



**Billing Code 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 84**

**[Docket No. CDC-2020-0036; NIOSH-335]**

**RIN 0920-AA69**

**Approval Tests and Standards for Air-Purifying Particulate Respirators**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Interim final rule with comment.

**SUMMARY:** The Department of Health and Human Service (HHS) is publishing this interim final rule to update the regulatory requirements used by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) to test and approve air-purifying particulate respirators for use in the ongoing public health emergency. With this rulemaking, parallel performance standards are added to existing regulatory requirements for PAPRs to allow for the approval of respirators in a new class, PAPR100, that may be better suited to the needs of workers in the healthcare and public safety sectors currently experiencing a shortage of air-purifying particulate respirators due to Coronavirus Disease 2019 (COVID-19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This rulemaking also consolidates the technical standards for all types of air-purifying particulate respirators into one subpart, and standards pertaining to obsolete respirators designed for dust, fume, and mist; pesticide; and paint spray are removed from the regulation entirely. This rulemaking will have no substantive impact on the continued certification testing and approval by the NIOSH National Personal Protective Technology Laboratory of existing

PAPR class HE (high-efficiency series) respirators or non-powered air-purifying particulate respirators, including N95 filtering facepiece respirators, currently in demand by healthcare workers and emergency responders. NIOSH expects that the addition of PAPR100 devices to the marketplace will help to relieve the current high demand for possibly hundreds of thousands of additional particulate filtering facepiece respirators needed specifically for healthcare and emergency medical response settings.

**DATES:** This rule is effective on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments must be received by **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** *Written comments:* Comments 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-2020-0036; NIOSH-335) or Regulation Identifier Number (0920-AA69) 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.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Palcic, NIOSH National Personal Protective Technology Laboratory (NPPTL), Pittsburgh, PA, (412) 386-5247 (this is not a toll-free number). Information requests can also be submitted by e-mail to 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. Any information in comments or supporting materials that is not intended to be disclosed should not be included. Comments may be submitted on any topic related to this interim final rulemaking, including the following:

- What operational and/or functional characteristics should be considered in establishing a standard for a healthcare PAPR?
- Should there be more than one class of healthcare PAPR, for example, surgical versus non-surgical?

**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 respirators to their employees whenever the employer requires the use of a respirator. (29 CFR 1910.134(d))

### **III. Background**

#### **A. Introduction**

Air-purifying respirators use either filters, cartridges, or canisters (or combinations of filters and cartridges or filters and canisters), to protect users from gases; vapors; aerosols, including viruses capable of being transmitted by aerosolized droplets; and other contaminants in the air. Since these respirators simply purify the ambient atmosphere and do not provide an independent supply of breathing air to the wearer, most types cannot be used in atmospheres that are immediately dangerous to life and health (IDLH).<sup>1</sup> Air-purifying particulate respirators, a subclass of air-purifying respirators, are approved by NIOSH pursuant to 42 CFR part 84. Currently, testing and performance standards for non-powered air-purifying particulate respirators are codified in part 84, subpart K; standards for powered air-purifying particulate respirators are codified in subpart KK.

Non-powered air-purifying particulate respirators include filtering facepiece respirators and elastomeric half- and full-facepiece respirators, and are used in a very wide variety of work settings.

Powered air-purifying particulate respirators (PAPRs) are used in many similar work settings and are distinguished from the non-powered type by the powered blower that moves air through the attached filters, canisters, and/or cartridges. This respirator type comes in a variety of sizes, weights, and mounting configurations. PAPRs play an

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<sup>1</sup> With the exception of gas masks designed for escape from IDLH atmospheres. See 42 CFR 84, subpart I—Gas Masks.

integral role in respiratory protection programs across multiple sectors, including general industry, healthcare, and police operations.

Current regulatory standards provide for the NIOSH approval of high-efficiency (HE) particulate filters which are incorporated into PAPRs. The NIOSH National Personal Protective Technology Laboratory has determined the need for increasing the utility of PAPRs in the workplace and offering a wider array of options for today's work practices. Although the current PAPR approval program has proven protections, these interim requirements offer the potential to extend the same proven level of protection to smaller, lighter systems which may be more comfortable to wear, as discussed below.

#### B. PAPR Certification and Approval

NIOSH currently approves PAPRs under 42 CFR part 84, *Approval of Respiratory Protective Devices*. Within part 84, subpart KK, *Dust, Fume and Mist; Pesticide; Paint Spray; Powered Air-Purifying High Efficiency Respirators and Combination Gas Masks*, specifies testing and certification requirements for PAPRs with high-efficiency particulate filters. NIOSH reviews and approves such respirators for use, for example, by industrial, healthcare, and public safety workers.

#### C. Scope of the Rulemaking

This rulemaking applies to air-purifying particulate respirators and gas and vapor respirators which also incorporate a particulate filter. NIOSH is (1) consolidating all air-purifying, particulate respirator requirements, whether powered or non-powered, into subpart K; (2) eliminating unneeded and archaic parts of the standard related to PAPRs

which were left in place since the 1995 promulgation of part 84; and (3) better aligning PAPR particulate filter testing for a new class of PAPR with the requirements for non-powered particulate respirators which were established in the 1995 rulemaking.

With this rulemaking, a new class of PAPR is established, PAPR100, in parallel with the current PAPR class HE, to open opportunities for designs offering the characteristics desired by many end-users, as revealed through user-sector input following the public meetings in 2003-2008 and a 2014 Institute of Medicine workshop, discussed below. PAPRs tested to the current requirements relocated from subpart KK are designated series “HE”; those requirements are otherwise unchanged. PAPR100s tested to the new alternative testing and approval requirements are designated either series “PAPR100-N,” which is not for use against oil-based aerosols, or “PAPR100-P,” which is strongly resistant to oil aerosols.

Requirements for the current class HE are unchanged because those devices have a proven track record and widespread use. The existing HE requirements result in the approval of PAPRs that are well-suited to heavy industry settings where the particulates of concern may be dense in terms of their airborne concentration. In those settings, the PAPR is often unavoidably challenged to remove a large quantity of larger, non-respirable particles while it is doing the important work of removing the much smaller, but much more hazardous, respirable-sized particles. While the existing silica dust test specified in subpart KK demonstrates a portion of the unit’s ability to remove the respirable-sized particles, it is a very good test to demonstrate the PAPR’s ability to provide ongoing filtration across the wider aerosol size spectrum in these “dirtier” industrial settings. With this rulemaking, NIOSH is promulgating a new standard for the

new class PAPR100, which replaces the silica dust test with a sodium chloride aerosol when testing PAPR100-N series filters, and with a dioctyl phthalate aerosol when testing PAPR100-P series filters. NIOSH will not designate either class specifically for industrial or non-industrial use, but it is thought that the PAPR class HEs will continue to be the design of choice in industrial settings. Since protections provided by the current class HE respirators are considered equivalent to the protections expected by the new PAPR100 devices, respiratory safety continues to be assured, regardless of the setting.

This rulemaking also eliminates the requirements for other obsolete types of respirators, including dust, fume, and mist; pesticide; and paint spray respirators identified in current subpart KK. Subpart KK is removed from part 84 in its entirety.

#### D. Need for Rulemaking

PAPRs are often used in high-hazard procedures in the healthcare setting because they are designed to filter chemicals, blood-borne pathogens, and aerosol-transmissible diseases. However, the size and weight of the PAPRs approved under the current regulations has been said to limit their widespread adoption in healthcare and by first responders. The current requirements for PAPR class HE (high-efficiency series) contained in 42 CFR part 84 were established in 1972 primarily for more industrial-type uses and exposures, such as mining and milling operations. The silica dust loading test is currently incorporated among the requirements which determine the PAPR filter efficiency. In order to pass the silica dust test, current NIOSH-approved PAPRs must provide a high flow of breathing air against a highly loaded filter for a duration of 4 hours. This generally results in approved PAPRs having blowers and batteries which may

be inconveniently large, heavy, or both. Respirator designers and end-users have expressed a desire for greater latitude in the regulatory requirements in order to reduce the bulk and weight of currently approved PAPR class HE devices, given the advances in modern battery and sensor technology that would allow for smaller, lighter designs with service durations continuously monitored by required flow-detection devices.

