclosures'' to make clear that alternative forms of isolation are also acceptable. In addition, USW and Materion recommended that proposed paragraph (f)(2)(i)(A)(3), which read ''local exhaust ventilation at the points of operation, material handling, or transfer'' be revised to read ''local exhaust ventilation such as at the points of operation, material handling, or transfer'' to broaden the applicability of the provision (Document ID 1680, p. 4). OSHA agrees that the suggested revision more accurately describes acceptable control measures, and has adopted the recommended change in the final standards (now designated as paragraph (f)(2)(i)(C)).

The seventh and final clarifying change to proposed paragraph (f)(2)(i) pertains to the proposed requirement for employers to demonstrate that airborne exposures are below the action level using personal breathing zone samples taken 7 days apart. In response to a comment from Ameren Corporation, which stated that some operations are short in duration and taking samples precisely 7 days apart may not be possible (Document ID 1675, p. 5), OSHA changed the text of the standards to ''at least 7 days apart'', which was the Agency's intention.

With these changes, final paragraph (f)(2)(i) of the general industry standard requires that, for each operation in a beryllium work area that releases airborne beryllium, the employer must ensure that at least one of the following is in place to reduce airborne exposure: (A) Material and/or process substitution; (B) isolation, such as ventilated partial or full enclosures; (C) local exhaust ventilation, such as at the points of operation, material handling, and transfer; or (D) process control, such as wet methods and automation. Final paragraph (f)(2)(ii) allows that an employer is exempt from using the above controls to the extent that: (A) The employer can establish that such controls are not feasible; or (B) the employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

Final paragraph (f)(2)(i) of the construction and shipyard standards also requires employers to ensure that one of the four enumerated types of control is in place to reduce airborne exposure and exempts employers who can establish that such controls are not feasible or demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least seven days apart, for each affected operation. However, the triggers in construction and shipyards differ from that in general industry: whereas the general industry standard requires employers to put one of the controls in place for each operation in a beryllium work area that releases airborne beryllium, the construction and shipyard standards do not require the establishment of beryllium work areas. In lieu of that trigger, the construction and shipyard provision requires the placement of a control where exposures are or can reasonably be expected to be at or above the action level. OSHA selected the action level as a trigger for this requirement because, as indicated above, the Agency finds that an exemption from the requirement to implement at least one of the controls is appropriate when exposures are below the action level.

Congressman Robert C. Scott, Ranking Member of the House Committee on Education and the Workforce, recommended that the final standards should require abrasive blasting (the primary source of beryllium exposure in construction and maritime) to be conducted within containments whenever feasible (Document ID 1672, p. 4). OSHA agrees that containment is an effective approach to limit exposures outside of the blasting operation, and is protective of workers in nearby areas or performing ancillary activities. However, because abrasive blasting is performed in a wide variety of occupational settings and alternative methods of exposure control (for example, use of wet methods) may be effective in some settings, OSHA does not require the use of containment whenever feasible in blasting operations. Rather, paragraph (f)(2) is intended to provide employers flexibility to determine an appropriate approach to maintain airborne exposures below the TWA PEL and STEL and, in accordance with (f)(2)(i), reduce airborne exposures that exceed the action level.

If exposures exceed the TWA PEL or STEL after the employer has implemented the control(s) required by paragraph (f)(2)(i), paragraph (f)(2)(iii) requires the employer 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 exhaust ventilation system to more effectively capture airborne beryllium at the source. The employer must use engineering and work practice controls, to the extent that such controls are feasible, to achieve the PELs.

Whenever the employer demonstrates that it is not feasible to reduce exposures to or below the PELs using the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii), however, paragraph (f)(2)(iv) requires the employer to 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. As indicated previously, OSHA's long-standing hierarchy of controls policy was supported by a number of commenters (*e.g.,* Document ID 1963, p. 12; 1655, pp. 8, 16; 1618, p. 8; 1689, p. 11; 1625, p. 6; 1664, p. 6). Paragraphs (f)(2)(iii) and (f)(2)(iv) in the final standards are substantively consistent with the proposal, with minor changes to clarify that the provisions address only airborne exposures, and that paragraph (f)(2)(iii) applies to both the TWA PEL and STEL.

Finally, paragraph (f)(3) of the proposed rule would have prohibited the employer from rotating workers to different jobs to achieve compliance with the PELs. As explained in the NPRM, worker rotation can potentially reduce exposures to individual employees, but increases the number of employees exposed. Because OSHA has determined 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 was considered prudent to limit the number of workers exposed at any concentration by prohibiting employee rotation.

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 PEL (*e.g.,* by exposing twice as many workers to beryllium for half the amount of time). It is not intended to bar the use of worker rotation 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 is included in the standards for 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), and cadmium (29 CFR 1910.1027 and 29 CFR 1926.1127), and methylenedianiline (29 CFR 1910.1050 and 29 CFR 1926.60). OSHA did not receive any objections to or comments on this provision and includes it in all three of the final standards to limit the number of employees at risk.

(g) Respiratory Protection

Paragraph (g) of the standard establishes the requirements for the use of respiratory protection. Specifically, this paragraph requires that employers provide respiratory protection at no cost to the employee and ensure that employees utilize such protection during the situations listed in paragraph (g)(1). As detailed in paragraph (g)(2), the selection and use of required respiratory protection must comply with OSHA's Respiratory Protection standard (29 CFR 1910.134). In addition, paragraph (g)(3) requires employers to provide employees entitled to respiratory protection with a powered air-purifying respirator (PAPR) instead of a negative pressure respirator, if a PAPR is requested by the employee.

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 paragraph (g)(1) unless the employer also ensures that each employee properly wears the respirator when required. Paragraph (g)(1) also requires employers to provide required respirators at no cost to employees. This requirement is consistent with the OSH Act's holding employers principally responsible for complying with OSHA standards, with similar provisions under other OSHA standards, and specifically 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. Paragraph (g)(1)(i) requires respiratory protection during the installation and implementation of feasible engineering and/or work practice controls where airborne exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. The Agency understands 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 or below the TWA PEL and STEL. In these cases, the Agency recognizes that installing appropriate engineering controls and implementing proper work practices may take time, and that exposures may be above the PELs until such work is completed. See paragraph (g)(1)(ii), discussed below. During this time, employers must demonstrate that they are making prompt, good faith efforts to obtain and install appropriate engineering controls and implement effective work practices, and to evaluate their effectiveness for reducing airborne exposure to beryllium to or below the TWA PEL and STEL.

Paragraph (g)(1)(ii) requires the provision and use 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 airborne 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 reducing exposures to or below the TWA PEL and STEL. The installation of necessary engineering controls, covered by paragraph (g)(1)(i), is a particular example of this more general circumstance. For another 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.

Paragraph (g)(1)(iii) requires the provision and use 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 some situations where feasible engineering and work practice controls are insufficient to reduce airborne exposure to beryllium to levels at or below the TWA PEL or STEL (see this preamble at section VIII.D, Technological Feasibility). In such cases, the standard requires that employers implement and maintain engineering and work practice controls to reduce exposure to the lowest levels feasible and supplement those controls by providing respiratory protection (paragraph (f)(2)(iv)). OSHA emphasizes that even where employers are able 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 the use of respirators to achieve the PELs is only a supplement, and not a substitute for, such ''lowest level feasible'' controls.

Paragraph (g)(1)(iv) requires the provision and use of respiratory protection in emergencies. Under the final standards, an emergency is defined as ''any uncontrolled release of airborne beryllium'' (see paragraph (b) of the standards). During emergencies, 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 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 airborne beryllium.

Boeing suggested limiting requirement of respirator use triggered by this definition of emergency, as it would not be practical to provide respirators to and train the large number of employees in the event of a fire or explosion (Document ID 1667, pp. 4–5). OSHA wishes to clarify that paragraph (g)(1)(iv) is not intended to require employers to provide respirators to all employees who may pass through areas where beryllium-releasing processes are housed, in the event of a general evacuation due to an event such as a fire or explosion. Rather, in the event that an uncontrolled release of beryllium occurs (f)(1)(iv) requires employers to provide respirators to employees who work in the vicinity of beryllium-releasing processes and employees who respond to such an emergency, because these employees will be in the immediate vicinity of an uncontrolled release.

Paragraph (g)(1)(v) requires the provision and use of respiratory protection when an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level. As explained in the summary and explanation of paragraph (l), Medical Removal Protection, an employee who is diagnosed with CBD or confirmed positive for beryllium sensitization and who works in a job with airborne exposure at or above the action level is eligible for medical removal protection (MRP). An employee who is eligible for MRP may choose medical removal from jobs with exposure at or above the action level, or may choose to remain in a job with exposure at or above the action level provided that the employee uses respiratory protection in accordance with the provisions of this paragraph (g), Respiratory Protection. This provision was not included in the proposed standard. However, OSHA received comments emphasizing the importance of reducing or eliminating the exposure of sensitized employees. For example, National Jewish Health (NJH) stated that ''removal from exposure is the best form of prevention'' (Document ID 1664, p. 4). The United Steelworkers (USW) commented that workers who are sensitized to beryllium or are in the early stages of chronic beryllium disease can significantly benefit from a reduction in their exposure to beryllium, based on evidence reviewed in Section VIII (Significant Risk) of the NPRM (Document ID 1963, p. 13). OSHA is cognizant that employees who are MRP-eligible (*i.e.,* confirmed positive for beryllium sensitization or diagnosed with CBD) may decide not to take medical removal protection (MRP) or otherwise alert the employer to their condition. Therefore, OSHA included paragraph (g)(1)(v) in the final standards to provide these employees access to respiratory protection if their airborne exposures are expected to be at or above the action level. While not as protective as removal from any beryllium exposure, NJH's comments indicate that such protection has the potential to delay or avoid the onset of CBD in sensitized individuals and to mitigate or retard the effects of CBD in employees who are in the early stages of CBD. Because OSHA has not made a finding of significant risk at exposure levels below the action level, OSHA has chosen not to require provision and use of respirators for employees exposed below the action level, including sensitized employees. However, OSHA does not assume the absence of risk below the action level, especially to this particularly vulnerable population Indeed, it is the Agency's recommendation that employers voluntarily provide such protection to employees who self-identify that they have tested positive for sensitization if they ask for it and will be exposed to beryllium below the action level, or for whom a licensed physician has recommended such protection. OSHA intends to issue additional guidance regarding non-mandatory respiratory protection for this group of at-risk employees along with other compliance guidance in connection with these standards.

OSHA received no comments objecting to paragraph (g)(1). Therefore, except for minor edits for clarity explained in the introduction to this section, it is unchanged from the proposal.

Whenever respirators are used to comply with the requirements of this 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 employees. 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 for tight-fitting respirators;
• Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
• Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise 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 OSHA's policy to avoid duplication and to establish regulatory consistency, paragraph (g)(2) incorporates by reference the requirements of 29 CFR 1910.134 rather than reprinting those requirements in this standard. OSHA notes that the respirator selection provisions in 29 CFR 1910.134 include requirements for Assigned Protection Factors (APFs) and Maximum Use Concentrations (MUCs) that OSHA adopted in 2006 (71 FR 50122 (Aug. 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. In incorporating the Respiratory Protection standard by reference, OSHA intends that any future change to that standard will automatically apply to this standard as well. As appropriate, OSHA will note the intended effect on this standard (and other standards) in either the text or preamble of the amended Respiratory Protection standard, but does not anticipate the need for a conforming amendment to this standard.

Moreover, the situations in which respiratory protection is required under these standards 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 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 paragraph (f) earlier in this section of the preamble).

OSHA received no comments objecting to paragraph (g)(2). OSHA added language to clarify that both the selection and use of respiratory protection must be in accordance with the Respiratory Protection standard. Other than that change and some minor edits for clarity, paragraph (g)(2) is unchanged from the proposal.

Paragraph (g)(3) requires the employer to provide a powered air-purifying respirator (PAPR) instead of a negative pressure respirator at no cost to the employee when an employee entitled to respiratory protection under (g)(1) of these standards requests a PAPR. The employee may select any form of PAPR (half mask, full facepiece, helmet/hood, or loose fitting facepiece), so long as the PAPR is selected and used in compliance with the Respiratory Protection standard (29 CFR 1910.134) and provides adequate protection to the employee in accordance with paragraph (g)(2) of these standards. For example if an employee is using a half mask respirator with an APF of 10 then a loose fitting PAPR with an APF of 25 would be an appropriate alternative. However, if the employee is required to use a full face respirator with an APF of 50 then the appropriate PAPR alternative would be a tight fitting PAPR.

The requirement to provide a PAPR upon request of the employee (paragraph (g)(3)) is similar to provisions in several previous OSHA standards, including inorganic arsenic (CFR 1910.1018), lead (CFR 1910.1025), cotton dust (1910.1043), asbestos (CFR 1910.1001), and cadmium (1910.1027). In promulgating these standards, OSHA cited several reasons why PAPRs can provide employees with better protection than negative pressure respirators, including superior reliability and comfort, reduced interference with work processes, and superior protection, especially for employees who cannot obtain a good face fit with a negative pressure respirator (*e.g.,* 43 FR 19584, 19619; 43 FR 52952, 52993; 51 FR 22612, 22698). Based on these considerations, OSHA required employers to provide PAPRs upon request to facilitate consistent and effective use of respiratory protection by employees when needed, and particularly in situations where respirator use is required for long periods of time (see 43 FR 52952, 52993; 51 FR 22612, 22698).

The PAPR provision was not included in the proposed standard. However, OSHA solicited public comment on the issue of whether employers should be required to provide employees with PAPRs upon request. During the public comment period and public hearing for the beryllium NPRM, several commenters supported a requirement for employers to provide a PAPR upon an employee's request, including the Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) (Document ID 1655, p. 8), a representative of the Department of Defense (Document ID 1684, Attachment 2, p. 4), ORCHSE Strategies (ORCHSE) (Document ID 1691, p. 4), NJH (Document ID 1664, p. 5), Kimberly-Clark Professional (KCP) (Document ID 1676, p. 3), and North America's Building Trades Unions (NABTU) (Document ID 1679, p. 9). Dr. Lisa Maier of the NJH stated, ''The beryllium standard should require employers to provide PAPRs when requested by the employee. We have consulted with clients on respiratory protection for beryllium exposure and found that employees are more likely to comply with respiratory protection requirements when they have an option regarding the type of respirator they wear'' (Document ID 1664, p. 7). Joann Kline of KCP similarly commented that ''[f]it, style, comfort and worker preference are significant factors in the effectiveness of protection . . . Allowing a worker to choose PPE, including PAPRs, makes it much more likely that it will be comfortable and accepted. PAPRs in particular add to worker comfort, especially in hot environments, because of the flow of fresh air on and around the wearer's face'' (Document ID 1676, p. 3).

Likewise, ORCHSE commented that ''[c]omfort is a significant factor in the ability of employees to wear respiratory protection consistently, especially during an entire work shift, and/or under hot or stressful conditions. Employees experiencing discomfort, which is likely with negative-pressure respirators, are more apt to remove or otherwise compromise the effectiveness of their respirators while in the workplace. It is thus prudent for employers to provide the type of respiratory protection employees are more likely to use consistently and correctly'' (Document 1691, p. 4). Chris Trahan of NABTU cited the susceptibility of some employees to beryllium sensitization as a reason to require employers to provide PAPRs to employees upon their request (Document ID 1679, p. 9). As discussed in Section V, some individuals are genetically susceptible to beryllium-induced sensitization and CBD, and may develop these conditions from exposure to beryllium at levels well below the PEL and STEL included in this standard. Genetically susceptible individuals may therefore benefit from the enhanced protection provided by a PAPR, which have APFs ranging from 50 to 1000 depending on type.

OSHA also received comments opposing a requirement for employers to provide PAPRs upon employee request. For example, Julie A. Tremblay of 3M commented that the incorporation of the Respiratory Protection Standard (29 CFR 1910.134) by reference, particularly paragraph (d)(1)(i) and paragraph (e)(6)(ii), adequately addresses issues of appropriate respirator selection (Document ID 1625, Attachment 1, p. 2). *1910.134(d)(1)(i)* directs the employer to select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability. 1910.134(e)(6)(ii) states that if the PLHCP finds a medical condition that may place the employee's health at increased risk if a negative pressure respirator is used, the employer shall provide a PAPR if the PLHCP's medical evaluation finds that the employee can use such a respirator; however, if a subsequent medical evaluation finds that the employee is medically able to use a negative pressure respirator, then the employer is no longer required to provide a PAPR. OSHA received a similar comment from Charlie Shaw of Southern Company (Document ID 1668, p. 5). Two other commenters, William Orr of Ameren Corporation (Ameren) and Daniel Shipp of the International Safety Equipment Association (ISEA), stated that respiratory protection selection should be based primarily on the required APF given the exposure concentration of beryllium (Document ID 1675, p. 12; 1682, p. 1). However, Mr. Orr also commented that workers handling beryllium-containing materials should have access to loose fitting respirators for added dermal protection so long as the respirator's APF is appropriate to the work performed (Document ID 1675, p. 12). Mr. Orr also argued that a PAPR option is not necessary in the beryllium context: ''A PAPR should only be required if the exposure level dictates that the protection of a PAPR is necessary. The level of protection in the asbestos standard (CFR 1910.1001) is applicable to protection from airborne fibers with the unique characteristics of asbestos. The level of protection for beryllium should closer resemble particulate metal protection such as seen in the standards for metals such as lead or hexavalent chromium'' (Document ID 1675, p. 12). (As discussed above, the Agency notes that the OSHA lead standard (CFR 1910.1025) does include a PAPR requirement, as does the standard for cadmium (1910.1027), also a metal).

Finally, OSHA received a comment from USW (Document ID 1681) recommending that OSHA limit the type of PAPR provided under (g)(3) to types with close-fitting facepieces. USW stated that ''[t]he types with close-fitting face pieces can be quite effective, but it is easy to over breathe other types, especially the loose-fitting helmets'' (Document ID 1681, p. 22).

OSHA has carefully considered all comments received on the issue of requiring employers to provide employees with PAPRs upon request, and agrees with Dr. Maier of NJH, Ms. Trahan of NABTU, and other commenters who have argued that providing employees a choice in selection of respiratory protection will improve the effectiveness of respiratory protection in reducing risk of sensitization and disease from occupational beryllium exposure. While the provisions of the Respiratory Protection standard provide important baseline requirements appropriate to all situations where respiratory protection is required, as discussed above, OSHA recognizes that provisions beyond those of the Respiratory Protection standard are appropriate in some circumstances to ensure that required respiratory protection is used on a consistent basis and as effectively as possible. As discussed in section V, Health Effects and section VI, Risk Assessment of this preamble, beryllium sensitization and CBD can result from small, short-term beryllium exposure in some individuals. Accordingly, consistent and effective respirator usage has played an important role in minimizing risk among workers in occupational settings such as beryllium processing, where it has proven difficult to reduce airborne exposures below 0.2 μg/m³ using engineering controls. Based on this evidence, OSHA concludes that provision of PAPRs at the employee's request will provide employees necessary protection beyond that found in provisions of the Respiratory Protection standard, where provision of a PAPR for reasons of fit, comfort and reliability is at the employer's discretion. Contrary to the comments of Mr. Orr and Mr. Shipp cited above, the evidence that beryllium sensitization can result from short-term, low-level airborne beryllium exposure supports the provision of PAPRs upon request rather than relying on APF alone. Finally, while OSHA agrees with the USW that PAPRs with close-fitting facepieces can be more effective than loose-fitting helmets, the Agency recognizes that loose-fitting helmets may be required in certain work conditions or due to difficulty achieving proper fit for some workers. Therefore, the standards allow for selection of any type of PAPR, but require that the PAPR selected provide adequate protection to the employee in accordance with the Respiratory Protection standard.

(h) Personal Protective Clothing and Equipment

Paragraph (h) of the standards 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 and where there is reasonable expectation of dermal contact with beryllium. Paragraph (h) also contains provisions for the safe removal, storage, cleaning, and replacement of the PPE required by the standards. To protect employees from adverse health effects, these PPE requirements are intended to prevent dermal exposure to beryllium, and prevent the accumulation of airborne beryllium on clothing, shoes, and equipment, which can result in additional inhalation exposure. The requirements also protect employees in other work areas, as well as employees and other individuals outside the workplace, from exposures that could occur if contaminated clothing were to transfer beryllium to those areas. The standards require 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 these standards and OSHA'S Personal Protective Equipment standards (29 CFR part 1910 Subpart I, 29 CFR part 1926 Subpart E, and 29 CFR part 1915 Subpart I). PPE, as used in the description of paragraph (h), refers to both clothing and equipment used to protect an employee from either airborne exposure to or dermal contact with beryllium. The requirements in paragraph (h) are the same in general industry, construction, and shipyards, except for the references to OSHA's Personal Protective and Life Saving Equipment standard for construction (29 CFR part 1926 Subpart E) in the construction standard and OSHA's Personal Protective Equipment standard for shipyards (29 CFR part 1915 Subpart I) in the shipyard standard. 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 (29 U.S.C. 655(b)(7)). The requirements for PPE are based upon widely accepted principles and conventional practices of industrial hygiene, and are similar to the PPE requirements in other OSHA health standards, such as chromium (VI) (29 CFR 1910.1026), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), and methylenedianiline (MDA; 29 CFR 1910.1050).

The final provisions in paragraph (h) are the same as the proposed provisions, with several exceptions. First, in the final standards OSHA has used the term ''contact'' instead of ''exposure'' where the standards refer to the skin, so as to distinguish clearly between exposure via the skin (dermal route) and the inhalation route of exposure in the regulatory text. Second, OSHA has deleted the proposed provision in paragraph (h)(1)(ii) requiring PPE where employees' skin may become ''visibly contaminated'' with beryllium and instead will require use of PPE whenever there is a reasonable expectation of dermal contact with beryllium. Third, the final standards' requirements for provision and use of PPE apply where employees may reasonably be expected to have dermal contact with beryllium regardless of whether the beryllium is in a soluble or poorly soluble (sometimes called 'insoluble') form, instead of just soluble beryllium compounds as in proposed paragraph (h)(1)(iii). Fourth, paragraph (h)(2)(iii) now requires that storage facilities for PPE prevent cross contamination. Finally, OSHA has made a few minor changes to clarify or streamline the regulatory text. The comments and OSHA's reasoning leading to these changes are discussed below.

Paragraph (h)(1)(i) requires the provision and use of PPE for employees exposed to any form of airborne beryllium above the TWA PEL or STEL, or where exposure can reasonably be expected to exceed 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. The term ''reasonably be expected'' is intended to convey OSHA's intent that the requirement for provision and use of PPE is defined by an employee's potential exposure, not by any particular individual's actual exposure. For example, if one employee's exposure assessment results indicate that the employee's exposure is above the PEL, it would be reasonable to expect that another employee doing a similar task would have exposures above the PEL and thus would require PPE.

Paragraph (h)(1)(ii) requires the provision and use of PPE where employees are reasonably expected to have dermal contact with beryllium. This requirement applies to beryllium-containing dust, liquid, abrasive blasting media, and other beryllium-containing materials that can penetrate the skin, regardless of the level of airborne exposure. It is not intended to apply to dermal contact with solid objects (for example, tools made of beryllium alloy) unless the surface of such objects is contaminated with beryllium in a form that can penetrate the skin. Dermal contact with beryllium can result in absorption of beryllium through the skin and induce sensitization, a necessary precursor to CBD, as discussed further in Health Effects, section V.A.2.

As mentioned above, the requirements of paragraph (h)(1) of the final standards differ from those of the proposed standard. Paragraph (h)(1) of the proposed standard required employers to provide employees with 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' skin is reasonably expected to be exposed to soluble beryllium compounds. In the NPRM, OSHA discussed concerns with the proposed requirements, requested public comment on proposed paragraph (h)(1), and presented Regulatory Alternative 13. Alternative 13, as described by OSHA, would replace the requirement for PPE where there is visible contamination with a requirement for appropriate PPE wherever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. OSHA requested comments on this alternative, including the benefits and drawbacks of a broader PPE requirement and any relevant data or studies the Agency should consider. As discussed below, OSHA adopted Regulatory Alternative 13 in the final standard based on comments received in the public comment period and public hearing and on the scientific evidence in the record.

The proposed requirement to use PPE where clothing or skin may become ''visibly contaminated'' with beryllium was a departure from most OSHA standards, which do not specify that contamination must be visible in order for PPE to be required. For example, the standard for chromium (VI) (29 CFR 1910.1026) 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). 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 (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. While OSHA's language regarding PPE requirements varies somewhat from standard to standard, previous standards emphasize the potential for contact with a substance that can cause health effects via dermal exposure, and do not condition the provision and use of PPE on visible contamination with the substance.

Nearly all comments OSHA received on the proposed requirement for employers to provide PPE where work clothing or skin may become ''visibly contaminated'' with beryllium stated that this provision would not be sufficiently protective of beryllium-exposed workers (Document ID 1615, p. 8; 1625, p. 2; 1655, pp. 9–10; 1658, p. 6; 1664, pp. 3–4; 1671, Attachment 1, p. 7; 1676, pp. 2–3; 1677, p. 2; 1679, p. 9; 1685, p. 3; 1688, p. 3; 1689, p. 12; 1691, pp. 4–5). Dr. Paul Schulte of NIOSH stated that ''visibly contaminated'' is not an appropriate trigger for PPE requirements, citing evidence from Day *et al.* (2007, Document ID 1548) that biologically relevant amounts of beryllium can accumulate on the skin without becoming visible, and evidence from Armstrong *et al.* (2014, Document ID 0502) that work surfaces in beryllium manufacturing facilities are typically contaminated with beryllium even where airborne exposures are low (Document ID 1671, Attachment 1, p. 7). Dr. Lisa Maier of NJH commented, ‘‘ ‘[v]isibly contaminated’ is not an appropriate trigger for PPE requirements; as noted by OSHA, ‘small particles may not be visible to the naked eye’ and as such PPE to protect from skin exposure should be worn for all tasks where there is potential for skin contact with beryllium particles’’ (Document ID 1664, pp. 3–4). Dr. Atul Malhotra of the American Thoracic Society (ATS) stated that ‘‘the use of ‘visibly contaminated’ as a trigger for PPE is problematic for multiple reasons . . . visual inspection cannot accurately estimate the amount of beryllium or its chemical state. Use of ‘visibly contaminated’ is also not supported by the literature cited, which demonstrates skin exposure and sensitization in work settings considered clean, with no visible contamination’’ (Document ID 1688, p. 3).

In addition, some comments and testimony indicated that the term ‘‘visibly contaminated’’ is ambiguous and likely to be confusing to employers and others responsible for implementing the PPE requirements of the beryllium standards. According to Mr. Daniel Shipp of the International Safety Equipment Association (ISEA), ‘‘ ‘[v]isible contamination’ is not an appropriate trigger for PPE. This term is too subjective to be useful’’ (Document ID 1682, p. 2).

Based on its evaluation of the evidence in the record, OSHA agrees with the commenters on these points. The Agency has determined that contact with and absorption of even minute amounts of beryllium through the skin may cause beryllium sensitization (see section V, Health Effects, subsection 2, Dermal Exposure) and that a ‘‘visibly contaminated’’ standard could allow for too much dermal exposure and be insufficiently protective of workers. In addition, as discussed in Section VI, Risk Assessment, studies conducted jointly by NIOSH and Materion Corporation (Materion) showed that a comprehensive approach to PPE is key to reducing risk of sensitization even in facilities that implement stringent exposure control and housekeeping programs (*See* Section VI. Risk Assessment).

Materion, whose joint submission with the United Steelworkers union of a proposed standard was the basis for the ‘‘visibly contaminated’’ language, discussed the use of the term in its post hearing comments (Document ID 1808, pp. 4–5). Materion indicated that the typical workplace cannot reasonably be expected to measure skin or surface contamination for the purpose of determining whether PPE use is necessary. Even if this was done, ‘‘such measures are lagging metrics which, by definition, are post potential exposure’’ (Document ID 1808, p. 5). Materion believed that a standard relying on visual cues to check for contamination is easily understood by workers and management and is a useful part of a beryllium worker protection model.

OSHA has considered Materion’s comments supporting use of the terms ‘‘visibly contaminated’’ and ‘‘visibly clean.’’ The Agency finds that the provision in the final standard requiring PPE wherever there is a reasonable expectation of any dermal contact with beryllium more clearly conveys to employers the idea that the provision and use of PPE should be used as a precaution against potential dermal contact. OSHA believes the proposed requirements for PPE where clothing or skin may become ‘‘visibly contaminated’’ may be reasonably interpreted by employers to mean that PPE is only required where work processes release quantities of beryllium sufficient to create deposits visible to the naked eye. If this were the case, employers’ provision of PPE to employees would certainly lag behind potential exposure, if such provision occurs at all. Additionally, National Jewish Health agreed with OSHA that small particles may not be visible to the naked eye (Document ID 1664 p. 4). Therefore, OSHA has determined that the language of the final standards is more easily understood and applied so as to preempt dermal contact with beryllium and therefore prevent adverse health effects caused by dermal contact, such as beryllium sensitization. OSHA also notes that employers are not required to measure skin or surface contamination under the provisions governing the use and handling of PPE. Thus the Agency concludes that the changes made to the proposed rule adequately address Materion’s concerns and more closely express OSHA’s intent.

OSHA also requested comment on proposed paragraph (h)(1)’s requirement for PPE to limit dermal contact with soluble beryllium compounds, and whether employers should also be required to provide PPE to limit dermal contact with poorly soluble (referred to as insoluble in the proposal) forms of beryllium. The solubility of beryllium was a consideration in the PPE requirements of the proposed standard because dermal absorption may occur at a greater rate for soluble beryllium than for poorly soluble beryllium.

Comments submitted on the topic of beryllium solubility and dermal absorption indicate that beryllium in poorly soluble forms, as well as soluble forms, can be absorbed through the skin and cause sensitization (Document ID 1664, p. 3; 1671, p. 7; 1688, p. 3). Dr. Schulte of NIOSH stated that PPE should be required to protect against exposure to poorly soluble compounds as these forms can produce soluble beryllium ions in sweat, and because beryllium in any form can enter the body through minor abrasions, which are commonly found on the skin of industrial employees (Document ID 1671, p. 7). (See further discussion in Section V, Health Effects, subsection 2, Dermal Exposure.)

General comments on whether OSHA should adopt more comprehensive PPE requirements similar to those specified in Regulatory Alternative 13 were, by and large, supportive. The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) (Document ID 1655, pp. 16–17), NJH (Document ID 1664, pp. 3–4, 7), NIOSH (Document ID 1671, p. 7), Kimberly-Clark Professional (KCP) (Document ID 1676, p. 2), the DOE’s National Supplemental Screening Program (NSSP) (Document ID 1677, p. 2), ISEA (Document ID 1682, p. 2), the American College of Occupational and Environmental Medicine (ACOEM) (Document ID 1685, p. 3), ATS (Document ID 1688, p. 3), the AFL–CIO (Document ID 1689, p. 12), and ORCHSE Strategies (ORCHSE) (Document ID 1691, p. 4) all urged OSHA to adopt Regulatory Alternative 13 or similar requirements. The BHSC Task Group commented that its experience at Department of Energy Sites ‘‘strongly suggests that this alternative should be adopted, since the concept of ‘visibly contaminated’ is not sufficient to ensure an absence of such contamination on the skin’’ (Document ID 1655, p. 17). In addition, the BHSC Task Group noted that elimination of dermal contact with beryllium helps reduce the risk of sensitization (Document ID 1655, p. 17).

Similarly, several commenters indicated that a more appropriate trigger for the provision and use of PPE under paragraph (h)(1) would be whenever an employee has the potential for skin contact with beryllium (Document ID 1664, p. 3; 1671, Attachment 1, p. 7; 1676, pp. 2–3). Dr. Lisa Maier from NJH indicated, in her testimony, that ''personal protective equipment (PPE) such as gloves, respirators, protective clothing should be used wherever there is a potential for respiratory or skin exposure'' (Document ID 1720 p. 6). Another commenter ''strongly recommend[ed] a PPE requirement wherever exposure to beryllium, soluble or insoluble, is reasonably expected'' (Kimberly-Clark Professional, Document ID 1676, p. 3).

In contrast, Ameren Corporation (Ameren) and NGK Metals (NGK) recommended against adoption of Regulatory Alternative 13. According to Ameren, ''[t]race beryllium in fly ash is unlikely to cause sensitization issues but PPE would be required under this alternative'' (Document ID 1675, p. 6). Ameren, however, did not provide further information or evidence to support this claim. NGK suggested the language ''visibly contaminated with beryllium particulate or solutions'' as a trigger for the standards' PPE requirements, to clarify that PPE is not required when handling clean, solid materials that contain beryllium (Document ID 1663, pp. 2, 5). OSHA does not find these comments persuasive. OSHA included operations and industries where beryllium is present as a trace contaminant in the scope of the beryllium standard only when these operations and industries have the potential to release airborne exposures exceeding the action level of 0.1 $\mu g/m^3$, at which sensitization is known to occur (see Section VI, Risk Assessment). With regard to NGK's suggested language, the Agency believes the commenter's intention to clarify OSHA's position on clean, solid materials is already captured in the regulatory text of the standards. Paragraph (h)(1)(ii) is not intended to require the provision of PPE to employees whose only contact with beryllium is handling articles that do not have surface contamination with beryllium.

In summary, OSHA has concluded that beryllium surface contamination may not be visible yet may still cause sensitization. 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. And although solubility may play a role in the level of sensitization risk, the available evidence indicates that contact with poorly soluble as well as soluble beryllium can cause sensitization via dermal contact (see this preamble at section V, Health Effects). Based on these considerations, OSHA has adopted Regulatory Alternative 13 in paragraph (h)(1)(ii) of the final standards, which requires the employer to provide PPE and ensure its use wherever there is a reasonable expectation of dermal contact with beryllium to any extent and of any type.

The USW recommended further specification of the PPE provisions, requesting clarification of the terms ''skin'' and ''exposure'' in the proposed standard's PPE requirements (Document ID 1680, p. 4; 1681, p. 12). As discussed previously, the term ''contact'' has replaced ''exposure'' where the final standard refers to the skin. This change was made in order to clearly distinguish between airborne and contact exposure in the text of the standards. OSHA's intention in using the term ''contact'' is straightforward, meaning any instance in which beryllium touches an employee's body. ''Skin'' refers to the exterior surface of all parts of an employee's body including face, arms, scalp, ears, and nostrils. OSHA notes that processes that have the potential to expose workers' eyes to beryllium will generally also expose the face, and forms of PPE such as face shields used to protect the face generally also protect the eyes (*e.g.,* face shields for use in situations where there is a danger of being splashed in the face with beryllium-containing liquid, or a hooded respirator where the employee is exposed to beryllium-containing fumes).

The USW also requested that OSHA include a specific requirement for provision of PPE to workers performing maintenance and repair activities and during non-routine tasks, to ensure that PPE is worn during tasks for which airborne exposure levels are not assessed (Document ID 1680, pp. 4–5; 1681, p. 12). This comment was submitted in response to the proposed standard, which would have required PPE where airborne exposures exceed the TWA PEL or STEL, but not in all cases where dermal contact occurs and airborne exposure levels are lower. OSHA believes the USW's concern has been addressed by the PPE requirements of the final standards, which apply wherever there is reasonable expectation of dermal contact with beryllium, including during maintenance and repair activities and non-routine tasks that involve beryllium-releasing processes or that are conducted in beryllium-contaminated areas.

OSHA also received a suggestion from the Boeing Company (Boeing) to amend proposed paragraph (h)(1)'s requirement to ensure use of appropriate PPE in accordance with the written exposure control plan, by adding ''or equally as effective documentation'' (Document ID 1667, p. 5). Boeing argued that the suggested language would allow employers to provide the required information through use of existing processes instead of through the creation of a second document (Document ID 1667, pp. 3–5). OSHA considered Boeing's comment, but decided against adding the suggested language. OSHA determined that it would create unnecessary ambiguity in the requirements for documentation in the context of both compliance and enforcement, as employers and CSHOs would need to determine what constitutes ''equally effective documentation.'' If an employer such as Boeing already has documents describing appropriate use of PPE that comply with the requirements of these standards, OSHA believes those documents can easily be incorporated into the employer's written exposure control plan. Taking this approach would eliminate the potential for confusion or redundancy caused by implementing multiple documents on PPE.

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), construction (29 CFR part 1926 Subpart E), and shipyards (29 CFR part 1915 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 means that individuals conducting hazard assessments must be familiar with the employer's work processes, materials, and work environment. A thorough hazard assessment should include a walk-through 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 from beryllium exposure. The requirements for choosing PPE under OSHA's personal protective equipment standards (*e.g.,* 29 CFR 1910 Subpart I for general industry) are performance-oriented, and are 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 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 paragraph (g) earlier in this section of the preamble.

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 employers must select and ensure the use of protective clothing that is worn in lieu of (rather than over) street clothing, and must provide change rooms under paragraph (i)(2).

The Abrasive Blasting Manufacturers Alliance (ABMA) asserted that the PPE requirements under this standard are not consistent with the abrasive blasting requirements for construction and maritime (*e.g.,* 29 CFR 1926.57(f), 29 CFR 1915.34) (Document ID 1673, pp. 22–23). OSHA disagrees, based on the performance-oriented nature of the PPE requirements in the final beryllium standards. If an employer provides PPE that is appropriate and suitable for abrasive blasting and that protects the employee's skin, this would be compliant with the requirements under this final beryllium standard.

Paragraph (h)(2) contains 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. An NJH 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 (Document ID 0474, 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 (Document ID 1875, Centers for Disease Control and Prevention, 2012, pp. 967–970).

Under paragraph (h)(2)(i), beryllium-contaminated PPE must be taken off at the end of the work shift, at the completion of tasks involving beryllium exposure, or when PPE becomes visibly contaminated with beryllium, whichever comes first. This provision is identical to the corresponding paragraph in the proposed standard, except for a slight reorganization to improve clarity and readability. Paragraph (h)(2)(i) 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 requires the employer to ensure that the employee wears is not intended to prevent them from wearing the PPE until the completion of their shift, unless it has become visibly contaminated with beryllium.

PPE that is visibly contaminated with beryllium should be changed at the earliest reasonable opportunity. This provision 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. Unlike the ''visibly contaminated'' language used in paragraph (h)(1)(ii) of the proposal, which has been removed, OSHA has determined that it is appropriate to use the same language here. Because the purpose of PPE is to serve as a barrier between an employee's body and ambient or surface beryllium, PPE becomes contaminated with beryllium immediately as part of its protective function. Requiring PPE to be changed upon contamination with any amount of beryllium is unreasonable and unnecessary to protect employees. This is because contamination of PPE with beryllium during work processes does not reduce the effectiveness of PPE or create hazards to employees unless sufficient beryllium accumulates on the PPE to impair its function or create additional exposures, such as by dispersing accumulated beryllium into the air. Furthermore, the process of changing contaminated PPE can create opportunities for both inhalation exposure and dermal contact with beryllium. The use of ''visibly contaminated'' protects employees from potential exposures while changing PPE by limiting requirements to change PPE during work tasks involving beryllium exposure to those circumstances when changing it is necessary to maintain its protective function and prevent deposits of beryllium from accumulating and dispersing.

Using the ''visible contamination'' trigger in (h)(1)(ii) to determine when employees must wear PPE in the first instance would have reduced the protectiveness of the standard. Thus, OSHA determined that it would be inappropriate to use such a trigger in that context. However, as explained above, using ''visibly contaminated'' in paragraph (h)(2)(i) actually increases the protectiveness of the standard. It provides a cue for when it is unacceptable for a worker to continue to work in his or her contaminated PPE, regardless of whether a shift or a task involving beryllium exposure has been completed. This common sense approach is supported by Materion in its post-hearing comments: ''If a job is such that company supplied work clothing may become dirty, wear a personal protective over-garment to keep your work clothing and your person clean. If your work clothing becomes dirty, change it.'' (Document ID 1752).

Paragraph (h)(2)(ii) requires employees to remove PPE consistent with the written exposure control plan required by 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. While proposed paragraph (h)(2)(ii) only required personal protective clothing to be removed pursuant to the written exposure control plan, the final language includes personal protective equipment as well as clothing. This change was made to ensure consistency with the rest of paragraph (h) and to confirm OSHA's intent that beryllium-contaminated personal protective equipment should be treated with the same care as contaminated clothing in order to prevent additional airborne exposure and dermal contact.

Paragraph (h)(2)(iii) requires employers to ensure that protective clothing is kept separate from employees' street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan. The language of this provision has been modified slightly from the proposed standard to emphasize prevention of cross-contamination as well as implementation of the written exposure control plan, consistent with other requirements intended to limit beryllium migration and cross-contamination. OSHA believes these provisions are necessary to prevent the spread of beryllium throughout and outside the workplace.

The remainder of paragraph (h)(2) is unchanged from the proposal and did not elicit comments from stakeholders. To further limit exposures outside the workplace, paragraph (h)(2)(iv) requires employers to ensure that beryllium-contaminated PPE is only removed from the workplace 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 these standards. The standards further require in paragraph (h)(2)(v) that PPE removed from the workplace for laundering, cleaning, maintenance, or disposal 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 should alert those handling the contaminated PPE of the potential hazards of exposure to beryllium. Such labels must conform with the hazard communication standard (29 CFR 1910.1200) and paragraph (m)(3) of these standards. These warning requirements are meant to reduce confusion and ambiguity regarding critical hazard information communicated in the workplace by requiring that this information be presented in a clear and uniform manner.

Paragraph (h)(3) of the standards addresses the cleaning and replacement of PPE. Proper cleaning is necessary to ensure that neither the workers who use the PPE nor those who clean and maintain it are exposed to beryllium via inhalation or dermal contact. Proper replacement is necessary to ensure that the PPE continues to function effectively in protecting workers from exposure. Paragraph (h)(3) is unchanged from the proposal.

Paragraph (h)(3)(i) requires the employer to ensure that reusable PPE is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness. In keeping with the performance orientation of the standards, OSHA does not specify how often PPE should be cleaned, repaired, or replaced. Appropriate time intervals for these actions 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, these requirements must be completed at a frequency, and in a manner, sufficient to ensure that PPE continues to serve its intended purpose of protecting workers from beryllium exposure.

Several commenters discussed the merits of the use of disposable PPE versus reusable PPE. These commenters indicated that OSHA should allow the use of disposable PPE, which could be both more protective and, in some cases, less costly, than reusable PPE (Document ID 1676, p. 3; 1682, p. 3). In response, OSHA notes that it is not prohibiting the use of disposable PPE. As discussed above, OSHA is leaving the decision regarding appropriate PPE to employers after they do their hazard assessments. While these commenters indicated that the regulatory text seems to focus on reusable PPE, the requirements specifically regarding reusable PPE are necessary to ensure that workers who handle this PPE downstream (for example, workers who launder or repair PPE) are protected and that reusable PPE is appropriately handled and cleaned before being reused. These provisions are not meant to indicate that OSHA prefers reusable PPE over disposable PPE.

Under paragraph (h)(3)(ii), removal of beryllium from PPE by blowing, shaking, or any other means which disperses beryllium in the air is prohibited as this practice could result in unnecessary and harmful exposure to airborne beryllium. Paragraph (h)(3)(iii) requires 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 beryllium, and of the need to handle the PPE in accordance with this standard. This provision is intended to limit dermal and inhalation exposure to beryllium, and to emphasize the need for hazard awareness and protective measures consistent with these standards among persons who clean, launder, or repair beryllium-contaminated items.

(i) Hygiene Areas and Practices

Paragraph (i) of the final standards for general industry, construction, and shipyards requires that, when certain conditions are met, the employer must provide employees with readily accessible washing facilities and change rooms. Additionally, paragraph (i) of the final standard for general industry requires that, when certain conditions are met, the employer must provide showers for employee use. Paragraph (i) of all three standards also requires the employer to take certain steps to minimize exposure in eating and drinking areas, and prohibits certain practices that may contribute to beryllium exposure. The final standards' hygiene provisions are consistent with other OSHA standards providing similar protection. For example, OSHA health standards for hexavalent chromium (29 CFR 1910.1026) and lead (29 CFR

1910.1025) include hygiene provisions along with engineering control requirements to protect workers from exposure to toxic substances. OSHA's standards addressing sanitation in general industry (29 CFR 1910.141), construction (29 CFR 1926.51) and shipyard employment (29 CFR 1915.88) also include hygiene provisions, requiring the employer to provide change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing whenever employees are required by an OSHA standard to wear protective clothing because of the possibility of contamination with toxic materials. The sanitation standards also include provisions for washing facilities and prohibit storage or consumption of food or beverages in any area exposed to a toxic material.

OSHA requested comment on the hygiene provisions of the proposed standard for general industry, which was similar in most respects to the hygiene provisions of the final general industry standard. It required employers to provide readily accessible washing facilities, change rooms and showers and to ensure the use of these facilities for each employee exposed to beryllium when necessary. The proposed standard also required employers to take certain steps to minimize exposure in eating and drinking areas and prohibited certain practices that may contribute to beryllium exposure. The remainder of this section discusses general comments on the hygiene section; explains the hygiene provisions of the final standards and OSHA's response to comments on each provision; and discusses differences between the proposed and final standards and differences between the final standards for each sector.

