



This document is scheduled to be published in the Federal Register on 08/12/2015 and available online at <http://federalregister.gov/a/2015-19750>, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket Number CDC-2015-0004; NIOSH-280]

RIN 0920-AA60

Closed-Circuit Escape Respirators; Extension of Transition Period

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: In March 2012, the Department of Health and Human Services (HHS) published a final rule establishing a new standard for the certification of closed-circuit escape respirators (CCERs) by the National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention (CDC). The new standard was originally designed to take effect over a 3-year transition period. HHS has determined that extending the concluding date for the transition is necessary to allow sufficient time for respirator manufacturers to meet the demands of the mining, maritime, railroad and other

industries. Pursuant to this final action, NIOSH extends the phase-in period until 1 year after the date that the first approval is granted to certain CCER models.

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

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I. Public Participation

On January 29, 2015, HHS published an interim final rule to amend the transition deadline established in 42 CFR 84.301 (80 FR 4801), and invited interested persons or organizations to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments were invited on any topic related to this rulemaking and specifically on the following question related to this rulemaking:

Will a compliance date 6 months after the date that the first approval is granted in each of three categories

of CCER types provide sufficient time for respirator manufacturers to develop production capacity to meet expected market demand, while not causing undue loss of sales revenue that may be expected from achieving the first successful design for the given size?

We received four submissions to the docket: one from a respirator manufacturer, one from a mining association, one from a coal company, and one from three coal companies and another mining association. A summary of comments and HHS responses are found in Section III, below.

II. Background

A. History of Rulemaking

Under Title 42 of the Code of Federal Regulations (42 CFR) part 84--Approval of Respiratory Protective Devices, NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres. The Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA) require U.S. employers to supply NIOSH-approved respirators to their employees whenever the employer requires the use of respirators.

A closed-circuit escape respirator (CCER) is an apparatus in which the wearer's exhalation is rebreathed after the carbon dioxide in the exhaled breath has been effectively removed and a suitable oxygen supply has been restored from a source within the device (e.g., compressed, chemical, or liquid oxygen). CCERs are 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 CCER, known in the mining industry as a self-contained self-rescuer, is used by miners to escape dangerous atmospheres in mines. It is also used by certain Navy and Coast Guard personnel, such as crews working below decks on vessels, where it is referred to as an emergency escape breathing device, and in the railroad industry, where it is known as an emergency escape breathing apparatus. To a lesser extent, it is also used by non-mining workers who work in tunnels, underground, or in confined spaces.

Requirements for the certification of CCERs were updated in a 2012 final rule, in which HHS codified a new Subpart O and removed only those technical requirements in 42 CFR part 84--Subpart H that were uniquely applicable to CCERs. All other applicable requirements of 42 CFR part 84 were unchanged. The purpose of these updated requirements

is to enable NIOSH and MSHA to more effectively ensure the performance, reliability, and safety of CCERs.

The effective date for the new standard in Subpart O was April 9, 2012. Beginning on that date, any new application for a certificate of approval for a CCER would be required to meet the new Subpart O standard.

Manufacturers were allowed to continue to manufacture, label, and sell respirators certified to the prior Subpart H standard until April 9, 2015.

On January 29, 2015, HHS published an interim final rule to amend the compliance deadline established in 42 CFR 84.301 (80 FR 4801). The interim final rule amended 42 CFR 84.301 to allow NIOSH to extend the original 3-year period for continued manufacturing, labeling, and sale of CCERs approved under Subpart H to allow for the orderly implementation of the new testing and certification requirements of Subpart O. The amendments authorized the continued manufacturing, labeling, and selling of CCERs approved under the former standard in Subpart H until either April 9, 2015 or 6 months after the date that NIOSH first approves a CCER model under the capacity rating categories Cap 1 (for mining applications) and Cap 3 (mining and non-mining) described in 42 CFR 84.304, whichever date came later.

B. Need for Rulemaking

HHS has determined that extending the concluding date for the transition is necessary to allow sufficient time for respirator manufacturers to meet the demands of the mining, maritime, railroad, and other industries. Two manufacturers recently received NIOSH approval for their small-capacity non-mining respirators; however, no large-capacity units designed for underground coal mining and other industries have received NIOSH approval to date. HHS published the interim final rule in response to concerns expressed by mining industry and maritime stakeholders that an adequate number of new CCERs would not be available for purchase by the Subpart O compliance deadline, leaving miners, sailors, and other workers with insufficient protection.