During the past 20 years, PAPRs have played an increasing role in respiratory protection programs in the United States in sectors beyond general industry, including healthcare. PAPRs are also frequently considered for public safety and other specialized industrial uses. The 2002 Severe Acute Respiratory Syndrome (SARS), the 2009 H1N1 influenza, and the 2014 Ebola virus outbreaks ushered in more extensive use of respiratory protection, and specifically PAPRs, for today's 18 million healthcare workers.

In a 2014 assessment designed to quantify the amount of personal protective equipment held in U.S. acute care hospitals, the Association of States and Territorial Health Officials (ASTHO) estimated that acute care hospitals across the United States had no more than 83,196 PAPRs on-hand in 2012 compared with 114,694,159 N95s, demonstrating that the currently approved PAPRs are not as widely-used in healthcare as the N95s.<sup>2</sup> However, the Association for Professionals in Infection Control and Epidemiology (APIC) reported that healthcare employers are expected to increase the relative number of PAPRs used in healthcare as the devices become less expensive and lighter.<sup>3</sup> PAPRs have a number of advantages over N95 filtering facepiece respirators, including that they are reusable and can be cleaned and disinfected, loose-fitting PAPR do not need to be fit tested and often can be worn with facial hair, and have a higher

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<sup>2</sup> ASTHO, *Assessment of Respiratory Personal Protective Equipment in U.S. Acute Care Hospitals—2012* (2014).

<sup>3</sup> See APIC public comment submitted to NIOSH Docket-272 for National Institute for Occupational Safety and Health, CDC, *Respiratory Protective Devices Used in Healthcare; Notice of Request for Information and Comment*, 79 FR 14515 (March 14, 2014).

assigned protection factor (as determined by the Occupational Safety and Health Administration in the Department of Labor). Designs not requiring fit testing are expected to be especially advantageous in a public health emergency, such as the Coronavirus Disease 2019 (COVID-19) response, by saving resources including both person-hours and the need to fit test multiple makes and models to find the right fit for an individual worker. Loose-fitting PAPR designs are also typically equipped with a head covering that delivers filtered air over the user's entire head, including the eyes and hair, thus offering greater overall protection from contact with any airborne infectious agents.

Healthcare workers and first responders are on the front line of efforts to contain COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus is thought to spread primarily by person-to-person contact through respiratory droplets produced when an infected person coughs or sneezes; it may also spread through contact with contaminated surfaces or objects. The ease of SARS-CoV-2 transmission has resulted in a surge in hospitalizations in many jurisdictions, resulting in a well-documented shortage of personal protective equipment, especially respiratory protection, for healthcare workers and emergency responders. An APIC survey conducted March 23-24, 2020 found that 20 percent of respondents indicated they do not have any respirators and 61 percent of respondents indicated they are almost out of respirators. Only 18 percent of respondents said they have a sufficient number of respirators.<sup>4</sup>

Between March 16 and April 3, 2020, five potential approval holders seeking to develop PAPRs to support the COVID-19 response solicited NIOSH to explore the

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<sup>4</sup> APIC, *Protecting Healthcare Workers During the COVID-19 Pandemic: A Survey of Infection Preventionists* (March 27, 2020), [https://apic.org/wp-content/uploads/2020/03/Protecting-Healthcare-Workers-Survey\\_Report\\_3\\_26\\_20\\_Final.pdf](https://apic.org/wp-content/uploads/2020/03/Protecting-Healthcare-Workers-Survey_Report_3_26_20_Final.pdf).

possibility of producing PAPRs for healthcare and emergency responders to increase the inventory of PAPRs across the nation. NIOSH expects that PAPR100s will be purchased to replace the current inventory of larger class HE devices designed for industrial use, as well as to substitute for the use of disposable N95 filtering facepiece respirators which require fit testing for effective use. NIOSH expects that the addition of PAPR100 devices to the marketplace will help to relieve the current high demand for possibly hundreds of thousands of additional particulate filtering facepiece respirators designed specifically for healthcare settings.

#### E. History of the PAPR100 Concept

NIOSH held a series of public meetings from 2003 through 2008 to discuss technical issues regarding a new PAPR concept.<sup>5</sup> Participants raised issues regarding the existing PAPR certification requirements and offered input on the need to eliminate the silica dust test and incorporate warnings for low air flow, pressure, and/or battery life.

In response to the growing number of PAPRs in healthcare, NIOSH sponsored an Institute of Medicine (IOM) workshop on the “Use and Effectiveness of PAPRs in Healthcare” in 2014.<sup>6</sup> The intent of the workshop was to assist NIOSH with prioritizing and updating approval requirements for NIOSH-approved PAPRs suitable for use in the healthcare sector. IOM workshop participants included government agencies, healthcare institutions, professional associations, respirator manufacturers, and unions representing healthcare workers. A general finding from the IOM workshop stated that current PAPR requirements are not always suitable for the healthcare work environment. Workshop

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<sup>5</sup> Transcripts of the public meetings as well as presentations and submissions from interested parties are available in NIOSH Dockets 008 and 008a.

<sup>6</sup> IOM [2015], *The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary* (National Academies Press: Washington D.C.).

participants indicated that powered air-purifying respirators should have the following attributes:

- Suitable for use in sterile field;
- Good visibility and communication;
- Ease of donning, doffing, and cleaning;
- Variable flows based on work rates;
- Smaller and less bulky;
- Sensors and alarms that monitor flow and power; and
- Training materials as part of certification.

In addition to the IOM workshop, NIOSH reached out to the International Safety Equipment Association (ISEA) and 10 manufacturers of NIOSH-approved PAPRs in August and September 2016 to better understand how current requirements impact PAPR designs and how today's technologies are being integrated into PAPR designs. According to the input NIOSH received, the aerosol threat in the healthcare setting, as compared with the industrial settings the current PAPR class HE requirements in part 84 are designed to address, is composed mainly of respirable-sized (or smaller) particles, with practically no other larger particles in the mix. Therefore, the ability to continue to provide needed air flow against high total filter loading is not a necessary consideration for PAPRs suitable for use in the healthcare setting. These experts indicated the following main areas of concern:

1. Silica dust testing adds to the size and weight of PAPR systems.
2. Silica dust test equipment is outdated and the test is a challenge to reproduce, not representative of today's workplace dust conditions, and requires operational safeguards to avoid the test operator's hazardous exposure to silica dust.
3. If the PAPR continuously monitors critical conditions such as flow, pressure, and battery life, the silica dust test would not be needed since the complete system is also evaluated with a quantitative human subject testing (corn oil test).
4. Technologies such as sensors and alarms for monitoring airflow rate, battery life, facepiece pressure, and other critical components are being integrated into many of today's PAPR designs. The current PAPR requirements prevent these technologies from being fully deployed.

NIOSH presented its new PAPR concept at the 2016 biennial International Society for Respiratory Protection (ISRP) conference in Yokohama, Japan and the 2017 meetings of the ISRP Americas Section in Pittsburgh, Pennsylvania and the National Academies Standing Committee on Personal Protective Equipment for Workplace Safety and Health. Attendees of these meetings generally supported the concepts presented.

By modifying and replacing some of the current PAPR requirements, NIOSH would enable manufacturers to take advantage of contemporary technology that could result in smaller and lighter-weight PAPRs having the same effective particulate protections while increasing workplace utility for today's diverse workforces. The addition of requirements for NIOSH-approved PAPRs intended for healthcare and other settings with lower overall particulate presence would allow stakeholders to incorporate additional technologies such as integrated circuits, sensors, batteries, motors, plastics, and fabrics to improve PAPR designs intended to be used in cleaner settings, such as healthcare.

#### F. Impact on Rulemaking and Other Activities of OSHA

The interim final rule would not require OSHA to make any changes to 29 CFR 1910.134, the OSHA respiratory protection requirements.

#### **IV. Issuance of an Interim Final Rule with Immediate Effective Date**

Rulemaking under the Administrative Procedure Act (APA) generally requires a public notice and comment period and consideration of the submitted comments prior to promulgation of a final rule (5 U.S.C. 553). However, the APA provides for exceptions to

its notice and comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In accordance with the provisions in 5 U.S.C. 553(b)(B), HHS finds good cause to waive the use of prior notice and comment procedures for this interim final rule and to make this action effective immediately.

