

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA-2017-N-7007]

RIN 0910-AH49

Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of January 26, 2018, a direct final rule to amend the general biologics regulations relating to time of inspection requirements and to also remove duties of inspector requirements. The comment period closed April 11, 2018. FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

DATES: The direct final rule published at January 26, 2018 (83 FR 3586), is withdrawn effective May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on January 26, 2018 (83 FR 3586) is withdrawn.

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-09589 Filed 5-4-18; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA-2018-0003]

RIN 1218-AB76

Revising the Beryllium Standard for General Industry

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

ACTION: Direct final rule; request for comment.

SUMMARY: On January 9, 2017, the Occupational Safety and Health Administration (OSHA) issued a final rule adopting a comprehensive general industry standard for exposure to beryllium and beryllium compounds. In this Direct Final Rule (DFR), OSHA is adopting a number of clarifying amendments to address the application of the standard to materials containing trace amounts of beryllium. OSHA believes this rule will maintain safety and health protections for workers while reducing the burden to employers of complying with the current rule.

DATES: This DFR will become effective on July 6, 2018 unless significant adverse comment is submitted (transmitted, postmarked, or delivered) by June 6, 2018. If DOL receives significant adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public that this DFR will not take effect (see Section III, "Direct Final Rulemaking," for more details on this process). Comments to this DFR, hearing requests, and other information must be submitted (transmitted, postmarked, or delivered) by June 6, 2018. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: The public can submit comments, hearing requests, and other material, identified by Docket No. OSHA-2018-0003, using any of the following methods:

Electronically: Submit comments and attachments, as well as hearing requests and other information, electronically at <http://www.regulations.gov>, which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments. Note that this docket may include several different **Federal Register** notices involving active rulemakings, so it is extremely important to select the correct notice or its ID number when submitting

comments for this rulemaking. After accessing "all documents and comments" in the docket (OSHA-2018-0003), check the "Rule" box in the column headed "Document Type," find the document posted on the date of publication of this document, and click the "Submit a Comment" link.

Additional instructions for submitting comments are available from the <http://www.regulations.gov> homepage.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693-1648. OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (e.g., studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Docket No. OSHA-2018-0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. These attachments must clearly identify the sender's name, the date, the subject, and the docket number (OSHA-2018-0003) so that the Docket Office can attach them to the appropriate document.

Regular mail, express delivery, hand delivery, and messenger (courier) service: Submit comments and any additional material to the OSHA Docket Office, Docket No. OSHA-2018-0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693-2350. (OSHA's TTY number is (877) 889-5627.) Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service. The Docket Office will accept deliveries (express delivery, hand delivery, messenger service) during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the Agency's name, the title of the rulemaking (Beryllium Standard: Direct Final Rule), and the docket number (OSHA-2018-0003). OSHA will place comments and other material, including any personal information, in the public docket without revision, and the comments and other material will be available online at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal

information (either about themselves or others), such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or to the OSHA Docket Office at the above address. The electronic docket for this direct final rule established at <http://www.regulations.gov> contains most of the documents in the docket. However, some information (e.g., copyrighted material) is not available publicly to read or download through this website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Mr. Frank Meilinger, OSHA Office of Communications, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3647, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General information and technical inquiries: William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3718, 200 Constitution Avenue NW, Washington, DC 20210; telephone (202) 693-1950.

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I. Background

On January 9, 2017, OSHA published its final rule Occupational Exposure to Beryllium and Beryllium Compounds in the **Federal Register** (82 FR 2470). OSHA concluded that employees exposed to beryllium and beryllium compounds at the preceding permissible exposure limits (PELs) were at significant risk of material impairment of health, specifically chronic beryllium disease and lung cancer. OSHA concluded that the new 8-hour time-weighted average (TWA) PEL of 0.2 µg/m³ reduced this significant risk to the

maximum extent feasible. Based on information submitted to the record, in the final rule OSHA issued three separate standards—general industry, shipyards, and construction. In addition to the revised PEL, the final rule established a new short-term exposure limit (STEL) of 2.0 µg/m³ over a 15-minute sampling period and an action level of 0.1 µg/m³ as an 8-hour TWA, along with a number of ancillary provisions intended to provide additional protections to 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 similar to those found in other OSHA health standards.

This DFR amends the text of the beryllium standard for general industry to clarify OSHA's intent with respect to certain terms in the standard, including the definition of Beryllium Work Area (BWA), the definition of emergency, and the meaning of the terms dermal contact and beryllium contamination. It also clarifies OSHA's intent with respect to provisions for disposal and recycling and with respect to provisions that the Agency intends to apply only where skin can be exposed to materials containing at least 0.1% beryllium by weight.

This direct final rule is expected to be an Executive Order (E.O.) 13771 deregulatory action. Details on OSHA's cost/cost savings estimates for this direct final rule can be found in the rule's economic analysis. OSHA has estimated that, at a 3 percent discount rate over 10 years, there are net annual cost savings of \$0.36 million per year for this direct final rule; at a discount rate of 7 percent, there are net annual cost savings of \$0.37 million per year. When the Department uses a perpetual time horizon, the annualized cost savings of the direct final rule is \$0.37 million with 7 percent discounting. While the 2017 Beryllium Final Rule went into effect on May 20, 2017, compliance obligations do not begin until May 11, 2018.

II. Consideration of Comments

OSHA will consider comments on all issues related to this action including economic or other regulatory impacts of this action on the regulated community. If OSHA receives no significant adverse comment, OSHA will publish a **Federal Register** document confirming the effective date of this DFR and withdrawing the companion Notice of Proposed Rulemaking (NPRM). Such confirmation may include minor

stylistic or technical changes to the document. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of this DFR as the date of promulgation.

III. Direct Final Rulemaking

In direct final rulemaking, an agency publishes a DFR in the **Federal Register**, with a statement that the rule will go into effect unless the agency receives significant adverse comment within a specified period. The agency may publish an identical concurrent NPRM. If the agency receives no significant adverse comment in response to the DFR, the rule goes into effect. OSHA typically confirms the effective date of a DFR through a separate **Federal Register** document. If the agency receives a significant adverse comment, the agency withdraws the DFR and treats such comment as a response to the NPRM. An agency typically uses direct final rulemaking when an agency anticipates that a rule will not be controversial.

