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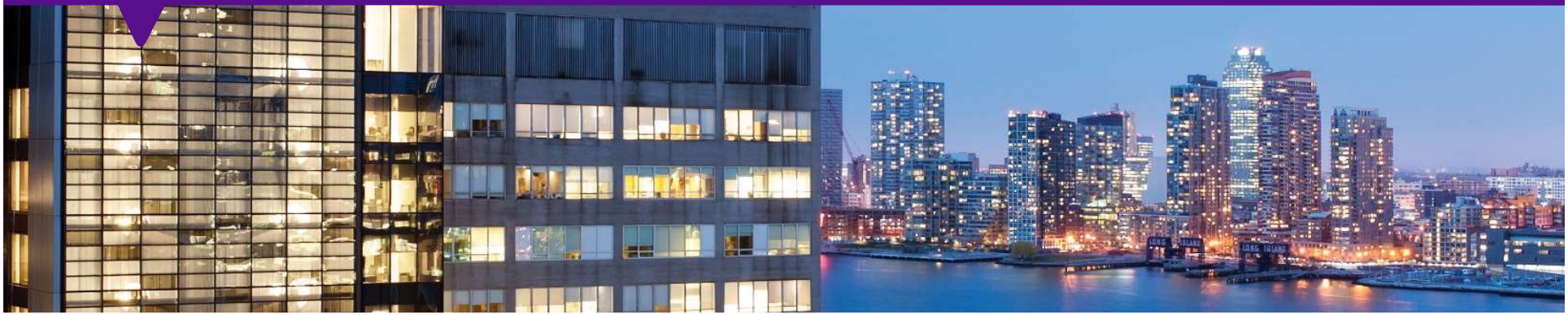
N95 RESPIRATOR DECON:

Administrative Challenges & Validation Protocols

Marta Figueroa, PhD, CIH

Environmental Health and Safety



NYU Langone Health

- In Patient Locations
  - Tisch Hospital - Kimmel Pavilion - Hassenfeld Children's Hospital
  - NYU Langone Orthopedic Hospital
  - NYU Langone Hospital – Brooklyn
  - NYU Winthrop Hospital
- >30 ambulatory care facilities in Manhattan, Bklyn, Queens and Long Island
- >200 faculty group practices
- 2 Schools of Medicine
  - NYU Grossman School of Medicine
  - NYU Long Island School of Medicine
- >40,000 employees

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FACTS & FIGURES

NYU Langone Health by the Numbers

7.85M*
Outpatient Visits

6
Inpatient Locations

4
Emergency Departments

12,228
Births

1,693
Beds

124
Operating Rooms

93,200+
Hospital Discharges

234,000+
Emergency Department Visits

7M+
Patients in Our Electronic Health Record

Represents September 2018–July 2019

* Represents projection for full fiscal year, September 2018–August 2019

N95 Respirator Supplies – Critical Shortages

The New York Times

It's Bedlam in the Mask Market, as Profiteers Out-Hustle Good Samaritans

Hospitals, governments, do-gooders and hucksters are all competing. Scams and prices are soaring.

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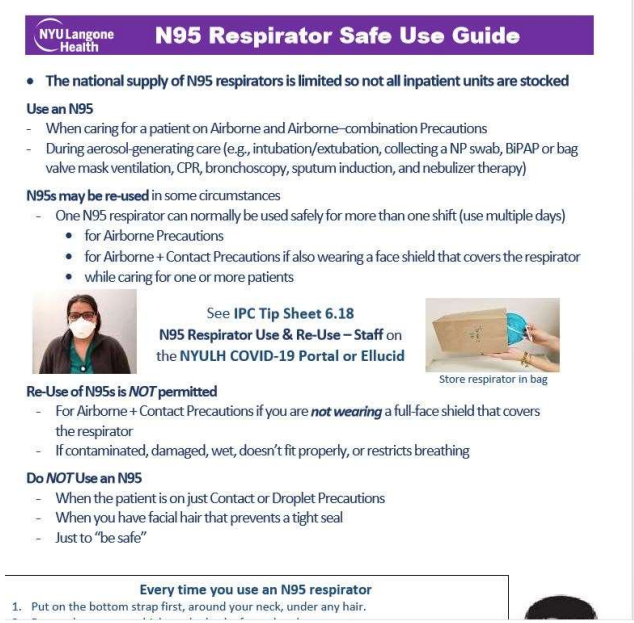
What did NYULH do about respirator shortages?

- Reinforced hierarchy of controls (aka infection control)
- Took control of respirator supplies
  - limited to units with isolation rooms, aerosol generating procedures, etc.
- Implemented N95 Extended Use and Re-Use plan
- Respirator Decontamination
  - Deconned respirators sent to storage - backup



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N95 Respirator Safe Use Guide

- **The national supply of N95 respirators is limited so not all inpatient units are stocked**

Use an N95
- When caring for a patient on Airborne and Airborne–combination Precautions
- During aerosol-generating care (e.g., intubation/extubation, collecting a NP swab, BiPAP or bag valve mask ventilation, CPR, bronchoscopy, sputum induction, and nebulizer therapy)

N95s may be re-used in some circumstances
- One N95 respirator can normally be used safely for more than one shift (use multiple days)
  - for Airborne Precautions
  - for Airborne + Contact Precautions if also wearing a face shield that covers the respirator
  - while caring for one or more patients

See **IPC Tip Sheet 6.18**
N95 Respirator Use & Re-Use – Staff on
the **NYULH COVID-19 Portal or Ellucid**

Store respirator in bag

Re-Use of N95s is *NOT* permitted
- For Airborne + Contact Precautions if you are ***not wearing*** a full-face shield that covers the respirator
- If contaminated, damaged, wet, doesn't fit properly, or restricts breathing

Do *NOT* Use an N95
- When the patient is on just Contact or Droplet Precautions
- When you have facial hair that prevents a tight seal
- Just to "be safe"

Every time you use an N95 respirator
1. Put on the bottom strap first, around your neck, under any hair.

