NIOSH Activities Supporting the Optimization of Respiratory Protection

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Sacramento Valley AIHA Workshop

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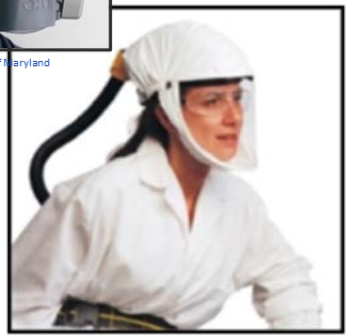

Photo credit: Honeywell International Inc.

Four topics will be addressed in the presentation

- Respiratory protection overview with an emphasis on filtering facepiece respirators (FFRs)
- Elastomeric half mask respirators (EHMRs)
- Powered air purifying respirators (PAPRs)
- Brief discussion of respirators, masks and barrier face coverings

NPPTL Mission and Responsibilities

- At the request of Congress, NIOSH established the National Personal Protective Technology Laboratory in 2001 with the mission to:
  - *Prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies.*
- Key Responsibilities:
  - Respirator conformity assessment,
  - Research on respirators and other types of personal protective equipment (PPE),
  - Outreach and communications.

Photo credit Moldex

Photo credit Draeger

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Respiratory protection overview with an emphasis on filtering facepiece respirators (FFRs)

Photo credit: 3M

Photo credit: 3M

The Respirator Conformity Assessment Program is the Cornerstone of NPPTL.

- Respirator approval
  - Over 9000 respirator systems approved
  - 90 manufacturers
  - 25 countries
- Post market evaluation
- Standards development

Conventional Routine Operations

- 30 approval decisions per month
- Approval decisions involve testing and evaluation and a quality assurance review

Three Key Factors Required for a Respirator to be Effective

Correct*

Incorrect

① The respirator must be put on correctly and worn during the exposure.

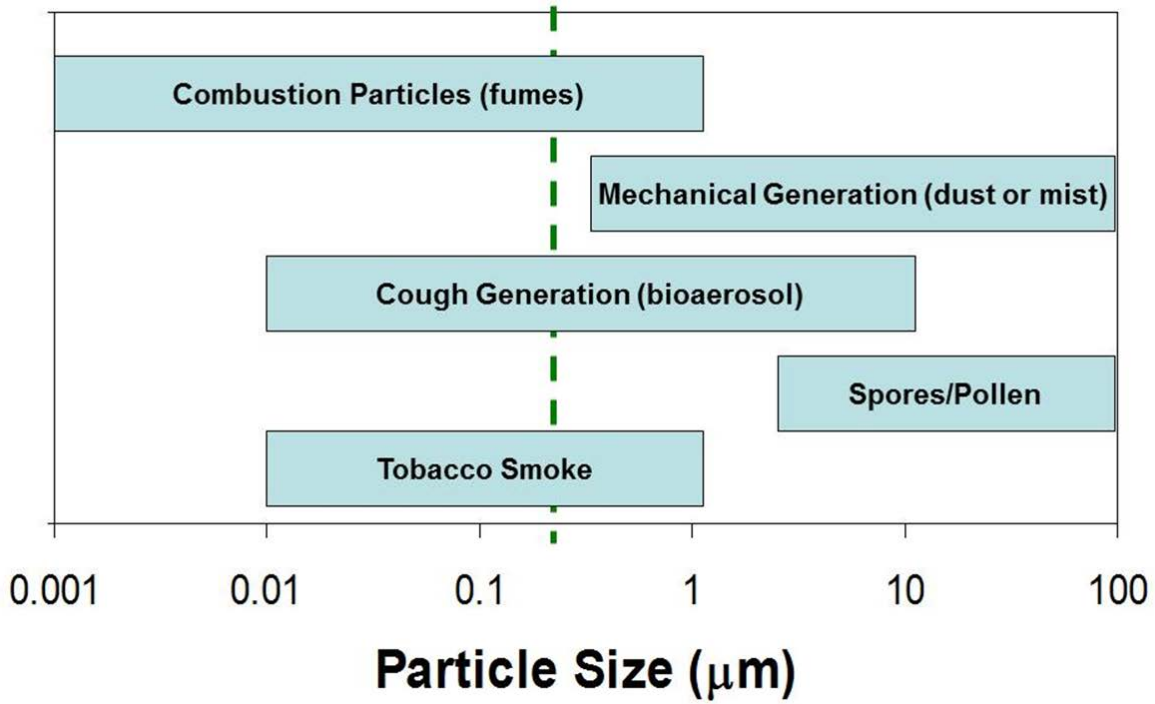
② The respirator must fit snugly against the user's face to ensure that there are no gaps between the user's skin and respirator seal.

③ The respirator filter must capture more than 95% of the particles from the air that passes through it.

CDC NIOSH

*If your respirator has a metal bar or a molded nose cushion, it should rest over the nose and not the chin area.

Filters in NIOSH-approved respirators are designed to filter many occupational hazards



Note: The dashed green line represents the 0.3 μm mass median aerodynamic diameter (MMAD) sodium chloride aerosol used by NIOSH for respirator filter testing of N95-class air-purifying respirators.

