Respiratory protection:
A closer look at FEMA-imported respirators from Asia

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Housekeeping.

Asking a question from the GoToWebinar page:

• Click on the orange box with a white arrow to expand your control panel (upper right-hand corner of your screen)
• Type a question in the question box and click send
Jessica works as an Application Engineer in 3M's Personal Safety Division.
Agenda.

1. Review of webinars 1 and 2 in series
2. How FEMA will distribute
3. Resources to help you prepare for FEMA imports
4. Overview of FEMA-imported filtering facepiece models
5. Where to find employee training materials
6. Q & A
This presentation is based on current United States federal requirements and recommendations as of May 2020. State, local or other country requirements may be different.

Always consult *User Instructions* and follow local laws and regulations.
Review: Part 1 and 2 of Series
### Respiratory Protection

#### Types

<table>
<thead>
<tr>
<th>Mask Type</th>
<th>Fit Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Mask</td>
<td>Loose</td>
<td>Loose</td>
</tr>
<tr>
<td>Surgical Mask</td>
<td>Loose</td>
<td>Loose</td>
</tr>
<tr>
<td>Filtering Facepiece Respirators (FFRs), such as N95</td>
<td>Snug</td>
<td>Helps reduce wearer’s exposure to airborne particles</td>
</tr>
<tr>
<td>Elastomeric Respirator</td>
<td>Snug</td>
<td>Components can be disinfected &amp; reused</td>
</tr>
<tr>
<td>Powered Air Purifying Respirator (PAPR)</td>
<td>Loose</td>
<td></td>
</tr>
</tbody>
</table>
Respiratory Protection. US regulating bodies

**OSHA**
- The Occupational Safety and Health Administration (OSHA) has a respiratory protection standard (29 CFR 1910.134) that specifies the requirements for employers assigning respiratory protection to workers.
- Requirements include: medical evaluations & fit testing

**NIOSH**
- The National Institute of Occupational Safety and Health (NIOSH) tests and approves respirators in the US
- Testing/certification is based on the respirators’ physical and performance characteristics

**FDA**
- Surgical masks and surgical respirators are cleared for use as medical devices by the U.S. Food and Drug Administration (FDA)

https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf
https://multimedia.3m.com/mws/media/1820267O/respiratory-protection-in-healthcare-qrg-fit-testing.pdf
CDC Recommendations. N95 respirator use

Conventional capacity strategies

• Decrease exposure through barriers, distancing, telemedicine.
• Utilization of alternative respirators: PAPR, elastomeric, etc.

Contingency capacity strategies

• Already implemented conventional capacity strategies.
• Could include: Suspending annual fit testing, extended use of N95s.

Crisis capacity strategies

• Already implemented conventional and contingency capacity strategies.
• Use of N95s past their shelf life, Use of respirators from other countries (non-NIOSH approved), limited reuse
• Decontamination and subsequent reuse of FFRs should only be practiced as a crisis capacity strategy.

https://multimedia.3m.com/mws/media/1824869O/decontamination-methods-for-3m-n95-respirators-technical-bulletin.pdf
Decontamination and reuse of filtering facepiece respirators:

- Only employed as a crisis capacity strategy
- CDC and NIOSH do not recommend decontamination and reuse of FFRs in Standard care.

One mitigation strategy:

- Virus survives up to 72 hours on a variety of surfaces

CDC Recommendations. Crisis capacity strategy

https://multimedia.3m.com/mws/media/1824869O/decontamination-methods-for-3m-n95-respirators-technical-bulletin.pdf
Decontamination methods for 3M N95 FFRs

3M has Completed Testing Regarding the Following Methods*:

<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M N95 Model Evaluated</th>
<th>Cycles Tested</th>
<th>Filtration Efficiency &amp; Fit Related Evaluation</th>
<th>US FDA EUA Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaporized hydrogen Peroxide: Steris V-PRO</td>
<td>1860, 8210, 1870+</td>
<td>10</td>
<td>Pass</td>
<td>✓</td>
</tr>
<tr>
<td>Vaporized hydrogen Peroxide: ASP, STERRAD®</td>
<td>1860, 8210,</td>
<td>2</td>
<td>Pass</td>
<td>✓</td>
</tr>
<tr>
<td>Vaporized hydrogen Peroxide: Sterilucent</td>
<td>1860, 8210, 1804</td>
<td>10</td>
<td>Pass</td>
<td>✓</td>
</tr>
<tr>
<td>Vaporized hydrogen Peroxide: Battelle</td>
<td>1860, 8210, 1804</td>
<td>3</td>
<td>Pass</td>
<td>✓</td>
</tr>
</tbody>
</table>

Other decontamination methods have passed 3M’s testing for filtration efficiency and fit, for certain models of 3M FFRs, but do not have an FDA Emergency Use Authorization (EUA), at this time. For more information, see 3M technical bulletin linked below.