This interim final rule amends 42 CFR part 84 to allow respirator manufacturers to produce an equally protective or equivalent new class of PAPR, the PAPR100, including both N-series and P-series particulate respirators, designed for use in healthcare or other workplace settings that will benefit the most from smaller, lighter devices. HHS has determined that it is impracticable to use prior notice and comment procedures for this interim final rule because of the ongoing public health emergency. As discussed above, respirator manufacturers have participated in discussions with NIOSH about the need for these new standards and are generally supportive of this effort. Recently, some manufacturers have notified NIOSH that they are ready to submit approval applications for PAPR100s that would be employable in the current public health emergency as soon as the effective date of this interim final rule. Thus, HHS is waiving the prior notice and comment procedures in the interest of protecting the health of healthcare workers and emergency responders who are on the front lines of the current public health emergency as soon as possible.

Under 5 U.S.C. 553(d)(3), HHS also finds good cause to make this interim final rule effective immediately. As stated above, in order to protect the health of healthcare workers and emergency responders, it is necessary that HHS act quickly to amend the existing standards in 42 CFR part 84 to allow NIOSH to approve a new class of PAPR

suitable for use in healthcare settings. The addition of this new class of respirator to the market will improve safety of healthcare workers because it will result in the development of PAPRs that are less bulky, less noisy, and more suitable for use in healthcare and emergency response settings to meet the immediate needs of those treating patients during the COVID-19 pandemic. The cost of these devices is expected to be lower than the costs of PAPRs currently on the market. Loose-fitting PAPRs do not require fit testing, and because the devices are reusable and have a higher filter efficiency and higher assigned protection factor, thus they are a cost-effective alternative to other respiratory protective devices currently on the market. Because these PAPRs are reusable, it is likely that 1 percent of the stock of PAPRs would be required compared to that of single-use items such as the N95 filtering facepiece respirator, assuming the ability to reuse a PAPR one hundred times. Healthcare organizations using PAPRs in healthcare settings have reported cleaning their PAPR filters for several years prior to replacement, which is well beyond the 1 percent estimate.

While amendments to part 84 are effective on the date of publication of this interim final rule, we request public comment on this rule. After full consideration of public comments, HHS will publish a final rule with any necessary changes. (See Section I. Public Participation, above.)

## **V. Summary of Interim Final Rule**

As discussed above, this interim final rule consolidates all air-purifying particulate respirator requirements in 42 CFR part 84, subpart K, and establishes alternative requirements for the testing and approval of class PAPR100 respirators

designed for use in settings such as healthcare, public safety, and other workplaces that require or otherwise place a premium on the use of smaller, lighter devices. Other existing sections in part 84 that reference subpart KK are updated as necessary.

The table directly below matches the reorganized part 84, subpart K, with the originating sections in the current regulation. These changes are discussed in full below the table.

**REORGANIZATION AND SECTION TITLE AMENDMENTS**

Interim final rule section		Originating section	
84.170(a)	Non-powered air-purifying particulate respirators (series N, R, and P).	84.170	Non-powered air-purifying particulate respirators; description
84.170(b)	Powered air-purifying particulate respirators (PAPR classes HE and PAPR100)	84.1100(d)	Scope and effective dates -- powered air-purifying particulate respirator
		84.1130(a)(4)	Respirators, description – air-purifying respirators  New for PAPR100 class
84.171	Required components and attributes	84.171	Non-powered air-purifying particulate respirators; required components
		84.1131	Respirators; required components
84.171(a)	Respiratory inlet covering	84.175	Half-mask facepiece, full facepiece, hoods, helmets, and mouthpieces; fit; minimum requirements
		84.171(a)	Non-powered air-purifying particulate respirators; required components
		84.1135	Half-mask facepiece, full facepiece, hoods, helmets, and mouthpieces; fit; minimum requirements
		84.1136	Facepieces, hoods, and helmets; eyepieces; minimum requirements
84.171(b)(1)	Filters for non-powered respirators	84.179	Non-powered air-purifying particulate respirators; filter identification
84.171(b)(2)	Filters for powered respirators	84.1130(a)(4)	Respirators; description -- Powered air-purifying particulate respirators; filter identification
84.171(c)	Valves	84.177 84.1137	Inhalation and exhalation valves; minimum requirements
84.171(d)	Head harness	84.178, 84.1138	Head harness; minimum requirements
84.171(e)	Breathing tube	84.172 84.1132	Breathing tubes; minimum requirements
84.171(f)	Drink tube		New

84.171(g)	Container	84.174 84.1134	Respirator containers; minimum requirements
84.171(h)	Harness	84.173 84.1133	Harnesses; Installation and construction; minimum requirements
84.171(i)	Attached blower	84.1156(f)	Minimum air flows
84.171(j)	Low-flow warning device		New
84.172	Airflow resistance test	84.180  84.1156(a)(1) and (2)  84.1157(a)	Airflow resistance tests  Pesticide respirators; performance requirements; general – breathing resistance test  Chemical cartridge respirators with particulate filters; performance requirements; general – breathing resistance test
84.173	Exhalation valve leakage test	84.182 84.1150	Exhalation valve leakage test; minimum requirements
84.174	Filter efficiency level determination test – non-powered series N, R, and P filtration	84.181	Non-powered air-purifying particulate filter efficiency level determination
84.175	Instantaneous filter efficiency level determination test – PAPR series HE, PAPR100-N, and PAPR100-P filtration	84.1151  84.1156(c)(2)	DOP filter test  Pesticide respirators; performance requirements; general – silica dust test
84.176(a)	Isoamyl acetate (IAA) fit test	84.1156(b)(5)	Pesticide respirators; performance requirements; general -- isoamyl acetate tightness test
84.176(b)	Generated Aerosol		New
84.177	Total noise level test – PAPR classes HE and PAPR100	84.1139	Air velocity and noise levels; hoods and helmets
84.178	Breath response type, airflow resistance test – PAPR classes HE and PAPR100		New
84.179	Silica dust loading test -- PAPR series HE filtration	84.1144  84.1152	Silica dust test for dust, fume, and mist respirators; single-use or reusable filters; minimum requirements  Silica dust loading test
84.180	Particulate loading test – PAPR series PAPR100-N and PAPR100-P filtration		New
84.181	Communication performance test – class PAPR100		New

## Section 84.2 Definitions

In this existing section, located in 42 CFR part 84, subpart A, HHS adds definitions for the terms “respiratory inlet covering,” “tight fitting,” “loose fitting,” and “warning device.”

*Section 84.126 Canister bench tests; minimum requirements.*

In this existing section in subpart I—Gas Masks, a new paragraph (f) specifies that PAPRs designed with one or more canisters and particulate filters must meet the end-of-service-life requirements both as received from the applicant and after being equilibrated at room temperature.

*Section 84.207 Bench tests; gas and vapor tests; minimum requirements; general.*

In this existing section in subpart L—Chemical Cartridge Respirators, a new paragraph (h) specifies that PAPRs designed with one or more canisters and particulate filters must meet the end-of-service-life requirements both as received from the applicant and after being equilibrated at room temperature.

*Subpart K—Air-Purifying Particulate Respirators*

Subpart K is retitled from “Non-Powered Air-Purifying Particulate Respirators” to “Air-Purifying Particulate Respirators.” The intent of the new title is to properly indicate the broadened scope of the subpart, which includes the requirements for both non-powered and powered air-purifying particulate respirators.

*Section 84.170 Air-purifying particulate respirators; description.*

This section provides a general description of air-purifying particulate respirators as a class of respirator. It is intended to inform the public and to serve as a legal and practical definition for the purposes of the NIOSH respirator approval program.

Paragraphs (a)(1), (2), and (3), which describe non-powered devices, remain substantively unchanged from the existing language. New paragraphs (b)(1), (2), and (3) describe PAPRs. Specifically, paragraph (b)(1) provides a general description of PAPRs and paragraph (b)(2) indicates that PAPRs are classified into one of two PAPR classes, HE or PAPR100, and one of three filter series, “HE,” “PAPR100-N,” and “PAPR100-P.” Paragraph (b)(3) establishes that the minimum efficiency level for filters employed as part of powered respirator configurations is 99.97 percent for all three filter series, HE (high-efficiency), PAPR100-N, or PAPR100-P.

Requirements for two series of filters have been established for the PAPR100 class to give manufacturers greater flexibility in designing these devices. The PAPR100-P series filter requirements are established to provide a filter that, like the existing PAPR class HE (high-efficiency series) filter, is suitable for use against all aerosols, including those which are comprised of oils.

