Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance document provides a proposed compliance policy for and information about respirators approved by the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) in accordance with 42 CFR part 84, specifically: 1) surgical N95 respirators and N95 filtering facepiece respirators (FFRs) classified under 21 CFR 878.4040; 2) other NIOSH approved, non-surgical respirators including powered air-purifying respirators (PAPRs),[1] non-powered, air-purifying particulate FFRs, and reusable respirators (e.g., elastomeric half and full facepiece respirators);[2] and 3) FFRs for use by the general public in public health medical emergencies classified under 21 CFR 880.6260. In this guidance document, these devices are collectively referred to as "certain FFRs and reusable respirators."

The Food and Drug Administration (FDA or the Agency) is proposing the compliance policy described in section IV below for certain FFRs and reusable respirators that are approved by NIOSH based on NIOSH's regulatory oversight of these devices, including the performance characteristics of these devices, and FDA's review of its postmarket data, as described in this guidance document (see section IV). These devices may provide a public health benefit in

[1] Per 42 CFR 84.2, a PAPR is "a device equipped with a facepiece, hood, or helmet, breathing tube, canister, cartridge, filter, canister with filter, or cartridge with filter, and a blower."

[2] See also the National Institute for Occupational Safety and Health infographic for "Types of Respiratory Protection."

accordance with current CDC respiratory virus prevention recommendations.[3] This guidance, once finalized, is intended to facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices.[4]

A device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body.[5] Intended use is determined by evaluating any relevant evidence, including statements and circumstances surrounding the manufacture and distribution of a medical product, including a variety of direct and circumstantial evidence.[6] Relevant evidence is not limited to labeling and promotional claims. Courts have considered relevant evidence to include, for example, actual use of the product by consumers and medical practitioners, and circumstances of sale in determining intended use.[7]

As discussed below, FDA considers FFRs and reusable respirators used to prevent wearer exposure to pathogenic biological airborne particulates to be devices intended for a medical purpose and within the scope of this guidance. The healthcare setting presents unique respiratory risks that do not ordinarily arise in other environments. Healthcare settings are necessarily places where people with respiratory illness seek treatment, presenting risk of exposure to respiratory disease to people working in such facilities. Disease pathogens can transmit in the healthcare setting through sneezes or coughs and through droplets or sprays of infectious body fluids. Treatment for respiratory disease, including intubation, extubation or aerosolized administration of medications (e.g. nebulizer treatments), may create or cause airborne particulates and/or pathogens. Other hospital activities require equipment that may aerosolize pathogens, including clinical, surgical, and laboratory procedures utilizing bone saws, centrifuges, and blenders. In addition, cleaning and disinfecting healthcare facilities can create potentially harmful airborne particulates. The CDC has stated: "The hospital environment contains hazards such as bacteria, viruses, and chemicals that may be inhaled by personnel and cause injury or illness . . . Healthcare personnel who care for patients with ATDs [aerosol transmissible diseases] must work in close proximity to the source of the hazard; even with controls in place, they are likely to have a higher risk of inhaling infectious aerosols (droplets and particles) than the general public."[8]

In general, FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended but not required.

[3] See the CDC website entitled, "Masks and Respiratory Viruses Prevention."
[4] See FDA's guidance document, "The Least Burdensome Provisions: Concept and Principles."
[5] See section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(h)(1).
[6] See 21 CFR 801.4; see also 86 FR 41383, August 2, 2021.
[7] See 86 FR 41383 at 41386-88.
[8] See DHHS (NIOSH) Publication 2015-117, Hospital Respiratory Protection Program Toolkit.

II. Background

FDA has a long history of coordinating with NIOSH to help ensure that respirators used for medical purposes are safe, effective, and available. All of the devices that are within the scope of this guidance document are also subject to approval by NIOSH in accordance with 42 CFR part 84.

A. Surgical N95 Respirators and N95 FFRs Classified Under 21 CFR 878.4040

Since 1988, surgical N95 respirators that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material generally have been classified as class II devices under 21 CFR 878.4040. Likewise, N95 FFRs used in healthcare settings during other procedures, including dental, isolation, and other medical procedures, to protect both the patient and healthcare personnel, are also generally classified as class II devices under 21 CFR 878.4040.[9]

In November 2017, FDA entered into a Memorandum of Understanding (MOU) with NIOSH, which outlines an agreement between the agencies conditioned on certain surgical N95 respirators and N95 FFRs becoming exempt from premarket notification requirements under section 510(k) of the FD&C Act.[10] The MOU became effective on May 17, 2018, when FDA issued a final order exempting from 510(k) requirements certain surgical N95 respirators and N95 FFRs (product code MSH), subject to certain conditions and limitations.[11]

B. Other NIOSH Approved, Non-Surgical Respirators

NIOSH approves other types of non-surgical respirators, including:

- PAPRs,
- Non-powered air-purifying particulate FFRs (e.g., N95, N99 FFRs), and
- Reusable respirators (e.g., elastomeric half and full facepiece respirators).

