FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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NIOSH-Approved Surgical N95 Filtering Facepiece Respirators

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Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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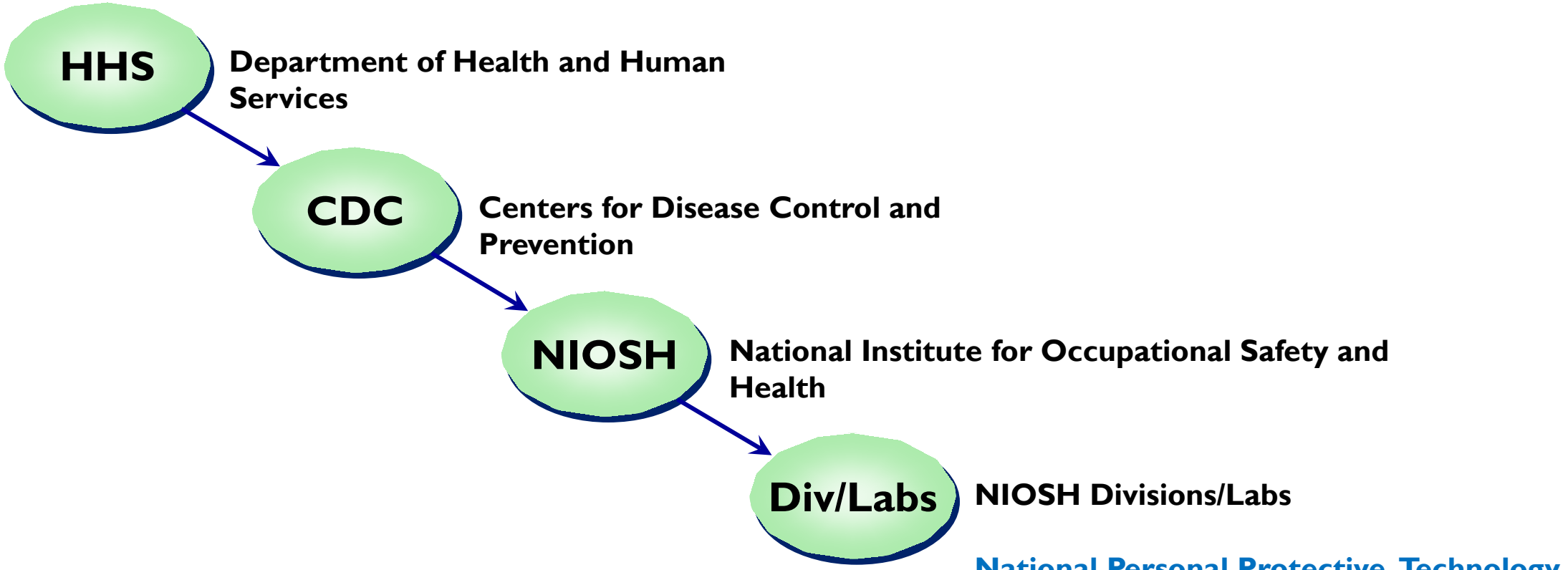
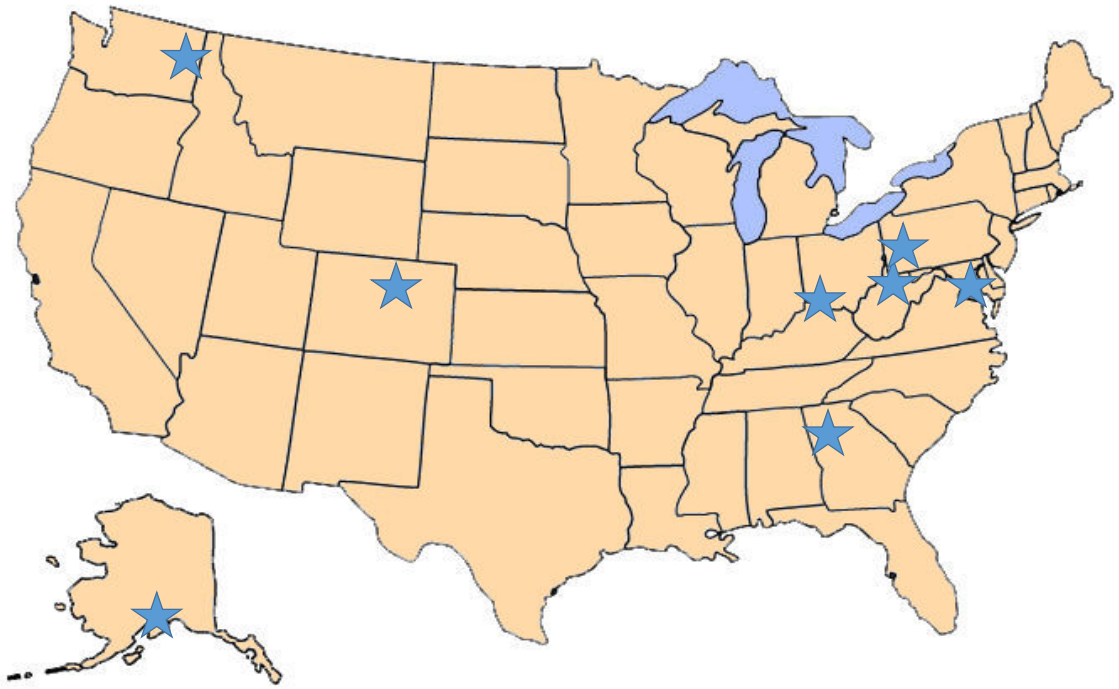
Where does NPPTL fit into the federal structure?

