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

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Introduction Rationale and Method:

The ongoing pandemic of SARS-CoV-2 resulting in COVID-19 has severely stressed the worldwide healthcare system and has created dangerous shortages of personal protective equipment (PPE) including N95 filtering facepiece respirators (N95 FFRs). In an effort to extend the stockpile of N95 FFRs at our institution and reduce risks associated with reuse of untreated, contaminated N95 FFRs, we developed a surface decontamination procedure involving the delivery of ultraviolet germicidal irradiation (UVGI) to used N95 FFRs. The evidence base supporting this program includes: 1) UVGI has been shown to effectively inactivate a wide range of human pathogens including coronaviruses and other human respiratory viruses; 2) UVGI has been demonstrated to inactivate human respiratory viruses, including coronaviruses, on various models of N95 FFRs; 3) levels of UVGI needed to inactive human respiratory viruses are well below the level of irradiation that adversely affects the fit and filtration characteristics of N95 FFRs; and 4) UVGI can be safely administered when appropriate safeguards are in place. We also recognize there is uncertainty regarding how long an N95 FFR maintains properties to achieve adequate fit, requiring providers to inspect FFRs before and after reuse. Any organization considering a decontamination strategy (including UVGI, vaporized hydrogen peroxide, warm moist heat, etc.) to deal with lack of supply or potential lack of N95 FFR should validate their own procedures, including desired surrogate microbial reduction and retained filter efficiency and fit. Herein, we briefly describe our procedure to surface decontaminate and reuse N95 FFRs. Additional resources are available to guide considerations when developing UVGI N95 FFR decontamination strategies from the U.S. FDA and Berkeley University

Literature supports UVGI exposures of 1 J/cm² are capable of decontaminating influenza virus on N95 FFRs and exposures as low as of 2-5 mJ/cm² are capable inactivating coronaviruses on surfaces (1-2). Given this range, we validated 60 mJ/cm² and 300 mJ/cm² exposure from room sensor for FFR decontamination. It is important to note that for our setup, UV sensor readings of 60 mJ/cm² represent a total mask exposure dose of 180 mJ/cm2 to 240 mJ/cm2 and a sensor reading of 300 mJ/cm² represent a total mask exposure dose of 900 mJ/cm2 to 1200 mJ/cm2 depending on mask placement on the mask hanging lines. These exposures were validated to reduce 6 log of bacterial and viral surrogate organisms. In our decontamination process, used N95 FFRs are subjected to UVGI at a sensor exposure of 300 mJ/cm². Exposure mapping of our system indicated N95 FFR received a dose of double the measured dose from each side of the N95 FFR. Single-stranded RNA viruses, such as SARS-CoV-2, are generally inactivated by UVGI exposure of 2-5 mJ/cm² (2). Thus, the UVGI exposure we have chosen exceeds, by at least several fold, the amount of exposure needed to inactivate SARS-CoV-2 and provides a wide margin of safety for surface decontamination.

Respirators are secured on wires that are strung across a room with two UVGI towers (ClorDiSys UVGI Light System, https://www.clordisys.com/products.php) on either side. Each of the two UVGI towers are equipped with eight 254 nm bulbs, these bulbs are routinely used in biosafety cabinets and produce 200 μ w/cm² at 10 feet distance for a dosage of 12 mJ/minute. Our system delivers 254 nm UV irradiation at an intensity of 400 μ W/cm² from each of the two UV

sources. We monitor the delivered UVGI exposure dose with a room UVGI meter that can be initiated and monitored from outside the room to verify that the desired exposure has been achieved. As UVGI can cause damage to eyes and skin, this protects our UVGI associate's safety. We plan to decontaminate and reuse the N95 FFRs multiple times until respirator fit is impacted (3-5). Prior to initiating the decontamination program, the walls and ceiling were covered with a UV- reflective coating (https://lumacept.com) with which our group had experience (5). Our program initially involved the units with high N95 FFR use such as the emergency department and our COVID-19 ward, but we plan to rapidly expand to ambulatory settings. We believe a variety of UV light sources could be used in a similar fashion including UV equipped biosafety or sterilization cabinets or other UV disinfection systems and that this method can be applied to a variety of other critical items such as procedure masks. The method described below is a result of multiple tests, a review of the scientific literature, and incorporation of current institutional practice.