Most commenters agreed with the need for hygiene areas and practices to protect workers from airborne exposure to and dermal contact with beryllium (Document ID 1664, p. 7; 1665, pp. 10–11; 1667, pp. 5–6; 1675, p. 13; 1679, p. 9; 1680, p, 5; 1689, p. 12). However, one commenter stated that its engineering control systems eliminated the need for hygiene facilities (Document ID 1615, p. 8). OSHA disagrees that engineering controls alone are sufficient to eliminate the need for hygiene areas and practices. Because significant risk of beryllium sensitization and CBD remain below the TWA PEL in the final beryllium standards, ancillary provisions such as requirements for hygiene areas and practices are appropriate to further reduce that risk. *See Building and Constr. Trades Dept.* v. *Brock (Asbestos II),* 838 F.2d 1258, 1274 (D.C. Cir. 1988). As discussed in this preamble at Section V, Health Effects and Section VI, Risk Assessment, dermal contact with beryllium can cause beryllium sensitization, the first step in the development of CBD. Compliance with the hygiene provisions of the final standards will reduce the amount and duration of employees' dermal contact with beryllium, and will therefore more effectively reduce employees' risk of developing CBD than would compliance with the TWA PEL alone.

Another commenter noted that hygiene areas and practices specified in the proposal exceed requirements for abrasive blasting operations discussed in OSHA's Ventilation standard for construction (29 CFR 1926.57) and Mechanical paint removers standard in maritime employment (29 CFR 1915.34) (Document ID 1673, p. 23). Ancillary provisions in standards for specific substances such as beryllium complement these general OSHA standards. As OSHA noted in Section XVIII of the NPRM, the standards for abrasive blasting provide protection primarily to blasting operators, and do not apply to other employees who are likely to experience beryllium exposures, such as blasting helpers and cleanup workers. In addition, OSHA expects the hygiene provisions in the final beryllium standards to decrease the airborne exposure and dermal contact even of employees who wear respiratory protection and PPE required by other standards, and will therefore reduce significant risk of beryllium-related health effects among abrasive blasters in construction and shipyards.

Paragraph (i)(1) of the proposed standard required that employers provide, for each employee working in a beryllium work area, readily accessible washing facilities to remove beryllium from the hands, face, and neck. It also required employers to ensure that each employee exposed to beryllium use these facilities when necessary.

The requirements for washing facilities will 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. As discussed in Section V of this preamble, Health Effects, respiratory tract, skin, eye, or mucosal contact with beryllium can result in beryllium 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 Sanderson *et al.* measured the levels of beryllium on workers' skin and vehicle surfaces at a machining plant. The study showed beryllium was present on workers' skin and in their vehicles, demonstrating that workers carried residual beryllium on their hands when leaving work (Sanderson *et al.,* 1999, Document ID 0474). In addition, dermal contact with beryllium has been shown to occur even at low airborne exposure levels. For example, 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 TWA PEL (Document ID 1878, pp. 8–9).

The requirements in the standards to use washing facilities are performance-oriented, simply requiring employees to use the washing facilities to remove beryllium from their skin when the criteria in paragraph (i)(1) of the standards are met. Typically, washing facilities will 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, cleaning agent, or drying mechanism. 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.

OSHA did not receive comment on this provision. Therefore, paragraph (i)(1) of the final standards is substantively unchanged from proposed paragraph (i)(1). Paragraph (i)(1) of the final standard for general industry requires the employer to provide readily accessible washing facilities for employees who work in beryllium work areas to remove beryllium from the hands, face, and neck and ensure that employees who have had dermal contact with beryllium use these facilities at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

Because the standards for construction and shipyards do not require beryllium work areas, the requirements for washing facilities set forth in paragraph (i)(1) of the construction and shipyard standards differ from the general industry standard in that they require employers to provide washing facilities for each employee required to wear personal protective clothing or equipment by the final standards—that is, where employees are reasonably expected to be exposed to beryllium above the TWA PEL or STEL or where there is a reasonable expectation of dermal contact with beryllium. Otherwise, the requirements for washing facilities are the same in all three standards.

Paragraph (i)(2) of the proposed standard required employers to provide affected employees with a designated change room and washing facilities in accordance with the proposed standard and the Sanitation standard where employees were required to remove their personal clothing.

Change rooms allow employees to remove their personal clothing in order to use personal protective clothing. 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. Requiring employers to provide employees with change rooms to change out of work clothes, which are then segregated from their street clothes, and to leave work clothing at the workplace significantly reduces the possibility of beryllium migration outside the workplace, providing added protection from take-home beryllium exposure to workers and their families.

One commenter recommended that change rooms be required only when there is required use of personal protective clothing and equipment (Document ID 1667, pp. 5–6). OSHA intends the change rooms requirement only to apply to 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. The standards do not create a requirement for employees to change their clothing. Note that paragraph (h) of all three standards 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.

Another commenter stated that the final rule should require employers to develop a program that defines approved storage areas for protective apparel and personal hygiene towels, restricts access to this area, provides for employee training when handling or reusing previously used items, and establishes an objective means for determining when an item can no longer be reused and must be laundered or discarded (Document ID 1962, p. 5). OSHA agrees that employers should develop and document procedures for limiting beryllium cross-contamination and migration, and has included such requirements in paragraph (f), Methods of Compliance, and paragraph (j), Housekeeping. These paragraphs of the final standards require each employer to develop, document, and implement procedures for limiting beryllium migration and cross-contamination in their facilities, which should address storage, handling and reuse of beryllium-contaminated items and access to storage facilities for beryllium-contaminated clothing and PPE, including towels if these are contaminated with beryllium during washing and showering.

After carefully reviewing the record, OSHA has decided to keep paragraph (i)(2) substantively unchanged. Paragraph (i)(2) of the final standard for general industry requires the employer to provide a designated change room for employees who work in a beryllium work area and are required to remove their personal clothing. Paragraph (i)(2) of the final standards for construction and shipyards requires the employer to provide a designated change room for employees who are required by the final standards to wear personal protective clothing or equipment and are required to remove their personal clothing. The changed trigger for change rooms in the construction and shipyard standards is due to the fact that there are no beryllium work areas in those standards, and requiring change rooms where employees are required to wear personal protective clothing or equipment provides a similar level of protection to the general industry standard. Change rooms must be designed in accordance with the written exposure control plan required by paragraph (f)(1) of all three standards, and with the applicable Sanitation standards in general industry (29 CFR 1910.141), construction (29 CFR 1926.51), and shipyards (29 CFR 1915.88). These Sanitation standards 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.

As in the proposed standard for general industry, paragraph (i)(3) of the final standard for general industry requires employers in general industry to provide and ensure the use of showers if employees are or can 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. Paragraph (i)(3)(ii) of the final standard for general industry, like the proposed standard for general industry, 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. The requirement is restricted to body parts other than the hands, face, and neck because if employees have dermal contact with beryllium on their hands, faces, or necks, they must use the washing facilities required by paragraph (i)(1)(i). This language is intended to convey that showers must be used immediately after work activities involving beryllium exposure have been completed for the day. For example, if employees perform work activities involving beryllium exposure that meet the requirements for showers 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 intended to require them to shower after the last task involving exposure, not after the completion of each such task.

The requirements of paragraph (i)(3) of the final standard for general industry are similar to requirements for provision and use of shower facilities in other substance-specific OSHA health standards, such as the standards for cadmium (29 CFR 1910.1027) and lead (29 CFR 1910.1025), which also require showers when exposures exceed the TWA 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.

A majority of the comments on the proposed hygiene areas and practices provisions for general industry concerned the requirement for showers. The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) expressed support for the mandatory use of showers for workers in beryllium regulated areas where airborne exposures can reasonably be expected to exceed the TWA PEL or STEL so that proper decontamination can occur and prevent beryllium from leaving the work area, and to ensure that workers and their families are not exposed to beryllium once workers leave their place of employment (Document ID 1665, pp. 10–11). Ameren Corporation (Ameren), the United Steelworkers (USW), and Materion Corporation (Materion) also supported the requirement for showers and their use by employees working in a beryllium regulated area (that is, where airborne exposures can reasonably be expected to exceed the TWA PEL or STEL) (Document ID 1675, p. 13; 1680, p. 5; 1681, p.12).

Some commenters supported the requirement for showers, but suggested that employers should be required to provide shower facilities to workers exposed at lower exposure levels than the TWA PEL or STEL. National Jewish Health (NJH) suggested that showers should be required for workers exposed above the action level rather than the TWA PEL or STEL and in facilities where beryllium can be expected to contaminate the employees' hair or other body parts (Document ID 1664, p. 7). The North America's Building Trades Unions (NABTU) suggested that any beryllium work area should include all necessary decontamination facilities, including showers (Document ID 1679, p. 9).

OSHA notes that NJH and NABTU's comments addressed the provisions of the proposed standard for general industry, which did not include a requirement to provide PPE wherever there is a potential for dermal contact with beryllium. As discussed previously in the Summary and Explanation for paragraph (h) of the final standards, OSHA has adopted much more comprehensive requirements for employers to provide and ensure the use of personal protective clothing and equipment (PPE) wherever exposure exceeds the TWA PEL or STEL or dermal contact with beryllium is reasonably expected to occur. The Agency believes that employees working in low-exposure contexts (where exposures do not exceed the TWA PEL or STEL) and using comprehensive PPE as required in paragraph (h) are unlikely to experience beryllium contamination that requires shower facilities to effectively remove beryllium from the hair and skin. OSHA therefore concludes that the required washing facilities and change rooms for general industry employees working in beryllium work areas in combination with the comprehensive PPE requirements described in paragraph (h) of the final standards are sufficient to protect workers in areas where exposures do not exceed the TWA PEL or STEL and where there is no reasonable expectation that body areas other than hands, face and neck will be contaminated with beryllium. OSHA therefore has decided not to require the provision of showers in general industry workplaces where exposure does not exceed the TWA PEL or STEL.

The Boeing Company (Boeing) suggested requiring showers only when beryllium visibly contaminates employees' hair or body parts other than hands, face, and neck (Document ID 1667, p. 6). However, as discussed previously in the Summary and Explanation of paragraph (h), Personal Protective Clothing and Equipment, dermal contact with beryllium can lead to adverse health effects regardless of whether sufficient beryllium-containing dust has accumulated to be visible to the naked eye. Therefore, OSHA has determined that requiring showers only where beryllium contamination is visible would not adequately protect employees from prolonged dermal contact with beryllium or adequately prevent transfer of beryllium outside the workplace.

Another commenter suggested that air showers for when employees leave the work area would be more cost effective and acceptable than water-based showers (Document ID 1596, p. 1). OSHA does not believe that air showers are appropriate for removing beryllium from workers' skin. Air showers are designed to remove accumulations of dust from the surface of work clothing, PPE, and exposed skin, but cannot remove residual beryllium as effectively as washing with water and soap. In addition, air showers can disperse beryllium-containing dust into the air and cause employees additional airborne exposure, whereas water-based showers do not re-entrain dust into the air.

OSHA has not included a requirement for showers in the final standards for construction and shipyards. Workers in these industries are exposed to beryllium primarily when an abrasive that contains trace amounts of beryllium, usually coal or copper slags, is used during abrasive blasting operations. These abrasive slags contain less than 0.1% beryllium but may result in significant airborne exposure to beryllium because of the high dust levels generated during abrasive blasting. However, workers conducting abrasive blasting with these abrasives are currently protected from dermal contact with beryllium under existing OSHA standards. The OSHA Ventilation standard for construction (29 CFR 1926.57) and the OSHA Mechanical paint removers standard for shipyard employment (29 CFR 1915.34) require personal protective clothing and respiratory protection for abrasive blasters. The Ventilation standard requires employers to use only respirators approved by NIOSH under 42 CFR part 84 for protecting employees from dusts produced during abrasive-blasting operations (29 CFR 1926.57(f)(5)(i)) and abrasive-blasting respirators must be worn by all abrasive-blasting operators (29 CFR 1926.57(f)(5)(ii)). These abrasive blasting respirators cover the entire head, neck and shoulder area to protect the worker from rebounding abrasive during these operations and prevent beryllium exposure to the head and neck area. The Mechanical paint removers standard has similar requirements for abrasive blasters including the use of hoods and airline respirators, along with protective clothing (29 CFR 1915.34(c)). Compliance with these requirements should effectively prevent contamination of abrasive blasters' bodies with beryllium; thus, use of showers to remove beryllium is unnecessary for these workers.

Abrasive blasting support workers such as pot tenders and cleanup workers are also potentially exposed to beryllium during abrasive blasting activities (Chapter IV, Technological Feasibility). However, their work is usually remote from the actual abrasive blasting or occurs prior to or after the operation is completed, resulting in lower exposures. OSHA's exposure profile for these workers shows a median exposure below the final standards' action level (0.09 μg/m^3 for pot tenders and helpers and 0.07 μg/m^3 for cleanup helpers) which is well below the median exposure level of 0.2 μg/m^3 for abrasive blasters (Chapter IV, Technological Feasibility) and well below the trigger for provision of showers established in the final standard for general industry. While abrasive blasting support workers are not exposed to the high dust levels experienced by the abrasive blasting operator, these workers are nevertheless protected under the personal protective clothing and equipment requirements in paragraph (h) of the final standards which requires the use of appropriate personal protective clothing and equipment where exposure can reasonably be expected to exceed the TWA PEL or STEL or where there is a reasonable expectation of dermal contact with beryllium. Based on the personal protective clothing and equipment requirements under OSHA standards for abrasive blasting operators and support workers, and the low exposure levels described above and in Chapter IV, Technological Feasibility, OSHA is not requiring showers in the final standards for construction and shipyards. OSHA also notes that providing showers can be impractical in some temporary worksites, such as those often used in construction settings.

Paragraph (i)(4) (eating and drinking areas) of OSHA's proposed rule for general industry required that whenever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that surfaces in eating and drinking areas are as free as practicable of beryllium to minimize the possibility of food contamination and the likelihood of additional exposure to beryllium through inhalation or ingestion. Proposed paragraph (i)(4) further required employers to ensure that no employee in eating and drinking areas is exposed to airborne beryllium at or above the action level, and that eating and drinking areas must comply with the Sanitation standard (29 CFR 1910.141). Paragraph (i)(5)(ii) (prohibited activities) of the proposed rule, also related to eating and drinking areas, required the employer to ensure that no employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, 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.

A commenter with the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) recommended that OSHA develop stronger language to ensure that exposure levels are ''well below'' the action level for eating and drinking areas and that surfaces are truly as free as practicable of beryllium (Document ID 1689, pp. 12–13). OSHA agrees with the commenter that airborne beryllium should be maintained well below the action level in eating and drinking areas and has decided not to include the proposal's hygiene provision that no employee in eating and drinking areas is exposed to airborne beryllium at or above the action level in the final standards. OSHA believes that this language may be interpreted to allow airborne exposure levels up to the action level in eating and drinking areas, which is not OSHA's intent. The requirements to maintain surfaces in these eating and drinking areas as free as practicable of beryllium and to ensure that employees do not enter eating and drinking areas with personal protective work clothing or equipment unless beryllium has been removed will limit contamination and airborne exposure to beryllium and provide workers with safe areas to eat and drink.

In comments on surface cleanliness pertaining to eating and drinking areas, Boeing suggested that the standard should define specific surface contaminant levels or instead simply rely on the existing OSHA Sanitation standard (1910.141) (Document ID 1667, p. 6). Kimberly-Clark Professional (KCP) suggested that OSHA should set a future goal of establishing maximum allowable surface contamination standards for toxic substances (Document ID 1962, p. 3). Materion suggests that its ''visibly clean'' standard is analogous to OSHA's standard of ''as free as practicable'' and that its cleaning program ensures that surfaces remain ''as free as practicable'' of beryllium (Document ID 1807, p. 5). Materion and USW proposed the term ''visibly clean'' because they ''have found it to be well understood by both workers and management'' (Document ID 1808, p. 4). However, Materion also points out that the use of the term ''as free as practicable'' has been understood by workers, management and OSHA compliance officers and has been successfully applied and effective in practice: ''[f]or decades, OSHA has used the term ''as free as practicable'' in its substance specific standards . . . OSHA's use of this term has been understood by workers, management and OSHA compliance officers. OSHA has successfully applied this compliance term in many prior OSHA standards which serves to demonstrate that its use is understandable and effective in practice'' (Document ID 1808, p. 5). In post-hearing comments, KCP states its belief that ''visibly contaminated'' is an inadequate standard and should not be used as a stand-in for ''as clean as practicable'' (Document ID 1962, p. 2).

In developing the final standards, OSHA carefully considered these comments on the use of ''as free as practicable'' and alternative requirements in reference to surface cleanliness in eating and drinking areas and elsewhere in the beryllium standards, and concluded that ''as free as practicable'' is the most appropriate terminology for requirements pertaining to surface cleanliness. Issues related to use of ''as free as practicable'' and alternatives to this language are also discussed in the Summary and Explanation for paragraph (j), Housekeeping.

The requirement to maintain surfaces as free as practicable of the regulated substance 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). Employers therefore have the benefit of previous experience interpreting and developing methods for compliance with requirements to maintain surfaces ''as free as practicable'' of toxic substances, as well as guidance from OSHA on compliance with such requirements. 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, 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, Document ID 0550). 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 the Chromium (VI) Standards provides additional detail on how OSHA interprets ''as free as practicable'' for enforcement purposes (OSHA, 2008, Document ID 0546, pp. 45–47). 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. Thus, OSHA believes that the term ''as free as practicable'' is clearly understood by employers through its use in other standards and as explained in letters of interpretation and is using this term in the hygiene provision of the final standards.

OSHA does not set quantitative limits for surface contamination because the best available scientific evidence on adverse health effects from dermal contact with beryllium does not provide sufficient information to link risk of adverse health effects with specific levels of surface contamination. As described above, OSHA finds that wipe sampling can be helpful in determining whether an employer is in compliance with a requirement to keep surfaces as free as practicable of toxic substances, but concludes that use of a specific target level of surface contamination should not define compliance with surface cleanliness requirements of the beryllium standards.

Based on these conclusions, paragraph (i)(4) of the final standards requires that wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that surfaces in these areas are as free as practicable of beryllium. The employer must also ensure that employees do not enter eating and drinking areas with personal protective work clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing and equipment by methods that do not disperse beryllium into the air or onto an employee's body, further protecting workers from beryllium contamination in areas where eating and drinking occurs. Eating and drinking areas must further comply with the Sanitation standards (29 CFR 1910.141(g), 1926.51(g), 1915.88(h)), which prohibit consuming or storing food or beverages in a toilet area or in any area exposed to a toxic material. In the final standards, the provisions for eating and drinking areas (paragraph (i)(4) of the general industry standard, paragraph (i)(3) of the construction and shipyard standards) and prohibited activities (paragraph (i)(5) of the general industry standard and paragraph (i)(4) of the construction and shipyard standards) have been retained with one exception and one structural change. The proposed requirement to ensure that no employee in eating and drinking areas is exposed to airborne beryllium at or above the action level has been removed for the reasons already discussed above. And the requirement concerning employees entering any eating or drinking area with personal protective clothing or equipment has been moved from the prohibited activities section of the proposed rule's hygiene provision to the eating and drinking areas section in the final standards.

Paragraph (i)(4) of the final standard for general industry and paragraph (i)(3) of the final standards for construction and shipyards do 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 is required to maintain the area in accordance with paragraph (i)(4) of the final standard for general industry or paragraph (i)(3) of the final standards for construction and shipyards, and with the applicable Sanitation standard (29 CFR 1910.141, 29 CFR 1915.1915.88, or 29 CFR 1926.51), and the employer must ensure that employees do not enter eating and drinking areas wearing contaminated personal protective clothing or equipment.

Paragraph (i)(5)(i) of the proposed standard, setting forth prohibited activities, required the employer to ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas. OSHA did not receive comment on this provision. Therefore, paragraph (i)(5) of the final standards is substantively unchanged from proposed paragraph (i)(5)(i). Paragraph (i)(4) of the final construction and shipyard standards is substantively identical to paragraph (i)(5) of the general industry standard.

Paragraph (i)(5) of the final standard for general industry and paragraph (i)(4) of the final standard for shipyards prohibit eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics in regulated areas (areas where airborne exposure to beryllium is expected to exceed the TWA PEL or STEL). Paragraph (i)(4) of the final standard for construction differs slightly in that the employer is required to ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in work areas where there is a reasonable expectation of exposure above the TWA PEL or STEL. This difference arises because the final standard for construction does not have a requirement for regulated areas but instead relies on a competent person provision (paragraph (e)) to restrict employee access to areas where exposures are, or can reasonably be expected to be, above the TWA PEL or STEL. Exposure at these levels creates a greater risk of beryllium contaminating the food, drink, tobacco, gum, or cosmetics. Prohibiting eating and drinking in these areas will reduce the potential for this manner of exposure.

For the foregoing reasons, OSHA has decided to promulgate all the requirements of the proposed hygiene areas and practices provisions in the beryllium final standard for general industry except for the eating and drinking areas action level limit noted above. For the final standards for construction and shipyards, OSHA has decided to include all of the hygiene areas and practices provisions proposed for general industry except for the requirement for showers and the eating and drinking areas action level limit.

(j) Housekeeping

Paragraph (j) of the final standard for general industry requires employers to maintain all surfaces in beryllium work areas as free as practicable of beryllium; promptly clean spills and emergency releases of beryllium; use appropriate cleaning methods; and properly dispose of materials containing or contaminated with beryllium. Paragraph (j) of the final standards for construction and shipyards requires employers to follow the written exposure control plan required under paragraph (f)(1) when cleaning beryllium-contaminated areas, use appropriate cleaning methods, and provide recipients of beryllium-containing materials for use or disposal with a copy of the warning described in paragraphs (m)(2) and (m)(3), respectively.

As discussed in more detail below, the housekeeping requirements in the final standards are similar to those included in the proposal. While some stakeholders submitted divergent opinions on certain aspects of the proposed provisions, several commenters offered broad support for the inclusion of housekeeping provisions in the final rule (*e.g.,* Document ID 1664, p. 7; 1681, Attachment 1, p. 13). For example, United Steelworkers (USW) stated that ''the proposed text provides employers with clear responsibilities and provides strong provisions to ensure worker protection'' (Document ID 1681, Attachment 1, p. 13). USW also expressed appreciation for the ''precautions incorporated into this section to minimize the amount of particulate suspended in the air'' (Document ID 1681, Attachment 1, p. 13). Another stakeholder, National Jewish Health (NJH), agreed with the proposed rule regarding housekeeping (Document ID 1664, p. 7). Similarly, the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) argued that ''housekeeping provisions are essential'' ''[b]ecause of the hazardous nature of beryllium and the significant risk of developing beryllium sensitization or disease'' (Document ID 1689, p. 13).

These comments support OSHA's view, as expressed in the NPRM, that these provisions are important because they minimize additional sources of exposure to beryllium that engineering controls do not completely eliminate. Good housekeeping measures are a cost-effective way to control worker 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. Moreover, housekeeping provisions may be especially critical in the final beryllium standards because contact with contaminated surfaces can 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. In addition, the housekeeping provisions in paragraph (j) of the standards for general industry, construction, and shipyards are generally consistent with housekeeping requirements in other OSHA standards for toxic metals, including cadmium (29 CFR 1910.1027, 1926.1127), chromium (VI) (29 CFR 1910.1026), and lead (29 CFR 1910.1025, 1926.62).

The Abrasive Blasting Manufacturers Alliance (ABMA) asserted that the proposed housekeeping requirements are not consistent with the abrasive blasting requirements for construction and shipyards (*e.g.,* 29 CFR 1926.57(f), 29 CFR 1915.34) (Document ID 1673, pp. 22–23). OSHA disagrees. The performance-oriented provisions in the final construction and shipyard standards for beryllium provide employers with a great deal of flexibility in cleaning beryllium-contaminated areas and spills and emergency releases of beryllium and disposing of materials designated for disposal or recycling. In essence, the text requires employers to choose cleaning methods that minimize the likelihood and level of airborne exposure (unless certain conditions are met), handle and maintain cleaning equipment in a way that minimizes exposure, and protect their employees when dry sweeping, brushing, or using compressed air to clean in beryllium-contaminated areas. When transferring materials containing beryllium to another party for use or disposal, the employer is required to advise the recipient of the beryllium content and hazards. These provisions complement, rather than contradict, the rules set out in 29 CFR 1926.57(f) and 29 CFR 1915.34, and are necessary for employee protection from beryllium-related adverse health effects.

Paragraph (j)(1)(i) of the proposed rule would have required employers to 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) and the cleaning methods required under paragraph (j)(2) of the proposed rule. In this context, the phrase ''as free as practicable'' set 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 in the Summary and Explanation for paragraph (i), Hygiene areas and practices, in this section of the preamble.

Although this requirement is often included in OSHA's substance specific regulations, a number of commenters expressed concern about its inclusion in this rulemaking. For example, USW argued that a ''requirement to maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium could lead to difficulties in assessing compliance, since 'as free as practicable' is open to interpretation''; instead, USW suggested that beryllium work areas should be required to be maintained ''visibly clean'' of accumulations (Document ID 1681, p. 13). Materion Corporation (Materion) also proposed the term ''visibly clean'' (Document ID 1808, p. 5; 1752, p. 1). However, Materion stated that OSHA has long used the term ''as free as practicable'' in its standards as a measure of cleanliness for work areas and eating areas, and the term is well understood by workers, management, and OSHA compliance officers. According to Materion, ''visibly clean'' is similar to ''as free as practicable'' and also well understood by workers and management (Document ID 1808, p. 5).

Kimberly-Clark Professional (KCP) stated that this ''ostensible equivalence'' between the ''as free as practicable'' and ''visibly clean'' standards is ''unfounded,'' in part, because ''[i]t is practicable using readily known and available methods to make many surfaces clean beyond that which is visibly apparent'' (Document ID 1962, p. 2). Instead, KCP recommended that OSHA ''establish surface contamination standards such that all subjectivity of surface cleanliness is removed'' (Document ID 1962, p. 2). KCP also argued that OSHA should require an employer's surface cleanliness protocol to be based on objective sampling and measurement. KCP maintained that there are many examples where surface sampling is used in economically feasible ways, including in the facilities governed by the Department of Energy (DOE). However, it acknowledged that the methods in other environments, including the DOE protocols for beryllium control in energy facilities, may not translate directly to industrial facilities. Nevertheless, KCP observed that ''there is sufficient ongoing successful use of such approaches to provide a framework for a more objective, data-driven protocol for surface control than 'visibly contaminated' '' (Document ID 1962, p. 3). The Boeing Company (Boeing) also requested that ''as free as practicable'' be replaced with defined surface contaminant levels (Document ID 1667, pp. 6).

Conversely, the Department of Defense (DOD) commented that employers should not be required to measure beryllium contamination on surfaces, as the relationship between level of surface contamination and health risk is unknown. It also stated that wipe samples are not an appropriate enforcement tool for determining that surfaces are ''as free as practicable'' of beryllium contamination (Document ID 1684, Attachment 1, p. 1). ORCHSE Strategies (ORCHSE) agreed that OSHA should not require measurement of beryllium contamination on surfaces (Document ID 1691, p. 18). And, the American Industrial Hygiene Association (AIHA) commented that ''the evaluation of 'visible' is subjective'' (Document ID 1686, p. 1).

After carefully considering these comments and other evidence in the record, OSHA has chosen not to require employers to measure beryllium contamination on surfaces, as suggested by KCP, or to otherwise ''define specific surface contaminant levels,'' as requested by Boeing Company. As DOD explains in its comments, the relationship between a precise amount of surface contamination and health risk is unknown. Therefore, OSHA cannot find that a particular level of contamination is safe. Rather, OSHA has determined that keeping surfaces as clean as practicable is appropriate because promptly removing beryllium deposits prevents them from becoming airborne, thus reducing employees' inhalation exposure, and helps to minimize the likelihood of skin contact with beryllium. The Agency notes, however, that wipe samples can be a helpful tool for employers. For example, wipe samples can be used by employers to detect the presence of beryllium on surfaces and help gauge when surfaces are as free as practicable of accumulations of beryllium.

Therefore, OSHA has decided to retain the requirement that employers maintain all surfaces in beryllium work areas as free as practicable of beryllium in paragraph (j)(1)(i) of the final general industry standard. The term ''as free as practicable'' is accepted language and used in other OSHA housekeeping requirements for toxic dusts (Asbestos, 29 CFR 1910.1001 and Cadmium, 29 CFR 1910.1027). As the Agency has explained in a letter of interpretation on this term as used in the lead standard, ''the requirement to maintain surfaces 'as free as practicable' is performance-oriented. . . . The requirement is met when the employer is vigilant in his efforts to ensure that surfaces are kept free of accumulations of lead-containing dust. The role of the Compliance Safety and Health Officer (CSHO) is to evaluate the employer's housekeeping schedule, the possibility of exposure from these surfaces, and the characteristics of the workplace'' (OSHA, Jan. 13, 2003, Letter of Interpretation.) The term ''surface'' has a common meaning but is not separately defined in the standard. This term has been used multiple times in OSHA's substance specific standards and OSHA has not found that it is a source of confusion for employers. As indicated in the preamble to the proposed standard, the term includes the outer parts of objects that workers come into contact with, such as equipment, floors, and items in storage facilities, as well as objects that workers may not directly contact, such as rafters and ledges. See 80 FR 47796. Because all surfaces in beryllium work areas could potentially accumulate beryllium that could become airborne or 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 also decided to remove the phrase ''accumulations of'' from (j)(1)(i), because OSHA believes the reference to ''accumulations'' may be misinterpreted to suggest that cleaning is only required when substantial deposits of beryllium-containing material have accumulated on surfaces. As discussed previously, dermal contact with small amounts of beryllium that are not visible to the naked eye can cause beryllium sensitization. Thus, the final standard for general industry requires the employer to maintain all surfaces in beryllium work areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard.

OSHA has not included the requirement that employers maintain all surfaces in beryllium work areas as free as practicable of beryllium in the final standards for construction and shipyards because certain conditions typical in these sectors warrant different approaches in the housekeeping provisions. As discussed in the Summary and Explanation for paragraph (a), Scope and application, in this preamble, although employees in the construction and shipyard industries may be exposed to beryllium during the demolition of beryllium-contaminated buildings and metal recycling or through the dressing of non-sparking tools, the primary exposure source of beryllium at construction worksites and in shipyards is from abrasive blasting operations (Document ID 1671, Attachment 1, p. 5; 1756, Tr. 97–99). Specifically, employees in the construction and shipyard industries are typically exposed when they use abrasive blasting media that contain beryllium.

Abrasive blasting in the construction and shipyard industries often occurs outdoors (see the Final Economic Analysis (FEA), Chapter IV. The surfaces being blasted can be large structures, such as buildings or ships. The blasting process itself can be transient and may occur for short periods of time. The work can be performed in the open or in temporary work enclosures when abrading large objects or structures that cannot be transported or are fixed. These enclosures are typically constructed of tarps and regularly moved from newly abraded areas to areas needing abrasion over very large distances (Document ID 1632, p. 6).

During the abrasive blasting process, large amounts of dust become airborne and then settle on nearby surfaces. Spent blasting media containing trace amounts of beryllium is cleaned up after the blasting operation is complete and has moved to a different area of the worksite. Paragraph (j)(2) of the construction and shipyard standards requires employers to ensure that employees use methods that minimize beryllium exposure during this cleaning process. However, due to the outdoor location of many worksites in construction and shipyards, OSHA finds it is not practical to require employers to maintain all surfaces in work areas as free as practicable of beryllium in construction or shipyards as for general industry. Therefore, OSHA has not included a reference to surfaces in the provisions of in paragraph (j)(1)(i) of the final standards for construction and shipyards. OSHA has modified paragraph (j)(1)(i) of these standards to require only that the employer follow the written exposure control plan required under paragraph (f)(1) when cleaning beryllium-contaminated areas.

When beryllium is released into the workplace as a result of a spill or emergency release, paragraph (j)(1)(ii) of the final standards, like paragraph (j)(1)(ii) of the proposal, requires the employer to ensure prompt cleanup. As defined in paragraph (b) of the final standards, the term ''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. Spills or emergency releases not attended to promptly are likely to result in additional employee exposure or skin contact.

Boeing objected to the proposed requirement that employers maintain surfaces and clean up spills or emergency releases in accordance with the written exposure control plans required by paragraph (f)(1), in part, because it did not believe OSHA should require employees to establish a written exposure control plan. Instead, Boeing suggested the Agency revise the standard to allow employers to use ''existing processes, such as a written beryllium worksite control procedure'' (Document ID 1667, p. 4). To that end, Boeing suggested that employers be allowed to ensure prompt and proper cleanup in accordance with the exposure control plan, ''or equally as effective documentation'' (Document ID 1667, pp. 6–7). As explained in the Summary and Explanation for paragraph (f), Methods of Compliance, in this preamble, OSHA disagrees with Boeing and has chosen to retain the requirement to establish, implement, and maintain a written exposure control plan. Final paragraphs (j)(1)(i) and (ii) of the standards, like proposed paragraphs (j)(1)(i) and (ii), thus require employers to perform housekeeping activities in accordance with the written exposure control plan required by paragraph (f)(1) and the cleaning methods required by paragraph (j)(2) of the standards.

Paragraph (j)(2) of the proposed rule included a few requirements regarding cleaning methods. Because OSHA recognizes that each work environment is unique, the Agency proposed performance-oriented requirements for housekeeping to allow employers to determine how best to clean beryllium work areas. Paragraph (j)(2)(i) of the proposed standard would have required that surfaces in beryllium work areas be cleaned by high-efficiency particulate air filter (HEPA) vacuuming or other methods that minimize the likelihood and level of beryllium exposure.

Some commenters, including NJH and USW, expressed support for the proposed requirement to use HEPA-filtered vacuuming (*e.g.,* Document ID 1664, p. 7; 1681, p. 13). NJH indicated that HEPA-filtered vacuuming is one of the methods that it recommends using because ''it has been shown to minimize exposures'' (Document ID 1664, p. 7). USW added that HEPA vacuums are common in the manufacturing industry and requiring their use should not burden employers (Document ID 1681, p. 13). Southern Company also noted that where beryllium is present as a trace element in coal-fired power generation, ''surfaces are cleaned and kept free of coal dust and ash by various methods, including vacuuming or washing,'' methods that may already comply with this proposed provision (Document ID 1668, p. 6).

KCP also indicated its support for HEPA vacuums, stating that vacuuming with HEPA filters is the safest way to remove dry contaminants from surfaces (Document ID 1676, Attachment 1, p. 5). However, KCP added that HEPA vacuums do not always work well in tight areas with recesses, crevices, and complex arrangements of equipment components and that workers are likely to use a towel to clean such areas. Because workers will naturally use nearby towels, KCP recommended that OSHA specify that towels used to clean surfaces must be wet, not dry.

The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) also expressed concern with the proposed provision's reliance on HEPA-filtered vacuuming. The BHSC Task Group observed that although HEPA-filtered vacuuming is considered to be the most effective method for cleaning surfaces, it is not necessarily effective in minimizing the spread of contamination because the vacuums fail in various ways during use. The BHSC Task Group further suggested that if OSHA were to prescribe HEPA-filtered equipment use, it should include a requirement for particle counting during use (Document ID 1665, p. 11).

OSHA finds that HEPA-filtered vacuuming is a highly effective method of cleaning beryllium-contaminated surfaces. However, the Agency acknowledges that any housekeeping equipment may fail and that maintaining the equipment according to the manufacturer's recommendations can be a critical part of ensuring that it functions as intended. (See summary and explanation of paragraph (j)(2)(v) which addresses maintenance of cleaning equipment.) Nevertheless, OSHA believes that when HEPA vacuums are maintained in proper working condition, it is not necessary to include a requirement for particle counting during the vacuuming. In addition, the Agency agrees with KCP that in certain circumstances other cleaning methods, such as wet wiping with towels, may also be effective in minimizing the likelihood and level of airborne exposure. Thus, paragraph (j)(2)(i) of the general industry standard retains the requirement that employers must ensure that surfaces in beryllium work areas are cleaned by HEPA-filter vacuuming or other cleaning methods that minimize the likelihood and level of airborne exposure. However, as discussed in detail below, OSHA has also added provisions to accommodate situations where cleaning with HEPA-filtered vacuums or other cleaning methods that minimize airborne exposure are not effective.

As explained above, OSHA has chosen not to include a provision requiring the cleaning of surfaces in the final construction and shipyard standards. And, as explained in the Summary and Explanation for paragraph (e), the construction and shipyard standards do not include a provision establishing beryllium work areas. Thus, references to surface cleaning and beryllium work areas have been removed from paragraph (j)(2)(i) of the construction and shipyard standards. Paragraph (j)(2)(i) in these standards requires employers to ensure the use of HEPA-filter vacuuming or other methods that minimize the likelihood and level of airborne exposure when cleaning spent blast media or performing other cleaning in beryllium-contaminated areas.

Paragraph (j)(2)(ii) of the proposed rule addressed the use of dry sweeping and brushing for cleaning in beryllium work areas. This proposed provision would have disallowed the use of dry sweeping and brushing unless the employer had tried cleaning with a HEPA-filtered vacuum or another method that minimizes the likelihood and level of exposure, and found that the method attempted was not effective under the particular circumstances found in the workplace. As explained in the proposal, OSHA included this provision to provide employers flexibility when exposure-minimizing cleaning methods would not be effective. See 80 FR 47796. However, the Agency indicated it was not aware of any circumstances in which dry sweeping or brushing would be necessary and requested comment on whether either of these cleaning methods would ever be necessary, and if so, under what circumstances. See 80 FR 47574.

Some commenters expressed general support for the prohibition on dry sweeping and brushing. For example, Ashlee Fitch, representing USW and Materion, commented that HEPA vacuums should be used whenever feasible, and stated that ''OSHA has appropriately characterized this provision relative to exceptions'' (Document ID 1680, p. 5). ORCHSE also agreed that prohibiting dry sweeping or brushing to clean surfaces in beryllium work areas is appropriate, and that employers should only be permitted to use dry sweeping and dry brushing when HEPA-filtered vacuuming have been tried and found not effective (Document ID 1691, Attachment 1, p. 5).

Commenters AFL–CIO, AWE, the BHSC Task Group, and North America's Building Trades Unions (NABTU), recommended prohibiting the use of dry sweeping under any circumstances (Document ID 1689, p. 13; 1615, p. 1, 9; 1655, p. 11; 1679, p. 9). For example, Clive LeGresley of AWE stated that AWE does not permit dry sweeping or brushing to clean surfaces and recommended banning this practice (Document ID 1615, p. 1). The BHSC Task Group recommended that dry sweeping be prohibited because it disturbs settled beryllium on surfaces, ''which can exacerbate airborne contamination'' (Document ID 1655, p. 11). It also argued that dry sweeping is not an effective cleaning method, and when dry cleaning is the only available option, dry pickup cloths rather than sweeping should be used (Document ID 1655, p. 13). The AFL–CIO recommended strengthening language in the final rule to prohibit dry housekeeping methods (Document ID 1689, p. 13). In addition, the AFL–CIO pointed out that under the DOE Chronic Beryllium Disease Prevention Program, 10 CFR 850.30 (Housekeeping), the use of dry methods for cleaning floors and surfaces in areas where beryllium is present is prohibited (Document ID 1689, p. 13). NABTU argued that there are no circumstances in which dry sweeping or brushing is necessary, that these practices are unsafe, and the use of such practices would trigger the need to decontaminate entire work areas before any work could be performed (Document ID 1679, p. 9). AFL–CIO additionally recommended that if dry cleaning methods are necessary due to feasibility issues, ''employers should be required to conduct an exposure assessment and provide a work process description'' (Document ID 1809, p. 2). OSHA has considered AFL–CIO's comment, and finds that the requirements for exposure assessment included in paragraph (d) of the final standards adequately address AFL–CIO's recommendation for exposure assessment. If an employer uses dry methods for cleaning beryllium-contaminated surfaces or areas, exposure from these methods should be included in exposure assessment, and re-assessment of exposures must be conducted when an employer adopts or changes dry methods because this could cause new or additional exposures.

In addition, OSHA has considered AFL–CIO's recommendation to require employers who use dry methods to provide a work process description, and finds that a work process description provides no clear benefit to workers using dry methods for cleaning. However, OSHA notes that paragraph (m) of this standard, which requires training for every employee who is or can reasonably be expected to be exposed to airborne beryllium, encompasses any use of dry cleaning methods in the demarcated beryllium work areas (or, in construction and shipyard settings, in beryllium-contaminated areas). Paragraph (m)(4) includes requirements that employees can demonstrate knowledge and understanding of hazards associated with beryllium exposure, operations that could result in airborne exposure, and measures employees can take to protect themselves from airborne exposure to and contact with beryllium. OSHA intends that employees who use dry methods for cleaning beryllium-contaminated surfaces or areas must be trained on the potential for airborne exposure during such cleaning, the hazards associated with such exposure, and the measures they can take to protect themselves, including the requirements of final paragraphs (j)(2)(iv) and (j)(2)(v) discussed later in this section. OSHA finds that these training requirements serve the purpose of providing information to employees regarding the work process, hazards and methods of protection related to dry sweeping, as OSHA believes the AFL–CIO's recommendation intended.

Several stakeholders cited problems with the use of HEPA-filtered vacuums or wet methods in particular circumstances, or noted specific circumstances where they believed the use of dry sweeping was necessary (Document ID 1676, p. 5; 1668, p. 6; 1807, pp. 2–3; 1756, Tr. 42–43). For example, as noted above, KCP argued that HEPA-filtered vacuums do not always work well in tight areas with recesses, crevices, and complex arrangements of equipment components. Materion commented that it generally prohibits the use of dry brushing or broom cleaning for cleaning but, in instances such as machining operations, the use of paint brushes to clean small chips is required. Materion also noted that some manufacturing processes may use dry brushes. It added that when it permits use of a brush, it performs an exposure assessment ''to help ensure the task is well controlled'' (Document ID 1807, Attachment 1, pp. 2–3). In addition, Jerrod Weaver from the Non-Ferrous Founders' Society (NFFS) testified that dry sweeping is ''not unusual'' in the foundry industry. He explained that the use of wet sweeping or other wet cleaning methods would be dangerous in foundries because when water hits molten metal, it can cause an explosion (Document ID 1756, Tr. 42–43).

Other stakeholders offered opinions on when the use of dry sweeping and dry brushing should be constrained. For example, the Southern Company argued that when dry sweeping does not result in exposure to beryllium above the action level, it should be considered a feasible cleaning option (Document ID 1668, p. 6). Similarly, Ameren Corporation stated that ''prohibiting dry sweeping should be based on employee exposure at or above the action level, not whether it's a beryllium work area'' (Document ID 1675, p. 6). As discussed in Section V, Health Effects, and Section VI, Risk Assessment, the best available scientific evidence suggests that adverse health effects such as beryllium sensitization and CBD can result from airborne exposures below the action level of 0.1 $\mu g/m^3$. In addition, OSHA does not see this suggestion as a practical solution where employers may feel obligated to perform exposure monitoring (or exposure assessments) every time housekeeping functions are performed. OSHA, as it has done in many other standards (*e.g.,* Chromium (VI), 29 CFR 1910.1026), continues to believe that a general prohibition is warranted considering the risk even at the action level.

After carefully reviewing the evidence in the record, OSHA finds that the use of dry sweeping and dry brushing can contribute to employee exposure. However, OSHA also finds convincing evidence that wet methods and HEPA-filtered vacuums may not be safe or effective in all situations in general industry. For example, wet sweeping in certain foundry work areas may be effective but is not safe because of the physical hazard created when water comes into contact with molten metal. Therefore, the Agency has retained both the prohibition on dry sweeping and dry brushing and the exceptions to that prohibition in paragraph (j)(2)(ii) of the final standard for general industry. Although OSHA has decided not to allow these methods based on a specific exposure level, OSHA has revised (j)(2)(ii) to clarify that employers may use dry sweeping or dry brushing to clean surfaces where HEPA-filtered vacuuming or other appropriate methods that minimize likelihood and level of exposure are not safe or effective. The proposed provision merely stated that employers could utilize the dry sweeping or brushing when HEPA-filtered vacuuming or the other methods were not ''effective.'' The Agency intended this term to encompass those situations in which HEPA-filtered vacuuming or the other chosen method would not accomplish the task at hand, *i.e.,* cleaning, and situations in which the use of HEPA-filtered vacuuming or the other methods were unsafe. OSHA has modified the text of the final rule to make this intent explicit.

In sum, final paragraph (j)(2)(ii) of the general industry standard states that the employer must 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 airborne exposure are not safe or effective. In situations where HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure would be ineffective, would cause damage, or would create a hazard in the workplace, the employer is not required to use these cleaning methods. The revised paragraph (j)(2)(ii) gives employers the necessary flexibility to use dry sweeping or dry brushing in such situations.