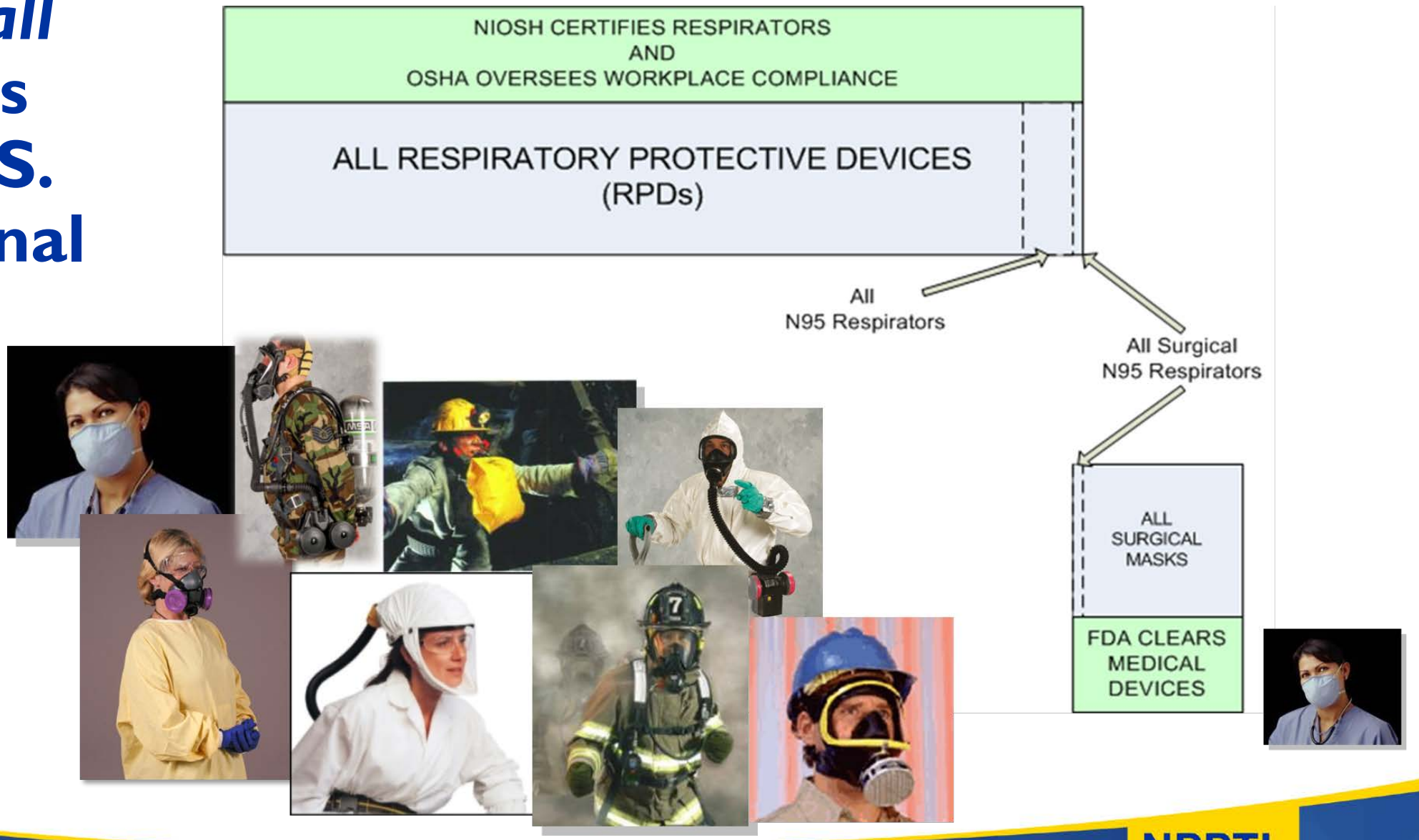


NIOSH Divisions & Laboratories



- Office of the Director, NIOSH
- Division of Field Studies & Engineering (DFSE)
- Division of Safety Research (DSR)
- Division of Science Integration (DSI)
- Division of Compensation Analysis and Support (DCAS)
- Health Effects Laboratory Division (HELD)
- **National Personal Protective Technology Laboratory (NPPTL)**
- Office of Extramural Programs (OEP)
- Pittsburgh Mining Research Division (PMRD)
- Respiratory Health Division (RHD)
- Spokane Mining Research Division (SMRD)
- Western States Division (WSD)
- World Trade Center Health Program Division (WTC)

NIOSH approves *all* respirators used in U.S. occupational settings.



Surgical N95 filtering facepiece respirators (SN95) Healthcare settings

- Occupational Safety and Health Administration (OSHA) requires that respirators used in occupational settings are NIOSH approved