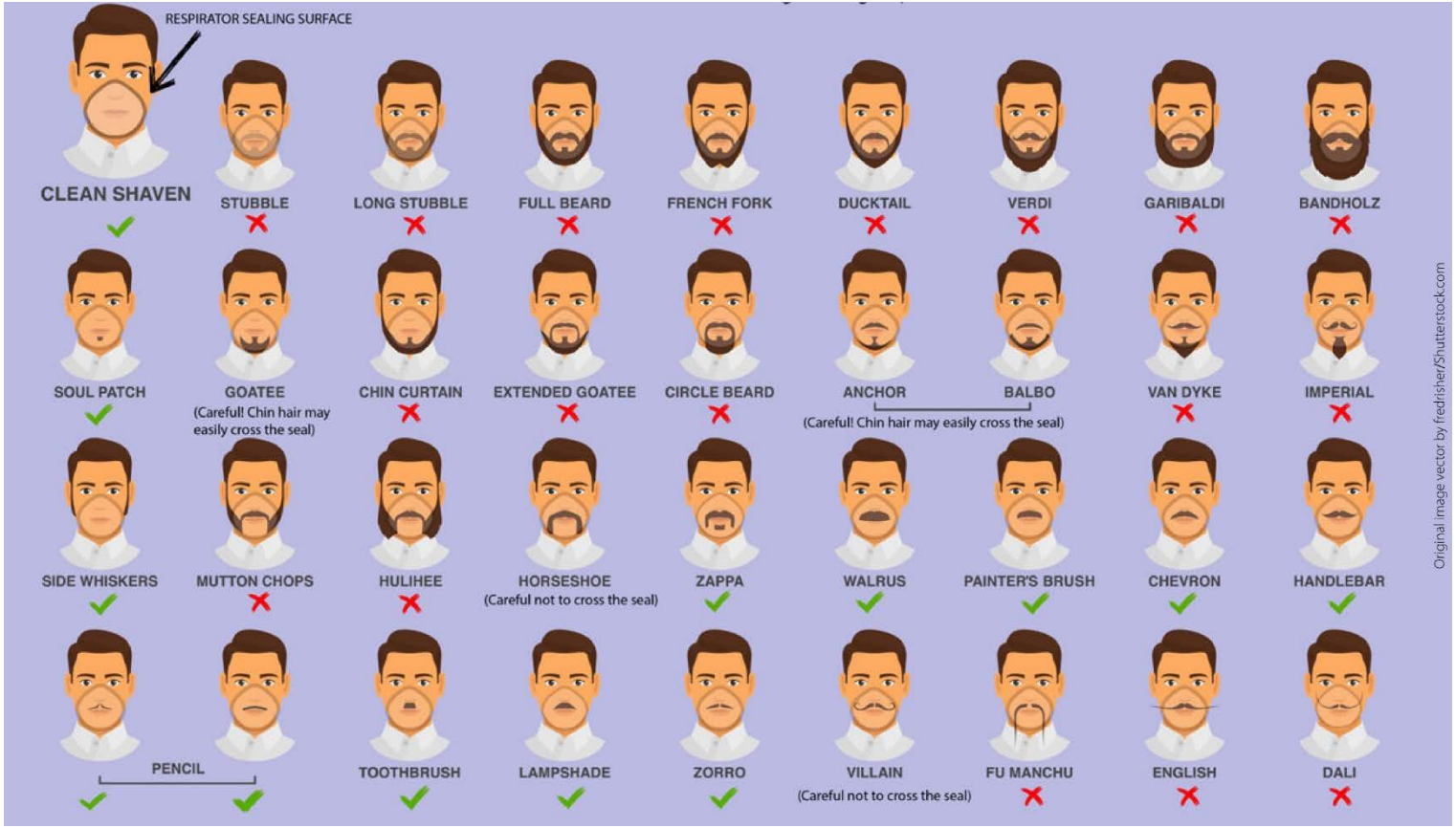
Respirators and face masks have a wide range of filter efficiencies*

Respirator/Mask Type	Filter Efficiency (%)
NIOSH P100 FFR / CE FFP3	>99.98
NIOSH N95 FFR / CE FFP2	>98.8
Unregulated Dust Mask	13-99
FDA Surgical Mask	12-98
Improvised Device	11-60
Cloth Mask	10-26

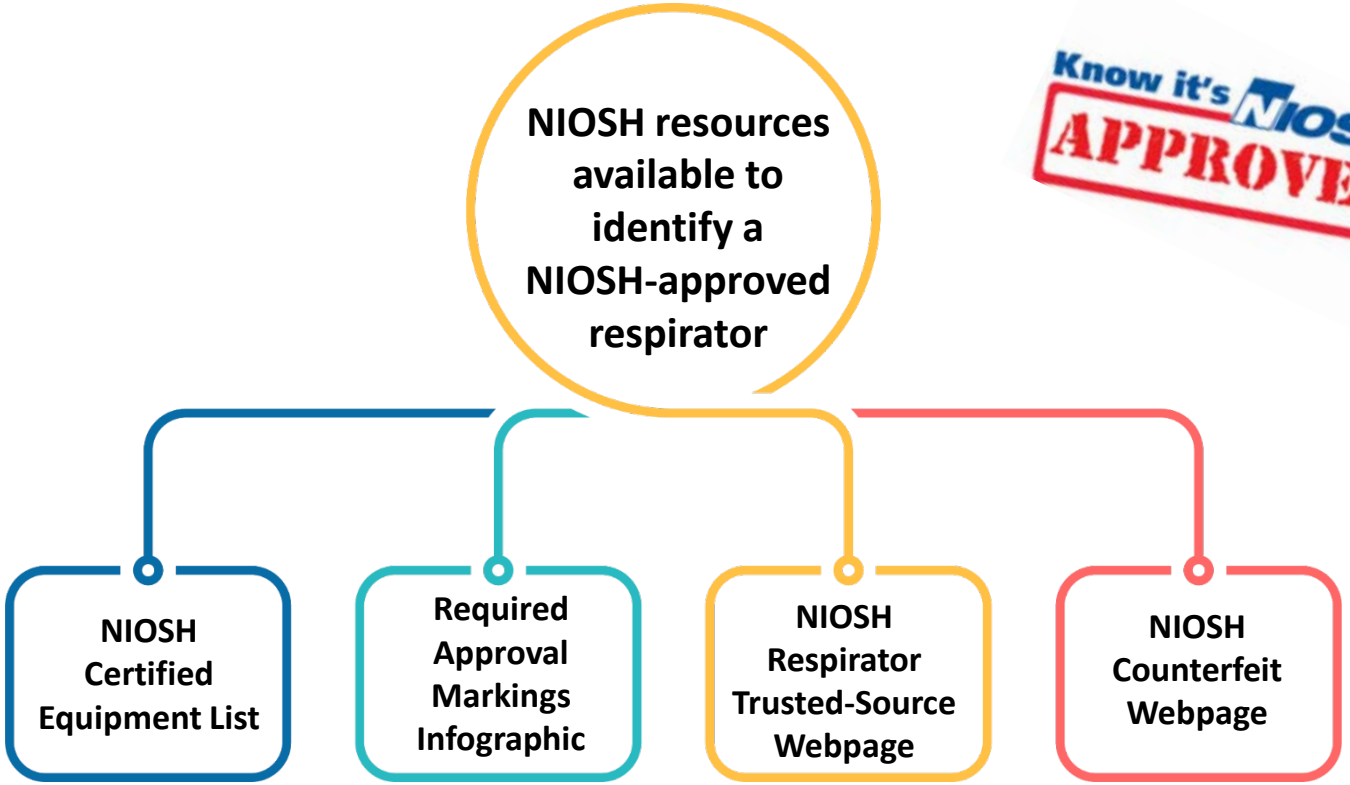
- Sample sizes (# of models): N95 FFR = 5, P100 FFR, FFP3, and FFP2 = 2, Surgical Mask = 5, Dust Mask = 5, Improvised Device = 12, Cloth Mask = 3
- Polydisperse Aerosol with Mass Median Diameter ~240 nm (TSI 8130)

Rengasamy, S.; Eimer, B.C.; Shafer, R.E. Nanoparticle Filtration performance of Commercially Available Dust Masks. Journal of the International Society for Respiratory Protection, Vol. 25. 2008.
Rengasamy, S.; Miller, A.; Eimer, B.C.; Shafer, R.E. Filtration performance of FDA-Cleared Surgical Masks. Journal of the International Society for Respiratory Protection, Vol. 26. 20098.