For purposes of this DFR, a significant adverse comment is one that explains why the amendments to OSHA's beryllium standard would be inappropriate. In determining whether a comment necessitates withdrawal of the DFR, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. OSHA will not consider a comment recommending an additional amendment to this rule to be a significant adverse comment unless the comment states why the DFR would be ineffective without the addition.

In addition to publishing this DFR, OSHA is publishing a companion NPRM in the **Federal Register**. The comment period for the NPRM runs concurrently with that of the DFR. OSHA will treat comments received on the companion NPRM as comments also regarding the DFR. Similarly, OSHA will consider significant adverse comment submitted to the DFR as comment to the companion NPRM. Therefore, if OSHA receives a significant adverse comment on either this DFR or the NPRM, it will withdraw this DFR and proceed with the companion NPRM. In the event OSHA withdraws the DFR because of significant adverse comment, OSHA will consider all timely comments received in response to the DFR when it continues with the NPRM. After carefully considering all comments to the DFR and the NPRM, OSHA will decide whether to publish a new final rule.

OSHA determined that the subject of this rulemaking is suitable for direct final rulemaking. This amendment to the standard is clarifying in nature and does not adversely impact the safety or health of employees. The amended standard will clarify OSHA's intent regarding certain terms in the standard, including the definition of Beryllium Work Area (BWA), the definition of emergency, and the meaning of the terms dermal contact and beryllium contamination. It will also clarify OSHA's intent with respect to provisions for disposal and recycling and with respect to provisions that the Agency intends to apply only where skin can be exposed to materials containing at least 0.1% beryllium by weight. The revisions do not impose any new costs or duties. For these reasons, OSHA does not anticipate objections from the public to this rulemaking action.

IV. Discussion of Changes

On January 9, 2017, OSHA adopted comprehensive standards addressing exposure to beryllium and beryllium compounds in general industry, construction, and shipyards. 82 FR 2470. Beryllium "occurs naturally in rocks, soil, coal, and volcanic dust," but can cause harm to workers through exposure in the workplace. 80 FR 47579. OSHA has thus set a general industry exposure limit for beryllium and beryllium compounds since 1971, modified most recently in 2017. *See* 80 FR 47578–47579; 82 FR 2471. This DFR amends that 2017 general industry beryllium standard (codified at 29 CFR 1910.1024) to clarify its applicability to materials containing trace amounts of beryllium and to make related changes. This DFR does not affect the construction and shipyard standards, which are being addressed in a separate rulemaking. *See* 82 FR 29182.

During the last rulemaking, OSHA addressed the issue of trace amounts of beryllium. In its notice of proposed rulemaking, OSHA proposed to exempt from its beryllium standard materials containing less than 0.1% beryllium by weight on the premise that workers in exempted industries are not exposed at levels of concern, 80 FR 47775, but noted evidence of high airborne exposures in some of those industries, in particular the primary aluminum production and coal-fired power generation industries. 80 FR 47776. Therefore, OSHA proposed for comment several regulatory alternatives, including an alternative that would "expand the scope of the proposed standard to also include all operations in general industry where beryllium

exists only as a trace contaminant." 80 FR 47730. After receiving comment, OSHA adopted in the final rule an alternative limiting the exemption for materials containing less than 0.1% beryllium by weight to where the employer has objective data demonstrating that employee exposure to airborne beryllium will remain below the action level (AL) of 0.1 µg/m³, measured as an 8-hour TWA, under any foreseeable conditions. 29 CFR 1910.1024(a)(2). In doing so, OSHA noted that the AL exception ensured that workers with airborne exposures of concern were covered by the standard:

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 [airborne] 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 [United Steelworkers] and acknowledging that workers can have significant [airborne] 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 [airborne] exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. 82 FR 2643.

As the regulatory history makes clear, OSHA intended to protect employees working with trace beryllium only when it caused airborne exposures of concern. OSHA did not intend for provisions aimed at protecting workers from the effects of dermal contact to apply in the case of materials containing only trace amounts of beryllium. Since the publication of the final rule, however, stakeholders have suggested that an unintended consequence of the final rule's revision of the trace exemption is that provisions designed to protect workers from dermal contact with beryllium-contaminated material could be read as applying to materials with only trace amounts of beryllium.

This DFR adjusts the regulatory text of the general industry beryllium standard to clarify that OSHA does not intend for requirements that primarily address dermal contact to apply in processes, operations, or areas involving only materials containing less than 0.1% beryllium by weight. These clarifications are made through changes to the definition of beryllium work area;

the addition of definitions of dermal contact, beryllium-contaminated, and contaminated with beryllium; clarifications of certain hygiene provisions with respect to beryllium contamination; and the clarifications to provisions for disposal and recycling. In addition, because under these changes it is possible to have a regulated area that is not a beryllium work area, this DFR makes changes to certain housekeeping provisions to ensure they apply in all regulated areas. Finally, this DFR also includes a change to the definition of "emergency", adding detail to the definition so as to clarify the nature of the circumstances OSHA intends to be considered an emergency for the purposes of the standard.

Definition of beryllium work area. Paragraph (b) of the beryllium standard published in January 2017 defined a beryllium work area as 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. This DFR amends the definition as follows: "Beryllium work area means any work area: (1) Containing a process or operation that can release beryllium and that involves materials that contain at least 0.1% beryllium by weight; and (2) 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." This change clarifies OSHA's intent that many of the provisions associated with beryllium work areas should only apply to areas where there are processes or operations involving materials at least 0.1% beryllium by weight.

Specifically, this change to the beryllium work area definition clarifies OSHA's intent that the following provisions associated with beryllium work areas do not apply where processes and operations involve only materials containing trace amounts of beryllium (less than 0.1% beryllium by weight): Establishing and demarcating beryllium work areas (paragraphs (e)(1)(i) and (e)(2)(i)); including procedures for minimizing cross-contamination within (paragraph (f)(1)(i)(D)) or minimizing migration of beryllium out of (paragraph (f)(1)(i)(F)) such areas in the written exposure control plan; ensuring that at least one engineering or process control is in place to reduce beryllium exposure where airborne beryllium levels meet or exceed the AL (revised paragraph

(f)(2)(ii)).¹ Additionally, for areas where beryllium is only present in materials at concentrations of less than 0.1% beryllium by weight, unless that area is also a regulated area, employers are not required to ensure that all surfaces in such areas are as free as practicable of beryllium (paragraph (j)(1)(i)); ensure that all surfaces in such areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure (paragraph (j)(2)(i)); or prohibit dry sweeping or brushing for cleaning surfaces in such areas (paragraph (j)(2)(ii)).

