NIOSH Activities Supporting the Optimization of Respiratory Protection

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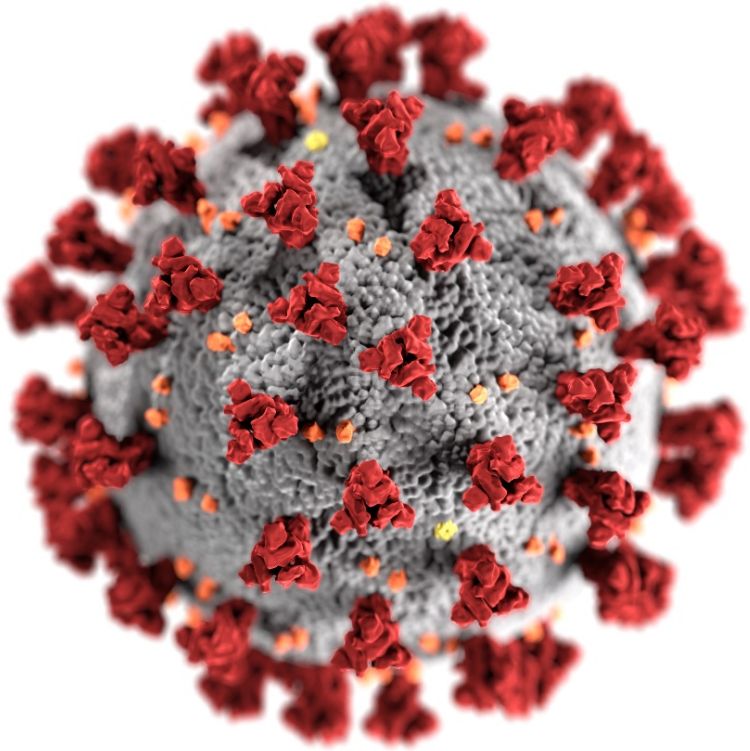

