Centers for Disease Control and Prevention

Promoting productive workplaces through safety and health research | NIOSH

NIOSH Conformity Assessment Letter to Manufacturers

Subject: Interim guidance regarding applications for NIOSH Approval of Filtering Facepiece Respirators in accordance with the Food and Drug Administration (FDA) Final Order published May 17, 2018, and FDA/NIOSH MOU 225-18-006, dated November 2017 (included as a reference in this notice).

Revision Supersedes the November 2018 version

NIOSH CA 2018-1010R1.0
Revised August 2020

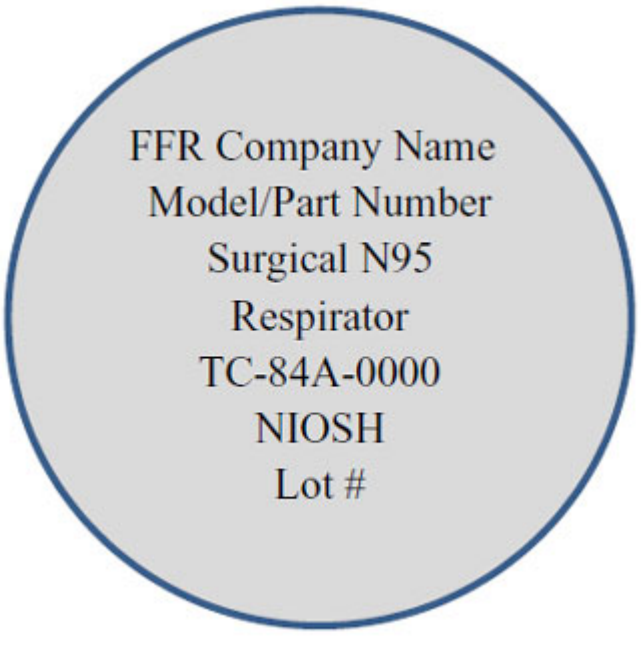
Summary

Beginning **August 24, 2020**, the National Institute for Occupational Safety and Health (NIOSH) will accept applications to implement the coordinated regulatory process to exempt a subset of single-use disposable N95 filtering facepiece respirators (FFRs) from Food and Drug Administration (FDA) premarket notification requirements. The N95 FFRs and data provided by the applicant must demonstrate:

- all applicable NIOSH N95 FFR requirements found in 42 CFR 84
- flammability, fluid resistance (penetration by synthetic blood), and biocompatibility, previously reviewed by the FDA, and evaluated by NIOSH in accordance with the Memorandum of Understanding (MOU) between the FDA/Center for Devices & Radiological Health and the Centers For Disease Control & Prevention/NIOSH/National Personal Protective Technology Laboratory when FDA Threshold Criteria is not exceeded
- flammability, fluid resistance, and biocompatibility data provided to NIOSH must be generated by a laboratory meeting FDA's Good Laboratory Practices requirement (21 CFR Part 58)
- no significant deviation from respirator designs previously cleared by the FDA under product code MSH, such as the addition of exhalation valves, novel head suspensions, sterility claims, antimicrobial treatments, drug delivery systems, or nano scale technologies
- consideration of FDA recommendations for labeling medical products to inform users that the product is not made with natural rubber latex.

Any device approved under this guidance will be labeled with the respiratory protection of "N95", referred to as a Surgical N95, and will also be documented as meeting the FDA specified flammability, fluid resistance, and biocompatibility requirements and can be used in healthcare settings. Monthly NIOSH Certified Equipment List updates **will** include searchable information about approved Surgical N95 respirators.

- **Surgical N95 respirator approval labels must include caution and limitation "S" defined as:** *Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.*
- **The User Instructions and packaging must state the following under the "S – Special or Critical User Instructions" heading:** ***This respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.***
- The approval label is no longer required to have the caution and limitation "P" – *NIOSH does not evaluate respirators for use as surgical masks.*
- The abbreviated label (what is printed on every FFR) will include additional wording to inform users: **"Surgical N95 Respirator"**. See the example below.