FDA considers these other types of respirators that are intended to prevent wearer exposure to pathogenic biological airborne particulates and used in healthcare settings, to be postamendments devices.[12] A postamendments device for which FDA has not issued a classification order (or

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[9] 83 FR 22846, May 17, 2018; *id.* at 22847 ("The N95 FFR is a single-use disposable, half-mask respiratory protective device that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is a class II device, regulated by FDA under § 878.4040."); 21 CFR 878.4040(b)(1).

[10] "Memorandum of Understanding Between the Food and Drug Administration, Center for Devices and Radiological Health, and the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory," MOU 225-18-006 (November 2017).

[11] 83 FR 22846.

[12] FDA considers these devices to be postamendments devices because FDA is not aware of any evidence that these devices were in commercial distribution before the Medical Device Amendments Act of 1976. Postamendments devices are automatically classified into class III under section 513(f)(1) of the FD&C Act, without any rulemaking

reclassification order under section 513(f)(3) of the FD&C Act) is referred to as a "not-classified device," and is one for which the Agency has not yet reviewed a marketing application or for which the Agency has not made a final decision on such a marketing application.[13]

In 2020, FDA addressed its policy regarding not-classified, NIOSH Approved FFRs and reusable respirators when it took a number of actions to help address the COVID-19 public health emergency,[14] including issuing emergency use authorizations for such devices with a medical purpose. On March 2, 2020, FDA issued an EUA authorizing NIOSH Approved FFRs to be distributed to healthcare personnel for use in healthcare settings intended to prevent wearer exposure to pathogenic biological airborne particulates. On March 11, 2020, FDA clarified that such respirators are devices because they are intended for a medical use, *i.e.*, to mitigate further transmission of COVID-19.[15, 16]

FDA is aware that healthcare personnel have used,[17] and will continue to use respirators in healthcare settings for medical purposes including protection from transmission of respiratory

process and regardless of the risks they pose, unless they are substantially equivalent to certain other devices (e.g., predicate devices which have been classified into class I or class II), FDA has reclassified the device into class I or class II in response to a petition, or FDA has granted a De Novo request classifying the device into class I or class II. Class III devices are subject to premarket approval (PMA) requirements under section 515 of the FD&C Act. PMA is the required process of scientific and regulatory review to assess the safety and effectiveness of class III devices. A class III device that is marketed without complying with applicable PMA requirements is adulterated under section 501(f) of the FD&C Act.

[13] See FDA's guidance document, "Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff."

[14] In 2019, an outbreak of respiratory disease caused by a novel coronavirus began. The virus was named "SARS-CoV-2," and the disease it causes was named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency (PHE) under section 319 of the Public Health Service (PHS) Act related to COVID-19 and mobilized the Operating Divisions of HHS. On May 11, 2023, the COVID-19 PHE declared under the PHS Act expired. Pursuant to section 564 of the FD&C Act, the Secretary of HHS declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak. In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. For more information on FDA's emergency use authorities under section 564 of the FD&C Act, see the guidance "Emergency Use Authorization of Medical Products and Related Authorities."

[15] See March 11, 2020, letter from RADM Denise M. Hinton, Chief Scientist, FDA to Robert R. Redfield, MD, Director, CDC.

[16] FDA amended and reissued the respirator EUA on multiple occasions, most recently on July 12, 2021. See NIOSH Approved Air-Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency (July 12, 2021). That EUA authorized the emergency use of FFRs and reusable respirators approved by NIOSH in accordance with 42 CFR part 84 and listed on the NIOSH Certified Equipment List for use in healthcare settings by healthcare personnel, as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the COVID-19 outbreak.

[17] See Institute of Medicine (US) Committee on Regulating Occupational Exposure to Tuberculosis; Field MJ, editor. Tuberculosis in the Workplace. Washington (DC): National Academies Press (US); 2001. F, Respiratory Protection and Control of Tuberculosis in Health Care and Other Facilities - Tuberculosis in the Workplace - NCBI Bookshelf (describing use of respirators in the 1990s to shield healthcare personnel from tuberculosis exposure).

viruses.[18,19] CDC maintains that, currently, NIOSH Approved FFRs are among the most protective respirators to protect against respiratory viruses and airborne particles.[20] Healthcare personnel have continued to utilize the respirators that are the subject of this guidance, and that are distributed to healthcare settings to protect against respiratory viruses, even after the PHE expired and respirator shortages have abated.