Although OSHA is allowing for dry sweeping and brushing, the Agency anticipates that the number of circumstances where these methods are necessary will be extremely limited. Where the employer uses dry sweeping or brushing, the employer must be able to demonstrate that HEPA-filtered vacuuming or other methods, such as wet sweeping, that minimize the likelihood or exposure are not safe or effective. To comply with the final rule, it is enough for employers to demonstrate that such cleaning methods are unsafe or ineffective—actually attempting the method on a particular worksite is unnecessary. However, as in the proposal, the employer bears the burden of providing that these methods are either unsafe or ineffective. OSHA has included a similar provision in final paragraph (j)(2)(ii) of the standards for construction and shipyards. Like the general industry provision, final paragraph (j)(2)(ii) of the standards for construction and shipyards disallows dry sweeping and dry brushing and includes an exception for circumstances where HEPA-filtered vacuuming, or other methods that minimize the likelihood of exposure are not safe or effective. Because the construction and shipyard standards do not include a provision establishing beryllium work areas, paragraph (j)(2)(i) of these standards requires the employer to ensure the use of HEPA-filter vacuuming or other methods that minimize the likelihood and level of airborne exposure when cleaning beryllium-contaminated areas. Paragraph (j)(2)(ii) states that the employer must not allow dry sweeping or brushing for cleaning in beryllium-contaminated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

OSHA notes that methods that minimize the likelihood and level of airborne exposure other than HEPA vacuuming may be appropriate for use in construction and shipyards. Use of wet methods, such as wet sweeping or wet shoveling, or using mechanical equipment to move wetted material, may be viable alternatives for cleaning large amounts of spent blasting media used in abrasive blasting operations.

Paragraph (j)(2)(iii) of the proposed rule would have prohibited the use of compressed air in cleaning beryllium-contaminated surfaces unless it was used in conjunction with a ventilation system designed to capture any resulting airborne beryllium. As OSHA indicated in the proposal, this provision was intended to limit airborne exposure by preventing the dispersal of beryllium into the air (80 FR 47796).

Stakeholders offered a number of comments on the use of compressed air. For example, NJH expressed support for this provision, and emphasized that compressed air should only be used in conjunction with a ventilation system (Document ID 1664, p. 7). Several commenters discussed the use of compressed air for cleaning and other processes. Materion commented that it generally prohibits the use of compressed air, but production operations may incorporate compressed air into manufacturing processes (Document ID 1807, Attachment 1, p. 3). Materion further commented that on the few occasions when it permits the use of compressed air, it performs an exposure assessment ''to help ensure the task is well controlled'' (Document ID 1807, Attachment 1, p. 3). Mr. Weaver, a representative of NFFS, testified that the use of compressed air in the foundry industry is ''not unusual'' (Document ID 1756, Tr. 42). He added that compressed air is useful for cleaning work surfaces (Document ID 1756, Tr. 42).

Some commenters, including the AFL–CIO, AWE, and United Automobile, Aerospace & Agricultural Implement Workers of America (UAW), objected to the use of compressed air for cleaning (Document ID 1615 p. 1; 1689, p. 13; 1693, p. 4). For example, the AFL–CIO noted that the DOE Chronic Beryllium Disease Prevention Program prohibits the use of compressed air and dry methods for cleaning floors and surfaces in areas where beryllium is present (Document ID 1689, p. 13). And, UAW stated that ''[c]apture hoods capable of reliably controlling particulates pushed by compressed air do not exist'' (Document ID 1693, p. 4).

OSHA has carefully considered these comments and finds that the use of compressed air to clean beryllium-contaminated surfaces may occasionally be necessary in general industry; particularly in manufacturing processes. Therefore, paragraph (j)(2)(iii) of the final standards allows for the use of compressed air to clean, but only where the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air. This provision is consistent with other recent substance-specific standards, such as the standard for respirable crystalline silica (29 CFR 1910.1053).

Because the standards for construction and shipyards do not include a provision establishing beryllium work areas, paragraph (j)(2)(iii) of these standards states that employers must not allow the use of compressed air for cleaning in beryllium-contaminated areas 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. OSHA intends this paragraph to apply when using compressed air to clean, for example, surfaces in work areas, tarps used for abrasive blasting enclosures, abrasive blasting equipment, and material designated for recycling or disposal in order to prevent dispersal of beryllium into workers' breathing zones.

OSHA recognizes that even the limited uses permitted under these standards of dry sweeping, dry brushing, and compressed air to clean can result in employee exposure to beryllium. To help mitigate the potential health risks, OSHA included a provision in the proposed rule to further protect employees who are using these cleaning methods. Under proposed paragraph (j)(2)(iv), where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer was required to provide respiratory protection and protective clothing and equipment and ensure that each employee use this protection in accordance with paragraphs (g) and (h) of this standard. As OSHA explained in the proposal, 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. See 80 FR 47796.

In its post-hearing comments, the AFL–CIO indicated support for this requirement. Specifically, the AFL–CIO argued that if dry housekeeping methods are permitted, ''workers should be provided a N–95 respirator—or a higher level of protection as required based on the exposure—and personal protective clothing'' (Document ID 1809, p. 2). After considering the record on this issue, OSHA concludes that requiring employers to provide respiratory protection and protective clothing and equipment in the limited situations where dry sweeping, brushing, or compressed air is used is essential to minimize exposure. Therefore, the Agency has included this provision in paragraph (j)(2)(iv) of the final standard for general industry. OSHA has also included a similar provision in paragraph (j)(2)(iv) of the final standards for construction and shipyards. Proposed paragraph (j)(2)(v) would have required employers to ensure that equipment used to clean beryllium from surfaces is handled and maintained in a manner that minimizes employee exposure and the re-entrainment of beryllium into the workplace environment. Re-entrainment occurs when particles that have settled on surfaces become airborne and remain suspended in the air. Beryllium particles that have been disturbed from surfaces and re-entrained contribute to employee's airborne beryllium exposure. Commenters generally supported the inclusion of this provision in the final rule. For example, Materion stated that preventing migration of beryllium requires ''looking at all those migratory pathways where material can move around in an operation,'' keeping the material as close to the source as possible, and keeping it off of people and off of surfaces (Document ID 1755, Tr. 150). The BHSC Task Group commented that HEPA vacuums ''must be maintained per the manufacturer's recommendations and oriented in such a manner that the exhaust side of the HEPA vacuum is not blowing hazardous dust into the work area'' (Document ID 1655, p. 11). Among other things, the BHSC Task Group said this provision would cause employers to ensure that cleaning and maintenance of HEPA-filtered vacuum equipment is done carefully to avoid exposure to beryllium. This provision would also require employers to ensure that filter changes and bag and waste disposal be performed in a manner that minimizes the risk of employee exposure to airborne beryllium and accidentally dispersing beryllium back into the workplace environment. After carefully reviewing these comments, OSHA finds that the provisions of paragraph (j)(2)(v) are necessary to the protection of employees from the adverse health effects associated with beryllium exposure, and has decided to include this provision (with minor changes) in paragraph (j)(2)(v) of the final standards. OSHA notes that paragraph (j)(2)(v) complements paragraph (f)(1)(i)(F), which requires employers to establish and implement a written exposure control plan that includes procedures for minimizing the migration of beryllium.

Paragraph (j)(3)(i) of the proposed rule would have required the employer to ensure that waste, debris, and materials visibly contaminated with beryllium and consigned for disposal were disposed of in sealed, impermeable enclosures, such as bags or containers. Paragraph (j)(3)(ii) would have further required such bags or containers to be labeled in accordance with paragraph (m)(3) of the proposed rule. Finally, paragraph (j)(3)(iii) of the proposed rule would have required materials designated for recycling that are visibly contaminated with beryllium to be either 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 the proposed rule.

OSHA intended these provisions to protect and inform workers who may be exposed to beryllium when handling waste or recycled materials. As discussed in the NPRM, alerting employers and employees who are involved in disposal to the potential hazards of beryllium exposure will better enable them to implement protective measures (80 FR 47771). OSHA reasoned that employers and employees should be similarly alerted if handling materials designated for recycling that have not been cleaned of visible particulate. The proposed requirements to use impermeable enclosures and/or clean materials of visible particulate were intended to reduce employees' risk of beryllium sensitization from dermal contact with beryllium in handling waste materials or materials designated for recycling. The options provided to employers in proposed paragraph (j)(3)(iii) were intended to allow employers flexibility to facilitate the recycling process.

In the NPRM, OSHA asked for feedback on proposed paragraph (j)(3) (80 FR 47574). A number of stakeholders responded. For example, NFFS argued that:

> [t]he sections regulating the manner in which waste product is labeled, packaged and shipped have already been regulated by both the [Environmental Protection Agency (EPA) (*e.g.* treatment, recycling and reuse of waste materials) and the DoT (*e.g.* shipping and placarding requirements, shipping containers for hazardous materials). Additionally, scrap and process coproducts in the non-ferrous foundry industry are treated as products and provided with appropriate labeling and SDS information as required by OSHA and the GHS/Hazard Communication standard. Requiring the non-ferrous casting industry to treat our process coproducts the same as waste and debris streams contradicts the requirements of the EPA and DoT regarding the identification, processing, packing, handling and transportation requirements of these materials'' (Document ID 1678, p. 5).

OSHA's requirement for warning labels must be consistent with the Hazard Communication Standard. Therefore, OSHA is not convinced that these are barriers to appropriately warning downstream users of beryllium contamination. In the Hazard Communication Standard (HCS), OSHA has carefully defined when other Agencies have jurisdiction for labeling requirements such as EPA and the Department of Transportation (DOT). Additionally, as OSHA further explainsed in the Summary and Explanation for paragraph (m), Communication of hazards, OSHA intends for the hazard communication requirements in the final standards to be substantively as consistent as possible with the HCS, while including additional specific requirements needed to protect employees exposed to beryllium, in order to avoid duplicative administrative burden on employers who must comply with both the HCS and this rule. To that end, OSHA allows employers to include the information required by these beryllium standards on the labels created to comply with the HCS. Thus, if NFFS's members are already supplying labels that conform to the HCS, they can add the beryllium-specific information to the existing labels. OSHA deems this information is warranted and would not contradict or cast doubt on the other information required on the label.

Some commenters, including USW, generally agreed with OSHA's proposed disposal and recycling requirements (*e.g.,* Document ID 1680, p. 6). Materion noted that a similar provision appeared in Materion and the USW's joint draft model standard (Document ID 1681, p. 12). In addition, Materion argued that OSHA should not require that all material to be recycled be decontaminated regardless of perceived surface cleanliness or require that all material disposed or discarded be in enclosures regardless of perceived surface cleanliness (Document ID 1681, p. 12). The company maintained that this requirement would be technologically and economically infeasible and extremely costly in many regards, particularly with regard to surface residue from abrasive blasting (Document ID 1681, p. 12). As discussed below, OSHA has decided for the construction and shipyard standards not to require decontamination or enclosure of materials designated for recycling or disposal due in part to concerns about the feasibility of such requirements in these sectors.

However, many other stakeholders argued in favor of cleaning or enclosing all beryllium-contaminated materials designated for recycling and enclosing such materials destined for disposal. For example, the BHSC Task Group, NJH, the National Institute for Occupational Safety and Health, Southern Company, NFFS, AIHA, NABTU, and ORCHSE disagreed with the proposal's use of the term ''visible'' when determining whether the provisions for containment and labeling included in proposed paragraph (j)(3) should apply to materials designated for recycling or disposal (*e.g.,* Document ID 1664, p. 7; 1671, Attachment 1, p. 7; 1668, p. 6; 1678, p. 5; 1686, p. 2; 1679, p. 10; 1691, p. 5). NJH and ORCHSE recommended that OSHA require all materials designated for recycling ''be decontaminated regardless of perceived surface cleanliness'' (Document ID 1664, p. 7; 1691, p. 5). NJH added that ''particles may not be visible to the naked eye'' and ''[d]econtaminating all materials ensures that exposure is minimized.'' It also recommended that materials designated for disposal be discarded per local hazardous waste regulations (Document ID 1664, p. 7). ORCHSE argued that for the protection of municipal and commercial disposal workers, materials discarded from beryllium work areas should be in bags or other containers (Document ID 1691, p. 5). NFFS asserted that ''visibly contaminated,'' ''cleaned to remove visible particulate,'' and ''sealed, impermeable enclosures'' are vague terms (Document ID 1678, p. 5).

As discussed previously in the Summary and Explanation for paragraph (h), Personal protective clothing and equipment, in this preamble, OSHA finds that ''visibly contaminated'' is a subjective trigger for most purposes in the final standards, and dermal contact with beryllium can cause beryllium sensitization even if the beryllium is not visible to the naked eye. OSHA therefore agrees with the commenters who criticized the use of ''visibly contaminated.'' (see, *e.g.* Document ID 1686, p. 1). The Agency intends that waste, debris, and materials be disposed of as specified in paragraph (j)(3) regardless of particulate visibility. However, OSHA does not intend for this requirement to extend to articles containing beryllium that are outside of the scope the standard, but to beryllium dust generated during processing. Similarly, materials designated for recycling must be cleaned to remove particulate or placed in sealed, impermeable enclosures, such as bags or containers, and labeled in accordance with paragraph (m)(3) of the standards, regardless of particulate visibility. To make this intention clear to employers, OSHA has removed the terms ''visibly'' and ''visible'' from paragraph (j)(3) of the final standard for general industry, and has replaced them with ''as free as practicable.'' OSHA discusses the meaning of ''as free as practicable'' and addresses comments on this phrase in this Summary and Explanation of paragraph (j), Housekeeping.

OSHA also agrees with ORCHSE that materials discarded from beryllium work areas in general industry should be in bags or other containers for the protection of municipal and commercial disposal workers (Document ID 1691, p. 5). However, OSHA disagrees with NFFS's comment that ''sealed, impermeable enclosures'' is problematically vague (Document ID 1678, p. 5). OSHA intends this term to be broad and the provision performance-oriented, so as to allow employers in a variety of industries flexibility to decide what type of enclosures (*e.g.,* bags or other containers) are best suited to their workplace and the nature of the beryllium-containing materials they are disposing or designating for reuse outside the facility. OSHA finds that the terms ''sealed'' and ''impermeable'' are commonly understood and should not cause employers confusion. OSHA intends these terms to mean that the enclosures selected should not allow the materials they contain to escape the enclosures under normal conditions of use.

In addition, the BHSC Task Group stated that certain beryllium-contaminated items should not be considered for recycling. According to the BHSC Task Group, only materials scheduled for use within beryllium regulated areas at other facilities, and not by the general public, should be recycled. The BHSC Task Group recommended surface wipe sampling to determine whether items should be decontaminated again and should be resampled prior to recycling; otherwise, if not meeting established limits, they should be disposed of according to ''appropriate waste management practices'' (Document ID 1655, p. 13). After careful consideration, OSHA has decided not to adopt the BHSC Task Group's suggestion. The Agency finds that the requirement to either clean and label or enclose and label beryllium-contaminated or containing materials designated for recycling should provide protection for later recipients of these items, as discussed in more detail below.

In addition to the previously discussed changes to the proposed rule, which were directly related to comments received by OSHA, the Agency has made several changes to better implement and communicate the intention of paragraph (j)(3). First, OSHA has modified the provisions of paragraph (j)(3) to state that it applies to materials that contain beryllium as well as materials contaminated with beryllium. OSHA finds that employers and employees who work with materials that were recycled or discarded by other facilities should be made aware of any beryllium-containing materials they process. Provisions to ensure awareness of beryllium in materials received from other facilities aid employers who otherwise might not know they are required to comply with the beryllium standard, and employees who otherwise might not be appropriately protected or adequately informed about potential beryllium exposures in their workplace.

Second, the requirements of (j)(3) regarding labeling materials designated for recycling have been modified. While the proposed rule required materials designated for recycling to be labeled in accordance with paragraph (m)(3) only if employers choose to enclose rather than clean them, the final standards require employers to label materials designated for recycling in either case. This modification, like OSHA's addition of the reference to beryllium-containing materials discussed above, ensures that employers and employees who work with materials that were recycled by other facilities are aware of any beryllium-containing materials they process. OSHA also modified the requirements of proposed paragraph (j)(3) for the construction and shipyard sectors. Paragraph (j)(3) of the construction and shipyard standards requires employers who transfer materials containing beryllium to another party for use or disposal to provide the recipient with a copy of the warning described in paragraph (m)(3) of the standards, for the same reasons this requirement was retained in the final general industry standard. However, employers in construction and shipyards are not required to place beryllium-containing materials in sealed, impermeable enclosures for use or disposal by other entities. OSHA made this change from paragraph (j)(3) of the general industry standard because the Agency believes that spent media from abrasive blasting operations will constitute the great majority of beryllium-containing materials designated for disposal or recycling in construction and shipyards and it is generally not practical for employers to enclose spent blasting media in sealed, impermeable bags or containers, because of the large volume of waste material generated in these operations OSHA finds that requiring employers in construction and shipyards to include a warning label on beryllium-containing materials designated for disposal or reuse, but not requiring them to seal such materials in impermeable enclosure, appropriately informs recipients of the potential hazards of handling the materials without imposing impractical containment requirements on these employers. In addition, these separate requirements for construction and shipyards are responsive to Materion's concern regarding the technological and economic feasibility of cleaning or enclosing materials contaminated with surface residue from abrasive blasting.

In summary, paragraph (j)(3)(i) of the final standard for general industry requires that items containing or contaminated with beryllium and designated for disposal be disposed of in sealed, impermeable bags or other sealed, impermeable containers, and requires these containers to be marked with warning labels in accordance with paragraph (m)(3) of the standards. Paragraph (j)(3)(ii) of the final standard for general industry requires materials designated for recycling that contain or are contaminated with beryllium be cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or to be placed in sealed, impermeable enclosures, such as bags or containers, that are so labeled. Paragraph (j)(3) of the construction and shipyard standards requires employers who transfer materials containing beryllium to another party for use or disposal to provide the recipient with a copy of the warning described in paragraph (m)(3) of these standards. The term ''use'' is intended to include recycling, as well as any other use the recipient may make of the beryllium-containing materials.

Finally, USW and Materion requested that OSHA make it clear that this provision does not apply to beryllium-containing scrap metals being reused within the facility (Document ID 1680, p. 6; 1661 p. 12). USW offered the example of copper beryllium machine turnings being utilized within the same facility. The union explained: ''In this example, it would not make sense to require cleaning or enclosing because they are either very clean to start with or have a thin coating of machining coolant. Requiring them to be cleaned before reuse in the facility might actually lead to greater worker exposures'' (Document ID 1680, p. 6).

OSHA did not intend to require employers to clean or enclose materials designated for reuse elsewhere in the same facility. Therefore, OSHA clarifies that paragraph (j)(3)(ii)'s requirements do not apply to scrap metals designated for reuse within the same facility.

(k) Medical Surveillance

Paragraph (k) of the final standards sets forth requirements for the medical surveillance provisions. The paragraph specifies which employees must be offered medical surveillance, as well as the frequency and content of medical examinations. It also sets forth the information that the licensed physician and CBD diagnostic center is to provide to the employee and employer. Many of the provisions in the final standards are substantively consistent with the 2012 joint draft recommended standard by Materion Corporation (Materion) and the United Steelworkers (USW) (Document ID 0754).

The purposes of medical surveillance for beryllium are: (1) To identify beryllium-related adverse health effects so that appropriate intervention measures can be taken; (2) to determine if an employee has any condition that might make him or her more sensitive to beryllium exposure; and (3) to determine the employee's fitness to use personal protective equipment such as respirators. The inclusion of medical surveillance in these final standards 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 the hazards addressed by the standard. Almost all other OSHA health standards, such as Chromium (VI) (29 CFR 1910.1026), Methylene Chloride (29 CFR 1910.1052), Cadmium (29 CFR 1910.1027), and Respirable Crystalline Silica (29 CFR 1910.1053), have also included medical surveillance requirements and OSHA finds that a medical surveillance requirement is appropriate for the beryllium standards because of the health risks resulting from exposure.

General. Consistent with the proposed standards, paragraph (k)(1)(i) of the final standards, requires employers to make medical surveillance available at no cost, and at a reasonable time and place, for each employee who meets a trigger for medical surveillance. As in previous OSHA standards, the ''no cost, and at a reasonable time and place'' requirement in the final beryllium standards is intended to encourage employee participation. Under this requirement, if participation requires travel away from the worksite, the employer will be required to bear the cost of travel, and employees will have to be paid for time spent taking medical examinations, including travel time.

OSHA clarifies that 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 final standard. Medical benefits provided to covered employees for covered beryllium diseases under the EEOICPA program are paid for by the federal government.

Employees covered by both the EEOICPA program and this final standard will not be required to choose between the programs. Rather, these dual-coverage employees may undergo medical examinations where they can receive the services and/or treatment covered under both programs. Treatment and services for covered beryllium disease of a covered beryllium employee under the EEOICPA program will be paid for by the federal government to the extent that the services provided are covered under the EEOICPA program. If this final standard requires services or treatment that are not covered by the EEOICPA program, the employer will be required to pay for these additional services.

OSHA received numerous comments during the public comment period regarding the inclusion of the medical surveillance provision for the beryllium standard. Most comments supported inclusion of medical screening or surveillance in the final beryllium standard, including those from National Safety Council (NSC), Materion, National Jewish Health (NJH), North America's Building Trades Union (NABTU), USW, the American College of Occupational and Environmental Medicine (ACOEM), the American Thoracic Society (ATS), the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), ORCHSE Strategies (ORCHSE), the National Institute of Occupational Safety and Health (NIOSH), and Public Citizen (*e.g.,* Document ID 1612, p. 3; 1661, p. 10; 1664, pp. 1, 8; 1679, pp. 11–12; 1681, pp. 13–14; 1685, p. 4; 1688, p. 2; 1689, pp. 13–14; 1691, Attachment 1, pp. 5–13; 1725, p. 33; 1964, p. 3). No commenters opposed the inclusion of a medical surveillance requirement.

In support of medical surveillance, the AFL–CIO and others indicated that medical surveillance is essential in screening for sensitization and preventing CBD (Document ID 1658, p. 3; 1689, p. 13). As noted in Section V, Health Effects, employees in the early stages of beryllium disease are often asymptomatic, and as a result, medical surveillance is critical to identify those employees who may benefit from interventions such as removal from exposure. ATS also commented that medical surveillance helps to identify those with sensitization and potentially CBD, as well as to define the risk of various work exposures, jobs, and tasks (Document ID 1688, p. 3). Commenter Evan Shoemaker said surveillance could ''inform employers that workplace controls and safeguards need updating'' (Document ID 1658, p. 3).

NJH commented that early disease detection, before symptoms occur, is the cornerstone for managing work-related disease (Document ID 1806, pp. 2–3). Studies highlighted by NJH show that medical surveillance could be important for identifying workers that might benefit from removal from exposure. Those studies show that rates of CBD development in sensitized workers are lower for short-term than long term workers (1.4% versus 9.1% in a study by Henneberger *et al.,* 2001, Document ID 1313). Other studies it cited showed improvements in gas exchange and radiography with decreased peak air concentrations of beryllium (Sprince *et al.,* 1978, as cited in Document ID 1806) and improvements in lung function in most patients after stopping beryllium exposures (Sood *et al.,* 2004, Document ID 1331).

NJH also submitted evidence showing that once employees do develop symptoms, the knowledge that the symptoms are caused by CBD could lead to treatment to improve outcome (Document ID 1806, pp. 2–3). NJH found that identifying disease at an early stage allows the use of inhaled corticosteroids for mild symptoms, which it found to be effective for reducing expected levels of lung function decline and improving lung function and cough in employees with lower lung function (Document ID 1811, Attachment 8). Early detection of beryllium disease and identification of employees who would benefit from oral corticosteroid treatment before fibrosis develops can result in regression of signs and symptoms and possibly prevent progression of the disease (Marchand-Adam *et al.,* 2008, Document ID 0370; 80 FR 47588). NJH concluded that early detection of beryllium disease allows for exposures to be decreased and symptoms to be treated at the earliest time point, which can result in decreases in medication doses, side effects, and risk of disease progression.

In paragraphs (k)(1)(i)(A)–(C) of the proposal, OSHA specified that employers must ''make medical surveillance as required by this paragraph available'' for each employee: (1) Who has worked in a regulated area for more than 30 days in the last 12 months; (2) 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; or (3) exposed to beryllium during an emergency. OSHA requested comments on these triggers and also presented alternatives to expand eligibility for medical surveillance to a broader group of employees (80 FR 47565, 47571, 47576). Under Regulatory Alternative #14, medical surveillance would have been available to employees who are exposed to beryllium above the proposed permissible exposure limit (PEL), including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would have expanded 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.[39] OSHA requested comment on these alternatives.

OSHA received numerous comments related to each of the proposed triggers. First, a number of stakeholders commented on the proposed trigger of working in a regulated area, *i.e.,* an area in the workplace where an employee's exposure exceeds, or can reasonably be expected to exceed, either the PEL or the short-term exposure limit (STEL), for more than 30 days in a 12-month period. For example, NIOSH argued that employees exposed above an action level of 0.1 μg/m³ for 30 days a year should be eligible for medical surveillance because ''substantial risk for [sensitization] and [chronic beryllium disease (CBD)] exists even at the [a]ction [l]evel'' (Document ID 1725, p. 32; 1755, Tr. 40). Public Citizen also advocated for an action level trigger based on risk of sensitization below the proposed PEL, arguing that triggering medical surveillance at the PEL, where significant risk remains, would be inconsistent with other OSHA health standards (Document ID 1964, p. 3). Public Citizen asked OSHA to consider the feasibility of making medical surveillance available to employees exposed at any level of beryllium for any duration of time (Document ID 1964, p. 3).

ATS and NJH supported expanding medical surveillance to all employees exposed to beryllium in beryllium work areas (above or below the action level), because of remaining significant risk at the PEL and because exposure monitoring is sporadic and may not always reflect higher exposures (Document ID 1664, p. 1; 1688, pp. 2, 4). Lisa Maier, M.D., from NJH further indicated that medical surveillance should be offered to these employees, regardless of the amount of time they spend in the work areas (Document ID 1756, Tr. 101–103). To support this recommendation, NJH referenced three studies (Henneberger *et al.,* 2001, Document ID 1313; Schuler *et al.,* 2005, (0919); and Taiwao et al, 2008, (1264)) that examine relationships between beryllium exposure and development of sensitization and CBD. NJH stated that exposure levels as low as 0.01 μg/m³ were associated with the development of sensitization and disease (Document ID 1720; 1756, Tr. 93–94). NJH also presented evidence showing that some individuals are genetically susceptible to developing beryllium sensitization and CBD (*e.g.,* Maier *et al.,* 2003, Document ID 0484; 1720, p. 3).

The National Supplemental Screening Program (NSSP), an organization that provides medical screening for former Department of Energy workers, and ACOEM supported an action level trigger, including for employees exposed for less than 30 days a year (Document ID 1677, p. 3; 1685, p. 4; 1756, Tr. 83–84). However, Lee Newman, MD, who represented ACOEM at the public hearing, testified that he personally felt that medical surveillance should be offered to anyone who has worked in a beryllium work area with measurable beryllium exposures (Document ID 1756, Tr. 84). Dr. Newman stated that his personal opinion was based upon his ''30 years of experience of working with people [exposed to beryllium'' and ''the studies that [he and his colleagues] have done'' (Document ID 1756, Tr. 84).

In contrast, Materion argued medical surveillance should be triggered by exposures above the PEL because Johnson *et al.* (2001) (Document ID 1505) concluded that 2.0 μg/m³ is sufficient to protect employees from developing clinical CBD, most recent scientific studies suggest that 0.2 μg/m³ is sufficient to protect against CBD, and the coke oven emissions standard and formaldehyde standards trigger medical surveillance at the PEL (Document ID 1661, p. 10). NGK Metals Corporation (NGK) was also opposed to setting the medical surveillance trigger at the action level, claiming that this would be burdensome, costly, and cause distress in employees who receive false positive results (Document ID 1663, p. 5). The Department of Defense (DOD) argued that medical surveillance should be triggered above the PEL to monitor the effectiveness of engineering controls and respiratory protection (Document ID 1684, Attachment 2, p. 1–9).

Based on the comments and other record evidence, OSHA finds that triggering medical surveillance at the action level of 0.1 μg/m³ better addresses residual significant risk and varying susceptibility of employees that can result in sensitization and CBD at lower exposure levels. OSHA disagrees

[39] OSHA also proposed Regulatory Alternative #21, which would have extended eligibility for medical surveillance 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, under Regulatory Alternative #21, all other provisions of the standard would have been in effect only for employers and employees that fell within the scope of the proposed rule. As discussed in the Summary and Explanation for paragraph (a), Scope and application, OSHA has decided to expand the proposal's scope to cover construction and shipyards. Therefore, Regulatory Alternative #21 is moot.

with Materion that a PEL trigger for medical surveillance is sufficiently protective because OSHA's own risk assessment shows significant risk remaining at the action level and PEL (see Section VI, Risk Assessment). In addition, OSHA is aware of individuals who are genetically predisposed to developing beryllium sensitization and CBD at beryllium levels that would not cause disease in other individuals (See Section V, Health Effects). As a result, OSHA is concerned that a PEL trigger is not sufficient to identify disease at an early stage in employees who are genetically susceptible to developing disease.

Moreover, OSHA finds that an action level trigger for medical surveillance encourages employers to maintain exposures below that level, which in turns provides reasonable assurance that exposures will not exceed the PEL on days when exposures are not measured (See Summary and Explanation for paragraphs (b), Definitions, and (d), Exposure Assessment). Therefore, an action level trigger in these standards is also appropriate to address stakeholder concerns, such as those raised by ATS and NJH, that exposure assessments might underestimate actual exposures due to variability in exposure levels or other factors.

Medical surveillance triggered by the action level is the norm for OSHA health standards. Materion noted two exceptions, observing that medical surveillance is not triggered at the action level in standards for formaldehyde and coke oven emissions. However, the Coke Oven Emissions standard does not include an action level, and the trigger for medical surveillance is employment in a regulated area, which is a discretely identified area on or around the coke oven battery, for at least 30 days a year (29 CFR 1910.1029). Significantly, the Coke Oven Emissions standard requires employers to assure that no employee in the regulated area is exposed to coke oven emissions at concentrations greater than the PEL (29 CFR 1910.1029(c)). Therefore, the trigger in the Coke Oven Emissions standard, which would include employees who are exposed to levels no higher than the PEL for at least 30 days per year, is more protective than a requirement that does not trigger medical surveillance until exposures exceed the PEL for 30 days a year. With the exception of formaldehyde, OSHA standards trigger medical surveillance at exposure levels at or below the PEL, and typically at the action level.

In sum, OSHA is persuaded that a lower trigger for medical surveillance is necessary because of the remaining health risk at both the action level and PEL. However, OSHA is not persuaded by those commenters who advocated triggering medical surveillance below the action level, in part, because nearly everyone in the general population is potentially exposed to beryllium as it is a naturally occurring compound in rocks and soil. In addition, the lack of conclusive evidence of non-industrial-related beryllium-related disease in the record suggests there is a level of exposure at which the risk of developing beryllium-related disease becomes negligible, but OSHA does not have information to precisely determine that level. As a result, offering medical surveillance to all potentially exposed employees would result in some low-risk employees receiving medical examinations when they have very little likelihood of benefiting from those examinations. OSHA is especially concerned by this because some medical examination components, such as the BeLPT, are invasive. In addition, OSHA finds that triggering surveillance at a level that is achievable for some employers is important because it provides employers with an incentive to keep exposures low to avoid the costs of providing medical surveillance. Employees benefit from those lower exposures because it reduces their risk of developing disease. Triggering medical surveillance at any level of exposure eliminates the incentive to keep exposures low and thus may be counterproductive to protecting employees.

In conclusion, an action level trigger is appropriate because it is a level at which risks are measurable and found to be lower than at the PEL, especially for employees who may be more susceptible to developing disease. The action level is achievable for many employers, and those employers are likely to maintain exposures below the action level to avoid the costs associated with exposure assessments and offering medical surveillance. Maintaining exposures below the action level also benefits employees because it decreases the chances that exposures will not exceed the PEL on a day on which exposure assessments are not conducted, and it lowers the risk of developing disease. For those reasons, an action level trigger is appropriate in the beryllium standard, consistent with the majority of OSHA standards.

Comments were also received on the 30-day duration as part of the medical surveillance trigger. NIOSH supported it (Document ID 1725, p. 32; 1755, Tr. 40). However, NJH, NSSP, and ACOEM did not support OSHA's proposed duration trigger of more than 30 days a year, stating that eligible employees exposed less than 30 days a year should be offered medical surveillance (Document ID 1664, p. 9; 1677, p. 3; 1685, p. 4).

Other stakeholders did not support extending medical surveillance to employees exposed for fewer than 30 days per year. For example, DOD commented that "[w]hile it is conceivable that workers can be sensitized to beryllium after brief exposures, it is unlikely that infrequent, brief exposures will cause either sensitization or chronic beryllium disease" (Document ID 1684, Attachment 2, p. 1–2).

After careful consideration of these comments and other evidence in the record, OSHA finds that maintaining the 30-day exposure-duration trigger is appropriate in the final standards because the Agency's risk assessment shows increasing risk of health effects from exposure at increasing cumulative exposures, which considers both exposure level and duration (See Section VI, Risk Assessment). OSHA finds that a 30-day trigger is a reasonable benchmark for capturing increasing risk from cumulative effects caused by repeated exposures. Including a 30-day exposure-duration trigger also maintains consistency with other OSHA standards, such as Chromium (VI) (29 CFR 1910.1026), Cadmium (29 CFR 1910.1027), Lead (29 CFR 1910.1025), Asbestos (29 CFR 1910.1001), and Respirable Crystalline Silica (29 CFR 1910.1053). As discussed in more detail below, OSHA notes that the triggers in final paragraphs (k)(1)(i)(B) and (C) may address employees who could be at risk, even though they may not have had repeated exposures.

Therefore, OSHA has decided to revise the first proposed medical surveillance trigger to require the offering of medical surveillance based on exposures at or above the action level, rather than the PEL (i.e, work in a regulated area). But the Agency will retain the 30-day-per-year-exposure-duration trigger. In addition, OSHA has chosen to revise the proposed trigger to require employers to make medical surveillance available to each employee "who is or is reasonably expected to be exposed . . . for more than 30 days a year," rather than waiting for the 30th day of exposure to occur. OSHA made this revision because the proposed provision, in combination with paragraph (k)(2)(i)(A), may not have resulted in timely medical examinations for new employees who are not exposed to beryllium concentrations above the action level every day. For example, a new employee exposed to beryllium once per week would not receive a medical examination until being employed for up to 34 weeks. As noted below, several stakeholders commented that a medical exam should be offered before or within 30 days of placement (*e.g.,* Document ID 1664, p. 7; 1685, p. 4, 1689, p. 13). OSHA agrees that a medical examination should be conducted shortly after placement to allow the employee to find out if he or she has any condition that may make him or her more sensitive to beryllium exposure. For these reasons, paragraph (k)(1)(i)(A) of the final standards require that employers make medical surveillance available to each employee who is or is reasonably expected to be exposed above the action level for more than 30 days per year.

The proposal's ''regulated area'' trigger corresponded to setting the trigger at the PEL, and so has been superseded by the final rule's action level trigger. The elimination of the ''regulated area'' trigger may also affect whether employees exposed above the short-term exposure limit (STEL) receive medical surveillance. As noted above and discussed extensively in the Summary and Explanation for paragraph (e), the proposed standard defined the term ''regulated area'' to mean 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). Proposed paragraphs (c) and (e) made clear that this definition included both the proposed 8-hour TWA PEL and the proposed STEL. Because the revised trigger in final paragraph (k)(1)(i)(A) focuses on the action level, rather than working in a regulated area, it does not directly require medical surveillance for employees who are exposed above the STEL, provided their airborne exposure levels do not exceed the action level for more than 30 days per year.

However, as explained in Chapter IV–Section 15 of the Final Economic Analysis and discussed in the Summary and Explanation for paragraph (c), Permissible Exposure Limits (PELs), the occurrence of one or more short-term exposures to elevated airborne concentration during a work shift can substantially increase a worker's 8-hour TWA exposure. For example, the TWA exposure of a worker who is exposed to a background level at the final action level of 0.1 $\mu g/m^3$ will be 0.16 $\mu g/m^3$ if that worker is exposed to a single 15-minute period at an exposure level just above 2.0 $\mu g/m^3$, the final STEL. Therefore, OSHA finds that the revised action level trigger will frequently address the STEL component of the proposed trigger because when exposures exceed the STEL, it is very likely that the action level will also be exceeded, thus triggering medical surveillance.

Signs or Symptoms. Proposed paragraph (k)(1)(i)(B)) required employers to ''make medical surveillance as required by this paragraph available'' to 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. As OSHA explained in the proposal, a sign-or-symptoms trigger is necessary, in part, because 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. A signs-or-symptoms trigger was also included in the draft standard submitted by Materion and USW (Document ID 0754).

One commenter, ORCHSE, argued that a symptom trigger should only apply to confirmed positive, *i.e.,* sensitized, employees because the types of symptoms listed are non-specific for CBD and would require employers to offer medical surveillance to employees who were never exposed to beryllium (Document ID 1691, Attachment 1, pp. 5–6). However, the majority of the stakeholders who opined on the signs-or-symptoms trigger supported its inclusion in the final rule. For example, NJH, ATS, and NIOSH supported a symptom trigger for medical surveillance (Document ID 1664, p. 4, 8; 1688, p. 3; 1725, p. 32). ACOEM and NJH indicated that skin symptoms should trigger medical examinations for employees exposed to beryllium (Document ID 1664, p. 4; 1685, p. 4). NJH and ACOEM also offered examples of specific symptoms or signs of skin disease, including rashes or nodules and dermatitis that is unresponsive to treatment but responsive to removal from exposure (Document ID 1664, pp. 4, 8; 1688, p. 3; 1725, p. 32). In addition, United Kingdom defense contractor, AWE, indicated that it allows its employees with ''insignificant likelihood of exposure'' to undergo a medical examination if they report symptoms (Document ID 1651, p. 10).

After carefully considering these comments, OSHA reaffirms its preliminary finding that the proposed signs-or-symptoms trigger serves as a valuable complement to the use of airborne exposure triggers as a mechanism for initiating medical surveillance. A signs-or-symptoms trigger is appropriate for employees covered by the standard because the risk of material impairment of health remains significant at the action level (see Section VI, Risk Assessment). Consequently, even employees exposed at the action level for fewer than 30 days in a year may be at risk of developing CBD and other beryllium-related diseases and adverse health effects. 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. By requiring covered employers to make a medical exam available when an employee exhibits signs or symptoms, the final standard protects all employees who may have developed CBD, including employees who have been exposed to beryllium in an emergency or for less than 30 days above the action level.

OSHA also finds that signs or symptoms of beryllium-related health effects other than CBD should also trigger medical surveillance (see Section V, Health Effects). As noted by NJH and ACOEM, these signs or symptoms can be indicative of beryllium-related skin disease or a sign of exposure that could lead to sensitization. For example, dermatitis that is unresponsive to treatment but responsive to removal from exposure may be a sign of a beryllium-related health effect. Other skin symptoms, such as reddened, elevated or fluid-filled lesions following contact with soluble beryllium compounds and ulceration or granulomas from soluble or poorly soluble beryllium compounds entering through cuts or scrapes, can also be a sign of a beryllium-related health effect (See Section V, Health Effects). Therefore, OSHA has revised paragraph (k)(1)(i)(B) to include signs or symptoms of other beryllium-related health effects.

OSHA disagrees with ORCHSE's recommendation that the final standards apply this trigger only to employees who have been confirmed positive, *i.e.,* are sensitized, for several reasons. First, limiting the sign-or-symptoms trigger in this way could prevent sensitized employees from finding out that they are sensitized. For example, as noted above, individuals who are genetically predisposed can develop beryllium sensitization and CBD at beryllium levels that would not cause disease in other individuals. Such an employee could conceivably become sensitized and develop CBD without meeting the action level or 30-day exposure trigger. Because this hypothetical employee would not otherwise be entitled to medical surveillance, he or she might not know that they are sensitized. If this employee began suffering from signs or symptoms of CBD, he or she would not be entitled to medical surveillance under ORCHSE's proposal, precisely because they are not entitled to the BeLPT that would detect sensitization and then entitle them to further medical surveillance.

Second, as discussed in more detail below, under the final standards, employers do not automatically find out whether their employees have been confirmed positive. If an employee chooses not to inform his or her employer of this fact, the employer may never find out. See paragraphs (k)(6) and (k)(7) of the final standards.

Third, OSHA recognizes that signs and symptoms associated with adverse health effects of beryllium such as CBD and skin sensitization may be non-specific (*i.e.,* they may be caused by factors other than beryllium exposure). However, it is important to realize the context in which signs and symptoms are expected to be used in medical surveillance. Signs and symptoms are generally expected to be self-reported by employees who could potentially be exposed to beryllium and as such are not intended to serve as a means for diagnosing adverse health effects or determining their causality. Rather, they serve as a useful signal that an employee may be suffering from a beryllium exposure-related health effect. Once these signals are recognized, the employee should be offered medical surveillance and see a PLHCP who can, with sufficient information about the employee's duties, potential exposures, and medical and work histories (as required by this standard and discussed later), make determinations about the beryllium-related effects, provide medical treatment, and make other referrals or recommendations where necessary.

However, ORCHSE's comment does raise the concern that the non-specific signs and symptoms listed in the proposal, *i.e.,* shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue, might cause the employer to offer medical surveillance to employees experiencing signs or symptoms that are not related to beryllium exposure. OSHA understands that many of these non-specific symptoms can have various causes unrelated to beryllium exposure. For example, a dry cough could be related to a respiratory infection or allergies. On the other hand, the symptoms listed in the proposal can also be symptoms of CBD where they are recurring or persistent. Therefore, OSHA has removed the specific examples of signs or symptoms of CBD that were included in the proposal. OSHA finds that removing these examples makes it less likely that this will be misinterpreted to require medical surveillance for employees experiencing signs or symptoms not related to beryllium exposure. OSHA also clarifies that signs or symptoms that are indicative of CBD or other beryllium-related effects are typically persistent or recurring.

Finally, OSHA emphasizes that although this provision requires employers to offer medical surveillance if persistent or recurring symptoms related to CBD or other beryllium-related health effects are reported to or observed by the employer (*e.g.,* if an employee ''shows'' a persistent cough), it is not intended to force employers to survey their workforce, make diagnoses, or determine causality. Self-reporting by employees is supported by the training required under paragraph (m)(4)(ii) on the health hazards of beryllium and the signs and symptoms of CBD, and the medical surveillance and medical removal requirements of the final standard in paragraphs (k) and (l). Section 11(c) of the OSH Act gives employees the right to report suspected work-related health effects and prohibits employers from retaliating against employees for exercising this right. Separately, OSHA's Recordkeeping Rule gives employees the right to report work-related illnesses such as CBD or other beryllium-related health effects, and Section 1904.35(b)(1)(iv) of that rule prohibits retaliation against employees for reporting these health effects.

Emergencies. Proposed paragraph (k)(1)(i)(C) required employers to offer medical surveillance to employees exposed during an emergency. Although an emergency trigger for medical surveillance was not included in the joint draft recommended standard by Materion and USW, none of the comments on the proposal objected to its inclusion in the final rule (Document ID 0754). At least one commenter, NJH, supported a trigger for employees exposed in an emergency (Document ID 1664, p. 4).

OSHA agrees with NJH that such a trigger is appropriate because emergency situations involve uncontrolled releases of airborne beryllium, and the significant exposures that can occur in these situations justify a requirement for medical surveillance. Therefore, OSHA has decided to include this provision as part of the final standards in paragraph (k)(1)(i)(C). As in the proposal, medical surveillance triggered by airborne exposures in emergency situations must be offered regardless of the airborne concentrations of beryllium to which these employees are routinely exposed in the workplace. The requirement for medical examinations after airborne 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), 1,3-Butadiene (29 CFR 1910.1051), and Methylene Chloride (29 CFR 1910.1052).

Periodic medical surveillance. As noted above, OSHA asked stakeholders to opine on which employees should be included in medical surveillance and, as discussed in more detail below, on the appropriate frequency for examinations (*e.g.,* 80 FR 47574, 47541). Several stakeholders, including Ameren Corporation (Ameren), NSSP, and ATS, submitted pre-hearing comments supporting the provision of continuing medical surveillance to employees who are confirmed positive (Document ID 1675, p. 16; 1677, p. 6; 1688, p. 3). For example, ATS commented that once an employee is sensitized, continued medical surveillance should be offered to determine if progression to CBD occurs (Document ID 1688, p. 3). Similarly, Ameren commented that sensitized employees should have the opportunity for further surveillance based on the recommendations of a pulmonologist (Document ID 1677, p. 6).

OSHA agrees that an employee who is confirmed positive should continue to receive medical surveillance to determine if progression from sensitization to CBD occurs and to monitor the severity of disease if progression does occur. As discussed below, the standards provide for medical surveillance every 2 years in certain cases, such as when the employee continues to be exposed above the action level for more than 30 days a year, when the employee continues to have signs or symptoms of CBD or other beryllium-related health effects, or when an employee is exposed to beryllium during an emergency. However, under these first three triggers, periodic surveillance would end if an employee no longer met those triggers. Thus, an employee who was confirmed positive and no longer meets these triggers might not qualify for medical surveillance again until he or she develops signs or symptoms of disease. This gap in coverage is especially concerning considering the potentially long lag time between sensitization and the development of CBD and the benefits of early detection (see Section V, Health Effects).