Four specific situations are noted:

- No immediate action under this guidance is required for an existing device that has previously obtained NIOSH approval and FDA 510(k) clearance (i.e., Surgical N95 FFRs). The existing approval will remain effective as long as the approval holder continues to 1) pay the annual NIOSH maintenance fee, 2) register and list your company with the FDA , and 3) meet NIOSH and FDA post market requirements. The approval holder will be expected to revise the User Instructions and packaging to include caution and limitation "S" and remove "P", as defined above, the next time that the approval is submitted for an extension of approval. And in some cases, the approval holder must update the abbreviated label to align with this guidance.
- If a manufacturer of an existing NIOSH-approved N95 FFR respirator has not previously sought FDA 510(k) clearance and **now seeks to label a device with the additional protections (flammability, fluid resistance, and biocompatibility)**, the manufacturer must **follow this guidance** to achieve **a NEW NIOSH approval for the Surgical N95 respirator**. The approval holder is encouraged to issue a new model/part number for the Surgical N95.
- If a manufacturer of an existing NIOSH-approved N95 FFR respirator has not previously sought FDA 510(k) clearance and **does not seek** to label this device with the additional protections (flammability, fluid resistance, and biocompatibility), **the existing NIOSH approval will remain effective**.
- If a manufacturer of a **NEW N95 FFR** seeks NIOSH approval for a Surgical N95, the manufacturer must **follow this guidance**.

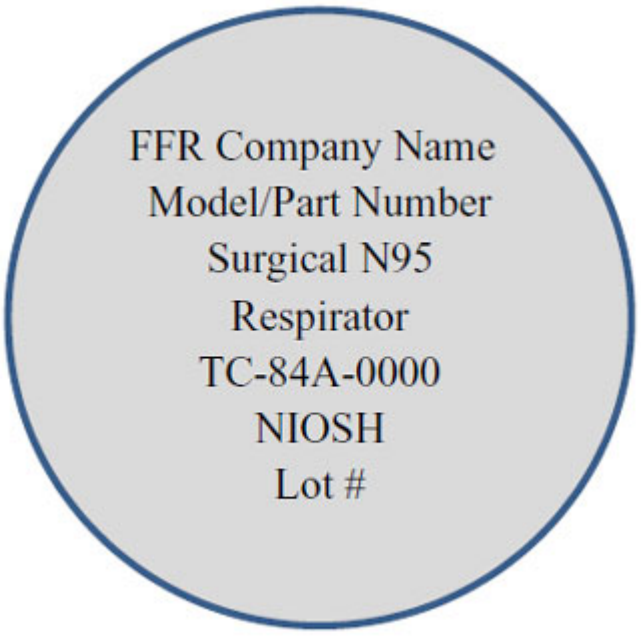
NEW NIOSH APPLICANTS:

If an applicant has never previously submitted any type of respiratory protective device for NIOSH approval, the applicant must first apply to NIOSH for a three-character Manufacturer's Code by completing the Prospective Approval Holder Form and returning it to the NIOSH NPPTL Records Room. Applicants can obtain this form by contacting the NIOSH NPPTL Records Room at recordsroom@cdc.gov. After obtaining the Manufacturer's Code, the manufacturer seeking approval for a Surgical N95 must follow this guidance.

NEW APPLICANTS AND EXISTING NIOSH APPROVAL HOLDERS APPLYING for SURGICAL N95 APPROVAL:

The applicant will use the NIOSH Standard Application Procedure (SAP) to complete the Standard Application Form. When completing the reason for application section (C.9), the applicant will indicate they are **using the consolidated process and seeking approval within the terms of the FDA Final Order (83 FR 22846) and the MOU.**

- The approval label provided as part of the NIOSH Surgical N95 application must include the **caution and limitation "S" defined as:** Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning. **The User Instructions and packaging (including all private label packaging) must state the following:** ***This respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.***
- The abbreviated label (what is printed on every FFR) will include additional wording to inform users: **"Surgical N95 Respirator"**. See the example below.



Applicants are required to provide documentation to NIOSH to indicate conformance to the FDA thresholds for flammability, fluid resistance, and biocompatibility, as described in the MOU. **All data must be received in electronic formats** as indicated in the NIOSH SAP. While NIOSH completes testing of hardware in accordance with 42 CFR 84 Subpart K, **NIOSH is not conducting testing to verify the flammability, fluid resistance, or biocompatibility performance of the respirator as part of the consolidated Surgical N95 approval process.**

During the NIOSH document review process, NIOSH will review flammability, fluid resistance, and biocompatibility test data and results provided by the applicant and in accordance with the Threshold Evaluation Criteria defined in the MOU.

In accordance with the MOU, **Surgical N95 Approval Holders are required to comply with the general controls required under the Federal Food, Drug, and Cosmetic Act (see section 513(a)(1) of the FD&C Act) and implementing regulations,** including annual registration and listing obligations, quality system regulations, post market requirements, and other requirements as established by the FD&C Act and implementing regulations (e.g., requirements set forth in 21 CFR Parts 803 and 820) and applicable special controls under 21 CFR 878.4040. Nothing in this document changes or affects applicable FDA regulatory requirements or authority.

Manufacturers making claims exceeding the threshold evaluation criteria defined in the MOU must consider the timelines as described in the MOU. (MOU Appendix, Section 2).