- Respirators used in healthcare are considered **medical devices** by the FDA, cleared through the 510(k) premarket notification program
- Previously, all N95s used in healthcare had to obtain NIOSH approval and then FDA clearance.
- 2016 National Academy of Medicine workshop
- 2017 Memorandum of Understanding (MOU) with NIOSH and FDA
- 2018 NIOSH guidance and process for executing the MOU
- **2020 NIOSH updates guidance for SN95 approval**

Today's webinar is on the **updated NIOSH guidance posted August 2020**: NIOSH approval for Surgical N95 filtering facepiece respirators

National Institute for Occupational Safety and Health NIOSH®

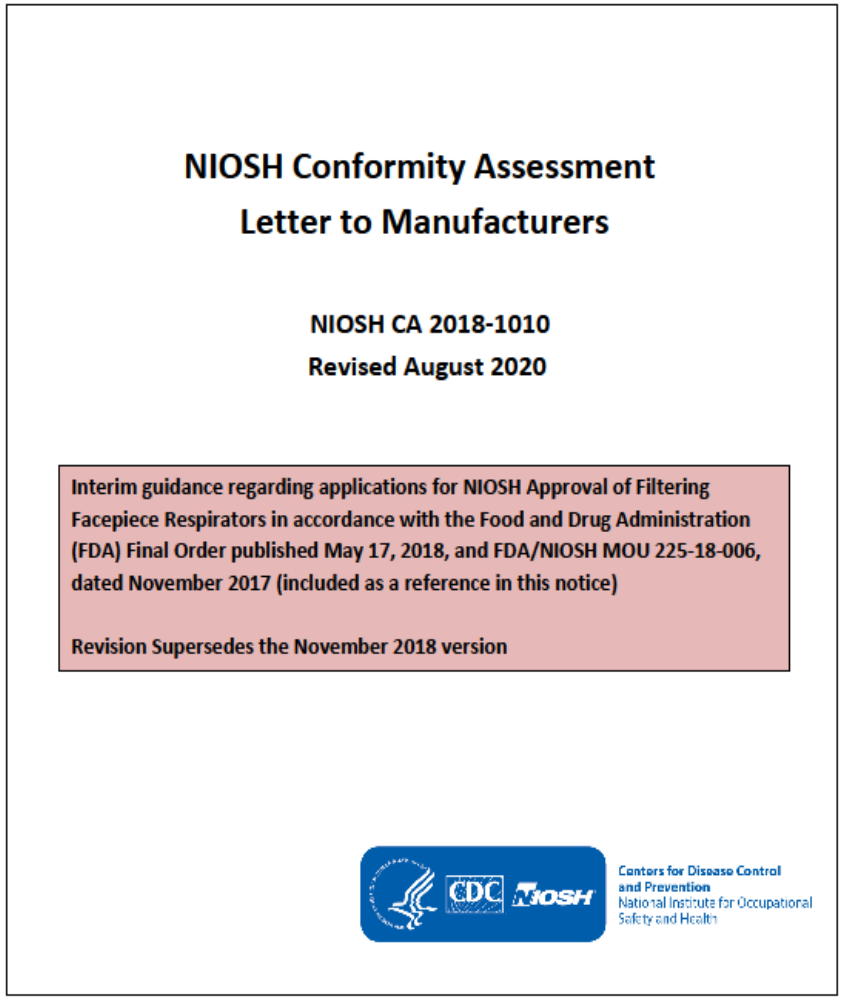
FDA

November 2018 guidance referred to these respirators as "N95-Fs**"*

NPPTL National Personal Protective Technology Laboratory

Revised guidance announced NIOSH is accepting SN95 approval applications as of August 24, 2020