This DFR also includes conforming changes to maintain the January 2017 rule's requirements for housekeeping in regulated areas. Because all regulated areas were also beryllium work areas under the January 2017 beryllium standard, OSHA did not specify whether requirements for beryllium work areas should also apply in regulated areas (areas in which airborne beryllium exposure meets or exceeds the TWA PEL or STEL). This DFR's clarification to the definition of beryllium work area, however, means that it is possible for a work area to be a regulated area, but not a beryllium work area. This would occur when processes that involve only materials containing less than 0.1% beryllium by weight nevertheless create airborne beryllium exposures at or above the TWA PEL or STEL. 82 FR 2583. It is thus important to clarify that housekeeping (paragraph (j)) requirements continue to apply in regulated areas, even if the processes or operations in these areas involve materials with only trace beryllium. Operations or processes involving trace beryllium materials must generate extremely high dust levels in order to exceed the TWA PEL or STEL. Following the housekeeping methods required by paragraph (j) will help to protect workers against resuspension of surface beryllium accumulations from extremely dusty operations and limit

workers' airborne exposure to beryllium.

The DFR accordingly amends paragraphs (j)(1)(i), (j)(2)(i), and (j)(2)(ii) to state explicitly that they apply to regulated areas, as follows. Paragraph (j)(1)(i), as amended, states that "[t]he employer must maintain all surfaces in beryllium work areas and regulated 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." Paragraph (j)(2)(i), as amended, states that "[t]he employer must ensure that surfaces in beryllium work areas and regulated areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure." Paragraph (j)(2)(ii), as amended, states that "[t]he employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas or regulated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective."

This DFR also makes conforming changes to the engineering controls requirements to ensure that the hierarchy of controls continues to apply in all regulated areas. Paragraph (f)(2) of the January 2017 beryllium standard provided that, if airborne exposures still exceed the PEL or STEL after implementing at least one control for each operation in a beryllium work area that releases airborne beryllium, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the limit exceeded. OSHA intended this provision to apply to all operations within the scope of the standard that can release airborne beryllium. 82 FR 2671–72. Because, under this DFR's revisions, not all regulated areas will be beryllium work areas, this DFR rearranges the regulatory text of paragraph (f)(2) to make clear that the hierarchy of controls will continue to apply in regulated areas that are not beryllium work areas.

Definitions related to beryllium contamination. To further clarify OSHA's intent that the standard's requirements aimed at reducing the effect of dermal contact with beryllium should not apply to areas where there are no processes or operations involving materials containing at least 0.1% beryllium by weight, this DFR defines "beryllium-contaminated or contaminated with beryllium" and adds those terms to certain provisions in the standard. The DFR defines those terms

as follows: "Contaminated with beryllium and beryllium-contaminated mean contaminated with dust, fumes, mists, or solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight." The DFR adds the terms to certain provisions in the standard's requirements for hygiene areas and disposal and recycling.

The use of this definition accordingly clarifies OSHA's intent that the following provisions, which apply where clothing, hair, skin, or work surfaces are beryllium-contaminated, do not apply where the contaminating material contains less than 0.1% beryllium by weight: Paragraph (h)(2)(i) and paragraph (h)(2)(ii), which require the employer to ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the appropriate time and as specified in the written exposure control plan required by paragraph (f)(1); and paragraph (h)(2)(iii) and paragraph (h)(2)(iv), which require the employer to ensure that measures to prevent cross contamination between beryllium-contaminated personal protective clothing and equipment and street clothing are observed and that beryllium-contaminated personal protective clothing and equipment are not removed from the workplace. This DFR also amends paragraph (h)(3)(ii), which requires the employer to ensure that beryllium is properly removed from PPE, by adding the term "beryllium-contaminated" so that this requirement applies only where the contaminating material contains at least 0.1% beryllium by weight. The amended paragraph (h)(3)(ii) reads as follows: "The employer must ensure that beryllium is not removed from beryllium-contaminated personal protective clothing and equipment by blowing, shaking, or any other means that disperses beryllium into the air."

Similarly, the DFR's inclusion of the term "contaminated with beryllium" in paragraphs (i)(3)(i)(B) and (i)(3)(ii)(B) clarifies OSHA's intent that those provisions, which require employers to provide and ensure use of showers where employees' hair or body parts other than hands, face, and neck can reasonably be expected to become contaminated with beryllium, do not apply where the contaminating material contains less than 0.1% beryllium by weight.

The DFR's adoption of the definition of "beryllium-contaminated" further clarifies the application of certain requirements that are meant to minimize re-entrainment of airborne beryllium and reduce the effect of

¹ As explained in the preamble to the January 2017 rule, in industries that process or handle materials with only trace amounts of beryllium and that encounter exposures to beryllium above the action level, the PEL would "be exceeded only during operations that generate [an] excessive amount of visible airborne dust." 82 FR 2583. OSHA therefore expects that if exposures in such a facility are below the PEL but above the AL, there is already at least one engineering or process control in place, so this requirement had no effect on primary aluminum production or coal-fired utilities. The 2017 FEA explained that this provision would only require additional controls in two job categories in two application groups, neither of which are in primary aluminum production or coal-fired utilities. (Document ID OSHA-H005C-2006-0870-2042, p. V-12).

dermal contact with beryllium. Specifically, it clarifies that paragraph (j)(2)(iii), which prohibits the use of compressed air for cleaning beryllium-contaminated surfaces except where used in conjunction with an appropriate ventilation system, and paragraph (j)(2)(iv), which requires the use of respiratory protection and PPE in accordance with paragraphs (g) and (h) of the standard when dry sweeping, brushing, or compressed air are used to clean beryllium-contaminated surfaces, do not apply where the contaminating material contains less than 0.1% beryllium by weight. OSHA does not expect the additional airborne exposure from dry brushing, sweeping, or using compressed air to significantly increase the levels of airborne exposure outside regulated areas when working with trace beryllium. This is because for trace beryllium to generate airborne exposures of concern, excessive amounts of dust would need to be generated, and this would not happen outside of regulated areas.

