

instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, EPA Region 10, 1200 Sixth Avenue, Suite 155, Seattle, WA 98101, at (206) 553-0256 or hunt.jeff@epa.gov.

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** of February 23, 2024 (89 FR 13622) (FRL-11593-01-R10) for 30 days, from March 25, 2024, to April 24, 2024.

This extension is in response to requests that the EPA received which asked for additional time to develop and submit comments on the proposed rulemaking. After considering several factors, the EPA believes it is appropriate to extend the comment period for 30 days to give stakeholders additional time to review the documents and prepare comments. As discussed in the **Federal Register** document of February 23, 2024 (89 FR 13622 (FRL-11593-01-R10)), the EPA is proposing approval of the regional haze state implementation plan revision submitted by Oregon on April 29, 2022, as supplemented on November 22, 2023, as satisfying applicable requirements under the Clean Air Act and the EPA's Regional Haze Rule for the program's second implementation period. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 8, 2024.

Casey Sixkiller,

Regional Administrator, Region 10.

[FR Doc. 2024-05510 Filed 3-14-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 52

[EPA-R05-OAR-2020-0055; FRL-11687-03-R5]

Air Plan Approval; Ohio; Withdrawal of Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule published February 22, 2024.

DATES: The comment period is extended to April 24, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2020-0055 at <https://www.regulations.gov>, or via email to arra.sarah@epa.gov. Additional instructions to comment can be found in the notice of proposed rulemaking published February 22, 2024 (89 FR 13304).

FOR FURTHER INFORMATION CONTACT: Christos Panos, Attainment Planning and Maintenance Section, Air Programs Branch (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-8328, panos.christos@epa.gov.

SUPPLEMENTARY INFORMATION: On February 22, 2024, EPA proposed to determine that its November 19, 2020, final action to remove the Air Nuisance Rule (ANR) from the Ohio State Implementation Plan using the Clean Air Act error correction provision was in error, and to correct that action by reinstating the ANR as part of the Ohio SIP. In response to a request in a public comment, EPA is extending the comment period for 30 days.

Dated: March 8, 2024.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2024-05448 Filed 3-14-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket No. CDC-2024-0005; NIOSH-351]

RIN 0920-AA83

Approval Tests and Standards for Combination Unit Respirators

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Service (HHS) proposes to amend regulatory requirements that would be used by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) to test and

approve combination unit respirators. This rulemaking would establish this new class of respiratory protective device, combination unit respirators (CURs), by incorporating by reference the performance requirements established in the National Fire Protection Association (NFPA) voluntary consensus standard NFPA 1987, Standard on Combination Unit Respirator Systems for Tactical and Technical Operations.

DATES: Comments must be received by May 14, 2024. Comments on the information collection approval request sought under the Paperwork Reduction Act must be received by May 14, 2024.

ADDRESSES:

Written comments: Comments, including those related to the Paperwork Reduction Act, may be submitted 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-2024-0005; NIOSH-351) or Regulation Identifier Number (0920-AA83) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>. Do not submit comments by email. CDC does not accept comments by email. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Peterson, NIOSH National Personal Protective Technology Laboratory (NPPTL), Pittsburgh, PA; (412) 386-6111 (this is not a toll-free number); email to NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations are invited to 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. Any information in comments or supporting materials that is confidential or inappropriate for public disclosure

should not be included. HHS will carefully consider all comments submitted in preparation of the final rule and may revise the final rule as appropriate.

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 (codified at 30 U.S.C. 842(h), 844, 957)), 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 Occupational Safety and Health Administration (OSHA) requires U.S. employers to supply NIOSH Approved^{® 1} respirators to their employees whenever the employer requires the use of a respirator (29 CFR 1910.134(d)(1)). The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) directs agencies to use voluntary consensus standards, instead of government-unique publications, when it is practical and consistent with law.

III. Background

The NIOSH Respirator Approval Program approves respiratory protective devices pursuant to the performance standards in 42 CFR part 84, *Approval of Respiratory Protective Devices*. A combination unit respirator is a respiratory protective device that employs the technology of at least two different types of respiratory protective devices, with one being an open-circuit self-contained breathing apparatus (SCBA)² and at least one other method being air-purifying or powered air-purifying,³ and that allows the wearer to select the operating mode. Despite the current lack of a NIOSH approval standard for CURs, they are used today

¹ NIOSH Approved[®] (NIOSH Approved) is a certification mark of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

² An open-circuit SCBA is designed for use during entry into and escape from or escape only from hazardous atmospheres. Oxygen is supplied to the wearer and the wearer's exhalations are vented to the atmosphere and are not rebreathed. See 42 CFR part 84, subpart H.