C. Scope

Pursuant to this final rule, which amends 42 CFR 84.301, NIOSH will extend the deadline for Subpart O compliance until 1 year after the date on which NIOSH approves the first CCER in each of the following three categories, described in 42 CFR 84.304: Cap 1 mining, Cap 3 mining, and Cap 3 non-mining.

CCER Cap 1 non-mining and Cap 2 mining and non-mining categories are not included in this rulemaking. Approval TC-13G-0001 was issued to Avon Protection Systems, Inc. on July 24, 2014 for its ER-2 emergency escape breathing device (EEBD). The ER-2 EEBD is certified by NIOSH as a Cap 1, 20-liter, CCER for use in non-mining applications. A second approval for a Cap 1 non-mining CCER was awarded to Ocenco Incorporated on December 2, 2014. The Cap 2 mining and non-mining categories are not included in this rulemaking because there are no units previously approved under Subpart H that are equivalent to the Cap 2 categories.

Approval TC-13G-003 was issued to Avon Protection Systems on May 13, 2015, for a Cap 1 unit for use in mining applications. The Avon approval triggered a 6-month transition for the category of Cap 1 mining respirators, in accordance with the language of the interim final rule. With the publication of this final rule, that extension is continued for an additional 6 months, until May 13, 2016.

III. Response to Public Comments

As discussed above in the Public Participation section, HHS received four submissions to the rulemaking

docket. Although the commenters were unanimous in their support of an extension, they cited a variety of reasons for the insufficiency of the 6-month extension established in the interim final rule.

Comment: Six months is an arbitrary date and HHS should have consulted respirator manufacturers regarding the amount of time necessary for approved devices to be available to end-users. The phase-in period should be extended from 6 to 16 months after the first approval to allow time for other manufacturers to obtain NIOSH approval and establish production capabilities, for the end-user to make procurement decisions, and for the manufacturer to finalize production activities after receiving procurement orders.

Response: NIOSH works closely with respirator manufacturers and did consult with several regarding the implementation of Subpart O. We also reached out to end-users and other stakeholders to learn about their current and future respirator needs. Although we received anecdotal reports that user demand is greater than the availability of units capable of being produced under the new standard, users did not validate those reports. Consequently, after consulting with manufacturers and end-users, we originally determined that the compliance deadline, 3 years after

publication of the new Subpart O standard, offered ample time for manufacturers to develop, produce, and deploy Subpart O CCERs. However, because only a handful of units were submitted to NIOSH for approval testing during the 3 years since the establishment of Subpart O, we decided to accommodate manufacturers by extending the transition period to 6 months after the first approval in each category. Based on our experience, we considered that the 6 month extension would allow for an estimated 8 weeks to begin production and another 8 weeks to develop sufficient capacity. We understand that this extension may still not be adequate for manufacturers to develop and produce CCERs in sufficient quantity to meet the needs of end-users. Accordingly, HHS agrees to extend the transition period further, as discussed below.

Comment: The 6-month extension after a first approval could create a monopoly if the first manufacturer to receive approval receives the approval long before competitors and then saturates the market, thus disincentivizing competitors.

Response: HHS has provided an extended implementation period for the development and provision of an adequate supply of Subpart O CCERs. This implementation period does not restrict the opportunity for competition but does

provide substantial incentive for timely development of compliant new technology, which is in the interest of worker safety. We expect that manufacturers who have been in the CCER market have incentive to stay in the market. We are not amending the regulatory text based on this comment.

Comment: HHS did not contact the two respirator manufacturers that have received approval for Cap 1 non-mining devices concerning the amount of time needed to produce units sufficient to meet demand.

Response: We did communicate with both manufacturers that have units approved and asked for input on production times. However, we did not receive timely feedback on this point. Because both companies received approvals for Cap 1 non-mining devices prior to publication of the interim final rule, and because those approvals were granted many months before the April 9, 2015 Subpart O transition deadline, we did not find it appropriate to offer an extension for this category. Accordingly, we are not offering an extension for Cap 1 non-mining CCERs in this final rule.

Comment: HHS could amend the rule text to allow the Subpart H standard to be extended until 6 months after the date of the NIOSH approval of "two or more" respirator models under each category. The extension of the transition

period must be of sufficient duration to accommodate the approval of multiple devices, in order to give the mining industry a choice in the selection of CCERs.