cdc.gov/coronavirus

Three topics will be addressed in the presentation

- Federal respirator and mask authorities
- Respirators
- Masks

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

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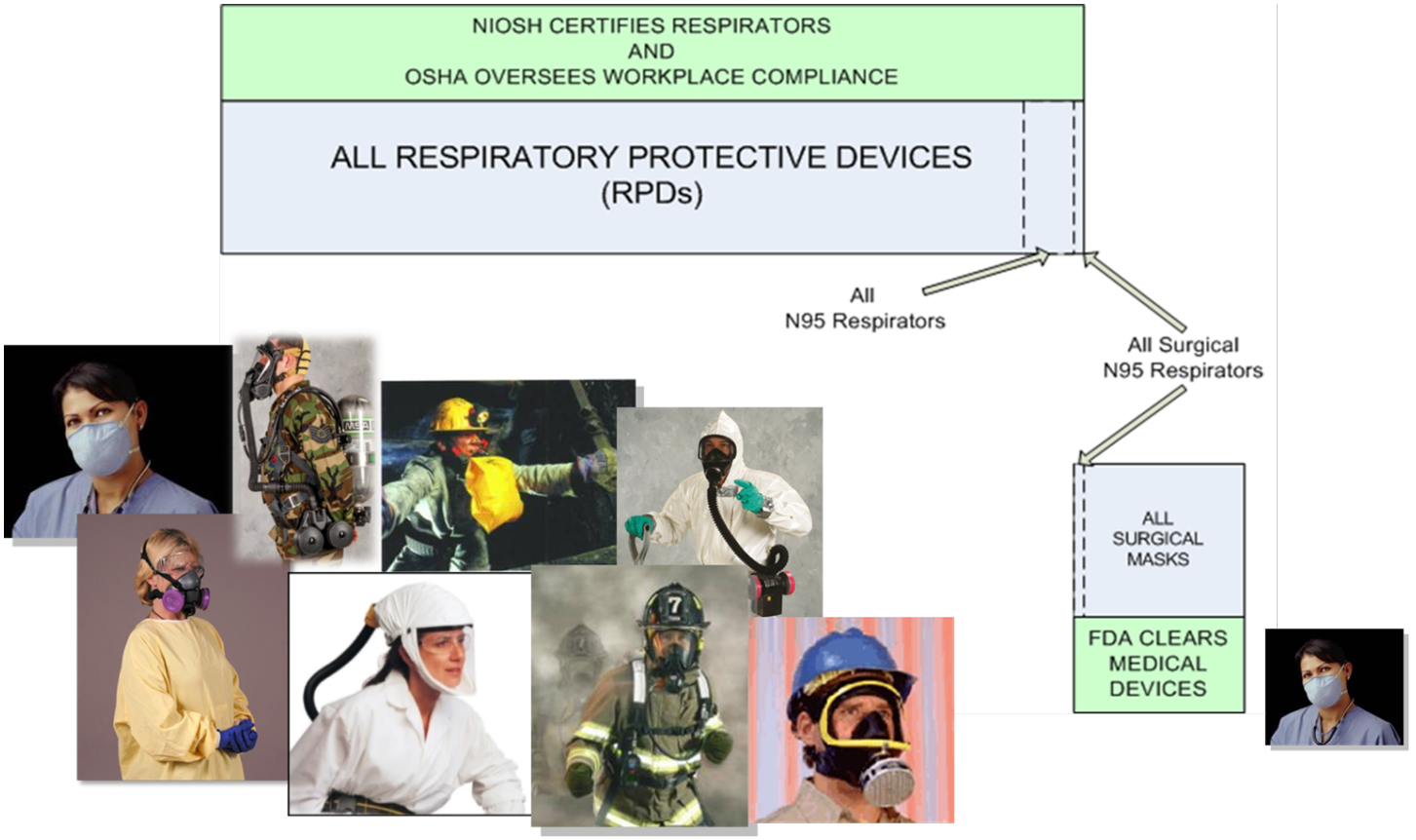
NIOSH, OSHA and FDA have regulatory authorities for certifying respirators in U.S. occupational settings



FDA has requirements for surgical N95 filtering facepiece respirators in healthcare settings

- Additional tests that must be performed at a qualified laboratory
  - Fluid penetration,
  - Flammability,
  - Biocompatibility,
    - Cytotoxicity
    - Sensitization
    - Irritation.
- Based on a Memorandum of Understanding between FDA and NIOSH, NIOSH is responsible for the conformity assessment of these requirements,
  - 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 .

Photo credit: 3M

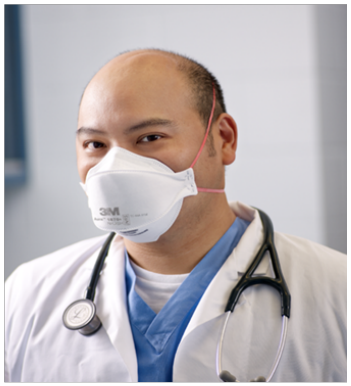
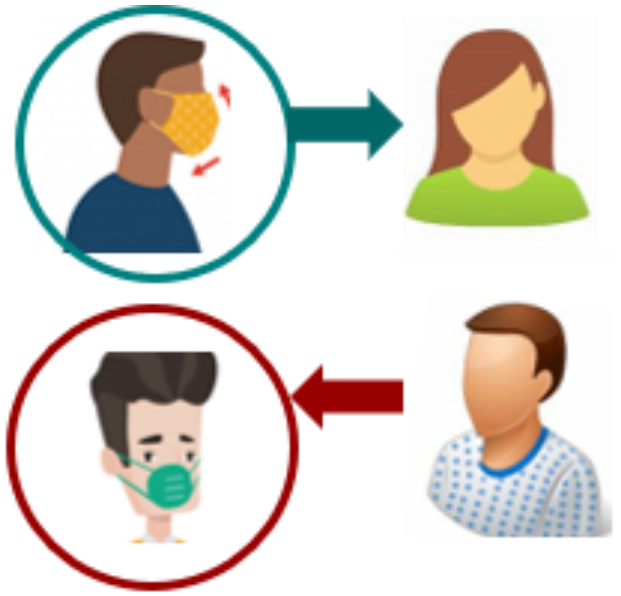