The PAPR100-N series filter, which is not intended to be used against oil-based aerosols, has also been added to allow for greater use of electrostatic filter media. New filter efficiency requirements in § 84.180 are intended to allow manufacturers to optimize PAPR100-N series filters for environments with very low concentrations of non-oil based (solid- or water-based) aerosols where disposal of the filter after each use is preferred over extended use. The minimum filtration efficiency for the two new series of PAPR

filters is maintained at 99.97 percent, the minimum filtration efficiency of the existing and ongoing HE series filters.

*Section 84.171 Required components and attributes.*

The title of this existing section is revised to describe the requirements for components and attributes that apply to both powered and non-powered air-purifying particulate respirators. The regulatory language itself is revised to replace terminology such as “facepiece, mouthpiece with nose clip, hood, or helmet” with “respiratory inlet covering”; “half-mask facepieces and full facepieces” with “tight-fitting respiratory inlet coverings”; and “hoods and helmets” with “loose-fitting respiratory inlet coverings.” The entire section is revised to not only include a list of the required components, but to include the required design attributes of those components.

Paragraph (a) specifies the required attributes for the respiratory inlet covering, currently described in §§ 84.175 and 84.1135.

Paragraph (b)(1) addresses the filter unit, currently described in § 84.179 for non-powered devices; paragraph (b)(2) includes new provisions specifying that powered devices must be labeled as series HE (high-efficiency) or series PAPR100-N or -P.

Paragraph (c) addresses valves, currently described in §§ 84.177 and 84.1137.

Paragraph (d) addresses the head harness, currently described in §§ 84.178 and 84.1138.

Paragraph (e) addresses the breathing tube, currently described in §§ 84.172 and 84.1132.

Paragraph (f) is new, and describes requirements for a drink tube, should the design require a drink tube.

Paragraph (g) addresses the container, currently described in §§ 84.174 and 84.1134.

Paragraph (h) addresses the harness, currently described in §§ 84.173 and 84.1133.

Paragraph (i) is moved from § 84.1156(f) to describe the airflow rate required of PAPR HE class and PAPR100 class tight-fitting and loose-fitting respiratory inlet coverings.

Finally, a new paragraph (j) requires a low-flow warning device for the new PAPR100 class respirators only. There are no requirements for PAPR warning devices in 42 CFR part 84 for class HE respirators. However, if any PAPR system is submitted for approval equipped with a warning device, NIOSH verifies that the warning functions properly as per the manufacturer's user instructions. In accordance with this paragraph, the required PAPR100 warning must alert users to breathing air flow that falls below 115 liters per minute for tight-fitting facepieces or 170 liters per minute for loose-fitting hoods and helmets (the minimum required in § 84.175). Warning devices must also be able to be heard or otherwise detected by the wearer and must also be readily distinguishable from one another. For example, if an optional low-battery warning is included in addition to the low-flow warning, it needs to be distinguishable from the required low-flow warning. The PAPR100 warning system must also not de-energize while the unit's blower is energized (*i.e.*, power to the warning system must be

prioritized), and must not switch off automatically or be able to be switched off manually. The warning should remain active until the reason for the warning is corrected.

*Section 84.172 Airflow resistance test.*

This section specifies the test criteria and acceptable performance criteria for inhalation and exhalation resistance of a complete air-purifying particulate respirator. The requirements for non-powered air-purifying particulate respirators are currently specified in § 84.180 and would be consolidated in § 84.172 with requirements for PAPRs, unchanged. The existing requirements for PAPR class HE are moved from § 84.1156(a)(1) and (2) and combined into § 84.172, where the maximum airflow resistance standard for the new class PAPR100 would also be established.

Paragraph (a) addresses the inhalation and exhalation resistance of the complete air-purifying particulate respirator. This paragraph is essentially unchanged in meaning but updated from the existing language in § 84.180(a) to reflect industry standard terminology, replacing “facepiece, mouthpiece, hood, or helmet” with “respiratory inlet covering.”

Paragraph (b) indicates that the airflow resistance of tight-fitting PAPRs is measured with the blower off if the model is designed not to be immediately doffed in the event of a blower failure.

Paragraph (c) maintains the current requirements in § 84.1157(a) for the maximum inhalation and exhalation resistances of complete PAPRs (both classes HE and PAPR100) and the current requirements in § 84.180(b) for non-powered air-purifying respirators.

*Section 84.173 Exhalation valve leakage test.*

This section contains the existing requirements in §§ 84.182 and 84.1150 that describe the NIOSH tests for exhalation valve leakage. The exhalation valve leakage testing is conducted on both non-powered and powered devices.

*Section 84.174 Filter efficiency level determination test – non-powered series N, R, and P filtration.*

Text from existing section § 84.181 specifies the test criteria and acceptable performance criteria for non-powered air-purifying particulate filter efficiency levels; it is re-numbered § 84.173. This section is also re-named to clarify the content and indicate its application for all types of air-purifying particulate respirators. The word “shall” is replaced with “will” throughout the section, to clarify intent and reflect plain language principles. No substantive changes are made to the testing requirements and technical standards for filter efficiency for non-powered devices.

*Section 84.175 Instantaneous filter efficiency level determination test – PAPR series HE, PAPR100-N, and PAPR100-P filtration.*

This new section describes the NIOSH filter efficiency testing requirements for both classes of PAPR and all three particulate series filters, HE, PAPR100-N, and PAPR100-P. This instantaneous dioctyl phthalate (DOP) test is unchanged from the current § 84.1151. PAPRs are tested at the minimum required flow rates specified in § 84.1156(c)(2).

Paragraph (a) indicates that three filters from each powered air-purifying particulate respirator will have their filtration efficiency evaluated using DOP.

Paragraph (b) describes the current atmospheric concentration of DOP. The test concentration, 100 milligrams per cubic meter, is unchanged. Paragraph (b) also includes the airflow rates for tight- and loose-fitting respiratory inlet coverings currently found in § 84.1156(c)(2).

Paragraph (c) indicates that PAPRs designed with multiple filters will be tested by dividing the specified flow rate by the total number of filters.

Finally, paragraph (d) requires the filters, including holders and gaskets, when separable, to be tested while mounted on a test fixture in the manner as used on the respirator. This allows NIOSH to test the assembly in a configuration as it will actually be used.

*Section 84.176 Fit test – PAPR classes HE and PAPR100.*

This section specifies the test criteria and acceptable performance criteria to fit test a complete PAPR. Two options are available to assess fit: isoamyl acetate (IAA) or generated aerosol.

Paragraph (a) specifies the existing IAA tightness test, originally established in subpart KK, § 84.1156(a)(5). The IAA testing standard is unchanged.

Paragraph (b) describes a new generated aerosol (corn oil) test, intended as an alternative to the IAA method for those powered devices that are equipped solely with particulate filters. The corn oil quantitative fit test was developed by NIOSH, at the behest of respirator manufacturers, and has been used as a voluntary substitute test in

place of the qualitative IAA test for series HE PAPRs since approximately 2008. This test utilizes a concentration of 20-40 milligrams per cubic meter of corn oil aerosol with a mass median aerodynamic diameter of 0.4 to 0.6 micrometers. Paragraph (b)(1) describes the work schedule performed by the wearer during the test. The activities that are specified in this paragraph – nodding and turning head, calisthenic arm movements, running in place, and pumping a tire pump – are used by the agency to test the facepiece fit of respirator types by simulating the types of activities workers might perform while wearing the respirator.

Paragraph (b)(2) allows NIOSH to verify that the facepiece is capable of adjustment and that the applicant’s donning instructions should be followed. Paragraph (b)(3) requires that the appropriate fit factors for the applicant respirator be exceeded.

*Section 84.177 Total noise level test – PAPR classes HE and PAPR100.*

This section replicates the testing standard for PAPR noise levels currently found in § 84.1139. The standard requires that the noise levels generated by any PAPR (*i.e.*, HE hood or helmet and any PAPR100) must not exceed 80 decibels using the A-weighting frequency response (dBA) measured at each ear location while the system operates at its maximum airflow obtainable. Today, PAPR designs include head-, neck-, and face-mounted blowers in closer proximity to the user’s ears. Additionally, for class HE hood and helmet designs, the provision is revised to clarify that the noise level measurement will be taken at the entrance to the ear rather than “inside the hood or helmet” as the standard currently states.

