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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

RIN 0920-AA38

[Docket No. CDC-2012-0009; NIOSH-258]

Self-Contained Breathing Apparatus Remaining Service-Life Indicator Performance Requirements

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: On June 25, 2012, the Department of Health and Human Services (HHS) published a notice of proposed rulemaking proposing to update respirator approval standards in response to a petition to amend our regulations, current requirements for self-contained breathing apparatus (SCBA) remaining service-life indicators or warning devices. These indicators are built

into a respirator to alert the user that the breathing air provided by the respirator is close to depletion. In this final rule, HHS responds to public comment on the proposed rule and revises the current standard, employed by the National Institute for Occupational Safety and Health (NIOSH) located within the Centers for Disease Control and Prevention (CDC), to allow greater flexibility in the setting of the indicator alarm to ensure that the alarm more effectively meets the different worker protection needs of different work operations. This final rule sets a minimum alarm point at 25 percent of the rated service time and allows the manufacturer to offer remaining service life set point at a higher value or values appropriate to the purchaser's use scenario.

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

FOR FURTHER INFORMATION CONTACT: Jonathan Szalajda, NIOSH National Personal Protective Technology Laboratory (NPPTL), P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236, (412) 386-5200 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The preamble to this final rule is organized as follows:

I. Public Participation

Interested persons or organizations were invited to participate in this rulemaking by submitting written views,

arguments, recommendations, and data. Comments were invited on any topic related to this proposal, but comments were specifically solicited regarding whether: (1) 25 percent of the rated service time of the respirator is an appropriate default setting for the indicator to alarm; (2) the rule should specify an upper limit that would require that the indicator be set to alarm no earlier than a set amount, such as 50 percent of rated service time; and (3) there are possible emergency or rescue scenarios for which one would want an indicator to alarm at 50 percent or more of the rated service time?

HHS received 8 submissions from the public in response to this rulemaking. Commenters represented local fire departments, manufacturers of self-contained breathing apparatus (SCBA) used in the fire service, and a firefighters' union. A summary of comments and the HHS response are found in Section III, below.

II. Background

In 2003, NIOSH received a petition from David Bernzweig of the Columbus (OH) Professional Firefighters International Association of Fire Fighters (IAFF) Local 67 requesting that the agency initiate rulemaking to amend 42

CFR 84.83(f).[1] The current rule requires that the self-contained breathing apparatus (SCBA) service-life indicator (also known in the firefighter community as an end-of-service-time indicator (EOSTI), or a low-air alarm) give an alarm within the 20 to 25 percent range. Stakeholders in agreement with Mr. Bernzweig requested that HHS eliminate the lower value (20 percent) and require the indicator to alarm no later than at 25 percent of rated service time. NIOSH considered the request and facilitated discussion among stakeholders by holding a public meeting to discuss underlying issues and technical matters on December 2, 2008, in Pittsburgh, Pennsylvania (73 FR 65860, November 5, 2008).[2]

The National Fire Protection Association (NFPA), which sets standards for personal protective equipment used in the fire service, initiated an effort in 2008 to develop consensus on the matter and recently decided to amend NFPA 1981: Standard on Open-Circuit Self-Contained Breathing

[1] National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, transcript of public meeting held December 2, 2008. Available at http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-034-A/0034-A-120208-Transcript.pdf. Last accessed October 25, 2011.

[2] The official transcript of this meeting as well as public comments are available on NIOSH Docket 34-A (See http://www.cdc.gov/niosh/docket/archive/docket034A.html). NIOSH had previously collected public comments on remaining service-life indicators in 2004 (See NIOSH Docket 34, http://www.cdc.gov/niosh/docket/archive/docket034.html).

Apparatus (SCBA) for Emergency Services[3] to require that the indicator alarm at 33 percent.

For reasons discussed in the notice of proposed rulemaking published in the Federal Register on June 25, 2012 (77 FR 37862), HHS finds that amending §84.83(f) to allow greater latitude with regard to setting the indicator alarm would not reduce the amount of protection afforded to firefighters and other SCBA users. In fact, HHS has determined that specifying a minimum setting of 25 percent and allowing manufacturers to offer different alarm settings more suited to purchasers' use scenarios will result in a more meaningful alarm that may offer greater protection for users.