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FDA Emergency Use Authorizations (EUA)

- March 29, 2020
  - Battelle Decontamination System – Vapor Phase Hydrogen Peroxide (VPHP)

- April 11, 2020
  - Advanced Sterilization Products (ASP) STERRAD Sterilization System
    - VPHP
    - Aerosolized hydrogen peroxide (aHP)
    - Hydrogen peroxide gas plasma (HPGP)

- June 13, 2020
  - Technical Safety Services (TSS) VHP (20-CS) Decontamination System

Respirator specific considerations

- Check with manufacturer
  - 3M Technical Bulletin – Sept 2020
    - Decontamination of 3M Filtering Facepiece Respirators, such as N95 Respirators in the US – Consiiderations
  - NIOSH
    - Respirator specific decontamination assessment results
  - Do not decon cellulose respirators or respirators with valves

n95decon.org/webinars

N95DECON PUBLICATIONS IMPLEMENTATION RESOURCES ABOUT FAQ GLOBAL

OUR WEBINARS

N95DECON and our partners provide webinars with live translations for the domestic and global healthcare community. Our webinars go into detail on the scientific evidence behind PPE use, N95 respirator decontamination and reuse, as well as cautions to be aware of when implementing N95 decontamination.

[June 23, 2020] N95DECON/Lifebox: N95 Decontamination and Reuse

Download Slides >

Translations: Français and Español

[May 21st, 2020] N95DECON/Assist International: N95 Decontamination and Reuse

Download Slides >

Translations: Amharic, French, Khmer, and Vietnamese >

[May 9th, 2020] N95DECON/MGB N95 Decontamination & Reuse Webinar: Evidence and Implementation

Download Slides >

[April 24th, 2020] N95DECON/AAMI N95 Decontamination & Reuse Webinar

[April 3rd, 2020] ACOEM N95 Decontamination & Reuse Webinar

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N95 Decontamination & Reuse Method Decision Matrix

The purpose of this tool is to provide a high-level comparative overview of methods for the decontamination and reuse of N95 respirators during the COVID-19 pandemic.
These methods should only be employed in crisis shortages and should be part of a PPE conservation strategy. Each method requires detailed protocol implementation for operator and user safety;
This tool is not intended to provide all information for implementation, but rather to allow quick comparison for decision-makers to select methods that best fit the local setting prior to detailed investigation for effective implementation [Version 1.0, published Aug. 8, 2020]

N95DECON

Method	Reprocessing Method Level of Decontamination	Demonstrated SARS-CoV-2 Viral Inactivation	Effect on N95 FFR Filtration Efficiency (FE) & Fit	Removal of Chemical Residue Required?	Regulatory Guidance for N95 FFRs***	LMIC Availability	Operator Hazard#	Startup Costs	Recurring Costs	Time per cycle	Protocol Available	Typical Scale of Operation	Requires electricity	Use for surgical masks	Number of Studies##	Scientific References	Implementation References
Methods being implemented in hospitals																	
Vaporized Hydrogen Peroxide	*			Yes	FDA EUA[1], CDC[2], NIOSH FE pass[3]	Low	Chemical#	$$$	$$$	4-8 hours	Hospital- implemented	Facility	Yes		++++	4###	5, 6, 7
Hydrogen Peroxide Gas Plasma	*			Yes	FDA EUA[1], CDC[2], NIOSH FE pass[3]	Low	Chemical#	$$$	$$	2-6 hours	Hospital- implemented	Facility	Yes		+++	4###	8
UV-C Room	**			No	CDC[2], NIOSH FE Pass[3]	Mid	Direct exposure#	$$$	$	System-dependent&	Hospital- implemented	Facility	Yes		+++	9###	10‡, 11, 12
UV-C Cabinet	**			No	CDC[2], NIOSH FE Pass[3]	Mid	Direct exposure#	$$	$	System-dependent&	Generic SOP	Facility	Yes		+++	9###	10‡, 13‡, 14‡
Humid Heat Oven	**			No	FDA EUA[15], CDC[2]	High	#	$	$	60 min	Generic SOP	Facility	Yes	Possibly; sparse data	++	16###	17‡, 18‡
Methods not well-established, but under investigation																	
Microwave Generated Steam	**			No	-	High	#	$	$	2-3 min	Generic SOP	Individual	Yes		+	16###	19, 20
Room Temperature Waiting Time	**			No	CDC[3]	High	#	$	$	7 days	Generic SOP	Both	No	Yes	++	21###	
Liquid Hydrogen Peroxide	**			Yes	CDC[3]	High	Chemical#	$	$	24 hours	None	Individual	No		+	4###	22, 23, 24
Steam Autoclave	*			No	NIOSH FE pass[3]	High	#	$$$$	$	<60 min	None	Facility	Yes		++	16###	23, 25, 26
Dry Heat Oven	**			No	NIOSH FE pass[3]	High	#	$$	$	>60 min	Generic SOP	Facility	Yes		++	16###	23
Container Immersion in Boiling Water	**			No	-	High	#	$	$	45 min	Generic SOP	Individual	No		+	16###	27‡
Multicooker	**			No	-	High	#	$	$	30 min	Generic SOP	Individual	Yes		+	16###	28, 29
Chlorine Dioxide commercial system	*			Yes	NIOSH FE pass[3]	Low	Chemical#	$$$$	$	1-12 hours	Generic SOP	Facility	Yes		++	30, 31	
Chlorine Dioxide small scale	*			Yes	NIOSH FE pass[3]	High	Chemical#	$	$	1-12 hours	Generic SOP	Both	No		++	30, 31	
Ozone	*			Yes	NIOSH FE pass[3]	Low	Chemical, environmental#	$	$	3-6 hours	None	Both	Yes		+	32	
Methods that are NOT recommended for use																	
Alcohol submersion				Yes	Not recommended	-	#	-	-	-	-	-	-		+++	22, 23	
Bleach submersion				Yes	Not recommended	-	Chemical#	-	-	-	-	-	-		+++	22, 23	
Soapy water submersion				No	Not recommended	-	#	-	-	-	-	-	-		++	23	
Sunlight				No	Not recommended	-	#	-	-	-	-	-	-		++	9###, 21###, 33	
Ethylene Oxide	*			Yes	CDC Caution	Low%	Chemical, carcinogen#	-	-	-	-	-	-		++	22, 23, 24	
Formaldehyde Vapor				Yes	Not recommended	-	Chemical, carcinogen#	-	-	-	-	-	-		+	35	
Gamma Ray				No	Not recommended	-	Direct exposure#	-	-	-	-	-	-		+	36‡	

