



Billing Code 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

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

RIN 0920-AA66

Clarification of Post-Approval Testing Standards for Closed-Circuit Escape Respirators; Technical Amendments.

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to modify current language found in Title 42 of the Code of Federal Regulations which addresses post-approval testing of closed-circuit escape respirators (CCERs). The revised language should clarify that post-approval testing of CCERs may exclude human subject testing and environmental conditioning, at the discretion of the National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention, HHS. The revision to the text in this paragraph will clarify the scope of post-approval testing conducted by NIOSH.

DATES: Comments must be received by [INSERT DATE 60 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.

- 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-2018-0003; NIOSH-309) or Regulation Identifier Number (0920-AA66) 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.

Docket: For access to the docket go to <http://www.regulations.gov>.

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 (Pub. L. 91-173), NIOSH is authorized to approve respiratory equipment and to conduct scientific investigations or tests concerning the safety and health of miners and other workers.

III. Background

The provisions in 42 CFR 84.310 govern the procedures NIOSH follows in conducting post-approval testing of closed-circuit escape respirators (CCERs) sold and distributed to employees. The post-approval testing program, known as the long-term field evaluation (LTFE) program, is designed to ensure the CCERs' continued safety and viability as emergency life support after having been exposed to harsh environments such as those found in mining. According to the existing language in § 84.310(c), post-approval testing is conducted pursuant to the methods promulgated in §§ 84.303 through 84.305, which establish general testing conditions and requirements, including capacity and performance testing.

In a rulemaking conducted in March 2012 to update the standards for the testing of CCERs,¹ NIOSH did not specify that neither the human subject trials specified in §§ 84.303-84.305, nor the environmental conditioning specified in § 84.305, would be conducted on post-market respirators (devices sold and distributed to employees) except at NIOSH's discretion. A clarification about human subject testing was issued in a September 2016 policy statement.²

NIOSH requires human subject testing only when new or modified devices are presented for approval evaluation. The human subject trials are included as a final check

¹ 77 FR 14168, March 8, 2012.

² See NIOSH National Personal Protective Technology Laboratory Document No. POL-NPPTL-2016-01, <https://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/LTFEpolicyFinalSigned-012617.pdf>.

of functionality in the as-used (worn by a human being) mode of operation. The inclusion of human subject tests addresses the goal of ensuring that no aspect of a design found to be in compliance with the bench tests specified in 42 CFR Part 84 is compromised by, or fails to adequately accommodate, the needs of the human/device interaction. Once established, there is no need to re-evaluate the apparatus with the aid of human subjects unless the design is changed.

Bench testing, using a breathing and metabolic simulator, eliminates the potential for human subjects to suffer adverse effects from defective CCERs. A post-market unit that does not function in accordance with the NIOSH approval requirements after potential damage from exposure to the deployment environment could pose a health risk to a human test subject. Further, requiring human subject testing constrains the number of fielded units NIOSH is able to test, due to the logistical complexity and higher cost of hiring human subjects.³

Environmental treatments are not conducted on post-market devices, because the intent of the post-market evaluation is to assess the actual effects of the deployed environment on respirators used in the field. The environmental treatments specified in NIOSH regulations involve exposing respirators to realistically harsh conditions representative of industrial environments in order to assess that they are reasonably robust for their intended service. The treatments are conducted only during the evaluation of a new or modified respirator design submitted to NIOSH for approval.

IV. Summary of Proposed Rule

The proposed changes to 42 CFR 84.310(c) would reflect current NIOSH policy

³ Historically, NIOSH employed both the human subject testing and the breathing and metabolic simulator testing to assess the results side-by-side, and to ground the simulator testing to the human subject results. NIOSH has determined that the simulator can reliably replicate human subject testing.

by clarifying that neither human subject testing nor environmental testing are required to be routinely conducted on respirators obtained by the LTFE program. The revision would allow NIOSH to conduct human subject testing or environmental treatments in the LTFE program only when NIOSH deems those tests to be necessary.

The language in existing paragraph (d) would be unchanged, and moved into a new paragraph (c)(2). The remainder of the paragraphs in § 84.310 would be redesignated 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 NIOSH the discretion to determine whether to conduct human subject tests or environmental treatments on fielded respirators chosen for post-approval testing. The current language requires NIOSH to conduct those tests.

Because this proposed rule is a technical correction and would not affect the cost of the activities authorized by 42 CFR 84.310(c), HHS has not prepared an economic

analysis. Accordingly, 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. Because OMB has determined that this rulemaking is not significant, pursuant to E.O. 12866, and because it 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. Because no substantive changes are being made to 42 CFR 84.310(c) as a result of this action, 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 rule. 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 11/30/2017). NIOSH is currently seeking approval for a renewal of the information collection; a 30-day notice was published in the **Federal Register** on February 20, 2018 (83 FR 7188). 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 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.”

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 will 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 84.310 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.

2. Amend § 84.310 by removing paragraph (d), redesignating paragraphs (e)-(g) as (d)-(f), and revising paragraph (c) to read 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 (a)(1) and(a) (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 in 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: March 16, 2018.

Alex M. Azar II

Secretary,

Department of Health and Human Services

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