May 5, 2020

Updated OSHA and FDA Information - Respiratory Protection
SARS-CoV-2

Moderator: John Staley, PhD, MSEH
Speakers: Craig Colton, CIH, Pat Curran, CIH
Previous Respiratory Protection Sessions

1. How to properly Put On (Don) and Take Off (Doff) a Disposable Respirator
   Aka Filtering Facepiece Respirator
   SARS-CoV-2

2. Current Issues Relating to Respiratory Protection – Stockpile, Decontamination and Reuse
   SARS-CoV-2

3. Updates: OSHA – Interim Enforcement Response Plan and FDA-EUAs for N95 FFR Decontamination
   SARS-CoV-2

Archived and can be found at: https://osherc.sph.unc.edu/
Go to link: Registration and access to previous seminars>>
FDA – Emergency Use Authorizations (EUA)

To Date:

FDA has issued 8 EUAs pertaining to respirators:

- 5 EUAs pertaining to the Decontamination of N95 FFR – All are HPV Based
- 3 EUAs pertain to the use of NIOSH approved and Non-NIOSH approved respirators

FDA – N95 FFR Decontamination

Each of the 5 EUA pertaining to N95 FFR Decontamination requires:

• Fact Sheet for Healthcare Personnel/Providers
• Instructions for Healthcare Facilities
• Instructions for Healthcare Personnel
<table>
<thead>
<tr>
<th>Recipient</th>
<th>Date</th>
<th># N95 FFR/Cycle</th>
<th>Time of Cycle</th>
<th>Maximum Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battelle Decontamination System</td>
<td>3/29/2020</td>
<td>10,000 per chamber load at a Battelle location</td>
<td>150 minutes of dwell time</td>
<td>20</td>
</tr>
<tr>
<td>STERIS Sterilization Systems for Decontamination of N95 Respirators</td>
<td>4/9/2020</td>
<td>10 Single User Reuse</td>
<td>28 minutes No Aeration</td>
<td>10</td>
</tr>
<tr>
<td>Advanced Sterilization Products (ASP) STERRAD Sterilization System</td>
<td>4/11/2020</td>
<td>10 Single User Reuse</td>
<td>24 to 55 minutes Aerate 1 hour</td>
<td>2</td>
</tr>
<tr>
<td>Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle</td>
<td>4/15/2020</td>
<td>20 Single User Reuse</td>
<td>45 to 53 minutes Aerate 24 hours</td>
<td>2</td>
</tr>
<tr>
<td>Sterilucent, Inc. Sterilization System</td>
<td>4/20/2020</td>
<td>12 Single User Reuse</td>
<td>35 minutes Aerate min. of 6 hours</td>
<td>10</td>
</tr>
</tbody>
</table>
FDA - EUA

NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency

• Date of First EUA Issuance: 3/02/2020; Reissued on 3/27/2020 & 3/28/2020

Authorized Respirators are

(1) Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the NIOSH Certified Equipment list (CEL) for non-powered air purifying respirators with particulate protection;

(2) Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the NIOSH CEL for PAPRs with particulate protection;

(3) FFRs that were NIOSH-approved but have since passed the manufacturers’ recommended shelf-life, are not damaged, and have been held in accordance with manufacturers’ storage conditions in strategic stockpiles; and,

(4) Any authorized respirator under (1) or (3) above that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system,
FDA - EUA
Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

- Date of First Issuance: 3/24/2020; Reissued on 3/28/2020

- FDA concluded that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety

- Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English

- These models will be new to the USA
  - OSHA TEG requires initial fit test
  - Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes
    3M Technical Data Bulletin, January, 2020, Revision 2
    Summarizes the performance requirements of FFRs from around the world
    https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf
Disposable FFRs that meet a given performance standard with acceptable product classifications