This DFR also adds the term “beryllium-contaminated” to certain requirements pertaining to eating and drinking areas to clarify that hygiene requirements in these areas apply only where materials containing more than 0.1% beryllium by weight may contaminate such areas. Paragraph (i)(4)(i), as amended by this DFR, states that wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that “[b]eryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium.” Paragraph (i)(4)(ii), as amended by this DFR, requires employers to ensure that “[n]o employees enter any eating or drinking area with beryllium-contaminated 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.”

Definition of dermal contact with beryllium. To clarify OSHA’s intent that requirements of the standard associated with dermal contact with beryllium should not apply to areas where there are no processes or operations involving materials at least 0.1% beryllium by weight, this DFR also adds a definition for dermal contact with beryllium. This new definition provides, “Dermal contact with beryllium means skin exposure to: (1) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight; (2) solutions containing beryllium in concentrations

greater than or equal to 0.1 percent by weight; or (3) dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight.” Accordingly, the definition clarifies that paragraph (h)(1)(ii), which requires an employer to provide and ensure the use of personal protective clothing and equipment where there is a reasonable expectation of dermal contact with beryllium, applies only where contact may occur with materials containing at least 0.1% beryllium by weight. This definition also clarifies that the requirements related to dermal contact in the written exposure control plan, washing facilities, medical examinations, and training provisions only apply where contact may occur with materials containing at least 0.1% beryllium by weight.

Definition of emergency. This DFR also clarifies the definition of “emergency” in paragraph (b) of the beryllium standard published in January 2017. That paragraph defined an emergency as “any uncontrolled release of airborne beryllium.” This DFR amends the definition as follows: “Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an uncontrolled and unintended release of airborne beryllium that presents a significant hazard.” This change clarifies the circumstances under which the provisions associated with emergencies should apply, including the requirements that employers provide and ensure employee use of respirators and that employers provide medical surveillance to employees exposed in an emergency. This change is consistent with OSHA’s intent as explained in the preamble to the 2017 final rule. 82 FR 2690 (“An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes.”). These examples show OSHA’s intent to define an “emergency” as something unintended as well as uncontrolled, and including the examples in the new definition make that clear. It is also consistent with other OSHA standards, such as methylenedianiline (1910.1050), vinyl chloride (1910.1017), acrylonitrile (1910.1045), benzene (1910.1028), and ethylene oxide (1910.1047).

Disposal and recycling. Finally, this DFR clarifies the application of the disposal and recycling provisions. Paragraph (j)(3) of the beryllium standard published in January 2017 required employers to ensure that 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 the standard. It also required that materials designated for recycling which 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 the standard, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of the standard. These provisions were designed to protect workers from dermal contact with beryllium dust generated during processing, where there is a risk of beryllium sensitization. See 82 FR 2694, 2695. This DFR accordingly limits those requirements to “materials that contain beryllium in concentrations of 0.1 percent by weight or more or are contaminated with beryllium,” consistent with OSHA’s intention that provisions aimed at protecting workers from the effects of dermal contact do not apply in the case of materials containing only trace amounts of beryllium. The hazard communication standard continues to apply according to its terms. See 29 CFR 1910.1200.

V. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970 (“OSH Act”; 29 U.S.C. 651 *et seq.*) 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 to promulgate and enforce occupational safety and health standards. 29 U.S.C. 655(b), 658. A safety or health standard is a standard that “requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.” 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate when a significant risk of material harm exists in the workplace and the standard would substantially reduce or eliminate that workplace risk. See *Industrial Union Dept., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 641–42 (1980) (plurality opinion).

OSHA need not make additional findings on risk for this DFR. As discussed above, this DFR will not diminish the employee protections put into place by the standard being amended. And because OSHA previously determined that the

beryllium standard substantially reduces a significant risk (82 FR 2545–52), it is unnecessary for the Agency to make additional findings on risk for the minor changes and clarifications being made to the standard. See, e.g., *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1502 n.16 (D.C. Cir. 1986) (rejecting the argument that OSHA must “find that each and every aspect of its standard eliminates a significant risk”).

OSHA has determined that these minor changes and clarifications are technologically and economically feasible. All OSHA standards must be both technologically and economically feasible. See *United Steelworkers v. Marshall*, 647 F.2d 1189, 1264 (D.C. Cir. 1980) (“*Lead I*”). The Supreme Court has defined feasibility as “capable of being done.” *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 509–10 (1981) (“*Cotton Dust*”). Courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility, “within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.” *Lead I*, 647 F.2d at 1272. With respect to economic feasibility, courts have held that “a standard is feasible if it does not threaten massive dislocation or imperil the existence of the industry.” *Id.* at 1265 (internal quotation marks and citations omitted). In the final economic analysis (FEA) for the 2017 beryllium rule, OSHA concluded that the rule was economically and technologically feasible. OSHA has determined that this DFR is also economically and technologically feasible, because it does not impose any new requirements or costs.

VI. Final Economic Analysis and Regulatory Flexibility Act Certification

Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)) require that OSHA estimate the benefits, costs, and net benefits of regulations, and analyze the impacts of certain rules that OSHA promulgates. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This DFR is not an “economically significant regulatory action” under Executive Order 12866, or a “major rule” under the Congressional Review Act (5 U.S.C. 801 *et seq.*), and its impacts do not trigger the analytical requirements of UMRA. Neither the

benefits nor the costs of this DFR would exceed \$100 million in any given year. This DFR would, however, result in a net cost savings for employers in primary aluminum production and coal-fired utilities, which are the only industries in General Industry covered by the 2017 Beryllium Final Rule that OSHA identified with operations involving materials containing only trace beryllium (less than 0.1% beryllium by weight).