Photo credit: 3M

It is important to know the difference between source control and respiratory protection during COVID-19

- Source control protects OTHERS.
- Respiratory protection protects the WEARER.



Due to possible respirator supply shortages, it is critical that those workers who need respiratory protection have it readily available to perform their work safely.

COVID-19 has led to an increased use of NIOSH-approved air purifying respirators in healthcare

Photo credit: 3M

Filtering facepiece respirators (FFR)

Photo credit: MSA

Elastomeric respirators

Photo credit: Honeywell International Inc.

Powered air purifying respirators (PAPRs)

Photo credit: 3M

Photo credit: University of Maryland

Photo credit: Ford Motor Company

Three Key Factors Required for a Respirator to be Effective

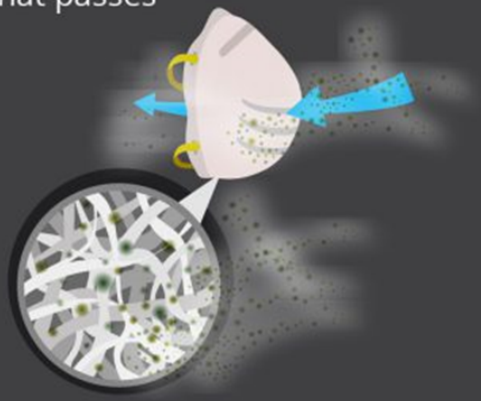
Correct*

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.

Proper use: If a respirator is not worn properly during an exposure, it may not provide adequate protection

- The Occupational Safety and Health Administration (OSHA) has regulations (29 CFR 1910.134) in place to address proper respirator use in the workplace
  - Medical evaluation
  - Formal training
  - Fit testing.
- Respirators used in the general public are NOT subject to the same regulations required in the workplace.

Fit testing is intended to improve protection by ensuring proper fit

- Seal leaking is the largest factor affecting the number of particles inside the FFR in manikin tests.
- Proper donning practices are important for minimizing face seal leakage.
- Less face seal leakage and less variation were found when performing a user seal check compared with not performing one.
- User seal check is not a substitute for a fit test, but offers some benefits for users in a respiratory protection program (e.g., fewer poor donnings).