³ Air-purifying respirators (APRs) “utilize the wearer’s negative inhalation pressure to draw the ambient air through the air-purifying filter elements (filters) to remove particulates from the ambient air. They are designed for use as respiratory protection against atmospheres with particulate contaminants at concentrations that are not immediately dangerous to life or health and that contain adequate oxygen to support life.” Powered air-purifying respirators (PAPRs) use a blower to move air through the filters. See 42 CFR part 84, subpart K.

in military, law enforcement, and some industrial settings where the versatility of these devices allows users to perform in various hazardous environments. A CUR allows the worker to carry or wear one respirator into an environment in which the hazards are either unknown or might change rapidly, and to readily switch between types of respiratory protection after assessing their individual risk.

Regulations in 42 CFR part 84 do not currently allow for NIOSH approval of a single respirator unit for more than one respirator class where the user can select the appropriate level of protection required from within a single respirator system. With this rulemaking, HHS proposes to establish performance standards for NIOSH approval of CURs in a new part 84, subpart P, by incorporating by reference the performance requirements in Chapter 7 of NFPA 1987, *Standard on Combination Unit Respirator Systems for Tactical and Technical Operations*, 2023 edition.⁴

A. Background and History

NIOSH has explored and discussed the need to develop a regulatory standard for NIOSH approval of combination unit respirators with manufacturers and other interested parties since at least 2006, while developing performance requirements for chemical, biological, radiological, and nuclear (CBRN) protections. The conceptual requirements for the CBRN CUR were presented to obtain initial comments from manufacturers and other interested parties during an October 12, 2006, public meeting.⁵ Using this input, NIOSH identified the need to promulgate a CUR performance standard in part 84. A public meeting dedicated to discussion of a combination respirator standard was held in December 2010; participants expressed their support for a standard that recognizes each type of respiratory protection comprising the combination.⁶

NIOSH conducted a respirator manufacturers’ meeting⁷ and a

⁴ See <https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=1987>.

⁵ NIOSH Docket Number 082 [Oct. 2006], Combination Units—SCBA/PAPR/APR, <http://www.cdc.gov/niosh/docket/archive/docket082.html>.

⁶ NIOSH Docket Number 082–A [Dec. 2010], Chemical, Biological, Radiological and Nuclear (CBRN) Combination Respirator Unit (CRU), <http://www.cdc.gov/niosh/docket/archive/docket082A.html>.

⁷ NIOSH–NPPTL [Feb. 3, 2015], Letter to All Respirator Manufacturers, Subject: Implementation Plan for the Respirator Certification Fees, <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/Manufacturers/pdfs/ltrr-02032015-508.pdf>.

stakeholder webinar⁸ in March 2015 to solicit additional stakeholder input regarding CUR research needs. It then engaged the National Academies Institute of Medicine (IOM) to examine aspects of CUR technology, use, and the development of a performance standard. In April 2015, IOM convened a public workshop, sponsored by NIOSH, on the development of a CUR performance standard.⁹ The workshop engaged OSHA, NFPA, and CUR manufacturers and users, including presenters and participants engaged in law enforcement, fire service, mining, military, and hazardous waste remediation. The CUR users and manufacturers gave presentations to attendees, after which the workshop participants, speakers, and committee members met in breakout groups to define priorities in three areas: research, standards and regulations, and training needs and hazard assessment. Participants discussed the unique attributes of CURs and expressed concern about a disconnect between OSHA and NIOSH regulations.¹⁰ Specifically, in 29 CFR 1910.134(d)(3)(i)(A), OSHA established its assigned protection factors (APFs) standard and requires that for a combination respirator “employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.”¹¹

In contrast, in 42 CFR 84.63(b), NIOSH classifies combination respirators “by the type of respirator in the combination which provides the least protection to the user.” So, for example, pursuant to § 84.63(b), a respirator that combines an air-purifying mode (APF=50) and an open-circuit self-contained mode (APF=10,000) will be classified by NIOSH as an air-purifying respirator, the least protective of the two modes. Thus, if OSHA requires that the hazards at a specific worksite necessitate respiratory protection with an APF of 10,000, then the employer cannot use the combined air-purifying/open-circuit SCBA

⁸ NIOSH–NPPTL [Feb. 18, 2015], Webinar Concerning Standard for Performance Requirements of the Combination Unit Respirator, <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/interestedparties/pdfs/ltrr-02182015-508.pdf>.

⁹ <https://www.nationalacademies.org/our-work/developing-a-performance-standard-for-combination-unit-respirators-a-workshop>

¹⁰ Institute of Medicine of the National Academies [2015], *Developing a Performance Standard for Combination Unit Respirators—Workshop in Brief*, <https://nap.nationalacademies.org/read/21765/chapter/1>.

¹¹ OSHA’s regulation requires employers to use the APFs to select a respirator that meets or exceeds the required level of employee protection.

respirator approved by NIOSH at the least protective level (in this example, 50) because the APF for air-purifying respirators is insufficient to meet the needs of the worksite.

