Access the recorded webinar here: https://attendee.gotowebinar.com/recording/6725411770768669448

Access speaker bios here: https://files.asprtracie.hhs.gov/documents/aspr-tracie-covid-19-optimizing-healthcare-ppe-and-supplies-webinar-bios.pdf

Access webinar transcript here: https://files.asprtracie.hhs.gov/documents/aspr-tracie-covid-19-optimizing-healthcare-ppe-and-supplies-webinar-transcript.pdf

Access the Q and A here: https://files.asprtracie.hhs.gov/documents/aspr-tracie-covid-19-optimizing-ppe-and-supplies-webinar-q-and-a.pdf

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HEALTHCARE EMERGENCY PREPAREDNESS INFORMATION GATEWAY

COVID-19: Optimizing Healthcare Personal Protective Equipment and Supplies

September 24, 2020

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

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Resources

- ASPR TRACIE COVID-19 Page
- ASPR COVID-19 Page
- CDC COVID-19 Page
- FDA COVID-19 Page
- NIOSH COVID-19 Information for the Workplace Page
- NIOSH National Personal Protective Technology Laboratory (NPPTL)
- Coronavirus.gov

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HEALTHCARE EMERGENCY PREPAREDNESS INFORMATION GATEWAY

Leslie Hintz, MS, COVID-19 Response Deployment Team Lead, Supply Preservation Support Team, Healthcare Resilience Working Group
Joselito Ignacio, MA, MPH, CIH, CSP, REHS, Captain, US Public Health Service; Deputy, Healthcare Resilience Working Group ***(Available for Q&A)***

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Moderator- John Hick, MD
Hennepin Healthcare

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Maryann D'Alessandro, PhD
Director, National Personal Protective Technology Laboratory,
National Institute for Occupational Safety and Health (NIOSH)

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Three Topics will be Addressed in this Presentation

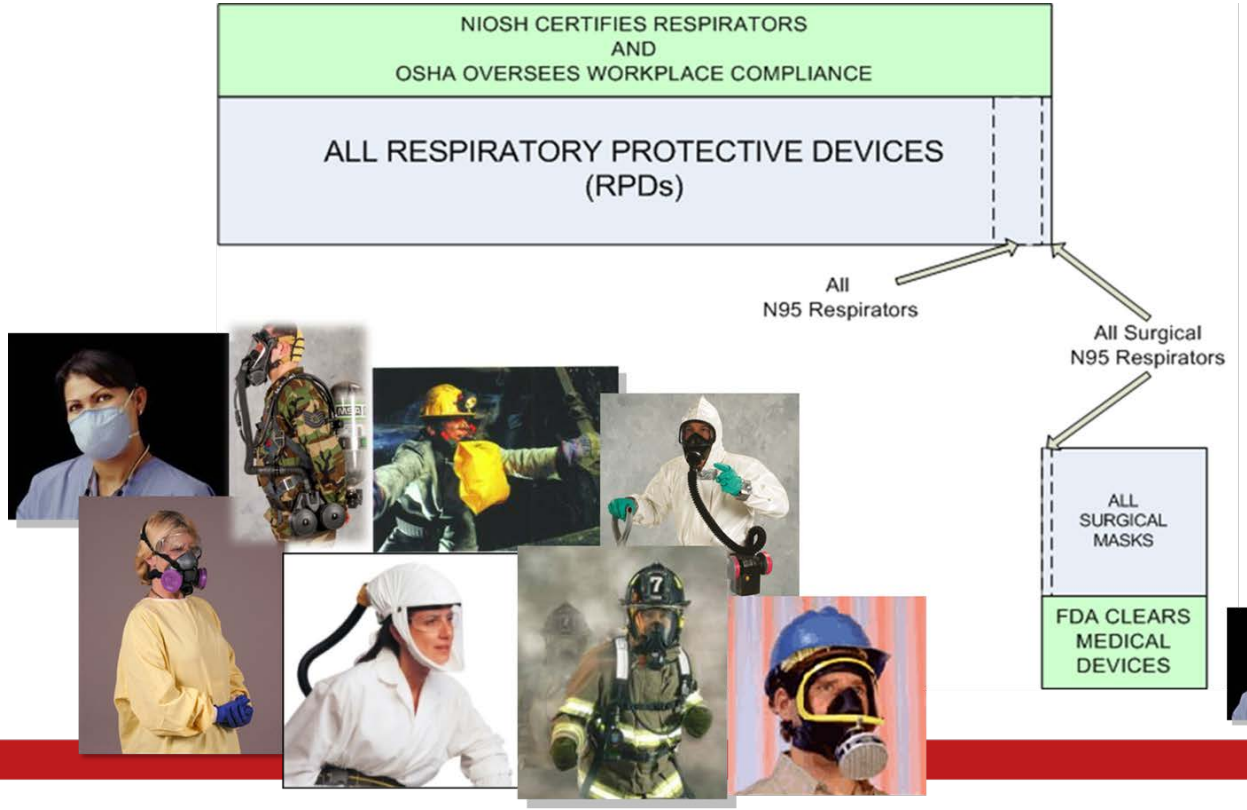
- Federal authorities and COVID-19
- NIOSH activities supporting respirator supply optimization
- Healthcare and related applications standards gaps supporting supply optimization

NIOSH National Personal Protective Technology Laboratory

VISION: Our vision is to be the leading provider of quality, relevant, and timely personal protective technology research, training, and evaluation

MISSION: The mission of the Personal Protective Technology Program and the National Personal Protection Technology Laboratory is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies

Three Agencies have Respirator Authorities in U.S. Occupational Settings



FDA has Requirements for Surgical N95 Filtering Facepiece Respirators in Healthcare Settings

Photo credit: 3M

- 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

COVID-19 Has Led to an Increased Use of NIOSH-Approved Air Purifying Respirators in Healthcare

Photo credit: 3M

Filtering facepiece respirators

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

CDC Authorized the Use of Respirators Conforming to Other International Standards as a Crisis Capacity Measure

- **NIOSH evaluated imported products**
  - >380 Reports Posted
- **Substandard products**
  - ~60% of international respirators provide below 95% filtration efficiency
- **Counterfeit/Mis-Use of NIOSH Approval**
  - Compare submitted records with approved application
- **Potential Standards Need**
  - Should there be a standard for evaluating international products?
  - NIOSH evaluates these products to an abbreviated NIOSH standard test procedure

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
People's Republic of China	GB 2626-2006 GB 2626-2019 GB19083-2010	KN/KP95	N95
		KN/KP100	N95
Europe	EN 149-2001	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea	KMOEL-2017-64	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/international-respirator-purchase.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

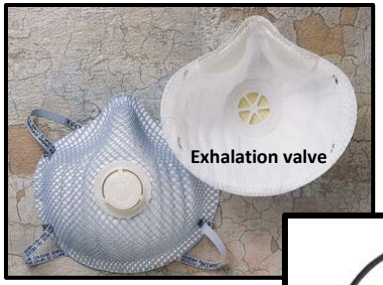


Photo credit: Moldex


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
  - Bessessen protocol used by several facilities
- **Crisis capacity guidelines**
  - CDC and NIOSH provide guidelines for disinfection, including the Bessessen protocol
  - Enclosed filter cartridges 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?

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

Example of filter enclosed in a cartridge

Photo credit: MSA

Example of "pancake" filter

Photo credit: MSA

CDC Provides PAPR Disinfection Guidance for Crisis Capacity Scenarios

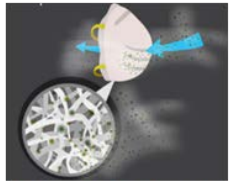
- **Routine operations**
  - Disinfection is not part of the NIOSH approval, NIOSH point to the manufacturers' instructions
  - OSHA permits employers to use the cleaning recommendations provided by the respirator manufacturer
- **Crisis capacity guidelines**
  - CDC Guidance provides recommendations for crisis capacity scenarios
- **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?