Note: Tuberculosis protection claims in accordance with CDC Guidance are allowed.

The NIOSH Surgical N95 Approval Holder must use NIOSH application procedures and notify NIOSH of any changes made to the NIOSH-Approved Surgical N95. Additional testing and data may be required before changes are approved by NIOSH.

REFERENCES

FDA Final Order
FDA Postmarket Requirements (Devices)
Approval of Respiratory Protective Devices, 42 C.F.R, Part 84
MOU 225-18-006 (also included below)

Reference: MEMORANDUM OF UNDERSTANDING (MOU) 225-18-006 , November 2017

BETWEEN THE FOOD & DRUG ADMINISTRATION/CENTER FOR DEVICES & RADIOLOGICAL HEALTH ANDTHE CENTERS FOR DISEASE CONTROL & PREVENTION/NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY & HEALTH/NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY

I. Purpose +

This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA), acting through its Center for Devices and Radiological Health (CDRH), and the Centers for Disease Control and Prevention (CDC), acting through its National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory

(NPPTL) (herein referred to as “the Agencies”), provides a framework for coordination and collaboration between the Agencies relating to their regulation of Surgical N95 Respirators and N95 Filtering Facepiece Respirators (FFRs)1 used in healthcare settings (herein collectively referred to as “N95s”).[1]

A coordinated process will help to ensure that the various regulatory activities of each agency related to N95s are streamlined and harmonized when possible. The intent of this MOU is to help reduce conflicting and duplicative premarket processes for these devices so that stakeholders can easily and seamlessly discern what steps must be taken to satisfy the applicable regulatory requirements.

Specifically, this MOU (1) describes the mechanisms by which specific information pertaining to N95s may be exchanged between the two Agencies and (2) provides a framework for efficient and coordinated regulatory oversight of N95s

II. Definitions +

Definitions of specific terms used in this MOU are provided in this section. Also, please note that the respirators described in this section and throughout this MOU are designed to be used in the context of a comprehensive respiratory protection program as required by the Occupational Safety and Health Administration (OSHA) in 29 CFR 1910.134.

Applicant: An individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval [from NIOSH] for such respirator.[2]

Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation,treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and
4. which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for theachievement of its primary intended purposes. The term does not include software functions excluded pursuant to section 520(o) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)(21 U.S.C. 360j(o)).[3]

Hazardous Atmosphere: Any atmosphere containing a toxic or disease producing gas, vapor, dust, fume, mist, or pesticide, either immediately or not immediately dangerous to life or health; or any oxygen-deficient atmosphere.[4]

Healthcare Personnel (HCP): All persons, paid and unpaid, working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP include, but are not limited to, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual personnel, home healthcare personnel, and persons not directly involved in patient care (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, chaplains, and volunteers) but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.[5]

Healthcare Settings: Healthcare settings include, but are not limited to, acute-care hospitals; long-term care facilities, such as nursing homes and skilled nursing facilities; physicians’ offices; urgent-care centers, outpatient clinics; and home healthcare. Examples of settings that are not included in this definition are schools and worksites. However, elements of this MOU may be applicable to specific sites within non-healthcare settings where care is routinely delivered (e.g., a medical clinic embedded within a workplace or school)).

Labeler: A “labeler” is any person who causes a label to be applied to a device, or who causes the label of a device to be replaced or modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.[7]

Labeling: As defined in section 201(m) of the FD&C Act.

N95 Filtering Facepiece Respirator (FFR): Single-use, disposable half-mask respiratory protective device (RPD) 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 21 CFR 878.4040 (FDA product code MSH).

N95s: Includes N95 Filtering Facepiece Respirator (FFR) used in healthcare settings and Surgical N95 Respirator.

NIOSH Approval: Approval means a certificate or formal document issued by NIOSH stating that an individual respirator or combination of respirators has met the minimum requirements of 42 CFR Part 84 and that the applicant is authorized to use and attach an approval label to any respirator, respirator container, or instruction card for any respirator manufactured or assembled in conformance with the plans and specifications upon which the approval was based, as evidence of such approval.

Particulate Material: Solid or liquid particles found in the air. These particles may include dust, dirt, soot, smoke, and drops of liquid, and airborne particles transmitted to and from HCP and patients.

Respiratory Protective Device (RPD): Any device designed to protect the user's respiratory tract against the inhalation of a hazardous atmosphere.[8]

Surgical N95 Respirator: Single-use, disposable respiratory protective device (RPD) used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH).[9]

III. Background +

FDA and NIOSH are sister Agencies within the Department of Health and Human Services (HHS). Both Agencies' missions include protecting the public health. Both Agencies are authorized to regulate certain RPDs but have different statutory authorities and responsibilities.