After the IOM published its workshop summary in June 2015, NIOSH determined there were no existing CUR performance standards that met the needs identified by the workshop participants. At that time, NIOSH considered the following alternative approaches to address those needs:

(1) develop the CUR performance standard and promulgate the standard into 42 CFR part 84;

(2) collaborate with a voluntary consensus standards development organization, such as NFPA, to develop the CUR performance standard and incorporate it into 42 CFR part 84 by reference; or

(3) develop the base respiratory protection requirements and collaborate with a standards development organization to develop additional unique requirements, such as communication and tactical equipment interoperability, to meet the needs of user groups for incorporation by reference into 42 CFR part 84.

NIOSH evaluated these options and considered both the formal request from a representative of the Federal Bureau of Investigation (FBI) and a subsequent Interagency Board endorsement letter of the FBI's request to the NFPA to develop CUR performance standards.¹² NIOSH determined that collaborating with NFPA to develop and adopt a CUR performance standard provided the most effective outcome for users and was the most efficient use of NIOSH resources. In a letter dated June 22, 2015, NIOSH endorsed the FBI's request that NFPA develop a CUR performance standard. In August 2015, NFPA responded to the FBI request by assigning this new project to the Technical Committee on Tactical and Technical Operations Respiratory Protection Equipment. User groups and CUR manufacturers participated throughout the NFPA CUR standard development process, and unique requirements such as communication and tactical equipment interoperability requirements were incorporated into the consensus standard to meet the needs of specific user groups. NIOSH provided additional expertise to conduct research, fully participated on the NFPA technical committee, and devoted agency resources to conduct the necessary research and development

testing and evaluation to support NFPA in developing the CUR standard.

B. Scope of the Proposed Rulemaking

This rulemaking proposes a new 42 CFR part 84, subpart P to create a new respirator class, combination unit respirators, which are respirators capable of protecting wearers (a) in open-circuit SCBA-mode during either entry into or escape from immediately dangerous to life or health (IDLH) environments, and (b) in air-purifying or powered air-purifying mode during entry into non-IDLH environments and escape from non-IDLH or IDLH environments. The combination unit respirator allows the wearer to select the operating mode and thus change from one APF to another as necessary.

C. Need for Rulemaking

Providing a mechanism to allow manufacturers to obtain NIOSH approvals of respirators conforming to the proposed standard for the new CUR class in subpart P would benefit those workers and employers who encounter various types of hazardous exposures and currently rely on multiple types of NIOSH Approved respiratory protective devices in the course of their duties on OSHA-regulated worksites. The flexibility provided using one NIOSH Approved respirator that can perform multiple functions might also benefit employers by allowing them to purchase fewer respirators, which NIOSH expects will result in cost savings. This rulemaking would also benefit employers who are required by OSHA to provide workers with NIOSH Approved respirators but currently use CURs that do not have NIOSH approval; HHS assumes that, as a result of this rulemaking, employers will choose to purchase NIOSH Approved products, allowing them to come into compliance with OSHA rules. Moreover, the proposed new subpart P would bring the regulations in 42 CFR part 84 into alignment with the OSHA APF standard 29 CFR 1910.134(d)(3)(i)(A), discussed above, allowing employers to purchase CURs rated at more than one APF.

This rulemaking would benefit approval holders that currently produce combination unit respirators, and new CUR manufacturers that would enter the NIOSH Approved CUR market if such approval were to become available. By promulgating this rule, HHS would be removing a barrier that currently prevents CUR manufacturers from accessing the market demand for NIOSH Approved respirators. Adding a new subpart P to part 84 would allow manufacturers to apply for and obtain NIOSH approval of CURs capable of

allowing the wearer to switch between operational modes, which can be identified by more than one APF.

This rulemaking also proposes the revision of an existing definition in 42 CFR 84.2 and the addition of two new terms to reflect NIOSH's ongoing and evolving relationship with business entities that produce and sell respirators. HHS proposes revising the existing definition of the term "applicant" to clarify the role and responsibilities of those parties who submit an application for NIOSH approval of a product's design, performance, configuration management, manufacture, quality, and support. A new definition of the term "approval holder" would be added to the existing definitions section. The terms "applicant" and "approval holder" would replace the term "manufacturers" throughout part 84, as appropriate, to reflect the fact that seeking and maintaining NIOSH approval includes more than the manufacturing of the respirator or respirator components. An approval holder has at least one respirator approval on the NIOSH Certified Equipment List (CEL), a directory of NIOSH Approved respirators, which would also be defined in § 84.2. The CEL is regularly updated as respirator approvals are added, made obsolete, or otherwise changed in status. The CEL is available in a searchable database at <https://wwwn.cdc.gov/niosh-cel/>.