Photo credit: Honeywell North

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

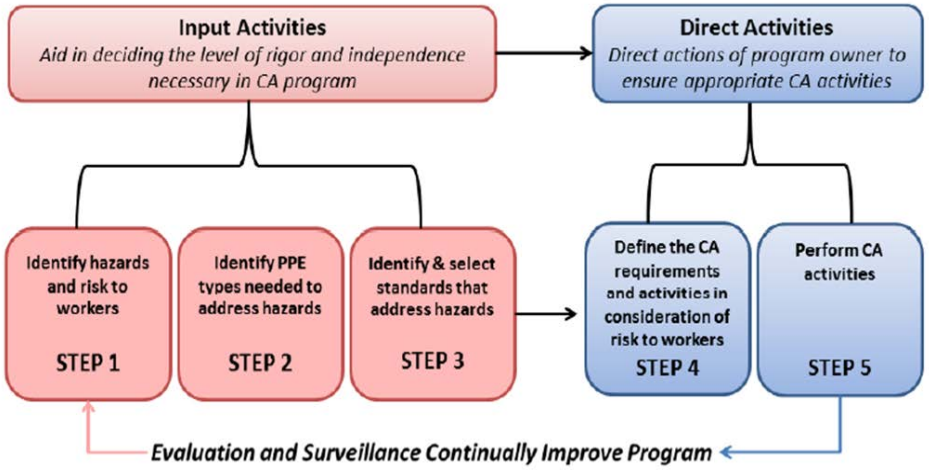
Comfort

Reuse

The COVID-19 Response has Revealed Several Standards and Conformity Assessment Gaps

Potential standards to optimize increase supply

- FFR exhalation valves
- Elastomeric exhalation valves
- Elastomeric disinfection
- PAPR disinfection



NIOSH Conformity Assessment Framework, NIOSH Pub. 2018-102

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HEALTHCARE EMERGENCY PREPAREDNESS INFORMATION GATEWAY

Aftin Ross, PhD

Senior Project Manager and Senior Science Health Advisor, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA)

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FDA’s Regulation of Respirators

- The FDA, NIOSH, and OSHA collaborate to assure safe use of respirators by healthcare personnel
  - FDA's oversight of respirators for use in healthcare spans the total product lifecycle from premarket review, postmarket surveillance, and compliance
- The FDA has authorized the emergency use of certain respirators and decontamination systems. FDA also has issued guidance on enforcement policies. Together these approaches help facilitate access to critical, quality medical supplies.
- **Decontamination systems and decontaminated respirators require an EUA and are not covered by enforcement policies**

FDA's Emergency Use Authorization (EUA)

- EUA authority allows the FDA to help strengthen the nation's public health protections by facilitating the availability and use of critical medical products during public health emergencies when certain criteria are met.
- Criteria for issuance
  - Serious or Life-Threatening Condition
  - Evidence of Effectiveness ("May be Effective") in diagnosing, treating, or preventing the serious or life-threatening disease or condition
  - Risk-Benefit Analysis
  - No Adequate, Approved, Available Alternatives (includes if there are insufficient supplies)

Emergency Use Authorization of Medical Products and Related Authorities

Face Masks and Respirators Guidance

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency

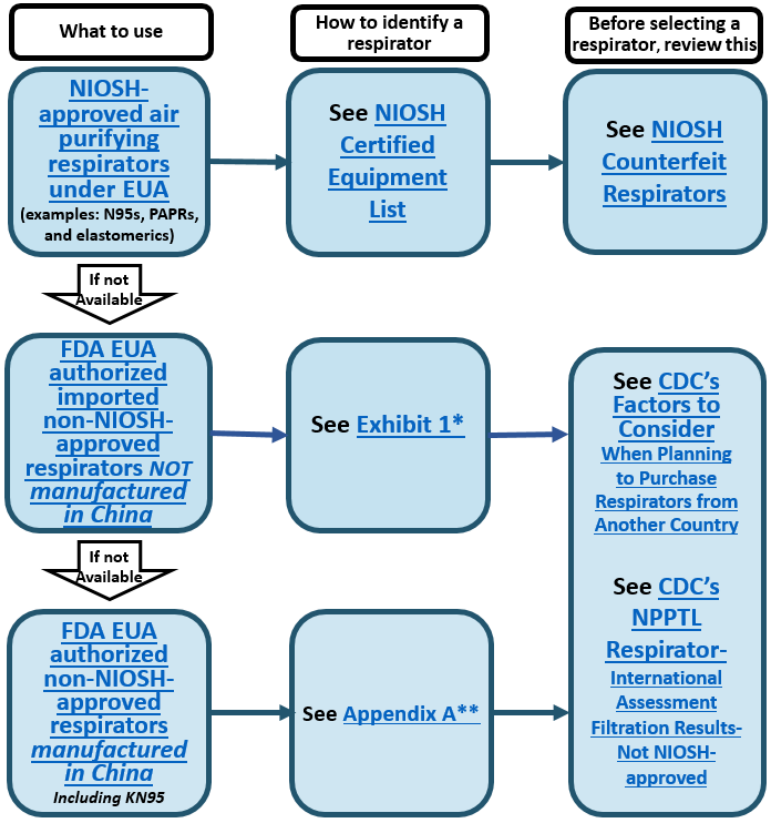
- Provide regulatory flexibility while assuring products are appropriate for their use
- Enforcement discretion as to certain FDA requirements
- Policy in effect for the duration of the public health emergency
- Policy applies to respirators not intended for a medical purpose
- States that **FDA clearance or EUA authorization** is necessary for respirators to be marketed in the U.S. for healthcare personnel use

Considerations for selecting respirators for your healthcare facility

*Exhibit 1 refers to FDA EUA Authorized Imported, Non-NIOSH Disposable Filtering Facepiece Respirators

**Appendix A refers to FDA EUA Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

Available at:
https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/considerations-selecting-respirators-your-health-care-facility



FDA's Actions

- FDA continues to identify and implement agile regulatory approaches to expand access to respirators by health care professionals
- As the pandemic continues, FDA's policy is refined to facilitate development and availability of essential devices
- FDA is engaging with public health and industry stakeholders to monitor respirator supply and demand and communicate current status of supply and mitigation actions undertaken to facilitate access
- FDA.gov website has educational resources for all stakeholders: medical device industry, health professionals, and the general public, covering Emergency Use Authorizations, Guidance, and Frequently Asked Questions

FDA Resources

- CDRH N95 Respirators, Surgical Masks and Face Masks
- Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency
- Personal Protective Equipment EUAs
- PPE Decontamination System EUAs
- Umbrella EUA for Surgical Masks (Authorized Surgical Masks)
- FDA EUA Authorized Imported, Non-NIOSH Disposable Filtering Facepiece Respirators (Authorized Imported Non-NIOSH-Approved FFRs)
- FDA EUA Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

COVID-19: Optimizing Healthcare Personal Protective Equipment and Supplies

ASPR TRACIE Webinar

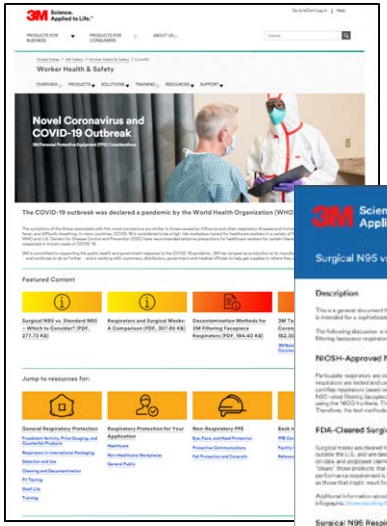
September 24, 2020

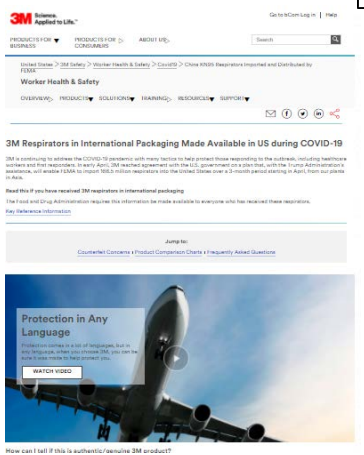
Nikki McCullough, PhD, CIH
Jessica Hauge, MPH, CIH, CSP