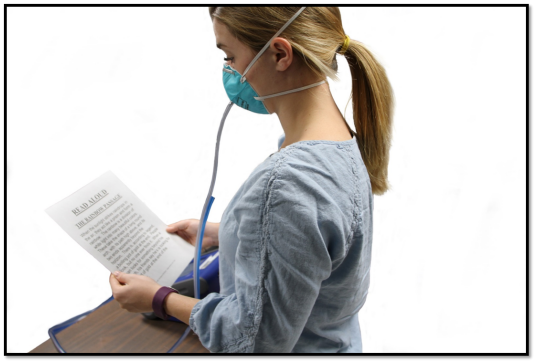
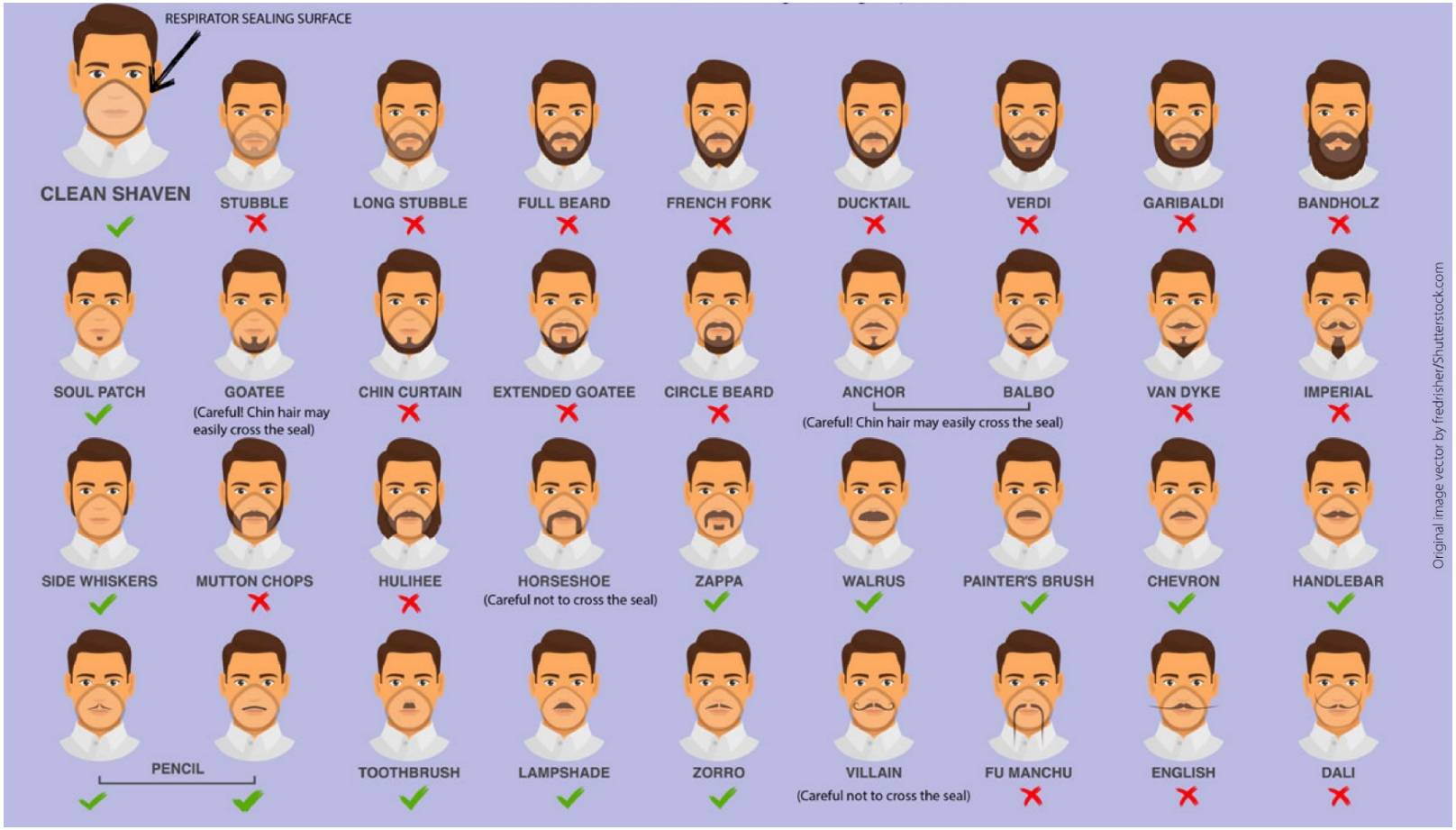


Photo Credits: NIOSH NPPTL

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



Filtration, What does a filter look like? How does it work?

- Filters are typically made from sheets of nonwoven polymer microfibers.
- Gaps between the fibers allow air to move through them easily.
- Particles in the air are trapped when they collide with one of the fibers.