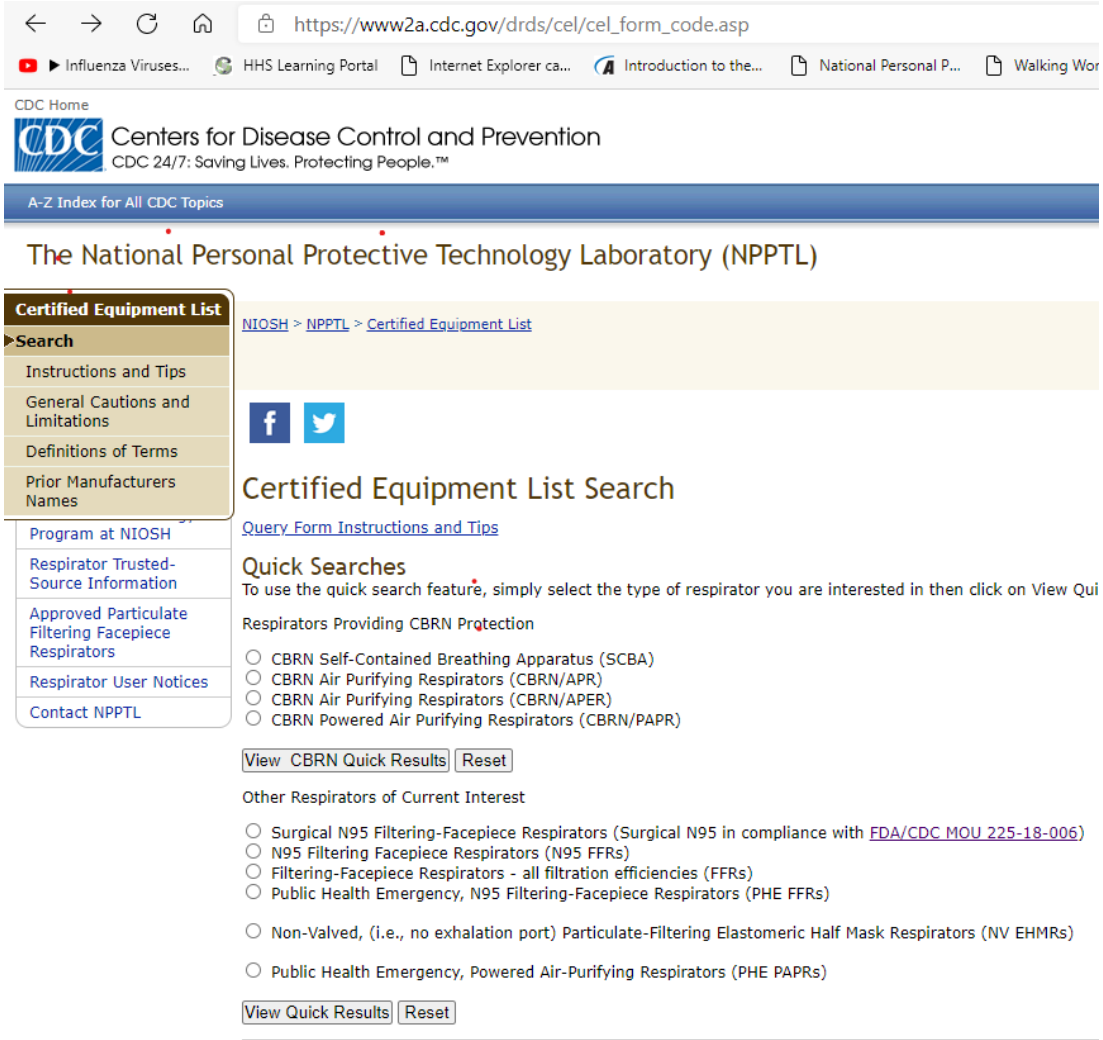
Facial hair that interferes with the respirator face seal area reduces the protection received by the wearer.



If worn appropriately, users can be confident that NIOSH-approved respirators will provide the expected level of protection



Every NIOSH approved respirator is available on the Certified Equipment List



NIOSH Certified Equipment List provides information about every approved respirator.

- NIOSH approved 8 new Surgical N95s since January 2020

Schedule	Approval #	Manufacturer	Product Identifiers	Facepiece Type
84A	9249	Honeywell International Inc.	Model DC370N95HC Filtering Facepiece	Filtering Facepiece
84A	9250	Honeywell International Inc.	Model DC365N95HC Filtering Facepiece	Filtering Facepiece
84A	9279	BYD Precision Manufacture Co.,Ltd.	Model DE2326 N95 Filtering Facepiece	Filtering Facepiece
84A	9288	ALG Health	Model PT-N95F-01S N95 Filtering Facepiece	Filtering Facepiece
84A	9290	ALG Health	Model PT-N95C-02S Filtering Facepiece	Filtering Facepiece
84A	9292	ALG Health	Model PT-N95CS-02S Filtering Facepiece	Filtering Facepiece
84A	9296	DemeTECH Corporation	Model DT-S95001-C Filtering Facepiece	Filtering Facepiece
84A	9297	DemeTECH Corporation	Model DT-S95002-F and DT-S95002-FS Filtering Facepieces	Filtering Facepiece

- Based on a Memorandum of Understanding between FDA and NIOSH, NIOSH is responsible for evaluation of fluid resistance, flammability and biocompatibility data
  - https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006
  - https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2018-1010-R1.html
- These products are now exempt from 510K clearance
- Manufacturers must list the device with FDA

19 New FFR Manufacturers were added to the NIOSH CEL in 2020.

- Aidway Personal Care Product Inc.
- ALG Health
- American PAPR LLC
- AmSafe Inc. (PHE-Only)
- DemeTECH Corporation
- Ford Motor Company (PHE-Only)
- FSSC, LLC; DBA Indiana Face Mask
- General Motors Company (PHE-Only)
- Hunter Engineering Company (PHE-Only)
- Lighthouse Worldwide Solutions
- Outdoor Research, LLC (PHE-Only)
- Pacific PPE Corporation
- Pandmedic, Inc. (PHE-Only)
- Plastikon Industries, Inc. (PHE-Only)
- Protective Health Gear, Inc. (PHE-Only)
- ThermoPore Materials Corporation (PHE-Only)
- United States Mask, LLC (PHE-Only)
- ViruDefense, Inc. (PHE-Only)
- WellSpan Health (PHE-Only)
- Whirlpool Corporation (PHE-Only)