D. Effects of Rulemaking on Federal Agencies

The proposed rule would not require OSHA to make any changes to 29 CFR 1910.134, the OSHA respiratory protection requirements. The proposed rule is expected to benefit Federal law enforcement agencies and military branches whose members currently rely on CURs that are not NIOSH Approved respirators. The performance requirements proposed in this rulemaking are designed to protect workers relying on CURs for their survival in IDLH atmospheres better than combination respirators approved pursuant to 42 CFR 84.63(b) or CURs not approved to any performance standard.

IV. Incorporation by Reference

With this rulemaking, HHS proposes to incorporate by reference the CUR performance requirements in Chapter 7 of NFPA 1987, *Standard on Combination Unit Respirator Systems for Tactical and Technical Operations*, 2023 edition, into a new part 84, subpart P. NFPA 1987 specifies the minimum requirements for the design,

¹² See *supra* note 4 at 1.

performance, testing, and certification of new combination unit respirator systems. Only the NFPA 1987, Chapter 7, respiratory performance requirements are incorporated into part 84, subpart P. NFPA 1987, 2023 edition, is reasonably available to interested parties. Interested parties may purchase a copy from NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, www.nfpa.org. All NFPA codes and standards can be viewed at no cost at nfpa.org/docinfo.

V. Summary of Proposed Rule

For the reasons discussed above, HHS proposes the following changes to 42 CFR part 84.

Section 84.2 Definitions

HHS proposes the addition of two new definitions to the existing Definitions section in 84.2: “approval holder” and “NIOSH Certified Equipment List (CEL).” An approval holder is an applicant who has at least one NIOSH Approved respirator on the NIOSH Certified Equipment List, which is the directory of NIOSH Approved respirators. Finally, HHS proposes a revision to the existing term “applicant,” to clarify that the applicant is the entity that maintains and demonstrates responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support. Throughout part 84, the words “manufacturer,” “manufacturers,” and “manufacturer’s” would be replaced with variations of “applicant” and “approval holder,” as appropriate.

Section 84.63 Test Requirements; General

Existing § 84.63(b) allows the combination of two or more classes of respirators and requires the resulting combination respirator to meet the minimum requirements for each class of respirator in the combination. Each resulting combination respirator will be classified by the class of respirator in the combination that provides the least amount of protection to the wearer. Paragraph (b) would be revised to clarify that CURs approved under the proposed new subpart P would be excepted from this general rule.

Section 84.400 Combination Unit Respirators (CUR); Description

In a new subpart P, a new § 84.400 would describe that CURs are intended to protect wearers using the CUR (a) in open-circuit SCBA-mode during either entry into or escape from immediately dangerous to life or health (IDLH) environments, and (b) in air-purifying or

powered air-purifying mode during entry into non-IDLH environments and escape from non-IDLH or IDLH environments.

Section 84.401 Technical Specifications and Performance Requirements

A new § 84.401(a) would incorporate by reference the performance requirements established in Chapter 7 of NFPA 1987, *Standard on Combination Unit Respirator Systems for Tactical and Technical Operations*, 2023 edition. Tables in paragraphs (a)(1), (2), (3), and (4) would specify the NFPA 1987 performance requirements for CUR systems, including the CUR open-circuit self-contained mode, the powered air-purifying mode, and the air-purifying mode. The incorporation of NFPA 1987 would establish systems evaluation and minimum performance requirements for each operational mode providing respiratory protection, including air-purifying, powered air-purifying, and open-circuit self-contained breathing apparatus; the ability to safely switch operational modes; universal emergency breathing safety system; end-of-service-time indicator; and for assessing the chemical, biological, radiological, and nuclear performance of the CUR. A new paragraph (b) would stipulate that the 42 CFR part 84 provisions prevail in the event that there is a conflict with the requirements of NFPA 1987.

Section 84.402 General Construction and Approval Requirements

A new § 84.402(a) would specify that CURs are required to meet the minimum construction requirements in subpart G of part 84. Paragraph (b) would specify that the prospective approval holder must concurrently submit the device to an organization accredited to ISO/IEC 17065, *Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services*, for NFPA 1987 certification. The conformity assessment body will assess those requirements in NFPA 1987 that are not incorporated by reference into 42 CFR part 84, subpart P. NIOSH approval is contingent upon the applicant receiving NFPA 1987 certification from a conformity assessment body. The certification letter issued by the conformity assessment body will be issued concurrent with the NIOSH National Personal Protective Technology Laboratory approval letter.

Updates to Internal References

In §§ 84.30, 84.50, 84.51, 84.52, 84.53, 84.60, 84.63, 84.64, 84.65, the text would be edited to point to the

technical standards in subparts H through the proposed new subpart P.