Several calculations illustrate the expected cost savings. At a discount rate of 3 percent, this DFR would yield annualized cost savings of \$0.36 million per year for 10 years. At a discount rate of 7 percent, this DFR would yield an annualized cost savings of \$0.37 million per year for 10 years. These net cost savings amount to approximately 0.6 percent of the original estimated cost of the 2017 Beryllium Final Rule for General Industry at discount rates of either 3 or 7 percent; to approximately 5.3 percent of the original estimated cost of the 2017 Beryllium Final Rule for primary aluminum production and coal-fired utilities only at a discount rate of 3 percent and 5.2 percent of the original estimated cost of the 2017 Beryllium Final Rule for primary aluminum production and coal-fired utilities only at a discount rate of 7 percent.² Under a perpetual time horizon, the annualized cost savings of this DFR is \$0.37 million at a discount rate of 7 percent.

1. Changes to the Baseline: Updating to 2017 Dollars and Removing Familiarization Costs

Because baseline costs typically reflect the costs of compliance *without* the changes set forth in an agency’s action—in this case, the DFR—OSHA has revised the baseline costs, as displayed in the FEA in support of the beryllium standard of January 9, 2017, in two ways. First, OSHA updated the projected costs for general industry contained in the FEA that accompanied the rule from 2015 to 2017 dollars, using the latest Occupational Employment Statistics (OES) wage data (for 2016) and inflating them to 2017 dollars. Second, OSHA excluded certain familiarization costs, included in the cost estimates developed in the beryllium FEA for the 2017 Beryllium Final Rule, because OSHA expects that those costs have already been incurred by affected employers. Thus, the baseline costs for

² The original estimated cost of the 2017 beryllium final rule for General Industry, and separately for primary aluminum production and coal-fired utilities, was updated to 2017 dollars and additionally adjusted and corrected, as subsequently explained in the text.

this FEA are the projected costs from the 2017 FEA, updated to 2017 dollars, less familiarization costs in the 2017 beryllium final rule (but including some new familiarization costs for employers to become familiar with the revised provisions). Throughout this analysis of costs and cost savings, the context is limited to employers in primary aluminum production and coal-fired utilities.

2. Discussion of Overhead Costs

As in the 2017 FEA, OSHA has not accounted for overhead labor costs in its analysis of the cost savings for this DFR due to concerns about consistency. There are several ways to look at the cost elements that fit the definition of overhead, and there is a range of overhead estimates currently used within the federal government—for example, the Environmental Protection Agency has used 17 percent,³ and government contractors have been reported to use an average of 77 percent.⁴ Some overhead costs, such as advertising and marketing, may be more closely correlated with output than with labor. Other overhead costs vary with the number of new employees. For example, rent or payroll processing costs may change little with the addition of 1 employee in a 500-employee firm, but may change substantially with the addition of 100 employees. If an employer is able to rearrange current employees’ duties to implement a rule, then the marginal share of overhead costs, such as rent, insurance, and major office equipment (e.g., computers, printers, copiers) would be very difficult to measure with accuracy.

If OSHA had included an overhead rate when estimating the marginal cost of labor, without further analyzing an appropriate quantitative adjustment, and adopted for these purposes an overhead rate of 17 percent on base wages, the cost savings of this DFR

³ See Grant Thornton LLP. 2015 Government Contractor Survey (Document ID OSHA–H005C–2006–0870–2153). The application of this overhead rate was based on an approach used by the Environmental Protection Agency, as described in EPA’s “Wage Rates for Economic Analyses of the Toxics Release Inventory Program,” June 10, 2002. This analysis itself was based on a survey of several large chemical manufacturing plants: Heiden Associates, Final Report: A Study of Industry Compliance Costs Under the Final Comprehensive Assessment Information Rule, Prepared for the Chemical Manufacturers Association, December 14, 1989.

⁴ For further examples of overhead cost estimates, please see the Employee Benefits Security Administration’s guidance at <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf>.

would increase to approximately \$0.39 million per year, at discount rates of either 3 percent or 7 percent.⁵ The addition of 17 percent overhead on base wages would therefore increase cost savings by approximately 7 percent above the primary estimate at either discount rate.

3. Cost Impact of the Changes to the Standard

OSHA estimates a net cost savings from this DFR for employers at primary aluminum production and coal-fired utilities, which again are the only two industries identified in the 2017 FEA as having costs associated with exposure to trace beryllium materials.⁶ Annualizing the present value of net cost savings over ten years, the result is an annualized net cost savings of \$0.36 million per year at a discount rate of 3 percent, or \$0.37 million per year at a discount rate of 7 percent. When the Department uses a perpetual time horizon, the annualized net cost savings of this DFR is \$0.37 million at a discount rate of 7 percent.

The undiscounted cost savings by provision and year are presented below in Table 1, and the cost savings by provision and discount rate are shown below in Tables 2 and 3. As described elsewhere in this document, the cost savings described in this FEA reflect savings only for provisions covered by the changes in this DFR as well as added familiarization costs. OSHA estimated no cost savings for the PEL, respiratory protection, exposure assessment, regulated areas, medical surveillance, medical removal protection, written exposure control plan, or training provisions because the DFR makes no changes of substance to those provisions.

⁵ OSHA used an overhead rate of 17 percent on base wages in a sensitivity analysis in the FEA (OSHA-2010-0034-4247, p. VII-65) in support of the March 25, 2016 final respirable crystalline silica standards (81 FR 16286) and in the PEA in support of the June 27, 2017 proposed beryllium standards in construction and shipyard sectors (82 FR 29201).