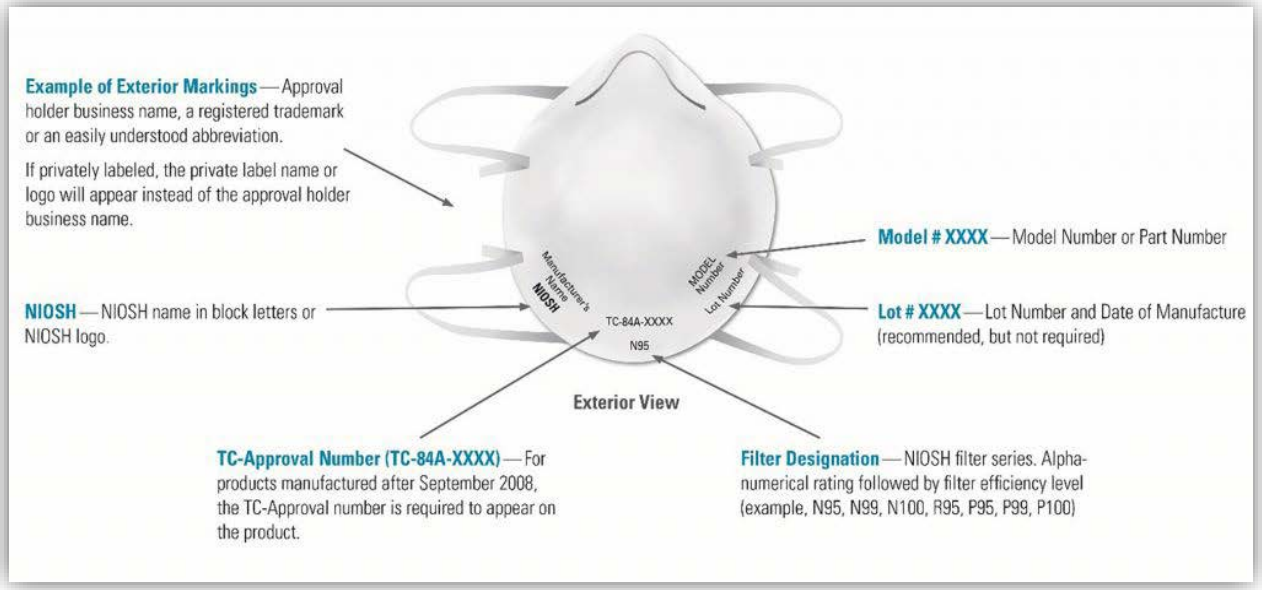
12 new manufacturers have FFRs approved as NIOSH Public Health Emergency Approvals.

Schedule	Approval #	Manufacturer	Product Identifiers	Facepiece Type
84A	PH01	GM Global Technical Center	Model GM 002 FFR-L N95 Public Health Emergency Filtering Facepiece	Filtering Facepiece
84A	PH03	WellSpan Health	Model RMD-N95-100R N95 Pubic Health Emergency Filtering Facepiece	Filtering Facepiece
84A	PH04	GM Global Technical Center	Model GM-FFR-003-1 N95 Public Health Emergency Filtering Facepiece	Filtering Facepiece
84A	PH05	Ford Motor Company	Model FMCN95 Public Health Emergency Filtering Facepiece	Filtering Facepiece
84A	PH06	ViruDefense, Inc.	Model VDI-100 N95 Public Health Emergency Filtering Facepiece	Filtering Facepiece
84A	PH07	WellSpan Health	Model RMD-N95-200R Public Health Emergency N95 Filtering Facepiece	Filtering Facepiece
84A	PH08	GM Global Technical Center	Model GM 005-FFR-S Public Health Emergency N95 Filtering Facepiece	Filtering Facepiece
84A	PH10	ThermoPore Materials Corporation	Model 110.118 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH11	ThermoPore Materials Corporation	Model 119.128 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH12	ThermoPore Materials Corporation	Model 123.138 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH13	ThermoPore Materials Corporation	Model 107.128 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH14	ThermoPore Materials Corporation	Model 124.124 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH15	Protective Health Gear, Inc.	Model 5160 (Part Number 879 N95) Public Health Emergency N95 Filtering Facepiece Respirator	Filtering Facepiece
84A	PH16	Pandmedic, Inc.	Model MedicPro N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH17	AmSafe Inc.	Model 506478-1 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH18	Outdoor Research, LLC	Model 283036 N95 Public Health Emergency Filtering Facepiece Respirator	Filtering Facepiece
84A	PH19	Plastikon Industries, Inc.	Model Plasma N95-01 N95 Public Health Emergency Filtering Facepiece	Filtering Facepiece
84A	PH20	United States Mask, LLC	Model 1836 (part number 183601) N95 Public Health Emergency Filtering Facepiece	Filtering Facepiece

Total records found: 18
Records shown: 1 to 18

Required approval markings on a NIOSH-approved FFR

- Since 2008, NIOSH has required the Approval number to be on the respirator or strap
- Respirator should state NIOSH and the protection level, i.e., N95
- Beware of false claims
  - Inspect the respirator
  - Inspect the packaging
  - Review the required labeling



https://www.cdc.gov/niosh/npptl/pdfs/N95-Infographic-Mask-Labeling-508.pdf

NIOSH Counterfeit/Misrepresentation Webpage

- NIOSH's authority only extends to companies who hold a NIOSH approval
- Misrepresentation vs. counterfeit
- Tips for spotting counterfeit respirators:
  - No markings at all on the filtering facepiece respirator (FFR)
  - No approval (TC) number on FFR or headband
  - No NIOSH markings or NIOSH spelled incorrectly
  - Presence of decorative fabric or other decorative add-ons (e.g., sequins)
  - Claims of approval for children (NIOSH does not approve any type of respiratory protection for children)
  - FFR has ear loops instead of headbands

Counterfeit Respirators / Misrepresentation of NIOSH-Approval

This is an example of a misrepresentation of a NIOSH-approved product. Products labeled as DermaCare or Espomega, with model numbers HY8710, HY8812, and HY8816, are NOT NIOSH approved. (8/7/2020)

This is an example of a misrepresentation of a NIOSH approval. Intech Safety Pvt. Ltd. is not a NIOSH approval holder or a private label holder. (8/7/2020)

NIOSH has been notified that Valmy model VRN95 is being misrepresented as NIOSH approved. This model has not been NIOSH approved since 2017. The product being sold is no longer compliant to the NIOSH approval. (8/25/2020)

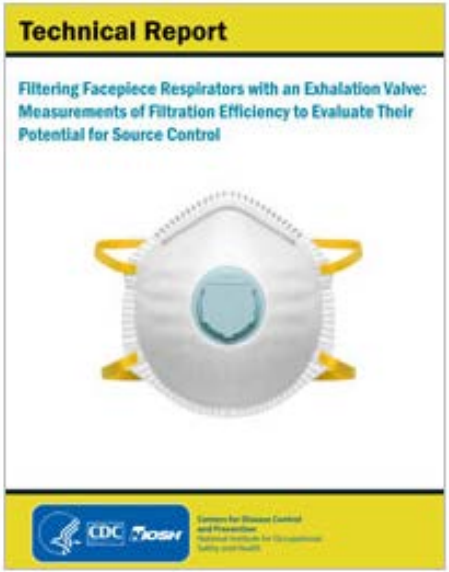
https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