Legend

GREY = Unknown due to insufficient or conflicting data

RED = Not expected to yield appreciable decontamination	RED = unlikely to inactivate SARS-CoV-2 to 3-log levels on N95 FFR material	RED = <95% Filtration Efficiency or poor N95 fit after method use	RED = Residue removal required and safe removal has NOT been clearly demonstrated on N95 FFRs.
YELLOW = Some level of decontamination. Demonstrated to inactivate SARS-CoV-2 or similarly-resistant viruses by at least 3-log. Will NOT inactivate bacterial spores.	YELLOW = Likely to inactivate SARS-CoV-2 to at least 3-log, demonstrated only with similar pathogens on N95 FFR material	YELLOW = Mixed or limited results for fit/filtration after method use	YELLOW = Residue removal required but safe removal for N95 FFRs demonstrated in literature.
GREEN = High-level disinfection (Validated process used to render a	GREEN= Demonstrated to inactivate SARS-CoV-2 to at least	GREEN = >95% Filtration Efficiency and passing fit test	GREEN = No residue removal required

* N95 respirators reprocessed with high-level disinfection techniques can be returned in a pooled fashion to any new user
** N95 respirators reprocessed with low-, or intermediate-level disinfection techniques must be returned to the initial user to prevent cross-contamination of other pathogens (e.g. bacteria, bacterial spores)
*** Refers to regulatory approval specific to the use of this method for N95 decontamination and reuse, including methods for removal of potential toxic residues.
The existence (or lack thereof) of an FDA EUA is not a definitive statement about effectiveness (or ineffectiveness) of a treatment method.
% EtO more common in Latin America, low availability in sub-Saharan Africa
& UV-C decontamination depends on dose; at least 1 J/cm^2 must be applied to all N95 surfaces for 3-log inactivation of enveloped viruses.
Because dose = irradiance x time, and irradiance of UV-C systems can vary widely, the time per cycle will vary but is typically on the order of minutes to hours.
\# Operator Hazard = ALL methods carry risk of self-contamination to the operator. PPE for droplet & contact precautions should be worn (Mask, gloves, long-sleeved gown, eye protection) while reprocessing PPE
$ **Startup Costs**: $$$$ = >$50,000, $$$ = $5,000 - $50,000, $$ = $500 - $5,000, $ = <$500
$ **Recurring Costs**: $$$$ = >$10 per respirator, $$$ = $1-$10 per respirator, $$ = $0.10 - $1 per respirator, $ = <$0.10 per respirator
Studies refer to peer-reviewed literature on specific method use (both supporting and controverting) for decontamination of N95 respirators (including pre-print studies closely reviewed by N95DECON)
Citation refers to N95Decon Technical Report (summary report with multiple citations therein)
‡ At least one author is affiliated with N95Decon

www.n95decon.org – Aug 8, 2020

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Methods being implemented in hospitals	
Vaporized Hydrogen Peroxide	*
Hydrogen Peroxide Gas Plasma	*
UV-C Room	**
UV-C Cabinet	**
Humid Heat Oven	**
Methods not well-established, but under investigation	
Microwave Generated Steam	**
Room Temperature Waiting Time	**
Liquid Hydrogen Peroxide	**
Steam Autoclave	*
Dry Heat Oven	**
Container Immersion in Boiling Water	**
Multicooker	**
Chlorine Dioxide commercial system	*
Chlorine Dioxide small scale	*
Ozone	*

Methods that are NOT recommended for use	
Alcohol submersion	
Bleach submersion	
Soapy water submersion	
Sunlight	
Ethylene Oxide	*
Formaldehyde Vapor	
Gamma Ray	

> or = 3 log decon - single user reuse **

> or = 6 log decon - pooled user reuse *

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Conflict in documents posted at FDA website

- June 6, 2020 revised FDA EUA
  - Cites ASP validation > 6 log decon
  - But still states authorization is for single user reuse

- ASP Instructions for healthcare facilities still states single user reuse (June 6, 2020)

FACT SHEET FOR HEALTHCARE PERSONNEL

ASP STERRAD Sterilization Systems for Decontaminating Compatible N95 Respirators June 6, 2020

Coronavirus Disease 2019 (COVID-19)

You have been given a **decontaminated N95 respirator** that has been decontaminated using a sterilization system that is authorized to return **the same respirator for reuse that you packaged for decontamination for use in a healthcare setting** to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated, compatible N95 respirators (hereafter referred to as "decontaminated N95 respirators"). These compatible N95 respirators have been decontaminated using one of three Advanced Sterilization Products, Inc. STERRAD Sterilization Systems: ASP STERRAD 100S Sterilization System in the 100S cycle, the ASP STERRAD NX Sterilization System in the Standard cycle, or the ASP STERRAD 100NX Sterilization System in the Express cycle (**hereafter** referred to as "**STERRAD Sterilization Systems**" throughout this Fact Sheet).

Whether or not you use a respirator, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

decontaminated N95 respirators?