*Section 84.178 Breath response type, airflow resistance test – PAPR classes HE and PAPR100.*

This new section specifies the minimum test criteria for a breath-responsive PAPR. Breath-responsive PAPRs are designed to maintain a positive pressure in the facepiece to match the user’s respiratory requirements. Current PAPR requirements in 42 CFR part 84 do not address these design features. Therefore, pursuant to 42 CFR §§ 84.60 and 84.63, these types of PAPRs have been evaluated using the requirements of 42 CFR § 84.157, which are applicable to certain types of atmosphere-supplying respirators.

This section specifies that the breath-responsive PAPR airflow will be measured with a breathing machine described in § 84.88(b) and (c). Paragraph (a) specifies that the minimum inhalation resistance shall be greater than zero. Paragraph (b) specifies that the maximum exhalation resistance must be less than 89 millimeters (3.5 inches) of water-column height, in accordance with current requirements in § 84.91(c) and (d).

*Section 84.179 Silica dust loading test -- PAPR series HE filtration.*

This section contains the requirements from existing §§ 84.1144 and 84.1152, which are themselves removed from part 84 in this action. This section specifies the test criteria for the silica dust loading test of a complete powered PAPR series HE. This test procedure is not used to test PAPR100-N or -P series devices, which NIOSH expects will allow PAPR100 designs to be smaller and lighter than series HE devices. Paragraphs (a) and (f), respectively, specify the test period and flowrate as well as the amount of unretained test suspension; these testing standards are taken from § 84.1152. Paragraphs

(b), (c), (d), and (e) establish the test chamber conditions and size and concentration of the test particulate.

*Section 84.180 Particulate loading test – PAPR series PAPR100-N and PAPR100-P filtration.*

This new section adopts the existing particulate loading test for non-powered air-purifying respirators in § 84.181, applying it to both PAPR100 series filters. Paragraph (a) specifies that NIOSH will test the efficiency of 20 filters of each powered air-purifying particulate respirator model submitted for a class PAPR100 approval.

Paragraph (a)(1) specifies that NIOSH will use a sodium chloride aerosol when testing PAPR100-N series filters. Paragraph (a)(2) specifies that NIOSH will use a dioctyl phthalate or equivalent aerosol when testing PAPR100-P series filters.

Paragraph (b) requires that 20 PAPR100-N series filters be preconditioned with humid air prior to being subjected to the filtration efficiency loading test specified in paragraph (d)(1).

Paragraph (c) specifies the continuous test aerosol flow rates for the filter efficiency testing. Single filters are to be tested at a rate of  $85\pm 4$  liters per minute; filters used in pairs at a rate of  $42.5\pm 2$  liters per minute through each filter; and filters used in threes at a rate of  $28.3\pm 1$  liters per minute through each filter.

Paragraph (d)(1) specifies the filter efficiency test aerosol for series PAPR100-N, sodium chloride or an equivalent solid aerosol. The test conditions for the solid aerosol are specified to be at  $25\pm 5$  degrees Celsius. The sodium chloride aerosol specified to be used in these tests is to be neutralized to the Boltzmann equilibrium state, and the

maximum concentration will not exceed 200 milligrams per cubic meter. This paragraph also specifies the particle size, and size distribution of the sodium chloride test aerosol at a count median diameter of  $0.075 \pm 0.020$  micrometer and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

Paragraph (d)(2) specifies the filter efficiency test aerosol for series PAPR100-P, DOP or an equivalent oil liquid particulate aerosol. The test conditions for the liquid aerosol are specified to be at  $25 \pm 5$  degrees Celsius. The DOP aerosol specified to be used in these tests is to be neutralized to the Boltzmann equilibrium state, and the maximum concentration will not exceed 200 milligrams per cubic meter. This paragraph also specifies the particle size, and sized distribution of the DOP test aerosol at a count median diameter of  $0.185 \pm 0.020$  micrometer and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

Paragraph (e) specifies that both the solid and the liquid aerosol filtration efficiency test must continue until minimum efficiency is achieved or until an aerosol mass of  $200 \pm 5$  milligrams has contacted the filter. This paragraph further specifies that for PAPR100-P series filters, if the filter efficiency is decreasing when the  $200 \pm 5$  mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.

Paragraph (f) requires the efficiency of the filter (*i.e.*, the amount of aerosol particles that are removed by the filter) to be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

Paragraph (g) requires the minimum filter efficiency for each of the 20 filters to be determined and recorded. The minimum efficiency of each tested filter must be greater than or equal to 99.97 percent for both PAPR100-N and PAPR100-P series filters.

*Section 84.181 Communication performance test – PAPR class PAPR100.*

This new section specifies testing criteria for PAPR communication performance. The 2014 IOM workshop highlighted the limitations posed by PAPRs with regard to communication with patients, potentially compromising patient safety. This test is intended to address healthcare, first responders, and other workers' needs for PAPR100s designed and tested to ensure a PAPR's ability to meet a minimum communication performance level of speech conveyance and intelligibility.

Paragraph (a) requires that PAPR100s are designed to allow minimum communication while being worn.

Paragraph (b) specifies that the Modified Rhyme Test (MRT) will be used to conduct the test. The MRT consists of lists of 50 monosyllabic, phonetically-balanced words and evaluates a listener's ability to comprehend single words spoken by the respirator wearer.

Paragraph (c) specifies that for each MRT trial the overall performance rating is calculated. The performance rating is the ratio of the number of correct responses to the number of incorrect responses with and without a respirator being worn. To obtain a passing score, the PAPR100 must obtain an average overall performance rating greater than or equal to 70 percent.

**VI. Regulatory Assessment Requirements**

A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This interim final rule has been determined to be a “significant regulatory action” under section 3(f) of E.O. 12866. The rulemaking is considered a deregulatory action because it removes a barrier to the manufacturing, labeling as NIOSH-approved, and selling of new PAPR designs intended for healthcare and other workplace settings. With the promulgation of the interim final requirements, manufacturers have a choice to submit approval applications under either the existing PAPR class HE standard or the new class PAPR100 standard.

The new PAPR100 respirators are required to meet most of the requirements and testing standards applied to class HE respirators except for the silica dust loading test in § 84.179, which requires that the device perform for a minimum service time of 4 hours. Three new requirements – a low-flow warning device (§ 84.171(j)), particulate loading test (§ 84.180), and communication performance testing (§ 84.181) – apply to class PAPR100 respirators only. HHS requests data that would facilitate quantification of: (a) the incremental cost savings resulting from the removal of the silica dust loading test

requirements, and (b) the incremental costs resulting from each of the three new requirements.

This rule does not impose any mandatory costs on the public and benefits manufacturers who choose to develop a product under these new technical requirements. Healthcare facilities that currently utilize PAPR class HE devices that are designed for industrial use may also see a cost saving because class PAPR100 respirators designed for healthcare or other workplace settings may be more affordable than the current devices. In discussions with NIOSH, manufacturers have indicated that the cost of future class PAPR100 respirators is likely to be substantially less than the current cost of class HE devices. HHS requests data that would facilitate estimation of: (a) the increase in PAPR device availability resulting from this likely cost reduction, and (b) the timing of such availability relative to the issuance of this interim final rule.

HHS also requests data or other comment relevant to the benefits of this rulemaking—including, but not limited to, quantitative evidence on the duration of worker exposure to the hazards that class PAPR100 devices and other respirators protect against.

#### B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking when a general notice of proposed rulemaking is not required. 5 U.S.C. 603 and 604. As noted previously, the Agencies have determined for good cause that it is impracticable and contrary to the public interest to publish a general notice of proposed rulemaking for this

joint final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

### 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 April 30, 2021). Due to this interim final rule, which would allow for the NIOSH approval of respirators in a new class, PAPR100, there is likely to be a change in burden in the approved collection of information.

Based on PAPR activity over the last several years and also the increased number of related inquiries in response to the COVID-19 pandemic, NIOSH estimates that up to 5 respirator manufacturers may submit approximately 23 applications for PAPR100 approvals to the National Personal Protective Technology Laboratory from April 2020 through April 2021. Each application is expected to require an average of 229 hours to complete and maintain.

Accordingly, NIOSH expects 5,267 burden hours to be attributed to applications for PAPR100 approvals. NIOSH estimates an hourly wage rate of \$79.89 (wage data is the average unspecified manufacturing industry engineer wage of \$45.68 as reported in

the 2016 National Sector NAICS Industry-Specific estimates multiplied by 1.06 inflation adjustment and 1.65 factor for overhead expenses).