* For more information regarding decontamination methods, cycles, and FFRs tested, please see 3M Technical Bulletin which is updated as new information is received. 3M does not test for decontamination efficacy.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

https://multimedia.3m.com/mws/media/1824869O/decontamination-methods-for-3m-n95-respirators-technical-bulletin.pdf
Respiratory Protection

Fit test hygiene during COVID-19

General infection prevention
- Stay home if sick
- Practice good hand hygiene

Fit test setup
- Subjects should stand 6 feet apart
- Fit tester should wear respirator since close proximity required

Disinfection Considerations
- Use same hood for each subject’s sensitivity and fit tests
- Use one set of nebulizers for each person being fit tested
- Disinfect outside of nebulizer nozzle and inside of hood between each fit test

Quantitative fit testing with 601 Adapter
- Disinfect narrow tube that gets inserted into respirator
General strategies for skin damage prevention

- Choose FFR that fits comfortably
- Place FFR headbands correctly
- Remove tight-fitting facial PPE every 2 hours* if possible
- Do not over-tighten FFR
- Don’t ignore pain
- Protect skin from moisture and friction

How FEMA will distribute
Regulatory Framework.

For FEMA to import PPE from Asia

**FEMA**
- Rated order from U.S. government

**FDA**
- Issued Emergency Use Authorizations

**OSHA**
- Guidance allowing respirator use

Resources:
How to Acquire.

FEMA to distribute

Need for PPE Identified

Local Emergency Management Agency

State Emergency Management Agency

FEMA Reg Response Coordination Cntr

FEMA National Response Coordination Cntr

Any requests of urgent resupply should include:

• Specific types, quantities (30, 60, and 90-day demand) and locations where PPE is needed
• Estimated time until shortage impacts operations based on PPE usage rate
• Consequences of the shortage and duration of its impact

Non-NIOSH Approved Respirators
Emergency User Authorization (EUA) End User Information
The following 3M respirators are listed in Appendix A of the April 3rd, 2020 EUA title imported, "Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China". Users should read the information below for their model before use. Please note these are also listed at 3M.com/coronavirus.

- 9552/9552V, 9502, 9542, 9542V
- 9501, 9501V, 9501V+, 9505+, 9541, 9541V
- 9001/9002
- 9502+/9502V+
- 8822 (AU), 8822 (K) and 8205J
- 9320+ and 9322+

China - KN95
User Instructions
- 3M™ Particulate Respirator 9541
- 3M™ Particulate Respirator 9541V
- 3M™ Particulate Respirator 9542
- 3M™ Particulate Respirator 9542V
- 3M™ Particulate Respirator 9505+
- 3M™ Particulate Respirator 9552
- 3M™ Particulate Respirator 9552V
- 3M™ Particulate Respirator 9501
- 3M™ Particulate Respirator 9501+
- 3M™ Particulate Respirator 9501V+
- 3M™ Particulate Respirator 9502
- 3M™ Particulate Respirator 9502+
- 3M™ Particulate Respirator 9502V+

Are FFRs from Asia authentic?

FEMA-acquired 3M respirators from Asia are distributed by FEMA.

If the respirator is one of the model numbers identified on the 3M website and was distributed for free and can be traced to a FEMA source of supply, it is more likely to be an authentic 3M product.

FEMA is the only entity that is acquiring significant quantities of 3M respirators directly from 3M in Asia and then importing and distributing those models of respirators in the United States.

If still unsure, contact the 3M fraud hotline at 1 (800) 426-8688 or visit the 3M fraud website at www.Go.3M.com/covidfraud.

Resources:
https://multimedia.3m.com/mws/media/1803670O/fraudulent-activity-price-gouging-and-counterfeit-products.pdf
Fractional Activity.

Price Gouging & Counterfeit Products

3M Respirators

• Should be sold only in 3M packaging, with model-specific user instructions accompanying the product.
• Should not be sold individually or without packaging (including User Instructions).
• Have strict quality standards, and therefore products that have missing straps, strange odors, blocked valves, misspelled words, etc. are likely not authentic 3M respirators.
• Are intended, labeled, packaged, and certified to meet the requirements of the countries in which 3M sells it (requirements differ around the world)

3M recommends purchasing our products only from a 3M authorized distributor or dealer, as that increases the likelihood that you will receive authentic 3M products.

Additional 3M Fraud Resources:

• 3M COVID-19 Fraud hotline: 1 (800) 426-8688
• Webpage: www.go.3m.com/covidfraud (also have webpages for Canada)
Resources on FEMA imports
Resources

- Product Comparison Tables
- User Instructions
- Training Videos
- Donning Posters
- Frequently Asked Questions
- Technical Support Helpline
3M Respirators in International Packaging Made Available in US during COVID-19

3M is continuing to address the COVID-19 pandemic with many tactics to help protect those responding to the outbreak, including the production of respirators. In April, 3M reached agreement with the U.S. government on a plan that, with the Trump Administration’s assistance, will enable 3M to ship respirators directly to the U.S. States over a 3-month period starting in April, from our plants in Asia.