To allow for continued medical surveillance to this limited group of high risk employees who would not otherwise be eligible for periodic examinations, OSHA has added final paragraph (k)(1)(i)(D), which requires that medical surveillance be made available when the most recent written medical opinion to the employer recommends continued medical surveillance. Under final paragraphs (k)(6) and (k)(7), the written opinion must contain a recommendation for continued periodic medical surveillance if the employee is confirmed positive or diagnosed with CBD, and the employee provides written authorization. Under these provisions, the employer will only receive the recommendation for continued periodic medical surveillance with the employee's written consent. However, even where the employee provides his or her written consent, the written opinion must not include any specific findings or diagnoses that led to the recommendation for continued surveillance. Instead, the licensed physician or CBD diagnostic center's written opinion would simply recommend continued periodic medical surveillance. As discussed in more detail below, OSHA chose this method to convey the need for continued medical evaluations for employees who are confirmed positive or diagnosed with CBD, while protecting the employee's privacy by not revealing to the employer the specific finding that triggered the recommendation for continuing medical examinations.

OSHA notes that although this requirement was not included in either the proposed standard or the joint draft recommended standard by Materion and USW (Document ID 0754), proposed paragraph (k)(1)(i)(D) (discussed below) would have allowed for limited medical surveillance (*i.e.,* low dose computerized tomography (LDCT)) for certain high risk individuals.

Low dose computerized tomography (LDCT). The proposal included a trigger to provide LDCT to some employees who met certain criteria regarding exposure levels, exposure duration, and age. The requirement is now included under paragraph (k)(3)(ii)(F) as a test that can be selected by the PLHCP for employees based on certain risk factors. A full discussion of LDCT scans and the reasons for this change is included below under the discussion of medical examination contents.

Licensed physicians. Proposed paragraph (k)(1)(ii) required that the employer ensure that all medical examinations and procedures required by the standard are performed by or under the direction of a licensed physician. OSHA chose to require licensed physicians, as opposed to the broader category of PLHCPs, to oversee medical surveillance in this standard, and to provide certain services required by this standard (see, *e.g.,* proposed 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 Respirable Crystalline Silica (29 CFR 1910.1053)). As explained in the NPRM, OSHA proposed that a licensed physician perform some of the requirements of paragraph (k) in response to Materion and USW's 2012 joint draft recommended standard (80 FR 47797). OSHA preliminarily found that this requirement struck 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, the Agency specifically requested stakeholder comment on this proposed requirement (80 FR 47575, 47797).

OSHA received comments on this subject from a variety of stakeholders, including public health officials and representatives from industry and labor. ATS stated that due to the complex nature of CBD and sensitization, including multi-organ involvement and atypical presentations, all medical procedures should be carried out by or under the direction a licensed physician (Document ID 1688, p. 4). Similar support for medical procedures to be carried out by or under the direction of a licensed physician was expressed by NJH, Ameren, NSSP, NIOSH, and ACOEM (Document ID 1664, p. 8; 1675, p. 18; 1677, p. 7; 1755, Tr. 27; 1756, Tr. 82). Materion commented that in the joint draft recommended standard, Materion and USW intended for a licensed physician to perform certain critical aspects of medical surveillance such as diagnosis and preparation of the written medical opinion (Document ID 1661, Attachment 2, p. 7). NABTU commented that medical and nursing experts supervise medical screening of Department of Energy workers in a program that is administered by the Center for Construction Research and Training (CPWR) (Document ID 1679, p. 10).

OSHA recognizes that the requirement for a licensed physician to provide oversight and some services required under the standard departs from policy in recent standards, such as Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053). In the recently promulgated Respirable Crystalline Silica standard, OSHA allowed medical services to be provided by a PLHCP, defined as an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health services required under the rule (81 FR 16818). To ensure competency while increasing flexibility for employers, OSHA found it appropriate to allow any healthcare professional to perform medical examinations and procedures made available under the standard when he or she is licensed by state law to provide those services. In the case of respirable crystalline silica, such a decision was justified because the record did not provide convincing evidence that such a requirement was not appropriate, and some stakeholders expressed concerns that healthcare professionals might be limited in certain geographical locations (81 FR 16818).

In contrast to the silica rulemaking record, the beryllium rulemaking record shows support for a licensed physician to oversee and perform certain functions of medical surveillance and lacks evidence showing that licensed physicians may be limited in certain areas. As a result, OSHA is requiring in final paragraph (k)(1)(ii) that the employer ensure that all medical examinations and procedures required by the standard are performed by, or under the direction of, a licensed physician. In the case of the beryllium standard, OSHA finds 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). Therefore, final paragraph (k)(1)(ii) requires the employer to ensure that all medical examinations and procedures required by the standard are performed by, or under the direction of a licensed physician.

Frequency. Proposed paragraph (k)(2) specified when and how frequently medical examinations were to be offered to those employees covered by the medical surveillance program. Under proposed paragraph (k)(2)(i)(A), employers would have been required to provide each employee with a medical examination within 30 days after determining that the employee had worked in a regulated area for more than 30 days in the past 12 months, unless the employee had received a medical examination provided in accordance with this standard within the previous 12 months. Under proposed paragraphs (k)(2)(i)(B) employers would have been required to provide medical examinations to employees exposed to beryllium during an emergency, and to those showing signs or symptoms of CBD, within 30 days of the employer becoming aware that these employees met those criteria.

As noted above, a number of stakeholders supported a baseline examination. For example, ACOEM recommended that the criteria for inclusion in the medical surveillance program be revised to clearly indicate a baseline examination and BeLPT for employees assigned to regulated areas (Document ID 1685, p. 4). Similarly, NABTU and AFL–CIO commented that medical screening of employees should be done before they start working in a beryllium area (Document ID 1679, p. 12; 1689, p. 13). NJH also recommended a BeLPT at the beginning of employment but stated that some of their clients do the exams within 30 days to not influence hiring practices (Document ID 1664, p. 7). Ameren and NSSP commented that 30 days from initial assignment is a reasonable period to provide an examination; however, NSSP recommended a baseline BeLPT at the time of employment, while Ameren indicated that a baseline BeLPT should be at the employer's discretion based on employment history (Document ID 1675, pp. 15–16; 1677, p. 6). These comments run contrary to the proposed requirement allowing employers to withhold offering medical surveillance until after more than 30 days of exposure.

OSHA is persuaded that it is appropriate to trigger medical surveillance within 30 days after making the determinations described in final paragraphs (k)(2)(i)(A) and (B). As a result of changes made to final paragraph (k)(1)(i)(A), the initial exam required under final paragraph (k)(2)(i)(A) is now triggered within 30 days after the employer determines that the employee is or is reasonably expected to be exposed at or above the action level for more than 30 days of year. This revised trigger for medical surveillance in the final beryllium standard is consistent with Ameren and NSSP recommendations to provide an exam within 30 days of initial assignment. OSHA finds that it is a reasonable period to offer medical surveillance because new employees are not likely to experience signs of beryllium exposure during that time, and it provides employers with administrative convenience because it gives them time to make the appointment, in addition to maintaining consistency with most OSHA standards, such as the Respirable Crystalline Silica (29 CFR 1910.1053). In response to Ameren's comment, OSHA acknowledges that an employee who was not previously exposed to beryllium would not be at risk for sensitization. However, an employer may not have a complete occupational exposure history to rule out prior beryllium exposure of the employee, and the employee may not be aware that he or she was exposed. OSHA considers a baseline BeLPT within 30 days of when the employer determines that the employee is reasonably expected to be exposed for more than 30 days a year to be prudent to rule out sensitization in an employee who may have previously been exposed to beryllium unknowingly. Providing a baseline examination is also consistent with the joint draft recommended standard by Materion and USW, which recommended that medical surveillance including a BeLPT be made available to employees who are expected to meet the trigger for medical surveillance (Document ID 0754, pp. 7–8).

Final paragraph (k)(2)(i)(A) also differs from the proposal in that in the proposed paragraph the employer did not have to offer an examination if the employee had received an equivalent examination within the last 12 months. In the final rule, this was increased to two years to align that provision with the frequency of periodic examinations, which is every two years in the final standards. The reason why frequency of periodic examinations was changed from every year to every two years is discussed below. In sum, paragraph (k)(2)(i)(A) requires the employer to make a medical examination available to employees who meet the criteria of paragraph (k)(1)(i)(A), unless the employee received a medical examination provided in accordance with the standard, within the last two years.

As noted above, proposed paragraph (k)(2)(i)(B) would have required 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 proposed paragraph (k)(1)(i)(B) or (C), regardless of whether these employees received an exam in the previous 2 years. OSHA is not aware of any comments from stakeholders about the time period to offer medical examinations following a report of symptoms or exposure in an emergency; however the 30-day requirement to offer medical examinations to employees experiencing signs or symptoms was included in the joint draft proposal by Materion and USW (Document ID 0754, p. 7). Moreover, OSHA finds that the 30-day trigger is administratively convenient for post-emergency surveillance as well as after CBD signs or symptoms (and other beryllium-related effects like rashes) are reported, insofar as it is consistent with other OSHA standards and with other triggers in the beryllium standards. OSHA is therefore retaining paragraph (k)(2)(i)(B), as proposed, in the final rule. Proposed paragraph (k)(2)(ii) would have required employers to provide an examination annually (after the first examination is made available) to employees who continue to meet the criteria of proposed paragraph (k)(1)(i)(A) or (B). The Agency requested comment on the frequency of this medical surveillance (80 FR 47574).

Ameren agreed with the proposed frequency of annual examinations, and USW commented that the proposed medical surveillance requirements would allow for timely detection of sensitization and health outcomes (Document ID 1675, p. 16; 1681, p. 13). AWE commented that it offers annual spirometry testing to its employees with ''significant likelihood for exposure'' (Document ID 1615, p. 10). DOD also provides annual medical surveillance for its beryllium-exposed employees (Document ID 1684, Attachment 2, p. 1–5). NIOSH commented that OSHA should require an annual questionnaire for symptoms (Document ID 1725, p. 32). However, other commenters argued that annual surveillance was not routinely required. For example, NJH and ACOEM supported offering medical examinations to eligible employees every two years (Document ID 1664, p. 4; 1685, p. 4); NJH indicated that after initial testing, biennial medical surveillance is adequate to identify any new cases of sensitization that may develop in the workplace. In addition, NJH, NSSP, and NGK were opposed to annual BeLPTs (Document ID 1664, p. 4; 1677, p. 3; 1663, p. 5). ATS and NIOSH recommended examinations every 1 to 3 years for sensitized individuals to determine if progression is occurring (Document ID 1688, p. 3; 1725, pp. 2, 32). Finally, NABTU agreed with the proposed frequency for screening but noted that Department of Energy workers participating in a medical screening program administered by CPWR are examined every three years (Document ID 1679, pp. 10–12).

After careful consideration of the record on this issue, OSHA agrees with commenters like NJH who recommended that a BeLPT every two years is appropriate. In addition, based on its review of beryllium health effects, which shows that CBD generally progresses slowly (See Section V, Health Effects), the Agency finds that a two-year frequency period is also appropriate for the remaining parts of the medical examinations. This two-year period is consistent with NJH's suggestion to offer medical examinations biennially after the initial exam and with ATS and NIOSH's recommendations for examinations every 1 to 3 years for sensitized individuals. However, OSHA disagrees with NIOSH that a yearly questionnaire for symptoms is needed because the standards already permit employees to receive medical surveillance by self-reporting signs and symptoms of CBD.

To align the requirements for BeLPTs with the medical and work history, the physical examination, and pulmonary function testing, OSHA is requiring that all those components of the examination be offered every two years. OSHA concludes that this approach is more convenient for employers to administer, while maintaining adequate protection of employees. Offering examinations every two years accomplishes the main goals of medical surveillance for employees exposed to beryllium, which are to detect beryllium sensitization before employees develop CBD, and to diagnose CBD and other adverse health effects at an early stage. Requiring examinations to be offered every two years also strikes a reasonable balance between the resources required to provide surveillance and the need to diagnose health effects at an early stage to allow for interventions.

In addition, OSHA finds that it is appropriate to extend the requirement for biennial surveillance under final paragraph (k)(2)(ii) for employees who continue to meet the criteria of final paragraph (k)(1)(i)(D), *i.e.,* each employee whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance. As discussed above, the recommendation for continued medical surveillance is based on a confirmed positive finding or a diagnosis of CBD. Employees such as those who are confirmed positive benefit from periodic surveillance to determine if sensitization progresses to CBD and monitor possible CBD progression.

Finally, OSHA revised proposed paragraph (k)(2)(ii) to specify that medical examinations were to be made available ''at least'' every two years. This change clarifies OSHA's intent that the employer need not wait precisely two years to make medical surveillance available to employees who continue to meet the criteria of (k)(1)(A), (B), or (D) of this standard.

Under the final standards, employees exposed in an emergency, who are covered by paragraph (k)(1)(i)(C), are not included in the biennial examination requirement unless they also meet the criteria of paragraph (k)(1)(i)(A) or (B), because OSHA expects that most effects of airborne exposure will be detected during the medical examination provided within 30 days of the emergency, pursuant to paragraph (k)(2)(i)(A). This is consistent with the proposal. An exception to this is beryllium sensitization, which OSHA finds may result from exposure in an emergency, but may not be detected within 30 days of the emergency. OSHA received no comments on this issue. To address possible delayed sensitization in employees exposed in an emergency, final paragraph (k)(3)(ii)(E) requires biennial BeLPTs for employees who have not been confirmed positive, including those exposed in emergencies. This paragraph is discussed in more detail later in this section of the preamble.

Proposed paragraph (k)(2)(iii) required the employer to offer a medical examination at the termination of employment, if the departing employee met any of the criteria of proposed paragraphs (k)(1)(i)(A), (B), or (C) at the time the employee's employment was terminated. This proposed requirement was waived if the employer provided the departing employee with an exam during the six months prior to the date of termination. OSHA explained that the provision of an exam at termination was intended to ensure that no employee terminates employment while carrying a detectable, but undiagnosed, health condition related to beryllium exposure (80 FR 47798). A similar provision was included in the draft joint recommended standard by Materion and USW (Document ID 0754, p. 8).

Commenters generally supported the inclusion of this provision in the final standard. NJH and NSSP agreed with the proposed requirement to perform a BeLPT at the time of termination and Ameren stated that a BeLPT is not needed if the employee was tested within the last six months (Document ID 1664, p. 7; 1675, p. 16; 1677, p. 6). However, NABTU indicated that the BeLPT need not be repeated if the employee's last test was done within the previous 60 days because the experience of their medical professionals indicates that a different test result is unlikely to occur within that time period (Document ID 1805, Attachment 1, p. 5). After considering these comments, OSHA reaffirms its preliminary decision to require employers to make medical surveillance available at the time of termination to eligible employers. Final paragraph (k)(2)(iii) requires the employer to make a medical examination available to each employee who meets the criteria of final paragraph (k)(1)(i)—the action level/30-day-exposure based trigger, shows signs or symptoms of CBD, or is exposed during an emergency—at the termination of employment, unless the employee received an exam meeting the requirements of the standards within the last 6 months. OSHA also finds that it is appropriate to extend the requirement to employees who meet the criteria of final paragraph (k)(1)(i)(D), *i.e.,* each employee whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance. Like the other employees covered by this provision, those employees could potentially have beryllium-related disease that was not present or detectable at their last examination or that has advanced.

As indicated in the proposal, OSHA finds that providing a BeLPT at the time of termination, unless the employee was tested within the last six months or the employee was confirmed positive, is important to ensure that no employee is unknowingly sensitized at the time he or she leaves the job. In addition, OSHA finds that the other components of the examination, such as a medical and work history, the physical examination, and lung function testing are also important to determine if an employee may have developed physical signs of disease or if existing disease may have progressed since the last examination. OSHA disagrees with NABTU that another BeLPT should be conducted if the employee's last BeLPT was done more than two months ago. Requiring another BeLPT if the employee has not had one within the past six months is an abundantly cautious approach considering that public health officials, such as NJH, recommend a BeLPT every two years, since that time period is considered adequate to identify any new cases of sensitization that may develop in the workplace (Document ID 1664, p. 4). Therefore, OSHA concludes that offering a BeLPT at termination, if the employee has not had one in the past six months, is an approach that adequately protects the employee's health.

Contents of Examination. Proposed paragraph (k)(3) detailed the contents of the examination. Proposed paragraph (k)(3)(i) required the employer to ensure that the PLHCP advised 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. As OSHA explained in the proposal, the 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, such as radiation risks from CT scans for lung cancer (80 FR 47798). The employer must make sure the PLHCP communicates those risks to the employee. This requirement was included in the draft proposed rule submitted to the Agency by Materion and USW (Document ID 0754, p. 8). In the absence of public comments on this issue, the requirement remains substantively unchanged from the proposal in final paragraph (k)(3)(i). OSHA did, however, make one minor change to clarify the intent of this provision. Under the final standards, the PLHCP who advises the employee must be the PLCHP who is conducting the examination. Proposed paragraphs (k)(3)(ii)(A)–(D) specified that the medical examination must consist of: A medical and work history, with emphasis on past and present exposure, smoking history, and any history of respiratory dysfunction; a physical examination with emphasis on the respiratory system; a physical examination for skin breaks and wounds; and a pulmonary function test, performed in accordance with guidelines established by the American Thoracic Society including forced vital capacity (FVC) and a forced expiratory volume in one second (FEV_1). Exam contents under the proposal also included a standardized BeLPT and, in some cases, a computerized tomography (CT) scan, both of which are discussed in more detail below. OSHA asked for comment on the contents of the medical surveillance exam in the proposal (80 FR 47574). Among other things, the Agency asked whether the required tests were appropriate, if additional tests should be included, and whether the skin should be examined for signs and symptoms of beryllium exposure or other medical issues, as well as for breaks and wounds. Stakeholders from the medical community and industry responded to OSHA's request for comment on the proposed contents for medical examinations. Ameren, NSSP, and NABTU agreed with the tests that OSHA proposed, including skin examinations (Document ID 1675, p. 16; 1677, p. 6; 1679, p. 12). ORCHESE was opposed to examining the skin for wounds and breaks because although skin injuries could allow for increased beryllium absorption, they are temporary conditions that could heal within days, thus making the finding observed during the exam irrelevant (Document ID 1691, Attachment 1, p. 7). NIOSH and ATS supported medical and work histories or questionnaires, but neither they nor NJH supported routine physical examinations and lung function testing of beryllium exposed employees (Document ID 1664, p. 8; 1688 p. 3; 1725, p. 32). ATS and NIOSH commented that physical examinations and lung function testing are not effective for identifying sensitization or CBD. NJH recommended that physical examinations and pulmonary function tests be offered to employees who do not have CBD but are experiencing symptoms, while NIOSH said that required tests should be determined by the PLHCP, based on responses to the questionnaire. Lung function (spirometry) testing is the only type of examination that AWE routinely does on its employees with ''significant likelihood for exposure'' (Document ID 1615, p. 10). DOD includes a history, physical exam, a chest X-ray, and spirometry in its surveillance program, and agreed that the skin should be examined (Document ID 1684, Attachment 2, p. 1–5). 3M agreed that an employee's fitness to wear a respirator should be evaluated, but they argued that incorporating requirements of the medical evaluation under the respiratory protection program (29 CFR 1910.134(e)) would be a better tool for evaluating fitness to wear a respirator than the proposed medical surveillance requirements. In support of this statement, it asserted that pulmonary function tests are a poor predictor for fitness to wear a respirator (Document ID 1625, pp. 3–5).

OSHA recognizes, as ATS, NIOSH, and NJH commented, that physical examinations and lung function testing are not effective for detecting sensitization or CBD. However, OSHA still finds that these tests should be included as part of medical surveillance examinations of beryllium exposed workers because they accomplish important goals of medical surveillance as part of an occupational health program. As indicated above, the major purposes of medical surveillance for beryllium-exposed employees go beyond identifying disease and include identifying conditions that put employees at increased risk from beryllium exposure and determining the employee's fitness to use personal protective equipment such as respirators. The medical examination for beryllium complements the medical evaluation under the respiratory protection program that must still be conducted before an employee is fitted for a respirator or uses the respirator in the workplace (29 CFR 1910.134(e)(1)). Physical examinations and lung function tests are objective measures that are valuable in accomplishing the goals of medical surveillance for beryllium and to determine fitness to use personal protective equipment. For example, listening to heart and lung sounds with a stethoscope and conducting lung function testing might identify an impairment in an employee who is not experiencing symptoms but might be at risk with use of a negative pressure respirator. Such impairments in employees lacking symptoms may not be identified in the medical evaluation for respirator use, which typically involves administering a questionnaire and may not involve an examination. Another example of how the required tests under the beryllium standard accomplish goals of medical surveillance is that an employee who is found to have a loss in lung function can be warned that lung function loss can be compounded if that employee develops CBD.

Skin examinations are also important because skin rashes could be a sign of dermal sensitization or also a sign that exposures that put the employee at risk of becoming sensitized have occurred. However, OSHA agrees with ORCHESE that conditions such as breaks and wounds are temporary and has therefore revised the proposed paragraph so that final paragraph (k)(3)(ii)(C) requires a physical examination for skin rashes, rather than an examination for breaks and wounds. OSHA notes that PLHCPs will nonetheless detect skin injuries during the skin examination, and when doing so can take that as an opportunity to educate the employee on the importance of using protective clothing, because beryllium absorption can be increased through broken skin.

OSHA also revised proposed paragraph (k)(3)(ii)(A), which would have required, among other things, ''a medical and work history, with emphasis on past and present exposure'' so that final paragraph (k)(3)(ii)(A) includes emphasis on past and present airborne exposure to or dermal contact with beryllium. OSHA added dermal contact to this list because, as noted by NJH and ACOEM, dermal contact can result in skin effects and sensitization (Document ID 1664, p. 5, 1685, p. 3). As discussed in Section V, Health Effects, dermal contact with beryllium can lead to respiratory and dermal sensitization and it is therefore an appropriate factor to consider as part of the medical and work history. With these changes, final paragraphs (k)(3)(ii)(A)–(D) require the medical examination to include: (1) Medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory dysfunction; (2) a physical examination with emphasis on the respiratory system; (3) a physical examination for skin rashes; and (4) a pulmonary function test, performed in accordance with guidelines established by the ATS including forced vital capacity (FVC) and a forced expiratory volume in one second (FEV_1).

Under proposed paragraph (k)(3)(ii)(E), an employee would have been offered a BeLPT or an equivalent test at the first examination, and then at least every two years after the first examination, unless the employee was confirmed positive. As OSHA explained in the preamble to the proposal, the proposed requirement to test for beryllium sensitization was intended to apply whether or not an employee was otherwise entitled to a medical examination in a given year (80 FR 47799). For example, for an employee exposed during an emergency who would have normally been entitled to 1 exam within 30 days of the emergency but not annual exams thereafter, the employer would still have been required to provide this employee with a test for beryllium sensitization every 2 years. OSHA further explained that this proposed biennial requirement would have applied until the employee was confirmed positive. The Agency preliminarily found that the biennial testing required under proposed paragraph (k)(3)(ii)(E) was adequate to monitor employees at risk of developing sensitization while being sufficiently affordable for employers.

The record showed strong support for use of BeLPT, with limited exceptions. NIOSH supported the BeLPT to identify sensitized employees, citing recent evidence that the BeLPT has a sensitivity of 66 to 86% and a specificity of >99%, which it stated is superior or comparable to other common medical screening test (Document ID 1725, pp. 32–33). In responding to comparisons of the BeLPT against World Health Organization (WHO) (Wilson) criteria (see next paragraph), NIOSH concluded that current evidence supports the use of the BeLPT to benefit both the individual employee and to identify improvements that could be made in work areas to prevent other workers from becoming sensitized (Document ID 1725, p. 33). BeLPT is also supported by or used in medical screening by medical authorities, unions, and industry stakeholders including Materion, NJH, Ameren, NSSP, USW, ACOEM, ATS, and ORCHSE (Document ID 1661, Attachment 2, pp. 7–8; 1664, p. 4; 1675, p. 16; 1677, pp. 5–6; 1681, p. 25; 1685, p. 4; 1688, p. 3; 1691, Attachment 1, p. 12). Ameren also commented that a BeLPT should be provided for employees diagnosed with sarcoidosis because of the potential for a misdiagnosis of CBD (Document ID 1675, p. 16). USW supported periodic BeLPTs because workers with a history of exposure remain at risk in the future (Document ID 1681, pp. 13–14). NJH supported biennial BeLPTs, which is consistent with the draft joint recommended standard by Materion and USW (Document ID 0754; 1664, p. 4).

In contrast, based on a false positive rate reported in a review done by AWE in 1990, AWE commented that it does not routinely use BeLPT in its medical surveillance program (Document ID 1615, p. 11). DOD did not support the BeLPT, arguing that it has not been shown to meet WHO guidelines as a screening tool (often referred to as the Wilson Criteria, which evaluates factors such as reliability of the assay and its usefulness to identify disease at an early stage in which treatment would be beneficial) (Document ID 1958, p. 8).

After carefully considering these comments, OSHA agrees with NIOSH that the BeLPT is appropriate based on its sensitivity and low false positive rate that is comparable or superior to other screening tests. Unlike DOD, OSHA finds that the BeLPT does meet a number of the Wilson criteria because it is an acceptable, reliable test that allows for a serious disease to be diagnosed at an early stage, when employees with symptoms could benefit from treatment, or in the case of occupational exposures, interventions such as removal from exposure. OSHA agrees with Ameren that a BeLPT is an important component for diagnosing lung disease in beryllium-exposed employees to prevent a misdiagnosis. And OSHA reaffirms that it is important to conduct the BeLPT at least every two years to screen for beryllium sensitization, until the employee is confirmed positive. As in the proposal, the biennial requirement to test for beryllium sensitization applies regardless of whether an employee is otherwise entitled to a medical examination in a given year. OSHA concludes that this continuing requirement is important because sensitization can occur after exposures end.

OSHA finds that in general, 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. However, one change to this provision compared to the proposed standard is to allow the test to be offered ''at least'' every two years, rather than every two years as proposed. This change clarifies OSHA's intent that the employer need not wait precisely two years to make the BeLPT available to employees.

Final paragraph (3)(ii)(E) contains a number of other differences compared to the proposed requirements. Consistent with the definition in the proposed standards, the proposed paragraph considered two abnormal test results necessary to confirm a finding of beryllium sensitization when using the BeLPT (''confirmed positive''). Therefore, the proposal would have required that the BeLPT be repeated within one month of an employee receiving a single abnormal result. As discussed in more detail in the Summary and Explanation for paragraph (b), Definitions, commenters including ACOEM and ATS indicated that retesting should also be done following borderline BeLPT results, and as ACOEM noted, one borderline and one positive test or three borderline tests have a high predictive value for sensitization (Document ID 1685, p. 4; 1688, p. 2). In response to such comments, OSHA changed the definition of confirmed positive to two abnormal test results, an abnormal test result and a borderline test result, or three borderline test results. Therefore, to make this paragraph consistent with the revised definition, the text was changed to indicate that a follow-up BeLPT must be offered within 30 days for results that are ''other than normal'' unless the employee has been confirmed positive. This language makes it clear that not only abnormal BeLPT results, but also borderline BeLPT results must be followed up according to the definition for confirmed positive. When an other than normal result is obtained, testing is to be repeated within 30 days, unless the employee is confirmed positive. This means that follow-up can stop as soon as it is determined that the employee is confirmed positive (*e.g.,* after receiving an abnormal and borderline test or three borderline tests).

The proposed paragraph indicated that the requirement for a repeat BeLPT was waived if a more reliable and accurate test were to become available that could confirm beryllium sensitization based on one test result. OSHA requested comments on the availability of more reliable and accurate tests than the BeLPT for identifying beryllium sensitization (80 FR 47575). ORCHSE took issue with the statement that retesting would not be required if a more reliable and accurate test became available that could confirm beryllium sensitization based on one test result. It interpreted the statement to mean that an employee who tested positive would not receive a second BeLPT or second test that is more reliable and accurate than the BeLPT, leaving the employee with only one abnormal test that was unconfirmed (Document ID 1691; Attachment 1, pp. 7–8).

To streamline the paragraph and avoid misunderstandings of the Agency's intent, OSHA removed the language waiving a second confirmatory test if a more accurate and reliable test became available that did not require retesting for confirmation of sensitization. Instead, final paragraph (k)(3)(E) requires a standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. This revision clarifies that only other than normal BeLPT results must be followed up within 30 days. Because the paragraph refers to follow-up testing for other than normal ''BeLPT'' results, the requirement would not apply to a more accurate and reliable test that would not require an abnormal result to be confirmed.

OSHA acknowledges that the ''more accurate and reliable'' alternative remains hypothetical as there are currently no tests for beryllium sensitization that allow for a confirmed diagnosis of sensitization based on one test. However, if developed and validated as described below, such a test would be an improvement because it would eliminate the need for an employee to go back to have blood drawn a second and possible third time. OSHA's intent was to allow the current BeLPT requirement to be replaced with a more accurate and reliable test that would not require retesting to confirm sensitization, if such a test were ever developed. To clarify the Agency's intent, final paragraph (k)(3)(ii)(E) now specifies that a standardized BeLPT ''or equivalent test'' is to be offered. OSHA considers an ''equivalent test'' to be a test that would accurately identify sensitization based on one test result. Thus, the original intent of that requirement is unchanged, but OSHA clarifies that an ''equivalent test'' could also be a validated test that is superior to the BeLPT for other reasons. For example, NJH commented that alternative tests to the BeLPT are being developed that could require less blood and less sample manipulation and provide earlier results (Document ID 1664, p. 9).

NJH commented on validating tests for beryllium sensitization that might be superior to a BeLPT (Document ID 1664, p. 9). It noted that validation could occur in a College of American Pathologists (CAP)/Clinical Laboratory Improvement Amendments (CLIA) laboratory. Once the assay is determined to be robust and reproducible, clinical validation should then be performed using samples from patients known to be sensitized and from unexposed controls. OSHA agrees and as explained in the Summary and Explanation for paragraph (b), Definitions, before any test could be considered ''equivalent'' to a BeLPT for identifying sensitization but based on a single test result, the test must undergo rigorous validation to ensure that it has comparable or increased sensitivity, specificity, and positive predictive value within one test result than the BeLPT. OSHA also recommends that before any test for sensitization is considered equivalent to a BeLPT, it should be widely accepted by authoritative sources, such as CDC/NIOSH, ACOEM, and ATS, based on the validation criteria described above. Such an approach is conceptually consistent with that in the draft recommended standard by Materion and USW that required the CDC to approve a more reliable test that could eliminate the need to confirm a positive finding. The joint draft recommended standard by Materion and USW required that the BeLPT be performed in a laboratory licensed by the CDC (Document ID 0754). In contrast, OSHA's proposed provision did not require that a BeLPT be conducted by a laboratory that was licensed or accredited. OSHA requested comment on whether testing should be performed by a laboratory accredited by an organization such as CLIA (80 FR 47575).

Commenters including NJH, Ameren, NSSP, Materion and USW, ACOEM, and ORCHSE supported the inclusion of a requirement that laboratories performing BeLPT be accredited by CAP and/or CLIA (Document ID 1664, pp. 8, 9; 1675, p. 19; 1677, p. 7; 1680, p. 7; 1685, p. 5; 1691, Attachment 1, p. 13). For example, NJH commented that a CAP/CLIA certification represents the standard for oversight for clinical testing to ensure proper quality control and testing (Document ID 1664, p. 9). ACOEM further added that those laboratories should undergo periodic proficiency testing (Document ID 1685, p. 5). Materion and USW also recommended that all laboratories that conduct BeLPT have a standard procedure and algorithm and that their BeLPT be approved by the FDA, but that these issues should not delay promulgation of the rule (Document ID 1680, p. 7). However, NJH indicated that while it would be preferable, standardization of interpretation algorithms across laboratories is challenging because it is influenced by many variables such as serum and reagent lots, sample quality, use of round versus flat bottomed plates, and technician skill (Document ID 1664, p. 8). NSSP commented that all current BeLPT laboratories have certifications from CAP and/or another accreditation organization approved under CLIA and have participated in inter-laboratory split specimen testing (Document ID 1677, p. 7).

After reviewing these comments and the remainder of the record on this issue, OSHA is convinced that requiring that the BeLPT be conducted by CAP/CLIA-certified laboratories would improve quality of BeLPT results. Based on comments from NSSP, all laboratories conducting BeLPTs are currently accredited. OSHA therefore finds that accredited laboratories are currently available and including such a requirement in the standards would not delay promulgation of the rule. The Agency also finds that CAP/CLIA certification helps improve proficiency in terms of obtaining accurate results that are appropriately interpreted and ensures that quality control procedures are followed. Therefore, to improve the accuracy and reliability of BeLPTs, the standards require that samples be analyzed by a laboratory certified under CAP/CLIA guidelines to perform the BeLPT.

As a result of the changes discussed above, final paragraph (k)(3)(E) specifies that the examination must include a standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed by a laboratory certified under the College of American Pathologists (CAP)/Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

Proposed paragraph (k)(3)(ii)(F) would have required a CT scan to be offered to employees who had been exposed to beryllium at concentrations above 0.2 μg/m³ for more than 30 days in a 12-month period for 5 years or more. As OSHA explained in the preamble, the five years of exposure did not need to be consecutive (80 FR 47799). As with the requirement for sensitization testing explained above, the CT scan would have been required to be offered to an employee who met the criteria of paragraph (k)(1)(i)(D) without regard to whether the employee was otherwise required to receive a medical exam in a given year. OSHA explained that the CT scan would have been offered to employees who met 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/m³ for more than 30 days in a 12-month period, whichever was 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 (Document ID 0754, p. 8).

OSHA requested comment on the proposed CT scan requirements, as part of the content of the medical examinations (80 FR 47574). In addition, OSHA asked stakeholders to opine on two regulatory alternatives related to CT scans: (1) Regulatory Alternative #18, which would have dropped the CT scan requirement from the proposed rule, and (2) Regulatory Alternative #19, which would have increased the frequency of periodic CT scans from biennial to annual scans (80 FR 47571).

A number of stakeholders responded to the Agency's request for comments on the proposed CT scan requirements. Two such commenters, Public Citizen and NJH, referenced criteria for low-dose CT lung cancer screening set forth by the U.S. Preventive Services Task Force (USPSTF), an independent, volunteer panel of national experts in prevention and evidence-based medicine (Document ID 1664, p. 4; 1964, p. 4). In December, 2013, the USPSTF recommended annual screening for lung cancer with LDCT for adults aged 55 to 80 years with a 30-pack-year smoking history and who either currently smoke or have quit within the past 15 years. Under USPSTF's criteria, screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery (Moyer *et al.,* 2014, Document ID 1791). The USPSTF recommendation was based on the findings of the National Lung Cancer Screening Trial (NLST), which was a large study of the effectiveness of using x-ray and LDCT screening for early detection of lung cancer.

The NLST enrolled asymptomatic men and women (n = 53,454), aged 55 to 74, that were current smokers or former smokers within the last 15 years and had a smoking history of at least 30 pack-years. The participants underwent annual lung cancer screening with either LDCT or chest radiography for three years. The results showed a statistically significant 20-percent relative reduction in lung cancer mortality with LDCT screening (Aberle, *et al.,* 2011, Document ID 1701). However, the trial also showed that LDCT screening results in a high false-positive rate; 24.2 percent of the total LDCT screening tests were classified as positive, with 96.4 percent of these positive results ultimately being false positives. In addition, 39.1 percent of the 26,722 (or about 10,450) participants in the LDCT screening group had at least one positive screening result out of three LDCT scans during the study (Alberle, *et al.,* 2011, Document ID 1701). Given that only 649 cancers were diagnosed after a positive screening test, and assuming that each of these cancers was in a different participant, it follows that only 6.2 percent of those with at least one positive test were ultimately diagnosed with lung cancer. This means that 36.7 percent of participants in the LDCT screening group had at least one false positive result. Most positive initial screening results in the NLST—many of which were false positives—were followed up with a diagnostic evaluation that included further imaging and, infrequently, invasive procedures (Alberle, *et al.,* 2011, Document ID 1701).

Given these findings, the USPSTF noted, in its recommendation for lung cancer screening for high-risk individuals, the importance of shared decision making. The USPSTF advised:

> Shared decision making is important for the population for whom screening is recommended. The benefit of screening varies with risk because persons who are at higher risk because of smoking history or other risk factors are more likely to benefit. Screening cannot prevent most lung cancer deaths, and smoking cessation remains essential. Lung cancer screening has substantial harms, most notably the risk for false-positive results and incidental findings that lead to a cascade of testing and treatment that may result in more harms, including the anxiety of living with a lesion that may be cancer. Overdiagnosis of lung cancer and the risks of radiation are real harms, although their magnitude is uncertain. The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms (Moyer, *et al.,* 2014, Document ID 1791, p. 333).

In addition to the USPSTF, several other organizations have recommended similar lung cancer screening protocols for high-risk individuals, including the American Cancer Society, American College of Chest Physicians, American Society of Clinical Oncology, American Lung Association, National Comprehensive Cancer Network, and the American Association for Thoracic Surgery. Each organization's specific screening recommendations are summarized by the U.S. Centers for Disease Control and Prevention: *http://www.cdc.gov/cancer/lung/pdf/guidelines.pdf.*

With regard to occupational exposure, OSHA is not aware of any definitive recommendations based on a large, well-conducted, randomized, controlled study examining the benefit of lung cancer screening with LDCT among occupationally-exposed workers. In its pre-hearing comments, NIOSH noted that the screened population must be at sufficiently high risk for lung cancer in order to assure that the benefit of LDCT screening for early detection exceeds the harm (Document ID 1671, Attachment 1, p. 8). NIOSH cited a report by the Finnish Institute of Occupational Health (FIOH) that recommended LDCT screening in asbestos-exposed individuals if their personal combination of risk factors, particularly smoking history, yields a risk for lung cancer equal to that needed for entry into the NLST. NIOSH noted that the absolute risk for lung cancer in the NLST and the threshold absolute risk for lung cancer proposed by FIOH as a trigger for LDCT screening was 1.34% over 6 years (Document ID 1671, Attachment 1, p. 8).

OSHA also received comments in the record pointing to the LDCT lung cancer screening recommendations of the National Comprehensive Cancer Network (NCCN), a nonprofit alliance of 27 cancer centers (Document ID 1805, Attachment 1; Document ID 1959). In addition to recommending screening for individuals (current smokers or former smokers that have quit within the last 15 years) who are 55 to 74 years of age with a smoking history of at least 30 pack-years, the NCCN recommended LDCT screening for individuals age 50 years or older with a smoking history of at least 20 pack-years and with one or more additional risk factors; these risk factors include a history of COPD or pulmonary fibrosis, a history of cancer, a family history of lung cancer, radon exposure, or occupational exposure to the carcinogens asbestos, arsenic, beryllium, cadmium, chromium, nickel, silica, or diesel fumes (Document ID 1815, Attachment 39). Like the USPSTF, NCCN noted that individuals who qualify under these LDCT screening recommendations should engage in shared decision making with their physician and discuss the benefits and harms of LDCT screening for lung cancer (Document ID 1815, Attachment 39).

Thus, the studies and recommendations discussed above indicate that age and smoking history are crucial risk factors that determine when the benefits of LDCT screening are likely to outweigh the risks from radiation exposure and false-positive results. The radiation exposure received from periodic LDCT scans increases the risk of lung and breast cancer, as well as leukemia. Public Citizen estimated the risk of these cancers that could result when workers are screened as described in OSHA's proposed rule (Document ID 1964, pp. 4–6). Public Citizen also estimated the total radiation dose received to range from 900 to 2,400 mrems, depending on age at which screening begins. The excess cancer risks resulting from these exposures, based on Public Citizen's use of the National Academies BIER VII report, ranged from 3.7 to 29.9 deaths per 1,000 workers for solid organ cancers, and from 0.5 to 2.3 deaths per 1,000 for leukemia (Document ID 1964, p. 6). These risk estimates are comparable to OSHA's estimated lung cancer mortality risk resulting from exposure to beryllium at the PEL of 0.2 μg/m³ over a working life (see Section VI, Risk Assessment). False-positive results carry the risk of additional radiation exposure from repeat scans, as well as unnecessary anxiety for the workers and his or her family, unnecessary invasive procedures that may have risks of medical complications, and unnecessary medical expenses (Document ID 1806, pp. 1–2; 1964, pp. 7–8).

A number of rulemaking participants agreed that the lung cancer risks from beryllium exposure are, for the vast majority of workers, unlikely to be so high that LDCT screening would be beneficial, including NJH, ATS, ORCHSE, NIOSH, Public Citizen, NGK, and the Aluminum Association (Document ID 1664, pp. 1, 4; 1688, p. 2; 1691, Attachment 1, p. 1; 1671, Attachment 1, pp. 8–9; 1964, p. 4; 1663, p. 3; 1666, pp. 3–4). For example, NJH commented that the risk of lung cancer associated with exposure to beryllium at the final rule's PEL of 0.2 μg/m³ was likely to be lower than that from the radiation exposure received from LDCT screening, particularly for workers under age 50 (Document ID 1664, p. 4). NJH also stated that the majority of beryllium-exposed workers are former smokers and many would not fit the criteria for the USPSTF recommendations (Document ID 1664, p. 4). ORCHSE argued that ''[e]xtrapolation of the results of the non-occupational National Lung Screening Trial for implementation in the occupational setting is premature, and fraught with a number of potential issues and concerns [*e.g.,* over-diagnosis, false positives, radiation dose, follow-on invasive procedures and attendant complications]. The requisite 30 pack-year trigger recommended for screening is associated with risks orders of magnitude higher than that associated with beryllium exposure'' (Document ID 1691, Attachment 1, p. 1). Similarly, in post-hearing comment, Public Citizen remarked that it would be a ''dangerous mistake'' to provide LDCT screening for the majority of non-smoking beryllium-exposed workers who are at low risk for lung cancer and thus would not benefit from such screening (Document ID 1964, p. 10).

The suggestion that beryllium exposure alone would lead to lung cancer risks too low to warrant LDCT screening was illustrated by NIOSH in an analysis of risk information. NIOSH used the mortality study by Schubauer-Berigan *et al.* (2011 b, Document ID 0521) to estimate the exposure levels to beryllium that would result in a risk level at least as high as that suggested by FIOH as a trigger for LDCT screening (*i.e.,* an absolute increased risk of 1.34 percent over a 6-year period). To reach risk levels of this magnitude, NIOSH found that a 40-year-old would have had to have been exposed to a mean daily weighted average exposure of 12 μg/m³ to achieve a lung cancer risk level sufficient to justify LDCT, and a 50-year-old worker would have had to have been exposed to a mean daily weighted average exposure of 2 μg/m³, a daily exposure equal to the previous PEL. It was not possible for NIOSH to estimate the required level of beryllium exposure necessary above age 60 to reach a risk level equal to that suggested by FIOH because the background rate of lung cancer already exceeded that level. Although there are uncertainties around the NIOSH estimates (for example, use of 10-year rather than 6-year age intervals, which would understate the required level of beryllium exposure), OSHA finds that the NIOSH analysis demonstrates that LDCT screening would benefit non-smoking workers exposed to beryllium only where the workers were exposed to very high concentrations of beryllium, *i.e.,* levels at and above the previous PEL.

Many of the rulemaking commenters who objected to the proposed requirement for LDCT screening also believed that the absence of any studies showing the effectiveness of LDCT screening on beryllium-exposed workers was further reason not to require LDCT screening based only on a history of beryllium exposure (Document ID 1664, p. 1; 1688, p. 2; 1691, Attachment 1, p. 1; 1756, pp. 123–125; 1806, pp. 1–2). For example, Dr. Newman, who represented ACOEM at the public hearing, in response to a question testified that

> . . . we don't have any data on beryllium—specifically looking at beryllium workers with the cluster of risk factors [*i.e.,* smoking plus Be exposure] that you've described. And I think that absent that it means that there is more of a question mark around . . . how far should OSHA go at this point with low dose CT (Document ID 1756, pp. 124–125).

In contrast to these commenters, inclusion of LDCT screening into the final rule was supported by USW in written comments and at the informal public hearing. Sara Brooks of the USW commented that

> The proposed inclusion of a low dose CT scan as part of medical surveillance is entirely justified. The low dose CT scan can effectively detect lung cancer at an early stage and has been demonstrated to reduce lung cancer mortality among high risk individuals. Since lung cancer is recognized as an outcome caused by beryllium exposure, inclusion of the low dose CT scan in the proposed rule is appropriate (Document ID 1681, Attachment 1, p. 14).

Dr. Steven Markowitz of the City University of New York, testifying on behalf of USW, supported OSHA requiring LDCT screening for beryllium-exposed workers, citing the NLST finding that screening reduced lung cancer mortality by 20 percent. He also noted that

> [t]he use of LDCT is rapidly increasing because of just how common lung cancer is. And this is an effective non-invasive technique. And that there can really [be] a display of leadership by including LDCT now in the proposed medical standard for beryllium (Document ID 1755, Tr. 110).

In post-hearing comment, Dr. Markowitz suggested limiting the proposal's requirement to apply to workers age 50 or more, and pointed out that this was consistent with OSHA's past practice (*i.e.,* medical surveillance requirements under the Cadmium standard, 29 CFR 1910.1027) and with NCCN recommendations (Document ID 1959, p. 1). Second, he argued that the assertion that LDCT should not be included in the rule based on the lack of studies showing efficacy of LDCT on beryllium-exposures workers was ''without merit'' (Document ID 1959, p. 1). He pointed out that many of the risk factors used by the medical community as a basis for recommending LDCT (*e.g.,* family medical history, presence of chronic obstructive lung disease) lack empirical evidence relating the effectiveness of LDCT to the presence of these risk factors. Thus, Dr. Markowitz argued that ''[t]he decision to undergo (by the individual) or to recommend (by the physician) LDCT for lung cancer screening is based on that individual's overall level of risk of lung cancer, not on the particular mix and magnitude of individual risk factors that constitute overall risk'' (Document ID 1959, p. 1). He also argued that because cancers caused by beryllium exposure are similar to the types of lung cancers from other causes, beryllium exposure is not more or less amenable to LDCT screening than are smoking history or other risk factors (Document ID 1959, p. 2). Dr. Markowitz concluded that the absence of studies on beryllium-exposed workers and LDCT screening ''should not be a decisive factor in determining whether LDCT should be included in the final OSHA standard on beryllium.'' (Document ID 1959, p. 3).

