4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket No. CDC-2018-0003; NIOSH-309]

RIN 0920-AA66

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

RIN 0920-AA67

Removal of Compliance Deadline for Closed-Circuit Escape Respirators and Clarification of Post-Approval Testing Standards for Closed-Circuit Escape Respirators.

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: With this deregulatory action, the Department of Health and Human Services (HHS) revises regulatory language to remove 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. In addition to removing the compliance deadline, HHS is also modifying regulatory language to clarify that post-approval testing of closed-circuit escape respirators may exclude human subject testing and

environmental conditioning, at the discretion of NIOSH.

DATES: This final rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations were invited to participate in this rulemaking by submitting written views, recommendations, and data. Substantive comments supportive of this action were submitted by three interested parties to the rulemaking docket for the closed-circuit escape respirator (CCER) compliance deadline notice of proposed rulemaking (NPRM), RIN 0920-AA67.[1] Commenters included a mining industry trade association, a mining company, and a respirator manufacturer. No comments were received on the post-approval testing standards NPRM, RIN 0920-AA66.[2] The public comments are described in section IV, below.

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

[1] Notice of proposed rulemaking: *Removal of Compliance Deadline for Closed-Circuit Escape Respirators*, 83 FR 53835 (October 25, 2018). *See* Docket No. CDC-2018-0068; NIOSH-318 to read public comments.
[2] Notice of proposed rulemaking: *Clarification of Post-Approval Testing Standards for Closed-Circuit Escape Respirators; Technical Amendments*, 83 FR 12527 (March 22, 2018).

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

As discussed in the October 2018 NPRM, NIOSH uses the terms "self-contained self-rescuer" (SCSR) and "closed-circuit escape respirator" (CCER) to distinguish closed-circuit devices approved under 42 CFR part 84, subpart H from those approved under subpart O, respectively. The SCSRs approved under subpart H and CCERs 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. SCSRs and CCERs are used by miners and other workers to escape dangerous atmospheres.

Since the publication of an April 2017 guidance document in which NIOSH announced its intent not to revoke any certificate of approval for subpart H 1-hour SCSRs manufactured, labeled, or sold prior to June 1, 2019,[3] no new CCER approvals have been issued by the NIOSH National Personal Protective Technology Laboratory. Accordingly, NIOSH 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. HHS published an NPRM in October 2018 to propose

[3] Notice of availability, *Closed-Circuit Escape Respirators; Final Guidance for Industry; Availability*, 82 FR 18002 (April 14, 2017).

revising 42 CFR part 84 to allow the continued manufacturing, labeling, and sale of subpart H SCSRs with current certificates of approval, indefinitely. The need for this rulemaking is discussed in greater detail in the NPRM, available in the docket for this action.

HHS also published a March 2018 NPRM to propose the clarification of regulatory text that failed to specify that neither the human subject trials described in 42 CFR §§ 84.303-84.305, nor the environmental conditioning described in § 84.305, would be conducted on post-market respirators (through the NIOSH National Personal Protective Technology Laboratory's Long-Term Field Evaluation program) except at NIOSH's discretion.

IV. Summary of Public Comments and HHS Response

Three comments were received on the CCER compliance deadline NPRM. All three commenters support the HHS proposal to revise the regulatory language in §§ 84.70 and 84.301 to allow the indefinite manufacturing, labeling, and sale of approved subpart H SCSRs.

One of the commenters expressed concern about whether subpart H SCSRs were available in sufficient quantity to replenish the portion of the inventory that reached the end of its service life in 2017 and 2018. The commenter asked that NIOSH coordinate with MSHA to determine whether a sufficient number of SCSRs will be produced to replace retiring units.

Throughout the history of this action, at no time was the manufacturing, labeling, or sale of 1-hour SCSRs for mining prohibited by the changing compliance deadline. HHS is

not aware that either SCSR manufacturer stopped production because of the compliance deadline extensions, and neither company has indicated to NIOSH that it was unable to fill orders to replace out-of-date units. NIOSH has and will continue to work closely with respirator manufacturers and other industry stakeholders to ensure the uninterrupted supply of NIOSH-approved escape respirators.

V. Summary of Final Rule

For the reasons discussed in the NPRM published in October 2018, 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, with this final rule HHS now allows 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. Accordingly, § 84.70 is 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 alleviates any confusion about the applicability of subpart H. The remainder of the section is unchanged but for the remaining paragraphs being redesignated (a) through (d).

Paragraph § 84.301(c) is 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) is redesignated as paragraph (b) and is 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) is 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 continues to state that major modifications to a design approved under subpart H will render that approval obsolete. In that case, the entire resulting redesign must fully meet the technical requirements of subpart O and the manufacturer will be issued a new approval accordingly.

For the reasons discussed in the March 2018 NPRM, HHS is revising 42 CFR § 84.310 to clarify that neither human subject testing nor environmental testing is required to be routinely conducted on respirators obtained by the NIOSH National Personal Protective Technology Laboratory's Long-Term Field Evaluation program. The revision allows NIOSH to forego human subject testing or environmental treatments in the Program when NIOSH deems either or both of those tests to be unnecessary. The language in existing paragraph (d) is unchanged, and moved into a new paragraph (c)(2). The remainder of the paragraphs in § 84.310 are redesignated accordingly.

VI. 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 final rule has been determined not to be a "significant regulatory action" under section 3(f) of E.O. 12866. The revision finalized in this notice allows 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.

Because this final 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 aforementioned 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. Thus, operators may experience cost-savings, as discussed below.

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-saving because it does not require any new action by stakeholders and because mine operators who rely on subpart H respirators can continue to purchase them as needed, which is likely to be more economical for some than switching to the subpart O devices.