III. Summary of Final Rule and Response to Public Comments

The amendment to 42 CFR 84.83(f) establishes that the low-air indicator must activate at a minimum setting of 25 percent of the SCBA's rated service time. If a purchaser has determined that an earlier alarm will benefit the specific occupational purpose for which the respirator is to be used, the purchaser may request that the manufacturer offer a remaining service-life indicator alarm set-point at

[3] NFPA 1981: Standard on open-circuit self-contained breathing apparatus (SCBA) for emergency services, Chapter 4. 2007 Edition.

a higher value (or values) appropriate to the purchaser's use scenario. If the manufacturer chooses to offer a respirator with a different set-point (at no less than 25 percent of the SCBA's rated service time), the modified respirator must be approved by NIOSH. Purchasers may also have the indicator setting modified for already fielded SCBA units by an authorized representative of the manufacturer, provided that the respirator model has received a new NIOSH approval specifying the new alarm set-point.

The final rule also codifies a long-standing NIOSH policy requiring the indicator for demand and pressure-demand open-circuit (OC)SCBA to alarm continuously until the respirator's breathing air supply is depleted.

Changes to the proposed rule text are made in response to public comment, to clarify our overall intent; to specify that the requirement for continuous alarming is intended for open-circuit, demand and pressure demand units only; and to require that manufacturers identify the indicator setting on each unit. Specific comments and responses are discussed below. The rule text is also amended slightly to better comply with Federal plain language requirements.

Comment: Two commenters were fully supportive of the rulemaking. One commenter stated that requiring fire service respirators to alarm when breathing air reaches 25 percent "does not serve the needs or interests of today's fire service." According to the commenter, "[t]here is no safety purpose served by not allowing an earlier set point for the EOSTI. An earlier set point would allow for a greater margin of safety for the end user. Not having an earlier set point would continue to place firefighters at risk by not having an adequate air reserve when the EOSTI activates." The commenter further agreed that the alarm should not be field-adjustable and that purchasers should be able to specify the setting at the time of purchase or service.

HHS response: We thank these commenters for their response.

Comment: We received two comments that appeared to confuse the standard proposed by HHS (a default of 25 percent unless the purchaser requests a different, higher, value) with the standard being developed by NFPA (alarm activation at 33 percent). One commenter expressed approval for giving purchasers the ability to set the remaining service-life indicator alarm between 33 percent and 50 percent. The other commenter expressed disapproval for

changing the indicator to activate at 33 percent rather than 25 percent.

HHS response: The amended standard is responsive to the various concerns. Manufacturers are not required to modify existing approvals to comply with this rule; they may continue to market and sell respirators approved under the current standard, indefinitely. If, in response to purchaser needs, the manufacturer chooses to market and sell respirators that activate at the 25 percent minimum requirement or earlier, the manufacturer must obtain a new or revised NIOSH approval.

Comment: One commenter supported the inclusion of a 50 percent upper limit for the alarm set-point; other commenters neither supported nor opposed the upper limit.

HHS response: We did not receive justification for applying a 50 percent upper limit. It is conceivable that some use scenarios might warrant an earlier alarm point. Accordingly, we have not revised the proposal in response to the comment.

Comment: One commenter suggested that allowing individual fire departments to determine their own remaining service-life indicator setting may cause "incident related" problems. The commenter further stated that there was no discussion in the notice of proposed

rulemaking about the use of the heads-up-display for monitoring breathing air depletion or the reliance on teamwork to maintain situational awareness.

HHS response: This comment raises training issues regarding the users' response to an alarm being activated. We understand that a change in the mechanical alarm setting may necessitate a change in training protocols. However, training for the proper use of these respirators is outside the scope of this rulemaking.

Comment: One commenter agreed with the intent of the proposed rule text but suggested a number of edits. The commenter stated that the proposed rule text did not account for the distinction between respirator models whose alarms are designed either to activate electronically or activate using the device's compressed air. According to the commenter, "[i]f the EOSTI is activated electrically then the alarm can sound continuously until the depletion of the breathing air supply. If the EOSTI is activated using the compressed air in the system then at some point the alarm sound will decrease in decibels and even cease to sound before the breathing air is depleted." The commenter suggested adding the text "if electrically controlled or to a pressure of 10 bar (145 psi) if operated by the compressed air in the system" to the text in §84.83(f).

HHS response: The purpose of the alarm is to advise the user that the system is depleting its air supply. While the rule text does not specifically identify models that alarm either electronically or using compressed air, we intend for the indicator to alarm until the air supply runs out in order to warn the user of the situation so they can take appropriate action for their setting. That the indicator may not continue to alarm until the air supply is absolutely depleted is understood and is evaluated in NIOSH testing (see NIOSH standard testing procedure RCT-ASR-STP-0124, Determination of Remaining Service-Life Indicator – Open-Circuit, Demand and Pressure-Demand, Self-Contained Breathing Apparatus, at http://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-ASR-0124.pdf, which will be updated to comport with this rulemaking).