Shared with ASPR 9/16/20

3M's COVID Response

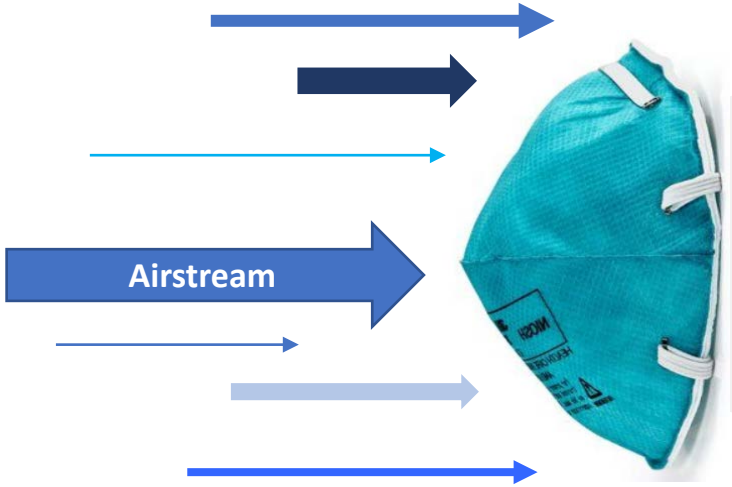
- Increasing capacity
- Providing technical information
- Highlighting government guidance
- Conducing research
- Supporting FEMA imports
- Media response

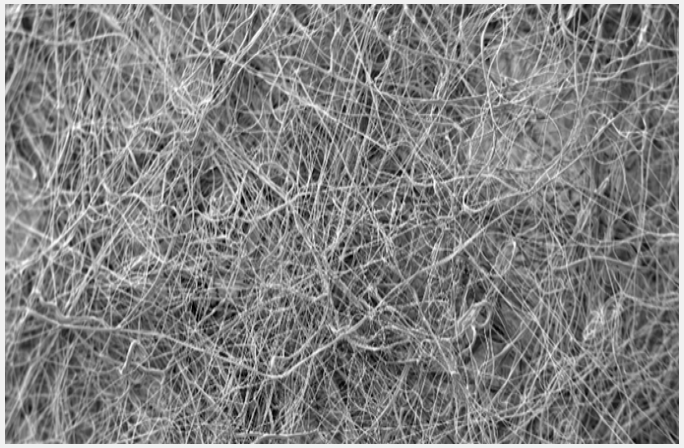




How N95s work

- FFRs contain many layers of crisscrossing, non-woven, fibrous filter material that capture particles
- As the airstream flows through the layers of filter media, particles are trapped/captured, by several mechanisms:
  - Very large particles in the airstream will settle out due to gravity
  - Other particles may impact a fiber and be captured
  - Very small particles are captured by diffusion





https://multimedia.3m.com/mws/media/1792732O/respiratory-protection-faq-healthcare.pdf
https://multimedia.3m.com/mws/media/1820270O/respiratory-protection-in-healthcare-qrg-n95-respirators.pdf
https://multimedia.3m.com/mws/media/409903O/respiratory-protection-against-biohazards.pdf
https://multimedia.3m.com/mws/media/1833770O/filtering-of-bioaerosols-by-filtering-facepiece-respirators.mp4

Masks and Respirators. Options

Procedure Mask

- Disposable, simple mask used to cover nose and mouth

Surgical Mask

- Disposable, mask used to cover nose and mouth
- Provides a fluid barrier

Filtering Facepiece Respirators (FFRs), such as N95

- Disposable, respirator used to cover nose and mouth
- Provides fluid barrier (surgical N95's)

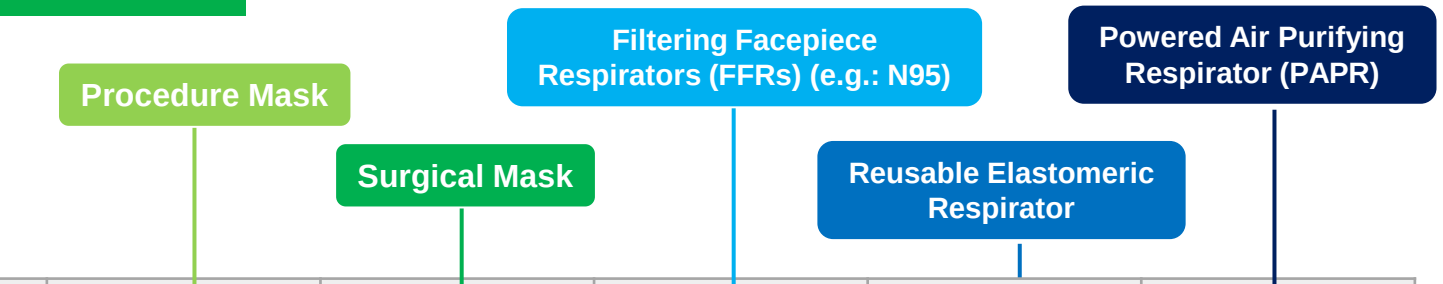
Elastomeric Respirator

- Reusable respirator
- Half & full facepiece offerings
- Multi-piece: facepiece and disposable filters

Powered Air Purifying Respirator (PAPR)

- Reusable respirator
- Multiple face/head cover offerings
- Multi-piece: head cover, tube, battery pack and belt

Masks and Respirators. Differences



Fitment	Loose	Loose	Tight	Tight	Loose
Recommended* as source control, to help capture spit or mucous expelled by the wearer	●	●	● Guidance for valves (link)	● Guidance for valves (link)	
FDA cleared for use in surgery		●	● Surgical N95s only (link)		
Provides fluid barrier (link)		●	● Surgical N95s only	★ Not FDA cleared	★ Not FDA cleared
Reduces wearer's exposure to airborne particulate hazards			●	●	●
At least 95% filtration efficiency against particulates			●	●	●
Some components can be cleaned/disinfected and reused				●	●

*Recommended by CDC and/or FDA as source control in healthcare setting.

Other respirator classes

FFRs are subject to various regulatory standards around the world. Some are considered very similar to N95.

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

- OSHA says respirators meeting certain other countries' standards may be used in place of N95s when respirators are in short supply during COVID-19 Public Health Emergency.
- CDC calls this practice a Crisis Capacity Strategy.

N95 Respirator Use.

CDC recommendations

Contingency and crisis strategies include:

- use of N95s past their shelf life
- extended use of N95s
- use of other types of respirators
- use of respirators from other countries
- re-use of respirators

…BEFORE decontamination of respirators

CDC Recommendations. Decontaminated FFR precautions prior to use

Even after decontamination, these FFRs should be handled carefully

Wash hands before and after touching or adjusting the FFR

Avoid touching the inside of the FFR

Use a pair of clean (non-sterile) gloves when donning and performing a user seal check

Visually inspect the FFR to determine if its integrity has been compromised

If integrity is compromised, or if can't perform successful user seal check, discard the FFR and try another FFR

Perform a user seal check immediately after donning each FFR, if unsuccessful, don't use that FFR

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

Decon Compatibility.