- The STERRAD Sterilization Systems have been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic to prevent exposure to pathogenic biological airborne particulates.
  - Compatible N95 respirators are those without exhalation valves that do not contain cellulose-based materials and are either NIOSH-approved and authorized by that EUA or authorized under the non-NIOSH-approved FFR EUA for respirators not manufactured in China.
  - The STERRAD Sterilization Systems are not authorized for use with the following:
    - Respirators or pouches containing cellulose-based materials;
    - Respirators that have exhalation valves; and
    - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through 2 decontamination cycles for viricidal activity, material compatibility, hydrogen peroxide residue, and filtration performance.
- **Preparing compatible N95 respirators for decontamination:**
  - ✓ Place compatible N95 respirators after use into a compatible sterilization pouch identified for use in vaporized hydrogen peroxide, such as a Tyvek© pouch with STERRAD Chemical Indicator
  - ✓ Write name and/or other identifier using a permanent marker so the respirator may be returned after successful decontamination
  - ✓ Place a tick mark on respirator and Tyvek pouch each time a respirator is prepared for decontamination
  - ✓ Seal the respirator in the Tyvek pouch, and place it into area for subsequent decontamination per

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Use the Correct Cycle and Compatible N95 Respirators When Decontaminating Respirators with STERRAD Sterilization Systems - Letter to Health Care Providers

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Letters to Health Care Providers

The U.S. Food and Drug Administration (FDA) reminds reprocessing staff in health care facilities to use the correct decontamination cycle associated with certain models of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and to only decontaminate compatible N95 or N95-equivalent respirators for reuse during the COVID-19 pandemic.

ASP STERRAD Sterilization Systems use vaporized hydrogen peroxide to decontaminate medical devices. Only the combination of certain models of the ASP STERRAD Sterilization System and their associated STERRAD Decontamination Cycle listed in the FDA's Emergency Use Authorization (EUA), and shown in the table below, are authorized for the decontamination of compatible N95 respirators.

ASP STERRAD Sterilization System	STERRAD Decontamination Cycle
STERRAD 100S	100S
STERRAD NX	Standard
STERRAD 100NX	Express

There have been no injuries reported to the FDA associated with the use of an incorrect decontamination cycle with the ASP STERRAD Sterilization Systems for decontaminating

Content current as of:
05/27/2020

Regulated Product(s)
Medical Devices

Health Topic(s)
Coronavirus

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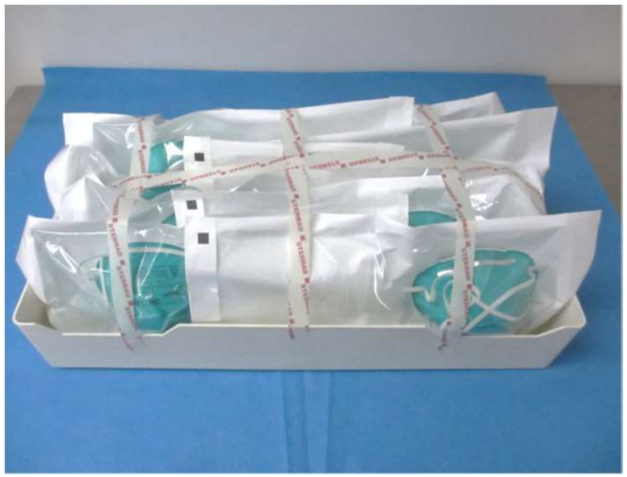
Our process – HPGP

- At Kimmel Pavilion Central Sterile
  - 4 Sterrad Machines, 1 had to be reserved for OR, 3 machines available
  - 8 masks per machine = full load
    - Set up time/take down time (5minutes)
    - Express cycle (24 minutes) 1 capsule of sterilant
    - Machines validated per/load w/Biological Indicator (Geobacillus stearothermophilus, 27 minute incubation time)
    - Express Cycle Capacity
      - 3 machines x 8 masks x 2 load p/hour = 48 x 24 hours = **1152 masks p/day***
- **Sterrad machines located in clean area of CSPD so respirators needed surface disinfection before decon**

Central Sterile Processing and Distribution (CSPD)

1. Dedicated Sterrad Technician receives the packaged masks
2. Apply index label
3. Apply lot sticker
4. Place 8 masks inside the sterilizer (4 per shelf)
5. Place biological indicator in chamber
6. Run cycle on express*
7. Empty complete cycle
8. Incubate biological (27 min)
9. Record biological results
10. Bag masks for return