⁶ As noted in Section IV of this preamble, coverage of dermal contact with trace beryllium materials was an unintended consequence of OSHA's decision to cover airborne exposures to beryllium above the action level caused by operations that generate excessive amounts of dust from trace beryllium materials. Likewise, in the 2017 FEA supporting OSHA's Beryllium Final Rule, through an oversight, OSHA made no distinction between trace and non-trace beryllium materials when determining the cost of requirements triggered by dermal contact with beryllium. The cost savings generated by this FEA are a result of correcting these oversights.

a. Beryllium work areas. OSHA is limiting the definition of "beryllium work area" to any work area containing a process or operation "that involves materials that contain at least 0.1% beryllium by weight. . . ." OSHA has determined that affected establishments in primary aluminum production and coal-fired utilities would thus no longer need to designate and demarcate beryllium work areas because their materials would not meet that threshold outside of the "regulated areas" in primary aluminum production where employee exposures to airborne beryllium would exceed the PEL. In its previous economic analysis, OSHA had estimated that each of the establishments in these categories required beryllium work areas in addition to "regulated areas," which were costed separately. The removal of these beryllium work area designations results in an annualized cost savings of \$12,913 using a 3 percent discount rate and \$15,682 using a 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

b. Protective work clothing and equipment. OSHA is recognizing no cost savings in this DFR for the elimination of PPE requirements associated with dermal contact in coal-fired utilities. In its 2017 FEA, OSHA listed the PPE compliance rate for utility workers at coal-fired utilities at 75 percent and therefore estimated PPE costs for the residual 25 percent of utility workers in the industry (where airborne exposures exceed the PEL or STEL or where there is dermal contact with beryllium). But upon further review, OSHA has determined that it should not have included those costs because affected employers in coal-fired utilities were already required to wear PPE under 29 CFR 1910.1018(j) to prevent skin and eye irritation from exposure to trace inorganic arsenic found in coal ash. As OSHA noted in its technological feasibility analysis, inorganic arsenic is often found in coal fly ash in "concentrations 10 to 1,000 times greater than beryllium," fly ash is the primary source of beryllium exposure for employees in coal-fired utilities, and employers in this application group indicated that they were already following a majority of the provisions of the rule to comply with OSHA requirements for other hazardous substances, such as arsenic (p. IV-652). Thus, in all of the areas within a facility

in which employees are likely to be exposed to beryllium, they are also likely to be exposed to concentrations of arsenic significantly high so as to trigger the arsenic PPE requirements. Accordingly, coal-fired utility compliance rates with the PPE requirement for affected workers should have been 100 percent in the prior FEA, and no costs for PPE for these workers should have been included in OSHA's cost estimates. Because OSHA should not have included new beryllium PPE costs for this group, OSHA is recognizing no cost savings in this DFR for the elimination of PPE requirements associated with dermal contact in coal-fired utilities.

There are, however, some small PPE cost savings for primary aluminum production. The January 2017 rule requires employers to provide PPE in two situations: (1) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; and (2) where there is a reasonable expectation of dermal contact with beryllium. 29 CFR 1910.1024(h)(1). It is the second of these two situations which OSHA believes will trigger cost savings. Because this DFR clarifies that "dermal contact with beryllium" does not include contact with beryllium in concentrations less than 0.1% beryllium by weight, gloves and other PPE requirements will be triggered by a reasonable expectation of dermal contact only with materials containing more than 0.1% beryllium by weight. In primary aluminum production, there is no dermal contact with materials containing beryllium above this threshold. As a result, the Agency has determined that in primary aluminum production, additional PPE is only necessary for workers exposed over the PEL. This change results in an annualized cost savings for employers in primary aluminum production of \$35,023 using a 3 or 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

c. Hygiene areas and practices. The DFR's adoption of a definition for "contaminated with beryllium" also reduces the costs of complying with the Hygiene Areas and Practices provision in primary aluminum production (the costs for coal-fired utilities would not be affected). The 2017 Final Beryllium Rule requires employers to provide showers where both of two conditions are met:

(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.

29 CFR 1910.1024(i)(3)(i). By revising (B) to incorporate the newly defined term "contaminated with beryllium," the condition in paragraph (B) will not be met in primary aluminum production because no employees in this application group can reasonably be expected to become "contaminated with beryllium." Thus, the beryllium standard does not require employers in this application group to provide showers. Similarly, employers need not provide the estimated lower-cost alternative of head coverings, discussed in the 2017 FEA.⁷ Removing the cost of head coverings for workers in this application group results in an annualized cost savings for employers in primary aluminum production of \$415 using a 3 or 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

d. Housekeeping. Similar to the above discussion about PPE in coal-fired utilities, OSHA is recognizing no cost savings in this DFR for coal-fired utilities as a result of the modification of the housekeeping requirements. In the FEA in support of the 2017 Beryllium Final Rule, the Agency listed the housekeeping compliance rate for affected workers at coal-fired utilities at 75 percent and therefore estimated housekeeping costs for the residual 25 percent of utility workers in a beryllium work area. But upon further review, OSHA has determined that affected employers in coal-fired utilities were already required to perform comparable housekeeping duties under 29 CFR 1910.1018(k) to prevent accumulations of inorganic arsenic found in coal ash. Accordingly, coal-fired utility compliance rates with the housekeeping requirements for affected workers should have been 100 percent in the prior FEA, and no costs for housekeeping for these workers should have been included in OSHA's cost

estimates. Consequently, OSHA is recognizing no cost savings in this DFR for coal-fired utilities as a result of the modification of the housekeeping requirements.

The rule clarification also means that employers in primary aluminum production facilities will typically only be required to comply with the beryllium housekeeping provisions in "regulated areas," which for cost purposes OSHA identified as employees exposed over the PEL in its exposure profile. There are several exceptions, none of which have a quantifiable impact on costs: Employers in this industry would still need to follow the housekeeping requirements when cleaning up spills and emergency releases of beryllium (paragraph (j)(1)(ii)), handling and maintaining cleaning equipment (paragraph (j)(2)(v)), and when necessary to reduce some workers exposures below the PEL (serving as an engineering control to prevent over-exposure to beryllium within regulated areas or the need for regulated areas). OSHA did not identify separate costs in its prior FEA for this use of housekeeping as a form of engineering control and does not do so here. Thus, for cost calculation purposes in this new FEA, OSHA removed housekeeping costs for all employees exposed below the PEL in its exposure profile. This change results in an annualized cost savings for employers in primary aluminum production of \$323,664 using a 3 percent discount rate and \$330,324 using a 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3. OSHA believes that these estimated cost savings might be slightly overstated to the extent that some housekeeping outside of the regulated areas will still be needed to perform an engineering-control function in some facilities, but the Agency is unable to quantify them now because of the variability among facilities and controls that employers may implement to comply with the standard.