Evaluation of compatibility with 3M N95s

Four key aspects of successful decontamination of N95s

Efficacy

- Must inactivate target organism

Safety

- Must be safe for person wearing respirator

Filtration

- Must not damage respirator's filtration

Fit

- Must not negatively affect respirator's ability to seal to the wear's face

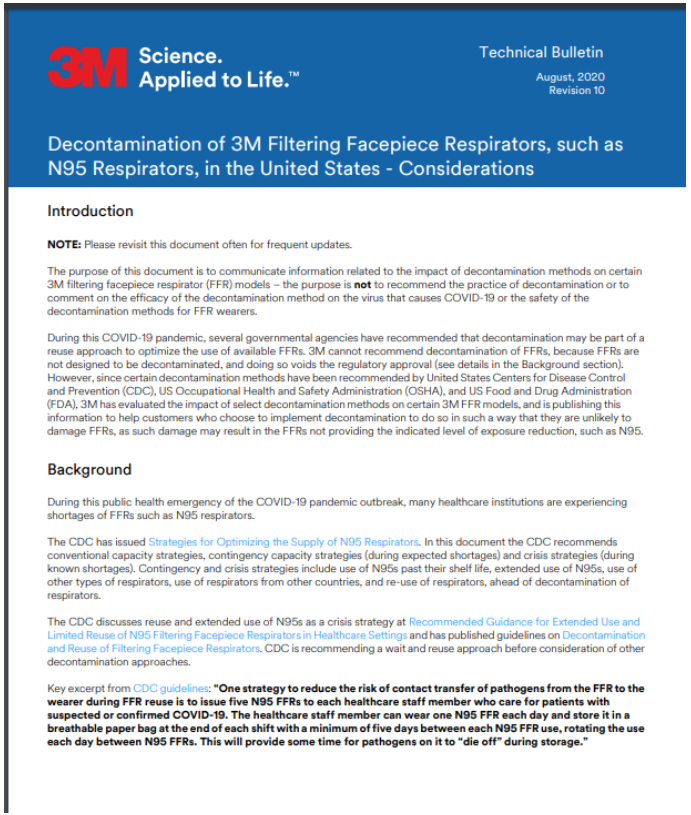
Developer of proposed decontamination method and EPA confirm germicidal efficacy of method

If filtration is damaged or the respirator does not fit, it will not help reduce exposure to airborne particles at the level indicated

Decontamination.

Can N95s be decontaminated?

- Per OSHA, and the FDA< decontamination of FFRs is only permissible for **healthcare** workplaces.
- https://multimedia.3m.com/mws/media/1824869O/decontamination-methods-for-3m-n95-respirators-technical-bulletin.pdf
- 3M does not recommend decontaminating FFRs.
- Decontamination does not extend life of FFRs.



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Technical Bulletin

August, 2020
Revision 10

Decontamination of 3M Filtering Facepiece Respirators, such as N95 Respirators, in the United States - Considerations

Introduction

NOTE: Please revisit this document often for frequent updates.

The purpose of this document is to communicate information related to the impact of decontamination methods on certain 3M filtering facepiece respirator (FFR) models – the purpose is **not** to recommend the practice of decontamination or to comment on the efficacy of the decontamination method on the virus that causes COVID-19 or the safety of the decontamination methods for FFR wearers.

During this COVID-19 pandemic, several governmental agencies have recommended that decontamination may be part of a reuse approach to optimize the use of available FFRs. 3M cannot recommend decontamination of FFRs, because FFRs are not designed to be decontaminated, and doing so voids the regulatory approval (see details in the Background section). However, since certain decontamination methods have been recommended by United States Centers for Disease Control and Prevention (CDC), US Occupational Health and Safety Administration (OSHA), and US Food and Drug Administration (FDA), 3M has evaluated the impact of select decontamination methods on certain 3M FFR models, and is publishing this information to help customers who choose to implement decontamination to do so in such a way that they are unlikely to damage FFRs, as such damage may result in the FFRs not providing the indicated level of exposure reduction, such as N95.

Background

During this public health emergency of the COVID-19 pandemic outbreak, many healthcare institutions are experiencing shortages of FFRs such as N95 respirators.

The CDC has issued Strategies for Optimizing the Supply of N95 Respirators. In this document the CDC recommends conventional capacity strategies, contingency capacity strategies (during expected shortages) and crisis strategies (during known shortages). Contingency and crisis strategies include use of N95s past their shelf life, extended use of N95s, use of other types of respirators, use of respirators from other countries, and re-use of respirators, ahead of decontamination of respirators.

The CDC discusses reuse and extended use of N95s as a crisis strategy at Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings and has published guidelines on Decontamination and Reuse of Filtering Facepiece Respirators. CDC is recommending a wait and reuse approach before consideration of other decontamination approaches.

Key excerpt from CDC guidelines: **"One strategy to reduce the risk of contact transfer of pathogens from the FFR to the wearer during FFR reuse is to issue five N95 FFRs to each healthcare staff member who care for patients with suspected or confirmed COVID-19. The healthcare staff member can wear one N95 FFR each day and store it in a breathable paper bag at the end of each shift with a minimum of five days between each N95 FFR use, rotating the use each day between N95 FFRs. This will provide some time for pathogens on it to "die off" during storage."**

Summary

- N95 respirators help reduce airborne exposures to particles
- Elastomeric reusable respirators and Powered Air Purifying Respirators are options
- OSHA, CDC/NIOSH and FDA offer guidance for selection and use
- As CDC contingency and crisis strategies are implemented for respiratory protection, it is important to consult all applicable government guidance as well as the manufacturer for model-specific information.

N95 Filtering Facepiece Respirators Ultraviolet Germicidal Irradiation (UVGI) Process for Decontamination and Reuse

John-Martin Lowe PhD
Assistant Vice Chancellor for Interprofessional Health Security Training and Education, Director of Research for Nebraska Biocontainment Unit, University of Nebraska Medical Center

N95 Respirator UVGI Process for Decontamination and Reuse

NETEC

Warnings

- Last Resort—first apply Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies
- Voids the NIOSH approval
- Decontamination technologies should be used cautiously
  - UVGI, vaporized hydrogen peroxide, warm moist heat, etc.
- Should only be done by the organization and trained professionals
- This was the result of multiple tests, a review of the scientific literature, and incorporation of current institutional practice

N95 Respirator UVGI Process for Decontamination and Reuse

NETEC

No one likes that we have to do this

CDC Crisis/Alternate Strategies

Personal Protective Equipment and Respiratory Protection

HCP use of non-NIOSH approved masks or homemade masks

In settings where N95 respirators are so limited that routinely practiced standards of care for wearing N95 respirators and equivalent or higher level of protection respirators are no longer possible, and surgical masks are not available, as a last resort, it may be necessary for HCP to use masks that have never been evaluated or approved by NIOSH or homemade masks. It may be considered to use these masks for care of patients with COVID-19, tuberculosis, measles, and varicella. However, caution should be exercised when considering this option.[1,2]

https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html

N95 Respirator UVGI Process for Decontamination and Reuse

NETEC

Number of methods previously evaluated

Food and Drug Administration (FDA)

- Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness
- Assessed UGVI on 15 FFR models
  - http://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/optimizing-respirator-decontamination-ensure-supplies-emergency-preparedness
- Assessing VHP on FFRs for up to 50 disinfection cycles
  - https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/investigating-decontamination-and-reuse-respirators-public-health-emergencies

National Institute of Occupational Safety and Health (NIOSH), CDC

- Reusability of Filtering Facepiece Respirators
  - https://www.cdc.gov/niosh/topics/flu/respiratory.html

N95 Respirator UVGI Process for Decontamination and Reuse

NETEC

Trust

- **Discussion with HCW**
  - Initial
  - Process Design
  - Process Evaluation
  - Operationalization
  - Feed Back
- **Communication**
  - Strategy
- **Safety**
  - Those Processing
  - Those Using