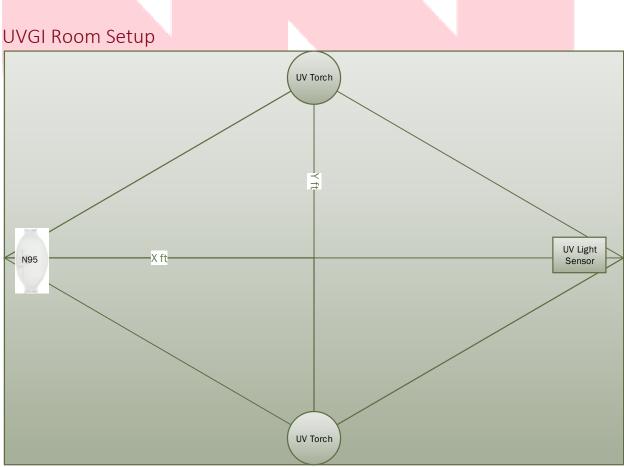


Figure 1 – Room Setup (Overhead View). The lines holding the N95 FFRs are 13 feet long and hold 30 respirators per line (3 across the room); the UVGI "torches" are located 4 feet from the center of the line and are 8 feet apart.

Process Map

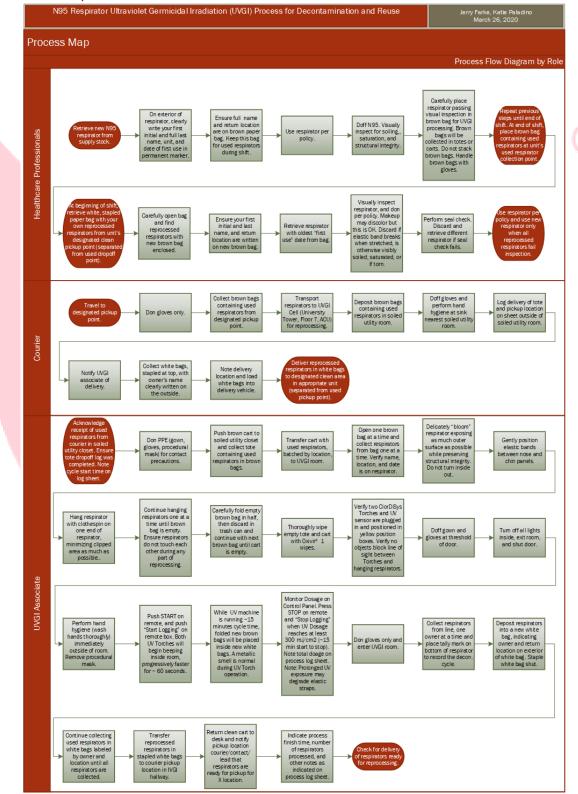


Figure 2 – Process flow diagram by role

Page 1

Roles

Healthcare Professional (HCP)

- Healthcare Professional retrieves new N95 FFR from secure Omnicell storage or other storage location
- Using a permanent marker, HCP writes needed information on front of respirator including first initial and last name, department/unit location*, and date of first use*. (This ensures correct respirator is returned to correct HCP and to the correct location; Date of first use is requested to monitor duration of use as well as number of decontamination cycles)
- HCP dons N95 FFR per policy ensuring integrity of respirator and proper fit
- HCP uses N95 FFR following extended use guidelines per policy (https://www.nebraskamed.com/sites/default/files/documents/covid-19/COVID-Extended-Use-Reuse-of-PPE-and-N95.pdf?date03212020)

Upon doffing:

- Remove N95 FFR following appropriate doffing guidelines
- Place used N95 FFR in brown paper bag ensuring brown bag is correctly labeled with HCP full name, and Department/Unit return location
- When ready to send brown bag, with used respirators, for decontamination, the HCP brings bag to department/unit designated "dirty" drop off location. This is separate from the department/unit "clean" location.