OSHA agrees in general that beryllium exposure should be considered as a risk factor when deciding whether LDCT screening is appropriate, and agrees that it is not appropriate to wait for specific studies to be conducted before considering that a history of beryllium exposure should be factored into a decision to undergo LDCT screening. This is, in fact, consistent with the NCCN's criteria for LDCT screening that include occupational exposures along with age, smoking history, and other risk factors. However, LDCT screening is not triggered under these criteria based on occupational exposures and age alone; there must also be a history of smoking (albeit a lower trigger than when considering only age and smoking). As discussed above, there is no evidence in the record that exposure to beryllium alone at the level used in the proposal to trigger LDCT screening results in a cancer risk sufficiently high to warrant LDCT screening.

For the final rule, OSHA considered increasing the threshold of beryllium exposure such that LDCT screening would be triggered at much higher exposures to beryllium (*e.g.,* average exposure above 2 μg/m³ for over several years), as was suggested by the NIOSH analysis. OSHA rejected this approach for three reasons. First, as pointed out by ORCHSE (Document ID 1691, Attachment 1, p. 6), it is unlikely that exposure records would be available for many workers to show that the trigger was met, except where workers had long employment tenure with their present employer. Second, establishing such a high exposure trigger for LDCT screening would, in fact, exclude workers with a history of lesser beryllium exposure even when other risk factors are present such that LDCT would be beneficial. Finally, OSHA is reluctant to fix a hard exposure trigger in the standard given that, as pointed out by USW, LDCT technology is likely to advance and increase the efficacy of screening to where screening becomes beneficial for those with lesser risk of lung cancer than is reflected by current recommendations.

Therefore, OSHA concludes that the best approach is to require LDCT screening for beryllium-exposed workers based on the recommendation of the physician conducting or overseeing the medical examination, after all relevant risk factors have been considered, and has accordingly reflected this approach in the final standards. For these reasons, paragraph (k)(3)(ii)(F) of the final standards requires the medical examination to include an LDCT scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, age, sex, and presence of existing lung disease.

The seventh and final item required as part of the medical examination under the proposal was any other test deemed appropriate by the PLHCP. OSHA explained that 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 (80 FR 47799). In addition, OSHA noted that medical examinations that include more invasive testing, such as bronchoscopy, alveolar lavage, and transbronchial biopsy, have been demonstrated to provide additional valuable medical information. The Agency preliminarily found that the PLHCP was in the best position to decide which medical tests are necessary for each individual examined. Although a requirement for other tests deemed appropriate by the PLCHP was not included in the draft joint recommended standard by Materion and USW (Document ID 0754), similar requirements have been included in previous OSHA health standards, such as Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053).

No stakeholders objected to the proposal's requirement that the medical examination include other tests deemed appropriate by the PLHCP. However, some commenters offered examples of tests that might be useful in certain situations. For example, for employees diagnosed with CBD, NJH recommended that the test battery include pulmonary function tests including diffusing capacity, exercise tolerance tests, chest X-ray or CT scan, bronchoscopy with lavage and biopsy, and bronchoalveolar lavage BeLPT (Document ID 1806, p. 12).

After reviewing the comments on this issue, OSHA reaffirms that allowing the PLHCP to select other tests is appropriate because there are no particular tests—beyond those listed in paragraph (k)(3)(ii)(A)–(E)—that are necessarily applicable to all employees covered by the medical surveillance requirements. This provision gives the examining PLHCP the flexibility to determine additional tests deemed to be appropriate for individual employees. While the tests conducted under this paragraph are for screening purposes, diagnostic tests may be necessary to address a specific medical complaint or finding related to beryllium exposure or the PLHCP may decide that the test battery needs to be expanded once an employee has been diagnosed with CBD. Although the tests suggested by NJH have been demonstrated to provide additional valuable medical information, OSHA considers the PLHCP to be in the best position to decide if any additional medical tests, especially the more invasive tests, are necessary for each individual examined. Under this provision, if a PLHCP decides another test related to beryllium exposure is medically indicated, the employer must make it available. OSHA intends the phrase ''deemed appropriate'' to mean that additional tests requested by the PLHCP must be both related to beryllium exposure and medically necessary, based on the findings of the medical examination.

Information Provided to the PLHCP. Proposed paragraph (k)(4) detailed which information must be provided to the PHLCP. Specifically, the proposed standard required the employer to ensure the examining PLHCP has a copy of the standard, and to provide to the examining PLHCP the following information, if known to the employer: A description of the employee's former and current duties that relate to the employee's occupational exposure ((k)(4)(i)); the employee's former and current levels of occupational exposure ((k)(4)(ii)); a description of any personal protective clothing and equipment, including respirators, 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, if the employee provides a medical release of the information ((k)(4)(iv)). A similar requirement was contained in the draft joint recommended standard by Materion and USW (Document ID 0754, p. 8). However, Materion and USW's standard did not require written authorization from the employee for the employer to release medical information to the PLHCP. OSHA has included similar provisions, with the exception of the employee's medical release, in previous OSHA standards, such as Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053).

OSHA did not receive any comments on the proposed requirement to provide information to the PLHCP. Therefore, the Agency is including it in the final standards with three modifications. First, OSHA has updated paragraph (k)(4)(i) to require the employer to provide a description of the employee's former and current duties that relate to both the employee's airborne exposure to and dermal contact with beryllium, instead of merely requiring the provision of information related to airborne exposures, as in the proposal. As indicated above with regard to the medical examination's medical and work history requirements, OSHA finds that this change is appropriate because the record indicates that dermal contact with beryllium can lead to respiratory and dermal sensitization.

Second, OSHA revised the requirement that the employer obtain a ''medical release'' before providing the PLHCP with information from records of employment-related medical examinations. ORCHSE recommended that paragraph (k)(4)(iv) be revised to indicate that the requirement to provide medical information to the PLHCP be waived if the employee refuses to sign a medical release (Document ID 1691, Attachment 1, pp. 10–11). After considering this comment, OSHA finds that a change to the provision is not needed because the employer can demonstrate a good faith effort in meeting this requirement by documenting the employee's refusal to provide a medical release. However, the Agency has chosen to use the phrase ''written consent'' instead of ''medical release'' in the final standards. This non-substantive change brings the language in this provision in line with the language used in final paragraphs (k)(6) and (k)(7), discussed below.

Third, OSHA revised the provision to indicate that the employer must ensure that the same information provided to the PLHCP is also provided to the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard. OSHA made this change because the CBD diagnostic center will need the same information as the PLHCP in order to effectively evaluate the employee.

OSHA concludes that making this information available to the PLHCP and CBD diagnostic center will aid in the 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. Providing the PLHCP and CBD diagnostic center with exposure monitoring results, as required under paragraph (k)(4)(ii), will assist them in determining if an employee is likely to be at risk of adverse effects from airborne beryllium exposure at work and indicate that information in the written medical report for the employee. A well-documented exposure history will also assist the PLCHP in determining if a condition (*e.g.,* dermatitis, decreased lung function) may be related to beryllium exposure.

Written medical reports and opinions. Paragraph (k)(5) of the proposed standard provided for the licensed physician to give a written medical opinion to the employer, but relied on the employer to give the employee a copy of that opinion; thus, there was no difference between information the employer and employee received. The final standards differentiate the types of information the employer and employee receive by including two separate paragraphs within the medical surveillance section that require a written medical report to go to the employee, and a more limited written medical opinion to go to the employer. The former requirement is in paragraph (k)(5) of the final standards; the latter requirement is in paragraph (k)(6) of the final standards. This summary and explanation for those paragraphs first discusses the proposed requirements and general comments received in response during the rulemaking. OSHA then explains in this subsection of the preamble its decision in response to these comments to change from the proposed requirement for a single opinion to go to both the employee and employer and replace it with two separate and distinct requirements: (1) A full report for the employee, which includes medical findings, any recommendations on the employee's use of respirators, protective clothing, or equipment or limitations on airborne exposure to beryllium, and any recommendations for referral to a CBD diagnostic center, continued periodic surveillance, and medical removal; and (2) an opinion for the employer, which focuses primarily on any recommended limitations on respirator, protective clothing, or equipment use, and with the employee's consent, recommendations for referral to a CBD diagnostic center, continued periodic surveillance, and medical removal. The ensuing two subsections will then discuss the specific requirements and the record comments and testimony relating to those specific requirements.

Proposed paragraphs (k)(5)(i)(A)–(C) would have required the employer to obtain from the licensed physician a written medical opinion containing: (1) 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 airborne exposure to beryllium; (2) any recommended limitations on the employee's airborne exposure to beryllium, including the use and limitations of protective clothing or equipment, including respirators; and (3) a statement that the PLHCP explained the results of the medical examination to the employee, including tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions related to use of protective clothing or equipment. Proposed paragraph (k)(5)(ii) would have required the employer to ensure that neither the licensed physician nor any other PLCHP revealed to the employer specific findings or diagnoses unrelated to airborne beryllium exposure or contact with soluble beryllium compounds. Finally, proposed paragraph (k)(5)(iii) would have required the employer to provide the employee with a copy of the opinion within two weeks of receiving it.

OSHA asked stakeholders to consider what if any information the PLHCP should give to the employer. Specifically, the Agency asked whether it should 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, OSHA explained, the employer could instead be required to obtain a certification from the PLHCP stating (1) when the examination took place, (2) that the examination complied with the standard, and (3) that the PLHCP provided the licensed physician's written medical opinion to the employee. Such an approach would require the employee to provide written consent for the medical opinion or any other medical information about the employee to be sent to the employer. OSHA asked stakeholders to 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. OSHA also asked that commenters explain the basis for their position and the potential impacts of such an approach (80 FR 47575).

OSHA received a number of comments related to the proposed provisions and the issues raised. Many of these comments related to the proposed contents of the PLHCP's written medical opinion and its transmission to the employer. Some commenters offered suggestions to address privacy concerns regarding the content of the proposed licensed physician's written medical opinion and the proposed requirement that the opinion be given to the employer instead of the employee. For example, David Weissman, M.D., the director of the Respiratory Health Division at NIOSH, objected to providing a specific diagnosis to employers and urged OSHA to adopt a policy consistent with the International Code of Ethics for Occupational Health Professionals established by the International Commission on Occupational Health (Document ID 1725, p. 33; 1815, Attachment 82). The policy recommends reporting only information on fitness for work and medically related limitations to management. NIOSH, AFL–CIO, and NABTU also recommended the ACOEM guidance on confidentiality as a model for the types of information submitted to the employer (Document ID 1679, p. 13; 1689, p. 14; 1725, p. 33). The ACOEM guidelines state:

> Physicians should disclose their professional opinion to both the employer and the employee when the employee has undergone a medical assessment for fitness to perform a specific job. However, the physician should not provide the employer with specific medical details or diagnoses unless the employee has given his or her permission (Document ID 1815, Attachment 60, p. 1).

Exceptions to this recommendation listed under the ACOEM guidelines include health and safety concerns.

Dr. Weissman also expressed concerns about employers' ability to ensure the confidentiality of the medical information obtained from workers (Document ID 1725, pp. 33–34). He argued that if OSHA were to require diagnoses of beryllium sensitization to be shared with employers, provisions would be needed to ensure that sensitive information was protected (Document ID 1725, p. 34). He maintained that ''[s]uch provisions are especially needed because employers are not necessarily covered entities under the Health Insurance Portability and Accountability Act (HIPPAA) Privacy Rule'' (Document ID 1725, p. 34). In fact, some employers who commented during the silica rulemaking expressed concerns about having to maintain confidential medical information (81 FR 16832).

Commenters representing employee interests also objected to giving the opinion to the employer, and offered solutions. For example, AFL–CIO fellow Mary Kathryn Fletcher testified that OSHA should consider the MSHA requirements for black lung, which requires health care providers to give their opinion directly to the employee (Document ID 1756, Tr. 201–202; 30 CFR 90.3).

OSHA has accounted for stakeholder privacy concerns in devising the medical disclosure requirements in the rule. OSHA understands that the need to inform employers about a licensed physician's recommendations on work limitations associated with an employee's exposure to beryllium must be balanced against the employee's privacy interests. As discussed in further detail below, OSHA finds it appropriate to distinguish between the licensed physician's recommendations and the underlying medical reasons for those recommendations. In doing so, OSHA intends for the licensed physician to limit disclosure to the employer to what the employer needs to know to protect the employee, which does not include an employee's diagnosis.

OSHA concludes that the employer primarily needs to know about any recommended work-related limitations or recommendations without conveying the medical reasons for the limitations. Thus, consistent with the weight of opinion in this rulemaking record and with evolving notions about where the balance between preventive health policy and patient privacy is properly struck, OSHA is taking a more privacy- and consent-based approach regarding the contents of the licensed physician's written medical opinion for the employer. The approach is similar to the approach that OSHA took in the recently promulgated Respirable Crystalline Silica standard, but more privacy-based compared to the proposed beryllium requirements and OSHA standards promulgated before the Respirable Crystalline Silica standard. These changes, which are reflected in paragraph (k)(6) of the standards, and the comments that led to these changes, are more fully discussed below.

Reinforcing the privacy concerns, stakeholders testified about job loss concerns when employees are diagnosed with an illness. For example, NABTU's Chris Trahan testified that workers in the construction industry get laid off if an employer finds out they are ill (Document ID 1756, Tr. 237–238). Mike Wright, Director of the Environmental Health and Safety Department, USW, testified that he has repeatedly seen employers fire employees who are in the early stages of occupational disease (Document ID 1751, p. 284). Dr. Weissman testified that if medical results are given directly to the employer, employees may fear that it would result in loss of their jobs and that would discourage them from participating in medical surveillance (Document ID 1755, Tr. 47–48). In commenting on a proposed standard provision that required an employer to get a signed release before sending medical information to a PLHCP, ORCHSE expressed concerns that employees are not compelled to sign releases (Document ID 1691, p. 10). The ORCHSE comment suggests that employees are reluctant to automatically have their medical information shared with medical professionals, much less their own employers. These comments mirror concerns voiced in the recent silica rulemaking. As part of that rulemaking, Dr. Weissman testified that fear of medical information being shared with employers is one of the biggest reasons that miners give for not participating in medical surveillance, and a number of employees testified that they would not participate in medical surveillance that lacked both employee confidentiality and antiretaliation and discrimination protection (81 FR 16831–16832). In addition, the Construction Industry Safety Coalition commented that some employers might refuse to hire an employee with silicosis for fear that they would be held liable or have to offer workers' compensation if the disease progressed (81 FR 16832)).

A number of stakeholders, including Southern Company, Ameren, and NSSP highlighted the importance of reporting beryllium-related findings to the employer for reasons such as evaluating the effectiveness of workplace programs and making workplace changes to protect employees (Document ID 1668, p. 7; 1675, p. 18; 1677, p. 7). NJH reflected similar views and also indicated that the employer would need medical information for medical follow-up and removal and to help the employee file for workers' compensation (Document ID 1664, p. 8). Materion opposed withholding medical information from employers. It commented that Materion has a cooperative process where employees are involved in problem identification and resolution, and when an employee is diagnosed with sensitization or CBD, senior and safety personnel conduct an investigation (Document ID 1755, Tr. 172–173; 1807, pp. 4–5). It indicated that the approach has resulted in improvements aimed at preventing other workers from developing CBD in the future (Document ID 1807, pp. 4–5).

Although USW agreed that patient confidentiality is essential, it argued in comments submitted before the hearing that the employer needs certain information to comply with the standard, identify over-exposures, and accommodate the needs of affected employees; it commented that the proposed rule struck the appropriate balance by giving the employer needed information while prohibiting the reporting of medical findings not related to beryllium exposure (Document ID 1681, p. 26). However, at the hearings USW presented a slightly different view, as Mike Wright testified:

> So in this circumstance, we'd like the employer to know that there's an operation that has caused illness. In a union setting, we can usually protect people, but we only represent a fraction of the workforce. In a nonunion setting, and even in the union setting, people who report an occupational illness put their jobs at peril. So we tend to resolve that dilemma in terms of privacy (Document ID 1756, Tr. 285).

When questioned how privacy concerns could be balanced with improving the work environment, Dr. Weissman testified that medical providers could provide aggregated medical data to employers that would let employers know there may be a problem but not identify the specific employees affected (Document ID 1755, Tr. 47–49). He also said that employers could foster a strong culture of safety so that employees would be more likely to share medical findings. Dr. Maier, from NJH, suggested a similar approach of analyzing combined data based on job task with employees de-identified (Document ID 1756, p. 145). However, Terry Civic, Director of Safety Health and Regulatory Affairs from Materion, and Dr. Newman argued that such an approach may not be able to maintain employee confidentiality in many cases, such as when very few employees are involved with a process or are employed by a small company (Document ID 1755, Tr. 173–174; 1756, Tr. 145).

Mr. Wright presented another view when he testified that risk can be determined in many ways, including air sampling and analyses of work processes. He went on to say that waiting for an employee to get sick is the least effective way of determining risk (Document ID 1756, Tr. 284–285). Chris Trahan of NABTU expressed similar thoughts in her testimony (Document ID 1756, Tr. 240). Rebecca Reindel, Senior Safety and Health Specialist from AFL–CIO, added:

> Employers don't need to hear about a disease in order to implement engineering controls. It's unlikely that a disease is necessarily going to trigger engineering controls more than what OSHA requires in its standards (Document ID 1756, Tr. 240).

OSHA acknowledges that identifying workers with beryllium-related disease has led to an increased understanding of exposures related to beryllium disease and development of controls to protect workers, and OSHA recognizes the efforts of employers who have promoted a strong health and safety culture and contributed to the knowledge on beryllium. However, OSHA also recognizes that many employees may fear possible repercussions of the release of medical information to their employers.

Moreover, OSHA agrees with commenters who said that employers should be basing their actions on exposure assessments and implementing controls, and it encourages employers to regularly evaluate their beryllium programs. The standards for beryllium require employers to review and evaluate the written exposure control plan if the employer is notified that an employee is eligible for medical removal, is referred to a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium (paragraph (f)(1)(ii)(B)). OSHA also encourages analyses of aggregated data when employers have the resources to do that and are able to maintain employee confidentially, which is not always possible. However, in the case where an employee may have disease related to beryllium exposure and the employer is effectively implementing controls to maintain exposures within the PEL, the only further action required by the employer would be to follow the licensed physician's recommendations to protect the employee who may be especially sensitive to exposure and may need special accommodations such as continuing medical examinations at a CBD diagnostic center or medical removal if requested by the employee. The employer does not need the specific health findings that contributed to those recommendations.

OSHA examined a number of other factors in determining what the possible outcomes could be of not providing medical findings to employers. One possible outcome is that employers would not be able to report or record illness according to OSHA's standard on recording and reporting occupational injuries and illnesses (29 CFR 1904). OSHA notes that if employees do not participate in medical surveillance because of discrimination or retaliation fears, illnesses associated with beryllium would also generally not be identified. Although not disclosing medical information to employers appears inconsistent with the objective of recording illnesses, the net effect of that decision to guard employee privacy is improving employee protections due to more employees participating in medical surveillance.

An additional possible outcome relating to what information goes to the employer is that withholding information, such as conditions that might place an employee at risk of health impairment with further exposure, may leave employers with no medical basis to aid in the placement of employees. For example, DOD opposed withholding medical information from employers because the information lets the employer know if the worker can continue to work without undue risk (Document ID 1684, Attachment 2, pp. 1–7). However, in the recent silica rulemaking, a number of stakeholders commented that because of the significance of job loss or modifications, employees that are able to perform work duties should make their own decisions on whether to continue working and that such decisions should be made with guidance from the PLHCP (81 FR

16833). OSHA finds that this is also true for beryllium-exposed employees. As a result of participating in medical surveillance, those employees will receive information about any health condition they have that might put them at further risk with exposure to beryllium and allow them to make employment choices to benefit their health.

Such an approach is not inconsistent with Materion's approach of letting employees make some employment decisions after learning that they are sensitized or have CBD, although Materion strongly supports providing employers with sensitization information (Document ID 1807, pp. 4–5; Attachment 6, pp. 75–76). At Materion, the confirmed positive finding is reported to management so an investigation can be conducted, and the Materion Medical Director informs the employee about the rates of progression from sensitization to CBD based on Materion's most recent epidemiological data. If the employee is diagnosed with CBD by his or her personal pulmonologist, the employee can choose to provide the information to Materion's Medical Director. Materion reported that employees ''often do [disclose their diagnosis of CBD] in choosing to apply for Materion benefits under its CBD policy'' (Document ID 1807, p. 4). Under the CBD policy, employees who are physically able to perform the job are given the choice of remaining in their current job, taking a job with lower beryllium exposures, or receiving benefits for 12 months. OSHA agrees with Materion's approach of letting employees decide how to proceed if they are confirmed positive or diagnosed with CBD, but disagrees that the employer must receive specific health findings before that can happen.

In review of this evidence, OSHA concludes that if employees decide to make employment changes to protect their health, there are ways to communicate recommended limitations or medical removal, without revealing the specific medical finding leading to those recommendations. Because of evolving views on medical privacy, such as those set forth in ACOEM's Confidentiality Guidelines, OSHA does not find that medical reasons for limitations or medical removal should be automatically reported to employers. In addition, providing confidential medical information to all employers presents challenges in some cases. Unlike Materion, many employers do not have medical departments and may not therefore be aware of medical privacy laws or have the resources to maintain medical records under strict confidentiality.

Another factor that OSHA considered was the value of giving health information to all employers, when some companies, such as small businesses, may not have in-house health and safety personnel to answer employee questions or emphasize the importance of protective measures, such as work practices or proper use of respirators. In such cases, employees are not likely to benefit from having their medical findings given to employers, who may have no deeper knowledge about health risks than the employee. OSHA expects that the training required under the standards will give employees knowledge to understand protective measures recommended by the PLHCP, and will make it more likely they will authorize PLHCP recommendations to be disclosed to the employer.

As was the case in the silica rulemaking, OSHA agrees that employees exposed to beryllium have the most at stake in terms of their health and employability, and they should not have to choose between continued employment and the health benefits offered by medical surveillance, which they are entitled to under the OSH Act. OSHA agrees that employees should make employment decisions, following discussions with the PLHCP that include the risks of continued exposure. Before that can happen, however, employees need to have confidence that participation in medical surveillance will not threaten their livelihoods. After considering the various viewpoints expressed during the rulemaking on these issues, OSHA concludes that the best way to maximize employee participation in medical surveillance, therefore promoting the protective and preventative purposes of this rule, is by limiting required disclosures of information to the employer to only the bare minimum of what the employer needs to know to protect employee health—recommended restrictions on respirator and protective clothing and equipment use and, only with consent of the employee, the licensed physician's recommended limitations on airborne exposure to beryllium and recommendations for evaluation at a CBD diagnostic center, continued medical surveillance, and removal from airborne exposure to beryllium. Thus, OSHA views this consent-based approach to reporting of medical surveillance findings critical to the ultimate success of this provision, which will be measured not just in the participation rate, but in the benefits to participating employees—early detection of beryllium-related disease so that employees can make decisions to mitigate adverse health effects and to possibly retard progression of the disease.

In sum, OSHA concludes that the record offers compelling evidence for modifying the proposed content of the licensed physician's written medical opinion for the employer. The evidence includes employee privacy concerns, as well as evidence on the limited utility for giving specific medical findings to employers. OSHA is particularly concerned that the proposed requirements would have led to many employees not participating in medical surveillance and thus not receiving its benefits. OSHA therefore has limited the information to be given to the employer under this rule, but is requiring that the employee receive a separate written medical report with more detailed medical information.

The requirements for the type of information provided to the employer are consistent with those in the Respirable Crystalline Silica standard (29 CFR 1910.1053), but are different from requirements in the majority of OSHA standards that were promulgated before that standard. The requirements in other standards remain in effect for those standards. The requirements for this rule are based on the evidence obtained during this rulemaking for beryllium, in particular that many employees, especially those who are not represented by a labor union or who work in a company that does not foster a strong health and safety culture, would not take advantage of medical surveillance without stronger privacy protections.

Licensed Physician's written medical report for the employee. OSHA did not propose a separate report given directly by the licensed physician to the employee, but as discussed in detail above, several commenters requested that a report containing medical information be given to the employee only. OSHA agrees and in response to those comments, final paragraph (k)(5) requires the employer to ensure that the PLHCP explains the results of the medical examination and that the licensed physician provides the employee with a written medical report within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). In other words, the examination does not end (and trigger the 45-day disclosure period) until all of the follow-up BeLPTs have been administered. This deadline is consistent with the deadline for the licensed physician's written medical opinion for the employer, which is discussed below.

The contents of the licensed physician's written medical report for the employee are set forth in final paragraphs (k)(5)(i)–(v). They include: The results of the medical examination, including any medical condition(s), such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as is defined in paragraph (b) of the standard), that may place the employee at increased risk from further airborne exposure; any medical conditions related to airborne exposure that require further evaluation or treatment; any recommendations on the employee's use of respirators, protective clothing, or equipment; and any recommended limitations on airborne beryllium exposure. If the employee is confirmed positive or diagnosed with CBD, the written medical report must also contain any recommendations for referral to a CBD diagnostic center, continued medical surveillance, and medical removal from airborne beryllium exposures, as described in paragraph (l) of the standard. Paragraph (l) specifies that medical removal applies only to work scenarios where airborne exposures exceed the action level. Paragraph (k)(5)(iii) also states that the licensed physician may recommend evaluations at a CBD diagnostic center based on any other reason deemed appropriate. For example, the physician might recommend an evaluation at a CBD diagnostic center because he or she suspects that results from the BeLPT are questionable based on signs or symptoms in the employee or other clinical findings that are consistent with CBD and wants a specialist in beryllium disease to examine the employee. However, OSHA notes that recommendations for referrals for evaluations at CBD diagnostic centers under this standard should only be given for health-related reasons that pertain to beryllium.

The health-related information in the licensed physician's written medical report for the employee is generally consistent with the proposed written medical opinion for the employer, with a few notable exceptions. The proposal required the written medical opinion to indicate ''whether the employee had any medical condition that would place the employee at increased risk of CBD from further [airborne] exposure.'' Although including a statement in the opinion that ''the employee has a medical condition that places him or her at increased risk of CBD'' implies that the employee is sensitized to beryllium, the proposal did not require that a specific finding such as ''confirmed beryllium sensitization'' be included in the opinion. Because only the employee will be receiving the written medical report, the written medical report will include any specific diagnoses, such as CBD or beryllium sensitization. OSHA added ''CBD'' as a condition to be included in the written medical report to the employee because employees who have CBD may be at risk of increased progression of the disease if they continue to be exposed. Including a confirmed positive finding or CBD diagnosis will also give the employee a record of his or her eligibility for medical removal. An additional change from the proposed to final requirement is that the proposed phrase of ''would place the employee at risk of CBD from further [airborne] exposure'' was changed to ''may place the employee at increased risk from further airborne exposure.'' The change of the word ''would'' to ''may'' was for clarification because the word ''would'' implies a certainty that does not exist.

The phrase ''risk of CBD'' was also changed to ''risk'' to clarify that risks may be increased by conditions other than CBD-related disease. For example, the employee may have lung function loss related to a disease such as chronic obstructive pulmonary disease and that lung function loss might be compounded if the employee develops CBD. As noted in the introduction to the Summary and Explanation, the word ''airborne'' was included as a modifier to the term ''exposure'' in many cases in the final standards to clarify that OSHA did not intend a change from the proposal. In this provision, OSHA included the term ''airborne'' to reaffirm its intent that the report must discuss any detected medical conditions that may place the employee at increased risk from further airborne exposure, rather than dermal exposure. OSHA finds that this distinction is appropriate because it is inhalation exposure and not dermal contact that increases the risk of CBD development in a sensitized employee or increases the risk of progression in an employee who has CBD. (For this same reason the word ''airborne'' was added to final paragraph (k)(5)(ii)(B).)

Finally, the proposed phrase ''including the use and limitations of protective clothing and equipment, including respirators'' was changed to ''use of respirators, protective clothing or equipment'' in final paragraph (k)(5)(ii)(A). That change reflected an edit to remove superfluous language and the intent of that requirement has not changed. OSHA intends this provision to cover situations where the physician might have recommendations on the use of respirators, protective clothing or equipment in general, *e.g.,* that the employee should wear long sleeves to limit the possibility of dermal exposure. OSHA also intends for the provision to address recommended limitations on an employee's use of respirators, protective clothing or equipment, *e.g.,* that the employee cannot safely wear a negative pressure respirator.

In addition to these changes, OSHA added a number of recommendations that the licensed physician is to include in the written medical report to the employee if the employee is confirmed positive or diagnosed with CBD: (1) Referral for an evaluation at a CBD diagnostic center (paragraph (k)(5)(iii)), (2) continued medical surveillance (paragraph (k)(5)(iv)), and (3) medical removal from airborne exposure to beryllium as described in paragraph (l) (paragraph (k)(5)(v). Aside from a confirmed positive or CBD diagnosis, if otherwise deemed appropriate by the licensed physician, the written medical report must also contain a referral for an evaluation at the CBD diagnostic center.

Each of these recommendations reflects another requirement of the final standard. For example, proposed paragraph (k)(6)(i) and (ii) indicated that an evaluation at a CBD diagnostic center was to occur when an employee was confirmed positive and agreed to the examination. OSHA updated the requirement to make it clear that an evaluation at a CBD diagnostic center should not be limited to employees who have been confirmed positive and want to find out if they have CBD, and should be extended to employees already diagnosed with CBD. Such employees would benefit from having a pulmonologist familiar with beryllium disease select appropriate tests to monitor progression of the disease. OSHA therefore expanded the trigger for referral to a CBD diagnostic center to include CBD in addition to sensitization in final paragraphs (k)(5)(iii), (k)(6)(iii), and paragraph (k)(7)(i).

The referral for continued medical surveillance for employees who are confirmed positive or have been diagnosed with CBD reflects the addition of paragraph (k)(1)(i)(D) that allows employees whose most recent medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance to continue receiving medical examinations, even if they do not qualify under any other trigger; a more detailed discussion is included under the summary and explanation for final paragraph (k)(1)(i)(D).

Finally, the triggers for a medical removal recommendation in paragraph (k)(5)(v) reflect the triggers under paragraph (l)(1)(i) and are discussed in more detail in the summary and explanation for final paragraph (l), medical removal protection. OSHA added these recommendations to the written medical report to make it clear to the licensed physician and employee that each of these recommendations is to occur when an employee is confirmed positive or diagnosed with CBD. A similar approach is applied in the Respirable Crystalline Silica standard, where the PLHCP is to include a statement that the employee should be examined by a specialist if that employee has X-ray evidence of silicosis.

The requirements for the health-related information to be included in the written medical report for the employee are consistent with the overall goals of medical surveillance: To identify beryllium-related adverse health effects so that the employee can consider appropriate steps to manage his or her health; to let the employee know if he or she can be exposed to beryllium in the workplace without increased risk of experiencing adverse health effects; and to determine the employee's fitness to use respirators. By providing the licensed physician's written medical report to employees, those who might be at increased risk of health impairment from airborne beryllium exposure will be able to consider interventions (*i.e.,* health management strategies) with guidance from the licensed physician. Such strategies might include employment choices to limit airborne exposures or using a respirator for additional protection.

The requirement for a verbal explanation from the PLHCP in paragraph (k)(5) allows the employee to confidentially ask questions or discuss concerns with the PLHCP. It also allows the PLHCP to inform the employee about any non-occupationally related health conditions so that the employee can follow-up as needed with his or her personal healthcare provider at the employee's expense. The requirement for a written medical report ensures that the employee receives a record of all findings. Employees would also be able to provide the written medical report to future health care providers.

Licensed physician's written medical opinion for the employer. As discussed in detail above, some commenters objected to OSHA's proposed content for the written medical opinion for the employer based on employee privacy concerns. OSHA shares these privacy concerns and is thus revising the contents of the written medical opinion. In developing the contents of the written medical opinion for the employer, OSHA considered what type of information needs to be included to provide employers with information to protect employee health, while at the same time protecting employee privacy as much as possible. NIOSH commented that the employer should only be provided with information on the employee's fitness for duty, in addition to restrictions and eligibility for medical removal benefits, as applicable (Document ID 1725, page pp. 33–34). AFL–CIO recommended that OSHA use the language from the respirable crystalline silica rule promulgated in March of 2016, and referred OSHA to the final brief it submitted for the silica rulemaking since the justifications for increased confidentiality apply to beryllium (Document ID 1809, p. 1; 1786). In the silica standard, OSHA required that only limitations on respirator use be included in the written medical opinion without the employee's consent. The decision was largely influence by physician testimony that giving the employer information on an employee's ability to use a respirator, but not specific medical information, strikes the appropriate balance between the employee's privacy and the employer's right to know because employees who are not fit to wear a respirator and then do so can be at risk of sudden incapacitation or death (81 FR 16835; see also Document ID 1786; pp. 89–90; 1805, Attachment 2, p. 133).

Based on the record evidence, OSHA has determined that for the beryllium standards, the written medical opinion for the employer must contain only the date of the examination, a statement that the examination has met the requirements of this standard, and any recommended limitations on the employee's use of respirators, protective clothing, and equipment; and a statement that the PLHCP explained the results of the examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment. These requirements are set forth in paragraph (k)(6)(i) of the standards.

OSHA is persuaded to include recommended limitations on the employee's use of respirators, protective clothing, and equipment, with no other medically-related information, in the written medical opinion for the employer without further consent from the employee. The Agency notes that the limitation on respirator use is consistent with information provided to the employer under the Respiratory Protection standard (29 CFR 1910.134). OSHA concludes that only providing information on respirator and protective clothing and equipment limitations in the written medical opinion for the employer is consistent with the ACOEM confidentiality guidelines that address the reporting of health and safety concerns to the employer (Document ID 1815, Attachment 60, p. 1). The date and statement about the examination meeting the requirements of this standard are to provide both the employer and employee with evidence that compliance with the medical surveillance requirements are current. Employees will be able to show this opinion to future employers to demonstrate that they have received the medical examination.

Paragraph (k)(6)(ii) states that if the employee provides written authorization, the written medical opinion for the employer must also contain any recommended limitations on the employee's airborne exposure to beryllium. Paragraphs (i)(6)(iii)–(v) state that if an employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain recommendations for evaluation at a CBD diagnostic center, continued medical surveillance, and medical removal from airborne exposure to beryllium as described in paragraph (l). If otherwise deemed appropriate by the licensed physician and the employee authorizes the information to be included in the written medical opinion, the opinion must also contain a referral for an evaluation at the CBD diagnostic center. As noted above, referrals for evaluations at CBD diagnostic centers under this standard should only be given for health-related reasons that pertain to beryllium.

OSHA intends for this provision to allow the employee to give authorizations for the written medical opinion for the employer to contain only the referral for evaluation at a CBD diagnostic center, only the recommendation for continued periodic surveillance, or only the recommendation for medical removal, or both. This will allow employees to choose one or more options that best fit their needs. For example, an employee may choose to only let the employer know that he or she wants continued medical surveillance but not at the CBD diagnostic center because he or she is satisfied with the care provided by the current PLHCP. In another case, an employee may decide that he or she wants only the recommendation for evaluation at a CBD diagnostic center reported to the employer because the employer wants to be evaluated by someone who is more specialized in beryllium disease before making any major employment decisions. In a third case, the employee may only want the recommendation for removal from airborne exposure reported to the employer because the employee is very concerned about his or her health and wants to be immediately removed without an evaluation at the CBD diagnostic center. OSHA expects that the written authorization could easily be accomplished through the use of a form that allows the employee to check, initial, or otherwise indicate which (if any) of these items discussed above the employee wishes to be included in the written medical opinion for the employer. OSHA concludes that allowing the employee to decide what if any additional information can be reported to the employer is warranted based on the seriousness and irreversibility of beryllium disease and the major impact that the decision may have on the employee's health and employment.

OSHA is convinced that routinely including recommended limitations on airborne exposure, evaluations at a CBD diagnostic center, and especially medical removal in the written medical opinion for the employer absent employee consent could adversely affect employees' willingness to participate in medical surveillance. The requirements for this paragraph are consistent with recommendations to let employees make their own health decisions. OSHA stresses that information given to the employer should not include an underlying diagnosis—only the specific recommendation or referral called for under the standards. OSHA considers this a reasonable approach that balances the need to maintain employee confidentiality with the employer's need to know that it may want to reevaluate its beryllium program. Reporting that a referral or medical removal is recommended, when authorized by the employee, allows the employer to reevaluate its written exposure control plan, as required under paragraph (f)(1)(ii)(B).

OSHA finds that this new format for the licensed physician's medical opinion for beryllium will better address concerns of ORCHSE, who feared it would be in violation if the written medical opinion for the employer included information that OSHA proposed the licensed physician or PLHCP not report to the employer, such as an unrelated diagnosis (Document ID 1691, p. 11). OSHA finds that removing the prohibition on unrelated diagnoses and instead specifying the only information that is to be included in the written medical opinion for the employer remedies this concern because it makes the contents of the opinion easier to understand and less subject to misinterpretation.

OSHA recognizes that some employees might be exposed to multiple OSHA-regulated substances at levels that trigger medical surveillance and requirements for written opinions. For example, Newport News Shipbuilding indicated that their employees already undergo medical surveillance for arsenic (Document ID 1657, p. 2). The licensed physician can opt to prepare one written medical opinion for the employer for each employee that addresses the requirements of all relevant standards, as noted in preambles for past rulemakings, such as Chromium (VI) (71 FR 10100, 10365 (2/28/06)). However, the combined written medical opinion for the employer must include the information required under each relevant OSHA standard. For example, if the PLHCP opts to combine written medical opinions for an employee exposed to both inorganic arsenic and beryllium, then the combined opinion to the employer must contain the information required by paragraphs (n)(6)(i) of the inorganic arsenic standard (29 CFR 1910.1018) and the information required by paragraphs (k)(6)(i) (and paragraphs (k)(6)(ii)–(v) with written authorization from the employee) of the beryllium standards.

NABTU noted that the black lung rule for coal miners protects confidentiality by prohibiting mine operators from requiring miners to provide a copy of their medical information (Document ID 1679, p. 13; 30 CFR 90.3). NABTU requested that the beryllium rule protect confidentiality by prohibiting employers from asking employees or the PLHCP for medical information (Document ID 1679, p. 13). Consistent with the Respirable Crystalline Silica standard, OSHA is not including such a prohibition in the beryllium standard because employers may have legitimate reasons for requesting medical information, such as BeLPT results. For example, employers might request such information for doing an investigation or helping employees file compensation claims. If employees are not concerned about discrimination or retaliation, or need the employer's help in filing a claim, they could provide the health information to the employer. Paragraph (k)(6)(vi) requires the employer to ensure that employees receive a copy of the written medical opinion for the employer within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee. The reason for the 45-day deadline to provide the written medical opinion is discussed below. OSHA is requiring that employees receive a copy of the written medical opinion for the employer, in addition to the written medical report, because they can present the written medical opinion as proof of a current medical examination to future employers. This is especially important in industries with high turnover because employees may work for more than one employer during a two-year period and this ensures that tests are not performed more frequently than required.

On the topic of transient employment, NSC asked OSHA to consider workers employed by staffing agencies and assigned to multiple host employers and possibly employees of contractors to the host employer, who might not receive medical surveillance because of the transient nature of their employment (Document ID 1612, p. 3). OSHA's July 15, 2014, memorandum titled *Policy Background on the Temporary Worker Initiative* indicates that both the host and staffing agency are responsible for the health and safety of temporary employees. For example, the policy memorandum indicates that host employers are well suited for assuming responsibility for compliance related to workplace hazards, while staffing agencies may be best positioned to provide medical surveillance. Under this policy, staffing agencies are expected to offer medical surveillance to eligible employees, and they could send a copy of the written medical opinion to the host employer so that the host employer would know about any limitations that might be recommended by the licensed physician. Similarly contract employers whose employees work at different job sites are expected to offer medical surveillance to their eligible employees. Also, OSHA revised the triggers for medical surveillance in paragraphs (k)(1)(i)(A) and (k)(2)(i)(A) so that employees must be offered medical surveillance within 30 days of when the employer determines they are reasonably expected to be exposed above the action level for 30 or more days a year. The revised trigger allows for more timely medical examinations than the proposed trigger, which would have allowed for the employee to be exposed for 30 days before the employer had to offer medical surveillance. As a result, more temporary workers who are employed for short periods of time will meet the trigger for medical surveillance.

As indicated above, the standards require that employers ensure that employees get a copy of the PLHCP's written medical report and opinion and that they get a copy of the written opinion within 45 days of each medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) (paragraphs (k)(5), (k)(6)(i), (k)(6)(vi)). By contrast, the proposed rule would have required that the employer obtain the licensed physician's written medical opinion within 30 days of the medical examination and then provide a copy to the employee within 2 weeks after receiving it. NJH commented that 45 days is a better time period for notifying employers because it can take more than 2 weeks to process the BeLPT (Document ID 1664, p. 8). ORCHSE expressed concern about the 30-day timeline, stating that the employer would be in violation if the physician took more than 30 days to deliver the report (Document ID 1691, pp. 11–12).

In light of NJH and ORCHSE's comments, OSHA has revised the proposed 30-day timeline to allow for 45 days. OSHA expects that the new 45-day period will give the licensed physician sufficient time to consider the results of any tests, including a follow-up BeLPT, done as part of the examination. OSHA finds that delivering the report to the employer within 45 days will still ensure that the employee and employer are informed in a timely manner and allows the employer to take any necessary protective measures within a reasonable time period. To ensure timely delivery of reports and opinions containing the correct information and demonstrate a good faith effort in meeting these requirements of the standard, the employer could inform licensed physicians about the time deadline and other requirements of the beryllium standard in a written agreement and follow up with the physician if there is concern about timely delivery or content of these documents. Because the licensed physician will be providing the employee with a copy of the written medical report, he or she could give the employee a copy of the written medical opinion at the same time. This would eliminate the need for the employer to give the employee a copy of the PLHCP's written medical opinion for the employer, but the employer would still need to ensure timely delivery.

OSHA has also revised this provision to account for the time to administer any follow-up BeLPT tests required under paragraph (k)(3)(ii)(E) of these standards. As discussed above, if the results of the BeLPT are other than normal, paragraph (k)(3)(ii)(E) requires a follow-up BeLPT to be offered within 30 days, unless the employee has been confirmed positive. In order to allow for the licensed physician to consider BeLPT results and prepare the written medical opinion, the Agency must allow time for the BeLPT to be administered, processed, and interpreted. Therefore, OSHA has decided to require the employer to obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard).

Evaluation at a CBD Diagnostic Center. OSHA proposed that within 30 days after an employer learned that an employee was confirmed positive, the licensed physician was to consult with the employee to discuss referral to a CBD diagnostic center that was mutually agreed upon by the employer and employee (proposed paragraph (k)(6)(i)). Following the consultation, if the employee decided to be clinically evaluated at a CBD diagnostic center, the employer was to provide the examination at no cost to the employee (proposed paragraph (k)(6)(ii)).

OSHA asked stakeholders to comment on the proposed requirement for evaluation at a CBD diagnostic center, especially whether the requirements for mutual agreement by the employee and employer is necessary and appropriate and how the diagnostic center should be chosen if the employer and employee cannot agree. OSHA also asked whether the standard should specify that evaluation at a diagnostic center must be at a reasonable location (80 FR 47574–47575).

The term CBD diagnostic center is defined in paragraph (b), Definitions, of the standards. As provided in paragraph (b) and explained in the Summary and Explanation, the CBD diagnostic center can be a hospital or other facility that has an on-site pulmonary specialist who can interpret biopsy pathology and bronchoalveolar lavage (BAL) results. The diagnostic center must also have onsite facilities that can do a clinical evaluation for CBD that includes pulmonary function testing according to ATS guidelines, transbronchial biopsy, and BAL, with the ability to transfer BAL samples to a laboratory for diagnostic evaluation within 24 hours.

Ameren supported a specialist exam but asserted that an examination by a pulmonologist was sufficient and that the pulmonologist could be allowed to work with a CBD diagnostic center to treat a sensitized employee (Document ID 1675, p. 17). Southern Company argued that rather than requiring an evaluation at a CBD diagnostic center, the standard should instead specify the types of exams required (Document ID 1668, pp. 2–3). DOD commented that employees should be referred to a board-certified pulmonologist who is capable of doing bronchoscopy, bronchial biopsy, and broncho-alveolar lavage (Document ID 1684, Attachment 2, p. 1–6), NSSP, NABTU, ACOEM, and ATS advocated for an examination at a CBD center for sensitized employees (Document ID 1677, p. 6; 1679, p. 12; 1685, p. 5; 1688, p. 3).