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Performance Standard</th>
<th>Acceptable product classifications</th>
<th>Standards/Guidance Documents</th>
<th>Protection Factor ≥ 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>ABNT/NBR 13698:2011</td>
<td>PFF3, PFF2</td>
<td>Fundacentro CDU 614.894</td>
<td>YES</td>
</tr>
<tr>
<td>Europe</td>
<td>EN 149-2001</td>
<td>FFP3, FFP2</td>
<td>EN 529:2005</td>
<td>YES</td>
</tr>
<tr>
<td>Japan</td>
<td>MHLW-2000</td>
<td>DS/DL3 DS/DL2</td>
<td>JIS T8150: 2006</td>
<td>YES</td>
</tr>
<tr>
<td>Korea</td>
<td>KMOEL-2017-64</td>
<td>Special 1st</td>
<td>KOSHA GUIDE H-82-2015</td>
<td>YES</td>
</tr>
</tbody>
</table>
## FDA - EUA
Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

Authorized Imported, Non-NIOSH Approved Respirators

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Respirator Model(s)</th>
<th>Country of Manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M</td>
<td>8205</td>
<td>Japan</td>
</tr>
<tr>
<td>3M</td>
<td>8822</td>
<td>South Korea</td>
</tr>
<tr>
<td>3M</td>
<td>9320+</td>
<td>UK, Singapore, Turkey</td>
</tr>
<tr>
<td>3M</td>
<td>9322+</td>
<td>UK, Singapore, Turkey</td>
</tr>
<tr>
<td>Dromex</td>
<td>Model 1020</td>
<td>South Africa</td>
</tr>
</tbody>
</table>
FDA - EUC
Non-NIOSH-Approved Disposable Filtering Facepiece Respirators
Manufactured in China

• Date of First Issuance: 4/03/2020

Authorized respirators should be used in accordance with CDC’s recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC’s webpage: *Strategies for Optimizing the Supply of N95 Respirators*

Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

Appendix A: Authorized Respirators
# Appendix A: Authorized Respirators

Updated: 4/24/2020

## A Partial List: Many More Authorized Respirators

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Respirator Model(s)</th>
<th>Country of Manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M</td>
<td>9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552</td>
<td>China</td>
</tr>
<tr>
<td>Allmed</td>
<td>KN95 Particulate Respirator LP220002</td>
<td>China</td>
</tr>
<tr>
<td>AOK Tooling Ltd. (aka Shenzhonghai Medical)</td>
<td>20130040, 20130045A, 20180021, 20130038, 20190019</td>
<td>China</td>
</tr>
<tr>
<td>Bei Bei Safety Co Ltd</td>
<td>B702, B702V, B704, B704V</td>
<td>China</td>
</tr>
<tr>
<td>Bei Bei (Dong Shan) Protective Supplies Co., LTD</td>
<td>B707</td>
<td>China</td>
</tr>
<tr>
<td>BYD Precision Manufacture Co. Ltd.</td>
<td>BYD KN95 Particulate Respirator (Model Number: DG3101)</td>
<td>China</td>
</tr>
<tr>
<td>Changsha JNEYL Medical Equipment Co., Ltd</td>
<td>JN-9501</td>
<td>China</td>
</tr>
<tr>
<td>Chengde Technology Co.</td>
<td>KN95 (PM 2.5) Protective Mask</td>
<td>China</td>
</tr>
</tbody>
</table>
NPPTL Respirator Assessments to Support the COVID-19 Response
April 30, 2020

NPPTL has completed assessments of the filter efficiency for several submitted FFR

For each model of respirator assessed, 10 respirators were submitted.

Typically, for NIOSH approval, a comprehensive quality assurance review of the quality process and manufacturing site is done.

None of these reviews were conducted during this limited assessment. Only filter efficiency was assessed.

Further, no certificates of approval were provided with the respirators.

Therefore, validation of the claims that the product meets a particular international standard cannot be made.

No conclusions can be made regarding equivalency to N95 products that are NIOSH approved.
NIOSH
NPPTL Respirator Assessments to Support the COVID-19 Response
April 30, 2020

Most of these products have an ear loop design. NIOSH-approved N95s typically have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

These assessments are not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process.