Specific to In-House Staff

- Donning gloves only, staff courier collects all used respirators (in brown bags) in a cart or tote.
- Staff courier takes cart/tote to Decontamination Unit. Only gloves need to be worn for this process.
- Staff courier places department/unit supply of brown bags (containing used respirators) in the Decontamination Unit's Dirty Storage area. Staff courier places tote or individual bags on the shelf designated for specific unit.
- Staff courier removes gloves and performs hand hygiene
- Staff courier logs requested information onto the drop off log sheet (name of individual dropping off, contact number, department/unit location, name of person to contact for pick up, pick up contact number)

Specific to Ambulatory Clinic and Immediate Care Clinic Staff

• Lidded tote, with brown bags containing used respirators, is picked up by courier from clinic site's designated location. Pick-ups are done at times specific to clinic site. Any used respirators, needing decontaminated, must be placed in tote prior to the specified pick up time.

Upon Completion of Decontamination Process:

Specific to In-House Staff

- The Decontamination unit calls contact person, provided on log sheet, to notify that department/unit decontaminated respirators are ready for pick up.
- Staff courier dons gloves and retrieves decontaminated respirators from the Decontamination Unit's designated clean pick up area.

- Decontaminated respirators are in new, clean white bags displaying HCP's and return location. A new brown bag is included in the clean white bag to serve as new "dirty" discard brown bag.
- Staff courier logs name and time of pick up on the log sheet
- White bags are returned to department/unit designated clean pick up location.
- HCP will notice a tally mark has been added, by the UVGI associate, after decontamination process, to track the number of times a particular mask has gone through the decontamination.

Specific to Ambulatory Clinic and Immediate Care Clinic Staff

- Clean white bags (containing decontaminated respirators) are returned, by courier, to each site's designated "clean" delivery location. White bags are labeled (by decontamination personnel) with each HCP's name and site location. A new brown bag is included in the clean white bag to serve as new "dirty" discard brown bag.
- HCP will notice a tally mark has been added, by the UVGI associate, after decontamination process, to track the number of times a particular mask has gone through the decontamination.
- Deliveries to clinic or ICC site are conducted at a time specific to site location.

* A note specific to in-house float staff: For HCP floating between multiple units, HCP may designate their unit/department as the most recently worked resulting in their white bag, with decontaminated bags, being returned to that location or, HCP may write "Float" as their unit/department location. For HCP that designate their location as "Float", their white bag, with decontaminated respirators, need be picked up personally in the Decontamination Unit's clean storage location designated for float staff.

UVGI Associate

- Acknowledge receipt of used respirators from courier in soiled utility closet. Ensure tote drop-off log was completed. Note cycle start time on log sheet.
- Don PPE (gown, gloves, procedural mask) for contact precautions.
- Push brown cart to soiled utility closet and collect tote containing used respirators in brown bags.
- Transfer cart with used respirators, batched by location, to UVGI room.
- Open one brown bag at a time and collect respirators from bag one at a time. Verify name, location, and date is on respirator.
- Delicately "bloom" respirator exposing as much outer surface as possible while preserving structural integrity. Do not turn inside out.
- Gently position elastic bands between nose and chin panels, if applicable.
- Hang respirator with clothespin on one end of respirator, minimizing the clipping area as much as possible.
- Continue hanging respirators one at a time until brown bag is empty. Ensure respirators do not touch each other during any part of reprocessing.
- Carefully fold empty brown bag in half, then discard in trash can and continue with next brown bag until cart is empty.