NIOSH Respirator Trusted-Source Webpage

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html

NIOSH NPPTL recently evaluated the source control potential of FFRs with exhalation valves

- Key findings from Dec. 2020 NIOSH FFR exhalation valve report
  - FFRs with exhalation valves allow some exhaled breath to leak through the valve without being filtered
  - FFRs with exhalation valves reduce submicron particle emissions more consistently than other face coverings used for source control
  - An electrocardiogram pad secured over the valve from the inside of the FFR can provide source control comparable to that of an FFR with no exhalation valve; the FFR manufacturer should authorize this strategy
- CDC is updating its recommendations to address outward leakage mitigation strategies when respirators with exhalation valves are needed due to supply shortages
- Research is ongoing for EHMRs



NIOSH FFR exhalation valve publication:
https://www.cdc.gov/niosh/docs/2021-107/default.html
NIOSH FFR and EHMR exhalation valve research page:
https://www.cdc.gov/niosh/npptl/respirators/exhalationvalve/default.html

First FFR Approval with exhalation valve cover accessory
3M™ 8511 Particulate Respirator with 3M™ Multi-Use Duct Tape

- **IMPORTANT: Keep these *User Instructions* for reference**
- NIOSH approved for use only with 3M™ 8511 Particulate Respirator and any color 3M™ Multi-Use Duct Tape (1.88 inch [48mm]).
  - Black (3920-BK, 3960-BK)
  - Red (3920-RD, 3960-RD)
  - White (3920-WH, 3960-WH)
  - Blue (3920-BL)
  - Brown (3920-BR)
  - Green (3920-GR)
  - Orange (3920-OR)
  - Yellow (3920-YL)
- WARNING!
  - Respirators help protect against certain airborne contaminants. **Misuse may result in sickness or death.** For proper use, see supervisor, or *User Instructions*, or call 3M in U.S.A., 1-800-243-4630. In Canada, call Technical Service at 1-800-267-4414.
  - Important information is provided in the *User Instructions* for 3M™ 8511 Particulate Respirators. Failure to follow *User Instructions* for these products **may result in sickness or death.**

Decontamination of FFRs is a crisis capacity strategy that can be used during periods of known FFR shortages

- CDC does not recommend that FFRs be decontaminated and then reused as standard care
  - FFR manufacturers guidance should be followed
- NIOSH's National Personal Protective Technology Laboratory (NPPTL) has assessed various FFR decontamination methods
  - https://www.cdc.gov/niosh/npptl/respirators/testing/DeconResults.html

Methods showing limited impact on FFR filtration or fit	Methods that may change FFR performance/function or present health hazard to wearer	
Vaporous hydrogen peroxide	Autoclave	Dry microwave irradiation
Ultraviolet germicidal irradiation	Dry heat	Bleach
Moist heat	Isopropyl alcohol	Disinfection wipes
Methylene blue*	Soap	Ethylene oxide**

**Novel approach, not authorized by the FDA*
***Not recommended as it may be harmful to the wearer*

CDC authorized the use of respirators conforming to other international standards as a crisis capacity measure

Post approval activities shifted from NIOSH-approved respirators to NIOSH-approved stockpiled respirators and non-NIOSH-approved respirators imported from other countries.

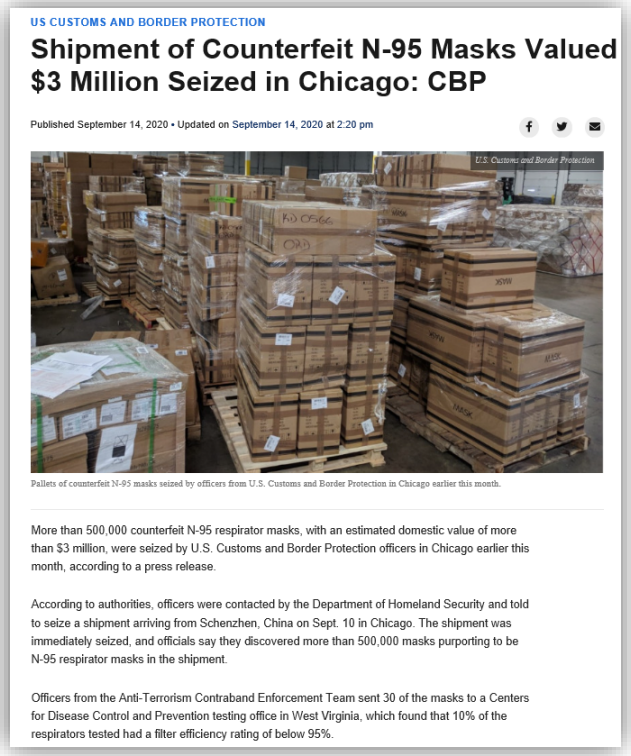
- **NIOSH evaluated imported products**
  - >500 Reports Posted.
- **International assessments finding substandard products**
  - ~60% of international respirators provide below 95% filtration efficiency.
- **New cases of counterfeit/Mis-Use of NIOSH Approval**
  - Compare submitted records with approved application.

Country	Testing Standard
Australia	AS/NZ S1716:2012
Brazil	ABNT/NBR 13698:2011
People'sRepublic of China	GB 2626:2006 GB 2626:2019 GB 19803:2010
Europe	EN 1492001
Japan	JMHLW2000
Korea	KMOEL2017-64
Mexico	NOM-116-2009

https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html

NIOSH assessments have supported the FDA EUA and counterfeit decisions

- **Impact of Assessments**
  - Supporting the FDA's Emergency Use Authorizations (EUA)
  - FDA EUA list currently includes 164 manufacturers with over 225 respirator models; after NIOSH assessments, 53 manufacturers have been removed
  - FDA modified their sampling to improve assessment
  - NIOSH testing efforts assist federal agencies to identify counterfeit respirators
- **Communication Outputs**
  - NIOSH Webinars
  - "Factors to Consider When Purchasing Respirators From Another Country". May 2020
  - "Importing Respirators for Health Care Personnel Use". June 2020 (FDA and NIOSH)
  - "How to spot a counterfeit! Understanding the Misrepresentation of NIOSH Approval". Sep. 2020
  - NIOSH Science Blog
  - "Understanding the Use of Imported Non-NIOSH-Approved Respirators". April 2020
  - NIOSH Reports
  - 380+ assessment-specific reports published online
  - PPE CASE Report: "Filtration Efficiency Performance of Non-NIOSH-Approved International Respiratory Protective Devices: Phase One"



US CUSTOMS AND BORDER PROTECTION

Shipment of Counterfeit N-95 Masks Valued $3 Million Seized in Chicago: CBP

Published September 14, 2020 • Updated on September 14, 2020 at 2:20 pm

Pallets of counterfeit N-95 masks seized by officers from U.S. Customs and Border Protection in Chicago earlier this month.