Comment: Another comment referred to long duration closed-circuit breathing apparatus (CCBA), which are also regulated under Subpart H in Part 84. The commenter stated that "it can be interpreted that even long duration CCBA would also need to meet the proposed new requirements. For example, this would require that a CCBA with a rated service time of 4 hours would need to have the EOSTI alarm continuously for 1 hour and this would be annoying to the users and may affect their activities in a negative

manner." The commenter accordingly suggested that the text in §84.83(f) should address only open-circuit devices, and offers a new §84.83(g) which suggests that, for closed-circuit devices, the indicator should alarm for a limited time period when the reserve capacity of the apparatus is reached, and a continuous alarm when a prescribed pressure is reached.

HHS response: HHS did not intend for the continuous alarm requirement to pertain to long-duration closed-circuit devices. However, the open-circuit demand and pressure-demand devices are expected to alarm continuously once activated. Accordingly, we have amended the final rule text to require that only open-circuit demand and pressure-demand (as described in 42 CFR 84.70(a)(2)(i) and 42 CFR 84.70 (a)(2)(ii)) respirators need to alarm continuously.

Comment: One commenter suggested that only purchasers who are required by a third-party standard to request an alarm set-point other than the default 25 percent be allowed to request a different alarm setting.

HHS response: We do not agree that the 25 percent default value should only be raised when prescribed by a third party standard. While §84.83(f) is amended in response to a petition on behalf of the U.S. fire service, we note that OC-SCBAs are used by industries and in

occupational settings other than firefighting. We intend to maintain flexibility with regard to the alarm setting requirement to avoid further limitations on the ability of purchasers to request an alarm set-point appropriate to their use scenarios and the ability of manufacturers to offer such respirators.

Comment: One commenter stated that the terms 'default' and 'adjusted' used in the rule summary are vague and "cause policy or test requirement issues." The commenter recommended that the word 'default' be removed because it "implies the product must meet the minimum setting and shall be capable of fulfilling a higher setting. We believe this is not the intent of the proposed changes and can lead to unnecessarily design-restrictive interpretations." The commenter requested that, in addition to adjustable designs, the rule should "allow flexibility to permit others such as dedicated set point designs." The commenter suggested that the rule text should be modified to state: "Each remaining service-life indicator or warning device shall give an alarm when the remaining service life of the apparatus is reduced to the manufacturers' specified range and shall alarm continuously until the breathing air supply approaches depletion. The manufacturer can specify either a

set point of 25 or 33 percent of its rated service time in response to the user's specific request."

HHS response: The terms 'default' and 'adjusted' do not occur in the rule text; however, HHS does intend for the product to be able to meet the 25 percent value as the minimum setting and/or any higher setting requested by the purchaser. During performance testing for approval, NIOSH will test the alarm setting identified by the manufacturer in its request for approval of the respirator system. If the manufacturer does not identify an alarm setting, the indicator will be tested to show that it activates at the value of 25 percent of its rated service life.

The rule does not specify or restrict how manufacturers must comply with its provisions; manufacturers who find it in their best interest may offer specific set-points. Manufacturers are not required to produce a device that is adjustable to different users' needs, and can continue to market and sell SCBA models approved by NIOSH prior to the effective date of this rule. However, should the manufacturer wish to modify such a model for any reason, including a change to their service-life indicator set point, the manufacturer is required to apply to NIOSH for a new approval.

Additionally, in evaluating this comment, HHS determined that the user should be able to readily identify a respirator's alarm setting to distinguish models from one another. Models that meet the revised performance requirements of this rule should have labels and/or markings that identify the alarm setting for that particular model. At the discretion of the manufacturer, these markings could be addressed as part of the cautions and limitations associated with these devices, or as an additional label. In accordance with this determination, the final rule text is amended to address labels and/or markings.

Comment: One commenter recommended that 42 CFR 84.82 "include an additional section for a 33 percent" remaining service-life indicator. According to the commenter, "[a]llowing manufacturers the ability to utilize the same gauge for both alarm set points will reduce cost and complexity within the market."

HHS response: HHS has determined that the provisions in 42 CFR 84.82 are sufficiently flexible to allow manufacturers to produce gauges that accurately indicate the amount of breathing air contained in a unit.