Response: The intent of this rulemaking is to permit the first awardee time to build a practical volume of inventory to meet market needs. We do not agree with the suggestion to amend the text to offer an extension after two or more models are approved because this would diminish the incentive of the remaining manufacturers (without an approved device) to be timely in the development of their Subpart O CCERs. Thus, we are not amending the regulatory text to offer an extension after two or more models are approved.

Comment: The 6-month extension will not allow time for manufacturers to fill purchase orders and may result in mines not being able to obtain sufficient numbers of units to meet MSHA requirements. This could result in mines having to stop operations until additional units could be obtained. Further, if only one type of respirator is approved under Subpart O and is the only new device available on the market and that device utilizes a different technology from the types of respirator used in a particular mine, the mine might be forced to mix units.

Mixing units would require additional training and could result in added stress and confusion during an emergency.

Response: We agree to extend the Subpart O transition deadline beyond the 6 months offered in the interim final rule. This should alleviate concerns regarding the availability of units. Regarding the mixing of units of different technologies, underground mines have been permitted to co-mingle respirator types in the past. This can be done safely provided all persons are trained on the available respirator types. We are not aware that co-mingling of respirators has jeopardized worker safety and do not anticipate any such safety concerns as a result of this action.

Comment: Significant delays in certification processing may occur because NIOSH is still refining the test equipment and training certification testing personnel and because there is no indication that any CCER will meet the Cap 3 requirements.

Response: Respirator application processing comprises several different steps, including initial review, quality assurance review, laboratory testing, and final review; NIOSH is able to process multiple respirator applications simultaneously. Approval processing and testing typically takes between 4 and 6 months, depending on the completeness

of the application and respirator complexity. Although our laboratory is only able to conduct certification testing on one CCER at a time, we do not anticipate any NIOSH-caused delays in the certification process as a result of equipment or personnel development. Nevertheless, HHS's interest is in ensuring at least one supplier of Subpart O CCERs in categories where Subpart H units currently exist. The extension offered in this final rule is designed to begin after NIOSH testing and approval of one application is complete.

We do expect NIOSH approval of Cap 3 CCERs to occur in short order. Because two manufacturers have recently received approvals for Cap 1 CCERs for non-mining applications, NIOSH expects that manufacturers will be able to meet the Cap 3 requirements, which require less of a performance increase from existing respirators in the general class than did the development of respirators to meet the Cap 1 requirements.

Comment: HHS must consider the cumulative effect on coal companies of expected advancements in respirator technology. The mining industry will only be able to accommodate one technology change in the coming years -- either CCERs that comply with the Subpart O standard or CCERs that have adopted new R&D developments for additional

functionalities, such as seamless changeover between units and verbal communication.

Response: HHS agrees that the scenario outlined in the comment is undesirable, but notes that Subpart O, as its forerunner, Subpart H, is a performance standard, not a design standard. HHS does not foresee any reason that desirable new technologies such as the ones identified in the comment cannot be incorporated into CCER designs which meet the Subpart O performance requirements. Although the schedule for adoption of additional functionalities is beyond the control of NIOSH and we cannot predict the timing of future R&D developments, extension of the transition deadline is one way to better accommodate any new technologies which may be imminently achievable in practical CCER designs.

Comment: The rule should recognize the significant distinctions between the underground coal mining industry and the maritime, railroad, and other industries.

Response: HHS agrees that this action should distinguish mining applications from non-mining and we did attempt to structure the extension to recognize the different needs of the different industries. For example, the maritime and railroad industries use Cap 1 non-mining devices; because two Cap 1 non-mining CCERs have already

been approved, Cap 1 non-mining devices are not addressed in this rulemaking. We are not amending the regulatory text based on this comment.

IV. Summary of Final Rule

This final rule amends 42 CFR 84.301 to allow NIOSH to extend the original 3-year period for continued manufacturing, labeling, and sale of CCERs approved under Subpart H to allow for the orderly implementation of the new testing and certification requirements of Subpart O. This provision allows NIOSH to extend the original transition period to allow manufacturers to obtain NIOSH approval, establish production capacity, and complete the modification of existing CCER designs, if necessary, or develop new designs that comply with the new testing and certification requirements. An extension also ensures that a constant supply of approved CCERs will remain available for purchase. The new Subpart O standard will continue to be applied to all new CCER designs that are submitted for approval. In accordance with this final rule, all types of CCERs approved under Subpart H that were manufactured and labeled as NIOSH-approved, and sold by April 9, 2015, and including those units manufactured and labeled as NIOSH-

approved and sold during the extended periods established by this rule, may continue to be used as NIOSH-approved respirators until the end of their service life.

