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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket No. CDC-2018-0068; NIOSH-318]

RIN 0920-AA67

Removal of Compliance Deadline for Closed-Circuit Escape Respirators

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: With this deregulatory action, the Department of Health and Human Services (HHS) proposes to revise regulatory language which establishes a deadline by which respirator manufacturers must discontinue the manufacturing, labeling, and sale of certain self-contained self-rescuer models. The National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention, HHS, has determined that discontinuing the manufacturing, labeling, and sale of certain self-contained self-rescuer models is likely to result in a shortage of person-wearable large capacity escape respirators for underground coal miners who rely on these devices.

DATES: Comments must be received by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: *Written comments:* You may submit comments by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions

for submitting comments to the docket.

- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 1090 Tusculum Avenue, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2018-0068; NIOSH-318) or Regulation Identifier Number (0920-AA67) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Office of the Director, NIOSH; 1090 Tusculum Avenue, MS:C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested parties may participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed. You may submit comments on any topic related to this notice of proposed rulemaking.

II. Statutory Authority

Pursuant to the Occupational Safety and Health (OSH) Act of 1970 (Pub. L. 91-596), the Organic Act of 1910 (Pub. L. 179), and the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 842(h), 844, 957; Pub. L. 91-173), NIOSH is authorized to approve respiratory equipment used in mines and other workplaces for the protection of employees potentially exposed to hazardous breathing atmospheres. The Department of Labor's Mine Safety and Health Administration (MSHA) requires U.S. coal mine operators to supply NIOSH-approved respirators to miners whenever the use of respirators is required.

III. Background

The closed-circuit escape respirator (CCER), one of two types of respirator considered "self-contained breathing apparatus," is known in the mining industry as a "self-contained self-rescuer" (SCSR). In order to distinguish closed-circuit devices approved under 42 CFR part 84, subpart H from those approved under subpart O, the former will be identified here as SCSRs and the latter will be identified as CCERs. The SCSR approved under subpart H and CCER approved under subpart O reflect two generations of the same respirator type used in certain industrial and other work settings during emergencies to enable users to escape from atmospheres that can be immediately dangerous to life and health. The SCSR and CCER are used by miners and other workers to escape dangerous atmospheres.

Technical requirements for the approval of CCERs were promulgated in a final rule published March 8, 2012, in which HHS codified the new subpart O, intended to eventually take the place of older requirements in 42 CFR part 84, subpart H that were applicable to

the SCSR closed-circuit escape respirators.¹ The purpose of these updated requirements is to enable NIOSH and MSHA to more effectively ensure the performance, reliability, and safety of escape respirators used in underground coal mining and in other workplaces, such as the maritime industry, where these devices are used. The March 2012 rulemaking was conducted in response to decades of reports from the field, particularly underground coal mines, documenting user concerns about the inability to check subpart H-approved SCSRs for internal damage and the damage sustained to such devices in harsh underground environments. Furthermore, incidents in which users did not receive the expected duration of breathing air were common. The subpart H performance rating system classifies SCSRs by the duration of breathing air, and is widely known to create confusion among users because performance duration is highly variable, dependent on a variety of factors such as breathing rate and physiology of the user which can result in less protection time than the wearer expects. The need for the rulemaking was discussed in greater detail in the March 2012 final rule; background documents, including public comments, are available in NIOSH Docket 005.

The subpart O CCER standards established a classification system based on the quantity (capacity) of oxygen available in an escape respirator. For the purpose of comparing the SCSR to the CCER, a device classified as a “10-minute” SCSR under subpart H may be approximately equivalent to a “Cap 1” unit under subpart O, delivering between 20 and 59 liters of oxygen. A “1-hour” SCSR under subpart H may be approximately equivalent to a “Cap 3” CCER under subpart O, delivering at least 80 liters of oxygen.² CCERs of any capacity used in mining are still required to pass the subpart H

¹ 77 FR 14168.

² See Metzler R, Rehak T, Szalajda J, Berry Ann R, *Understanding the Breathing Gas Capacities (Rating) of Escape Respirators for*

“Man Test 4.”³ This test is used to demonstrate that CCERs used in mining will continue to meet the criteria established by MSHA in 30 CFR part 75 by providing a minimum duration of breathing air.

Because NIOSH determined that the resulting advances in CCER performance and reliability warranted accelerated adoption of the enhanced standards, manufacturers were authorized to continue to manufacture, label, and sell subpart H-approved SCSRs only until April 9, 2015. The three-year period between April 9, 2012 and April 9, 2015, was provided for manufacturers to obtain certificates of approval for CCER designs developed under the subpart O standards. Beginning on April 10, 2012, no new applications for approval of subpart H SCSRs have been accepted.