https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2018-1010-R1.html



NIOSH Conformity Assessment
Letter to Manufacturers

NIOSH CA 2018-1010
Revised August 2020

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

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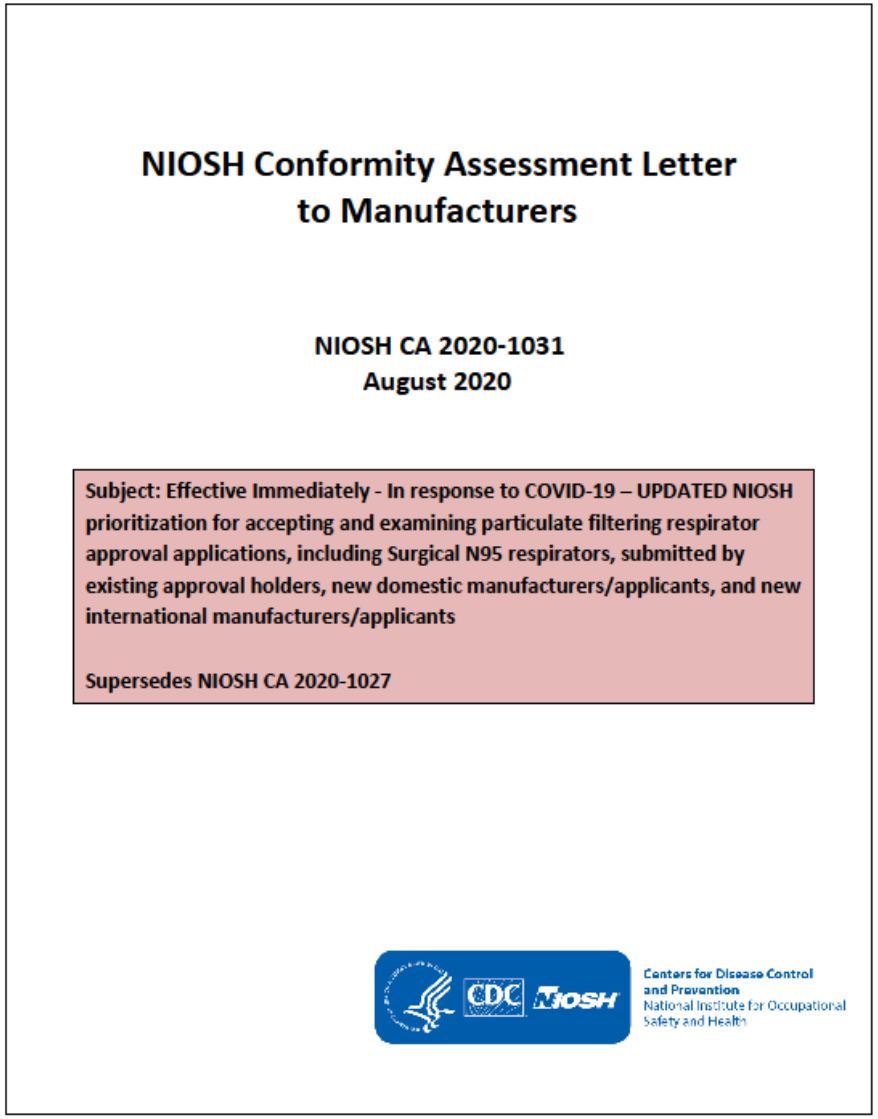
National Institute for Occupational Safety and Health

NIOSH posted the third prioritization notice on August 24, 2020, to include SN95 applications

https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2020-1031.html



NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2020-1031
August 2020

Subject: Effective Immediately - In response to COVID-19 – UPDATED NIOSH prioritization for accepting and examining particulate filtering respirator approval applications, including Surgical N95 respirators, submitted by existing approval holders, new domestic manufacturers/applicants, and new international manufacturers/applicants

Supersedes NIOSH CA 2020-1027

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National Institute for Occupational Safety and Health

Applicant for NIOSH Approval

- **Designs or controls the respirator design**
- **Manufactures, assembles, or controls the assembly of a respirator**

Four specific scenarios
NIOSH CA 2018-1010R1

- No immediate action under this guidance is required for an existing device that has previously obtained NIOSH approval and FDA 510(k) clearance.
- If a manufacturer of an existing NIOSH-approved N95 FFR 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 the guidance** to achieve **a NEW NIOSH approval for the SN95 respirator**.
- If a manufacturer of an existing NIOSH-approved N95 FFR 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 the guidance**.