C. FFRs for Use by the General Public in Public Health Medical Emergencies Classified Under 21 CFR 880.6260

In 2007, FDA issued a final rule that classified FFRs for use by the general public in public health emergencies under 21 CFR 880.6260 as class II devices.[21] In issuing the classification regulation for this type of device, FDA also issued a special control requiring that, among other things, this device type be certified by NIOSH as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95.[22]

III. Scope

A. Device Types Within the Compliance Policy

The proposed compliance policy described in section IV applies to certain respirators that are NIOSH Approved in accordance with requirements under 42 CFR part 84.[23,24,25] The types of FFRs and reusable respirators used for a medical purpose that are within the scope of this guidance are listed in Table 1:

[18] See the CDC website entitled, "DHHS (NIOSH) Publication No. 2025-102, Respirator Selection Guide for the Healthcare Industry" (selecting appropriate respirators in healthcare facilities).
[19] Young CC, Byrne JD, Wentworth AJ, Collins JE, Chu JN, Traverso G. Respirators in Healthcare: Material, Design, Regulatory, Environmental, and Economic Considerations for Clinical Efficacy. Glob Chall. 2022 Apr 12;6(10):2200001. 10.1002/gch2.202200001.
[20] See the CDC website entitled, "Masks and Respiratory Viruses Prevention."
[21] 72 FR 36360, July 3, 2007.
[22] Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies - Class II Special Controls Guidance for Industry and FDA Staff. See also 72 FR 36472, July 3, 2007.
[23] See 42 CFR part 84 for NIOSH approval requirements.
[24] See also NIOSH infographic entitled, "Required Labeling of NIOSH-Approved N95 Filtering Facepiece Respirators" for an example of required labeling elements.
[25] NIOSH respirator approvals can be verified by checking the NIOSH Certified Equipment List (CEL).

Table 1. Device Types within the Scope of the Guidance

Product Code	Device Type or Product Code Name	Regulation Number
MSH	Respirator, Surgical	21 CFR 878.4040
Not Assigned[26]	Respirator, Other[27]	Not classified
NZJ	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	21 CFR 880.6260[28]

B. Device Types Not Within the Compliance Policy

This guidance *does not* apply to other types of respirators, including but not limited to those listed in Table 2:

Table 2: Device Types Outside the Scope of the Guidance

Product Code	Device Type or Product Code Name	Regulation Number
ORW	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	21 CFR 880.6260
ONT	N95 Respirator with Antimicrobial/Antiviral Agent	21 CFR 878.4040

This guidance also does not apply to products representing or suggesting that the product is safe or effective for the mitigation or prevention of any specific diseases and/or infection prevention, viral or bacterial filtration performance, antimicrobial function, hypoallergenicity, or filtration of surgical smoke or plumes. In addition, products that contain, or represent that they contain, antimicrobial coatings, coatings intended to modify the performance of the product that are not related to the product's respiratory protection characteristics, drug delivery systems, nanoscale technologies such as particles, fibers, wires, tubes, self-assembly products on a nanoscale (e.g.,

[26] At the time of publication, these device types are not-classified, as described above in section II.B., and do not yet have product codes.

[27] See Section II.B.

[28] The regulation set forth at 21 CFR 880.6260, Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies, classifies such FFRs that meet certain special controls, including certification by NIOSH with a minimum filtration efficiency classification of N95, and therefore, this classification regulation is not limited to N95 respirators.

an antimicrobial coating), the combination of a respirator with another FDA-regulated product, or innovative or emerging technologies (e.g., such as germicidal ultraviolet technology) are outside the scope of this proposed compliance policy. Devices outside the scope of the proposed compliance policy could be new or modified products that require NIOSH approval and premarket submission to the FDA. Manufacturers of such devices may want to seek FDA detailed feedback via the Q-submission Program.[29]

If a firm intends to market its product as a respirator, it should engage with NIOSH regarding requirements to obtain NIOSH approval of the product.