N95 Respirator Decontamination and Re-Use Process

Key Points:

- All N95 Respirators MUST be labeled with your first initial, last name, date of first use and department location **(this is important to ensure return of your mask)**
- Please limit the daily donning of new respirators as much as possible (extended use, per policy, is strongly encouraged)
- All Used N95 Respirators are to be discarded in your *brown* "dirty" paper bag
- Respirators sent for decontamination will be returned to you in a new *white* "clean" paper bag stapled at the top
  - It will include a new *brown* bag to be used as your "dirty" discard bag. **Tally marks will be added to the respirator by decontamination staff each time the mask undergoes the decontamination process.** Ensure your name and return location are on supplied brown bag
- All decontaminated N95 Respirators will be kept in the *white* "clean" paper bag
- Note the location of your department/unit/site "dirty drop off" and "clean pick up" stations
- Each health care professional is responsible for ensuring the proper fit and integrity of each respirator upon re-use

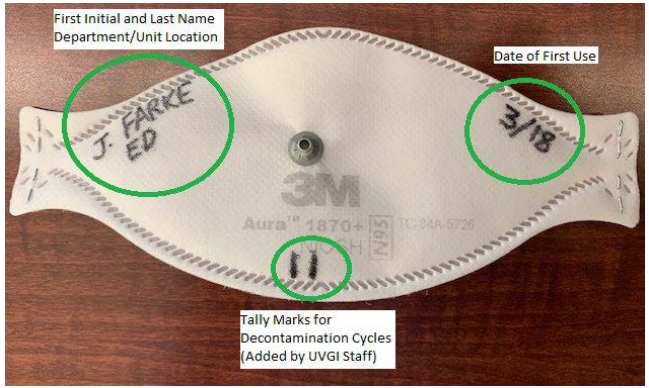
Note to Float Staff-
You can choose to note your return location as your last worked unit/department/site
OR
You can designate your return location as "Float" in which case you can retrieve your clean white bag from the Decon. Unit's holding area on 7th floor UT (old Adult Crisis Unit)

More detailed information, including a detailed training document, can be found on the link below or by scanning this QR code with your phone:
https://www.nebraskamed.com/covid

3/21/2020

Nebraska Medicine

N95 Respirator UVGI Process for Decontamination and Reuse



N95 Respirator UVGI Process for Decontamination and Reuse

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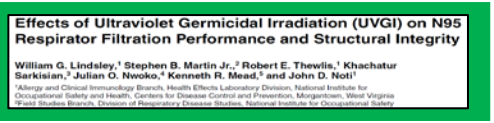
Why we use UVGI – Possibility and Familiarity

Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity


Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity

William G. Lindsley,[1] Stephen B. Martin Jr.,[2] Robert E. Thewlis,[1] Khachatur Sarkisian,[3] Julian O. Nwoko,[4] Kenneth R. Mead,[5] and John D. Noti[1]

[1]Allergy and Clinical Immunology Branch, Health Effects Laboratory Division, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Morgantown, West Virginia
[2]Field Studies Branch, Division of Respiratory Disease Studies, National Institute for Occupational Safety

Ultraviolet Germicidal Irradiation of Influenza-contaminated N95 Filtering Facepiece Respirators

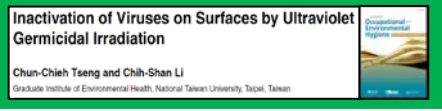
https://www.ajicjournal.org/article/S0196-6553(18)30140-8/fulltext


American Journal of Infection Control

Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators

Inactivation of Viruses on Surfaces by Ultraviolet Germicidal Irradiation

https://www.tandfonline.com/doi/full/10.1080/15459620701329012?scroll=top&needAccess=true&


Inactivation of Viruses on Surfaces by Ultraviolet Germicidal Irradiation

Chun-Chieh Tseng and Chih-Shan Li

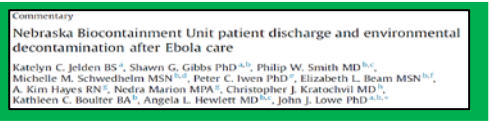
Graduate Institute of Environmental Health, National Taiwan University, Taipei, Taiwan

Ultraviolet (UV)-reflective Paint with Ultraviolet Germicidal Irradiation (UVGI) Improves Decontamination of Nosocomial Bacteria on Hospital Room Surfaces


Ultraviolet (UV)-reflective paint with ultraviolet germicidal irradiation (UVGI) improves decontamination of nosocomial bacteria on hospital room surfaces

Nebraska Biocontainment Unit Patient Discharge and Environmental Decontamination After Ebola Care

https://www.ajicjournal.org/article/S0196-6553(14)01375-3/abstract


Commentary

Nebraska Biocontainment Unit patient discharge and environmental decontamination after Ebola care

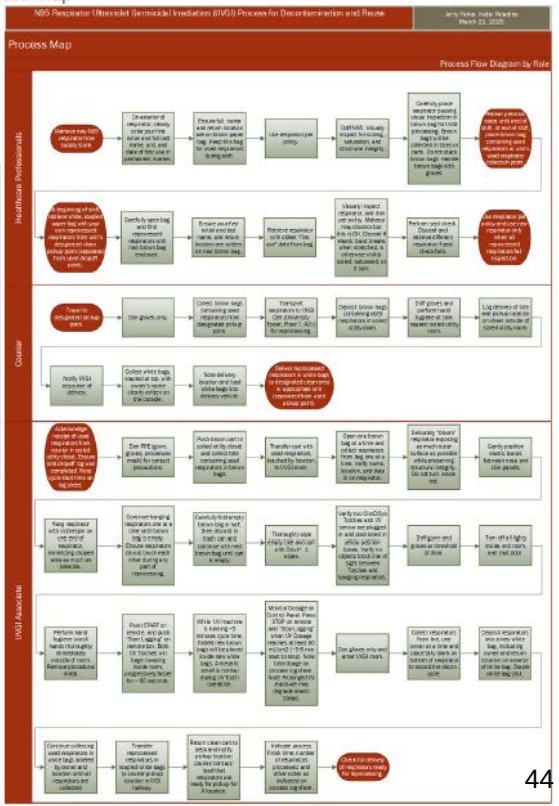
Katelyn C. Jelden BS[a], Shawn G. Gibbs PhD[a,b], Philip W. Smith MD[b,c], Michelle M. Schwedhelm MSN[b,d], Peter C. Iwen PhD[e], Elizabeth L. Beam MSN[b,f], A. Kim Hayes RN[b], Nedra Marion MPA[b], Christopher J. Kratochvil MD[b], Kathleen C. Boulter BA[b], Angela L. Hewlett MD[b,c], John J. Lowe PhD[a,b,c]

N95 Respirator UVGI Process for Decontamination and Reuse

Process Map

- Principles
- Clear
- Step by Step
- Flow from each use through reprocessing through reuse
- Everyone knows their role
- Refresher training on Donning and Doffing
- Principles