****Process requires 3.5 FTEs per day for CSPD**



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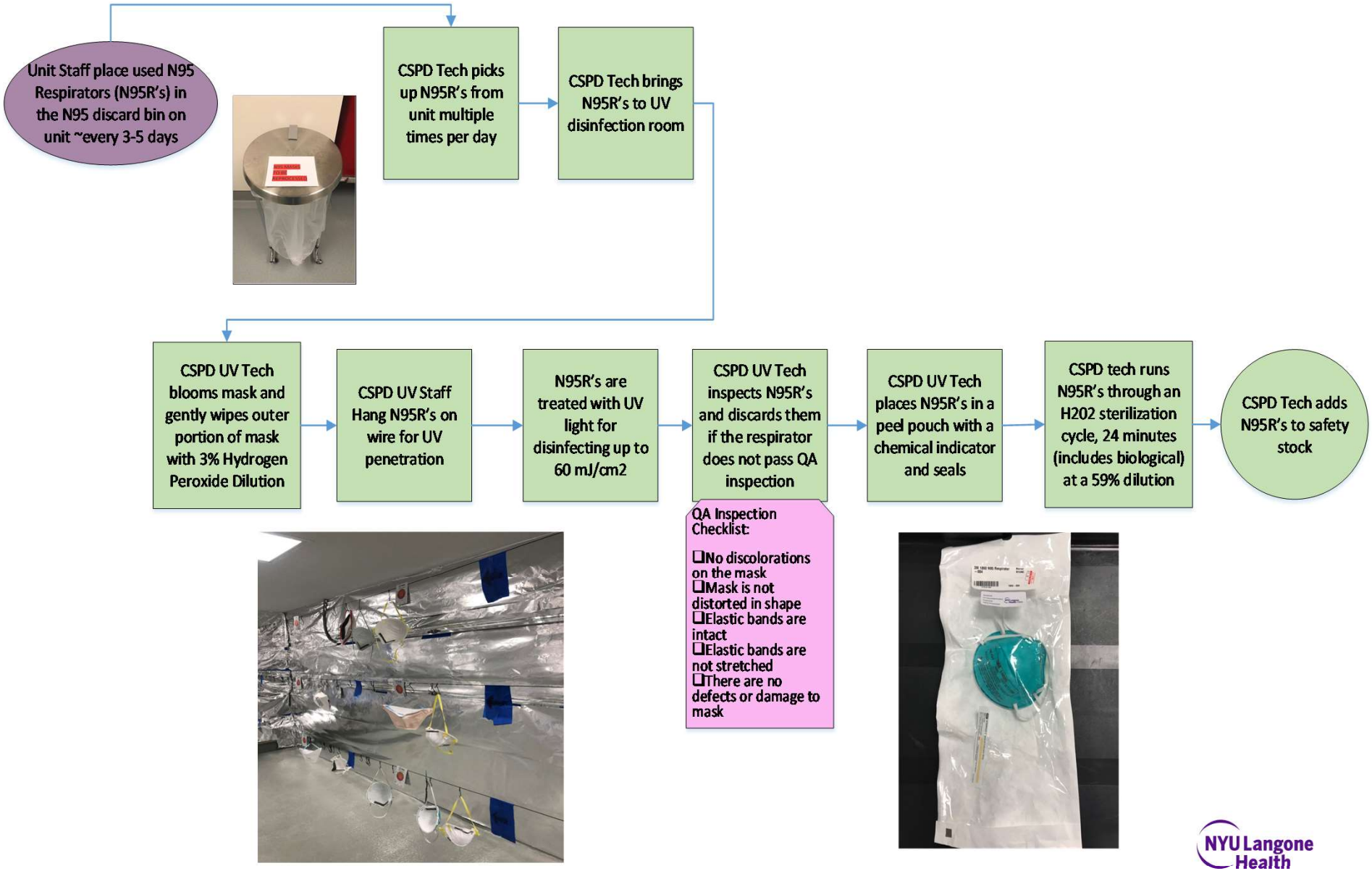
How does the process work?



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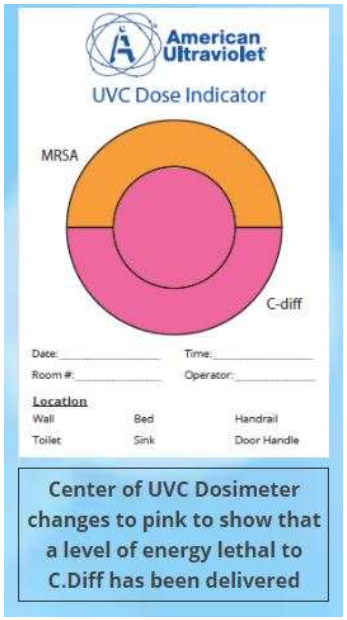
Validation – UV rooms

UV Rooms

- UVC meters –
  - Univ of Nebraska protocol – 60 mJ/cm2
- UVC dose indicator cards
  - Colormetric
  - *C. dificile* criteria



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Validation – UV rooms

- Different UV room constructions = different exposure time requirements
  - Univ of Nebraska protocol respirator exposure dose of 180 mJ/cm2 to 240 mJ/cm2

    Kimmel - 5 min

    Brooklyn – 3 min

    LOH – 6.5 min
  - Single-stranded RNA viruses, such as SARS-CoV-2, are generally inactivated by UVGI exposure of 2-5 mJ/cm2

- Challenges
  - Lack of adherence to site specific SOP requirements for timing of exposure, use of timer
  - Room locations where lower doses were recorded and N95 placement, markers and staff education
  - Site specific plans for placement of UVC dosimeter cards

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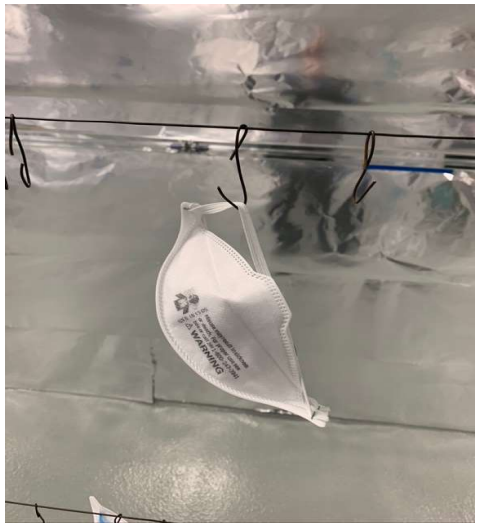
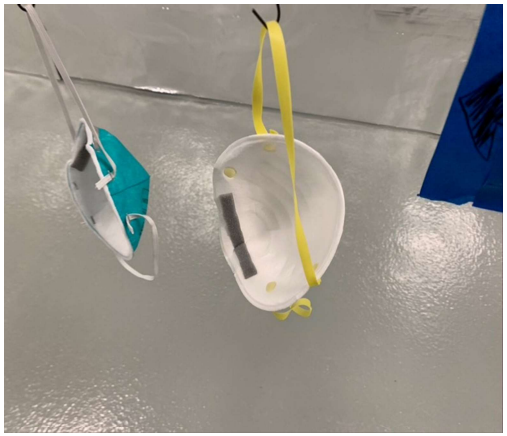
Microbiological Testing – Kimmel UV Room