IV. Compliance Policy

FDA does not intend to prioritize enforcement of certain requirements under the FD&C Act that are applicable to certain FFRs and reusable respirators distributed, marketed, or labeled for medical purposes within the scope of this guidance, including, but not limited to: registration and listing and premarket notification requirements (21 CFR part 807); labeling requirements (21 CFR part 801); requirements as set forth in the Quality Management System regulation (21 CFR part 820), other than general recordkeeping and complaint handling;[30] Medical Device Reporting (MDR) requirements (21 CFR part 803); Unique Device Identification requirements (21 CFR parts 830 and 801 subpart B); Reports of Corrections and Removals (21 CFR part 806); and any special controls not related to NIOSH approval.

Manufacturers of certain FFRs and reusable respirators distributed, marketed, or labeled for medical purposes within the scope of this guidance are expected to meet the recordkeeping and complaint handling requirements under 21 CFR 820.35 so that manufacturers assess whether their product meets specifications, and so that, if FDA has safety concerns, FDA can review complaint records to support, among other things, postmarket surveillance activities.[31]

FDA is proposing the above compliance policy for the devices within the scope of this guidance based on NIOSH's regulatory oversight[32] and FDA's review of its postmarket data, as discussed further below. Additionally, FDA believes the proposed compliance policy will facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices.

NIOSH approval requires initial site qualification, maintenance of product performance, and active quality assurance to maintain the conditions of approval as granted.[33] To obtain NIOSH approval, manufacturers must submit, among other things, descriptions of the respirator, drawings, specifications, respirator samples, the design and construction requirements the

[29] See FDA's guidance document, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

[30] On February 2, 2024, the FDA issued a final rule amending the device good manufacturing practice requirements of the quality system regulation at 21 CFR part 820. That rule became effective on February 2, 2026. The requirements addressing recordkeeping previously set forth at 21 CFR 820.180, and the requirements addressing complaint files previously set forth at 21 CFR 820.198, are each set forth at 21 CFR 820.35.

[31] Id.

[32] 42 CFR part 84.

[33] Id. See also Know Before You Apply: Summarized Quality Requirements Needed to Achieve NIOSH Approval

manufacturer will meet during commercial production of the respirator, the respirator label design, and the quality control plan.[34] NIOSH issues certificates of approval for individual, completely assembled respirators after examination, inspection, and testing, when applicable requirements are met, and NIOSH maintains a conformity assessment program.[35] After approval and once respirators are on the market, NIOSH conducts postmarket conformity evaluations, such as product audits, on different types of respirators to ensure that respirators continue to be manufactured according to the approval holder's quality system, perform according to NIOSH standards, be correctly labeled, and protect the respirator user as intended.[36] NIOSH also conducts site audits about every two years.[37] Further, NIOSH may revoke, for cause, certificates of approval (e.g., for failure to maintain or cause to be maintained the quality control requirements of the certificate of approval), or take other measures to address noncompliance.[38]

In considering the risks of FFRs and reusable respirators within the scope of the proposed compliance policy described in this guidance document, FDA reviewed MDRs for certain FFRs and reusable respirators, received between January 2020 and December 2024, and did not identify a safety signal.[39] During the same time period, manufacturers of FFRs conducted two voluntary recalls, neither of which was initiated due to reports of patient harm.[40]

In sum, based on the rigor of NIOSH approval and oversight and FDA's evaluation of postmarket data, FDA believes that the proposed compliance policy (including FDA's focus on certain postmarket requirements) described in this guidance document is appropriate and will facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices.

As with any compliance policy, FDA may revise its policy as circumstances warrant, for safety reasons, or if the circumstances that inform this policy change, consistent with FDA's good guidance practices.[41] Additionally, regardless of the proposed compliance policy discussed above for certain FFRs and reusable respirators, as with any compliance policy, FDA retains the discretion to pursue enforcement action for violations of the FD&C Act at any time and intends to do so when appropriate.

[34] 42 CFR part 84.
[35] 42 CFR 84.30; see NIOSH's website, "Conformity Assessment Notices."
[36] See NIOSH's website, "Post Market Evaluations Conducted by NIOSH."
[37] Id.
[38] 42 CFR 84.34; see also NIOSH's website, "Post Market Evaluations Conducted by NIOSH."
[39] See FDA's website, Manufacturer and User Facility Device Experience (MAUDE) Database.
[40] One manufacturer recalled a specific lot of FFRs with product code MSH because a sample failed a filtration efficiency test. See FDA's website, "Class 2 Device Recall FLUIDSHIELD 3 N95." Another manufacturer recalled 528 of its PAPR respirators because the rivets securing the elastic headband to the face shield had the potential to be mis-assembled, potentially making the headband loose from the face shield. See FDA's website, "Class 2 Device Recall PAPR (Powered Air-Purifying Respirator)."
[41] Section 701(h) of the FD&C Act, 21 CFR 10.115.