Comment: HHS received one comment on the E.O. 12866 and E.O. 13563 analysis in Section IV.A., below. According to

the commenter, "[i]t is important to realize that additional costs for multiple or adjustable set points are inevitable. In addition to added design and documentation costs, options introduced into production will increase assembly and inspection times. Inventory costs increase with optional material warehousing....While they may be independent, other pressure gauges and electronic systems must be designed to correlate with the RSLI and the system(s) must be thoroughly verified. Differing RSLI settings may require differing gauge faces and electronics/programming designs to maintain correlation. For all these reasons, costs will increase."

HHS response: The commenter misunderstands the requirement. HHS does not require manufacturers to produce products with new features allowing for adjustment of the service life indicator alarm set point, or for various product models with different set points. Any manufacturer can choose to meet product demand by either manufacturing products with fixed set points or by manufacturing products with manufacturer-adjustable set points. Alternatively, the manufacturer can choose to take no action, and continue to sell respirators under existing NIOSH approvals. HHS is reducing the longstanding constraint on these product designs for a single alarm set point. Accordingly, we

continue to conclude that there are no costs associated with this rulemaking, and solely benefits in terms of greater flexibility for manufacturers to meet the diverse needs of their customers.

IV. Regulatory Assessment Requirements

A. Executive Orders 12866 and 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).

This final rule is not being treated as a "significant" action under E.O. 12866. It modifies the settings for an indicator required by current regulation, as well as codifies a long-standing policy of requiring that the OC demand and pressure demand SCBA indicator alarm continuously once it has begun. The current rule requires that a remaining service-life indicator activate when the breathing air provided by an OC demand and pressure demand SCBA reaches between 20 and 25 percent of its rated limit.

The final rule replaces the range with a default value of 25 percent, and allows manufacturers to offer indicator set-point values at a higher limit than 25 percent of remaining breathing air.

All approved OC demand and pressure demand SCBA models have a remaining service-life indicator for which alarm limits are set during manufacturing. Allowing respirator manufacturers to offer a respirator with an earlier activation set-point value will ensure that the alarm more effectively meets the varying worker protection needs of different work operations.

Although HHS determined that there are no costs and only benefits associated with this rulemaking, we received one comment on this economic analysis, summarized above. As discussed above, HHS continues to conclude that there are no costs associated with this rulemaking, and solely benefits in terms of greater flexibility for manufacturers to meet the diverse needs of their customers.

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. As discussed above, all OC demand and pressure-demand SCBA models are equipped with a remaining service-life indicator that will not require additional expenditure of resources to set at the activation limit. This final rule allows small organizations such as local fire departments to request an earlier indicator activation set-point when purchasing new devices from the manufacturer. The Secretary of HHS has certified to the Chief Counsel, Office of Advocacy of the Small Business Administration, that this rule does not have a significant impact on a substantial number of small entities. Accordingly, no regulatory impact analysis is required.

C. Paperwork Reduction Act of 1995

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. This rule does not contain any information

collection requirements; thus HHS has determined that the PRA does not apply to this rule.

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.), HHS will report to Congress the promulgation of a final rule, once it is developed, prior to its taking effect. The report will state that HHS has concluded that the 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 final 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, adjusted annually for inflation. For 2012, the inflation-adjusted threshold is $139 million.

F. Executive Order 12988 (Civil Justice)

This final rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform, and will not unduly burden the Federal court system. The amendment to an existing respirator approval standard will apply uniformly to all applicants. This final rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The final 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 final rule on children. HHS has determined that the final rule will 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 final 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 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. HHS did not receive any public comments on this matter.

V. Final Rule

List of Subjects in 42 CFR Part 84

Occupational safety and health, Personal protective equipment, Respirators.

Text of the 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. 577a, 651 et seq., and 657(g); 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

2. In § 84.83, revise paragraph (f) to read as follows:

§84.83 Timers; elapsed time indicators; remaining service life indicators; minimum requirements.

* * * * *

(f) Each remaining service-life indicator or warning device must give an alarm when the remaining service life is reduced to a minimum of 25 percent of its rated service time or any higher minimum percent value or values as specified in the approval. Open-circuit demand and pressure-demand respirators must alarm continuously until depletion of the breathing air supply. The percent value set for indicator activation must be identified by labels and/or markings on each respirator unit.

Dated: December 28, 2012.

Kathleen Sebelius,

Secretary.

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