More than 500,000 counterfeit N-95 respirator masks, with an estimated domestic value of more than $3 million, were seized by U.S. Customs and Border Protection officers in Chicago earlier this month, according to a press release.

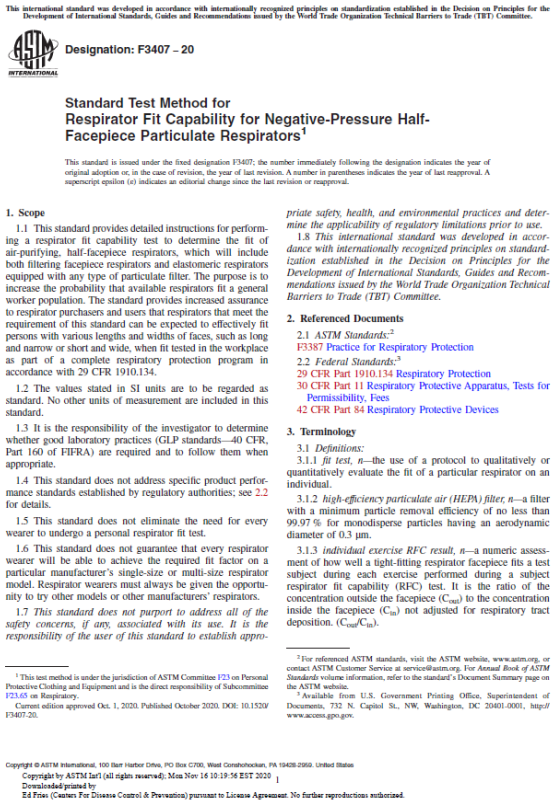
According to authorities, officers were contacted by the Department of Homeland Security and told to seize a shipment arriving from Schenzhen, China on Sept. 10 in Chicago. The shipment was immediately seized, and officials say they discovered more than 500,000 masks purporting to be N-95 respirator masks in the shipment.

Officers from the Anti-Terrorism Contraband Enforcement Team sent 30 of the masks to a Centers for Disease Control and Prevention testing office in West Virginia, which found that 10% of the respirators tested had a filter efficiency rating of below 95%.

Respirator Fit Capability Standard

FFRs meeting the Respirator Fit Capability Standard could provide better assurance of fit.

- ASTM F3407 Standard Test Method
- Methodology
  - 25-member NIOSH Bivariate Panel
  - Sodium chloride aerosol in chamber measured with condensation nuclei counter
  - 13 or more subjects must have a factor ≥ 100
- Expected outcome
  - Higher probability of fitting a general worker population
- Does not replace workplace fit testing
- Does not guarantee every respirator will fit ever wearer



This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: F3407 – 20

Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators[1]

This standard is issued under the fixed designation F3407; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard provides detailed instructions for performing a respirator fit capability test to determine the fit of air-purifying, half-facepiece respirators, which will include both filtering facepiece respirators and elastomeric respirators equipped with any type of particulate filter. The purpose is to increase the probability that available respirators fit a general worker population. The standard provides increased assurance to respirator purchasers and users that respirators that meet the requirement of this standard can be expected to effectively fit persons with various lengths and widths of faces, such as long and narrow or short and wide, when fit tested in the workplace as part of a complete respiratory protection program in accordance with 29 CFR 1910.134.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 It is the responsibility of the investigator to determine whether good laboratory practices (GLP standards—40 CFR, Part 160 of FIFRA) are required and to follow them when appropriate.

1.4 This standard does not address specific product performance standards established by regulatory authorities; see 2.2 for details.

1.5 This standard does not eliminate the need for every wearer to undergo a personal respirator fit test.

1.6 This standard does not guarantee that every respirator wearer will be able to achieve the required fit factor on a particular manufacturer's single-size or multi-size respirator model. Respirator wearers must always be given the opportunity to try other models or other manufacturers' respirators.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]
F3387 Practice for Respiratory Protection

2.2 *Federal Standards:*[3]
29 CFR Part 1910.134 Respiratory Protection
30 CFR Part 11 Respiratory Protective Apparatus, Tests for Permissibility, Fees
42 CFR Part 84 Respiratory Protective Devices

3. Terminology

3.1 *Definitions:*

3.1.1 *fit test, n*—the use of a protocol to qualitatively or quantitatively evaluate the fit of a particular respirator on an individual.

3.1.2 *high-efficiency particulate air (HEPA) filter, n*—a filter with a minimum particle removal efficiency of no less than 99.97 % for monodisperse particles having an aerodynamic diameter of 0.3 µm.

3.1.3 *individual exercise RFC result, n*—a numeric assessment of how well a tight-fitting respirator facepiece fits a test subject during each exercise performed during a subject respirator fit capability (RFC) test. It is the ratio of the concentration outside the facepiece (C_{out}) to the concentration inside the facepiece (C_{in}) not adjusted for respiratory tract deposition. (C_{out}/C_{in}).

[1] This test method is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.65 on Respiratory.
Current edition approved Oct. 1, 2020. Published October 2020. DOI: 10.1520/F3407-20.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.
[3] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.

ASTM F3407 Standard for Respirator Fit Capability Impact

- Respirator manufacturers could use to develop models that fit the worker population with better fitting characteristics.
- Respiratory protection program costs will be lower due to the reduced number of different models needed in the program to fit all wearers.
- Purchasers could reference standard in their procurement packages to ensure receiving those with good fitting characteristics.
- Conformity assessment program owners (e.g., NIOSH) will be able to use the RFC standard in their program to evaluate respirator designs.
- Wearers will be better protected.

Elastomeric half mask respirators (EHMRs)

Photo credit: MSA

Photo credit: University of Maryland

Elastomeric Half-mask Respirators (EHMRs)

- Tight-fitting respirators that are made of synthetic or rubber material permitting them to be repeatedly disinfected, cleaned, and re-donned
  - Equipped with replaceable filters
  - May have disposable components
- NIOSH-approved
- OSHA assigned protection factor (APF) same as N95 FFRs
- Fit-testing required (same process as N95 FFRs)
- NIOSH has been exploring the use of EHMRs in healthcare since 2014

Photo Courtesy of MSA

Photo courtesy UMSM

EHMRs have several benefits...