VI. Regulatory Impact Analyses

HHS has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999).

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Executive Order 14094 (Modernizing 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). The Executive Order 14094 entitled “Modernizing Regulatory Review” (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. A

regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year).

This proposed rule has been determined not to be a “significant regulatory action” under section 3(f) of E.O. 12866. The rulemaking is intended to remove regulatory barriers to the manufacturing, labeling, and selling of new CUR designs with NIOSH approval that include both open-circuit self-contained breathing apparatus and either air-purifying or powered air-purifying respirator capabilities. This rulemaking would give applicants the option to seek NIOSH approval of CURs meeting the performance requirements in chapter 7 of NFPA 1987, *Standard on Combination Unit Respirator Systems for Tactical and Technical Operations*, 2023 edition, incorporated by reference into a new 42 CFR part 84, subpart P. NIOSH approval would be contingent on concurrent NFPA 1987 certification from the certification body.

Costs

This rule would not impose any mandatory costs on the public and would benefit applicants who choose to develop a product under these new

technical requirements and the employers who purchase CURs. HHS estimates the fees associated with CUR approvals, including applications, site qualifications, and testing fees, pursuant to 42 CFR part 84, subpart C—Fees and Fee Schedule B—Application-Based Fees in part 84, appendix B. Because CUR-specific testing fees must be added to Fee Schedule B by rulemaking,¹³ until HHS can conduct such a rulemaking, fees associated with those tests would be assessed pursuant to § 84.24, which authorizes NIOSH to conduct or cause to be conducted any additional examinations, inspections, or tests it deems necessary to determine the quality and effectiveness of any respirator submitted to NIOSH for the purposes of seeking a certificate of approval.

CUR-specific testing fees would be charged under the New and Unspecified Tests category of Fee Schedule B, allowing the NIOSH Respirator Approval Program to recoup \$500 per day plus the actual cost of non-NIOSH staff (typically medical staff and test subjects), which is roughly equivalent to the actual costs of those tests. The application plus NIOSH testing and evaluation fees are estimated to be \$15,600 in total.

The costs associated with the CBRN chemical warfare agent (CWA) tests,

which NIOSH requires to be conducted by the U.S. Army Combat Capabilities Development Command (DEVCOM), Chemical Biological Center (CBC), are estimated to cost \$101,000. These fees are established by CBC.

Fees associated with the independent certification body NFPA 1987 certification will be assessed by the certification body utilized. HHS estimates that NFPA 1987 certification will cost \$90,000 for initial testing and evaluation and \$42,000 annually thereafter. Finally, HHS estimates that the application itself will take an average of 240 hours to complete, costing applicants approximately \$11,374 per application (*see* Section V.C., below).

In addition to the one-time cost of a new NIOSH approval, pursuant to Respirator Certification Fee Schedule A—Annual (Fixed) Fees, the annual NIOSH approval maintenance costs to maintain one approval are estimated to be \$10,691.

In total, HHS estimates that the initial cost of a new CUR approval application submitted to NIOSH will be \$217,974. HHS further estimates that the total cost of maintaining a NIOSH CUR approval will be \$52,691. *See* Table 1.

TABLE 1—ESTIMATED COST OF NIOSH CUR APPROVAL
[2023\$]

Fees	Estimated first-year costs for 1 approval	Estimated annual costs for 1 approval
NIOSH approval, Fee Schedule A	\$10,691
NIOSH approval, Fee Schedule B	\$15,600
Application paperwork burden	11,374
CBRN testing by DEVCOM	101,000
NFPA 1987 certification	90,000
NFPA 1987 certification annual fee	42,000
Total	217,974	52,691

Benefits

HHS anticipates that the benefits of this rulemaking far outweigh the costs to applicants of obtaining NIOSH CUR approval. CURs without NIOSH approval currently cost from \$7,500 to \$12,000; HHS does not have information about the potential cost of NIOSH Approved CURs but expects CUR approval holders to recoup the full cost of the NIOSH approval and profit from the sale of CURs to end users.

Moreover, this rulemaking would open up a new market segment to approval holders, allowing them to sell NIOSH Approved CURs to employers

who are only able to purchase NIOSH Approved respirators as well as those who currently use non-NIOSH Approved CUR but wish to use NIOSH Approved respirators. Such employers are likely to include State and local law enforcement agencies in states that have an OSHA-approved State Plan, Department of Defense contractors, and private businesses where workers encounter hazards in industrial settings.

HHS expects that employers who must supply workers on OSHA-regulated jobsites with more than one type of NIOSH Approved respirator to protect them from more than one type

of inhalational hazard would see a cost savings when those respirators are replaced with one NIOSH Approved CUR. Employers may also save resources by reducing employee trainings on multiple types of respirators.