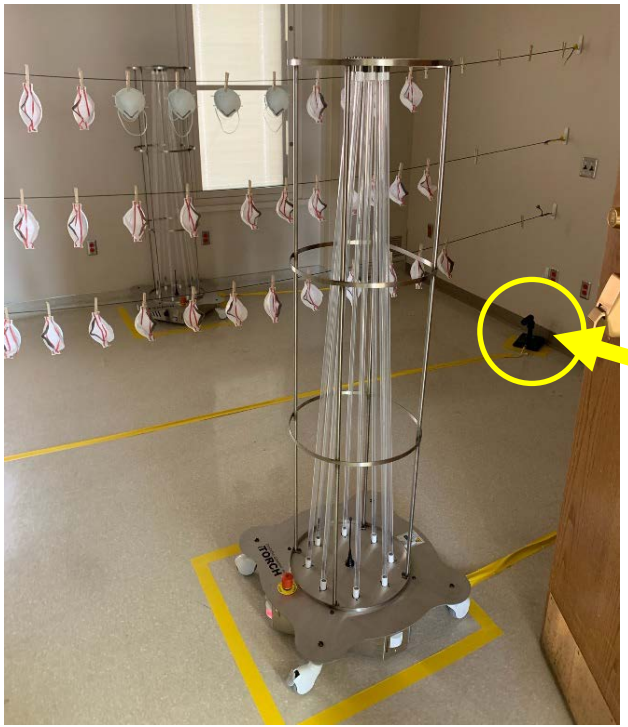
Process Map



N95 Respirator UVGI Process for Decontamination and Reuse

Optimizing Process

- **Trial and error**
  - **Placement**
  - **Exposure times**
- **Surface decontamination process not entire FFR**
- **UVGI is measured by room UV meter**



N95 Respirator UVGI Process for Decontamination and Reuse

Process Confirmation

Organism Kill

- Used BSL2 bacterial and viral surrogates seeded on FFR surface to refine dosage in room
- *Staphylococcus aureus*
- Chikungunya virus
- 10 FFR at each UVGI exposure route
- 10^6 organism kill at each round

FFR Fit

- Ran 5 FFR through qualitative fit tests to assure maintained filtration efficiency and fit
- Didn't use quantitative as it would destroy FFR
- Don't know how many UVGI cycles the mask can take.
- Others indicate in unpublished data — filter loading from spittle

Guidance for Respiratory and Eye Protection: Extended Use, Reuse & Reuse After Decontamination

NETEC

Extended Use

- **Wearing the same N95 for extended periods**
  - **Good condition**
  - **Not soiled**
  - **Free from defects or damage**
  - **MUST be capable of forming a seal to the wearer's face**

Guidance for Respiratory and Eye Protection: Extended Use, Reuse & Reuse After Decontamination

NETEC

N95 Reuse

- Reuse N95s
- Store between use
- Same person, several times, one day only
- Limited reuse – restrict the amount of reuse
- When reusing – must be functional, not soiled, free from defects and the wearer must obtain a successful seal check

https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.htm

Guidance for Respiratory and Eye Protection: Extended Use, Reuse & Reuse After Decontamination

NETEC

N95 Reuse

- Discard after aerosolizing procedures
- Discard if grossly contaminated with blood or other bodily fluids
- Discard if used for a patient co-infected with another respiratory infection
- Protect the N95 with a face shield or procedure mask

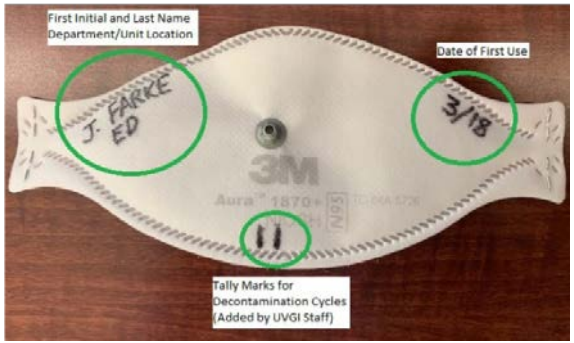
https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

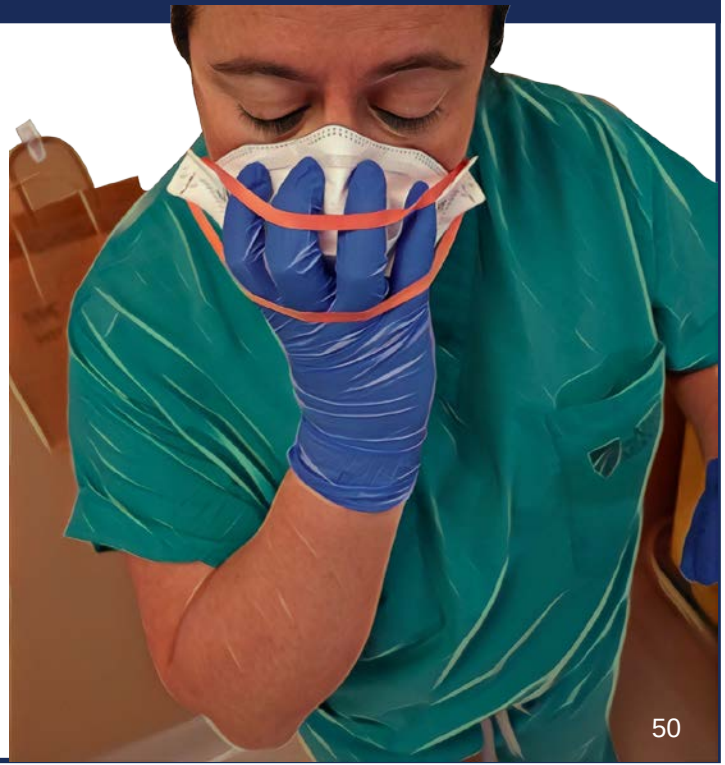
Guidance for Respiratory and Eye Protection: Extended Use, Reuse & Reuse After Decontamination

NETEC

N95 Reuse

- **Store used N95s in a clean breathable container**
- **Hand hygiene**





https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.htm

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HEALTHCARE EMERGENCY PREPAREDNESS INFORMATION GATEWAY

Neil Carlson, MS, CIH
Industrial Hygienist, Department of Environmental Health & Safety, University of Minnesota

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ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Testing for the State of Minnesota

Type of Respirator	Total Number tested	Total # Passed Fit factor > 100	Total # Failed
N-95/N99	39	8/20%	31/80%

- TSI Portacount fit test – One subject – fit factor of 100 through standard fit protocol
- N-95s vary widely in quality

Reuse of Respirators Fitted Using a TSI Portacount - Aluminum tape

Respirator Decontamination

Rx

- 5 x 5 rule
- 5 days (7days) for 5 times
- Store in paper bag with desiccant. Include name and dates used.

Portable UVC Decontamination Device

UVC UVGI Meter with 254 nm Wavelength

Measuring UVC Light Dose

Condition	Rate mJ/cm2/minute	Time to 216 mJ/cm2
1 Sensor pointed at UVC light – Cabinet with vertical orientation	156	1.4 minutes
2 Inside respirator, The UVC light was underneath. The sensor was pointed at the ceiling – Worse case exposure. Cabinet in horizontal orientation	39.6	5.5 minutes

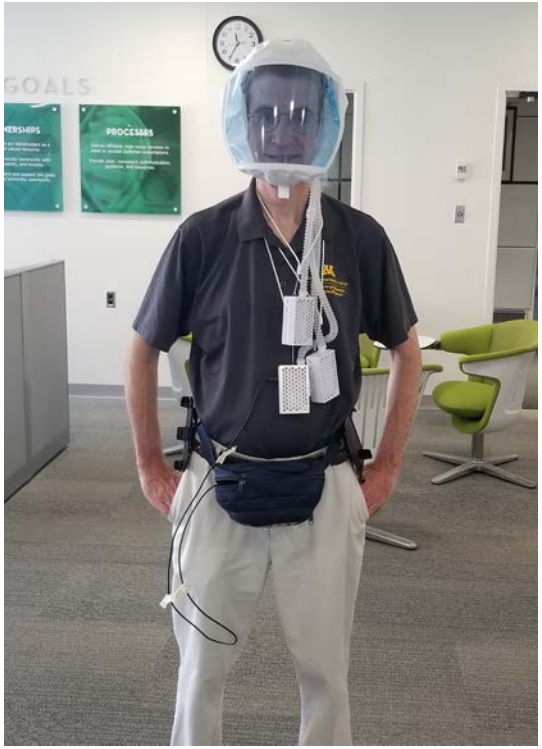
Repurpose Eye Glass Decontamination Cabinet

