



April 1, 2020

NC OSHERC COVID-19 Respiratory Protection Series: Session 2



Session 1 – March 25, 2010

How to properly Put On (Don) and Take Off (Doff) a Disposable
Respirator

Aka Filtering Facepiece Respirator

SARS-CoV-2

Session 1 has been archived and can be found at:

<https://osherc.sph.unc.edu/>

Go to link: Registration and access to previous seminars>>



April 1, 2020

Current Issues Relating to Respiratory Protection

SARS-CoV-2

Moderator: John Staley, PhD, MSEH
Speakers: Craig Colton, CIH, Pat Curran, CIH

Are FFR N95 Respirators Ever Really Meant to be Sterilized?

- Short answer: No.
- 42 CFR 84.2 bb) Single-use respirator means a respirator that is entirely discarded after excessive resistance, sorbent exhaustion, or physical damage renders it unsuitable for further use
- 30 CFR 11 Reusable Filter could be cleaned twice for up to three uses. Respirator manufacturer had to supply information to show this was acceptable
- Elastomeric respirators have parts that can be reused, but filters and cartridges are single use.

CDC - Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies

“Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. This document summarizes research about decontamination of FFRs before reuse.”

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

CDC - Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies

- Summary of research on FFR decontamination
- 4 tables worth a look
 - Table 1. Summary of crisis standards of care decontaminations recommendations
 - Table 2. Summary of the decontamination method and effect on FFR performance
 - Table 3. Summary of decontamination method antimicrobial efficacy
 - Table 4. Decontamination methods evaluated for each FFR model
- 20 references of decontamination work
- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

CDC - Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies

- **Decontamination methods that changed FFR performance or function**
- Autoclaving and the use of disinfectant wipes are not recommended as crisis strategies as they may alter FFR performance
- Decontamination using an autoclave, 160°C dry heat, 70% isopropyl alcohol, microwave irradiation and soap and water caused significant filter degradation to both FFRs and particle penetration levels did not meet the levels that NIOSH would allow for approval. Decontamination with bleach caused slight degradation in filtration performance and created an odor that would not be suitable for use [2, 7].

FDA Emergency Use Authorizations (EUAs) as of March 31, 2020

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

1. Non-powered air-purifying particulate FFRs and reusable respirators such as with particulate protection
NIOSH approved, 42 CFR 84, listed in the NCEL
535 NIOSH filtering facepiece respirator approvals as of March 12, 2020
2. Powered air purifying respirators (PAPRs) with particulate protection
NIOSH approved, 42 CFR 84, listed in NCEL
3. FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life. Not damaged, stored in accordance with manufacturers' storage conditions in strategic stockpiles referred to as "expired FFRs" by FDA)
4. Any respirator under (1) or (3) above that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system
5. Battelle Decontamination System

Stockpiled FFRs*

- Based on NIOSH study
 - 10 facilities, 11 different FFR N95s
 - <https://www.cdc.gov/niosh/npptl/ppecase.html>
- Based on preliminary information, many models have continued to perform in accordance with NIOSH performance standards
- Accordingly, CDC/NIOSH believes the following products, despite being past their manufacturer-designated shelf life, should provide the expected level of protection to the user if:
 - the stockpile conditions have generally been in accordance with the manufacturer-recommended storage conditions and
 - an OSHA-compliant respiratory protection program is used by employers.

* For purposes of this authorization, strategic stockpiles refer to stockpiles of authorized respirators held by public health agencies that have legal responsibility and authority for responding to a public health emergencies, based on political or geographical boundaries (e.g., city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (e.g., law enforcement, public health, military health) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation.

Stockpiled FFRs (cont.)

- In alphabetical order, these models are:

- 3M 1860
- 3M 1870
- 3M 8210
- 3M 9010
- 3M 8000
- Gerson 1730
- Medline/Alpha Protech NON27501
- Moldex 1512
- Moldex 2201
- <https://www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html>



Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (3/24/20)

<https://www.fda.gov/media/136403/download?from=groupmessage&isappinstalled=0>

- 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 (see slide 17)
- 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/17915000/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
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

Decontaminated Authorized Respirators

- Each manufacturer and/or operator of an authorized decontamination system for decontamination of authorized respirators must comply with the Conditions of Authorization and authorized labeling as set forth in the Letter of Authorization for the authorized decontamination system.
- Source: *FDA Enforcement Policy for Face Masks and Respirators.....*
<https://www.fda.gov/media/136449/download>

Enforcement Policy on Face Masks and Respirators

- FDA is issuing this guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals during this pandemic.
- FDA will work with reproprocessors through its EUA process to facilitate expedited evaluation of the request
- send FDA as much of the following information you have available:

FDA Enforcement Policy for Reprocessors

- A description of the process for disinfection/reprocessing controls
- Validation of bioburden reduction/disinfection
- Description of chain of custody and safeguards to prevent inadvertent exposure
- Material compatibility
- Filtration performance
- Fit test data
- A copy of the reprocessed device product labeling