OSHA is not persuaded by Southern Company's argument that the final standards should detail specific tests for confirmed positive employees, instead of requiring an examination at a CBD diagnostic center. As described above, the types of evaluations required for an employee who has a confirmed positive finding or is diagnosed with CBD must be determined on a case-by-case basis, and therefore determining appropriate testing requires a pulmonologist with the expertise described in the definition for CBD diagnostic center. In addition, many of the procedures that a pulmonologist may recommend are invasive and therefore involve risks. As a result, these tests should only be performed by a pulmonologist familiar with beryllium disease at a facility that meets the definition of a CBD diagnostic center, after the pulmonologist has carefully considered the employee's medical and occupational history. For these reasons, OSHA reaffirms that it is essential that eligible employees be evaluated at a CBD diagnostic center. Requiring that the diagnostic center be able to perform all the functions described under the Definitions section also makes the exam more convenient for the employer and the employee because the employee will not have to go to multiple facilities in order to undergo different procedures.

Southern Company disagreed with the proposed requirement that both the employee and employer agree upon the CBD diagnostic center, asserting that the requirement could conflict with selection of a physician under workers' compensation laws, because OSHA does not have a mechanism to settle disputes, and because similar requirements are not included in other OSHA standards (Document ID 1668, pp. 6–7). Ameren and ORCHSE also opposed the requirement for mutual agreement on a CBD diagnostic center and recommended that location be considered when the employee and employer cannot reach agreement

(Document ID 1675, p. 17; 1691, p. 10). NJH supported mutual agreement on the CBD diagnostic center between the employee and employer and stated that location, expertise of the center, and feasibility should all be accounted for when agreement cannot be reached (Document ID 1664, p. 8).

OSHA acknowledges the concerns of these stakeholders, but maintains that the employee should be given a choice in the selection of a CBD diagnostic center because of the risks involved with procedures that the employee may have to undergo and because of the life-changing decisions that the employee might have to make based on the results of the evaluation. The employer and employee should make a good faith effort to agree on a CBD diagnostic center that is acceptable to them both. In making the decision, the first consideration is identifying qualified CBD diagnostic centers. The next considerations in the decision should include requirements under other laws and geographical location. OSHA expects that once these criteria are considered, there will not be unlimited options, which will help the employee and employer come to a decision.

Although OSHA was not convinced that changes needed to be made based on public comments, OSHA did find changes were required to make the final provision consistent with other requirements of the final standard. First, OSHA changed the trigger for referral to a CBD diagnostic center to include both confirmed positive and a CBD diagnosis for consistency with paragraphs (k)(5)(iii) and (k)(6)(iii). The reasoning for this change is described above in the discussion of paragraph (k)(5)(iii). Second, OSHA removed the requirement for a consultation between the physician and employee within 30 days after the employer learned that the employee was confirmed positive. Under paragraph (k)(6)(D), the employer already must ensure that the PLHCP explains findings to the employee, including conditions related to airborne beryllium exposures that require further evaluation or treatment within 30 days of the medical examination. The discussion about recommended referral can occur as part of that conversation, and OSHA does not find that a separate consultation with the physician or PLHCP is necessary.

The third major change to this provision was detailing how the employer would be informed that the employee is eligible for an evaluation at a CBD diagnostic center. The change reflects updates made to paragraph (k)(6) to allow the employee more privacy and control over the type of information the employer receives. Under final paragraph (k)(6), the employee must authorize the written medical opinion to contain recommendations for an evaluation at a CBD diagnostic center, and the licensed physician would then provide the employer that recommendation in the written medical opinion. Under paragraph (k)(5), the employee's written medical report is to contain medical findings, including a confirmed positive test result and a CBD diagnosis. The report must also contain a referral for an evaluation at a CBD diagnostic center if the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate. The employee has the option of providing the employer with a copy of the written medical report indicating a confirmed positive finding or diagnosis of CBD, or recommending referral. OSHA is providing the option for a written medical report listing a confirmed positive finding or diagnoses of CBD to be offered as proof of eligibility for an evaluation at a CBD diagnostic center, in the event that a licensed physician did not recommend a referral to a CBD diagnostic center in either the written medical report or the written medical opinion.

As the result of the changes discussed above, final paragraph (k)(7) requires that employers provide a no-cost evaluation at a CBD-diagnostic center that is mutually agreed upon by the employee and employer within 30 days of receiving a medical opinion that recommends the referral (paragraph (k)(7)(i)(A)) or within 30 days after the employee presents the employer with a written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center (paragraph (k)(7)(i)(B)). As is the case with the PLHCP's examination, the employer is responsible for providing the employee with a medical examination at a CBD diagnostic center, at no cost, and at a reasonable time and place.

Under paragraph (k)(7)(ii) of the standards the employer must ensure that the CBD diagnostic center explains medical findings to the employee and gives the employee a written medical report within 30 days of the examination. Like the licensed physician's written medical report, the written medical report from the CBD diagnostic center must contain the results of the examination, including conditions such as sensitization or CBD that might increase the employee's risk from airborne exposure to beryllium; any medical conditions related to beryllium that require further follow-up; any recommendations on the employee's use of respirators, protective clothing, or equipment; and any recommended limitations on beryllium exposure. If the employee is confirmed positive or diagnosed with CBD, the written medical report must also contain recommendations for continued periodic medical surveillance and recommendations for removal from exposure to beryllium, as described in paragraph (l). The reasons why the CBD diagnostic center is to give the employee this information are the same as discussed above, under the requirements for the licensed physician's written medical report for the employee. This provision was added to the final standards to ensure that the employee gets a written record from the CBD diagnostic center and to allow the employee to consult with the CBD diagnostic center about the findings.

Paragraph (k)(7)(iii) requires that the CBD diagnostic center provides the employer with a written medical opinion within 30 days of the medical examination. The written medical opinion must contain the date of the examination, any recommended limitations on the employee's use of respirators, protective clothing, or equipment, and a statement that a PLHCP explained the results of the medical examination to the employee. It must also contain a statement that the examination met the requirements of the standard, if a periodic examination was conducted for an employee who chooses examinations conducted at the CBD diagnostic center as specified under paragraph (7)(iv). If the employee provides written authorization, the written medical opinion for the employer must also contain any recommended limitations on the employee's airborne exposure to beryllium. If an employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain recommendations for continued medical surveillance, and/or medical removal from exposure to beryllium, as described in paragraph (l).

This provision was not in the proposed standard or the joint draft recommended standard by Materion and USW but was added to the final standards to allow for transmittal of CBD diagnostic center recommendations to the employer without revealing the specific medical reason for those recommendations. The structure parallels the written medical opinion from the licensed physician, which was developed based on stakeholder requests to increase confidentiality of medical findings. A separate written medical opinion from the CBD diagnostic center is needed because the recommendations may differ from those of the licensed physician and usually comes from a different provider. For example, the employee may have wanted only a recommendation for evaluation at a CBD diagnostic center to be included on the written medical opinion from the physician, but, after evaluation at a CBD diagnostic center, may decide to include the recommendation for medical removal from exposure on the CBD diagnostic center's written medical opinion.

Paragraph (k)(7)(iv) requires the employer to ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee. As discussed above with regard to paragraph (k)(6)(vi), requiring the provision of all written medical opinions to employees can permit employees to provide that information to future employers without divulging private medical information and also present the opinion as proof of a current examination that meets the requirements of the beryllium standard.

The deadlines for submittal of the written medical opinion and report are shorter for the CBD diagnostic center (30 days) than the licensed physician (45 days). The reasoning is because CBD diagnostic centers are not expected to routinely conduct BeLPTs, which as noted above, take 2 weeks to process. They will not, therefore, be affected by the same time limitations as licensed physicians.

In the NPRM, OSHA asked stakeholders to comment on whether sensitized employees should be given the opportunity to be examined at a CBD diagnostic center more than once and how frequently those employees should be evaluated (80 FR 47574). This provision was not included in the draft standard or the joint draft recommended standard by Materion and USW (Document ID 0754).

NABTU commented that a sensitized employee should continue to be periodically evaluated at a CBD diagnostic center because it cannot be predicted when a sensitized employee will develop CBD (Document ID 1679, p. 12). NSSP, ACOEM, and ATS agreed with continued periodic surveillance at a CBD diagnostic center for sensitized employees (Document ID 1677, p. 6; 1685, p. 5; 1688, p. 3). ATS recommended that sensitized employees be evaluated every one to three years and NSSP recommended that the original physician, CBD diagnostic center, and employee determine the frequency of medical examinations. Finally, Ameren stated that the standard should allow for follow-up based on pulmonologist recommendations (Document ID 1675, p. 16).

OSHA agrees that continued evaluation at a CBD diagnostic center is appropriate for sensitized employees and employees diagnosed with CBD. Specialized evaluation is needed to determine the appropriate tests to monitor for possible progression from sensitization to CBD and to monitor the progression of CBD if it does occur. Therefore, after considering the record, OSHA added the requirement for continued evaluation at a CBD diagnostic center for these employees.

This new requirement is contained in paragraph (k)(7)(v), which specifies that after an employee has received a clinical evaluation at a CBD diagnostic center described by paragraph (k)(7)(i) of the standards, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center. The evaluations must continue to be done at a CBD diagnostic center mutually agreed upon by the employee and employer and provided at no cost to the employee. To allow for continued medical surveillance for those employees who would not otherwise be entitled under (k)(1) or (k)(2), the employee must authorize the recommendation for continued periodic medical surveillance to be included in the most recent written medical opinion from the CBD diagnostic center (paragraph (k)(7)(iii)). Under paragraph (k)(2)(ii), the CBD diagnostic center can recommend continued surveillance every two years. OSHA is not including a provision for more frequent examinations because, as indicated above, surveillance done every two years is appropriate to monitor for sensitization and CBD progression in most employees.

Proposed paragraph (k)(7) had required that employers were to convey the results of beryllium sensitization tests to OSHA for evaluation and analysis at the request of OSHA. The employer was to remove all personally identifiable information (*e.g.,* names, social security numbers) before sending the results to OSHA. A similar provision was included in the joint draft recommended standard by Materion and USW. OSHA asked for comment on this provision, specifically if such a requirement would be burdensome for employers and whether it would be more appropriate to send the information to other organizations (80 FR 47575).

Some commenters did not support the inclusion of this requirement in the final rule. For example, Ameren commented that the proposed requirement would be burdensome because it would be cumbersome to get signed releases for this information (Document ID 1675, p. 20). ORCHSE also argued that employees would have a difficult time complying with this requirement because employees would not likely sign a release (Document ID 1691, p. 13). DOD also claimed that the requirement would be burdensome and said that it would be better to send the results to NIOSH but not routinely (Document 1684, Attachment 2, pp. 1–7–1–8). On the other hand, NJH supported this requirement because it believed the information would help OSHA identify industries where sensitization is occurring (Document ID 1664, p. 9). However, NJH added that small companies may need help complying with this requirement (Document ID 1664, p. 9). In addition, NJH and ATS recommended that the rule specify that employers routinely and systematically analyze medical screening results along with job and exposure data to identify employees who may be at risk of sensitization and working conditions contributing to sensitization and CBD risk (Document ID 1664, p. 8; 1688, 4).

Consistent with the concerns of Ameren and ORCHSE regarding getting releases from employees, OSHA has given much thought to maintaining confidentiality of medical findings as discussed in detail above. As a result of changes made in the standards to enhance employee privacy, the Agency eliminated the proposed paragraph for the written medical opinion to the employer to include a statement about whether the employee had a condition that would put him or her at risk of developing CBD with further beryllium exposure. That provision suggested that the written medical opinion might include findings such as beryllium sensitization. In the final standard, it is explicit that the employer will not receive information about sensitization or CBD in the written medical opinion to the employer, and the employer will only receive that information when an employee presents the employer with the employee's written medical report. As a result, many employers may not have that information to submit to OSHA or to otherwise conduct a systematic analysis of medical screening results. As discussed above, even if employers were provided aggregated medical findings, it may still be difficult to maintain confidentiality when companies are small or few employees are involved in a process.

OSHA has other ways to obtain medical findings if needed. For example, as noted in the Summary and Explanation for paragraph (n), Recordkeeping, OSHA's Access to Employee Exposure and Medical Records standard (29 CFR 1910.1020) requires employers to ensure that most employee medical records are retained for the duration of employment plus 30 years for employees employed more than one year, and requires that those records be made available to OSHA upon request (29 CFR 1910.1020 (d)(1)(i) and (e)(3)). OSHA therefore deleted proposed paragraph (k)(7) from the final standard.

(l) Medical Removal

Paragraph (l) of the standards for general industry, shipyards, and construction provide for medical removal protection (MRP). This paragraph applies only to workers with airborne exposure to beryllium at or above the action level who are diagnosed with CBD or confirmed positive and provide documentation of their diagnosis of CBD or confirmed positive status or a physician's recommendations for removal from exposure to beryllium to their employers. Under this paragraph, employees must provide eligible employees with a choice of removal from exposure at or above the action level or remaining in their job with airborne exposure at or above the action level and wearing a respirator. If the employee chooses removal, the employer is required to remove the employee to comparable work in a work environment where the airborne exposure is below the action level, if such work is available. If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first. The employee's earnings under MRP can be diminished by the amount of compensation received from certain other sources.

OSHA included medical removal provisions in the proposed rule as a protective, preventative health mechanism that was intended to work in concert with the proposed medical surveillance provisions. As OSHA explained in the proposal, the Agency preliminarily found 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. *See* 80 FR 47802. The Agency further explained that the inclusion of MRP in the proposal was in keeping with the recommendation of beryllium health specialists in the medical community and with the draft recommended standard provided by union and industry stakeholders (Document ID 0754).

OSHA solicited comments on the health effects that should trigger MRP and the proposed provisions for MRP. In addition, the Agency included several specific questions to guide stakeholders in their response, including whether beryllium sensitization and CBD are appropriate triggers for medical removal, whether there were other medical conditions or findings that should trigger medical removal, and the amount of time for which a removed employee's benefits should be extended. OSHA also included questions regarding the costs and benefits of MRP (*see* 80 FR 47575).

During the public comment periods and informal public hearing, numerous stakeholders submitted comments supporting the inclusion of MRP in this rulemaking (*e.g.,* Document ID 1664, pp. 3–4, 9; 1680, pp. 1, 7; 1681, p. 14–15; 1683, p. 3; 1688, p. 2; 1689, pp. 8, 13–14; 1690, pp. 1, 3–4; 1691, Attachment 1, pp. 13, 15; 1755, Tr. 26, 168; 1756, Tr. 142–143; 1809, p. 1; 1963, pp. 13–14). The commenters who commented on the issue supported MRP in general terms; none opposed inclusion of MRP in the final rule. Some of these stakeholders noted that they supported MRP because it promotes participation in medical surveillance programs. For example, National Council on Occupational Safety and Health (National COSH) argued that MRP benefits are crucial to a successful medical surveillance program (Document ID 1690, pp. 3–4). National COSH maintained that ''workers will not willingly participate in medical surveillance or disclose early signs and symptoms of disease if doing so means they lose their job and can no longer pay their bills. For this reason, an effective medical surveillance program for CBD must include . . . [MRP] benefits'' (Document ID 1690, p. 3). NIOSH similarly argued that ''[f]ear of job loss and associated loss of income and other benefits is an important barrier to translating medical screening and surveillance findings into secondary prevention. Inclusion of medical removal provisions is critical to addressing that barrier'' (Document ID 1755, Tr. 26). The American Association for Justice agreed, observing that ''MRP benefits are an essential tool to ensure that workers with signs and symptoms of disease step forward without fear of reprisal and seek medical advice'' (Document ID 1683, p. 3).

Other commenters indicated that the option for removal was necessary for workers' health. For example, the USW argued that the inclusion of MRP is necessary to provide a safe and healthful workplace (Document ID 1963, p. 13). USW further commented that Section VIII (Significance of Risk) of the NPRM shows that existing evidence within the docket indicates that workers who are sensitized to beryllium or are in the early stages of chronic beryllium disease can significantly benefit from MRP (Document ID 1963, p. 13). National Jewish Health (NJH) generally agreed with USW's opinion, stating that ''removal from exposure is the best form of prevention'' (Document ID 1664, p. 4).

Other stakeholders indicated that the inclusion of a medical removal provision might lower exposures in the workplace as a whole. For example, USW testified that MRP provides employers with a financial incentive to keep beryllium exposures low (Document ID 1755, Tr. 167–68). Mike Wright from USW observed that this incentive helped to lower exposure levels in the context of the lead standard:

> But what really, I think, best protected workers was medical removal protection because employers did not want to pay people to stay at home until their blood leads got down. So I think if you look at the real benefits of MRP, it isn't simply that it removes workers from exposure, who might be harmed by further exposure. It is that it really provides an incentive for employers to keep exposures low in the first place. And that's been our experience (Document ID 1755, Tr. 167–68).

After careful consideration of these comments, OSHA has decided to include MRP in the final standards. As noted by commenters, MRP serves three main interrelated purposes. First, it increases employee participation and confidence in the standards' medical surveillance program. Under paragraph (k)(1)(i)(B), employers must offer medical examinations to 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 comparable work or earnings, seniority, and other rights and benefits for a period of time can help allay an employee's fear that a CBD diagnosis or being confirmed positive 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 52952, 52973, November 14, 1978), Benzene (52 FR 34460, 34557, September 11, 1987), and Cadmium (57 FR 42102, 42367–42368, 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).

Second, by requiring the employer to remove employees with the highest risk of suffering material impairment of health (if the employee chooses removal), MRP may benefit sensitized employees and those with CBD. OSHA notes that there remains some scientific uncertainty regarding the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD. For example, Steven Markowitz, MD, a medical consultant for USW, acknowledged during the informal public hearing that ''there's a paucity of evidence that removal from exposure results in improvement of CBD'' (Document ID 1755, Tr. 101). Nonetheless, most members of the medical community support removal from beryllium exposure as a prudent step in the management of beryllium sensitization and CBD. As noted above, physicians at NJH recommend that individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry should have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour TWA, which is 10 times below the action level of 0.1 micrograms per cubic meter (*http://www.nationaljewish.org/healthinfo/conditions/beryllium-disease/environment-management/*) (Document ID 0637). Furthermore, OSHA received comments from Lisa Maier, MD and Margaret Mroz, MSPH from NJH during the public comment period supporting MRP for workers with sensitization or CBD (Document ID 1664; 1806, pp. 3–4). Specifically, Ms. Mroz commented that ''eliminating or reducing exposure can lead to improvement in symptoms'' for beryllium workers and that ''[r]emoval or reduction in exposure may prevent the development of CBD'' (Document ID 1806, p. 3–4). And, during the informal public hearing, Dr. Lee Newman, testifying on behalf of the American College of Occupational and Environmental Medicine (ACOEM), commented that ''removal from exposure is the right thing to do for somebody who is at a stage of being beryllium sensitized or any stage beyond that'' (Document ID 1756, Tr. 143). Thus, even though CBD and sensitization are considered to be irreversible, OSHA finds removal may still benefit sensitized employees and those with CBD.

Finally, MRP may provide employers with an additional incentive to keep employee exposures low. Precisely because MRP will impose additional costs on employers, MRP can increase the protection afforded workers by the beryllium standards not only directly by improving medical surveillance but also indirectly by providing employers with economic incentives to comply with other provisions of the standard. The costs of MRP are likely to decrease as employer compliance with other provisions of the standard increases. Employers who comply with other provisions of the standard may have to remove relatively few employees. With only a small number of employees requiring removal, complying employers are more likely to be able to find positions available to which removed employees can be transferred. By contrast, employers who make only cursory attempts to comply with the central provisions of these standards are likely to find that the greater their degree of noncompliance, the greater the number of employees requiring medical removal and the greater the associated MRP costs. Thus, as OSHA explained in the preambles to its substance-specific standards on Cadmium and Lead, the inclusion of MRP in a final rule can serve as a strong stimulus for employers to protect worker health and rewards employers who through innovation and creativity derive new ways of protecting worker health not contemplated by these standards (57 FR 42102, 42368 (Sep. 14, 1992); 43 FR 54354, 54450 (Nov. 21, 1978)).

OSHA has the authority to include MRP in this standard. Indeed, the Court of Appeals for the D.C. Circuit recognized the Agency's authority to adopt such provisions more than 35 years ago in its review of the Agency's Lead standard (Lead I, 647 F.2d at 1229–1236). There, the Court found that MRP ''appears to lie well within the general range of OSHA's powers,'' and reasonable in the case of lead because it would help prevent impermissibly high blood lead levels and mitigate potential employee concerns about cooperating with the medical surveillance program (Id. at 1232, 1237). And, in the three and a half decades since the Lead I decision, OSHA has adopted MRP in five other substance-specific health standards: Cadmium (29 CFR 1910.1027), Benzene (29 CFR 1910.1028), Formaldehyde (29 CFR 1910.1048), Methylenedianiline (29 CFR 1910.1050), and Methylene chloride (1910.1052).

Paragraph (l)(1) of the proposed standard detailed the eligibility requirements for medical removal. The provision explained that an employee would be eligible for medical removal if he or she works in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive for sensitization. OSHA specifically asked for comments on whether beryllium sensitization and CBD are appropriate triggers for medical removal and whether there are other medical conditions or findings that should trigger medical removal.

Stakeholders generally supported the proposed triggers. ORCHSE Strategies (ORCHSE) argued that confirmed beryllium sensitization and CBD are appropriate triggers for medical removal (Document ID 1691, Attachment 1, p. 15). ORCHSE explained that since CBD is a chronic, progressive lung disease with no known cure, it is imperative that signs of health impairment be found early and exposure be terminated to avoid further impairment (Document ID 1691, Attachment 1, p. 15). NJH also commented that confirmed beryllium sensitization and CBD are appropriate triggers for medical removal (Document ID 1664, p. 9). Ameren, North America's Building Trades Unions (NABTU), Materion Corporation (Materion), and USW agreed (Document ID 1675, p. 20; 1679, p. 14; 1680, p. 7; 1681, pp. 14–15). USW commented that medical removal could prevent the progression of disease in workers diagnosed with sensitization or CBD (Document ID 1681, p. 15). However the Department of Defense argued that CBD but not beryllium sensitization is an appropriate trigger for medical removal and that sensitization is an appropriate trigger for advising employees about risk and requiring use of personal protective equipment if the employee chooses to return to work (Document ID 1684, Attachment 2, p. 1–8). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) indicated support for the action level exposure trigger (Document ID 1809, p. 1; 1809, Attachment 2, Tr. 930–931; 942–943).

After reviewing the record on this issue, OSHA has decided that a CBD diagnosis and a confirmed positive test for sensitization are appropriate triggers for medical removal. OSHA disagrees with the DOD and concludes that sensitization is an appropriate trigger for medical removal because removal from exposure may prevent the onset of CBD. Therefore, OSHA is retaining the triggers of both sensitization and CBD.

Final paragraph (l)(1), consistent with the proposal, states that the employee is eligible for medical removal if the employee works in a job with exposure at or above the action level, but contains more specificity about the types of documentation that are submitted to the employer to demonstrate eligibility for medical removal. This change was made to track employee privacy protections included in the licensed physician's medical opinion in paragraph (k)(6) and the CBD diagnostic center's medical opinion in paragraph (k)(7)(iii). Under paragraphs (k)(5) and (k)(7)(ii), the standards now specify that the licensed physician or CBD diagnostic center provides only the employee a medical report that contains detailed medical findings, such as confirmed positive findings or a diagnosis of CBD. In cases where the employee is confirmed positive or diagnosed with CBD, the physician or CBD diagnostic center also includes recommendations for removal from exposure in the written medical report. However, under paragraphs (k)(6) and (k)(7)(iii), employers do not receive a written medical opinion that contains an employee's medical information (other than any recommended limitations on the employee's use of respirators) without the employee's written consent. The written opinion to the employer may contain a recommendation for removal from exposure, without the medical reason for the recommendation, only if the employee authorizes that recommendation to be included in the opinion. This allows an employee who is eligible for medical removal and chooses that option to provide official documentation requesting removal, without disclosing a specific medical condition.

Thus, paragraph (l)(1) allows an employee's eligibility for removal to be established by four different types of documentation:

- The employee may provide a (k)(5) or (k)(7)(ii) written medical report indicating a confirmed positive finding or diagnoses of CBD and recommending removal because of that finding or diagnosis.
- The employee may provide a (k)(5) or (k)(7)(ii) written medical report in which the confirmed positive finding or diagnosis has been obscured or removed, but still contains the recommendation of removal because of that finding or diagnosis. An employee might do this if, consistent with the approach of paragraph (k), the employee wishes to keep the details of the condition private.
- The employee may provide any reliable medical documentation establishing a confirmed positive finding or diagnosis of CBD, regardless of whether it was issued in compliance with paragraph (k)(5). An employee might do this if, for example, the documentation predates this standard. This documentation would be a "written medical report" for purposes of (l)(1)(i)(A).
- The employer receives a (k)(6) or (k)(7)(iii) written medical opinion recommending removal from the licensed physician or CBD diagnostic center.

OSHA added the language "in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard" to (l)(1)(i)(B) and "in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of the standard" to (l)(1)(ii) to be clear that medical removal is required under those provisions only when the removal recommendation is based on a confirmed positive finding or a diagnosis of CBD.

Paragraph (l)(2) of the proposal laid out the options for employees who are eligible for MRP. Specifically, paragraph (l)(2) required eligible employees to choose removal, as described under paragraph (l)(3), or to remain in a job with exposure at or above the action level as long as they wear a respirator in accordance with paragraph (g) of this standard. While both ORCHSE and Public Citizen supported the MRP provision, neither supported making removal optional (Document ID 1691, Attachment 1, p. 13; 1756, Tr. 189). ORCHSE specifically stated that utilizing respiratory protection as a means of protecting workers violates the hierarchy of controls and removal is most prudent for worker protection (Document ID 1691, Attachment 1, p. 13).

After careful consideration of these comments, OSHA has decided to allow employees to choose between removal and remaining in a job with airborne exposure at or above the action level, provided that the employee uses respiratory protection for exposures at or above the action level, as contemplated in the proposal. OSHA recognizes that removal may reduce the risk of the onset of CBD and lead to reduction of symptoms. However, CBD is unlike triggers for MRP in some other OSHA standards, such as lead and benzene, because CBD is not reversible. Thus, without the respirator option, mandatory removal would require that the employee switch careers permanently. OSHA believes the worker should be given a voice in such a fundamental life decision where the confirmed positive employee may be able to minimize the risk of CBD through the consistent and careful use of respiratory protection in a workplace where feasible controls are implemented to maintain exposures within the PEL. Indeed, mandatory permanent removal might lead workers to hide their symptoms or not seek treatment, which is directly contrary to the purpose of MRP. For these reasons, the Agency finds mandating removal is not appropriate in this rulemaking. Therefore, paragraph (l)(2) of the final standards requires employers to provide eligible employees with the employee's choice of: (i) Removal as described in paragraph (l)(3) of these standards; or (ii) remaining in a job with airborne exposure at or above the action level, provided that the employee uses respiratory protection that complies with paragraph (g) of these standards whenever exposures are at or above the action level.

Although paragraph (l)(2) of the final standards tracks OSHA's intent as expressed in the proposal, the final provision contains several clarifying changes. First, final paragraph (l)(2) explicitly places the responsibility for providing the choices on the employer, while the proposal merely implied that the employer would do so. OSHA believes that this clarification eliminates the possibility of confusion. Second, final paragraph (l)(2)(ii) refers to paragraph (g) of these standards, instead of referring to the Respiratory Protection standard (29 CFR 1910.134). OSHA made this second change to bring this provision into line with a similar provision in paragraph (e) of the final standards; it does not affect the employer's obligations as set forth in the proposed rule. Third, final paragraph (l)(2)(ii) expressly requires employers to ensure that employees use the respiratory protection whenever airborne exposures meet or exceed the action level. Again, this requirement was implied in the proposal, but OSHA believes that making the requirement express helps employers understand their obligations under these standards.

Proposed paragraph (l)(3) contained requirements that would have applied if an eligible employee elected removal. Under the proposal, when an employee chooses removal, the employer would have been required to remove the employee to comparable work if such work was available. Proposed paragraph (l)(3)(i) explained that 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. As explained in the preamble to the proposal, this provision would not have required an employer to place an employee on paid leave under proposed paragraph (l)(3)(iii) if the employee refused comparable work offered under paragraph (l)(3)(i).

If comparable work was not immediately available, paragraph (l)(3)(ii) of the proposal would have required the employer to place the employee on paid leave for six months or until comparable work becomes available, whichever occurs first. Proposed paragraph (l)(3)(ii) further explained that if comparable work became available before the end of the six month paid leave period, the employer would have been obligated to offer the open position to the employee. However, OSHA explained that if the employee declined the position, the employer would have had no further obligation to provide paid leave.

Proposed paragraph (l)(3)(iii) would have continued a removed employee's rights and benefits for six months, regardless of whether the employee was removed to comparable work or placed on paid leave. The six-month period would have begun when the employee was removed, which means either the day the employer transferred the employee to comparable work, or the day the employer placed the employee on paid leave. For this period, the provision would have required 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. OSHA explained that this provision is typical of medical removal provisions in other OSHA standards, such as Cadmium (29 CFR 1910.1027), Benzene (29 CFR 1910.1028), Formaldehyde (29 CFR 1910.1048), Methylenedianiline (29 CFR 1910.1050), and Methylene Chloride (29 CFR 1910.1052).

As detailed above, there is widespread support among stakeholders for the inclusion of removal and wage protection for eligible employees in this rulemaking. The provisions included in the proposal were consistent with the recommendation of beryllium health specialists in the medical community and with the draft recommended standard provided by Materion and USW (Document ID 0754). However, not all commenters agreed with the proposed provisions. One commenter, NABTU, argued that ''[i]f an employer who has placed an employee at risk cannot offer alternative employment [within six months], then a better solution would be to provide MRP until the employee has obtained new and equivalent employment, provided that the employee is making *a good faith effort at finding new employment* [emphasis added].'' (Document ID 1679, p. 15).

OSHA is sympathetic to NABTU's position—some employers, especially small employers, may lack the flexibility and resources to provide comparable positions for MRP-eligible employees (Document ID 0345, p. 24), and as a result, employees' base earnings and benefits would only be maintained for a six-month period. However, OSHA also recognizes that the requirement to maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for even a six-month period may be difficult for some employers. After weighing these two concerns, OSHA finds that the requirement to provide medical removal protection for a six-month period strikes a reasonable balance between protecting employees and limiting the burden on employers. Therefore, OSHA has decided to retain these provisions in the final standard with minor edits, as follows.

First, OSHA reorganized and edited paragraph (l)(3)(i) to clarify and emphasize the employer's responsibilities. Like the proposed provision, final paragraph (l)(3) applies where an eligible employee chooses removal. If a comparable job is available where exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, final paragraph (l)(3)(i) requires the employer to remove the employee to that job. Although each of these requirements was expressly stated in the NPRM in either the regulatory text or the preamble (80 FR 47802), OSHA has chosen to make its intent express in the final regulatory text. For example, the NPRM implied in regulatory text and explained in the preamble that an employer's obligation under proposed paragraph (l)(3)(i) arose where comparable work was available, but the final text makes the trigger for this obligation explicit (see 80 FR 47802; proposed paragraph (l)(3)(ii) (which applied ''if comparable work is not available)).

Second, OSHA omitted the proposed requirement in paragraph (l)(3)(i) that ''[t]he employee must accept comparable work if such work is available'' from final paragraph (l)(3)(i). As stated in the preamble to the proposal, OSHA included this statement in proposed paragraph (l)(3)(i), in part, to make clear that if the employee declines an offer of comparable work, then the employer was not obligated to place the employee on paid leave under paragraph (l)(3)(ii) (80 FR 47802). However, because OSHA regulates employers, this requirement is better expressed as a clarification to the employer's responsibilities. OSHA concludes that the opening clause to proposed and final paragraphs (l)(3)(ii), which indicates that an employer's obligation to maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal arises ''[i]f comparable work is not available'' makes this sufficiently clear.

Third, OSHA eliminated proposed paragraphs (l)(3)(iii), which stated that ''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.'' In the final rule, proposed (l)(3)(iii)'s requirements have been incorporated into final paragraphs (l)(3)(i) and (ii). OSHA believes that this simplification will clarify the Agency's intent.

OSHA has also omitted the phrase ''paid leave'' from final paragraph (l)(3)(ii) because, with the incorporation of proposed paragraph (l)(3)(iii)'s temporal and benefits requirements into final paragraph (l)(3)(ii), it is unnecessary to specify what an employee who has been removed but is not working in a comparable job would be doing. In addition, OSHA wishes to give employers the flexibility to work with removed employees to create alternatives to merely placing the employee on paid leave. For example, employers might choose to offer the employee the opportunity to train for more than one month so that he or she could qualify for a different job. Provided that the employer otherwise complied with final paragraph (l)(3)(ii), such an arrangement would be permissible under the final standards.

Finally, proposed paragraph (l)(4) provided that an employer's obligation to provide MRP benefits to a removed employee would be reduced 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. OSHA retained this requirement unchanged in final paragraph (l)(4). OSHA clarifies that benefits received under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) do not constitute wage replacement; therefore, EEOICPA benefits would not offset the employee's MRP benefits.

OSHA did not receive any comments specifically directed to this provision, but, as noted above, several stakeholders commented that they supported the MRP provisions contained in the proposal as a whole (*i.e.,* Document ID 1664, pp. 3–4, 9; 1680, pp. 1, 7; 1681, pp. 14–15; 1683, p. 3; 1688, p. 2; 1689, pp. 8, 13–14; 1690, pp. 1, 3–4; 1691, Attachment 1, pp. 13, 15; 1755, Tr. 26, 168; 1756, Tr. 142–143; 1809, p. 1; 1963, pp. 13–14). After considering all comments and the record as a whole on MRP, OSHA finds that a provision for MRP is a necessary part of the final rule. As discussed above, MRP protects an employee's rights and benefits during the first six months of removal, and OSHA structured the MRP provisions to provide for ways to reduce in certain circumstances an employer's obligation to compensate employees for earnings lost. OSHA emphasizes, however, that MRP is not intended to serve as a workers' compensation system. The primary reason the Agency is including MRP in this standard is to provide eligible employees a six-month period to adjust to the comparable work arrangement or to seek alternative employment, without any further exposure at or above the action level. The Agency finds that this provision accomplishes that goal while providing for allowing the employer to control costs in many cases. In addition, this provision is consistent with other standards such as Formaldehyde (29 CFR 1910.1048), Methylenedianiline (29 CFR 1910.1050), and Methylene Chloride (29 CFR 1910.1052).

For the reasons discussed above, OSHA finds that maintaining the MRP provision, with the clarifying changes noted above, in the final rule provides workers the incentive to participate in the medical surveillance program and provides workers with sensitization or CBD the opportunity and means to minimize further exposure to beryllium.

(m) Communication of Hazards

Paragraph (m) of the standards for general industry, construction, and shipyards sets forth the employer's obligations to comply with OSHA's Hazard Communication Standard (HCS) (29 CFR 1910.1200) relative to beryllium, and to take additional steps to warn and train employees about the hazards of beryllium. Employees need to know about the hazards to which they are exposed, along with the associated protective measures, in order to understand how they can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and safety data sheets (SDSs). 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. Several commenters, including Ameren Corporation (Ameren) and United Steelworkers (USW), generally supported inclusion of a hazard communication requirement in the beryllium standards (*e.g.,* Document ID 1675, p. 7; 1681, p. 15).

As a general matter, the HCS requires a comprehensive hazard evaluation and communication process, aimed at ensuring that the hazards of all chemicals are evaluated, and also requires that the information concerning chemical hazards and necessary protective measures is properly transmitted to employees. The HCS achieves this goal, in part, by requiring chemical manufacturers and importers to review available scientific evidence concerning the physical and health hazards of the chemicals they produce or import to determine if they are hazardous. For every chemical found to be hazardous, the chemical manufacturer or importer must develop a container label and an SDS, and provide both documents to downstream users of the chemical. All employers with employees exposed to hazardous chemicals must develop a hazard communication program and ensure that all containers of hazardous chemicals are labeled and employees are provided access to SDSs and are trained on the hazardous chemicals in their workplace. Because OSHA preliminarily found beryllium to be a hazardous chemical, the Agency determined that hazard communications provisions should be included in the proposal. OSHA intends for the hazard communication requirements in the final standards to be substantively as consistent as possible with the HCS, while including additional specific requirements needed to protect employees exposed to beryllium, in order to avoid duplicative administrative burden on employers who must comply with both the HCS and this rule. Proposed paragraph (m)(1)(i) required chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the HCS (29 CFR 1910.1200) for beryllium. Stakeholders did not offer any comments on this provision. After reviewing the full record, including all available evidence, and as discussed in this preamble at Section V, Health Effects, and Section VI, Risk Assessment, OSHA finds that beryllium is a hazardous chemical for purposes of the HCS. Therefore, the Agency includes paragraph (m)(1)(i) of the final standards for general industry, construction, and shipyards to require chemical manufacturers, importers, distributors, and employers to comply with their duties under HCS. The final provision in these standards is substantively unchanged from the proposed provision. Paragraph (m)(1)(ii) of the proposal required employers to address at least the following, in classifying the hazards of beryllium: Cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation. 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)). Commenters did not object to this provision. Therefore, after considering the record, including the general comments in favor of the proposed hazard communications provisions and the evidence presented in Section V, Health Effects, and Section VI, Risk Assessment, regarding the enumerated hazards of exposure to beryllium, OSHA has decided to retain this proposed provision substantively unchanged in final paragraph (m)(1)(ii) of the standards for general industry and shipyards. However, OSHA has revised the language to bring it into conformity with other substance specific standards so it is clear that chemical manufacturers, importers, and distributors are among the entities required to classify the hazards of beryllium (See 77 FR 17748–50).

OSHA has chosen not to include an equivalent requirement in the final standards for construction and shipyards since employers in construction and shipyards are downstream users of beryllium products (blasting media) and would not therefore be classifying chemicals (Chapter IV of the Final Economic Analysis).

Proposed paragraph (m)(1)(iii) required 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 and is trained in accordance with the HCS and paragraph (m)(4) of this section. Stakeholders did not object to any part of this provision. After reviewing the record, OSHA reaffirms that employees exposed to beryllium need additional training and information. Therefore, OSHA has decided to include the approach set forth in the proposed rule in the final paragraph (m)(1)(iii) of the final standards for general industry and shipyards and final paragraph (m)(1)(ii) of the standard for construction. The final provisions are substantively unchanged from the proposal.

Paragraph (m)(2)(i) of the proposed standard required employers to 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. Proposed paragraph (m)(2)(ii) of the standards required employers to ensure that warning signs 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

A number of stakeholders offered opinions on these provisions. Some stakeholders, like the USW, supported the proposed provisions (*e.g.,* Document ID 1681, p. 15). Other stakeholders offered specific critiques regarding the proposed required language for the signs. For example, NGK Metals Corporation (NGK) and Materion Corporation (Materion) strongly opposed having cancer warnings displayed on warning signs. These commenters requested that OSHA strike out the cancer warning based on the results of a recent study by Boffetta, *et al.* (2014) (Document ID 0403) that does not show an elevated risk of cancer to workers exposed to beryllium (Document ID 1663, p. 3; 0403; 1958, pp. 3–5). Materion added that the cancer warning masks the true risk, CBD, and that the wording on warning signs should be changed to ''Causes Damage to Lungs'' to reflect the true hazard (Document ID 1958, pp. 4–5).

OSHA has decided to retain the hazard statement about cancer as a requirement for the warning signs. As discussed in this preamble at Section V, Health Effects, and Section VI, Risk Assessment, OSHA has reviewed the scientific literature for beryllium carcinogenicity, including the Boffeta study, and has concluded that beryllium is carcinogenic. The Agency's finding 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. Furthermore, 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 (Document ID 0651; 0389, pp. 1–3; 1304; 0345, p. 4). In light of this evidence, OSHA finds the comments opposing the cancer warning language on signs unpersuasive. However, with regard to Materion's suggested language, OSHA agrees that a warning that beryllium can cause damage to lungs is appropriate and retains that language, as proposed, in the final standards for general industry and shipyards.

A few other stakeholders also suggested edits or additions to the proposed sign legend. For example, NGK recommended that the phrase, WEAR RESPIRATORY PROTECTION AND PROTECTIVE EQUIPMENT IN THIS AREA be changed to WEAR RESPIRATORY PROTECTION AND PROTECTIVE EQUIPMENT PRIOR TO ENTERING THIS AREA, on warning signs to emphasize that personal protective equipment (PPE) must be put on before entering the restricted work area (Document ID 1663, p. 3). OSHA agrees that employees need to don PPE prior to entering the regulated area, but finds the suggested language requiring respiratory protection and PPE ''in this area'' is sufficient to alert the workers to put their equipment and respirators on prior to entering the restricted work area. Therefore, OSHA has decided to retain the text ''in this area'' as stated in the final standards for general industry and shipyards. OSHA also notes that this language is consistent with the HCS and other previous health standards, such as Benzene (29 CFR 1910.1028).

One stakeholder proposed a provision particular to shipyards. In hearing testimony, Ashlee Fitch of USW commented that warning signs ''demarking abrasive blasting operations with beryllium-containing materials'' should be posted (Document ID 1756, p. 245). OSHA has chosen not to incorporate this suggestion. The signs required by paragraph (m)(2) of this final rule 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 rule and 29 CFR 1910.1200(h) for training requirements). OSHA does not believe it is necessary for the signs to denote the precise activity occurring within the regulated area in order to accomplish these goals. However, employers may choose to include additional information on the signs required under this rule, provided that the additional information included is not confusing or misleading and does not detract from required warnings.

Thus, paragraph (m)(2)(i)) of the final standards for general industry and shipyards requires employers to 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. Pursuant to final paragraph (m)(2)(ii), employers must ensure that these warning signs legible and readily visible and include the specified legend. The only alteration to the legend from the proposal is the addition of the words, ''REGULATED AREA'' following the word, ''DANGER.'' OSHA has not included these regulated area signage requirements in the final standard for construction, because the construction standard does not contain requirements for establishing regulated area and uses the competent person (paragraph (e) of the construction standard) to limit access to areas where exposures have the potential to be above the PEL. In summary, OSHA finds that 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 require access to regulated areas to avoid those areas. 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 who may require medical surveillance or may be subject to the other requirements associated with working in a regulated area.

Proposed paragraph (m)(3) required that labels be affixed to all bags and containers of clothing, equipment, and materials visibly contaminated with beryllium. OSHA also included a requirement that the labels contain the following statement:

DANGER

CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

The USW supported the proposal's requirement that bags and containers storing materials visibly contaminated with beryllium have specific warning labels to alert workers of the dangers of beryllium exposure (Document ID 1681, p. 15). However, as discussed in the Summary and Explanation on paragraph (h) on personal protective clothing and equipment, several commenters objected to the use of the term ''visibly contaminated.'' For example, the Non-Ferrous Founder's Society (NFFS) commented that the definition of ''visibly contaminated with beryllium'' was not provided in the proposed rule and was vague (Document ID 1679, p. 5). OSHA agrees that the term is ambiguous and has chosen to remove the term visibly from the final standards. OSHA has therefore relied on terminology that is commonly used in other substance specific standards for metals, such as Chromium (VI) (29 CFR 1910.1026). NGK also recommended that OSHA insert the word ''particulate'' (Document ID 1663, pp. 3–4). OSHA declines to adopt this suggestion. The addition of the term ''particulate'' is unnecessary and may cause confusion since the final standards cover beryllium in all forms, compounds, and mixtures. Several stakeholders also weighed in on other aspects of these provisions. For example, NGK and Materion offered comments on the proposed wording of the required labels, which restated their requests that the cancer warnings be struck from the proposed language (Document ID 1663, pp. 3–4; 1958, pp. 3–5). OSHA has decided to retain the cancer warning labeling requirements in the final rule for the reasons discussed in response to their comments on paragraph (m)(2) above.

ORCHSE Strategies (ORCHSE) also commented on the labeling requirements of containers and bags in paragraph (m)(3). First, it argued that the provision would require the precautionary statements ''Avoid creating dust'' and ''Do not get on skin'' for all bags and containers which it maintained is inconsistent with the HCS precautionary statements (Document ID 1691, Attachment 1, p. 23). OSHA acknowledges that these ''precautionary statements'' are not from Appendix C of the HCS. However, OSHA is requiring alternate language for the unique situation for bags of contaminated clothing or equipment where workers handling these materials may not have access to other more in-depth forms of information. The Agency is therefore requiring that employers place appropriate warning language on bags and containers containing beryllium-contaminated materials. This provision is consistent with other substance-specific health standards.

Second, ORSCHSE argued that the proposed labeling requirements are inconsistent with the HCS. It stated that paragraph (m)(1) required compliance with the HCS, which covers warning labels for hazardous chemicals other than beryllium, ''so using the same standard for beryllium labels would promote consistency throughout the workplace.'' Therefore, it suggested that paragraph (m)(3) be deleted, because paragraph (m)(1) already requires observation of ''all requirements'' of the HCS. Additionally, ORCHSE commented that the HCS does not require labeling for carcinogens on bags and containers unless the concentration is 1% or more (Document ID 1691, Attachment 1, pp. 23–24).