M3 Mask – Origami Mask

- Available in kits of over 100 masks. Self assemble with bands and staples.
- Cummings filter material
- Fit factor depends on assembly
- Generally performs as well or better than KN-95 respirator
- Decontaminate by heating at 75C in oven for 30 minutes

Nano PAPR Research

- Several manufacturers make battery powered filter units to supply filtered air to a respirator or a hood
- Currently problems with QC some filter very well others average
- It makes wearing a respirator more comfortable

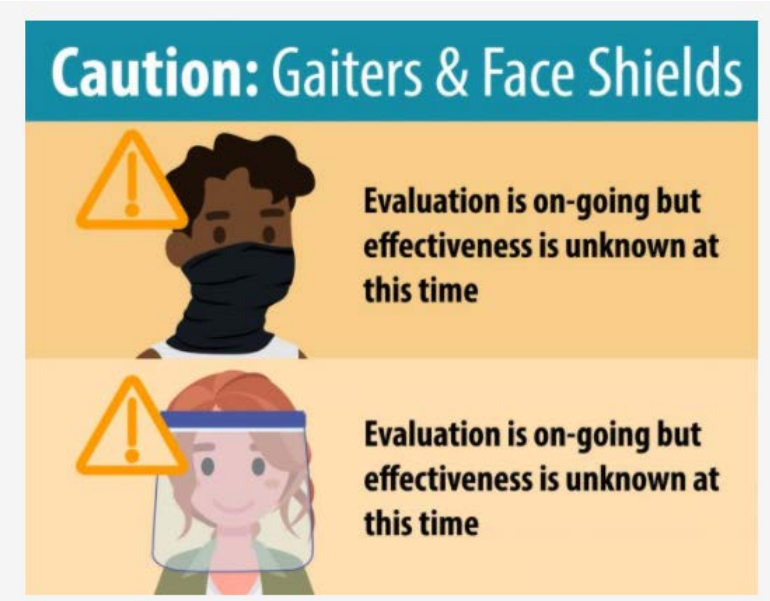


Hole Punch for Nano PAPR

Options for Testing Cloth Face Covering

1. Portacount – real time fit factor test
2. Portacount – inject highly filtered air inside covering and determine how well the face covering holds the reduced particle count
3. Tissue/candle test

Face Shields and Gaiters (Tissue Test)



https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html?deliveryName=USCDC_2067-DM36401

Tissue Test for Cloth Face Covering – Layers and Type of Fabric Matter

Tissue Test for Cloth Face Covering – Layers and Type of Fabric Matter – Type is Less Important

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HEALTHCARE EMERGENCY PREPAREDNESS INFORMATION GATEWAY

Philip Madvig, MD, Interim Chief Medical Officer, Kaiser Permanente
Mary Beth Lang, ScD, Chief Supply Chain and Procurement Officer, Kaiser Permanente

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

COVID-19: Acquiring, Distributing, & Managing Use of PPE

- Kaiser Permanente overview
- National Command Center & COVID-19 response
- Implementation & innovation

The Nation's Largest Integrated Health System

23,371 physicians deliver high-quality care

12.4 M members served in 8 markets

$84.5B revenue

CARE AND COVERAGE TOGETHER

217K + employees improve health for people and communities

39 hospitals

715 medical offices

63,306 nurses are at the center of our care

Responding to COVID-19

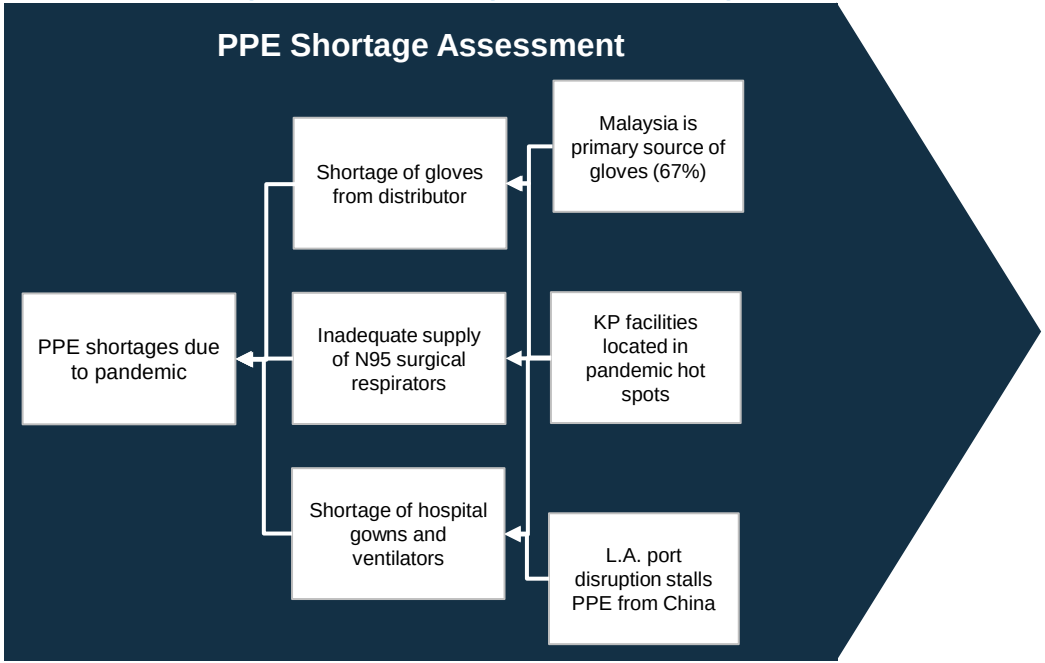
- Activated national incident command structure
- Established COVID-19 Executive group with physician and organizational leaders, and convened expert groups
- Created tracking system and published daily tracker of cases, bed use, supplies, regulatory issues

Responding to COVID-19 *(cont.)*

- Instituted scenario planning for potential surge
- Forecast and planned for needs for space, staff, and stuff
- Reduced non-COVID-19 demand
- Disseminated policies

Pursuing Additional Supplies

Global supply chains are fragile and no longer capable of responding to increasing numbers of unplanned disruptions in complex environments

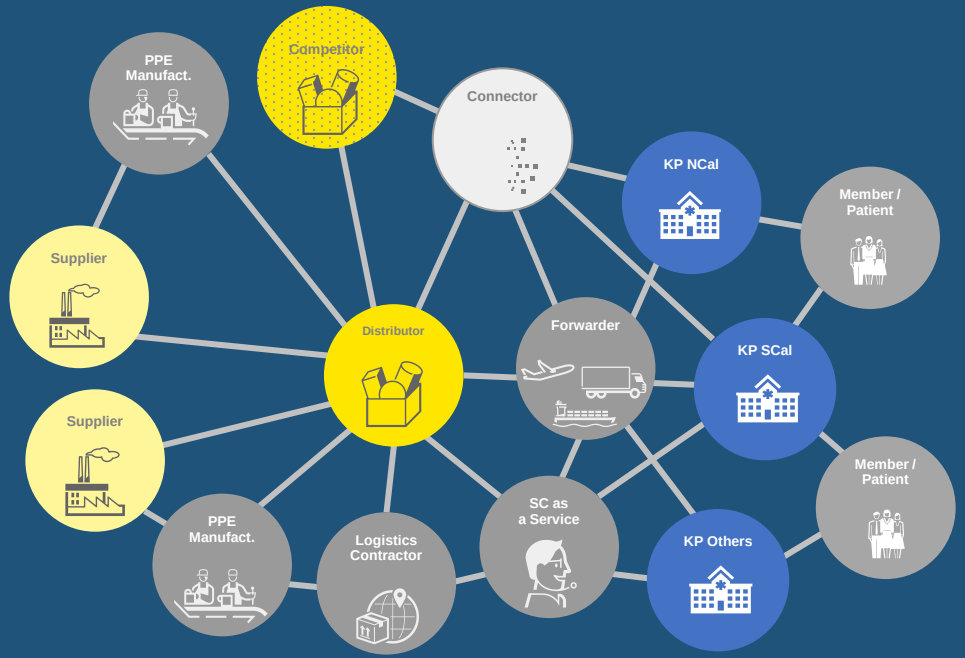


Sourcing Considerations

Buy To Pay Command Center

NIOSH	Authenticity/Certification
FDA/CDC/OSHA	Trade Barriers
Clinical Acceptance	Delivery Date