- 19 wipe samples
  - Included wipes of four different respirators - inside and outside surface
    - Two cup shaped
    - Duck billed
    - Flat fold 3M
  - cultured for bacteria and fungal spores
    - 2% malt extract agar (MEA) for environmental fungal spores (aspergillus, penicillium, Cladosporium etc.) and in tryptose soy agar (TSA) for a broad spectrum of human commensal bacteria
  - 5 min requirement for Kimmel room
    - CFUs noted on outside and inside of 3 of 4 masks (5 to 410 CFU)
    - No fungal growth detected
    - Duck billed/folded masks performed better
    - nose foam pads on inside may harbor bacteria





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Quantitative fit testing – Unused respirators

1. 16 unused respirators – 1 cycle of decon -
   a. Five different respirators (3M 1860, 3M 1870, 3M 8210, 3M 9210, Halyard)
   b. All passed fit testing

2. 8 unused respirators – 2 cycles of decon
   a. Four different respirators (3M 1860, 3M 1870, 3M 9210, Halyard)
   b. Two fit test failures, one strap broke

3. 7 unused respirators – 3 cycles of decon
   a. Five different respirators (3M 1860, 3M 1870, 3M 8210, 3M 9210, Halyard)
   b. All failed fit testing

Fit testing performed on student and staff volunteers

Quantitative fit testing – Used respirators

1. 10 used respirators – 1 cycle of HPGP
   a. Five different respirators (3M 1860, 3M 1870, 3M 8210, 3M 9210, Halyard)
   b. 6 passed, 2 failed, 2 broken straps

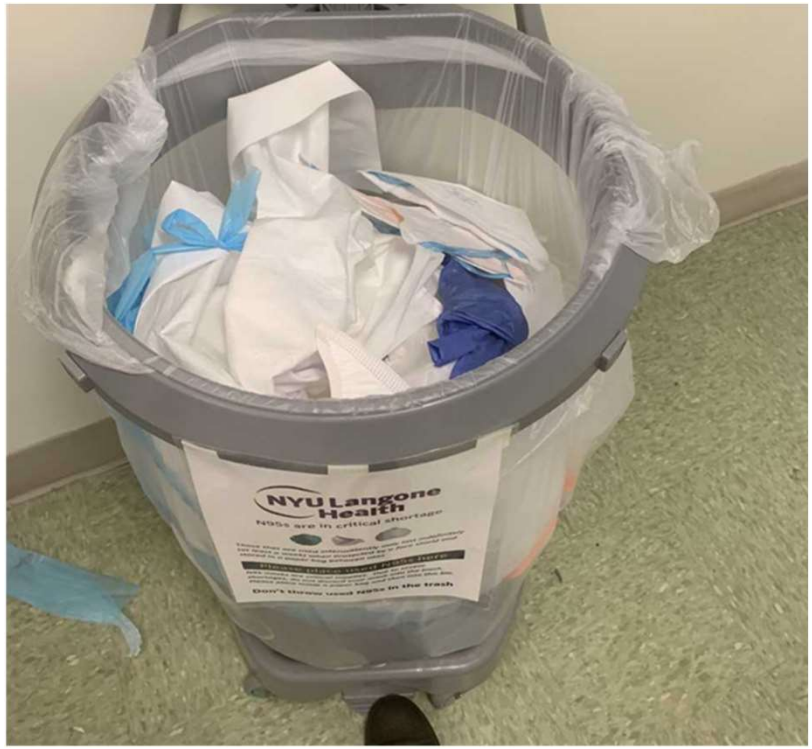
2. 6 used respirators – 2 cycles of HPGP
   a. Four different respirators (3M 1860, 3M 1870, 3M 8210, 3M 9210)
   b. 5 passed, one failed, 1 strap stretched and discolored

3. 8 used respirators – 3 cycles of HPGP
   a. Five different respirators (3M 1860, 3M 1870, 3M 8210, 3M 9210, Halyard)
   b. All failed

4. Results from other facilities were consistent

Fit testing performed on staff volunteers, on respirator models and sizes they had previously passed on.

Collection challenges



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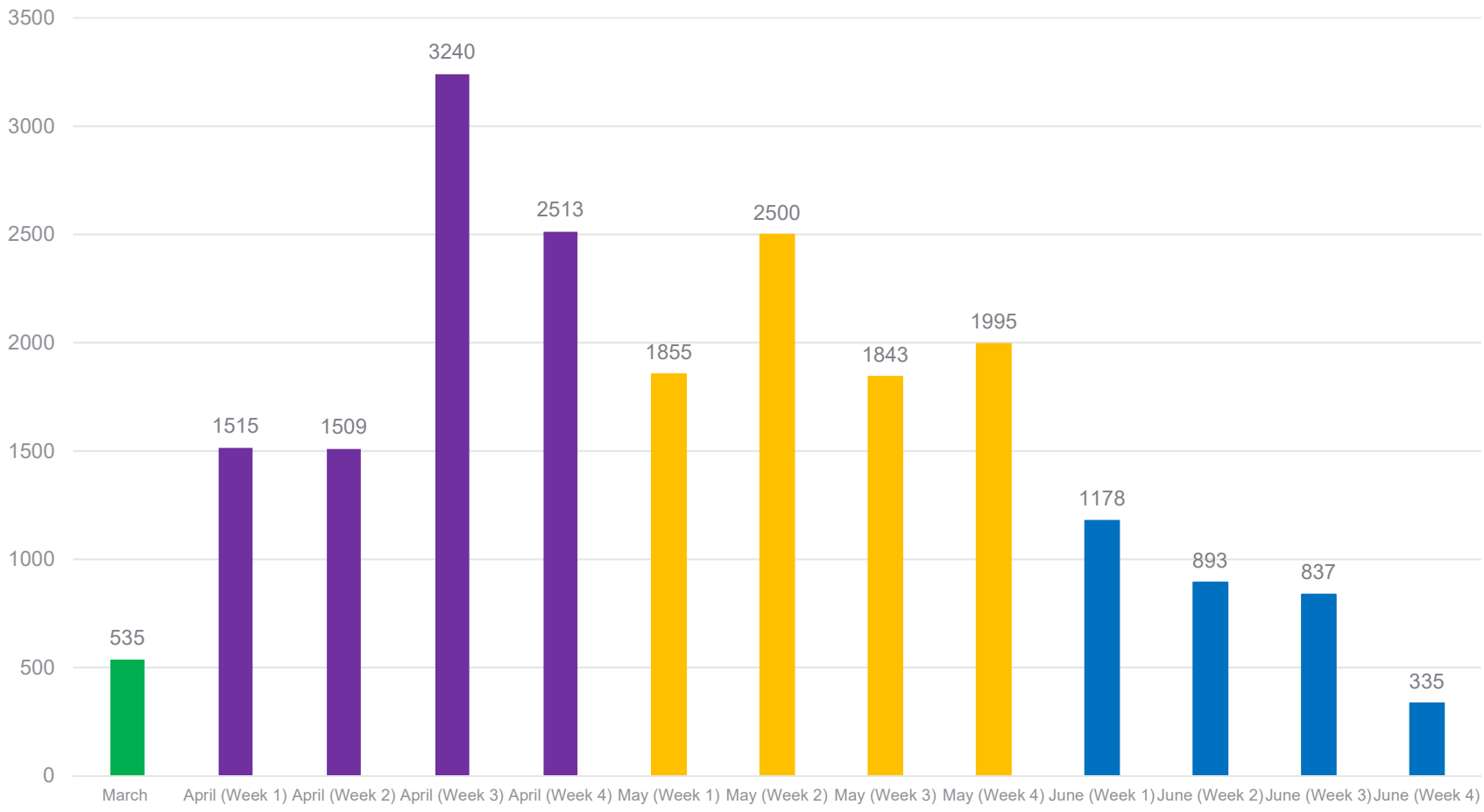
N95 Collections