e. Additional familiarization. In the FEA in support of OSHA's 2017 Beryllium Final Rule, the Agency determined that employers would need to spend time familiarizing themselves with the rule and allocated 4, 8, and 40 hours, depending on establishment size (fewer than 20 employees, between 20

and 499 employees, and 500 or more employees, respectively). OSHA has similarly determined that establishments will need to spend time familiarizing themselves with this DFR. As the affected provisions in this DFR are only a fraction of all the provisions in the 2017 final rule and would not require any new actions on the part of employers, the Agency has estimated familiarization time of 2, 4, and 20 hours per employer, depending on establishment size, for a supervisor to review the changes to the beryllium rule reflected in this DFR. This results in an annualized cost of \$9,404 using a 3 percent discount rate and \$11,421 using a 7 percent discount rate. Annualized costs by provision and discount rate—3 and 7 percent—can be seen below in Tables 2 and 3, respectively.

f. Unchanged provisions. As discussed earlier, this DFR primarily serves to clarify OSHA's intent with respect to certain terms and requirements in OSHA's 2017 beryllium general industry standard. These changes largely deal with clarifying the application of various requirements to trace beryllium. The triggers for most provisions in the standard—the PEL, respiratory protection, exposure assessment, regulated areas, medical surveillance, medical removal protection, written exposure control plan, and training provisions⁸—are determined by factors other than beryllium concentration and are unchanged by this DFR. Similarly, the revised definition of "emergency" in this DFR would not affect the costs estimated for the other provisions in the standard.

4. Economic and Technological Feasibility

In the FEA for the 2017 beryllium standard, OSHA concluded that the rule was economically and technologically feasible. This DFR does not impose any new requirements and has the net impact of removing a small amount of cost, so OSHA has determined that this final rule is also economically and technologically feasible.

⁸ While the changes in the standard do not mandate any additional employee training, OSHA notes that it had previously accounted for costs of annual re-training required by the standard (Document ID OSHA-H005C-2006-0870-2042, p. V-221).

⁷ In the previous FEA, OSHA had included costs for head coverings in lieu of showers, reasoning that employees could avoid the need for showers because the head coverings and other PPE would prevent their hair or body parts from becoming contaminated with beryllium.

5. *Effects on Benefits*

This DFR clarifies aspects of the 2017 general industry beryllium standard to address unintended consequences regarding the applicability of provisions designed to protect workers from dermal contact with beryllium-containing materials and trace amounts of beryllium. This DFR makes clear that OSHA did not, and does not, intend to apply the provisions aimed at protecting workers from the effects of dermal contact to industries that only work with beryllium in trace amounts where there is limited or no airborne exposure.

In the prior FEA, OSHA did not identify any quantifiable benefits from avoiding beryllium sensitization from dermal contact (see discussion at p. VII–16 through VII–18). Thus, the revisions in this DFR, which are focused on dermal contact, do not have any impact on OSHA's previous benefit estimates.

6. *Regulatory Flexibility Act Certification*

This DFR will result in cost savings for affected small entities, and those savings fall below levels that could be said to have a significant positive

economic impact on a substantial number of small entities.⁹ Therefore, OSHA certifies that this direct final rule would not have a significant impact on a substantial number of small entities.

⁹ OSHA investigated whether the projected cost savings would exceed 1 percent of revenues or 5 percent of profits for small entities and very small entities for every industry. To determine if this was the case, OSHA returned to its original regulatory flexibility analysis (in the 2017 FEA) for small entities and very small entities. OSHA found that the cost savings of this DFR are such a small percentage of revenues and profits for every affected industry that OSHA's criteria would not be exceeded for any industry.

TABLE 2—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE FINAL BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY—Continued
[In 2017 dollars using a 3 percent discount rate]

Application group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	House-keeping	Training	Total program costs
Maritime Subtotal.		0	0	0	0	0	0	0	0	0	0	0	0
Total, All Industries.	-9,404	0	0	12,913	0	0	0	35,023	415	323,664	0	362,610	

TABLE 3—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE FINAL BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY
[In 2017 dollars using a 7 percent discount rate]

Application Group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	House-keeping	Training	Total program costs
331313	Alumina Refining and Primary Aluminum Production.	-\$291	\$0	\$0	\$3,205	\$0	\$0	\$0	\$35,023	\$415	\$330,324	\$0	\$368,675

Aluminum Production

Application Group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	House-keeping	Training	Total program costs
221112	Fossil Fuel Electric Power Generation.	-7,541	0	0	9,822	0	0	0	0	0	0	0	2,281
311221	Wet Corn Milling	-342	0	0	315	0	0	0	0	0	0	0	-27
311313	Beet Sugar Manufacturing	-428	0	0	368	0	0	0	0	0	0	0	-60
311942	Spice and Extract Manufacturing.	-50	0	0	53	0	0	0	0	0	0	0	3
312120	Breweries	-66	0	0	53	0	0	0	0	0	0	0	-13
321219	Reconstituted Wood Product Manufacturing.	-24	0	0	26	0	0	0	0	0	0	0	3
322110	Pulp Mills	-39	0	0	26	0	0	0	0	0	0	0	-12
322121	Paper (except Newsprint) Mills.	-531	0	0	289	0	0	0	0	0	0	0	-242
322122	Newsprint Mills	-856	0	0	631	0	0	0	0	0	0	0	-225
322130	Paperboard Mills	-543	0	0	421	0	0	0	0	0	0	0	-123
325211	Plastics Material and Resin Manufacturing.	-103	0	0	105	0	0	0	0	0	0	0	2
325611	Soap and Other Detergent Manufacturing.	-28	0	0	26	0	0	0	0	0	0	0	-2
327310	Cement Manufacturing	-48	0	0	53	0	0	0	0	0	0	0	5
333111b	Farm Machinery and Equipment Manufacturing.	-29	0	0	26	0	0	0	0	0	0	0	-3
336510b	Railroad Rolling Stock Manufacturing.	-31	0	0	26	0	0	0	0	0	0	0	-5
611310	Colleges, Universities, and Professional Schools.	-471	0	0	237	0	0	0	0	0	0	0	-234
Total: General Industry Subtotal.	-11,421	0	0	15,682	0	0	0	35,023	415	330,324	0	370,022	

Coal Fired Utilities

Construction Subtotal.....	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Maritime Subtotal.....	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total, All Industries.....	-11,421	0	0	0	15,682	0	0	0	0	0	0	0	35,023	415	330,324	0	0	0	0	0	0	0	0	370,022	0

VII. OMB Review Under the Paperwork Reduction Act of 1995

This rule contains no information collection requirements subject to OMB approval under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, and its implementing regulations at 5 CFR part 1320. The PRA defines a *collection of information* as *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.* See 44 U.S.C. 3502(3)(A). While not affected by this rulemaking, the Department has cleared information collections related to occupational exposure to beryllium standards—general industry, 29 CFR 1910.1024; construction, 29 CFR 1926.1124; and shipyards, 29 CFR 1915.1024—under control number 1218–0267. The existing approved information collections are unchanged by this rulemaking. The Department welcomes comments on this determination.