After considering these comments and the record on this issue, OSHA has decided to retain proposed paragraph (m)(3) with the minor alteration described above. The final provision, which appears in paragraph (m)(3) of the final standards for general industry and shipyards and paragraph (m)(2) of the final standard for construction, requires employers to label each bag and container of clothing, equipment, and materials contaminated with beryllium. The required label must, at a minimum, include the language specified in the proposal. The warning label language for the signal word (danger) and hazard statements (may cause cancer) are consistent with the GHS. However, OSHA has decided that the precautionary statements needed to be slightly different due to the nature of the exposure and the fact that sensitization can result from short term exposures (see Health Effects section V of this preamble).

While ORCHSE correctly notes that the HCS contains a concentration cutoff (0.1% for category 1 carcinogens, and 1% for category 2 carcinogens), that cutoff is difficult to apply in the case of clothing or other material that has been contaminated with beryllium-containing dust. As a practical matter, it may be difficult to determine whether the cutoffs have been exceeded with dust contamination. Moreover, the cutoffs were developed for mixtures that are products and more homogeneous in nature, rather than materials contaminated with dust. If contaminated clothing or other materials are handled in a way that generates dust, exposures of concern might occur more readily than with homogenous mixtures of similar concentration. OSHA believes the clearer approach is to require all contaminated materials with a uniform labelling scheme, as it has for other substance-specific standards (*e.g.,* Lead, 29 CFR 1910.1025; Cadmium, 29 CFR 1910.1027; Coke Oven Emissions, 29 CFR 1910.1029). Including this provision will ensure that downstream workers who might receive the contaminated material have notice of the contamination. As discussed in the summary and explanation for paragraph (b) the term ''materials'' includes waste, scrap, debris, and any other items contaminated with beryllium.

The Agency finds that the final labeling requirements will help 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.

Proposed paragraph (m)(4) contained requirements for employee information and training. The proposed provisions applied to each employee who is or can reasonably be expected to be exposed to airborne beryllium. ORCHSE strongly urged OSHA to rewrite this provision to align with the HCS training, arguing that ''there is no need to include chemical hazard training requirements in a substance specific standard'' (Document ID 1691, Attachment 1, p. 20). While OSHA agrees that the HCS is designed to cover all chemical hazards in the workplace, an employer may choose to train by specific chemical or by hazard. In this substance specific standard, OSHA find that employees need to be trained on the hazards specifically associated with beryllium, in addition to the training they receive under the HCS. These types of requirements are not uncommon in substance specific hazards. For example, the Lead standard requires annual training on the specific hazards associated with lead exposure (see 29 CFR 1910.1025 (l)(1)). Consequently, OSHA is not persuaded by ORCHSE that OSHA should substantially change the training provisions in the final rule.

The Boeing Company (Boeing) suggested that OSHA add the text ''within the scope of this standard'' to the end of this requirement (Document ID 1667, p. 7). It contended that its recommended language would ''set a measurable boundary consistent with the scope of the standard,'' while the proposal would create an ''open ended boundary that would confuse compliance efforts.'' OSHA has considered the suggestion but does not find Boeing's argument persuasive. OSHA does not believe this adds additional clarity to employer on which employees should be trained. OSHA expects that once the employer is covered under the standard they are in the best position to determine who would be potentially exposed to beryllium. Additionally, this language is consistent with other substance specific standards, such as Benzene (29 CFR 1910.1028).

NGK also commented on the proposed trigger. Specifically, it suggested the training requirements should be consistent with the lead standard (29 CFR 1910.1025(l)(1)(ii)) in that the training should be done for those workers exposed above the action level (Document ID 1663, p. 4). OSHA declines to adopt this suggestion. As discussed in Section V, Health Effects, and Section VI, Risk Assessment, risk of material impairment to health remains at exposure levels below the action level. Because of this risk, OSHA concludes that it is necessary and appropriate to train all employees who may be exposed to airborne beryllium at any level. The Agency finds that all such employees will benefit from this training. Therefore, OSHA is continuing to trigger the training requirements proposed in paragraph (m)(4)(i) based on airborne exposure, or anticipated exposure, at any level. The final provisions are contained in paragraph (m)(4)(i) of the standards for general industry and shipyards and paragraph (m)(3)(i) of the standard for construction.

Proposed paragraph (m)(4)(i)(A) required employers to provide employees who are or can reasonably be expected to be exposed to airborne beryllium with 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.

OSHA did not receive any objections to or comments on this provision. After a review of the rulemaking record, the Agency continues to believe that the provision of information and training in accordance with the HCS will benefit employees. For example, 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)). Therefore, OSHA has included proposed paragraph (m)(4)(i)(A) substantively unchanged from the proposal in paragraph (m)(4)(i)(A) of the final standards for general industry and shipyards and paragraph (m)(3)(i)(A) of the final standard for construction.

Proposed paragraphs (m)(4)(i)(B) and (C) specified when an employer's obligation to train covered employees should begin and how often training should occur. Proposed paragraph (m)(4)(i)(B) required initial training 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. Under proposed paragraph (m)(4)(i)(C), employers were required to repeat training at least annually thereafter. USW supported the requirement of initial and annual training for workers who are or can be reasonably expected to be exposed to beryllium (Document ID 1681, p. 15).

After reviewing the record on this topic, OSHA has decided to retain proposed paragraphs (m)(4)(i)(B) and (m)(4)(i)(C) in paragraph (m)(4)(i)(B) and (C) of the final standards for general industry and shipyards and paragraph (m)(3)(i)(B) and (C) of the final standard for construction. OSHA finds that initial training and annual retraining are necessary due to the serious and debilitating health effects of beryllium exposure, and for reinforcement of employees' knowledge of those hazards. The initial training requirement is consistent with the HCS, which requires that employers provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment (29 CFR 1910.1200(h)(1)). In addition, while the triggers may be slightly different, the initial and annual training requirement are 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 1,3-Butadiene (29 CFR 1910.1051).

Proposed paragraph (m)(4)(ii) required 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. ORCHSE and NGK objected to this proposed requirement. ORCHSE suggested that OSHA replace ''can demonstrate knowledge of'' with ''has been informed of'' in paragraph (m)(4)(ii). ORCHSE also argued that employers can control what information they provide, but cannot control what information the employee retains, and a literal interpretation of the requirement that employees must ''demonstrate knowledge of'' the nine enumerated categories of information will result in citations whenever ''any employee, at any moment, is unable to recite detail'' on those topics (Document ID 1691, Attachment 1, pp. 21–23). Similarly, NGK commented that the requirement that employers must ensure that employees who may be exposed to beryllium can demonstrate knowledge of enumerated subjects should be replaced with a requirement that employers ensure employee participation in a training program, consistent with the lead standard (29 CFR 1910.1025(l)(1)(ii)) (Document ID 1663, p. 4).

OSHA does not find these arguments persuasive. Because beryllium is a hazardous chemical with serious and debilitating health effects, it is imperative that employers can ensure that employees can demonstrate that they understand the material and have knowledge of the topics covered during the training sessions, as previously indicated. To adjust the text to read ''has been informed of'' or to require the employer to ensure employee participation in training will not ensure employee comprehension and consequently could lead to employees not understanding the health effects associated with beryllium exposure and safety concerns to protect themselves from exposure. This language would also be inconsistent with the HCS, which requires effective training which OSHA indicates must be in a manner which an employee comprehends.

The Agency understands that employers would like more clarity on how to determine whether training requirements are met. However, OSHA has decided that the training requirements under the final beryllium standards, like those in HCS, are best accomplished when they are performance-oriented. But, as in past standards, the Agency does offer some suggestions.

First, although OSHA finds that the employer is in the best position to determine how the training can most effectively be accomplished, the Agency notes that hands-on training, videotapes, DVD or slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. Second, 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 videotape presentations or computer-based programs are used, this requirement may be met 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. Although it is important that employees be able to ask questions, OSHA finds that the employer is in the best position to determine whether the instructor must be available for questions during training or if an instructor or trainer can answer questions after the training session. Such performance-oriented requirements are intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program for each workplace.

Third, in addition to being performance-oriented, these training requirements are also results-oriented. As discussed in the respirable crystalline silica standard, there are a variety of methods employers can use to determine whether employees have the requisite knowledge. For example, employers may choose to facilitate discussions of the required training subjects or administer written tests or oral quizzes. Any of these methods could alert an employer to an employee knowledge gap.

Finally, OSHA has included a modification in the final standards that was prompted by ORCHSE and NGK's questions. In the final standards (paragraph (m)(4)(ii) of the standards for general industry and shipyards and paragraph (m)(3)(ii) of the standard for construction), OSHA requires that the employer must ensure that employees demonstrate understanding, in addition to knowledge. As discussed above this is consistent with the HCS and emphasizes that it is not enough for an employee to simply be provided with the information; the employer must also ensure that the employee understands the topics on which he or she is trained.

This change is consistent with Assistant Secretary David Michaels' memorandum to OSHA Regional Administrators (Document ID 1754, p. 2). The memorandum explains that because employees have varying educational levels, literacy, and language skills, training must be presented in a language, or languages, and at a level of understanding that accounts for these differences in order to ensure that employees understand the training. As stated by Assistant Secretary Michaels:

> [A]n employer must instruct its employees using both a language and vocabulary that the employees can understand. For example, if an employee does not speak or comprehend English, instruction must be provided in a language that the employee can understand. Similarly, if the employee's vocabulary is limited, the training must account for that limitation. By the same token, if employees are not literate, telling them to read training materials will not satisfy the employer's training obligation (Document ID 1754, p. 2).

This may mean, for example, providing materials, instruction, or assistance in Spanish rather than or in addition to English if some of the employees being trained are Spanish-speaking and do not understand English. However, the employer is not required to provide training in the employee's preferred language if the employee understands the language used for training.

Finally, Boeing suggested that OSHA add the text ''or equally as effective documentation'' to paragraph (m)(4)(ii)(B), so that the employer could satisfy its obligations by ensuring that employees who are or can reasonably be expected to be exposed to airborne beryllium could demonstrate knowledge of ''[t]he written exposure control plan, or equally as effective documentation, 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.'' They contend that this added language would allow employers ''to provide the required information through the use of existing processes instead of through the creation of a second redundant document'' (Document ID 1667, p. 7).

OSHA has considered Boeing's suggestion but does not find its arguments persuasive. Paragraph (m)(4)(ii)(B) of the final standards specifically requires the employer to ensure that employees can demonstrate understanding and knowledge of the topics covered in the written control plan, not from a similar document. The suggested language makes it unclear whether the employee would get the appropriate training needed and still gain the same knowledge and understanding required by the beryllium standard. OSHA, therefore, has decided to retain paragraph (m)(4)(ii)(B)'s requirements from the proposed rule in these final standards. That said, employers are free to incorporate their current exposure control program into the written control program required by paragraph (f)(1) if their program meets the requirements of that paragraph. If they do so, and train their employees on that program, paragraph (m)(4)(ii)(B) requires no ''second redundant document.''

Proposed paragraph (m)(4)(ii)(A)–(I) specified the contents of training for employees who are or can reasonably be expected to be exposed to airborne beryllium. The proposed list required employers to ensure that employees can demonstrate knowledge of: (1) The health hazards associated with exposure to soluble beryllium compounds, including the signs and symptoms of CBD; (2) the written exposure control plan, with emphasis on the location(s) of beryllium work areas, including any regulated areas, and the specific nature operations that could result in employee exposure, especially employee exposure above the TWA PEL or STEL; (3) the purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators; (4) applicable emergency procedures; (5) measures employees can take to protect themselves from exposure to beryllium and contact with soluble beryllium compounds, including personal hygiene practices; (6) the purpose and a description of the medical surveillance program required by paragraph (k) of this standard, including risks and benefits of each test to be offered; (7) the purpose and a description of the medical removal protection provided under paragraph (l) of this standard; (8) the contents of this standard; and (9) the employee's right of access to records under the Records Access Standard (29 CFR 1910.1020).

Stakeholders offered several comments on these proposed training topics. For example, ORCHSE commented that the employer should just ''provide information and training as specified in the HCS'' (Document 1691, Attachment 1, p. 23). OSHA has chosen not to adopt this suggestion because it finds that employees need training specific to beryllium and its hazards, not only the general training required by the HCS on the hazards in the workplace. The Agency concludes that providing information and training on the topics proposed is essential to ensuring that employees are informed about the hazards attributed to beryllium exposures, the measures necessary to protect themselves, and the rights accorded to them under these standards.

Stakeholder comments support OSHA's finding that training will lead to better work practices and hazard avoidance. For example, in hearing testimony, Chris Trahan from North America's Building Trades Unions (NABTU) commented that in construction, she does not ''see a high level of awareness about hazards related to beryllium'' (Document ID 1756, pp. 207–08). NABTU also commented that it ''developed a survey to determine the level of awareness of beryllium hazards and knowledge of exposures among building trades trainers,'' and found widespread ignorance of beryllium health risks even among survey respondents responsible for delivering hazard awareness training (Document ID 1679 p. 5). Ashlee Fitch from the USW testified that in her experience in abrasive blasting, there was no training specific to what the material contained, and ''the health effects associated with . . . blasting media'' were not discussed (Document ID 1756, p. 247). Thus, OSHA concludes that mandating information and training on the topics specific to beryllium as outlined in proposed paragraph (m)(4)(ii) is particularly important.

In light of these comments, OSHA reaffirms its finding that all nine of the training topics listed in proposed paragraph (m)(4)(ii)(A)–(I) should be included in the final standards. The Agency has thus retained these topics in final paragraphs (m)(4)(ii)(A)–(I) of the standards for general industry and shipyards and paragraph (m)(3)(ii)(A)–(I) of the standard for construction, with minor alterations for consistency with triggers that were updated from the proposal to the final. For example, OSHA has changed the (m)(4)(ii)(A) from ''contact with soluble beryllium'' to ''contact with beryllium.''

OSHA is not mandating additional training for a competent person in paragraph (m) of the standards for construction. As discussed in more detail in the summary and explanation of *Written Exposure Control Plan,* the knowledge required by an individual implementing the written exposure control plan required by these standards already ensure a high level of competence. OSHA recognizes that there may be situations in which an employee needs additional training in order to ensure that he or she has the knowledge, skill, and ability to be a designated competent person, but because of unique scenarios in the construction and shipyard environments, those training requirements would vary widely. OSHA concludes, therefore, that it is the employer's responsibility to identify and provide any additional training that the competent person would need to implement the written exposure control plan.

Proposed paragraph (m)(4)(iii) required employers to provide additional 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. OSHA did not receive any comments on this provision, and retains it in the final to ensure that employees are aware of new or additional hazards. This training must be provided at the time of (or prior to) the new or increased exposure, even if a year has not passed since the previous training. New training would be required under the standard if the employer changes work production operations or personnel in a way that would require equipment to be operated differently to avoid exposures above the TWA PEL or STEL. Additional training would also be required if employers introduce new production or personal protective equipment to employees who 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. Similarly, 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 has concluded that the additional training requirement in this final rule 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.

Proposed paragraph (m)(4)(iv) required the employer to make a copy of the standard and its appendices readily available at no cost to each employee and designated employee representative(s). OSHA did not receive any comments on this provision, and the Agency has retained the requirement in paragraph (m)(4)(iv) of the standards for general industry and shipyards and paragraph (m)(3)(iv) of the standard for construction. This is a common requirement in OSHA standards such as Chromium (VI) (29 CFR 1910.1026), Acrylonitrile (29 CFR 1910.1045), respirable crystalline silica (29 CFR 1910.1053), and Cotton Dust (29 CFR 1910.1043). The provision leaves employers free to determine the best way to make the standard available, which could include giving the employer a copy of the standard or placing a printed or electronic copy in a central location that the employees can easily access. In order to help ensure employees are protected against beryllium hazards, they need to be familiar with and have access to the beryllium standard applicable to their workplace (general industry, shipyard, or construction), and be aware of the employer's obligations to comply with it.

(n) Recordkeeping

Paragraph (n) of the final standards for general industry, construction, and shipyards sets forth the employer's obligation to comply with requirements to maintain records of air monitoring data, objective data, medical surveillance, and training. The recordkeeping requirements are 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 recordkeeping provisions are also consistent with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard at 29 CFR 1910.1020, which addresses access to employee exposure and medical records.

As discussed in more detail below, the recordkeeping requirements in the final standards are similar to those included in the proposal. In the proposed rule, OSHA identified recordkeeping requirements for exposure measurements, historical monitoring data, objective data, medical surveillance, and training, and required employers to comply with Record Access standard requirements regarding access to and transfer of these records. Ameren Corporation (Ameren) expressed support for these requirements (Document ID 1675, p. 7). All other comments regarding the recordkeeping requirements focused on specific areas of the recordkeeping requirements and are discussed in the appropriate subject section.

Proposed paragraph (n)(1)(i) required employers to maintain records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of the standard. OSHA did not receive comments on this provision and has decided to retain it in the final rule, in part, because it will enable both employers and OSHA to ensure compliance with exposure assessment requirements under paragraph (d) of the standards. It will also allow employers to ascertain which of the final standards' provisions that are triggered at various exposure levels apply to their employees. Thus, OSHA is retaining the proposed provision with one minor modification. Specifically, the Agency has added the words ''make and'' prior to ''maintain'' in order to clarify that the employer's obligation is to create and preserve such records. This clarification has also been made for other records required by the final beryllium standards. The revised language is consistent with OSHA's Records Access standard, which refers to employee exposure and medical records that are made or maintained (29 CFR 1910.1020(b)(3)).

Proposed paragraph (n)(1)(ii) required that records of all measurements taken to monitor employee exposure include at least the following information: The date of measurement for each sample taken; the operation being monitored; the sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) recommended that the recordkeeping provision should include the purpose and rationale for the sampling performed as this would show that the exposure monitoring requirements are being met (Document ID 1665, p. 2). After careful consideration, OSHA has decided not to require that records include the purpose and rationale for the sampling. The Agency points out that the purpose and rationale for the sampling performed are dictated by the exposure assessment provision in paragraph (d), which requires the employer to assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either a performance option or the scheduled monitoring option. The air monitoring requirements described in paragraph (d) and the air monitoring data retention described in this section (paragraph (n)) provide adequate information to show whether the exposure monitoring requirements are being met. Furthermore, paragraphs (n)(1)(ii)(A)–(F) of the standards are generally consistent with other OSHA standards, such as respirable crystalline silica (29 CFR 1910.1053), chromium (VI) (29 CFR 1910.1026), and methylene chloride (29 CFR 1910.1052).

OSHA received several comments regarding the requirement in paragraph (n)(1)(ii)(F) that the employer include employee social security numbers in exposure measurement records. The American Dental Association (ADA), the Boeing Company (Boeing), and ORCHSE Strategies (ORCHSE) cited employee privacy and identity theft concerns (Document ID 1597, p. 4 (pdf); 1667, pp. 7–8; 1691, Attachment 1, p. 19). Boeing and ORCHSE suggested the use of an identifier other than the social security number, such as an employee identification number or another unique personal identification number. The ADA recommended that employers with fewer than ten employees should not be required to include employee social security numbers in records required by the standard. It further stated that some state statutes ''impose data security and breach notification requirements on those who collect social security numbers,'' and in small businesses, ''the risk to employees of identity theft outweighs the difficulty of identifying employee records'' (Document ID 1597, p. 2–4 (pdf)).

OSHA has considered these comments and decided to retain the requirement for including the employee's social security number in the recordkeeping requirements of the rule. The requirement to use an employee's social security number is a long-standing OSHA practice, because a social security number is unique to an individual, is retained for a lifetime, and does not change when an employee changes employers. The social security number is therefore a useful tool for evaluating an individual's exposure over time, particularly where exposures are associated with chronic beryllium disease (CBD), which has a varying rate of progression during which time an employee may have several employers or had beryllium exposure sometime in the past.

OSHA recognizes the privacy concerns expressed by commenters regarding this requirement, and understands the need to balance that interest against the public health interest in requiring the social security identifier. Instances of identity theft and breaches of personal privacy are widely reported and concerning. However, OSHA has concluded that this rule should adhere to the past, consistent practice of requiring employee social security numbers on exposure records mandated by every OSHA substance-specific health standard, and that any change to the Agency's requirements for including employee social security numbers on exposure records should be comprehensive and apply to all OSHA standards, not just the standards for beryllium.

OSHA is proposing to delete the requirement that employers include employee social security numbers in records required by its substance-specific standards in the Agency's Standards Improvement Project—Phase IV (SIP–IV) proposed rule (81 FR 68504, 68526–68528 (10/4/16)). OSHA will revisit, if necessary, its decision to require employers to maintain employee social security numbers in beryllium records in light of the decision it makes in the SIP–IV rulemaking. In the meantime, OSHA has included the requirement to use and retain social security numbers in the final standards.

The ADA also urged OSHA to pursue Regulatory Alternative #1b, which would exempt, except for recordkeeping purposes, operations where the employer can show that employee exposures will not meet or exceed the action level or exceed the STEL. It further argued under this option that OSHA should limit employers' recordkeeping requirements to those records that show that employees' exposure will not meet or exceed the action level or exceed the STEL (Document ID 1597, p. 3 (pdf)). It maintained that this is reasonable because the ''employees are not at significant risk of exposure'' and ''the record retention period is onerous'' (Document ID 1597, p. 3 (pdf)).

OSHA disagrees with this suggestion for several reasons. First, the OSH Act states that standards adopted by OSHA must require employers maintain ''accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6.'' OSH Act § 8(c)(3). Thus, on its face, the Act requires records of all exposure measurements required by the final standards to be maintained, not just high ones. The OSH Act also requires that employees have access to exposure records, (id.), and requiring the employer to maintain those records helps to fulfill that right. Further, as discussed in Section V, Health Effects, and Section VII, Significant Risk, employees who are exposed below the action level may still be at risk. Maintaining records of those exposures may assist in the diagnosis of employee disease long after the exposure occurs. It also allows employees to have confidence that their exposures are within the requirements of the final standards, and valuable insights about exposure control methods may be gained through the review of exposure records, even those that are below the action level. In addition, as the Supreme Court noted in the *Benzene* case, air monitoring and medical testing, when done for employees exposed below the PEL, ''keep a constant check on the validity of the assumptions made in developing'' the PEL, giving a basis to lower the PEL if necessary. *Benzene,* 448 U.S. at 657–58. Requiring the employers to maintain those records furthers that purpose. Other OSHA substance-specific rules also require employee exposure records to be maintained, regardless of exposure level, such as the standards addressing exposure to respirable crystalline silica (29 CFR 1910.1053), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

Second, employee information and training requirements under paragraph (m) of the standards apply to each employee who is or can reasonably be expected to be exposed to airborne beryllium. As discussed in paragraph (m) of the Summary and Explanation in this preamble, OSHA finds that all employees who are or can be reasonably expected to be exposed in this manner will benefit from the specified forms of training. The creation and maintenance of training records will permit both OSHA and employers to ensure that the required training has occurred on schedule. Finally, OSHA notes that employers may reduce their recordkeeping burden in some cases by ensuring their employees are only exposed below the action level. For example, under paragraph (k), employers are required to offer medical surveillance those employees who meet certain exposure thresholds. By keeping exposures level below the action level, employers decrease the likelihood that their employees will fall into one of the enumerated groups. If employers do not have any employees covered by medical surveillance under paragraph (k), then they have no medical surveillance records to retain under these standards.

As to the expense and difficulty of maintaining the records required under these standards, OSHA recognizes that there will be time, effort, and expense involved in maintaining medical records. However, as stated earlier, OSHA expects that employers will have a system for maintaining these records, just as they do for their other business records. In addition, the Agency allows employers to use whatever method works best for them in meeting these requirements, paper or electronic (29 CFR 1910.1020(d)(2)).

In summary, paragraph (n)(1)(ii) in the final standards is substantively unchanged from the proposed rule. However, OSHA has made one editorial modification to paragraph (n)(1)(ii)(B), which is to change ''operation'' to ''task.'' Both ''task'' and ''operation'' are commonly used in describing work. However, OSHA uses the term ''task'' throughout the rule, and the Agency is using ''task'' in the recordkeeping provision for consistency and to avoid any potential misunderstanding that could result from using a different term. This editorial change neither increases nor decreases an employer's obligations as set forth in the proposed rule. The requirements of paragraph (n)(1)(ii) are generally consistent with those found in other OSHA standards, such as the standards for respirable crystalline silica (29 CFR 1910.1053), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

Proposed paragraph (n)(1)(iii) required the employer to maintain exposure records in accordance with OSHA's Records Access standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(1)(ii)). The Agency did not receive comment on this provision. However, OSHA has changed the requirement that the employer ''maintain this record as required by'' OSHA's Records Access standard to ''ensure that exposure records are maintained and made available in accordance with'' that standard. OSHA believes that the language of the final standard more clearly conveys the Agency's intent that in addition to maintaining records, employers must make records available to employees and others as specified in the Records Access standard. As noted above, this clarifying change is editorial and neither increases nor decreases an employer's obligations as set forth in the proposed rule. This clarification has also been made for other records required by the final beryllium standards.

Proposed paragraph (n)(2) contained the requirement to retain records of any historical monitoring data used to satisfy the proposed standard's the initial monitoring requirements. As explained in the Summary and Explanation of paragraphs (b) and (d) in this preamble, the definition of the term ''objective data'' in the final rule includes all information that demonstrates airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. Historical data that reflects workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations would be considered objective data under the final rule. The requirement to keep records of objective data is addressed under a separate paragraph. Therefore, OSHA has chosen to delete the separate recordkeeping requirement for historical data.

Proposed paragraph (n)(3) contained the requirements to keep accurate records of objective data. Proposed paragraph (n)(3)(i) required 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 was required to contain at least 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 supported the exemption; and other information demonstrating that the data met the requirements for objective data in accordance with paragraph (d)(2)(ii).

OSHA did not receive comments regarding this provision, and the Agency finds that it should be included in the final rule. Since 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. Objective data are intended to provide the same degree of assurance that employee exposures have been correctly characterized as would exposure assessment. The specified content elements are required to ensure that the records are capable of demonstrating to OSHA a reasonable basis for the conclusions drawn by the employer from the objective data.

Therefore, OSHA has included proposed paragraph (n)(3) as paragraph (n)(2) in the final standards, with minor alterations. Specifically, in the final standards, OSHA has changed paragraphs (n)(2)(ii)(D) to require the record to contain ''[a] description of the process, task, or activity on which the objective data were based,'' and paragraph (n)(2)(ii)(E) to require the record to contain ''[o]ther data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.'' These changes are editorial, and intended to clarify the maintenance and availability of objective data records. They are only intended to aid employers in determining the precise information to be retained. They do not affect the employer's obligations as set forth in the proposed rule.

Proposed paragraph (n)(3)(iii) required the employer to maintain a record of objective data relied upon as required by the Records Access standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(1)(ii)). The Agency did not receive comment on this provision. Objective data may include employee exposure records that must be maintained, and therefore, the Agency has retained it in the final standards as paragraph (n)(2)(iii). OSHA notes that this final provision, like all of the final provisions in this paragraph related to the Records Access standard, includes the non-substantive change from the proposed requirement to maintain the record as required by the Records Access standard, to the requirement to maintain and make available the record in accordance with the Records Access standard. OSHA's reasons for this change are discussed above.

Paragraph (n)(3) of the final standards, like paragraph (n)(4) of the proposal, addresses medical surveillance records. Under proposed paragraph (n)(4)(i), employers had to establish and maintain medical surveillance records for each employee covered by the medical surveillance requirements in paragraph (k) of the proposed standard. Proposed paragraph (n)(4)(ii) listed the categories of information that an employer was required to record: The employee's name, social security number, and job classification; a copy of all licensed physicians' written medical opinions; and a copy of the information provided to the PLHCP as required by paragraph (k)(4) of the proposed standard.

The ADA and ORCHSE questioned the requirement that the employee's social security number be included in medical surveillance records (Document ID 1597, pp. 2–4 (pdf); 1691, Attachment 1, p. 19). As noted above in the discussion on exposure measurement records, OSHA finds the privacy and security issues associated with the required use of social security numbers are of concern. However, for the same reasons discussed above, the Agency has decided to retain the requirement for use of social security numbers in medical records. OSHA is examining the requirements for social security numbers separately from this rulemaking.

Medical records document the results of medical surveillance and are especially important when an employee's medical condition places him or her at increased risk of health impairment from further exposure to beryllium in the workplace. Furthermore, the records can be used by the Agency and others to identify illnesses and deaths that may be attributable to beryllium exposure, evaluate compliance programs, and assess the efficacy of the standards. OSHA concludes that medical surveillance records are necessary and appropriate for protection of employee health, enforcement of the standards, and development of information regarding the causes and prevention of occupational illnesses. Therefore, OSHA has decided to retain proposed paragraph (n)(4)(ii)'s requirements regarding medical surveillance records in paragraph (n)(3)(ii) of the final standards. However, OSHA has changed the requirement in proposed paragraph (n)(4)(ii)(B) that the record include copies of all licensed physicians' written opinions to the requirement that the record include copies of all licensed physicians' written medical opinions for each employee in paragraph (n)(3)(ii)(B) of the final standards. These changes are editorial and intended to clarify that employees are entitled to their own written medical opinion, not all written opinions. This change neither increases nor decreases an employer's obligations as set forth in the proposed rule.

Proposed paragraph (n)(4)(iii) required the employer to maintain employee medical records for at least the duration of the employee's employment plus 30 years in accordance with OSHA's Records Access Standard at 29 CFR 1910.1020(d)(1)(i). The ADA objected to this provision, arguing that the proposed retention period is onerous (Document ID 1597, p. 3 (pdf)). OSHA has considered this comment and concluded that the best approach is to maintain consistency with 29 CFR 1910.1020 and its required retention periods of (1) 30 years for exposure records and objective data, and (2) the duration of employment plus 30 years for medical surveillance records. It is necessary to keep medical records for these extended time periods because of the varying rate of progression for CBD and the long latency period between exposure and development of lung cancer. OSHA recognizes that in some cases, the latency period for beryllium-related cancer may extend beyond 30 years. However, the Agency concludes that the retention periods specified in 29 CFR 1910.1020 represent a reasonable balance between the need to maintain records and the administrative burdens associated with maintaining those records for extended time periods. Because the 30-year, and the duration of employment plus 30-year, record retention requirements are currently included in 29 CFR 1910.1020, these time periods are consistent with longstanding Agency and employer practice. Other substance-specific rules are also subject to the retention requirements of 29 CFR 1910.1020, such as the standards addressing exposure to respirable crystalline silica (29 CFR 1910.1053), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026). Thus, OSHA finds that the 30-year retention period is necessary and appropriate for exposure records, historical monitoring data, and objective data, and that the duration of employment plus 30-year retention period is necessary and appropriate for medical surveillance records.

Therefore, OSHA has decided to include the retention periods provided by the Records Access standard in paragraph (n)(3)(iii) of the final standards. For the reasons discussed above, OSHA has added ''and made available'' after ''maintained'' in paragraph (n)(3)(iii) of the standards. Under the final standards, the employer is responsible for the maintenance of records in his or her possession. The employer is also responsible for ensuring the retention of records in the possession of the licensed physician (*e.g.,* the written medical reports described in paragraph (n)(3) that are created pursuant to this rule's medical surveillance requirements). This responsibility, which derives from 29 CFR 1910.1020(b), means that employers must ensure that the licensed physician retains a copy of medical records for the employee's duration of employment plus 30 years. The employer can generally fulfill this obligation by including the retention requirement in its agreement with the licensed physician. The requirements are consistent with other OSHA health standards, such as Hexavalent Chromium (VI) (29 CFR 1910.1026), respirable crystalline silica (29 CFR 1910.1053), and Methylene Chloride (29 CFR 1910.1052).

Paragraph (n)(4) of the final standards, like proposed paragraph (n)(5), addresses training records. Proposed paragraph (n)(5)(i) required employers to prepare records of any training required by these standards. At the completion of training, the employer was required to prepare a record that included 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 also applied to records of annual retraining or additional training as described in paragraph (m)(4).

The ADA and ORCHSE questioned the requirement that the employee's social security number be included in training records (Document ID 1597, p. 2–4 (pdf); 1691, Attachment 1, p. 19). As noted above in the discussions on exposure measurement and medical surveillance records, OSHA finds the privacy and security issues associated with the required use of social security numbers are of concern. However, for the same reasons discussed above, the Agency has decided to retain the requirement for use of social security numbers in training records. As stated above, OSHA is examining the requirements for social security numbers separately from this rulemaking. In the meantime, OSHA has retained the social security requirement in the final standards.

No other comments were received on this provision. Proposed paragraph (n)(5)(i) is now paragraph (n)(4)(i) in the final standards. Paragraph (n)(4)(i) in the final standards is substantively unchanged from the proposal.

Proposed paragraph (n)(5)(ii) required employers to retain training records, including records of annual retraining or additional training required under these standards, for a period of three years after the completion of the training. North America's Building Trades Unions (NABTU) commented that employers ''must maintain documentation of [any] training'' required for beryllium construction workers (Document ID 1679, p. 3). OSHA agrees. As noted above, OSHA finds that the creation and maintenance of training records will permit both OSHA and employers to ensure that the required training has occurred on schedule. Thus, the Agency has included this provision in the standard for construction, as well as the standards for general industry and shipyards. Proposed paragraph (n)(5)(ii) is now paragraph (n)(4)(ii) in the final standards, and is substantively unchanged from the proposal. The three-year time period is consistent with the Bloodborne Pathogens standard (29 CFR 1910.1030).

Paragraph (n)(5) of the final standards, like proposed paragraph (n)(6), addresses access to records. Proposed paragraph (n)(6) required employers to make all records mandated by these standards 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). OSHA did not receive comment on this provision, and includes it in the final standards to emphasize and ensure proper employee and government access to records.

Paragraph (n)(6) of the final standards, like proposed paragraph (n)(7), addresses transfer of records. Proposed paragraph (n)(7) required that employers comply with the Records Access standard regarding the transfer of records. 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. OSHA did not receive comment on this provision, and includes it the final standards to help ensure consistent records access.

(o) Dates

Paragraph (o) of the standards for general industry, construction, and shipyards sets forth the effective date of the standards and the dates for compliance with their requirements. OSHA proposed that the final rule would become effective 60 days after its publication in the **Federal Register**, and that 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), while the requirements for establishing change rooms and implementing engineering controls would begin one year and two years after the effective date, respectively. Ameren, AFL–CIO, and United Steelworkers expressed support for the proposed effective and compliance dates (Document ID 1675, p. 7; 1681, Attachment 1, p. 15; 1689, p. 15).

OSHA sets the effective date to allow sufficient time for employers to obtain the standard and read and understand its requirements. Unchanged from the proposal, paragraph (o)(1) provides that the standards will become effective on March 10, 2017.

OSHA sets the compliance dates to allow sufficient time for employers to undertake the necessary planning and preparation for compliance with the various provisions of the standards. In addition to the default compliance date of 90 days that applied to most provisions, OSHA's proposal included extended compliance dates for the provisions that require the establishment of change rooms and the implementation of engineering controls in order to give affected employers sufficient time to design and construct change rooms where necessary, and to design, obtain, and install any required control equipment. In response to comments stating that more time is necessary to prepare for compliance, the compliance dates in the final rule have been extended from those proposed.

Paragraph (o)(2) of the standards establishes the dates for compliance with the requirements of the standard. Several employers and industry representatives commented that the proposal's default compliance date (90 days after the effective date) provided inadequate time to prepare for compliance. ORCHSE Strategies (ORCHSE) commented that an additional six months are needed ''to make necessary changes to facilities, broad-based exposure assessments, and delineate work and regulated areas'' (Document ID 1691, Attachment 1, p. 24). Also, the Boeing Company (Boeing) commented that the standard should require compliance two years after the effective date, explaining that ''it will take, for a company of our size, between 1 and 2 years to accurately and comprehensively determine what our exposures are, prior to developing and implementing an exposure plan'' (Document ID 1667, p. 8).

The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) also commented on the amount of time needed to comply with the ''Accuracy of Measurement'' requirement in paragraph (d)(1)(v) of the proposal, which has been renamed ''Methods of sample analysis'' and moved to paragraph (d)(5) in the final standards (Document ID 1665, p. 3). Specifically, BHSC Task Group expressed concern that laboratories would need to adopt newer analytical methods not widely used by the majority of analytical laboratories to perform beryllium measurements to the level of accuracy specified by the standard. BHSC Task Group acknowledges that although the OSHA rule does not require it, a Department of Energy requirement for accreditation that exists in their Beryllium Worker Safety and Health Program would drive laboratories to obtain accreditation by an external accrediting body to use these newer methods, which can take well over 150 days. (Document ID 1665, p. 3–4). OSHA rejects the reasoning behind BHSC Task Group's concern on the amount of time needed to comply the accuracy of measurement requirement, as the newer analytical methods for beryllium are available and, as pointed out by BHSC Task Group, OSHA does not require laboratories to be accredited in these methods to comply with the standards.

Nonetheless, OSHA recognizes the concerns expressed by Boeing, ORCHSE, and BHSC Task Group that employers may need additional time to assess exposures and undertake the necessary planning and preparation for compliance with the obligations of the standards, and has determined that some of those concerns are reasonable. OSHA has therefore extended the final standards' default compliance date, which applies to all provisions except for those with separate compliance dates under paragraphs (o)(2)(i) and (o)(2)(ii), to one year from the effective date.

Paragraph (o)(2)(i) of the standards provides the date for compliance with the requirement in paragraph (i) to establish change rooms, and in the general industry standard, to provide showers. OSHA proposed a compliance date of one year after the effective date for establishing change rooms, but commenters indicated that more time was needed to modify their facilities. Boeing requested that the compliance date for establishing change rooms begin three years after the effective date, stating that ''for large facilities, modifications such as showers, clothing storage and change rooms need a significant amount of time to be planned, designed, contracted, and constructed within operating factory sites'' (Document ID 1667, p. 8). ORCHSE also indicated that additional time is needed to ''make necessary changes to facilities'' (Document ID 1691, Attachment 1, p. 24).

OSHA expects that most employers will be able to establish change rooms and showers within a year of the effective date, but the Agency understands that some employers, both large and small, may need additional time to plan and construct these areas. OSHA is persuaded by the concerns expressed by the commenters that employers may need additional time to modify their facilities, and has extended the compliance date for the general industry standard's change rooms and showers requirements to two years after the effective date. Providing an extended compliance date for establishing change rooms and providing showers is consistent with the approach taken in OSHA's general industry standard for Cadmium (29 CFR 1910.1027(p)(2)(vi)(B)).

The construction and shipyard standards do not require employers to provide showers, but OSHA recognizes that construction and shipyard employers may also need additional time to plan and establish change rooms at construction sites and shipyard industry establishments. Change room facilities in these industries may be permanent or temporary, including mobile units that can be purchased or rented. OSHA has thus set the compliance date for the construction and shipyard standards' requirement to establish change rooms to two years after the effective date.

Paragraph (o)(2)(ii) of the standards provides the date for compliance with the requirements in paragraph (f) to implement engineering controls. OSHA proposed a compliance date of two years after the effective date for employers to comply with the engineering control requirements in paragraph (f). Boeing, however, commented that the compliance date for implementing engineering controls should be extended to four years after the effective date, explaining that ''for large companies, exposure assessments and feasibility studies would have to be completed on a vast scale, and then engineering controls may have to be installed,'' making four years ''a reasonable time frame for these compliance measures'' (Document ID 1667, pp. 8). The Non-Ferrous Founders' Society (NFFS) also commented that a two-year implementation period was insufficient because it takes 12 to 24 months to obtain an Environmental Protection Agency (EPA) permit for changes to ventilation systems, and foundries cannot begin work to modify ventilation systems until they obtain a permit (Document ID 1756, Tr. 61–62).

OSHA recognizes the concerns expressed by Boeing regarding the time needed to implement engineering controls, but does not agree that four years are needed to comply with the engineering control requirements. OSHA expects that many workplaces with beryllium will already have engineering controls in place for other hazardous materials that will need only modification or updating to comply with the final standards. For new installations, most types of engineering controls for working with materials such as beryllium are readily available.

Furthermore, because beryllium is regulated under EPA rules as a ''hazardous air pollutant'' with a relatively low volume threshold for a permit requirement, foundries that already exhaust beryllium in any quantity would likely already be subjected to the permitting requirements. Therefore, OSHA predicts that any changes to ventilation systems to comply with the final beryllium standards would generally only be subject to routine reporting requirements or permit modifications. Cases that are unusually problematic, however, can be addressed through OSHA's enforcement discretion if the employer can show that it has made good faith efforts to implement engineering controls, but has been unable to implement such controls due to the time needed for environmental permitting.

However, OSHA acknowledges that some general industry, construction and shipyard employers may need more than two years to comply with the engineering control obligations in paragraph (f), including the need to update any permits before modifying ventilation systems, and has extended the standards' compliance date for the engineering control requirements to three years from the effective date. OSHA has determined that setting a compliance date three years after the effective date will ensure that employers have sufficient time to complete the process of designing, obtaining, and installing the necessary control equipment.

OSHA's decision here to provide employers with an extended deadline for complying with engineering control requirements is consistent with what the Agency has done in health standards, including standards for respirable crystalline silica (29 CFR 1910.1053(l)), Chromium (VI) (29 CFR 1910.1026(n)(3), 29 CFR 1915.1026(l)(3), 29 CFR 1926.1126(l)(3)), and Cadmium (29 CFR 1910.1027(p)(2)(v)). Extending the compliance deadline for implementation of engineering controls will allow those firms that need extensive engineering controls time to adequately plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers. OSHA has also determined that the extension will have the ancillary benefit of limiting the economic impact of the rule by providing employers with additional time to plan for and absorb the costs associated with compliance. Based on its review of the rulemaking record, OSHA has concluded that employers will be able to implement engineering controls within the extended time frame that is established in the final rule.

(p) Appendix A to 29 CFR 1910.1024—Control Strategies To Minimize Beryllium Exposure

Appendix A to the final standard for general industry, 29 CFR 1910.1024, provides information to employers on control options that employers could use to comply with paragraph (f)(2)(i) of the final rule, which requires employers to ensure that at least one of the types of controls listed in paragraph (f)(2)(i) is in place to reduce airborne exposure for each operation in a beryllium work area that releases airborne beryllium. Appendix A is for informational and guidance purposes only and none of the statements in Appendix A should be construed as imposing a mandatory requirement on employers that is not otherwise imposed by the standard. In addition, this appendix is not intended to detract from any obligation that the rule imposes.

The control strategies to minimize beryllium exposure were in Appendix B of the proposed rule, but proposed Appendix B has been redesignated as Appendix A in the final standard for general industry, following the deletion (discussed below) of proposed Appendix A. The information on control strategies presented in the appendix was derived from OSHA's analysis of the technological feasibility of the PELs, presented in Chapter IV of the Final Economic Analysis. The content of Appendix A of the final standard for general industry remains unchanged from that contained in Appendix B of the proposal.

The proposed rule also contained a non-mandatory appendix (designated in the proposal as Appendix A) that provided technical information on the BeLPT test. OSHA has determined that the information contained in proposed Appendix A is more suitable for separate guidance that will be issued in conjunction with the standards. OSHA will be able to more readily update this separate guidance to reflect technological advances and changes in recommendations from the medical community. Therefore, OSHA is not including proposed Appendix A in the final standards.

OSHA has also not included any appendices in the final standards for construction and shipyards since OSHA has identified only one principle operation (abrasive blasting) in these sectors involving worker exposure to beryllium.

List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Beryllium, Cancer, Chemicals, Hazardous substances, Health, Occupational safety and health, Reporting and recordkeeping requirements.

Authority and Signature

This document was prepared under the direction of 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.

The Agency issues the sections under the following authorities: 29 U.S.C. 653, 655, 657; 40 U.S.C. 3704; 33 U.S.C. 941; Secretary of Labor's Order 1–2012 (77 FR 3912 (1/25/2012)); and 29 CFR part 1911.

Signed at Washington, DC, on December 14, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons set forth in the preamble, Chapter XVII of Title 29, parts 1910, 1915, and 1926, of the Code of Federal Regulations is amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—[Amended]

■ 1. The authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: 29 U.S.C. 653, 655, 657) Secretary of Labor's Order No. 12–71 (36 FR 8754), 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 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 5101 *et seq.*

■ 2. In § 1910.1000, paragraph (e):

■ a. Amend Table Z–1—Limits on Air Contaminants, by revising the entry for ''Beryllium and beryllium compounds (as Be)'' and adding footnote 8.

■ b. Amend Table Z–2 by revising the entry for ''Beryllium and beryllium compounds (Z37.29–1970)''; and adding footnote d.

The revisions read as follows:

§ 1910.1000 Air contaminants.

* * * * *

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 [8]	7440–41–7			
*	*	*	*	*

* * * * * * *

[8] *See* Table Z–2 for the exposure limits for any operations or sectors where the exposure limits in § 1910.1024 are stayed or otherwise 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 (Z37.29–1970) [d]	2 μg/m³	5 μg/m³	25 μg/m³	30 minutes.

TABLE Z–2—Continued

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
* * *	*	*	*	*
* * *	*	*	*	*

[d] This standard applies to any operations or sectors for which the exposure limits in the beryllium standard, § 1910.1024, are stayed or is otherwise not in effect.

* * * * *

■ 3. Add § 1910.1024 to read as follows:

§ 1910.1024 Beryllium.

(a) *Scope and application.* (1) This standard applies to occupational exposure to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of this standard.