The distinctions between NIOSH and FDA regulation of N95s may create confusion among stakeholders. The collaboration outlined below, which is intended to streamline regulatory oversight of N95s used in healthcare settings, is expected to help ensure the availability of safe and effective products, particularly during times of increased demand.

The Agencies may update this MOU to include other RPDs utilized within the healthcare setting at a future date. However, note that any updates to the MOU will not automatically revise the conditions or limitations of exemption from 510(k).

We note that the MOU is drafted on the assumption that FDA has issued a notice in the Federal Register exempting certain N95s from 510(k) review (subject to applicable conditions and limitations of exemption, such as 21 CFR 878.9 and 21 CFR 878.4040(b)(1)). Generally, 21 CFR 878.4040(b)(1) exempts those N95s that (1) are determined not to exceed the threshold evaluation criteria and (2) have met the approval criteria and have NIOSH approval under its regulation. If such a notice is not finalized this MOU would not become effective (see section IX) or may need to be amended before becoming effective.

IV. Statutory Authorities +

a. FDA

The FD&C Act grants FDA authority to regulate devices, as defined in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). FDA classifies devices into one of three regulatory classes – class I, II, or III – based on the level of control necessary to ensure the safety and effectiveness of the device. Class I devices are subject to the fewest regulatory controls and class III devices are subject to the most regulatory controls.

Generally, class II devices must receive premarket clearance from FDA under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) before they can be legally marketed.10 FDA provides premarket clearance for devices that are "substantially equivalent"—as the term is defined in section 513(i)(1)(A) of the FD&C Act (21 U.S.C. 360c(i)(1)(A))—to a predicate device. In

certain circumstances, FDA can exempt class II devices from these 510(k) requirements (see section 510(m) of the FD&C Act (21 U.S.C. 360(m))).

N95s are regulated by the FDA as class II devices under 21 CFR 878.4040 (FDA product code MSH). As of the effective date of this MOU (see section IX), N95s are exempt from 510(k) requirements (subject to applicable conditions and limitations to the exemption, such as those in 21 CFR 878.9 and 21 CFR 878.4040(b)(1)). Generally, 21 CFR 878.4040(b)(1) exempts N95s if (1) they are determined not to exceed the threshold evaluation criteria and (2) have met the approval criteria and have NIOSH approval.

b. NIOSH

NIOSH is responsible for approval of RPDs intended for occupational use. The authority is granted to NIOSH in accordance with standards established in 42 CFR Part 84. NIOSH also addresses quality assurance requirements for the manufacturing of respiratory protective equipment.

Enforcement agencies, such as OSHA, require employers to provide NIOSH-approved respirators. In addition, private sector certification scheme owners such as the National Fire Protection Association use the NIOSH approval as the basis for their certification.

V. Scope +

This MOU applies to N95s used in healthcare settings, which protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material.[11]

Future iterations of this MOU may extend this scope to other RPDs utilized in a healthcare setting based on concurrence between the Agencies. However, note that any updates to the MOU will not revise the conditions or limitations to the exemption for 510(k) as identified in the Federal Register Notice.

VI. Roles and Responsibilities +

Under this MOU, the Agencies agree to the following roles and responsibilities:

- The Agencies agree to share relevant information pertaining to N95s with each other, while ensuring that the exchange of such information complies with applicable law (see section VII).
- The Agencies agree that N95s that are intended to be worn in healthcare settings to protect against the transfer of microorganisms, body fluids, and particulate material are devices under the FD&C Act and subject to regulatory oversight by FDA. Currently, N95s are class II devices.
- The Agencies agree to the following framework for NIOSH and FDA review of N95s that are intended to be used in healthcare settings (details on this framework, including the Agencies'mutually agreed upon threshold evaluation and NIOSH approval criteria, are included in the Appendix):
    - NIOSH first will evaluate whether applicants' devices exceed the threshold evaluation criteria and make a recommendation.
    - For devices that do not exceed the threshold evaluation criteria, NIOSH will evaluate whether applicants' devices meet the approval criteria. NIOSH will update its Respirator Approval Program to reflect the approval criteria. Devices that subsequently meet the approval criteria will be approved by NIOSH. As noted above, such NIOSH-approved devices are exempt from FDA's 510(k) requirements subject to applicable conditions and limitations to the exemption.
    - For devices that exceed the threshold evaluation criteria and/or exceed the conditions and limitations of the exemption, FDA will review 510(k)s submitted to the Agency. Inits review, FDA will consider information provided to FDA from NIOSH regarding whether applicants' devices meet the approval criteria. This will allow FDA to focus on other relevant aspects of the device in its substantial equivalence review.
- The Agencies agree that while NIOSH makes a recommendation regarding whether an applicant's device exceeds the threshold evaluation criteria, this recommendation does not change any requirements of a device manufacturer under the FD&C Act. This includes general controls under the FD&C Act and the requirement for manufacturers to assess whether their device exceeds the conditions and limitations of exemption as identified in 21 CFR 878.9 and 21 CFR 878.4040(b)(1).
- The Agencies agree that NIOSH may hire certified third party test laboratories to conduct performance testing and may leverage the performance evaluation of those laboratories in its approval.