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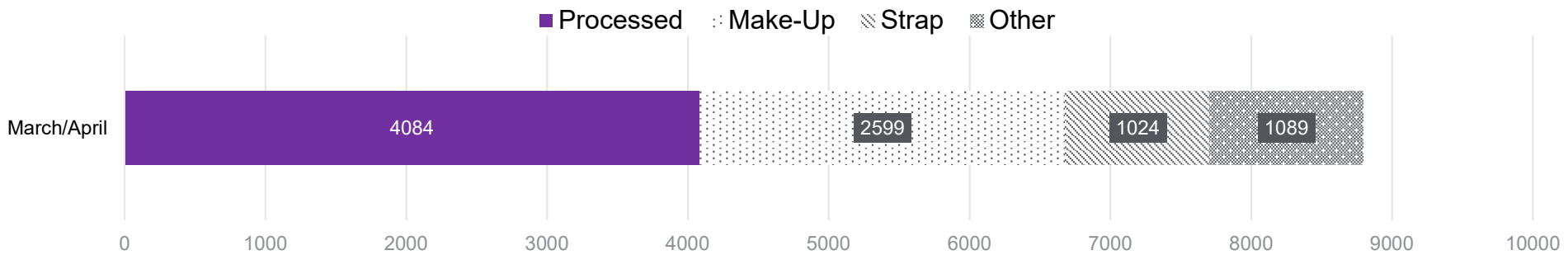
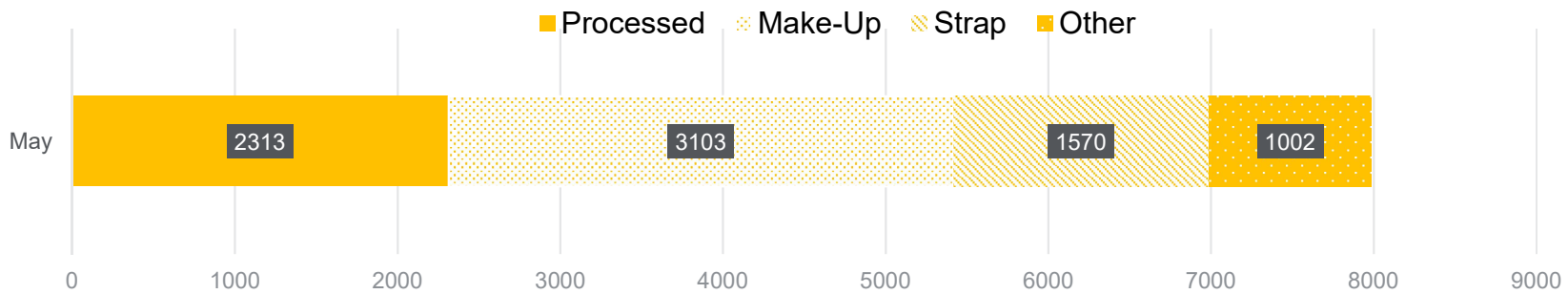
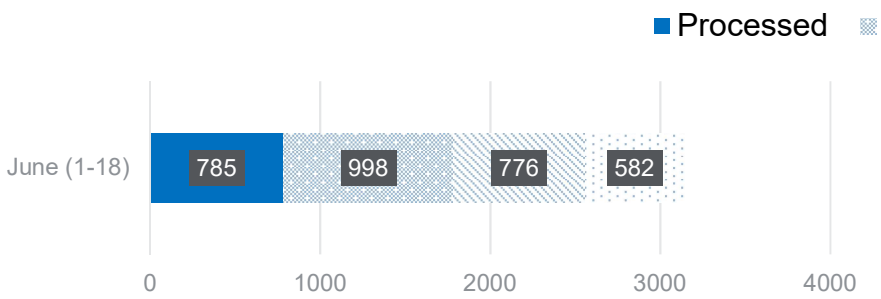
N95 Collection Report: YTD (Gross 19,925)







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Make up policy

Policy

Pursuant to HR Dress Code Policy, “Departments can create their own dress and appearance policy when necessary.”

Employee must cease wearing make-up, including foundation, lipstick, lip gloss, etc. when utilizing an N95 respirator. The use of make-up is no longer allowed when utilizing an N-95 respiratory because residual make-up can adhere to the respirator interfering with decontamination and sterilization.