(2) This standard does not apply to articles, as defined in the Hazard Communication standard (HCS) (§ 1910.1200(c)), that contain beryllium and that the employer does not process.

(3) This standard does not apply to materials containing less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

(b) *Definitions.* As used in this standard:

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air (μg/m^3) calculated as an 8-hour time-weighted average (TWA).

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

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.

Beryllium work area means any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic lung disease associated with airborne exposure to beryllium.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. 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.

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.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

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, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's airborne exposure exceeds, or can reasonably be expected to exceed, either the time-weighted average (TWA) permissible exposure limit (PEL) or short term exposure limit (STEL).

This standard means this beryllium standard, 29 CFR 1910.1024.

(c) *Permissible Exposure Limits (PELs)*—(1) *Time-weighted average (TWA) PEL.* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 0.2 μg/m^3 calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 2.0 μg/m^3 as determined over a sampling period of 15 minutes.

(d) *Exposure assessment*—(1) *General.* The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this standard.

(2) *Performance option.* The employer must assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

(3) *Scheduled monitoring option.* (i) The employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne

exposure of employees on each shift, for each job classification, and in each work area.

(ii) The employer must perform initial monitoring to assess the short-term exposure from 15-minute personal breathing zone air samples measured in operations that are likely to produce airborne exposure above the STEL for each work shift, for each job classification, and in each work area.

(iii) Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet the requirements of this paragraph (d)(3). In representative sampling, the employer must sample the employee(s) expected to have the highest airborne exposure to beryllium.

(iv) If initial monitoring indicates that airborne exposure is below the action level and at or below the STEL, the employer may discontinue monitoring for those employees whose airborne exposure is represented by such monitoring.

(v) Where the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring.

(vi) Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL, the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring.

(vii) Where the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the action level, the employer must repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue 8-hour TWA exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(viii) Where the most recent exposure monitoring indicates that airborne exposure is above the STEL, the employer must repeat such monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken 7 or more days apart, are below the STEL, at which time the employer may discontinue short-term exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(4) *Reassessment of exposure.* The employer must reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

(5) *Methods of sample analysis.* The employer must ensure that all air monitoring samples used to satisfy the monitoring requirements of paragraph (d) of this standard are evaluated by a laboratory 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.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this standard, the employer must notify each employee whose airborne exposure is represented by the assessment of the results of that assessment individually in writing or post the results in an appropriate location that is accessible to each of these employees.

(ii) Whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must describe in the written notification the corrective action being taken to reduce airborne exposure to or below the exposure limit(s) exceeded where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(7) *Observation of monitoring.* (i) The employer must provide an opportunity to observe any exposure monitoring required by this standard to each employee whose airborne exposure is 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 personal protective clothing or equipment (which may include respirators) is required, the employer must provide each observer with appropriate personal protective clothing and equipment at no cost to the observer and must ensure that each observer uses such clothing and equipment.

(iii) The employer must ensure that each observer follows all other applicable safety and health procedures.

(e) *Beryllium work areas and regulated areas*—(1) *Establishment.* (i) The employer must establish and maintain a beryllium work area wherever the criteria for a ''beryllium work area'' set forth in paragraph (b) of this standard are met.

(ii) The employer must 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 must 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 must identify each regulated area in accordance with paragraph (m)(2) of this standard.

(3) *Access.* The employer must 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)(7) of this standard; and

(iii) Persons authorized by law to be in a regulated area.

(4) *Provision of personal protective clothing and equipment, including respirators.* The employer must provide and ensure that each employee entering a regulated area uses:

(i) Respiratory protection in accordance with paragraph (g) of this standard; and

(ii) Personal protective clothing and equipment in accordance with paragraph (h) of this standard.

(f) *Methods of compliance*—(1) *Written exposure control plan.* (i) The employer must establish, implement, and maintain a written exposure control plan, which must contain:

(A) A list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium;

(B) A list of operations and job titles reasonably expected to involve airborne exposure at or above the action level;

(C) A list of operations and job titles reasonably expected to involve airborne exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination, including preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas;

(E) Procedures for keeping surfaces 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) A list of engineering controls, work practices, and respiratory protection required by paragraph (f)(2) of this standard;

(H) A list of personal protective clothing and equipment required by paragraph (h) of this standard; and

(I) Procedures for removing, laundering, storing, cleaning, repairing, and disposing of beryllium-contaminated personal protective clothing and equipment, including respirators.

(ii) The employer must review and evaluate the effectiveness of each written exposure control plan at least annually and update it, as necessary, 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 airborne exposure to beryllium;

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or

(C) The employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

(iii) The employer must make a copy of the written 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 (§ 1910.1020(e)).

(2) *Engineering and work practice controls.* (i) For each operation in a beryllium work area that releases airborne beryllium, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(ii) An employer is exempt from using the controls listed in paragraph (f)(2)(i) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

(iii) If airborne exposure exceeds the TWA PEL or STEL after implementing the control(s) required by paragraph (f)(2)(i) of this standard, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the exposure limit(s) exceeded.

(iv) Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii) of this standard, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

(3) *Prohibition of rotation.* The employer must not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer must provide respiratory protection at no cost to the employee and ensure that each employee uses respiratory protection:

(i) During periods necessary to install or implement feasible engineering and work practice controls where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(ii) During operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(iii) During operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce airborne exposure to or below the TWA PEL or STEL;

(iv) During emergencies; and

(v) When an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level, as permitted by paragraph (l)(2)(ii) of this standard.

(2) *Respiratory protection program.* Where this standard requires an employer to provide respiratory protection, the selection and use of such respiratory protection must be in accordance with the Respiratory Protection standard (§ 1910.134).

(3) The employer must provide at no cost to the employee a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when

(i) Respiratory protection is required by this standard;

(ii) An employee entitled to such respiratory protection requests a PAPR; and

(iii) The PAPR provides adequate protection to the employee in accordance with paragraph (g)(2) of this standard.

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer must 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 standard and OSHA's Personal Protective Equipment standards (subpart I of this part):

(i) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; or

(ii) Where there is a reasonable expectation of dermal contact with beryllium.

(2) *Removal and storage.* (i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

(ii) The employer must ensure that each employee removes beryllium-contaminated personal protective clothing and equipment as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iii) The employer must ensure that each employee stores and keeps beryllium-contaminated personal protective clothing and equipment separate from street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iv) The employer must ensure that no employee removes beryllium-contaminated personal 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 personal protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When personal protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer must ensure that personal 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 standard and the HCS (§ 1910.1200).

(3) *Cleaning and replacement.* (i) The employer must ensure that all reusable personal protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer must ensure that beryllium is not removed from personal protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal 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 must:

(i) Provide readily accessible washing facilities in accordance with this standard and the Sanitation standard (§ 1910.141) to remove beryllium from the hands, face, and neck; and

(ii) Ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees who work in a beryllium work area with a designated change room in accordance with this standard and the Sanitation standard (§ 1910.141) where employees are required to remove their personal clothing.

(3) *Showers.* (i) The employer must provide showers in accordance with the Sanitation standard (§ 1910.141) where:

(A) Airborne 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 standard must ensure that each employee showers at the end of the work shift or work activity if:

(A) The employee reasonably could have had airborne exposure 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.* Wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, 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; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (§ 1910.141).

(5) *Prohibited activities.* The employer must ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(j) *Housekeeping*—(1) *General.* (i) The employer must maintain all surfaces in beryllium work areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard; and

(ii) The employer must ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard.

(2) *Cleaning methods.* (i) The employer must ensure that surfaces in beryllium work areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must 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 airborne exposure are not safe or effective.

(iii) The employer must 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 must provide, and ensure that each employee uses, respiratory protection and personal protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard.

(v) The employer must ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of airborne exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* The employer must ensure that:

(i) Materials designated for disposal that contain or are contaminated with beryllium are disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard; and

(ii) Materials designated for recycling that contain or are contaminated with beryllium are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard.

(k) *Medical surveillance*—(1) *General.* (i) The employer must make medical surveillance required by this paragraph available at no cost to the employee, and at a reasonable time and place, to each employee:

(A) Who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year;

(B) Who shows signs or symptoms of CBD or other beryllium-related health effects;

(C) Who is exposed to beryllium during an emergency; or

(D) Whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) of this standard recommends periodic medical surveillance.

(ii) The employer must 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 must provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A), unless the employee has received a medical examination, provided in accordance with this standard, within the last two years; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C).

(ii) At least every two years thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A), (B), or (D) of this standard.

(iii) At the termination of employment for each employee who meets any of the criteria of paragraph (k)(1)(i) of this standard at the time the employee's employment terminates, unless an examination has been provided in accordance with this standard during the six months prior to the date of termination.

(3) *Contents of examination.* (i) The employer must ensure that the PLHCP conducting the examination 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 must ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory system dysfunction;

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

(C) A physical examination for skin rashes;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1);

(E) A standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed in a laboratory certified under the College of American Pathologists/Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

(F) A low dose computed tomography (LDCT) scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, sex, age, and presence of existing lung disease; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer must ensure that the examining PLHCP (and the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard) has a copy of this standard and must provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium;

(ii) The employee's former and current levels of airborne exposure;

(iii) A description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that personal 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 written consent from the employee.

(5) *Licensed physician's written medical report for the employee.* The employer must ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) and that the PLHCP explains the results of the examination to the employee. The written medical report must contain:

(i) A statement indicating the results of the medical examination, including the licensed physician's opinion as to whether the employee has

(A) Any detected medical condition, such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as defined in paragraph (b) of this standard), that may place the employee at increased risk from further airborne exposure, and

(B) Any medical conditions related to airborne exposure that require further evaluation or treatment.

(ii) Any recommendations on:

(A) The employee's use of respirators, protective clothing, or equipment; or

(B) Limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, the written report must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l) of this standard.

(6) *Licensed physician's written medical opinion for the employer.* (i) The employer must obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). The written medical opinion must contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this standard;

(C) Any recommended limitations on the employee's use of respirators, protective clothing, or equipment; and

(D) 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 airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment;

(ii) If the employee provides written authorization, the written opinion must also contain any recommended limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, and the employee provides written authorization, the written opinion must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l) of this standard.

(vi) The employer must ensure that each employee receives a copy of the written medical opinion described in paragraph (k)(6) of this standard within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee.

(7) *CBD diagnostic center.* (i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of:

(A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or

(B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center.

(ii) The employer must ensure that the employee receives a written medical report from the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv), and (v) of this standard and that the PLHCP explains the results of the examination to the employee within 30 days of the examination.

(iii) The employer must obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination. The written medical opinion must contain only the information in paragraph (k)(6)(i), as applicable, unless the employee provides written authorization to release additional information. If the employee provides written authorization, the written opinion must also contain the information from paragraphs (k)(6)(ii), (iv), and (v), if applicable.

(iv) The employer must ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee.

(v) After an employee has received the initial clinical evaluation at a CBD diagnostic center described in paragraph (k)(7)(i) of this standard, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center mutually agreed upon by the employer and the employee, and the employer must provide such examinations at no cost to the employee.

(l) *Medical removal.* (1) An employee is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either:

(i) The employee provides the employer with:

(A) A written medical report indicating a confirmed positive finding or CBD diagnosis; or

(B) A written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard; or

(ii) The employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of this standard.

(2) If an employee is eligible for medical removal, the employer must provide the employee with the employee's choice of:

(i) Removal as described in paragraph (l)(3) of this standard; or

(ii) Remaining in a job with airborne exposure at or above the action level, provided that the employer provides, and ensures that the employee uses, respiratory protection that complies with paragraph (g) of this standard whenever airborne exposures are at or above the action level.

(3) If the employee chooses removal:

(i) If a comparable job is available where airborne exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, the employer must remove the employee to that job. The employer must maintain for six months from the time of removal the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(ii) If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first.

(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 must comply with all requirements of the HCS (§ 1910.1200) for beryllium.

(ii) In classifying the hazards of beryllium, at least the following hazards must be addressed: Cancer; lung effects (CBD and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation.

(iii) Employers must include beryllium in the hazard communication program established to comply with the HCS. Employers must 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 (§ 1910.1200) and paragraph (m)(4) of this standard.

(2) *Warning signs.* (i) *Posting.* The employer 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.

(ii) *Sign specification.* (A) The employer must ensure that the warning signs required by paragraph (m)(2)(i) of this standard are legible and readily visible.

(B) The employer must ensure each warning sign required by paragraph (m)(2)(i) of this standard bears the following legend:

DANGER
REGULATED AREA
BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PERSONAL PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

(3) *Warning labels.* Consistent with the HCS (§ 1910.1200), the employer must label each bag and container of clothing, equipment, and materials contaminated with beryllium, and must, 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 has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium:

(A) The employer must provide information and training in accordance with the HCS (§ 1910.1200(h));

(B) The employer must provide initial training to each employee by the time of initial assignment; and

(C) The employer must repeat the training required under this standard annually for each employee.

(ii) The employer must ensure that each employee who is, or can reasonably be expected to be, exposed to airborne beryllium can demonstrate knowledge and understanding of the following:

(A) The health hazards associated with airborne exposure to and contact with beryllium, 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 airborne exposure, especially airborne 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 airborne exposure to and contact with beryllium, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this standard 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 standard;

(H) The contents of the standard; and

(I) The employee's right of access to records under the Records Access standard (§ 1910.1020).

(iii) When a workplace change (such as modification of equipment, tasks, or procedures) results in new or increased airborne exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer must provide additional training to those employees affected by the change in airborne exposure.

(iv) *Employee information.* The employer must 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) *Air monitoring data.* (i) The employer must make and maintain a record of all exposure measurements taken to assess airborne exposure as prescribed in paragraph (d) of this standard.

(ii) This record must include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task 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 must ensure that exposure records are maintained and made available in accordance with the Records Access standard (§ 1910.1020).

(2) *Objective data.* (i) Where an employer uses objective data to satisfy the exposure assessment requirements under paragraph (d)(2) of this standard, the employer must make and maintain a record of the objective data relied upon.

(ii) This record must 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 process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.

(iii) The employer must ensure that objective data are maintained and made available in accordance with the Records Access standard (§ 1910.1020).

(3) *Medical surveillance.* (i) The employer must make and maintain a record for each employee covered by medical surveillance under paragraph (k) of this standard.

(ii) The record must include the following information about each employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written medical opinions for each employee; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

(iii) The employer must ensure that medical records are maintained and made available in accordance with the Records Access standard (§ 1910.1020).

(4) *Training.* (i) At the completion of any training required by this standard, the employer must 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 must be maintained for three years after the completion of training.

(5) *Access to records.* Upon request, the employer must 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 (§ 1910.1020).

(6) *Transfer of records.* The employer must comply with the requirements involving transfer of records set forth in the Records Access standard (§ 1910.1020).

(o) *Dates*—(1) *Effective date.* This standard shall become effective March 10, 2017.

(2) *Compliance dates.* All obligations of this standard commence and become enforceable on March 12, 2018, except:

(i) Change rooms and showers required by paragraph (i) of this standard must be provided by March 11, 2019; and

(ii) Engineering controls required by paragraph (f) of this standard must be implemented by March 10, 2020.

(p) *Appendix.* Appendix A—Control Strategies to Minimize Beryllium Exposure of this standard is non-mandatory.

Appendix A to § 1910.1024—Control Strategies To Minimize Beryllium Exposure (Non-Mandatory)

Paragraph (f)(2)(i) of this standard requires employers to use one or more of the control methods listed in paragraph (f)(2)(i) to minimize worker exposure in each operation in a beryllium work area, unless the operation is exempt under paragraph (f)(2)(ii). This appendix sets forth a non-exhaustive list of control options that employers could use to comply with paragraph (f)(2)(i) for a number of specific beryllium operations.

TABLE A.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.

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 4. The authority citation for part 1915 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 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 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 5. In § 1915.1000 amend Table Z—Shipyards, by revising the entry for ''Beryllium and beryllium compounds (as Be)'' and adding footnote q.

The revisions read as follows:

* * * * *

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z—SHIPYARDS

Substance	CAS No.[d]	ppm [a*]	mg/m3 [b*]	Skin designation
*	*	*	*	*
Beryllium and beryllium compounds (as Be); see 1915.1024 [(q)]	7440–41–7		0.002	
*	*	*	*	*

* 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.

* * * * * * *

[d] 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.

* * * * * * *

[q] This standard applies to any operations or sectors for which the beryllium standard, 1915.1024, is stayed or otherwise is not in effect.

* * * * *

■ 6. Add § 1915.1024 to read as follows:

§ 1915.1024 Beryllium.

(a) *Scope and application.* (1) This standard applies to occupational exposure to beryllium in all forms, compounds, and mixtures in shipyards, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of this standard.

(2) 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.

(3) This standard does not apply to materials containing less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

(b) *Definitions.* As used in this standard:

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).

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

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.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic lung disease associated with airborne exposure to beryllium.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. 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.

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.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

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, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's airborne exposure exceeds, or can reasonably be expected to exceed, either the time-weighted average (TWA) permissible exposure limit (PEL) or short term exposure limit (STEL).

This standard means this beryllium standard, 29 CFR 1915.1024.

(c) *Permissible Exposure Limits (PELs)*—(1) *Time-weighted average (TWA) PEL.* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 0.2 μg/m³ calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 2.0 μg/m³ as determined over a sampling period of 15 minutes.

(d) *Exposure assessment*—(1) *General.* The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this standard.

(2) *Performance option.* The employer must assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

(3) *Scheduled monitoring option.* (i) The employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area.

(ii) The employer must perform initial monitoring to assess the short-term exposure from 15-minute personal breathing zone air samples measured in operations that are likely to produce airborne exposure above the STEL for each work shift, for each job classification, and in each work area.

(iii) Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet the requirements of paragraph (d)(3) of this standard. In representative sampling, the employer must sample the employee(s) expected to have the highest airborne exposure to beryllium.

(iv) If initial monitoring indicates that airborne exposure is below the action level and at or below the STEL, the employer may discontinue monitoring for those employees whose airborne exposure is represented by such monitoring.

(v) Where the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring.

(vi) Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL, the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring.

(vii) Where the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the action level, the employer must repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue 8-hour TWA exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(viii) Where the most recent exposure monitoring indicates that airborne exposure is above the STEL, the employer must repeat such monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken 7 or more days apart, are below the STEL, at which time the employer may discontinue short-term exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(4) *Reassessment of exposure.* The employer must reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

(5) *Methods of sample analysis.* The employer must ensure that all air monitoring samples used to satisfy the monitoring requirements of paragraph (d) of this standard are evaluated by a laboratory 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.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this standard, the employer must notify each employee whose airborne exposure is represented by the assessment of the results of that assessment individually in writing or post the results in an appropriate location that is accessible to each of these employees.

(ii) Whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must describe in the written notification the corrective action being taken to reduce airborne exposure to or below the exposure limit(s) exceeded where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(7) *Observation of monitoring.* (i) The employer must provide an opportunity to observe any exposure monitoring required by this standard to each employee whose airborne exposure is 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 personal protective clothing or equipment (which may include respirators) is required, the employer must provide each observer with appropriate personal protective clothing and equipment at no cost to the observer and must ensure that each observer uses such clothing and equipment.

(iii) The employer must ensure that each observer follows all other applicable safety and health procedures.

(e) *Regulated areas*—(1) *Establishment.* The employer must 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.* The employer must identify each regulated area in accordance with paragraph (m)(2) of this standard.

(3) *Access.* The employer must 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)(7) of this standard; and

(iii) Persons authorized by law to be in a regulated area.

(4) *Provision of personal protective clothing and equipment, including respirators.* The employer must provide and ensure that each employee entering a regulated area uses:

(i) Respiratory protection in accordance with paragraph (g) of this standard; and

(ii) Personal protective clothing and equipment in accordance with paragraph (h) of this standard.

(f) *Methods of compliance*—(1) *Written exposure control plan.* (i) The employer must establish, implement, and maintain a written exposure control plan, which must contain:

(A) A list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium;

(B) A list of operations and job titles reasonably expected to involve airborne exposure at or above the action level;

(C) A list of operations and job titles reasonably expected to involve airborne exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination;

(E) Procedures for minimizing the migration of beryllium within or to locations outside the workplace;

(F) A list of engineering controls, work practices, and respiratory protection required by paragraph (f)(2) of this standard;

(G) A list of personal protective clothing and equipment required by paragraph (h) of this standard; and

(H) Procedures for removing, laundering, storing, cleaning, repairing, and disposing of beryllium-contaminated personal protective clothing and equipment, including respirators.

(ii) The employer must review and evaluate the effectiveness of each written exposure control plan at least annually and update it, as necessary, 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 airborne exposure to beryllium;

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or

(C) The employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

(iii) The employer must make a copy of the written 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) Where exposures are, or can reasonably be expected to be, at or above the action level, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(ii) An employer is exempt from using the controls listed in paragraph (f)(2)(i) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

(iii) If airborne exposure exceeds the TWA PEL or STEL after implementing the control(s) required by (f)(2)(i), the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the exposure limit(s) exceeded.

(iv) Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii), the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

(3) *Prohibition of rotation.* The employer must not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer must provide respiratory protection at no cost to the employee and ensure that each employee uses respiratory protection:

(i) During periods necessary to install or implement feasible engineering and work practice controls where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(ii) During operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(iii) During operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce airborne exposure to or below the TWA PEL or STEL;

(iv) During emergencies; and

(v) When an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level, as permitted by paragraph (l)(2)(ii).

(2) *Respiratory protection program.* Where this standard requires an employer to provide respiratory protection, the selection and use of such respiratory protection must be in accordance with the Respiratory Protection standard (29 CFR 1910.134).

(3) The employer must provide at no cost to the employee a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when

(i) Respiratory protection is required by this standard;

(ii) An employee entitled to such respiratory protection requests a PAPR; and

(iii) The PAPR provides adequate protection to the employee in accordance with paragraph (g)(2) of this standard.

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer must 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 standard and OSHA's Personal Protective Equipment standards for shipyards (subpart I of this part):

(i) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; or

(ii) Where there is a reasonable expectation of dermal contact with beryllium.

(2) *Removal and storage.* (i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

(ii) The employer must ensure that each employee removes beryllium-contaminated personal protective clothing and equipment as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iii) The employer must ensure that each employee stores and keeps beryllium-contaminated personal protective clothing and equipment separate from street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iv) The employer must ensure that no employee removes beryllium-contaminated personal 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 personal protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When personal protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer must ensure that personal 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 standard and the HCS (29 CFR 1910.1200).

(3) *Cleaning and replacement.* (i) The employer must ensure that all reusable personal protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer must ensure that beryllium is not removed from personal protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee required to use personal protective clothing or equipment by this standard, the employer must:

(i) Provide readily accessible washing facilities in accordance with this standard and the Sanitation standard (§ 1915.88) to remove beryllium from the hands, face, and neck; and

(ii) Ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees required to use personal protective clothing by this standard with a designated change room in accordance with the Sanitation standard (§ 1915.88) where employees are required to remove their personal clothing.

(3) *Eating and drinking areas.* Wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, 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; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (29 CFR 1915.88).

(4) *Prohibited activities.* The employer must ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(j) *Housekeeping*—(1) *General.* (i) When cleaning beryllium-contaminated areas, the employer must follow the written exposure control plan required under paragraph (f)(1) of this standard; and

(ii) The employer must ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the written exposure control plan required under paragraph (f)(1).

(2) *Cleaning methods.* (i) When cleaning beryllium-contaminated areas, the employer must ensure the use of HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning in beryllium-contaminated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

(iii) The employer must not allow the use of compressed air for cleaning in beryllium-contaminated areas 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 in beryllium-contaminated areas, the employer must provide, and ensure that each employee uses, respiratory protection and personal protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard.

(v) The employer must ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of airborne exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* When the employer transfers materials containing beryllium to another party for use or disposal, the employer must provide the recipient with a copy of the warning described in paragraph (m)(3) of this standard.

(k) *Medical surveillance*—(1) *General.* (i) The employer must make medical surveillance required by this paragraph available at no cost to the employee, and at a reasonable time and place, to each employee:

(A) Who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year;

(B) Who shows signs or symptoms of CBD or other beryllium-related health effects;

(C) Who is exposed to beryllium during an emergency; or

(D) Whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance.

(ii) The employer must 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 must 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 standard, unless the employee has received a medical examination, provided in accordance with this standard, within the last two years; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C) of this standard.

(ii) At least every two years thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A), (B), or (D) of this standard.

(iii) At the termination of employment for each employee who meets any of the criteria of paragraph (k)(1)(i) of this standard at the time the employee's employment terminates, unless an examination has been provided in accordance with this standard during the six months prior to the date of termination.

(3) *Contents of examination.* (i) The employer must ensure that the PLHCP conducting the examination 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 must ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory system dysfunction;

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

(C) A physical examination for skin rashes;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1);

(E) A standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed in a laboratory certified under the College of American Pathologists/Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

(F) A low dose computed tomography (LDCT) scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, sex, age, and presence of existing lung disease; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer must ensure that the examining PLHCP (and the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard) has a copy of this standard and must provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium;

(ii) The employee's former and current levels of airborne exposure;

(iii) A description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that personal 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 written consent from the employee.

(5) *Licensed physician's written medical report for the employee.* The employer must ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) and that the PLHCP explains the results of the examination to the employee. The written medical report must contain:

(i) A statement indicating the results of the medical examination, including the licensed physician's opinion as to whether the employee has

(A) Any detected medical condition, such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as defined in paragraph (b) of this standard), that may place the employee at increased risk from further airborne exposure, and

(B) Any medical conditions related to airborne exposure that require further evaluation or treatment.

(ii) Any recommendations on:

(A) The employee's use of respirators, protective clothing, or equipment; or

(B) Limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, the written report must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(6) *Licensed physician's written medical opinion for the employer.* (i) The employer must obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). The written medical opinion must contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this standard;

(C) Any recommended limitations on the employee's use of respirators, protective clothing, or equipment; and

(D) 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 airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment;

(ii) If the employee provides written authorization, the written opinion must also contain any recommended limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, and the employee provides written authorization, the written opinion must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(vi) The employer must ensure that each employee receives a copy of the written medical opinion described in paragraph (k)(6) of this standard within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee.

(7) *CBD diagnostic center.* (i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of:

(A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or

(B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center.

(ii) The employer must ensure that the employee receives a written medical report from the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv), and (v) and that the PLHCP explains the results of the examination to the employee within 30 days of the examination.

(iii) The employer must obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination. The written medical opinion must contain only the information in paragraphs (k)(6)(i), as applicable, unless the employee provides written authorization to release additional information. If the employee provides written authorization, the written opinion must also contain the information from paragraphs (k)(6)(ii), (iv), and (v), if applicable.

(iv) The employer must ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee.

(v) After an employee has received the initial clinical evaluation at a CBD diagnostic center described in paragraph (k)(7)(i) of this standard, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center mutually agreed upon by the employer and the employee, and the employer must provide such examinations at no cost to the employee.

(l) *Medical removal.* (1) An employee is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either:

(i) The employee provides the employer with:

(A) A written medical report indicating a confirmed positive finding or CBD diagnosis; or

(B) A written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard; or

(ii) The employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of this standard.

(2) If an employee is eligible for medical removal, the employer must provide the employee with the employee's choice of:

(i) Removal as described in paragraph (l)(3) of this standard; or

(ii) Remaining in a job with airborne exposure at or above the action level, provided that the employer provides, and ensures that the employee uses, respiratory protection that complies with paragraph (g) of this standard whenever airborne exposures are at or above the action level.

(3) If the employee chooses removal:

(i) If a comparable job is available where airborne exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, the employer must remove the employee to that job. The employer must maintain for six months from the time of removal the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(ii) If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first.

(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 must comply with all requirements of the HCS (29 CFR 1910.1200) for beryllium.

(ii) Employers must include beryllium in the hazard communication program established to comply with the HCS. Employers must 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 standard.

(2) *Warning signs.* (i) *Posting.* The employer 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.

(ii) *Sign specification.* (A) The employer must ensure that the warning signs required by paragraph (m)(2)(i) of this standard are legible and readily visible.

(B) The employer must ensure each warning sign required by paragraph (m)(2)(i) of this standard bears the following legend:

DANGER
REGULATED AREA
BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PERSONAL PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

(3) *Warning labels.* Consistent with the HCS (29 CFR 1910.1200), the employer must label each bag and container of clothing, equipment, and materials contaminated with beryllium, and must, 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 has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium:

(A) The employer must provide information and training in accordance with the HCS (29 CFR 1910.1200(h));

(B) The employer must provide initial training to each employee by the time of initial assignment; and

(C) The employer must repeat the training required under this standard annually for each employee.

(ii) The employer must ensure that each employee who is, or can reasonably be expected to be, exposed to airborne beryllium can demonstrate knowledge and understanding of the following:

(A) The health hazards associated with airborne exposure to and contact with beryllium, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the location(s) of any regulated areas, and the specific nature of operations that could result in airborne exposure, especially airborne 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 airborne exposure to and contact with beryllium, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this standard 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 standard;

(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 airborne exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer must provide additional training to those employees affected by the change in airborne exposure.

(iv) *Employee information.* The employer must 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) *Air monitoring data.* (i) The employer must make and maintain a record of all exposure measurements taken to assess airborne exposure as prescribed in paragraph (d) of this standard.

(ii) This record must include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task 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 must ensure that exposure records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(2) *Objective data.* (i) Where an employer uses objective data to satisfy the exposure assessment requirements under paragraph (d)(2) of this standard, the employer must make and maintain a record of the objective data relied upon.

(ii) This record must 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 process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.

(iii) The employer must ensure that objective data are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(3) *Medical surveillance.* (i) The employer must make and maintain a record for each employee covered by medical surveillance under paragraph (k) of this standard.

(ii) The record must include the following information about each employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written medical opinions for each employee; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

(iii) The employer must ensure that medical records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(4) *Training.* (i) At the completion of any training required by this standard, the employer must 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 must be maintained for three years after the completion of training.

(5) *Access to records.* Upon request, the employer must 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).

(6) *Transfer of records.* The employer must 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 March 10, 2017.

(2) *Compliance dates.* All obligations of this standard commence and become enforceable on March 12, 2018, except:

(i) Change rooms required by paragraph (i) of this standard must be provided by March 11, 2019; and

(ii) Engineering controls required by paragraph (f) of this standard must be implemented by March 10, 2020.

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart D—Occupational Health and Environmental Controls

■ 7. The authority citation for subpart D of part 1926 is revised to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 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 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1926.61 also issued under 49 U.S.C. 5101 *et seq.*

Section 1926.62 also issued under 42 U.S.C. 4853.

Section 1926.65 also issued under 126 of Public Law 99–499, 100 Stat. 1613.

■ 8. In § 1926.55, amend appendix A by revising the entry for ''Beryllium and beryllium compounds (as Be)'' and adding footnote q.

The revisions read as follows:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

* * * * *

Appendix A to § 1926.55—1970 American Conference of Governmental Industrial Hygienists' Threshold Limit Values of Airborne Contaminants

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION

Substance	CAS No.[d]	ppm [a*]	mg/m [3b]	Skin designation
* * * *	*	*	*	*
Beryllium and beryllium compounds (as Be); see 1926.1124 [(q)]	7440–41–7		0.002	

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION—Continued

Substance	CAS No.[d]	ppm [a*]	mg/m [3b]	Skin designation
* * *	*	*	*	*

[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.

* * * * * * *

[d] 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.

* * * * * * *

[q] This standard applies to any operations or sectors for which the beryllium standard, 1926.1124, is stayed or otherwise is not in effect.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 9. The authority for subpart Z of part 1926 is revised to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 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 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 10. Add § 1926.1124 to read as follows:

§ 1926.1124 Beryllium.

(a) *Scope and application.* (1) This standard applies to occupational exposure to beryllium in all forms, compounds, and mixtures in construction, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of this standard.

(2) 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.

(3) This standard does not apply to materials containing less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

(b) *Definitions.* As used in this standard:

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).

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

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.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic lung disease associated with airborne exposure to beryllium.

Competent person means an individual who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of this standard.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. 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.

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.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

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.

This standard means this beryllium standard, 29 CFR 1926.1124.

(c) *Permissible Exposure Limits (PELs)*—(1) *Time-weighted average (TWA) PEL.* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 0.2 μg/m³ calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 2.0 μg/m³ as determined over a sampling period of 15 minutes.

(d) *Exposure assessment*—(1) *General.* The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this standard.

(2) *Performance option.* The employer must assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of any

combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

(3) *Scheduled monitoring option.* (i) The employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area.

(ii) The employer must perform initial monitoring to assess the short-term exposure from 15-minute personal breathing zone air samples measured in operations that are likely to produce airborne exposure above the STEL for each work shift, for each job classification, and in each work area.

(iii) Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet the requirements of paragraph (d)(3). In representative sampling, the employer must sample the employee(s) expected to have the highest airborne exposure to beryllium.

(iv) If initial monitoring indicates that airborne exposure is below the action level and at or below the STEL, the employer may discontinue monitoring for those employees whose airborne exposure is represented by such monitoring.

(v) Where the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring.

(vi) Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL, the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring.

(vii) Where the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the action level, the employer must repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue 8-hour TWA exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(viii) Where the most recent exposure monitoring indicates that airborne exposure is above the STEL, the employer must repeat such monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken 7 or more days apart, are below the STEL, at which time the employer may discontinue short-term exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(4) *Reassessment of exposure.* The employer must reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

(5) *Methods of sample analysis.* The employer must ensure that all air monitoring samples used to satisfy the monitoring requirements of paragraph (d) of this standard are evaluated by a laboratory 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.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this standard, the employer must notify each employee whose airborne exposure is represented by the assessment of the results of that assessment individually in writing or post the results in an appropriate location that is accessible to each of these employees.

(ii) Whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must describe in the written notification the corrective action being taken to reduce airborne exposure to or below the exposure limit(s) exceeded where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(7) *Observation of monitoring.* (i) The employer must provide an opportunity to observe any exposure monitoring required by this standard to each employee whose airborne exposure is 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 personal protective clothing or equipment (which may include respirators) is required, the employer must provide each observer with appropriate personal protective clothing and equipment at no cost to the observer.

(iii) The employer must ensure that each observer follows all other applicable safety and health procedures.

(e) *Competent person.* Wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL, the employer must designate a competent person to

(1) Make frequent and regular inspections of job sites, materials, and equipment;

(2) Implement the written exposure control plan under paragraph (f) of this standard;

(3) Ensure that all employees use respiratory protection in accordance with paragraph (g) of this standard; and

(4) Ensure that all employees use personal protective clothing and equipment in accordance with paragraph (h) of this standard.

(f) *Methods of compliance*—(1) *Written exposure control plan.* (i) The employer must establish, implement, and maintain a written exposure control plan, which must contain:

(A) A list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium;

(B) A list of operations and job titles reasonably expected to involve airborne exposure at or above the action level;

(C) A list of operations and job titles reasonably expected to involve airborne exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination;

(E) Procedures for minimizing the migration of beryllium within or to locations outside the workplace;

(F) A list of engineering controls, work practices, and respiratory protection required by paragraph (f)(2) of this standard;

(G) A list of personal protective clothing and equipment required by paragraph (h) of this standard;

(H) Procedures for removing, laundering, storing, cleaning, repairing, and disposing of beryllium-contaminated personal protective clothing and equipment, including respirators; and

(I) Procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors.

(ii) The employer must review and evaluate the effectiveness of each written exposure control plan at least annually and update it, as necessary, 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 airborne exposure to beryllium;

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or

(C) The employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

(iii) The employer must make a copy of the written 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) Where exposures are, or can reasonably be expected to be, at or above the action level, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(ii) An employer is exempt from using the controls listed in paragraph (f)(2)(i) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

(iii) If airborne exposure exceeds the TWA PEL or STEL after implementing the control(s) required by paragraph (f)(2)(i) of this standard, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the exposure limit(s) exceeded.

(iv) Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii), the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

(3) *Prohibition of rotation.* The employer must not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer must provide respiratory protection at no cost to the employee and ensure that each employee uses respiratory protection:

(i) During periods necessary to install or implement feasible engineering and work practice controls where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(ii) During operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(iii) During operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce airborne exposure to or below the TWA PEL or STEL;

(iv) During emergencies; and

(v) When an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level, as permitted by paragraph (l)(2)(ii) of this standard.

(2) *Respiratory protection program.* Where this standard requires an employer to provide respiratory protection, the selection and use of such respiratory protection must be in accordance with the Respiratory Protection standard (29 CFR 1910.134).

(3) The employer must provide at no cost to the employee a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when

(i) Respiratory protection is required by this standard;

(ii) An employee entitled to such respiratory protection requests a PAPR; and

(iii) The PAPR provides adequate protection to the employee in accordance with paragraph (g)(2) of this standard.

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer must 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 standard and OSHA's Personal Protective and Life Saving Equipment standards for construction (29 CFR part 1926 Subpart E):

(i) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; or

(ii) Where there is a reasonable expectation of dermal contact with beryllium.

(2) *Removal and storage.* (i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

(ii) The employer must ensure that each employee removes beryllium-contaminated personal protective clothing and equipment as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iii) The employer must ensure that each employee stores and keeps beryllium-contaminated personal protective clothing and equipment separate from street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iv) The employer must ensure that no employee removes beryllium-contaminated personal 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 personal protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When personal protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer must ensure that personal 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)(2) of this standard and the HCS (29 CFR 1910.1200).

(3) *Cleaning and replacement.* (i) The employer must ensure that all reusable personal protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer must ensure that beryllium is not removed from personal protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee required to use personal protective clothing or equipment by this standard, the employer must:

(i) Provide readily accessible washing facilities in accordance with this standard and the Sanitation standard (§ 1926.51) to remove beryllium from the hands, face, and neck; and

(ii) Ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees required to use personal protective clothing by this standard with a designated change room in accordance with this standard and the Sanitation standard (§ 1926.51) where employees are required to remove their personal clothing.

(3) *Eating and drinking areas.* Wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, 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; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (§ 1926.51).

(4) *Prohibited activities.* The employer must ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in work areas where there is a reasonable expectation of exposure above the TWA PEL or STEL.

(j) *Housekeeping*—(1) *General.* (i) When cleaning beryllium-contaminated areas, the employer must follow the written exposure control plan required under paragraph (f)(1) of this standard;

(ii) The employer must ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the written exposure control plan required under paragraph (f)(1) of this standard.

(2) *Cleaning methods.* (i) When cleaning beryllium-contaminated areas, the employer must ensure the use of HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning in beryllium-contaminated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

(iii) The employer must not allow the use of compressed air for cleaning in beryllium-contaminated areas 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 in beryllium-contaminated areas, the employer must provide, and ensure that each employee uses, respiratory protection and personal protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard.

(v) The employer must ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of airborne exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* When the employer transfers materials containing beryllium to another party for use or disposal, the employer must provide the recipient with a copy of the warning described in paragraph (m)(2) of this standard.

(k) *Medical surveillance*—(1) *General.* (i) The employer must make medical surveillance required by this paragraph available at no cost to the employee, and at a reasonable time and place, to each employee:

(A) Who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year;

(B) Who shows signs or symptoms of CBD or other beryllium-related health effects;

(C) Who is exposed to beryllium during an emergency; or

(D) Whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance.

(ii) The employer must 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 must provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A), unless the employee has received a medical examination, provided in accordance with this standard, within the last two years; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C).

(ii) At least every two years thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A), (B), or (D) of this standard.

(iii) At the termination of employment for each employee who meets any of the criteria of paragraph (k)(1)(i) of this standard at the time the employee's employment terminates, unless an examination has been provided in accordance with this standard during the six months prior to the date of termination.

(3) *Contents of examination.* (i) The employer must ensure that the PLHCP conducting the examination 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 must ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory system dysfunction;

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

(C) A physical examination for skin rashes;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1);

(E) A standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed in a laboratory certified under the College of American Pathologists/ Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

(F) A low dose computed tomography (LDCT) scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, sex, age, and presence of existing lung disease; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer must ensure that the examining PLHCP (and the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard) has a copy of this standard and must provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium;

(ii) The employee's former and current levels of airborne exposure;

(iii) A description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that personal 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 written consent from the employee.

(5) *Licensed physician's written medical report for the employee.* The employer must ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) and that the PLHCP explains the results of the examination to the employee. The written medical report must contain:

(i) A statement indicating the results of the medical examination, including the licensed physician's opinion as to whether the employee has

(A) Any detected medical condition, such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as defined in paragraph (b) of this standard), that may place the employee at increased risk from further airborne exposure, and

(B) Any medical conditions related to airborne exposure that require further evaluation or treatment.

(ii) Any recommendations on:

(A) The employee's use of respirators, protective clothing, or equipment; or

(B) Limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, the written report must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(6) *Licensed physician's written medical opinion for the employer.* (i) The employer must obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). The written medical opinion must contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this standard;

(C) Any recommended limitations on the employee's use of respirators, protective clothing, or equipment; and

(D) 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 airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment;

(ii) If the employee provides written authorization, the written opinion must also contain any recommended limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, and the employee provides written authorization, the written opinion must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(vi) The employer must ensure that each employee receives a copy of the written medical opinion described in paragraph (k)(6) of this standard within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee.

(7) *CBD diagnostic center.* (i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of:

(A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or

(B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center.

(ii) The employer must ensure that the employee receives a written medical report from the CBD diagnostic center that contains all the information required in paragraphs (k)(5)(i), (ii), (iv), and (v) of this standard and that the PLHCP explains the results of the examination to the employee within 30 days of the examination.

(iii) The employer must obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination. The written medical opinion must contain only the information in paragraph (k)(6)(i) of this standard, as applicable, unless the employee provides written authorization to release additional information. If the employee provides written authorization, the written opinion must also contain the information from paragraphs (k)(6)(ii), (iv), and (v), if applicable.

(iv) The employer must ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee.

(v) After an employee has received the initial clinical evaluation at a CBD diagnostic center described in paragraph (k)(7)(i) of this standard, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center mutually agreed upon by the employer and the employee, and the employer must provide such examinations at no cost to the employee.

(l) *Medical removal.* (1) An employee is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either:

(i) The employee provides the employer with:

(A) A written medical report indicating a confirmed positive finding or CBD diagnosis; or

(B) A written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard; or

(ii) The employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of this standard.

(2) If an employee is eligible for medical removal, the employer must provide the employee with the employee's choice of:

(i) Removal as described in paragraph (l)(3) of this standard; or

(ii) Remaining in a job with airborne exposure at or above the action level, provided that the employer provides, and ensures that the employee uses, respiratory protection that complies with paragraph (g) of this standard whenever airborne exposures are at or above the action level.

(3) If the employee chooses removal:

(i) If a comparable job is available where airborne exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, the employer must remove the employee to that job. The employer must maintain for six months from the time of removal the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(ii) If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first.

(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 must comply with all requirements of the HCS (29 CFR 1910.1200) for beryllium.

(ii) Employers must include beryllium in the hazard communication program established to comply with the HCS. Employers must 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 standard.

(2) *Warning labels.* Consistent with the HCS (29 CFR 1910.1200), the employer must label each bag and container of clothing, equipment, and materials contaminated with beryllium, and must, 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

(3) *Employee information and training.* (i) For each employee who has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium:

(A) The employer must provide information and training in accordance with the HCS (29 CFR 1910.1200(h));

(B) The employer must provide initial training to each employee by the time of initial assignment; and

(C) The employer must repeat the training required under this standard annually for each employee.

(ii) The employer must ensure that each employee who is, or can reasonably be expected to be, exposed to airborne beryllium can demonstrate knowledge and understanding of the following:

(A) The health hazards associated with airborne exposure to and dermal contact with beryllium, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the specific nature of operations that could result in airborne exposure, especially airborne 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 airborne exposure to and dermal contact with beryllium, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this standard 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 standard;

(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 airborne exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer must provide additional training to those employees affected by the change in airborne exposure.

(iv) *Employee information.* The employer must 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) *Air monitoring data.* (i) The employer must make and maintain a record of all exposure measurements taken to assess airborne exposure as prescribed in paragraph (d) of this standard.

(ii) This record must include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task 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 must ensure that exposure records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(2) *Objective data.* (i) Where an employer uses objective data to satisfy the exposure assessment requirements under paragraph (d)(2) of this standard, the employer must make and maintain

a record of the objective data relied upon.

(ii) This record must 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 process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.

(iii) The employer must ensure that objective data are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(3) *Medical surveillance.* (i) The employer must make and maintain a record for each employee covered by medical surveillance under paragraph (k) of this standard.

(ii) The record must include the following information about each employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written medical opinions for each employee; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

(iii) The employer must ensure that medical records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(4) *Training.* (i) At the completion of any training required by this standard, the employer must 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 must be maintained for three years after the completion of training.

(5) *Access to records.* Upon request, the employer must 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).

(6) *Transfer of records.* The employer must 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 March 10, 2017.

(2) *Compliance dates.* All obligations of this standard commence and become enforceable on March 12, 2018, except:

(i) Change rooms required by paragraph (i) of this standard must be provided by March 11, 2019; and

(ii) Engineering controls required by paragraph (f) of this standard must be implemented by March 10, 2020.

[FR Doc. 2016–30409 Filed 1–6–17; 8:45 am]

BILLING CODE 4510–26–P