Read this if you have received 3M respirators in international packaging

The Food and Drug Administration requires this information be made available to everyone who has received these respirators.

Key Reference Information
FEMA-imported respirator models
Respirator Models.

Types being imported

Important Notes:
- Some models are the same as U.S. models
- FEMA is importing respirators from other manufacturers also

Resource: 3M’s FEMA-Imported Respirator Table
Approval information

Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes

Description

Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an “N95, FFP2, or equivalent” respirator.

This document is only intended to help clarify some key similarities between such references, specifically to the following FFR performance standards:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149:2001)
- KN95 (China GB2626-2006)
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS (Japan JMHLW-Notification 214, 2018)

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarly to one another, based on the performance requirements stated in the standards and confirmed during conformity testing.
### Unvalved KN95

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Certification(s)</th>
<th>Color</th>
<th>Band Style</th>
<th>NIOSH Approval / EUA</th>
<th>Instructional Video</th>
<th>User Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>9010</td>
<td>NIOSH N95</td>
<td>White</td>
<td>Headbands</td>
<td>TC-84-4243</td>
<td>Vertical Flatfold Video</td>
<td>9010 UI</td>
</tr>
<tr>
<td>9552</td>
<td>KN95 (China)</td>
<td>White</td>
<td>Headband</td>
<td>April 3rd FDA EUA Appendix A</td>
<td>Vertical Flatfold Video</td>
<td>9552 UI</td>
</tr>
<tr>
<td>9132</td>
<td>NIOSH N95 KN95 (China)</td>
<td>Blue</td>
<td>Headband</td>
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<td>Vertical Flatfold Video</td>
<td>Pending</td>
</tr>
</tbody>
</table>

### Valved KN95 – Imported from China

<table>
<thead>
<tr>
<th>Example Image*</th>
</tr>
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<tr>
<th>Model Number</th>
<th>9501V+</th>
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<tbody>
<tr>
<td>N95 Comparable</td>
<td>x</td>
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</tr>
<tr>
<td>Band Style</td>
<td>Earloop</td>
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### Understanding KN95 and KN90

<table>
<thead>
<tr>
<th>Mask</th>
<th>U.S. Approval</th>
<th>China Approval</th>
<th>Govt. Recommended Respirator for COVID-19 Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95</td>
<td>APF 10 ≥ 95% filtration efficiency</td>
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<tr>
<td>KN95</td>
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<td>APF 10 ≥ 90% filtration efficiency</td>
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</tr>
<tr>
<td>KN90</td>
<td>APF 10 ≥ 90% filtration efficiency</td>
<td></td>
<td>NOT Govt. Recommended respirator for COVID-19 response</td>
</tr>
</tbody>
</table>
FEMA-Imported FFRs

Comparison to U.S. FFRs

Similarities
- 2 bands and a nose clip
- Some are same as common U.S. models
  - Note - packaging will be in Asian languages
  - Fit testing should be conducted

Differences
- Vertical Flatfold design uncommon in U.S.
- Earloops not featured on U.S. respirators
- Designed for facial features common in Asia
- May not fit as well as respirators designed for US
Earloops

In the US earloops are not on NIOSH-approved respirators (headbands)

Outside the US 3M does manufacture some certified respirators with earloops

Respirators with earloops are designed for facial features common in Asia

NIOSH states users must ensure a proper fit is achieved

Resources:
https://multimedia.3m.com/mws/media/1832150O/3m-filtering-facepiece-respirators-imported-to-u-s-from-asia-by-fema.pdf
FEMA-Imported FFRs. Will they fit my workforce?

It depends

• Some imported models have different design than U.S. respirators

• Those with different facial features may not be able to achieve a satisfactory fit

• U.S. customers may experience lower fit test pass rates

If a fit test cannot be conducted, or the wearer cannot pass a fit test, then these products should be used as a facemask, not a respirator.

Employee training materials
How to fit test FEMA-imported respirators?

U.S. OSHA respirator standard mandates training and a fit test prior to the first time using a new respirator model.

Always read and follow all user instructions and conduct a user seal check.

Conduct fit testing the same way as N95 respirators typically sold and used in the U.S.

*qualitative fit testing using Bitrex™ or saccharin
*quantitative fit testing using a TSI PortaCount®

Respirator fit testing resources can be found on https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/#fit-test-resources.
## Training Support

Product table contains training links

3M.com/airlift

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### Valved KN95 – Imported from China

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Questions?