In response to the public comments, HHS is amending § 84.301(a) and thereby authorizes the continued manufacturing, labeling, and selling of CCERs approved under the former standard in Subpart H until 1 year after the date that NIOSH first approves a CCER model under the capacity rating categories Cap 1 (for mining applications) and Cap 3 (mining and non-mining) described in 42 CFR 84.304. This extension is in accordance with the comment requesting an increase in the duration of the extension from 6 to 16 months, as we understand that the 16-month request includes at least 5 months for manufacturers to receive NIOSH approval after a first approval in a given category (leaving 11 months, in the commenter's estimation, for completion of the manufacturing and procurement processes). We anticipate that most applications will have been submitted to NIOSH by the time a first approval is granted, and find that building additional time into the extension for the approval process will unnecessarily delay the Subpart O transition.

We have also amended the paragraph to clarify that a Cap 1 device under Subpart O is comparable to a device with

a rated service time of less than 20 minutes under Subpart H, and a Cap III device under Subpart O is comparable to a device with a rated service time of greater than 50 minutes under Subpart H. Finally, we have removed reference to April 9, 2015 in paragraph (a), as that date has passed.

HHS received no comments on the provisions of paragraphs (b) or (c) and, accordingly, they are unchanged. Paragraph (b) clarifies that any non-major modifications to those approved devices must continue to meet the prior Subpart H standard. CCERs with major modifications that will result in a new NIOSH approval must conform to the new Subpart O standard. Paragraph (c) states that Subpart O applies to all CCERs submitted to NIOSH for approval after the effective date of the final rule, April 9, 2012.

V. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

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 is not being treated as a “significant” action under E.O. 12866. It amends existing 42 CFR 84.301 to allow NIOSH to extend the deadline for a respirator certification standard established in 2012, and does not result in any costs to affected stakeholders; it does not raise any novel legal or policy issues. Accordingly, HHS has not prepared an economic analysis and the Office of Management and Budget (OMB) has not reviewed this rulemaking.

The rule does not interfere with State, local, or tribal governments in the exercise of their governmental functions.

B. 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 final rule will not have a significant economic impact on a substantial number of small entities, including both small

manufacturers of CCERs and the small mining operators that are required to purchase them, within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 et seq., requires an agency to invite public comment on and to obtain OMB approval of any rule of general applicability that requires recordkeeping, reporting, or disclosure requirements.

NIOSH has obtained approval from OMB to collect information from respirator manufacturers under "Information Collection Provisions in 42 CFR Part 84--Tests and Requirements for Certification and Approval of Respiratory Protective Devices" (OMB Control No. 0920-0109, exp. November 30, 2017), which covers information collected under 42 CFR Part 84. This rulemaking does not increase the reporting burden on respirator manufacturers.

D. 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.), the Department will report the promulgation of this rule to Congress prior to its effective date. The

report will state that the Department has concluded that this rule is not a "major rule" because it is not likely to result in an annual effect on the economy of \$100 million or more.

E. 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.

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. NIOSH has provided clear deadline extension requirements that will be applied uniformly to all applications from manufacturers of

CCERs in certain categories. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The rule does 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.”

H. 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 effect on children.

I. 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 will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law No. 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 final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 84

Incorporation by reference, 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 is revised to read as follows:

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

2. Revise § 84.301 to read as follows:

§ 84.301 Applicability to new and previously approved CCERs.

(a) 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 \leq 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 \geq 50 minutes), until 1 year after the date of the first NIOSH approval of a respirator model under each respective category specified.

(b) Any manufacturer-requested modification to a device approved under the former subpart H standard must comply with the former subpart H standard 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 number must meet and be issued approvals under the requirements of this subpart O.

(c) This subpart O applies to all CCERs submitted to NIOSH for a certificate of approval after April 9, 2012.

Dated: August 5, 2015.

Sylvia M. Burwell,
Secretary,

Department of Health and Human Services.

Billing Code: 4163-18-P

[FR Doc. 2015-19750 Filed: 8/11/2015 08:45 am; Publication

Date: 8/12/2015]