Section	Title	Number of respondents	Average responses per respondent	Average burden per response (hr)	Total burden (hr)
§ 84.170	Air-purifying particulate respirators; description	5	4.6	229	5,267

Section	Title	Total Burden Hours (from above)	Estimated Hourly Wage Rate	Total Cost of Hour Burden
§ 84.170	Air-purifying particulate respirators; description	5,267	79.89	\$420,780

The agency will submit the adjustment in burden for OMB Control No. 0920-0109 to OMB for its emergency review and approval.

D. Congressional Review Act

As required by Congress under the Congressional Review Act (5 U.S.C. 801 *et seq.*), HHS will report the promulgation of this rule to Congress prior to its effective date. This rule is not likely to result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of

Information and Regulatory Affairs designated this rule as not a “major rule,” as defined by 5 U.S.C. 804(2).

#### 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 interim 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.

#### F. Executive Order 12988 (Civil Justice Reform)

This interim final 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.

#### G. Executive Order 13132 (Federalism)

HHS has reviewed this interim final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this interim final rule on children. HHS has determined that the rule would have no environmental health and safety 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 interim 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 interim final rule 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**

Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

**Final Rule**

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

**PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES**

1. The authority citation for part 84 continues to read as follows:

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

**Subpart A—General Provisions**

2. Amend § 84.2 by adding definitions for “Loose fitting”, “Respiratory inlet covering”, “Tight fitting”, and “Warning device” in alphabetical order to read as follows:

**§ 84.2 Definitions.**

\* \* \* \* \*

*Loose fitting* means respiratory inlet covering that covers the wearer’s head and neck, or head, neck, and shoulders, or whole body (when integral to the design).

\* \* \* \* \*

*Respiratory inlet covering* means that portion of a respirator that forms the protective barrier between the user’s respiratory tract and an air-purifying device or breathing air source, or both.

\* \* \* \* \*

*Tight fitting* means a respiratory inlet covering that forms a complete gas tight or dust tight seal with the face or neck.

\* \* \* \* \*

*Warning device* is a component of a respiratory protective device that informs the wearer to take some action.

### **Subpart G—General Construction and Performance Requirements**

#### **§ 84.60 [Amended]**

3. Amend § 84.60, in paragraph (a), by removing the words “subparts H through KK” and adding in their place the words “subparts H through O”.

#### **§ 84.63 [Amended]**

4. Amend § 84.63, paragraphs (a) through (c) by removing the words “subparts H through KK” and adding in their place the words “subparts H through O”.

#### **§ 84.64 [Amended]**

5. Amend § 84.64, in paragraph (b), by removing the words “subparts H through KK” and adding in their place the words “subparts H through O”.

#### **§ 84.65 [Amended]**

6. Amend § 84.65, in paragraph (a), by removing the words “subparts H through KK” and adding in their place the words “subparts H through O”.

### **Subpart I—Gas Masks**

#### **§ 84.125 [Amended]**

7. Amend § 84.125 by removing the words “§§ 84.170 through 84.183, except for the airflow resistance test of § 84.181” and adding in their place the words “§§ 84.170 through 84.181, except for the airflow resistance test of § 84.172”.

8. Amend § 84.126 by adding paragraph (f) to read as follows:

#### **§ 84.126 Canister bench tests; minimum requirements.**

\* \* \* \* \*

(f) Powered air-purifying respirators with a canister(s) and particulate filter(s) must meet the as-received minimum service-life requirements and half of the equilibrated minimum service-life requirements set forth in Tables 5, 6, and 7 of subpart I using the flows specified in subpart K, § 84.175(b) and equilibrated in accordance with paragraphs (a) through (e) of this section using the flows specified in subpart K, § 84.175(b).

## **Subpart L—Chemical Cartridge Respirators**

### **§ 84.206 [Amended]**

9. Amend § 84.206, in paragraph (b), by removing the words “§§ 84.179 through 84.183” and adding in their place the words “§§ 84.170 through 84.181”.

10. Amend § 84.207 by adding paragraph (h) to read as follows:

### **§ 84.207 Bench tests; gas and vapor tests; minimum requirements; general.**

\* \* \* \* \*

(h) Powered air-purifying respirators with a cartridge(s) and particulate filter(s) must meet the as-received minimum service-life requirements and half of the equilibrated minimum service-life requirements set forth in table 11 of subpart L using the flows specified in subpart K, § 84.175(b) and equilibrated in accordance with paragraphs (a) through (g) of this section using the flows specified in subpart K, § 84.175(b).

11. Subpart K is revised to read as follows:

## **Subpart K—Air-Purifying Particulate Respirators**

Sec.

84.170 Air-purifying particulate respirators; description.

84.171 Required components and attributes.

84.172 Airflow resistance test.

84.173 Exhalation valve leakage test.

84.174 Filter efficiency level determination test – non-powered series N, R, and P filtration.

- 84.175 Instantaneous filter efficiency level determination test – PAPR series HE, PAPR100-N, and PAPR100-P filtration.
- 84.176 Fit test – PAPR classes HE and PAPR100.
- 84.177 Total noise level test – PAPR classes HE and PAPR100.
- 84.178 Breath response type, airflow resistance test – PAPR classes HE and PAPR100.
- 84.179 Silica dust loading test – PAPR series HE filtration.
- 84.180 Particulate loading test – PAPR series PAPR100-N and PAPR100-P filtration.
- 84.181 Communication performance test – PAPR class PAPR100.

## **Subpart K—Air-Purifying Particulate Respirators**

### **§ 84.170 Air-purifying particulate respirators; description.**

(a) *Non-powered air-purifying particulate respirators (series N, R, and P).* (1)

Non-powered air-purifying particulate respirators 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.

(2) Non-powered air-purifying particulate respirators are classified into three series, N-, R-, and P-series. The N-series filters are restricted to use in those workplaces free of oil aerosols. The R- and P-series filters are intended for removal of any particulate that includes oil-based liquid particulates.

(3) Non-powered air-purifying particulate respirators are classified according to the efficiency level of the filter(s) as tested according to the requirements of this part.

(i) N100, R100, and P100 filters must demonstrate a minimum efficiency level of 99.97 percent.

(ii) N99, R99, and P99 filters must demonstrate a minimum efficiency level of 99 percent.

(iii) N95, R95, and P95 filters must demonstrate a minimum efficiency level of 95 percent.

(b) *Powered air-purifying particulate respirators (PAPR classes HE and PAPR100)*. (1) Powered air-purifying particulate respirators utilize a blower to move the ambient air through the air-purifying filter elements (filters) to remove particulate contaminants and deliver clean air to the respiratory inlet covering. They are designed for use as respiratory protection against atmospheres considered not immediately dangerous to life or health and that contain adequate oxygen to support life.

(2) Powered air-purifying particulate respirators are classified into two classes, HE and PAPR100, and three series, HE, PAPR100-N, and PAPR100-P. The N-series filters are restricted to use in those workplaces free of oil aerosols. The P-series filters are intended for removal of any particulate that includes oil-based liquid particulates.

(3) All three filter series, HE, PAPR100-N, and PAPR100-P, for powered air-purifying particulate respirators must demonstrate a minimum efficiency level of 99.97 percent.

**§ 84.171 Required components and attributes.**

The components of each air-purifying particulate respirator must meet the minimum construction requirements set forth in subpart G of this part. Each air-purifying particulate respirator described in § 84.170 must, where its design requires, contain the following component parts:

(a) *Respiratory inlet covering*. (1) Tight fitting respiratory inlet coverings must be designed and constructed to fit persons with various facial shapes and sizes either:

(i) By providing more than one size; or

(ii) By providing one size which will fit varying facial shapes and sizes.

(2) Full facepieces must provide for optional use of corrective spectacles or lenses, which must not reduce the respiratory protective qualities of the respirator.

(3) Loose fitting respiratory inlet coverings must be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(4) Mouthpieces must be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight seal.

(5) Respiratory inlet coverings that incorporate a lens or faceshield must be designed to prevent eyepiece fogging.

(6) Half-mask facepieces must not interfere with the fit of common industrial safety spectacles, including corrective safety spectacles.

(7) Respiratory inlet coverings must be designed and constructed to provide adequate vision which is not distorted by the eyepieces.