- Reusable→cost-savings
- Replaceable cartridges
- One EHMR assigned to each worker
- Offer at least equivalent or more protection to N95 FFRs
- Adjustable straps → better fit
- Reported by healthcare workers to be
  - More comfortable
  - Perceived as having increased protection

Photos courtesy Google Images

...and some potential challenges

- Lack of familiarity/experience among healthcare and emergency personnel
- May interfere with communication and downward gaze
- Carried by healthcare personnel during workday
- Storage between work shifts
- Cleaning and disinfection

Photo Courtesy of Shutterstock

Photo Courtesy of NIOSH NPPTL

CDC provides elastomeric disinfection guidance for crisis capacity scenarios

- **Routine operations**
  - **Disinfection is not part of the NIOSH approval.**
    NIOSH points to the manufacturers' instructions.
  - OSHA permits employers to use the cleaning recommendations provided by the respirator manufacturer.
  - Bessesen protocol used by several facilities.
- **Crisis capacity guidelines**
  - CDC and NIOSH provide guidelines for disinfection, including the Bessesen protocol.
  - Enclosed filter cartridges are recommended.
  - EPA authorized disinfectants are identified.
- **Science-based standards are needed for routine operations**
  - Lawrence et al. found that EHMRs could be cleaned up to 150 times without significant degradation or performance and functionality.
  - Integrity of filter media should not degrade.
  - Ancillary components should not degrade.
  - Off-gassing should not be an issue in the facepiece.

***CDC optimization strategies* for EHMR use, cleaning, disinfection storage, and filters:**
https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html

Example of filter enclosed in a cartridge

Photo credit: MSA

Example of "pancake" filter

Photo credit: MSA

Some users identify a need for improved communications when using respirators.

- Interim Final Rule for the PAPR standard provides improved standards for healthcare, including a communications requirement

https://www.cdc.gov/niosh/npptl/respstandards/papr.html

- There are no other communications requirement for air purifying respirators
  - Some elastomeric half mask respirators are equipped with a speech diaphragm

Photo credit: Honeywell International Inc.

There are many NIOSH-approved EHMR models available on the U.S. market

Photo courtesy of Gerson

Photo courtesy of JSP

Photo courtesy of Honeywell

Photo courtesy of Moldex

Photo courtesy of Moldex

Photo courtesy of SAS

Photo courtesy of North

Photo courtesy of Gerson

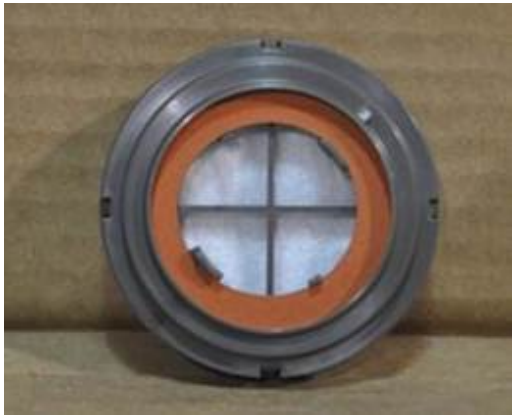
NIOSH approved two EHMRs w/o an exhalation valve.

- Inhaled/exhaled air passes through filters
- Can be used for both respiratory protection and source control

Photo courtesy of MSA

Comfort Air Nx MD Photos courtesy of Dentec

First Elastomeric Approval with exhalation valve cover accessory 3M™



NIOSH has several EHMR studies currently underway for specific organization types and work units

NIOSH-contracted Organization	Rapid Fit Testing	EHMR Cleaning/ Disinfection Process	EHMR use and perceptions in routine patient care	Develop EHMR Hospital Best Practices Guidelines
EMORY HEALTHCARE	✓	✓	✓	
Wayne State University	✓		✓	
UTHealth The University of Texas Health Science Center at Houston School of Public Health	✓	✓	✓	
University of Maryland School of Medicine			✓	✓
Allegheny Health Network			✓	✓

Photos Courtesy Google Images

University of Maryland's Implementation Guide to Support Use of Elastomeric Half Mask Respirators in Healthcare is Posted

This document serves as a guide to support implementation of elastomeric respirator-based respiratory protection programs in healthcare settings. Based on best practices employed in hospital and ambulatory practices at the University of Maryland-Baltimore, the guide includes background evidence, logistics on fit-testing, distribution and decontamination, and a summary of cost estimates associated with this form of respiratory protection. The guide includes tools like Information Sheets, checklists, training tools and photos to help other programs set up their own programs.

Centers for Disease Control and Prevention (CDC)
Contract # 75D30120P09044

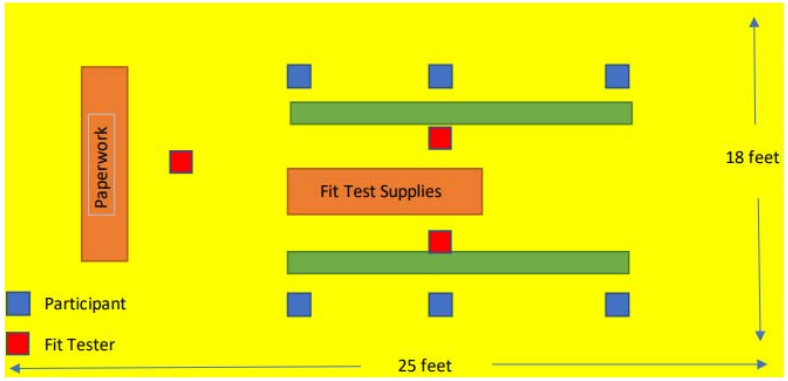


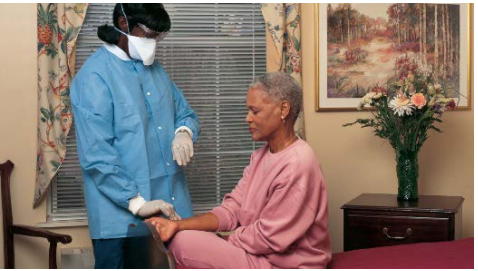
Figure 8. Example room layout to accommodate 6-person fit-testing with social distancing.

Figure 9. EHMR Fit-Testing.

Credit University of Maryland

Implementation Guide to Support Use of Elastomeric Half Mask Respirators in Healthcare (umaryland.edu)




Photos Courtesy Kimberly Clark, Moldex, Shutterstock

In collaboration with the SNS, NIOSH posted an EHMR Federal Register Notice* (FRN) to…

- Identify organizations to:
  - Receive EHMRs purchased by the Strategic National Stockpile (SNS)
  - Collect and provide user and implementation experiences using NIOSH-developed tools
  - Review and provide input on two already existing EHMR Hospital Implementation Guidelines

*FRN posted 09/14/2020 and closed **12/14/2020.** FRN was open to all healthcare and first responder organizations. ~ 90 responses

Organizations in California responding to the FRN

- Stanford Healthcare
- San Mateo Medical Center
- Ridgecrest Regional Hospital
- Laguna Honda Hospital and Rehabilitation Center
- San Joaquin General Hospital
- University of California San Francisco Health

Powered Air Purifying Respirators (PAPRs)

Photo credit: Honeywell International Inc.