- The Agencies agree to update, as appropriate, the threshold evaluation and approval criteria. Appropriate procedures, which follow notice and comment, will be followed for any updates that affect the 510(k) exemption.
- The Agencies agree to utilize their existing post market and surveillance authorities:
    - N95s will continue to be subject to post market and other requirements as established by the FD&C Act and implementing regulations (e.g., requirements set forth in 21 CFR Parts 803 and 820).
    - NIOSH will utilize post market and surveillance authorities set forth in 42 CFR Part 84.
- The Agencies agree that this MOU does not affect registration and listing obligations under section 510 of the FD&C Act (21 U.S.C. 360).
- The Agencies will ensure that their databases identifying registered establishments and any associated N95s are reconciled on a pre-determined schedule to ensure that consistent information is being conveyed to the user community.
- N95 labelers will continue to be subject to FDA's requirements for Unique Device Identification.12
- The Agencies have defined approval criteria based on standards for effective performance, reliability,and quality of N95s.
- The Agencies agree to identify and assign staff and other resources (e.g., laboratories) as needed to complete N95 assessment.

VII. Information Sharing +

1. FDA and CDC recognize and agree that information exchanged under this MOU that contains any of the following types of information must be protected from unauthorized use and disclosure: (1)confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C. 1905)), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191), Section 319L(e) of the PHS Act (42 U.S.C. 247d-7e(e)), and disclosure restrictions subject to 41 U.S.C. 2101-2107 (Procurement Integrity Act) and 48 CFR 3.104 (Federal Acquisition Regulation).

2. Both parties will establish safeguards to ensure that any nonpublic information shared under this MOU is protected from unauthorized disclosure or use. Those safeguards should include the marking of any confidential materials as "confidential" prior to disclosure to the other party or the use of encryption technologies when appropriate. Information consisting of confidential commercial information or trade secrets may be shared pursuant to the procedures set forth in the Memorandum of Understanding Between FDA and CDC, which describes information sharing procedures between FDA and CDC (FDA MOU No. 225-24-0017, available at http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm402130.htm).

3. Each agency agrees to promptly notify the other of any actual or suspected unauthorized disclosure of information shared under this MOU.

4. If records provided by either party under this agreement are the subject of a FOIA request submitted to the party that received the records, that party will refer the FOIA request and relevant records to the party that provided the records for processing. If the FOIA request seeks both parties' records or if the request is for records created by one party that incorporates information provided by the other party, in accordance with the HHS FOIA regulations at 45 CFR pt. 5, the party receiving the FOIA request will forward all such requests to the respective FOIA offices for disposition.

VIII. Fees +

This MOU does not affect fees assessed by NIOSH and FDA in alignment with their current fee structure. N95s that are exempt from 510(k) requirements are not subject to the medical device user fees associated with submission of a 510(k) (i.e., fees under section 738(a)(2)(A)(viii) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)(viii))).

IX. Relevant Dates +

- This MOU shall be effective upon FDA's publishing an order in the Federal Register that sets forth a final determination

that N95s are exempt from 510(k) requirements (subject to applicable conditions and limitations to the exemption, as identified in 21 CFR 878.9 and 21 CFR 878.4040(b)(1)). Generally,21 CFR 878.4040(b)(1) exempts N95s if they (1) are determined not to exceed the threshold evaluation criteria and (2) have met the approval criteria and have NIOSH approval under its regulation.

- The MOU will continue to be in effect until canceled in writing by either of the Agencies with adequate notice no less than 180 calendar days.

X. Miscellaneous +

Conflicts that arise relating to the MOU after the MOU is in effect will be resolved by CDRH and NIOSH NPPTL Points of Contact (see section XI). If conflicts cannot be resolved at this level, then the signatory authorities for this MOU will resolve the conflicts either by coming to informal agreement or by amending the MOU.

- This MOU may be amended in writing at any time by mutual agreement of the parties.
- This MOU will be reviewed annually by the Points of Contact to determine if any mutually agreed upon changes or amendments should be made to the MOU. Any such changes or amendments will be formally incorporated in the MOU after adequate procedures for amending the 510(k) exemption have been followed.