(b) *Filter unit.* The respirator manufacturer, as part of the application for certification, must specify the filter series and the filter efficiency level (*i.e.*, “N95,” “R95,” “P95,” “N99,” “R99,” “P99,” “N100,” “R100,” “P100,” “HE,” “PAPR100-N” or “PAPR100-P”) for which certification is being sought.

(1) Filters for non-powered respirators (series N, R, and P) must be prominently labeled as follows:

(i) N100 filters must be labeled “N100 Particulate Filter (99.97% filter efficiency level)” and must be a color other than magenta.

(ii) R100 filters must be labeled “R100 Particulate Filter (99.97% filter efficiency level)” and must be a color other than magenta.

(iii) P100 filters must be labeled “P100 Particulate Filter (99.97% filter efficiency level)” and must be color coded magenta.

(iv) N99 filters must be labeled “N99 Particulate Filter (99% filter efficiency level)” and must be a color other than magenta.

(v) R99 filters must be labeled “R99 Particulate Filter (99% filter efficiency level)” and must be a color other than magenta.

(vi) P99 filters must be labeled “P99 Particulate Filter (99% filter efficiency level)” and must be a color other than magenta.

(vii) N95 filters must be labeled as “N95 Particulate Filter (95% filter efficiency level)” and must be a color other than magenta.

(viii) R95 filters must be labeled as “R95 Particulate Filter (95% filter efficiency level)” and must be a color other than magenta.

(ix) P95 filters must be labeled as “P95 Particulate Filter (95% filter efficiency level)” and must be a color other than magenta.

(2) Filters for powered respirators (classes HE and PAPR100) must be prominently labeled as follows:

(i) HE filters must be labeled as “HE Particulate Filter (99.97% filter efficiency level)” and must be color coded magenta.

(ii) PAPR100-N filters must be labeled as “PAPR100-N Particulate Filter (99.97% filter efficiency level)” and must be color coded magenta.

(iii) PAPR100-P filters must be labeled as “PAPR100-P Particulate Filter (99.97% filter efficiency level)” and must be color coded magenta.

(c) *Valves*. (1) Inhalation and exhalation valves must be protected against distortion.

(2) Inhalation valves must be designed and constructed and provided where necessary to prevent excessive exhaled air from adversely affecting filters, except where filters are specifically designed to resist moisture.

(3) Exhalation valves must be:

(i) Provided where necessary;

(ii) Protected against damage and external influence; and

(iii) Designed and constructed to prevent inward leakage of contaminated air.

(d) *Head harness*. (1) All facepieces must be equipped with head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

(2) Facepiece head harnesses, except those employed on filtering facepiece respirators, must be adjustable and replaceable.

(3) Mouthpieces must be equipped, where applicable, with adjustable and replaceable harnesses, designed and constructed to hold the mouthpiece in place.

(e) *Breathing tube*. Flexible breathing tubes used in conjunction with respirators must be designed and constructed to prevent:

(1) Restriction of free head movement;

(2) Disturbance of the fit of facepieces, mouthpieces, or loose fitting respiratory-inlet covering;

(3) Interference with the wearer's activities; and

(4) Shutoff of airflow due to kinking, or from chin or arm pressure.

(f) *Drink tube.* (1) For particulate respirators equipped with a drink tube, the respirator must meet all requirements of the standard with the drink tube in place.

(2) Dry drinking tube assembly will be subjected to a suction of 75 mm water column height while in a normal operating position (closed).

(3) Leakage through the drinking tube assembly must not exceed 30 mL per minute.

(g) *Container.* (1) Except as provided in paragraph (b) of this section, each respirator must be equipped with a substantial, durable container bearing markings which show the applicant's name, the type of respirator it contains, and all appropriate approval labels.

(2) Containers for respirators may provide for storage of more than one respirator; however, such containers must be designed and constructed to prevent contamination of respirators which are not removed, and to prevent damage to respirators during transit.

(h) *Harness.* (1) Each respirator must, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(2) Harnesses must be designed and constructed to permit easy removal and replacement of respirator parts, and, where applicable, provide for holding a full facepiece in the ready position when not in use.

(i) *Attached blower –PAPR classes HE and PAPR100.* Blowers must be designed to achieve the air flow rates required by the testing standards in § 84.175.

(j) *Low-flow warning device – PAPR class PAPR100.* (1) The design must include a low-flow warning. It must actively and readily indicate when flow inside the respiratory inlet covering falls below the minimum air flow defined in § 84.175.

(2) Any warning must be detectable by the wearer without any intervention by the wearer.

(3) Warning devices must be configured so that they may not be de-energized while the blower is energized.

(4) During use, warning devices must not switch off automatically and must not be capable of being switched off by the wearer.

(5) Any warnings which require different reactions by the wearer must be distinguishable from one another.

(6) If the warning provided is audible only, or other warnings are not readily apparent to the wearer, the minimum sound level must be 80 dBA.

**§ 84.172 Airflow resistance test.**

(a) Resistance to airflow will be measured in the tight-fitting respiratory inlet covering of a complete particulate respirator mounted on a test fixture with air flowing at continuous rate of  $85 \pm 2$  liters per minute, before each test conducted in accordance with § 84.173.

(b) Resistance of a complete tight-fitting powered air-purifying particulate respirator system will be measured with the blower off if the manufacturer indicates that the respirator should not be doffed in the event of a blower failure.

(c) The maximum allowable resistance requirements for air-purifying particulate respirators are as follows:

**MAXIMUM RESISTANCE  
(mm water-column height)**

Respirator Type	Inhalation		Exhalation
	Initial	Final	
Non-Powered (N, R, and P)	35	N/A	25
Powered (tight fitting) (HE class and PAPR100 class)	50	70	20

**§ 84.173 Exhalation valve leakage test.**

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat must not exceed 30 mL per minute.

**§ 84.174 Filter efficiency level determination test – non-powered series N, R, and P filtration.**

(a) Twenty filters of each non-powered air-purifying particulate respirator model will be tested for filter efficiency against:

(1) A solid sodium chloride particulate aerosol as per this section, if N-series certification is requested by the applicant.

(2) A dioctyl phthalate (DOP) or equivalent liquid particulate aerosol as per this section, if R-series or P-series certification is requested by the applicant.

(b) Filters including holders and gaskets, when separable, will be tested for filter efficiency level, as mounted on a test fixture in the manner as used on the respirator.

(c) Prior to filter efficiency testing of 20 N-series filters, the 20 to be tested will be taken out of their packaging and placed in an environment of 85 ±5 percent relative humidity at 38 ±2.5 °C for 25 ±1 hours. Following the pre-conditioning, filters will be sealed in a gas-tight container and tested within 10 hours.

(d) When the filters do not have separable holders and gaskets, the exhalation valves will be blocked so as to ensure that leakage, if present, is not included in the filter efficiency level evaluation.

(e) For non-powered air-purifying particulate respirators with a single filter, filters will be tested at a continuous airflow rate of  $85 \pm 4$  liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate will be  $42.5 \pm 2$  liters per minute through each filter.

(f) Filter efficiency test aerosols:

(1) When testing N-series filters, a sodium chloride or equivalent solid aerosol at  $25 \pm 5$  °C and relative humidity of  $30 \pm 10$  percent that has been neutralized to the Boltzmann equilibrium state will be used. Each filter will be challenged with a concentration not exceeding  $200 \text{ mg/m}^3$ .

(2) When testing R-series and P-series filters, a neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at  $25 \pm 5$  °C that has been neutralized to the Boltzmann equilibrium state will be used. Each filter will be challenged with a concentration not exceeding  $200 \text{ mg/m}^3$ .

(3) The test will continue until minimum efficiency is achieved or until an aerosol mass of at least  $200 \pm 5$  mg has contacted the filter. For P-series filters, if the filter efficiency is decreasing when the  $200 \pm 5$  mg challenge point is reached, the test will be continued until there is no further decrease in efficiency.