These results are not to be used by manufacturers, distributors, suppliers, and importers to make claims about their products and/or to influence purchasers.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model Number/Product Line</th>
<th>International Standard</th>
<th>Filtration Efficiency (%)</th>
<th>Test Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>An Hui Su Bo Lun Clothing Co., Ltd.</td>
<td>SU KN95</td>
<td>GB2626</td>
<td>95.10 28.45</td>
<td>2020-55.1pdf icon</td>
</tr>
<tr>
<td>Changning Lingjiakang Protective Products Factory</td>
<td>KN95 Stereo Protective Mask</td>
<td>EN149</td>
<td>50.74 33.75</td>
<td>2020-10.3pdf icon</td>
</tr>
<tr>
<td>CTT Co., Ltd.</td>
<td>KN95 (8410)</td>
<td>EN149, GB2626</td>
<td>98.83 85.70</td>
<td>2020-87.1</td>
</tr>
<tr>
<td>Dongguan Xianda Medical Equipment Co., Ltd.</td>
<td>KN95 Protective Mask</td>
<td>EN149, GB2626</td>
<td>35.00 24.10</td>
<td>2020-23.1pdf icon</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Model Number/Product Line</td>
<td>International Standard</td>
<td>Filtration Efficiency (%)</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------------------------------</td>
<td>-------------------------</td>
<td>----------------------------</td>
<td></td>
</tr>
<tr>
<td>Guanyang Yuhan Textile Co., Ltd.</td>
<td>KN95 Protective Face Mask</td>
<td>GB2626</td>
<td>56.59 42.15</td>
<td></td>
</tr>
<tr>
<td>Hangzhou Senrunqing Technology Co., Ltd.</td>
<td>KN95 Mask-C</td>
<td>EN149, GB2626</td>
<td>85.90 78.70</td>
<td></td>
</tr>
<tr>
<td>Honeywell Safety Products (Shanghai) Co., Ltd.</td>
<td>H801 Particulate Respirator</td>
<td>GB2626</td>
<td>99.32 98.40</td>
<td></td>
</tr>
</tbody>
</table>
Determining the Reliability of Imported Respirators

- Devices supplied by current NIOSH approval holders who also produce respirators under the various standards authorized in other countries will provide the advertised level of protection, if a proper fit is achieved.

- Devices developed by manufacturers who are not NIOSH approval holders but who conform to the standards of one of the countries or regions listed in the FDA EUA, should have a certificate of approval from an authorized test laboratory confirming that they meet the standards identified in the CDC Guidance described in the Crisis Contingency Strategy.

- Non-NIOSH-approved products developed by manufacturers who are not NIOSH approval holders (and do not have a certificate of approval from an authorized test laboratory from one of the countries identified within the FDA EUA) should only be used in crisis situations when no NIOSH-approved N95 respirator (or a listed device within the FDA EUA) is available. These devices should not be used during aerosol-generating medical procedures unless the alternative is a loose-fitting surgical mask or improvised device.

CDC/NIOSH Webinar
Considerations for Purchasing International Respirators

May 7, 2020 at 1:00 pm EDT

• Factors to consider when planning to purchase respirators from another country, including KN95 respirators from China

• See the NIOSH webpage for more information about the webinar, including the panel of speakers.

• Or, go directly to the webinar registration page.
Certified Equipment List Search

Manufacturer

Scott Health & Safety, Ltd.
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Shanghai Gangkai Purifying Products Co., Ltd.
Shenyang Baianda Safety Co., Ltd.
Shigematsu Works Co., Ltd.
Shining Star Electronic Technology Co., Ltd.

Approval Date Date range _______ to _______ (i.e. 2/12/1998)

Facepiece Type

Both Hood and Helmet
Filtering Facepiece

Powered ○ Non-Powered ○ Both ○

https://www2a.cdc.gov/drds/cel/cel_form_code.asp
Counterfeit/Misrepresented Respirators Revisited Again!

- When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, we will post them here to alert users, purchasers, and manufacturers.

- [https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html](https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html)
Signs that a respirator may be counterfeit:

- No markings at all on the filtering facepiece respirator
- No approval (TC) number on filtering facepiece respirator or headband
- No NIOSH markings
- NIOSH spelled incorrectly
- Presence of decorative fabric or other decorative add-ons (e.g., sequins)
- Claims for the approval for children (NIOSH does not approve any type of respiratory protection for children)
- Filtering facepiece respirator has ear loops instead of headbands
Conventional Strategies During Non-Surge Demand Situations

Elastomeric Respirators

Terminology – Air-purifying elements

- **Filters** – particulate filters, gas filters

  US based terminology: “filter” ≈ particulate filter

- **Filter cartridges** – particulate filters in a container

- **Cartridges** – for gases and vapors

- **Chemical cartridges**

Contingency Capacity Strategies During Surge Demand Situations

Elastomeric Respirators

Equipped with replaceable filters

- Some replaceable filters are cartridge style in which the filtration media is housed inside of a cartridge
- Others consist of flexible, disc or pancake-style filters, in which the filter media are not housed within a cartridge body.