However, manufacturers were unable to develop Cap 3 CCERs in time to meet this transition deadline and, as a result, NIOSH initiated a rulemaking to extend the deadline. On August 12, 2015, NIOSH issued a final rule extending the concluding date for the transition to the subpart O technical requirements to 1 year after the date that the first approval was granted to certain CCER models.⁴ On February 10, 2016, NIOSH issued a *Federal Register* notice announcing the first approval of a Cap 3 CCER on January 4, 2016, issued to Ocenco Incorporated (Ocenco) of Pleasant Prairie, Wisconsin. In accordance with the August 2015 final rule, respirator manufacturers were permitted to continue to manufacture, sell, and label 1-hour Subpart H-approved SCSRs until January 4, 2017. The manufacturing, sale, or labeling of such devices subsequent to this date,

Mineworker Use, DHHS (NIOSH) Publication No. 2013-148, May 2013, <https://www.cdc.gov/niosh/docs/2013-148/pdfs/2013-148.pdf>.

³ See NIOSH National Personal Protective Technology Laboratory, *Standard Testing Procedure (STP) to Conduct Man Test 4 for Closed-Circuit Escape Respirators (CCERs) to be Used in Underground Coal Mines*, <https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-CCER-STP-0615-508.pdf>.

⁴ The regulatory text, promulgated at 42 CFR 84.301(a), reads: “The continued manufacturing, labeling, and sale of CCERs previously approved under subpart H is authorized for units intended to be used in mining applications with durations comparable to Cap 1 (all CCERs with a rated service time ≤ 20 minutes), and units intended to be used in mining and non-mining applications with durations comparable to Cap 3 (all CCERs with a rated service time ≥ 50 minutes), until 1 year after the date of the first NIOSH approval of a respirator model under each respective category specified.” See 80 FR 48268.

however, could result in NIOSH revoking, for cause, the certificate of approval under 42 CFR 84.34 or 84.43(c). The deadline extensions have contributed to the availability of new escape respirator designs which conform to the subpart O requirements, and have addressed the needs of certain broad segments of the market for such devices; however, MSHA has recently expressed concern that a market gap is imminent in the underground coal mining industry.⁵

In November 2016, the NIOSH National Personal Protective Technology Laboratory had a series of communications with representatives from MSHA, the underground coal mine industry, and two respirator manufacturers concerning the current supply of person-wearable escape respirators. Specifically, all but one of the manufacturers expressed concern that, without continued authorization to manufacture, label, and sell 1-hour, person-wearable SCSRs, manufacturers would be unable to fulfill the unmet needs of the underground coal mines that require the use of 1-hour person-wearable devices to satisfy MSHA regulatory requirements.⁶

MSHA regulations require that two “approved self-rescue device or devices” each sufficient to provide at least one hour of protection be available to every person underground in a coal mine;⁷ at least one escape respirator of any size must be “worn or carried at all times by each person when underground.”⁸ Mine operators are allowed the discretion to determine whether to require miners to carry a 1-hour respirator and cache at least one additional 1-hour respirator per miner, or carry a 10-minute respirator and cache

⁵ Joe Main, Assistant Secretary of Labor, MSHA, letter to John Howard, Director, NIOSH, December 14, 2016. This letter is available in NIOSH docket 285.

⁶ NIOSH and MSHA received a letter on December 12, 2016 from Ocenco Incorporated stating its opposition to extension of the January 4, 2017 deadline for the sale of subpart H-approved SCSR devices. Steven K. Berning, Ocenco Incorporated, letter to Mr. Joseph A. Main, Assistant Secretary of Labor, MSHA and [Dr.] John Howard, Director, NIOSH, December 12, 2016.

⁷ 30 CFR 75.1714(a), 75.1714-4.

⁸ 30 CFR 75.1714-2(b).

two additional 1-hour units.⁹ MSHA and others argue that although both CSE Corporation, of Export, Pennsylvania, and Ocenco hold approvals for Cap 3 CCERs for mining, neither is effectively person-wearable.¹⁰ Ocenco offers an approved Cap 1 mining CCER which is person-wearable, but provides only 10 minutes of oxygen under the current approval requirements.