(g) The sodium chloride test aerosol will have a particle size distribution with count median diameter of  $0.075 \pm 0.020$   $\mu\text{m}$  and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility

particle sizer or equivalent. The DOP aerosol will have a particle size distribution with count median diameter of  $0.185 \pm 0.020 \mu\text{m}$  and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

(h) The efficiency of the filter will be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

(i) The minimum efficiency for each of the 20 filters will be determined and recorded and must be equal to or greater than the filter efficiency criterion listed for each level as follows:

<b>Filter Series</b>	<b>Efficiency (%)</b>
P100, R100, N100.....	$\geq 99.97$
P99, R99, N99.....	$\geq 99$
P95, R95, N95.....	$\geq 95$

**§ 84.175 Instantaneous filter efficiency level determination test – PAPR series HE, PAPR100-N, and PAPR100-P filtration.**

(a) Three filters from each powered air-purifying particulate respirator for efficiency will be tested against a neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at  $25 \pm 5 \text{ }^\circ\text{C}$  that has been neutralized to the Boltzmann equilibrium state.

(b) Single air-purifying particulate respirator filter units will be tested in an atmosphere concentration of  $100 \text{ mg/m}^3$  of DOP at the following continuous flow rates for a period of 5 to 10 seconds:

<b>Type of Respiratory Inlet Covering</b>	<b>Airflow rate (liters per minute)</b>
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Tight-fitting.....115

Loose-fitting.....170

(c) Powered air-purifying particulate respirators with multiple filter units will be tested by dividing the flow rate specified in paragraph (b) of this section by the total number of filters used.

(d) The filter will be mounted on a connector in the same manner as used on the respirator and the total efficiency must be  $\geq 99.97$  percent.

**§ 84.176 Fit test – PAPR classes HE and PAPR100.**

NIOSH will assess powered air-purifying respirator fit using either isoamyl acetate or generated aerosol.

(a) *Isoamyl acetate (IAA) fit test.* The applicant must provide a charcoal-filled canister or cartridge of a size and resistance similar to the filter unit with connectors which can be attached to the facepiece in the same manner as the filter unit.

(1) The canister or cartridge will be used in place of the filter unit, and persons will each wear a modified half-mask facepiece for 8 minutes in a test chamber containing 100 parts (by volume) of isoamyl acetate vapor per million parts of air.

(i) The following work schedule will be performed by each wearer in the test chamber:

- (A) Two minutes nodding up and down, and turning head side to side; and
- (B) Two minutes calisthenic arm movements.
- (C) Two minutes running in place.
- (D) Two minutes pumping with tire pump.

(ii) The facepiece must be capable of adjustment, according to the applicant's instructions, to each wearer's face, and the odor of isoamyl acetate must not be detectable by any wearer during the test.

(2) Where the respirator is equipped with a full facepiece, hood, helmet, or mouthpiece, the canister or cartridge will be used in place of the filter unit, and persons will each wear the modified respiratory inlet covering for 8 minutes in a test chamber containing 500 parts (by volume) of isoamyl acetate vapor per million parts of air, performing the work schedule specified in paragraph (b)(2) of this section.

(b) *Generated aerosol fit test.* The powered air-purifying particulate respirator system is tested in an atmosphere containing 20-40 mg/m<sup>3</sup> corn oil aerosol having a mass median aerodynamic diameter of 0.4 to 0.6 µm.

(1) The following activities will be performed by each wearer in the test chamber:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

(iii) Two minutes, running in place; and

(iv) Two minutes, pumping with a tire pump into a 28-liter (1 ft<sup>3</sup>) container.

(2) The respiratory inlet covering will be adjusted, according to the applicant's instructions, to each wearer's face.

(3) The appropriate fit factor must be exceeded during the entire test.

**§ 84.177 Total noise level test – PAPR classes HE and PAPR100.**

Noise levels generated by any powered air-purifying respirators that cover the ears (*i.e.*, hood or helmet) will be measured at the entrance to each ear at maximum airflow obtainable and must not exceed 80 dBA.

**§ 84.178 Breath response type, airflow resistance test – PAPR classes HE and PAPR100.**

Resistance to airflow will be measured with a breathing machine as described in § 84.88.

(a) Minimum inhalation resistance must be greater than zero mm of water-column height.

(b) Maximum exhalation resistance must be less than 89 mm of water-column height.

**§ 84.179 Silica dust loading test -- PAPR series HE filtration.**

(a) Three powered air-purifying particulate respirators will be tested for a period of 4 hours each at a flowrate not less than 115 liters per minute for tight-fitting facepieces, and not less than 170 liters per minute for loose-fitting hoods and helmets.

(b) The relative humidity in the test chamber will be 20-80 percent, and the room temperature approximately 25°C.

(c) The test suspension in the chamber will not be less than 50 nor more than 60 mg of flint (99 + percent free silica) per m<sup>3</sup> of air.

(d) The flint in suspension will be 99 + percent through a 270-mesh sieve.

(e) The particle-size distribution of the test suspension will have a geometric mean of 0.4 to 0.6 µm and the standard geometric deviation will not exceed 2.

(f) The total amount of unretained test suspension in samples taken during testing must not exceed 14.4 mg for a powered air-purifying particulate respirator with tight-fitting facepiece, and 21.3 mg for a powered air-purifying particulate respirator with loose-fitting hood or helmet.

**§ 84.180 Particulate loading test – PAPR series PAPR100-N and PAPR100-P filtration.**

(a) Twenty filters of each powered air-purifying particulate respirator design will be tested for filter efficiency against:

(1) A solid sodium chloride particulate aerosol, in accordance with paragraph (d)(1) of this section, if series PAPR100-N approval is requested by the applicant.

(2) A dioctyl phthalate or equivalent liquid particulate aerosol, in accordance with paragraph (d)(2) of this section, if series PAPR100-P approval is requested by the applicant.

(b) Prior to filter efficiency testing of 20 series PAPR100-N filters, the 20 to be tested will be taken out of their packaging and placed in an environment of  $85 \pm 5$  percent relative humidity at  $38 \pm 2.5$  °C for  $25 \pm 1$  hours. Following the pre-conditioning, filters will be sealed in a gas-tight container and tested within 10 hours.

(c) For powered air-purifying particulate respirators with a single filter, filters will be tested at a continuous airflow rate of  $85 \pm 4$  liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate will be  $42.5 \pm 2$  liters per minute through each filter.

(d) Filter efficiency test aerosols:

(1) Series PAPR100-N filters:

(i) A sodium chloride or equivalent solid aerosol at  $25 \pm 5$  °C and relative humidity of  $30 \pm 10$  percent that has been neutralized to the Boltzmann equilibrium state will be used. Each filter will be challenged with a concentration not exceeding 200 mg/m<sup>3</sup>.

(ii) The sodium chloride test aerosol will have a particle size distribution with count median diameter of  $0.075 \pm 0.020 \mu\text{m}$  and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

(2) Series PAPR100-P filters:

(i) A neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at  $25 \pm 5^\circ\text{C}$  that has been neutralized to the Boltzmann equilibrium state will be used. Each filter will be challenged with a concentration not exceeding  $200 \text{ mg/m}^3$ .

(ii) The DOP aerosol shall have a particle size distribution with count median diameter of  $0.185 \pm 0.020 \mu\text{m}$  and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

(e) The test will continue until minimum efficiency is achieved or until an aerosol mass of at least  $200 \pm 5 \text{ mg}$  has contacted the filter. For PAPR100-P series filters, if the filter efficiency is decreasing when the  $200 \pm 5 \text{ mg}$  challenge point is reached, the test will be continued until there is no further decrease in efficiency.

(f) The efficiency of the filter will be monitored and recorded throughout the test period by a suitable forward-light scattering photometer or equivalent instrumentation.

(g) The minimum efficiency for each of the 20 filters will be determined and recorded and must be equal to or greater than the filter efficiency criterion for PAPR100-N and PAPR100-P, efficiency  $\geq 99.97$  percent, pursuant to § 84.170(b).

**§ 84.181 Communication performance test – PAPR class PAPR100.**

(a) Powered air-purifying respirators must be designed to allow for proper communication while worn.

(b) A Modified Rhyme Test<sup>7</sup> will be used to test the wearer's ability to communicate efficiently.

(c) The communications requirement is met if the overall performance rating is greater than or equal to 70 percent.

**Subpart KK [Removed]**

12. Subpart KK, consisting of §§ 84.1100 through 84.1158 and the tables, is removed.

Dated: April 7, 2020.

**Eric D. Hargan,**  
*Deputy Secretary,*  
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<sup>7</sup> The Modified Rhyme Test is used in speech intelligibility experiments. See <https://www.nist.gov/ctl/pscr/modified-rhyme-test-audio-library>.

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