More Guidance on Decontamination

- OSHA Enforcement Guidance
  - Employer good faith effort
    - Use other strategies first
      - Contingency strategies e.g. extended use
      - Crisis strategies
        - Use beyond shelf life
        - Non NIOSH
        - Limited reuse
        - Prioritize use of available respirators

  - If using non-approved method, avoid use in surgical procedures, aerosol generating procedures, high risk procedures.

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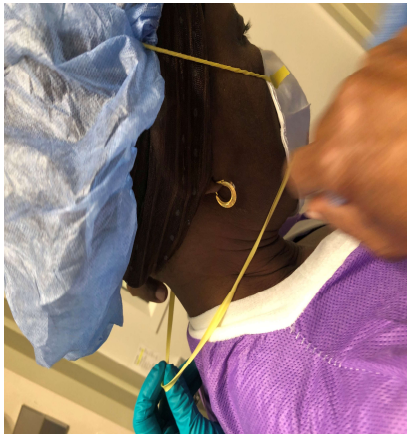
More Guidance on Decontamination

- CDC decontamination guidance
  - Monitor your decontamination process
    - Track # decon cycles closely
    - Establish process for monitoring adverse effects
      - Skin irritation
      - Smells
      - Symptoms
    - Sample deconned respirators frequently
      - Filtration efficiency
      - Fit performance



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More Guidance on Decontamination

- Employee training and information
  - Risk and limitations of deconned respirators
  - Inspection of respirators
  - **Seal check**
  - Process to report problems

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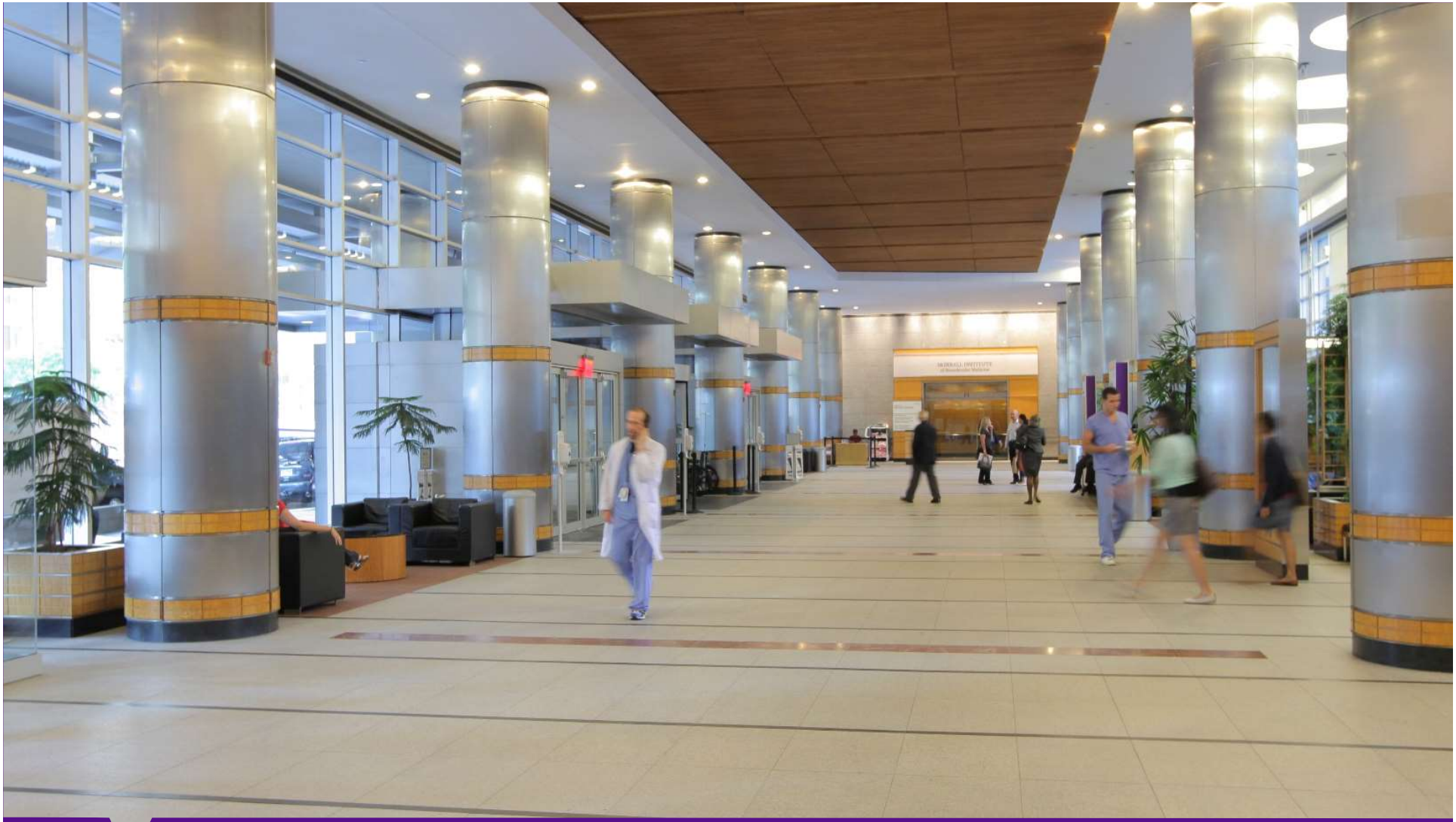
Going forward…

- To continue – we must fully validate combined process or restrict to one validated method
  - Address non-uniform SOP implementation at UV rooms
    - Review signage, markers for placement of respirators and dosimeter cards, use of timers, staff education, QC monitoring
  - Restrict HPGP decontamination to one cycle only

- Consider other decontamination methods
  - Cost, resources, user perception
  - Monitoring outcomes
  - Training

- Re-usable respirators!



THANK YOU

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