According to MSHA,¹¹ in many underground coal mines, miners traveling to multiple stations underground during their shift may not presently have access to caches with 1-hour respirators (as required by MSHA regulations), and therefore must be provided with a 1-hour or Cap 3 person-wearable escape respirator to be in compliance and ensure their safety. MSHA also indicates that miners may have to search for a cache of escape respirators during an emergency, and if so, the lack of a person-worn, 1-hour SCSR or Cap 3 CCER would constitute a reduction in protection since they would have less time to find a cache. Accordingly, although the newly-approved subpart O CCERs meet the higher performance requirements of the new standard, MSHA is concerned that the protection offered to miners currently wearing a subpart H-approved, 1-hour device called the “SRLD,” the only 1-hour, belt-wearable escape respirator currently available on the market, would be diminished if they were required to switch to a 10-minute person-wearable subpart O CCER. MSHA further asserts that data on escape respirators deployed in underground coal mines indicate that in mines that rely on 1-hour person-wearable respirators, a substantial portion of their respirator inventory was expected to reach the end of its service life in 2017 and 2018. According to MSHA, these would need to be replaced with additional belt-wearable 1-hour SRLDs since the Cap 3 CCERs approved by NIOSH

⁹ 30 CFR 75.1714-1(a) and (b).

¹⁰ Although the CSE respirator, the SR2000, is designed to be person-wearable, MSHA has asserted that the size and weight prevent them from being worn in underground coal mines.

¹¹ *Supra* note 5.

that are belt or person-wearable are heavier and bulkier than their subpart H counterparts. Accordingly, MSHA asked that NIOSH extend the deadline.

In a letter to the NIOSH National Personal Protective Technology Laboratory, CSE Corporation, manufacturer of the 1-hour belt-wearable SCSR model named “SRLD,” reported similar concerns among its mining industry customers.¹² On behalf of its customers, CSE expressed two primary concerns: (1) “how to implement the new Cap 3 CCER technology under the current budgetary constraints,” and (2) “the Cap 3 CCER technology is so new that many in the mining industry have not had the opportunity to evaluate it as related to their operational needs let alone even see a new Cap 3 CCER.” CSE concluded that, “[a]s a result of these concerns, many in the mining industry have not fully issued purchase orders for either technology SCSR or Cap 3 CCER to replace the expiring SCSRs.” CSE received NIOSH approval for its Cap 3 mining CCER on March 28, 2016,¹³ and planned to be in full production in May 2017. CSE informed NIOSH that it had a backlog of orders for subpart H SCSRs, which it was unable to fill before the January 4, 2017 manufacturing deadline.

Finally, a mining industry representative communicated with NIOSH National Personal Protective Technology Laboratory to register similar concern about the availability of the 60-minute belt-wearable CSE model SRLD.¹⁴

In response to the requests from MSHA, the mine industry, and respirator manufacturers, NIOSH announced an interim guidance document and requested public

¹² Scott Shearer, CSE Corporation, letter to Maryann D’Alessandro, Director, NIOSH National Personal Protective Technology Laboratory, Subject: Cap 3 Closed-Circuit Escape Respirators Transition Plan, November 4, 2016. This letter is available in NIOSH docket 285.

¹³ See NIOSH National Personal Protective Technology Laboratory Certified Equipment List, https://www2a.cdc.gov/drds/cel/cel_form_code.asp.

¹⁴ Allen Dupree, Contura Energy, letter to Maryann D’Alessandro, November 23, 2016, Subject: Concerns regarding SCSR Rule. This letter is available in NIOSH docket 285.

comment in a *Federal Register* document published on December 28, 2016.¹⁵ In a final guidance document published on April 14, 2017, NIOSH announced our intent not to revoke any certificate of approval for 1-hour escape respirators, approved under subpart H, that are manufactured, labeled, or sold prior to June 1, 2019, provided that no cause for revocation exists under NIOSH regulations.¹⁶

Since the publication of the guidance document, no new CCER approvals have been issued by the NIOSH National Personal Protective Technology Laboratory. Accordingly, NIOSH has determined that removing further restrictions on manufacturers' abilities to manufacture, label, or sell subpart H SCSRs is necessary for the safety of underground coal miners who rely on these devices. Therefore, HHS proposes to allow the continued manufacturing, labeling, and sale of subpart H SCSRs with current certificates of approval, indefinitely. No new approvals under subpart H will be issued.

IV. Summary of Proposed Rule

In order to remove administrative barriers to an adequate market supply of SCSRs and CCERs, HHS proposes to make revisions to part 84, including revising §§ 84.70 and 84.301. Section 84.70 would be revised by removing paragraph (a), which was added in 2012 to limit the scope of subpart H to open-circuit escape respirators and those closed-circuit escape respirators approved under subpart H. Removing this paragraph will alleviate any confusion about the applicability of subpart H. The remainder of the section would be unchanged but for the remaining paragraphs being redesignated (a) through (d).

¹⁵ 81 FR 95623.

¹⁶ 82 FR 18002.

Paragraph § 84.301(c) would be redesignated as paragraph (a) and revised to state plainly that any CCER approvals issued after April 9, 2012, the original effective date for the subpart O standards, must comply with the technical requirements of subpart O.