FDA EUA and Battelle Decontamination System

- Battelle Memorial Institute has developed a decontamination system, using vapor phase hydrogen peroxide (VPHP), that decontaminates “compatible” N95 or “N95-equivalent respirators”
- On March 28, 2020 FDA issued an initial EUA to Battelle to operate “the Battelle Decontamination System” on site to decontaminate compatible N95 or N95-equivalent respirators
- On March 29, 2020 FDA revised the initial EUA to allow decontamination at multiple locations

<https://www.fda.gov/media/136529/download>

Definitions from the EUA for Emergency Use of the Battelle Decontamination System

- Compatible N95 respirators means:
 - any N95 or N95-equivalent respirator that does not contain cellulose-based materials. Respirators containing cellulose-based materials are incompatible with the Battelle Decontamination System
- N95-equivalent respirators:
 - refers to respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, available at:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

FDA EUA and Battelle Decontamination System

- Decontamination system provides for up to 20 decontamination cycles per compatible N95 respirator
- Each system can decontaminate up to 80,000 respirators per day
- Establishes procedures for contaminated respirator collection, labelling and information to healthcare facilities and providers
- Battelle must operate the decontamination system and shall not distribute to third parties





Extended Use, Limited Reuse and Decontamination of N95 Respirators

ACOEM Webinar:

"COVID-19: Protecting Health Care Workers – Reuse and Decontamination of N95 Respirators"

- Date Time: Apr 3, 2020 12:00 PM Eastern Time (US and Canada)

Registration Link:

https://zoom.us/webinar/register/WN_WFaVzJ4XSE6UV8uTL0nCWA

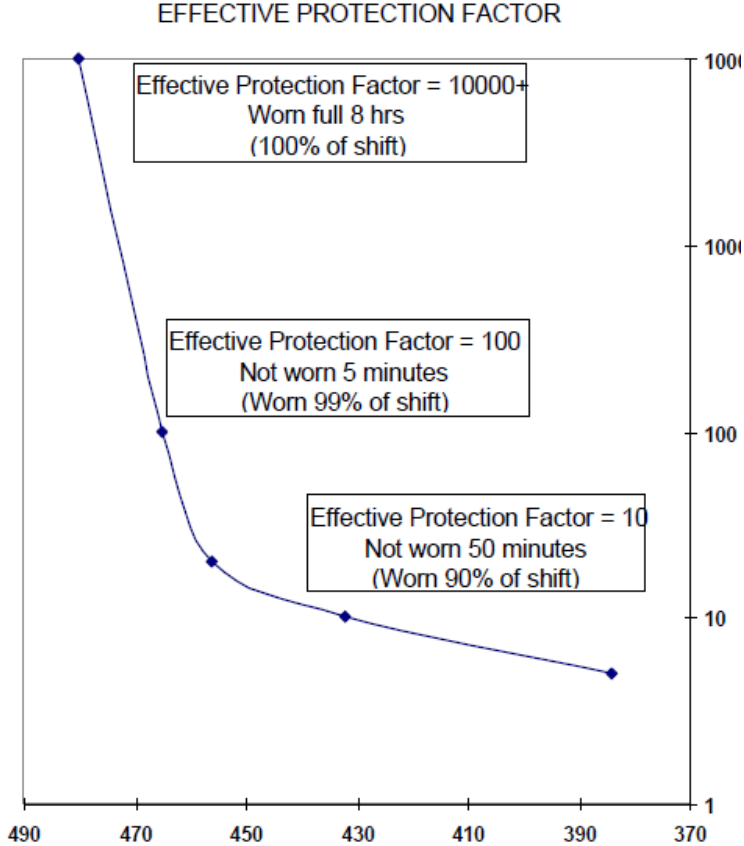


Extended Use, Limited Reuse of N95 Respirators

Some Publication Addressing Extended Use and Limited Reuse of N95 Respirators

- “Strategies for Optimizing the Supply of N95 Respirators” – Updated February 29, 2020
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>
- “Checklist for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response” – last reviewed March 5, 2020
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>
- “Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings” – last reviewed March 28, 2018
<https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

Effective Protection Factor Versus Wear Time of A Respirator



Effective Protection Factors

Time Worn During Shift

	<u>APF</u>	<u>90%</u>	<u>80%</u>
Half Facepiece	10	5	4
Full Facepiece	100	9	5
SAR PD	1000	10	5
SCBA	10,000	10	5



OSHA

Temporary Enforcement Guidance

OSHA – March 14, 2020

- Issues Temporary Enforcement Guidance

“Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak”

- Relaxes enforcement of annual fit testing of respirators to conserve respirators
- Other requirements such as initial fit testing, maintenance, care and training remain in effect

<https://www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit>



Thank You

Questions and Comments from today's session will be collected and responses posted on the OSHERC Website: osherc.sph.unc.edu

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