Finally, the performance requirements proposed in this rulemaking are designed to protect workers relying on CURs for their survival in IDLH atmospheres better than combination respirators approved pursuant to 42 CFR 84.63(b) or CURs that are not approved to any performance standard. CURs approved under this new subpart will

¹³ 42 CFR part 84, Appendix B.

demonstrate that the NIOSH Approved CUR maintains a minimum level of protection when the modes of protection are switched by the user, as needed to perform their work. The concurrent NFPA 1987 approval issued by NIOSH and the ISO 17065 certification body ensures minimum performance is demonstrated for the respiratory and non-respiratory requirements needed to protect these users. Although HHS lacks information on the number of workers annually who rely on a CUR for their survival and the quantifiable benefit they would derive from this rule, HHS anticipates that the use of NIOSH Approved CURs will result in cost savings associated with reducing illness, death, or disability resulting from work in IDLH atmospheres.

HHS encourages submission to the docket of any information or data that would inform our understanding of the impact of this rulemaking on regulated entities.

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. The Secretary certifies that this proposed rule would have “no significant economic impact upon a substantial number of small entities” within the meaning of the RFA. HHS estimates that two

manufacturers considered to be small businesses are currently producing combination unit respirators used in military, law enforcement, and some industrial settings. HHS expects that any economic burden accrued through compliance with this rulemaking would not disproportionately or unfairly impact small CUR manufacturers and that any such burden would be offset by economic gains from compliance with the new CUR performance standard.

C. 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. The Office of Management and Budget (OMB) has already approved the information collection and recordkeeping requirements for certification and approval of respiratory protective devices 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 March 31, 2024). Due to this proposed rule, which would allow for the NIOSH approval of respirators in a new class, combination unit respirators, there is likely to be a change in burden in the approved collection of information.

Comments are invited on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents. Written comments must be received within 60 days of the publication of this notice. The addition of additional paperwork requirements resulting from this proposed rule will increase the burden associated with the addition of a new 42 CFR part 84, subpart P.

Based on known manufacturers of combination unit respirators on the market, NIOSH estimates that up to 5 respirator manufacturers may submit approximately 15 applications for CUR approvals to the National Personal Protective Technology Laboratory from April 2024 to April 2025. Each application is expected to require an average of 240 hours to complete and maintain.

Accordingly, NIOSH expects 3,600 burden hours to be attributed to applications for CUR approvals under the new subpart P. NIOSH estimates an average hourly wage rate of \$47.39 for industrial engineers.¹⁴

Section	Title	Number of respondents	Average responses per respondent	Average burden per response (hr)	Total burden (hr)
84.400	Combination unit respirators (CUR); description	5	3	240	3,600

Section	Title	Total burden hours (from above)	Estimated hourly wage rate	Total cost of hour burden
84.400	Combination unit respirators (CUR); description	3,600	\$47.39	\$170,604

D. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and on the private sector “other than to the extent that such regulations incorporate requirements specifically set forth in law.” Section 202 of the

UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately \$177 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector, and this rule would not impose a mandate that will result in the

expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$177 million in any 1 year.

E. 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 proposed rule has been

¹⁴ U.S. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2022: 1702112*

Industrial Engineers, <https://www.bls.gov/oes/current/oes172112.htm>.

reviewed carefully to eliminate drafting errors and ambiguities.

F. 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.”

G. 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 proposed rule would have no environmental health and safety effect on children.

H. 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 proposed rule will not have a significant adverse effect.

I. 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 issuing the notice of proposed rulemaking consistent with the Federal Plain Writing Act guidelines but notes that these standards are technical in nature.

List of Subjects in 42 CFR Part 84

Fees, Incorporation by reference, Labeling, Laboratories, Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 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.*, and 657(g); 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

Subpart A—General Provisions

■ 2. Amend § 84.2 by revising the definition for “Applicant” and adding the definitions for “Approval holder” and “NIOSH Certified Equipment List” in alphabetical order to read as follows:

§ 84.2 Definitions.

Applicant means an individual, partnership, company, corporation, association, or other organization that controls the design, manufactures, and controls the assembly of a respirator and who seeks to obtain a certificate of approval for such respirator. The applicant demonstrates responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support. The applicant may be an existing approval holder.

* * * * *

Approval holder means an applicant who has successfully received and maintains at least one approval currently listed on the NIOSH Certified Equipment List. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, quality, and support.

* * * * *

NIOSH Certified Equipment List (CEL) means a directory maintained by NIOSH of respirators which have been granted approval.

* * * * *

Subpart B—Application for Approval

§ 84.10 [Amended]

■ 3. Amend § 84.10(d) by replacing “manufacturers” with “approval holders”.

Subpart C—Fees

§ 84.22 (c) [Amended]

■ 4. Amend § 84.22(c) by removing “manufacturer” and adding in its place “applicant or approval holder”.