HHS has determined that for most of the respirator models currently deployed in underground coal mines, the cost of a new subpart O CCER is presently greater than the cost of a comparable subpart H SCSR. Assuming that mine operators will replace subpart H SCSRs that have reached the end of their service life (10 or 15 years, depending on the model) with an identical subpart H SCSR, rather than a more expensive subpart O CCER, HHS expects mine operators to experience cost savings as a result of not being required to purchase the more costly units.

To estimate potential cost savings, HHS reviewed the 2018 inventory of all SCSRs and CCERs currently used in underground coal mines. Of the six models of subpart H SCSRs and three models of subpart O CCERs in use, HHS was able to obtain current pricing on six models (*see* Table 1).

Table 1. Current prices of subpart H SCSRs and subpart O CCERs

Respirator type	Respirator model	Per unit cost ($)
Subpart H 1-hour	SRLD	854.05
	EBA 6.5	673.00
Subpart O Cap 3	SR 2000	831.25
	EBA 7.5	852.15
Subpart H 10-minute	M 20.2	408.00
Subpart O Cap 1	M 20.3	489.00

Because the price of a

subpart H 1-hour SRLD is greater than the price of a comparable subpart O Cap 3 SR 2000, the portion of the coal mining respirator market relying on the SRLD models is not affected and hence was not included in this analysis. HHS found that, because the subpart H 1-hour SCSR manufactured by Ocenco Inc., the EBA 6.5, costs less than the subpart O Cap 3 CCER, the EBA 7.5, mine operators would save $179.15 per unit by not purchasing the subpart O CCER. By not replacing the subpart H 10-minute SCSR manufactured by Ocenco, the M 20.2, with the subpart O Cap 1 CCER, the M 20.3, mine operators would save $81.00 per unit. By eliminating the compliance deadline requiring coal mine operators to purchase newer Subpart O Cap 3 CCERs to replace older Subpart H 1-hour SCSRs that have reached the end of their service life, HHS estimates that mine operators may experience a cost savings between approximately $16 million and $20 million over the course of the 15 years that subpart H SCSRs must be replaced (*see* Tables 2 and 3). This is likely an over-estimate, since it is foreseeable that the cost of subpart O CCERs and the number of coal miners who must be supplied with escape respirators will both decrease in future years.

Table 2. Cost saved by not replacing Subpart H 1-hour SCSRs with Subpart O Cap 3 CCERs (2018 $)

Year	# deployed EBA 6.5 units to be replaced with EBA 7.5 units	Undiscounted ($)	Discounted 3% ($)	Discounted 7% ($)
2019	266	47,653.90		
2020	439	78,646.85	76,358.23	73,503.35
2021	4,101	734,694.15	692,522.71	641,681.87
2022	11,865	2,125,614.75	1,945,150.06	1,735,139.32
2023	12,131	2,173,268.65	1,930,949.20	1,657,986.65
2024	7,843	1,405,073.45	1,212,016.36	1,001,817.37
2025	12,781	2,289,716.15	1,917,637.28	1,525,637.87
2026	24,943	4,468,538.45	3,633,368.61	2,782,558.89
2027	15,908	2,849,918.2	2,249,725.48	1,658,652.39
2028	14,429	2,584,955.35	1,981,109.78	1,405,957.21
2029	6,795	1,217,324.25	905,810.97	618,765.92
2030	4,114	737,023.10	532,425.49	350,159.67
2031	9,130	1,635,639.50	1,147,237.55	726,223.94
2032	8,531	1,528,328.65	1,040,791.81	634,256.39

2033	1,775	317,991.25	210,224.01	123,317.01
Total cost savings		**24,194,386.65**	**19,475,327.54**	**14,935,657.85**

Table 3. Cost of replacing Subpart H 10-minute SCSRs with Subpart O Cap 1 CCERs (2018 $)				
Year	# deployed M 20.2 units to be replaced with M 20.3 units	Undiscounted ($)	Discounted 3% ($)	Discounted 7% ($)
2019	16	1,296.00	1,258.29	1,211.24
2020	35	2,835.00	2,672.27	2,476.09
2021	653	52,893.00	48,402.38	43,176.56
2022	1,070	86,670.00	77,066.30	66,120.54
2023	874	70,794.00	61,066.90	43,540.70
2024	462	37,422.00	31,340.93	24,934.28
2025	1,504	121,824.00	99,055.09	75,871.99
2026	3,647	295,407.00	233,194.29	171,926.87
2027	2,551	206,631.00	158,362.00	112,386.60
2028	2,076	168,156.00	125,124.88	85,490.51
2029	2,412	195,372.00	141,136.73	92,821.24
2030	3,180	257,580.00	180,666.61	114,365.52
2031	2,659	215,379.00	146,673.10	89,382.29
2032	1,318	106,758.00	70,577.71	41,400.75
2033	602	48,762.00	31,300.38	17,676.23
Total cost savings		**1,867,779.00**	**1,407,897.86**	**982,781.41**

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 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 revisions 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 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 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 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 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 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 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.

Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 84 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.

4. Amend § 84.310 by revising paragraph (c), removing paragraph (d), and redesignating paragraphs (e) through (g) as (d) through (f).

The revision reads as follows:

§ 84.310 Post-approval testing.

* * * * *

(c) NIOSH will conduct such testing pursuant to the methods specified in §§

84.303 through 84.305, except as provided under paragraphs (c)(1) and (2) of this section:

(1) Post-approval tests may exclude human subject testing and environmental conditioning at the discretion of NIOSH.

(2) The numbers of units of an approved CCER to be tested under this section may exceed the numbers of units specified for testing in §§ 84.304 and 84.305.

* * * * *

Dated: April 9, 2019

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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