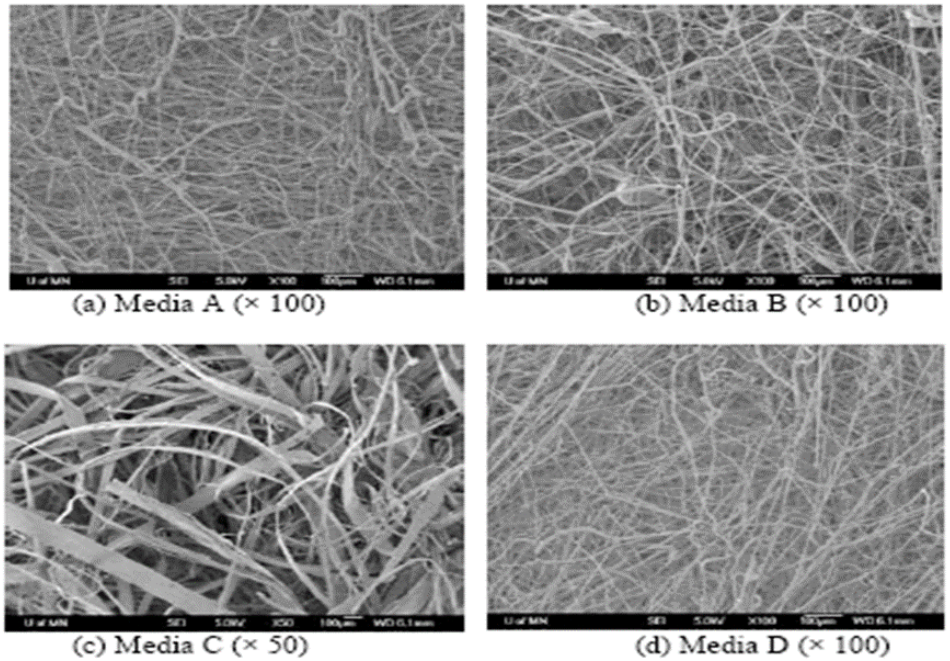
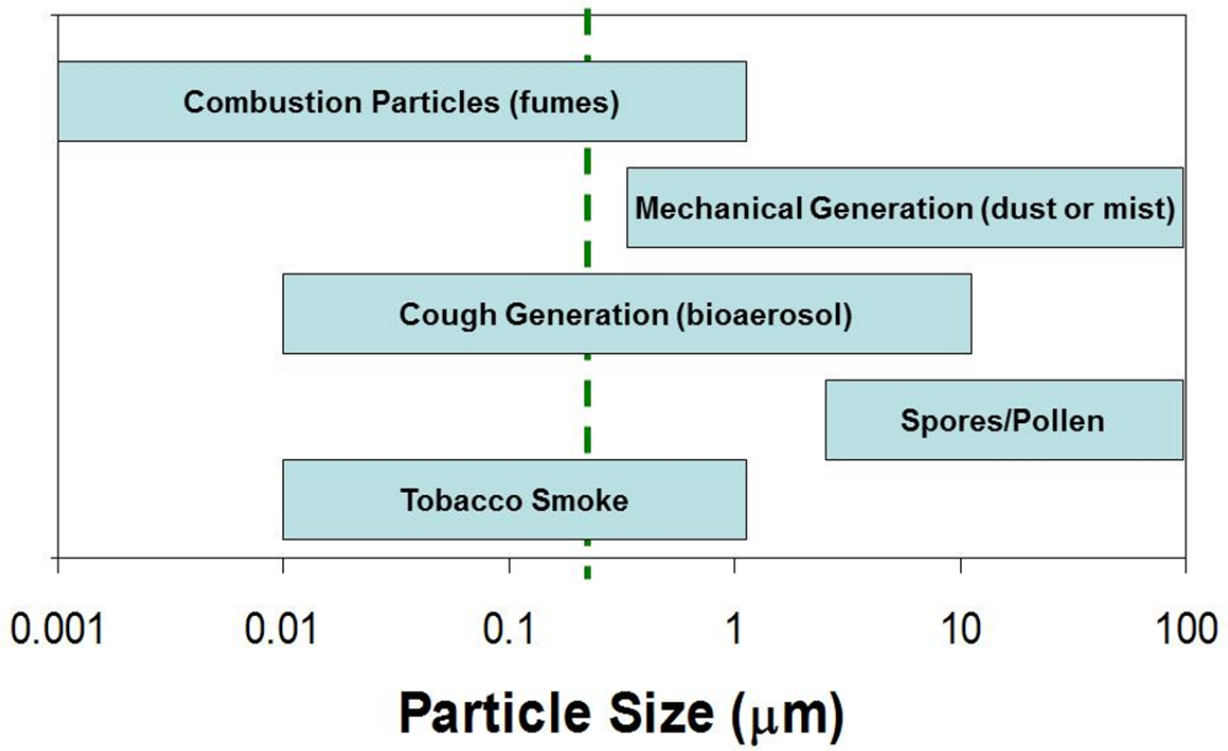