Subpart D—Approval and Disapproval

§ 84.30 [Amended]

■ 5. Amend § 84.30(a) by removing “H through L” and adding in its place “H through P”.

Subpart F—Classification of Approved Respirators; Scope of Approval; Atmospheric Hazards; Service Time

§ 84.50 [Amended]

■ 6. Amend § 84.50 by removing “G through L” and adding in its place “G through P”.

§ 84.51 [Amended]

■ 7. Amend § 84.51 by removing “H through L” and adding in its place “H through P”.

§ 84.52 [Amended]

■ 8. Amend § 84.52 by removing “H through L” and adding in its place “H through P”.

§ 84.53 [Amended]

■ 9. Amend § 84.53(a) by removing “H through L” and adding in its place “H through P”.

Subpart G—General Construction and Performance Requirements

§ 84.60 [Amended]

■ 10. Amend § 84.60(a) by removing “H through O” and adding in its place “H through P” and (b) by removing “H through L” and adding in its place “H through P”.

§ 84.63 [Amended]

■ 11. Amend § 84.63 by:
 ■ A. In paragraphs (a) and (c) remove “H through O” and add in its place “H through P”.
 ■ B. In paragraph (b) removing the phrase “except as specified in § 84.70(b)(2)” and adding in its place the phrase “except as specified in § 84.70(b)(2) and subpart P”.

§ 84.64 [Amended]

■ 12. Amend § 84.64 by removing “H through O” and adding in its place “H through P”.

§ 84.65 [Amended]

■ 13. Amend § 84.65 by removing “H through O” and adding in its place “H through P”.

Subpart J—Supplied-Air Respirators

§ 84.149 [Amended]

■ 14. In § 84.149, amend paragraph (b) by removing “manufacturer” and adding in its place “applicant” and amend paragraph (d)(2) by removing “manufacturer’s” and adding in its place “applicant’s”.

Subpart K—Air-Purifying Particulate Respirators

§ 84.171 [Amended]

■ 15. Amend § 84.171(b) by removing “The respirator manufacturer, as part of the application for certification,” and adding in its place “The applicant”.

§ 84.172 [Amended]

■ 16. Amend § 84.172(b) by removing “manufacturer” and adding in its place “applicant”.

Subpart N—Special Use Respirators

§ 84.252 [Amended]

■ 17. Amend § 84.252 by removing “manufacturer’s” and removing “a manufacturer” and adding in its place “an applicant”.

§ 84.257 [Amended]

■ 18. Amend § 84.257(a) by removing “manufacturer’s” and adding in its place “approval holder’s”.

Subpart O—Closed-Circuit Escape Respirators

§ 84.301 [Amended]

■ 19. Amend § 84.301(c) by removing “manufacturer-requested” and adding in its place “approval holder-requested”.

§ 84.302 [Amended]

■ 20. Amend § 84.302(a)(2) and (c) by removing “manufacturer” and adding in its place “applicant”.

§ 84.304 [Amended]

■ 21. Amend § 84.304(a)(3) and (c) by removing “manufacturer” and adding in its place “applicant”.

§ 84.305 [Amended]

■ 22. Amend § 84.305(d) by removing “manufacturer’s” and adding in its place “applicant’s”.

§ 84.306 [Amended]

■ 23. Amend § 84.306(b)(1) by removing “manufacturer” and adding in its place “applicant”.

§ 84.309 [Amended]

■ 24. Amend § 84.309(d) by removing “manufacturer” and adding in its place “applicant”.

■ 25. Add subpart P to read as follows:

Subpart P—Combination Unit Respirators

Sec.

84.400 Combination unit respirators (CUR); description.

84.401 Technical specifications and performance requirements.

84.402 General construction and approval requirements.

§ 84.400 Combination unit respirators (CUR); description.

(a) Combination unit respirators including all completely assembled respirators are designed for use as respiratory protection during:

(1) Entry into or escape from atmospheres immediately dangerous to life or health, when active in the open-circuit self-contained operational mode, and

(2) Entry into atmospheres not immediately dangerous to life or health, or escape only from hazardous atmospheres containing adequate oxygen to support life when active in the air-purifying or powered air-purifying operational mode.

(b) A respirator that meets the minimum requirements for such respirators set forth in this subpart will be classified as a combination unit respirator.

§ 84.401 Technical specifications and performance requirements.