Supply Channel Considerations



Facing Constraints

- Partnered with infectious disease chiefs on clinical acceptability; partnered with Labor on implementation
- Asserted systemwide supply control, including security, redistribution
- Modified use guidelines including mask policies, extended use, reprocessing
- Developed communications and job tools

  - Daily Supply Update
  - Rolling 12-week Current Inventory and Resupply Tracker
  - Ventilator/Disposables Surge Modeler
  - Supply Inventory, Days Inventory on Hand and Consumption Trends
  - Re-Entry Supply Impact of OR and Non-OR Procedures

Factors Guiding Resumption of Standard Use

Supply Chain Security

- Supply Chain Resiliency Measures
- PPE Contracts Based on Product Access
- Reserve Warehouse

Adequate Supply on Hand

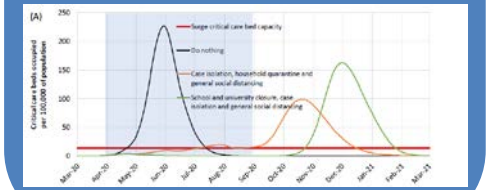
- Conservation

  Reuse
  Reprocessing
  Extended Use

- EUA
- Testing Protocols
- COVID/PUI Procedures

Forecast Demand

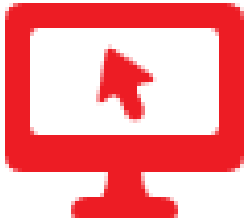
- Mini-surges
- COVID-19 plus Flu Surge
- 90-day Reserve at 40% Attack Rate



Adoption of critical indicators - ability to act if change in demand, use, supply

Question & Answer

Contact Us



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HEALTHCARE EMERGENCY PREPAREDNESS INFORMATION GATEWAY

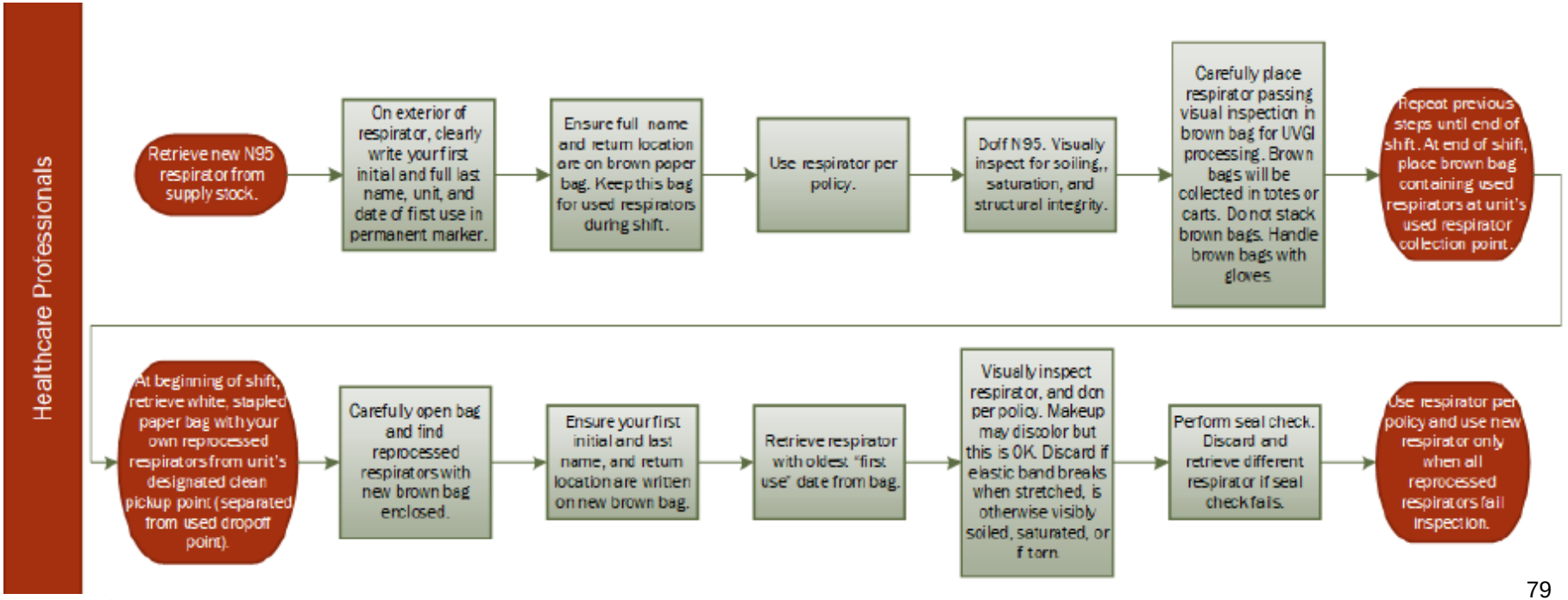
ADDITIONAL SLIDES

ASPR

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

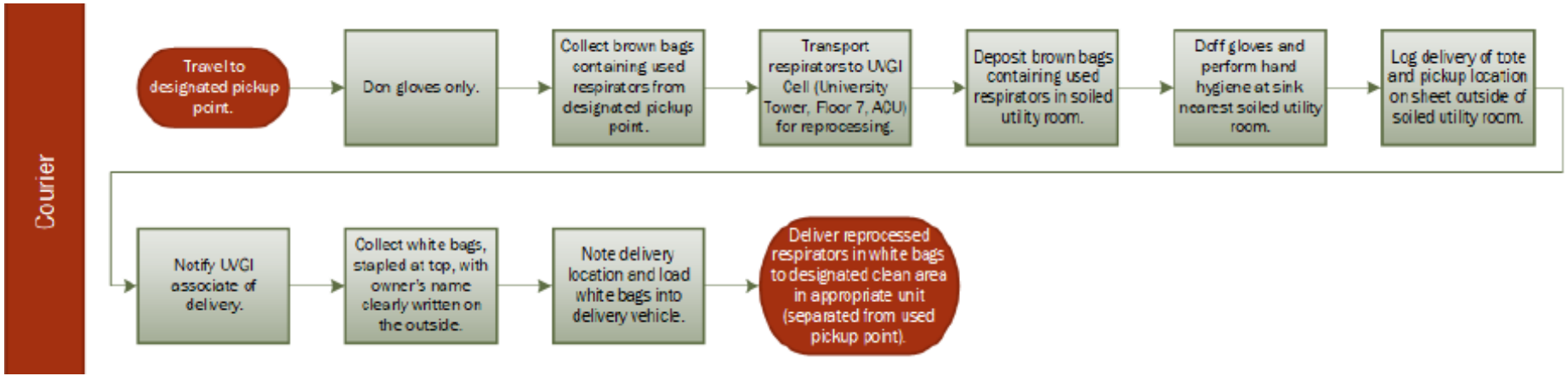
N95 Respirator UVGI Process for Decontamination and Reuse

Process Map: Healthcare Professionals



N95 Respirator UVGI Process for Decontamination and Reuse

Process Map: Courier



N95 Respirator UVGI Process for Decontamination and Reuse

Process Map: UVGI Associate