Paragraph § 84.301(a) would be redesignated as paragraph (b) and would be revised to indicate that the manufacturing, labeling, and sale of SCSRs already holding a subpart H approval for units intended to be used in mining may continue indefinitely. Finally,

paragraph § 84.301(b) would be redesignated as paragraph (c) and revised to strike the word “former,” to indicate that the subpart H technical requirements would still be used for maintenance of subpart H approvals. The paragraph would continue to state that major modifications to a design approved under subpart H must meet the technical requirements of subpart O and be issued a new approval accordingly.

V. Regulatory Assessment Requirements

A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

Executive Orders 12866 and 13563 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, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule has been determined not to be a “significant regulatory action”

under section 3(f) of E.O. 12866. The revision proposed in this notice would allow respirator manufacturers to continue the indefinite manufacturing, labeling, and sale of SCSRs approved under subpart H of 42 CFR part 84 and co-approved by MSHA pursuant to 30 CFR 75.1714-1. In accordance with current NIOSH guidance, manufacturers are currently expected to discontinue the manufacturing, labeling, and sale of subpart H SCSRs after June 2019.

Because this proposed rule is intended to remove a restriction on the future sale of subpart H SCSRs, HHS expects that manufacturers holding approvals under subpart H will continue making and selling these devices without the uncertainty caused by the sunset clause in 42 CFR 84.301 and the NIOSH guidance document. Manufacturers will not be forced to stop making and selling previously approved subpart H devices, nor will they need to develop new respirators under subpart O. Mine operators will be able to choose between purchasing subpart H devices, some of which are belt-wearable, and subpart O devices, some of which are also belt-wearable but may be larger, heavier, and more expensive.

This deregulatory action will not impose costs on either manufacturers or mine operators. Accordingly, HHS has not prepared an economic analysis and the Office of Management and Budget (OMB) has not reviewed this rulemaking.

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order 13771 requires executive departments and agencies to eliminate at least two existing regulations for every new significant regulation that imposes costs. HHS has determined that this rulemaking is cost-neutral because it does not require any

new action by stakeholders. The rulemaking ensures that mine operators who rely on subpart H respirators can continue to purchase them as needed, which is likely to be more economical than switching to the subpart O devices. Because OMB has determined that this rulemaking is not significant, pursuant to E.O. 12866, and because it is both a deregulatory action and does not impose costs, OMB has determined that this rulemaking is exempt from the requirements of E.O. 13771. Thus it has not been reviewed by OMB.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. HHS certifies that this proposed rule has “no significant economic impact upon a substantial number of small entities” within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

D. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. In accordance with section 3507(d) of the PRA, HHS has determined that the Paperwork Reduction Act does apply to information collection and recordkeeping requirements included in this rulemaking. The Office of Management and Budget (OMB) has already approved the information collection and recordkeeping requirements under OMB Control Number 0920-0109, *Information Collection Provisions in 42 CFR part 84 - Tests and*

Requirements for Certification and Approval of Respiratory Protective Devices (expiration date 4/30/2021). The proposed amendments in this rulemaking would not impact the collection of data.

E. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), HHS will report the promulgation of this rule to Congress prior to its effective date.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector “other than to the extent that such regulations incorporate requirements specifically set forth in law.” For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local, or Tribal governments in the aggregate, or by the private sector.

G. Executive Order 12988 (Civil Justice Reform)

This proposed rule has been drafted and reviewed in accordance with Executive Order 12988 and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

H. Executive Order 13132 (Federalism)

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The rule would not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

I. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this proposed rule on children. HHS has determined that the rule would have no environmental health and safety effect on children.

J. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this proposed rule on energy supply, distribution or use, and has determined that the rule would not have a significant adverse effect.

K. Plain Writing Act of 2010

Under Public Law 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal government administers or enforces. HHS has

attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 84

Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

Proposed Rule

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 42 CFR 84.70 and 84.301 as follows:

PART 84--APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

1. The authority citation for part 84 continues to read as follows:

Authority: 29 U.S.C. 651 *et seq.*; 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

§ 84.70 [Amended]

2. Amend § 84.70 by removing paragraph (a) and redesignating paragraphs (b) through (e) as (a) through (d).

3. Revise § 84.301 to read as follows:

§ 84.301 Applicability to new and previously approved CCERs.

(a) Any CCER approval issued after April 9, 2012 must comply with the technical requirements of subpart O.

(b) The continued manufacturing, labeling, and sale of closed-circuit apparatus previously approved under subpart H is authorized for units required for use in underground coal mines pursuant to 30 CFR 75.1714-1.

(c) Any manufacturer-requested modification to a device approved under the subpart H technical requirements must comply with the subpart H technical requirements and address an identified worker safety or health concern to be granted an extension of the NIOSH approval. Major modifications to the configuration that will result in a new approval must meet and be issued approvals under the requirements of this subpart O.

Dated: October 9, 2018.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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