VIII. Federalism

OSHA reviewed this DFR in accordance with the Executive Order on Federalism (E.O. 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when clear constitutional and statutory authority exists and the problem is national in scope. E.O. 13132 provides for preemption of State law only with the expressed consent of Congress. Any such preemption is to be limited to the extent possible.

Under Section 18 of the OSH Act, 29 U.S.C. 651 *et seq.*, Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as “State Plan States” (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State Plan States are free to develop and enforce under State law their own requirements for safety and health standards.

This DFR 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 DFR would limit State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA approved State Plans, this rulemaking does not significantly limit State policy options.

IX. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 28 States and U.S. Territories with their own OSHA approved occupational safety and health plans (“State Plan States”) must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.*, because an existing State standard covering this area is “at least as effective” as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, must be applicable to both the private and public (State and local government employees) sectors, and must be completed within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States are not required to amend their standards, although the Agency may encourage them to do so. The 28 States and U.S. Territories with OSHA approved occupational safety and health plans are: 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; Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands have OSHA approved State Plans that apply to State and local government employees only.

This DFR clarifies requirements and addresses the unintended consequences associated with provisions intended to address the effects of dermal contact with beryllium as applied to trace beryllium. It imposes no new requirements. Therefore, no new State standards would be required beyond those already required by the promulgation of the January 2017 beryllium standard for general industry. State-Plan States may nonetheless choose to conform to these revisions.

X. Unfunded Mandates Reform Act

OSHA reviewed this DFR according to the Unfunded Mandates Reform Act of

1995 (“UMRA”; 2 U.S.C. 1501 *et seq.*) and Executive Order 12875 (58 FR 58093). As discussed above in Section VI (“Economic Analysis and Regulatory Flexibility Certification”) of this preamble, the Agency determined that this DFR does not impose significant additional costs on any private- or public-sector entity. Accordingly, this DFR does not require significant additional expenditures by either public or private employers.

As noted above under Section IX (“State-Plan States”), the Agency’s standards do not apply to State and local governments except in States that have elected voluntarily to adopt a State Plan approved by the Agency. Consequently, this DFR does not meet the definition of a “Federal intergovernmental mandate” (see Section 421(5) of the UMRA (2 U.S.C. 658(5))). Therefore, for the purposes of the UMRA, the Agency certifies that this DFR does not mandate that State, local, or Tribal governments adopt new, unfunded regulatory obligations. Further, 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.

List of Subjects in 29 CFR Part 1910

Beryllium, General industry, Health, Occupational safety and health.

Signed at Washington, DC, on April 27, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons stated in the preamble, OSHA amends 29 CFR part 1910 as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—Toxic and Hazardous Substances

- 1. The authority section for subpart Z of part 1910 continues 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. Amend § 1910.1024 as follows:

- a. Revise the definition of “Beryllium work area” in paragraph (b);
- b. Add definitions for “Contaminated with beryllium and beryllium-contaminated” and “Dermal contact with beryllium” in alphabetical order in paragraph (b);
- c. Revise the definition of “Emergency” in paragraph (b);
- d. Revise paragraph (f)(2);
- e. Revise paragraph (h)(3)(ii);
- f. Revise paragraphs (i)(3)(i)(B), (i)(3)(ii)(B), (i)(4)(i) and (ii); and
- g. Revise paragraphs (j)(1)(i), (j)(2)(i) and (ii), and (j)(3).

The revisions and additions read as follows:

§ 1910.1024 Beryllium.

* * * * *

(b) * * *

Beryllium work area means any work area:

(i) Containing a process or operation that can release beryllium and that involves material that contains at least 0.1 percent beryllium by weight; and

(ii) 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.

* * * * *

Contaminated with beryllium and beryllium-contaminated mean contaminated with dust, fumes, mists, or solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight.

Dermal contact with beryllium means skin exposure to:

(i) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight;

(ii) Solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight; or

(iii) Dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight.

* * * * *

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an uncontrolled and unintended release of airborne beryllium that presents a significant hazard.

* * * * *

(f) * * *

(2) *Engineering and work practice controls.* (i) The employer must use engineering and work practice controls to reduce and maintain employee airborne exposure to beryllium to or below the PEL and STEL, unless the

employer can demonstrate that such controls are not feasible. Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs with 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 using respiratory protection in accordance with paragraph (g) of this standard.

(ii) 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.

(iii) An employer is exempt from using the controls listed in paragraph (f)(2)(ii) 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.

* * * * *

(h) * * *

(3) * * *

(ii) The employer must ensure that beryllium is not removed from beryllium-contaminated personal protective clothing and equipment by blowing, shaking, or any other means that disperses beryllium into the air.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(B) Employee’s hair or body parts other than hands, face, and neck can reasonably be expected to become contaminated with beryllium.

(ii) * * *

(B) The employee’s hair or body parts other than hands, face, and neck could reasonably have become contaminated with beryllium.

(4) * * *

(i) Beryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with beryllium-contaminated 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

* * * * *

(j) * * *

(1) * * *

(i) The employer must maintain all surfaces in beryllium work areas and regulated 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

* * * * *

(2) * * *

(i) The employer must ensure that surfaces in beryllium work areas and regulated 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 or regulated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

* * * * *

(3) *Disposal and recycling.* For materials that contain beryllium in concentrations of 0.1 percent by weight or more or are contaminated with beryllium, the employer must ensure that:

(i) Materials designated for disposal 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 are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or place in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard.

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