Photos courtesy of 3M
Contingency capacity strategies are for emergency situations in which each elastomeric respirator is issued for the exclusive use of an individual employee. The respirators are cleaned and disinfected as often as necessary to remain unsoiled and sanitary. Their description and use should be part of a written OSHA respiratory protection program (RPP). If there is deviation from the standard RPP, it should be authorized and documented by the program’s administrator.
What is an N95 Respirator?

It can be..........

N95 Filtering Facepiece Respirator

Half Face Elastomeric Respirator with Replaceable N95 Filters

Full Face Elastomeric Respirator with Replaceable N95 Filters
Filters

There are 9 categories of filters approved by NIOSH: N95, N99, N100, R95, R99, R100, P95, P99, P100

Note: Any of the 9 categories of NIOSH approved filter PROVIDE PROTECTION for SARS-CoV-2
There are several NIOSH Approved Chemical Cartridges that can be used with Air Purifying Respirators:

- Organic Vapor
- Acid Gases
- Organic Vapor & Acid Gases
- Methyl Amine & Ammonia
- Others

Caution: These NIOSH Approved Chemical Cartridges DO NOT PROVIDE PROTECTION For SARS-CoV-2
Filter & Cartridge

There are several NIOSH Approved Combination Filter & Chemical Cartridges that can be used with Air Purifying Respirators:

- N95/Organic Vapor
- P100/Organic Vapor
- N95/Acid Gases
- P100/Acid Gases
- Others......

Note: These NIOSH Approved Combination Filter & Chemical Cartridges PROVIDE PROTECTION For SARS-CoV-2
Particulate Filters

There are several types of filter media for use with NIOSH-approved reusable, half-facepiece elastomeric respirators. All are sufficient at removing droplet and viral size particles when worn correctly for the duration of the exposure.

Chemical cartridges (cartridges) do not protect against particles.
Crisis Capacity Strategies During Surge Demand Situations

Conventional practice is to discard the filter component.

Contingency practices may necessitate cleaning and disinfecting the filter housing, but care must be taken to not expose the filter media to any cleaning solutions. The performance of filter media can be degraded by contact with the disinfectant.
Crisis Capacity Strategies During Surge Demand Situations

**Crisis capacity strategies** are for

- emergency use, limited respirator and/or respirator component supplies such as filters, cartridges, or canisters, and valves
- situations in which it is impossible for individual HCP to have a dedicated elastomeric respirator, for example when the same respirator must be used by multiple HCP

When used by more than one HCP, respirators must be cleaned and disinfected before being worn by different individuals

The use of elastomeric respirators should be part of a written OSHA RPP. If there is any deviation from the conventional RPP, it should be **authorized and documented** by the program’s administrator.
Waiving the Fit Test

Crisis Strategy

While this is not ideal, in this scenario, HCP should work with their employers to choose the respirator that fits them best, as, even without fit testing, a respirator will provide better protection than using no respirator at all or using a surgical mask.

The level of protection received is unknown
Waiving the Fit Test


• If possible, the HCP should start with the size used previously for fit testing, but as size can vary by manufacturer and model, a different size may be needed to achieve a good fit.

• If fit testing has never been done, the following recommendations are still useful.

• If using a half facepiece respirator, it should fit over the nose and under the chin. If a good face seal cannot be achieved when performing a user seal check, try a different model or size.
Very limited types of particulate filters exist for PAPRs

HE filter – high efficiency filter, sometimes called HEPA filter

PAPR100

PAPR100-P: intended for removal of any particulate that includes oil-based liquid particulates

PAPR100-N: restricted to use in those workplaces free of oil aerosols
Thank You!

Please contact johnstaley@unc.edu for questions about this presentation.