Photo credit: Ford Motor Company

Powered Air-Purifying Respirators (PAPRs)

- APRs that use a blower to force air through filter cartridges or canisters
- Tight-fitting facepiece (APR 50 or 1,000; requires fit testing) or a loose-fitting hood or helmet (APR ≥25; no fit testing requirement)
- Advantages
  - Reusable → cleaned, disinfected, re-used, and shared
  - High-efficiency filters are used → greater filtration efficiency than N95 FFRs
  - May be more comfortable from a physiological/breathing resistance perspective
- Challenges
  - May interfere with field of view
  - Hearing may be reduced due to blower noise
  - Batteries must be recharged/replaced
  - Storage

Photo Courtesy: Bullard

***CDC optimization strategies* for PAPR use, cleaning, disinfection storage, and filters:**
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/powered-air-purifying-respirators-strategy.html

CDC provides PAPR disinfection guidance for crisis capacity scenarios.

- **Routine operations**
  - **Disinfection is not part of the NIOSH approval**, NIOSH point to the manufacturers' instructions
  - OSHA permits employers to use the cleaning recommendations provided by the respirator manufacturer
- **Crisis capacity guidelines**
  - CDC Guidance provides recommendations for crisis capacity scenarios
- **Science-based standards are needed for routine operations**
  - Lawrence et al. found that PAPRs and elastomeric respirators could be cleaned up to 150 times without significant degradation or performance and functionality
  - Integrity of filter media should not degrade
  - Ancillary components should not degrade

Photo credit: Honeywell International Inc.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/powered-air-purifying-respirators-strategy.html

Five PAPRs are approved as NIOSH Public Health Emergency Approvals.

Schedule	Approval #	Manufacturer	Product Identifiers	Facepiece Type
21C	PH02	Ford Motor Company	Public Health Emergency, Powered Air Purifying Respirator with Hood and Filter	Hood
21C	PH03	Allegro Industries	Model Allegro PAPR HE Class Public Health Emergency, Powered Air Purifying Respirator with Hood and Filter	Hood
21C	PH04	American PAPR LLC	Model Felix100 Public Health Emergency, Powered Air Purifying Respirator PAPR100-N Series	Hood
21C	PH05	AirBoss Defense	Model FlexAir Public Health Emergency, Powered Air Purifying Respriator with Hood and Filter	Hood
21C	PH06	Hunter Engineering Company	Model Hunter/VHA ADAPT374-1 Public Health Emergency, Powered Air Purifying Respriator with Hood and Filter	Hood

Total records found: 5
Records shown: 1 to 5

Respirators, Medical Masks, and Barrier Face Coverings

Understanding Product Differences

Respirators

"3.1.8 *respirator, n*—Personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous atmospheres."

Medical Face Masks

"3.1.7 *medical face mask, n*—an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures."

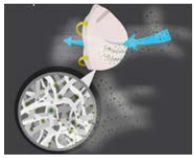
Barrier Face Coverings

"3.1.3 *barrier face covering, n*—a product worn on the face specifically covering at least the wearer's nose and mouth with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter."

	Cloth Mask	Non medical mask	Medical Mask	Barrier Face Covering	Respirators
Use as source control?	yes	yes	yes	yes	yes
Use as respiratory protection	no	no	no	no	Yes, when fitted and used properly
Can be tested to limit leakage evaluate fit	no	no	no	standard has leakage assessment requirement, could be quantitative	Yes, when fitted and used properly
Have standard for performance	no	no	ASTM F2100	ASTMF3502	42 CFR Part 84
Regulated Testing and approval	no	no	Cleared by FDA	3rd Party testing for filtration efficiency and breathability	Approved by NIOSH
Intended users?	General public	General public	Health Care General Public	General Workers Healthcare General public	Users who need respiratory protection.

NIOSH is involved in several initiatives to address gaps in non-occupational respiratory protection and source control

- **American Society of Testing & Materials Standard:** ***"Specification for Barrier Face Coverings"***
  - Barrier Face Coverings are disposable or reusable protective devices for general public use that are neither a respirator nor a surgical mask.
  - Standard will provide a consistent way to benchmark products to inform user selection decisions and will define performance requirements for source control and protective capability.
  - NIOSH studies will validate the minimum performance requirements.
- **National Academy of Medicine workshop (August 2020) and Consensus Study (Feb 2022)**
  - Discussed non-occupational respirator use and initiated follow-on comprehensive consensus study.
  - Need for a conformity assessment approach for a consistent way to evaluate respiratory protective devices for protection and source control for the general public.



Particulate filtration efficiency

Fit

Comfort

Reuse

https://www.nap.edu/catalog/25951/current-issues-in-the-assessment-of-respiratory-protective-devices-for-occupational-and-non-occupational-uses

https://www.nationalacademies.org/our-work/respiratory-protection-for-the-public-and-workers-without-respiratory-protection-programs-at-their-workplaces

Respirator Resources

- FDA and NIOSH Memorandum of Understanding (MOU) for surgical N95s
  - https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006
  - https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2018-1010-R1.html
- NIOSH NPPTL COVID-19 Respirator Assessments and Results
  - https://www.cdc.gov/niosh/npptl/respirators/testing/default.html
  - https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html
- NIOSH Certified Equipment List (CEL)
  - https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html
- NIOSH Respirator Trusted-Source Information
  - https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html
- NIOSH FFR Approval Markings Infographic
  - https://www.cdc.gov/niosh/npptl/pdfs/N95-Infographic-Mask-Labeling-508.pdf
- NIOSH Respirator Counterfeit Information
  - https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
- NIOSH FFR Exhalation Valve Technical Report
  - https://www.cdc.gov/niosh/docs/2021-107/default.html
- NIOSH FFR and EHMR Exhalation Valve Research Webpage
  - https://www.cdc.gov/niosh/npptl/respirators/exhalationvalve/default.html
- EHMR NIOSH Science Blog
  - https://blogs.cdc.gov/niosh-science-blog/2020/09/08/elastomeric/
- Bessesen Reusable Respirator Disinfection
  - Bessesen M, Adams JC, Radonovich L, Anderson J [2015]. *Disinfection of Reusable Elastomeric Respirators by Health Care Workers: A Feasibility Study and Development of Standard Operating Procedures*. American Journal of Infection Control 43(6):629-634.
- CDC PPE FAQ
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html
- CDC PPE Optimization Strategies (gloves, N95 and other FFRs, EHMRs, PAPRs, gowns, face masks, and eye protection)
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

Questions

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