(a) Combination unit respirators must meet those respiratory protection performance requirements established in NFPA 1987, *Standard on Combination Unit Respirator Systems for Tactical and Technical Operations*, 2023 edition, specified in paragraphs (a)(1), (2), (3), and (4) of this section. Accordingly, the NFPA 1987 performance requirements in Chapter 7, specified in paragraphs (a)(1), (2), (3), and (4), are incorporated by reference into this section and have been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the National Institute for Occupational Safety and Health (NIOSH) and at the National Archives and Records Administration (NARA). Contact NIOSH at National Personal Protection Technology Laboratory, P.O. Box 18070, 626 Cochran Mill Road, Pittsburgh, PA 15236. To arrange for an inspection at NIOSH, call 412-386-6111 or email PPEConcerns@cdc.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the National Fire Protection Association at: phone: 800-344-3555; email: custserv@nfpa.org; website: <https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=1987>.

(1) CUR system performance requirements:

NFPA 1987 performance requirements	NFPA 1987 section
(i) Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur Mustard (HD) and Sarin (GB) Performance Requirements	7.1.1
(ii) Laboratory Respiratory Protection Level (LRPL)	7.1.2
(iii) Flexible Facepiece Lens Abrasion Resistance Performance	7.1.5

(2) CUR/open-circuit self-contained mode performance requirements:

NFPA 1987 performance requirements	NFPA 1987 section
(i) Service Time Performance	7.2.2
(ii) Human Subject Performance Test for Low-Temperature Operations	7.2.3
(iii) Human Subject Performance Tests During Physical Exertions	7.2.4
(iv) Integrity of Couplings Performance	7.2.5
(v) CUR Standby Air Supply Airflow Performance	7.2.6
(vi) CUR Connection to a Standby Air Source Performance	7.2.7
(vii) CUR Air Flow Capabilities in Event of Second-Stage Regulator Failure Performance	7.2.8
(viii) CUR Gauge Accuracy Performance	7.2.9

(3) CUR/powerd air-purifying mode performance requirements:

NFPA 1987 performance requirements	NFPA 1987 section
(i) PAPR Airflow Performance	7.3.1
(ii) PAPR Silica Dust Loading Performance	7.3.2
(iii) Airflow Resistance Performance in Breath-Responsive, Powered Air-Purifying Respirators	7.3.3
(iv) PAPR Performance with the Blower Off	7.3.4

(4) CUR/air-purifying mode performance requirements:

NFPA 1987 performance requirements	NFPA 1987 section
(i) Breathing Resistance	7.4.1
(ii) Hydration Leakage	7.4.2
(iii) Canister Test Challenge and Test Breakthrough Concentrations	7.4.3
(iv) Particulate/Aerosol Canister	7.4.4
(v) Low-Temperature/Fogging	7.4.5
(vi) ESLI Drop Test for Canisters	7.4.6
(vii) ESLI Test for Canisters	7.4.7

(b) To the extent there is a conflict between the terms or provisions of NFPA 1987 and this part, the provisions of this part control.

§ 84.402 General construction and approval requirements.

(a) Each CUR must meet the minimum construction requirements set forth in subpart G of this part.

(b) Applications for NFPA 1987 certification must be submitted to a conformity assessment body accredited to ISO/IEC 17065, *Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services*, at the same time the CUR approval application is submitted to NIOSH. NIOSH approval is contingent upon and will be issued in conjunction with NFPA 1987 certification.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024-03849 Filed 3-14-24; 8:45 am]

BILLING CODE 4163-18-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket Nos. 22-271, 22-272; FCC 24-21; FR ID 207048]

Space Innovation; Facilitating Capabilities for In-Space Servicing, Assembly, and Manufacturing

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) adopted a Notice of Proposed Rulemaking that seeks comment on a proposed new framework for licensing space stations engaged in in-space servicing, assembly, and manufacturing (ISAM).

DATES: Comments are due on or before April 29, 2024. Reply comments are due on or before May 29, 2024.

ADDRESSES: You may submit comments, identified by IB Docket Nos. 22-271 and 22-272, by any of the following methods:

- *Electronic Filers.* Comments may be filed electronically using the internet by accessing the ECFs, <http://apps.fcc.gov/ecfs>.

- *Paper Filers.* Parties who choose to file by paper must file an original and one copy of each filing.

- Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission’s Secretary, Office of the Secretary, Federal Communications Commission.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health

and safety of individuals, and to mitigate the transmission of COVID-19. See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy, Public Notice, DA 20-304 (March 19, 2020). <https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy>.

Persons with Disabilities. To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice) or 202-418-0432 (TTY).

FOR FURTHER INFORMATION CONTACT: Jameyanne Fuller, Space Bureau, Satellite Programs and Policy Division, 202-418-0945, jameyanne.fuller@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Notice of Proposed Rulemaking (NPRM), in IB Docket Nos. 22-271 and 22-272; FCC 24-21, adopted February 15, 2024, and released February 16, 2024. The full text of this document is available at <https://docs.fcc.gov/public/attachments/FCC-24-21A1.pdf>.

Ex Parte Presentations

The Commission will treat this proceeding as a “permit-but-disclose” proceeding in accordance with the Commission’s *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different