Photo Credit: NIOSH NPPTL

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 (2007), Rengasamy (2008a, 2008b), Rengasamy (2009a, 2009b), Rengasamy (2010)

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**
  - >380 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 149-2001
Japan	JMHLW-2000
Korea	KMOEL-2017-64
Mexico	NOM-116-2009

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

Respirators with exhalation valves protect the worker, but the level of source control provided is unclear

- **In the absence of data, CDC posted guidance regarding exhalation valves.**
  - Wear a respirator without an exhalation valve when both source control and respiratory protection are required.
  - If only a respirator with an exhalation valve is available and source control is needed, cover the exhalation valve with a surgical mask, procedure mask, or a cloth face covering that does not interfere with the respirator fit.
- **Science-based standards are needed to improve guidance.**
  - Some elastomeric respirators have a diverter exhalation valve cover.
  - More research is needed to evaluate what is coming out of the exhalation valve.
  - NIOSH is currently conducting several studies to quantify this to provide additional guidance.

Photo credit: Moldex


Photo credit: Honeywell North

https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html

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 PAPRs 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.

Example of filter enclosed in a cartridge

Photo credit: MSA

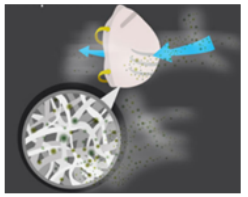
Example of "pancake" filter

Photo credit: MSA

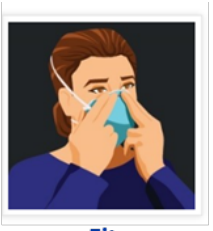
https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html

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

- **National Academy of Medicine workshop (August 2020)**
  - 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.
- **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.



Particulate filtration efficiency



Fit

Comfort

Reuse

Masks

A suite of measures together are important to prevent the spread of the virus that causes COVID-19

- Social distance - Avoid close contact.

- Wear cloth masks.

- Wash your hands often with soap and water for at least 20 seconds. Use a hand sanitizer with 60% alcohol if soap and water are not readily accessible.

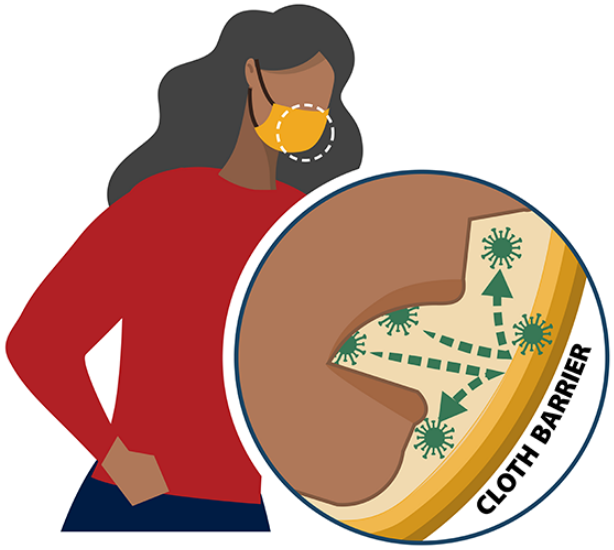
- Clean and disinfect frequently touched surfaces.