XI. Points of Contact +

Director, National Personal Protective Technology Laboratory (NPPTL)
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Pittsburgh, PA

Director, Emergency Preparedness/Operations and Medical Countermeasures
Center for Devices and Radiological Health
Food and Drug Administration
Silver Spring, MD

Appendix: NIOSH and FDA Review Processes for N95s

Section 1. Review Process +

1. **Review Processes for N95s:** NIOSH and FDA review processes for N95s consist of the following steps (also see Figure 1):

- **Applicant submission to NIOSH.** Submission must include design documentation, performance(pre-test) data, and information on an applicant's quality assurance program per 42 CFR Part 84.
- **Threshold Evaluation Review by NIOSH.** During the threshold evaluation review, NIOSH utilizes the criteria that the Agencies have agreed upon (see Appendix Section 2 for specific criteria). NIOSH plans to perform this review, and make a recommendation to FDA regarding whether a device exceeds the threshold evaluation criteria, within 10 working days of receipt of the applicant's submission. FDA will make a final determination as to whether a device exceeds the threshold evaluation criteria and communicate that determination to NIOSH within 10 working days.
- **Review for N95s that Do Not Exceed the Threshold Evaluation Criteria.**
    - **NIOSH Approval Review.** NIOSH will strive to complete its approval review of these devices within 90 calendar days of receiving the submission. NIOSH determines whether the N95 receives approval based on pass/fail criteria for performance testing and the assessment of the other components of the submission (see Appendix Section 3 for specific criteria). NIOSH will notify FDA of its decision to approve (or not approve)the N95.
    - **FDA Consult.** Throughout the threshold evaluation and approval reviews, NIOSH may request a consult from FDA regarding general questions as well as for assistance in determining whether the threshold evaluation and/or approval criteria are met. FDA plans to respond to consult requests from NIOSH as soon as possible, and within 10 working days of receipt when they relate to the approval review, to enable NIOSH to meet its 90-calendar-day review goal.
- **Review for N95s that Exceed the Threshold Evaluation Criteria.**

- **FDA 510(k) Review.** For such devices, in accordance with section VII of this MOU on information sharing, FDA plans to notify NIOSH of all 510(k)s submitted within 10 working days of receipt of the 510(k). Within 30 calendar days of receipt, FDA will also notify NIOSH as to whether the 510(k) warrants the review of clinical data FDA will strive to complete its 510(k) review within 60 calendar days of receiving the submission. NIOSH continues its approval review and in its 510(k) review, FDA will consider information provided to FDA from NIOSH regarding whether the device meets the Agencies' mutually agreed upon approval criteria (see Appendix Section 3 for specific criteria), which will allow FDA to focus on other relevant aspects of the device inits substantial equivalence review. Examples of other relevant aspects of device performance may include but are not limited to bacterial/viral filtration efficiency,additional biocompatibility evaluations such as gas pathway safety assessments,toxicology, etc.

NIOSH Approval Review. NIOSH will perform its approval review of these N95s using the mutually agreed upon approval criteria (see Appendix Section 3 for specific criteria) and share information from this review with FDA such that it can be considered in FDA's 510(k) review.