How to achieve SN95 FFR Approval

- **Step** 1: Perform pre-submission testing
  - Inhalation resistance, exhalation resistance, particulate filter efficiency
  - Additional tests that must be performed at a GLP certified laboratory
    - Fluid penetration
    - Flammability
    - Biocompatibility
      - Cytotoxicity
      - Sensitization
      - Irritation

How to achieve SN95 FFR Approval Continued

- **Step 2**: Prepare documents and submit application to NIOSH, include final packaging
- **Step 3**: MOU defined FDA requirements evaluated by NIOSH, based on data provided
- **Step 4**: Evaluation and testing based on NIOSH requirements
- **Step 5**: SN95 approval issued, NIOSH CEL is updated
- **Step 6**: Manufacturer responsible for listing device with the FDA

NIOSH QUALITY ASSURANCE requirements - 42 CFR Part 84

- **Quality Manual**
  - Include the requirements outlined in NIOSH CA 2019-1019, and 42 CFR 84.
  - The quality control plan is sufficient enough to determine that the respirator is safe.
- **Inspection Procedures**
  - Incoming inspection procedures are clearly defined and serve to verify that the materials received conform to the specifications that were ordered.
  - Final inspection procedures are clearly defined and serve to verify that the fully assembled respirator conforms to the specifications on the drawing and the required performance specifications.
- **PQPs/sampling plans**
  - The definition of a lot or batch is clearly listed in the documentation.
  - The sampling plan used for each inspection is clearly stated. If a procedure other than those approved by NIOSH is used, the equivalency is explained *(see September 24, 2012 Letter to Manufacturers for further clarifications)*. Table 1 below shows widely accepted equivalent plans.

Exemptions from review under the MOU

- Respirators with exhalation valves or designs that are different than what the FDA has previously cleared (novel head suspensions)
- Specific disease and/or infection prevention
- Specific viral or bacterial filtration performance
- Antimicrobial or antiviral functions
- Hypo allergenicity
- Filtration of surgical smoke or plumes
- Nanotechnology
- Drug delivery systems
- Sterility claims
- Anything that isn't an N95…Review the guidance and the MOU!

How will NIOSH-approved SN95s be labeled?

- 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.*

NIOSH is developing a Respiratory Protective Device Information Notice about Surgical N95s (SN95)

- The NIOSH-approved SN95 offers the same respiratory protection as a NIOSH-approved N95 filtering facepiece respirator (FFR).
- Additionally, the SN95 conforms to FDA specified flammability, fluid resistance, and biocompatibility requirements and is intended for use in healthcare settings within, as well as outside, of the Operating Room.
- A SN95 is therefore ***not*** limited to use during surgery, but is **intended for use in all other healthcare settings** where respiratory protection is needed to protect the wearer.

Check these additional resources

The NIOSH Certified Equipment List (CEL)

NIOSH SN95 Trusted Resource Page

42 CFR Part 84

NIOSH Air-Purifying Standard Test Procedures

NIOSH Conformity Assessment Notices

NIOSH Respirator Approval Information

Disclaimer:
Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.

Quality Partnerships Enhance Worker Safety and Health

Join NIOSH/NPPTL for Respiratory Protection Week, September 8-11, 2020 and visit us at www.cdc.gov/niosh/npptl/

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. Mention of a company or product name does not constitute endorsement by NIOSH.

Question and Answers

- NIOSH, FDA, and OSHA experts are standing by to answer your questions.
- Questions specific to an applicant will be identified for follow-up by NIOSH or the FDA, after the webinar.

Thank you for your time and attention today!

Resources

Slide Presentation, Transcript and Webinar Recording will be available at:

https://www.fda.gov/training/cdrhlearn

Under Heading: Specialty Technical Topics and Sub-heading

Personal Protective Equipment (PPE)

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immediately following the conclusion of the live webinar.