Considerations for Wearing Masks

- CDC recommends that people wear masks in public settings and when around people who don't live in their household, especially when other social distancing measures are difficult to maintain.
- Masks may help prevent people who have SAR-CoV-2 from spreading it to others.
- People infected with SARS-CoV-2 who do not have symptoms still can spread the virus to others. In fact, a large proportion of new infections are spread by people with COVID-19 in the days before they develop symptoms.
- Masks are most likely to reduce the spread of COVID-19 when they are widely used by people in public settings.

Evidence for Effectiveness of Masks

- Masks prevent respiratory droplets from traveling into the air and onto other people. **This is called source control.**
- Masks reduce the spray of droplets when worn over the nose and mouth.
- COVID-19 spreads mainly among people who are in close contact with an infected person (within 6 feet for summed total of 15 minutes during a 24-hour period). https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html
- Use masks **especially** in crowded indoor settings where social distancing is hard to maintain.



Masks: How to select

When selecting a mask, there are many choices.
Here are some dos and don'ts.

Masks: How to select (cont.)

Gaiters & Face Shields

Wear a gaiter with two layers, or fold it to make two layers

Caution: Evaluation is ongoing but effectiveness is unknown at this time

Special Situations: Glasses

If you wear glasses, find a mask that fits closely over your nose or one that has a nose wire to limit fogging

Special Situations: Children

If you are able, find a mask that is made for children

If you can't find a mask made for children, check to be sure the mask fits snugly over the nose and mouth and under the chin

Who Should Not Wear a Mask

- Masks should **not** be worn by:
  - Children younger than 2 years old
  - Anyone who has trouble breathing
  - Anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance

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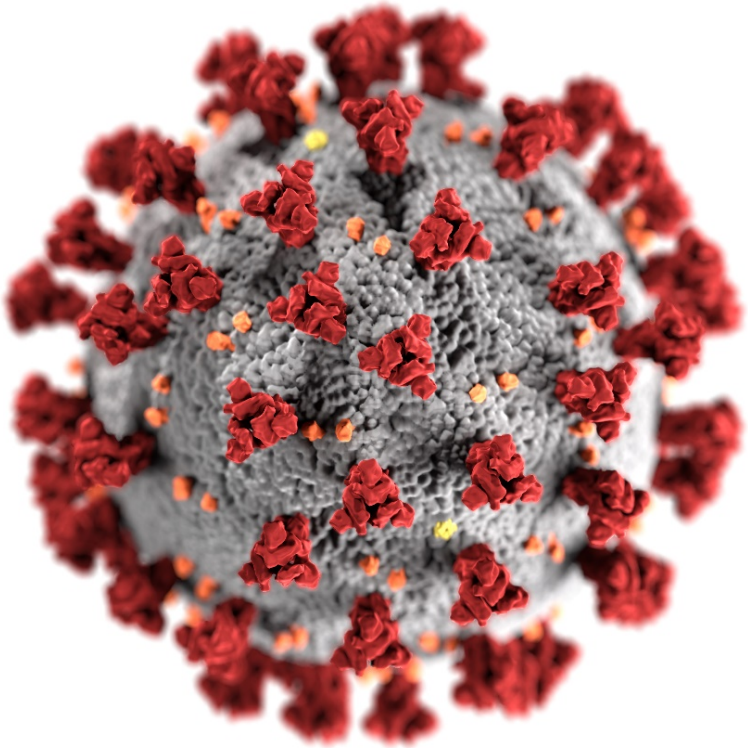
Visit us at: http//www.cdc.gov/niosh/npptl



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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