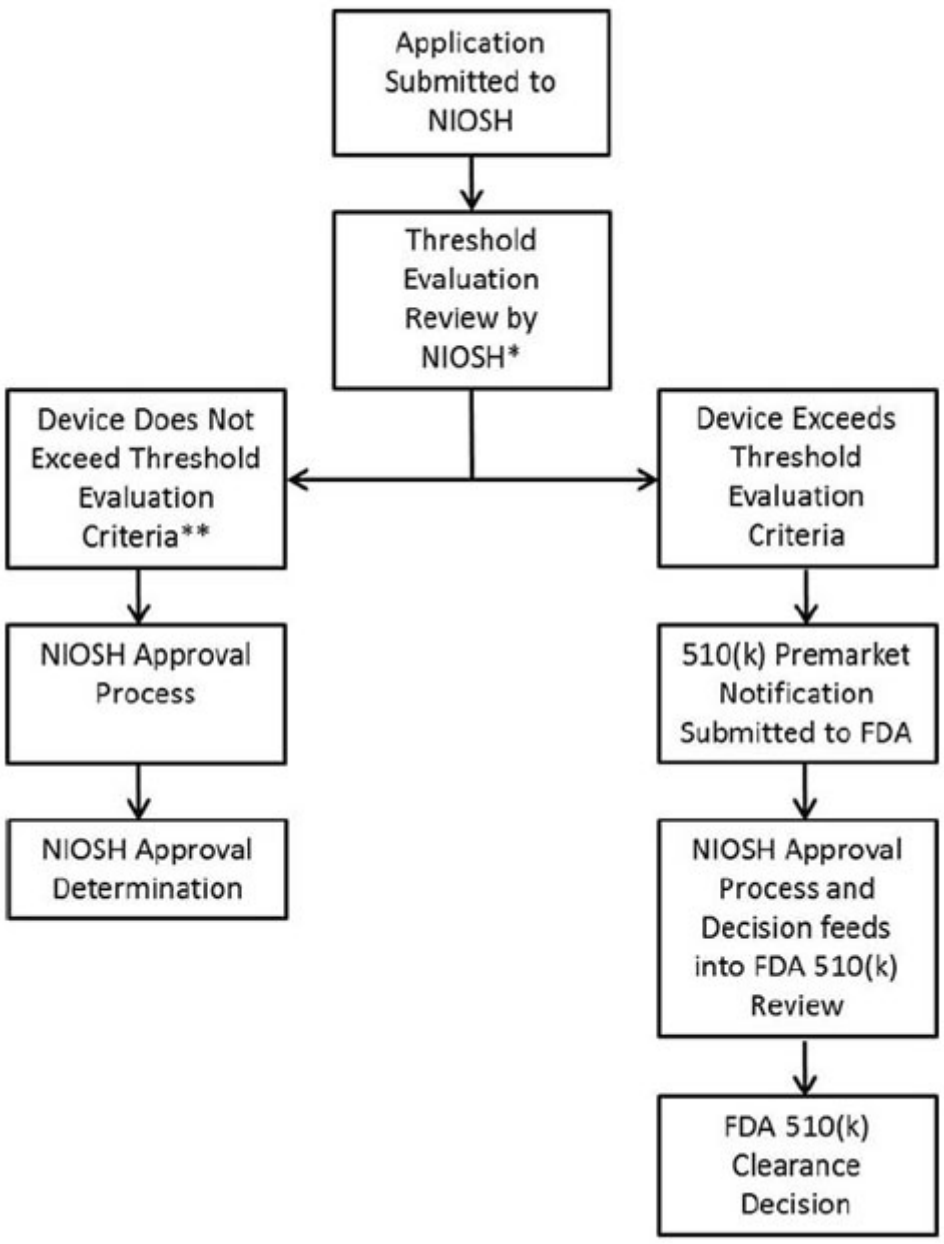


Figure 1. N95 Review Processes Flowchart

*NIOSH makes a recommendation regarding whether an applicant's device exceeds the threshold evaluation criteria, this recommendation does not change any requirements of a device manufacturer under the FD&C Act. This includes general controls under the FD&C Act and the requirement for manufacturers to assess whether their device exceeds the conditions and limitations of exemption as identified in 21 CFR 878.4040(b)(1) and 878.9.

**Refer to Appendix Section 2 for threshold evaluation criteria

Section 2. Threshold Evaluation Criteria +

2. **Threshold Evaluation Criteria:** An N95 EXCEEDS the threshold evaluation criteria (and thus would likely not be exempt from 510(k) requirements even if subsequently approved by NIOSH), if:

- The N95 is intended for any of the following intended uses or it is labeled or otherwise represented (e.g., the instructions for use) for:
  - Specific disease and/or infection prevention (including, but not limited to, protection against Methicillin-resistant Staphylococcus aureus (MRSA), Haemophilus influenzae, or H1N1)

- Viral or bacterial filtration performance (e.g., filters 95% of bacteria)
- Antimicrobial (antiviral/antibacterial) function
- Hypoallergenicity (e.g., for users with sensitive skin)
- Filtration of surgical smoke or plumes
  OR

- The N95 contains technologies including, but not limited to:
  - 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
  - Products that contain nanoscale technologies such as particles, fibers, wires, tubes, self-assembly products on a nanoscale (e.g., an antimicrobial coating)
  - The combination of an N95 with another FDA-regulated product.

Section 3. NIOSH Approval Criteria +

5. **Approval Criteria:** NIOSH will assess the performance of the N95 with respect to differential pressure, particulate filtration efficiency (PFE), exhalation valve leakage, biocompatibility, flammability, and fluid resistance. The evaluation of flammability, fluid resistance, and biocompatibility on the final finished N95 will be new assessments for NIOSH; they have historically been a part of FDA's premarket evaluation only.

