May 5, 2020

NC OSHERC COVID-19 Respiratory Protection Series: Session 4

UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

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

UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

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**

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe

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**

FDA N95 FFR Decontamination EUAs

Recipient	Date	# N95 FFR/Cycle	Time of Cycle	Maximum Cycles
Battelle Decontamination System	3/29/2020	10,000 per chamber load at a Battelle location	150 minutes of dwell time	20
STERIS Sterilization Systems for Decontamination of N95 Respirators	4/9/2020	10 Single User Reuse	28 minutes No Aeration	10
Advanced Sterilization Products (ASP) STERRAD Sterilization System	4/11/2020	10 Single User Reuse	24 to 55 minutes Aerate 1 hour	2
Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle	4/15/2020	20 Single User Reuse	45 to 53 minutes Aerate 24 hours	2
Sterilucent, Inc. Sterilization System	4/20/2020	12 Single User Reuse	35 minutes Aerate min. of 6 hours	10

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

Jurisdiction	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	MHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES

FDA - EUA
Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

Authorized Imported, Non-NIOSH Approved Respirators

Manufacturer	Respirator Model(s)	Country of Manufacture
3M	8205	Japan
3M	8822	South Korea
3M	9320+	UK, Singapore, Turkey
3M	9322+	UK, Singapore, Turkey
Dromex	Model 1020	South Africa

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

Manufacturer	Respirator Model(s)	Country of Manufacture
3M	9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552	China
Allmed	KN95 Particulate Respirator LP220002	China
AOK Tooling Ltd. (aka Shenzhonghai Medical)	20130040, 20130045A, 20180021, 20130038, 20190019	China
Bei Bei Safety Co Ltd	B702, B702V, B704, B704V	China
Bei Bei (Dong Shan) Protective Supplies Co., LTD	B707	China
BYD Precision Manufacture Co. Ltd.	BYD KN95 Particulate Respirator (Model Number: DG3101)	China
Changsha JNEYL Medical Equipment Co., Ltd	JN-9501	China
Chengde Technology Co.	KN95 (PM 2.5) Protective Mask	China

NIOSH
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

NIOSH
NPPTL Respirator Assessments to Support the COVID-19 Response
April 30, 2020

Manufacturer	Model Number/Product Line	International Standard	Filtration Efficiency (%)		Test Report
			Maximum	Minimum	
An Hui Su Bo Lun Clothing Co., Ltd.	SU KN95	GB2626	95.10	28.45	2020-55.1pdf icon
Changning Lingjiakang Protective Products Factory	KN95 Stereo Protective Mask	EN149	50.74	33.75	2020-10.3pdf icon
CTT Co., Ltd.	KN95 (8410)	EN149, GB2626	98.83	85.70	2020-87.1
Dongguan Xianda Medical Equipment Co., Ltd.	KN95 Protective Mask	EN149, GB2626	35.00	24.10	2020-23.1pdf icon

NIOSH
NPPTL Respirator Assessments to Support the COVID-19 Response
April 30, 2020

Manufacturer	Model Number/Product Line	International Standard	Filtration Efficiency (%)	
			Maximum	Minimum
Guanyang Yuhan Textile Co., Ltd.	KN95 Protective Face Mask	GB2626	56.59	42.15
Hangzhou Senrunqing Technology Co., Ltd.	KN95 Mask-C	EN149, GB2626	85.90	78.70
Honeywell Safety Products (Shanghai) Co., Ltd.	H801 Particulate Respirator	GB2626	99.32	98.40

Guangzhou Baoweikang (Powecom) Personal Protection Equipment Co., Ltd.	KN95 Protective Mask	GB2626	99.40	99.21

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.

https://blogs.cdc.gov/niosh-science-blog/2020/04/23/imported-respirators/

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

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

https://www2a.cdc.gov/drds/cel/cel_form_code.asp

Powered ○ Non-Powered ○ Both ◉

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

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

See terminology in, ASTM F3387-19, Standard Practice for Respiratory Protection, http://www.astm.org/cgi-bin/resolver.cgi?F3387-19

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 During Surge Demand Situations
Elastomeric Respirators

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

Elastomeric Facepiece Respirator with N95 Filters

Elastomeric Facepiece Respirator with P100 Filters

Note: Any of the 9 categories of NIOSH approved filter PROVIDE PROTECTION for SARS-CoV-2

Cartridge

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 protectant 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 exposed 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

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

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

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

- 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.

Considerations for Optimizing the Supply of Powered Air-Purifying Respirators

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

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.