The mutually agreed upon approval criteria are described in greater detail below. An N95 intended to be used in healthcare settings will be evaluated for the following *approval criteria:*

- Differential pressure: NIOSH requirement as indicated in 42 CFR 84.180. The N95s must be evaluated using the appropriate NIOSH standard test procedures (STPs) and meet the evaluation criteria specified in 84.180.
- Particulate filtration efficiency: NIOSH requirement as indicated in 42 CFR 84.181. The N95s must be evaluated using the appropriate NIOSH STPs and meet the evaluation criteria specified in 84.181.
- Exhalation valve leakage: NIOSH requirement as indicated in 42 CFR 84.182. The N95s must be evaluated using the appropriate NIOSH STPs and meet the evaluation criteria specified in 84.182.
- Biocompatibility (new): Appropriate analysis and testing (such as that outlined in the ISO-10993-1 standard, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process.")13 must demonstrate the biocompatibility of N95s. Tests selected must be appropriate for duration and level of contact with the device (e.g., limited contact devices including skin). N95s will be tested on a pass/fail basis with respect to cytotoxicity, sensitization,and irritation. In general, N95s are made of melt blown/spun bound polypropylene layers. NIOSH will consult with FDA regarding any materials that have not been used in N95s previously. For example, the use of different materials may result in the need to include additional biocompatibility evaluations such as gas pathway safety assessments of any leachates coming from the final finished N95.
- Flammability (new): Flammability is met if any of the standards and test methods identified below is utilized in the evaluation of flammability by class, and the material is determined to be National Fire Protection Association (NFPA) class I or II. N95s comprised of NFPA class I and class II flammability materials are recommended. Devices with a NFPA class 3 rating should have a flammability warning. Devices with a NFPA class 4 rating will be considered to have failed this criterion because such devices are not appropriate for use in the operating room.
  - CPSC CS-191-53 Flammability Test Method (16 CFR Part 1610)
  - Standard for Flammability of Clothing Textiles NFPA Standard 702-1980
  - Standard for Classification of Flammability of Wearing Apparel UL 2154
- Fluid resistance (new): Fluid resistance is met if the N95 passes the test method below, or comparable test method, at any specific velocity as identified in the labeling. N95s are tested on a pass/fail basis at specified velocities.
  - ASTM F 1862: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood

Approvals +

Approved and Accepted CDC/NIOSH
Maryann D'Alessandro, Ph.D

Director
National Personal Protective Technology Laboratory
November 2017

Approved and Accepted FDA
Jeffrey Shuren, M.D., J.D
Director
Center for Devices and Radiological Health
November 2017

References +

1. NIOSH has regulatory authority over several categories of FFRs. This MOU is only focused on one of these categories, the N95 FFR used in healthcare settings.
2. This is the same as the definition of “applicant” in 42 CFR 84.2.
3. This is the same as the definition of “device” in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).
4. This is the same as the definition of “hazardous atmosphere” in 42 CFR 84.2.
5. This definition is the same as the 2008 Department of Health and Human Services (HHS) definition of HCP, which was adopted by CDC in its guidance on Prevention Strategies for Seasonal Influenza in Healthcare Settings (see http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm).
6. This is the same definition as that adopted by CDC in its guidance on Prevention Strategies for Seasonal Influenza in Healthcare Settings (see http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm).
7. Note this is an FDA definition. See 21 CFR 801.3.[0]
8. This is very similar to the definition of “respirator” in 42 CFR 84.2.
9. This definition does not include other respirators, including those regulated under 21 CFR 878.4040(FDA product code ONT) and those regulated under 21 CFR 880.6260 (FDA product codes NZJ and ORW).
10. Devices legally in commercial distribution before May 28, 1976 are “grandfathered” and do not require 510(k) clearance unless the device has been significantly modified or there has been a change in intended use. At the time of the publication of this MOU, neither FDA nor NIOSH is aware of any marketed N95s that were in distribution before May 28, 1976.
11. See 21 CFR 878.4040 (FDA product code MSH).
12. Information on Unique Device Identification, including applicable requirements and compliance dates, is located at the following web address: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ .
13. Note that FDA has recognized this complete standard with a few exceptions. See FDA’s Recognized Consensus Standards database for a list of exceptions, available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm .

Revision (R)	Date	Reason for Revision
1.0	14 August 2020	NIOSH revised this notice to remove references to “N95-F” filtering facepiece respirators. On June 29,2020 FDA and NIOSH agreed to use existing terminology “Surgical N95” to define these FFRs approved before and after the 2018 MOU.

Interim guidance regarding applications for NIOSH Approval of Filtering Facepiece Respirators in accordance with the Food and Drug Administration (FDA) Final Order published May 17, 2018, and FDA/NIOSH MOU 225-18-006, dated November 2017. Revision Supersedes the November 2018 version. [PDF – 407]

Page last reviewed: August 17, 2020