- Thoroughly wipe empty tote and cart with Oxivir[®] 1 wipes.
- Verify two ClorDiSys Torches and UVGI sensor are plugged in and positioned in yellow position boxes. Verify no objects block line of sight between Torches and hanging respirators.
- Doff gown and gloves at threshold of door.
- Turn off all lights inside, exit room, and shut door.
- Perform hand hygiene (wash hands thoroughly) immediately outside of room. Remove procedural mask.
- Push START on remote, and push "Start Logging" on UVGI meter box. Both UVGI Torches will begin beeping inside room, progressively faster for ~ 60 seconds.
- While UVGI machine is running ~15 minutes cycle time, folded new brown bags will be placed inside new white bags. A metallic smell is normal during UV Torch operation.
- Monitor Dosage on Control Panel. Press STOP on remote and "Stop Logging" when UV Dosage reaches at least 300 mJ/cm² (~15 min start to stop). Note elapsed time and total dosage on process log sheet. Note: Prolonged UVGI exposure may degrade elastic straps.
- Don gloves only and enter UVGI room.
- Collect respirators from line, one owner at a time and place tally mark on bottom of respirator to record the decontamination cycle.
- Deposit respirators into a new white bag, indicating owner and return location on exterior of white bag. Staple white bag shut.
- Continue collecting used respirators in white bags labeled by owner and location until all respirators are collected.
- Transfer reprocessed respirators in stapled white bags to courier clean pickup location in UVGI hallway.
- Return clean cart to desk and notify pickup location courier/contact/lead that respirators are ready for pickup for their location.
- Indicate process finish time, number of respirators processed, and other notes as indicated on process log sheet.
- Check for delivery of respirators ready for reprocessing.

Appendix

Process Photos



Figure 3 - Required respirator markings.

Courier



Figure 4 – Deposit brown bags containing respirators on rack in soiled utility room.



Figure 5 – Perform hand hygiene.

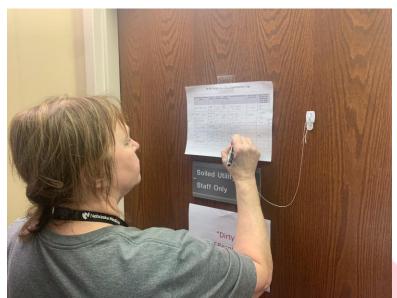


Figure 6 – Log respirator drop-off (must note contact for pickup of respirators when decontaminated).

UVGI Associate



Figure 7 – Place bags with respirators on cart and transport to UVGI Room.



Figure 8 – Indicate name of respirator owner on new white bag, and number of respirators to return.



Figure 9 – Wipe cart thoroughly with Oxivir[®] 1 wipes. Doff at threshold and exit room. Perform hand hygiene.



Figure 10 – Do not block UVGI arc from light to respirators.



Figure 11 – Shut off lights and close door.



Figure 12 – Start cycle on remote. Start logging on touchscreen.



Figure 13 – While cycle runs, write name on new brown bag and place in corresponding labeled white bag.

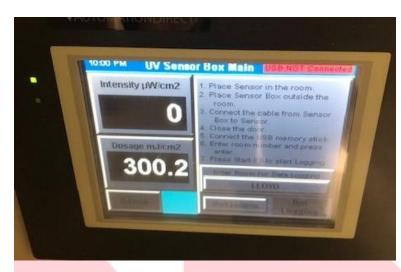


Figure 14 – Run cycle until dose is not less than 300 mJ/cm².



Figure 15 – Stop cycle on remote as soon as possible after minimum required dose.



Figure 16 – Enter room with gloves and procedure mask.



Figure 17 – Add tally to respirator to indicate number of UVGI cycles.



Figure 18 – Carefully place respirator one at a time in corresponding bag for each owner.



Figure 19 – Staple shut clean white bag with decontaminated respirators.



Figure 20 – Place stapled bags with decontaminated respirators in totes.



Figure 21 – Contact staff indicated on drop-off log to communicate respirators are ready for pickup.

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Disclaimer: We are sharing the processes we've adopted and other resources we've found beneficial as information that may be helpful to others fighting COVID-19. It is very important to note that there is great variation in materials and local rules which must be considered before adopting any process and which may impact the effectiveness of processes. We disclaim all liability in respect to any actions taken or not taken based on any or all of the contents of this (site/document/resource) or any use thereof. Do not act or refrain from acting upon this information without consulting your own professional advisors and considering your own circumstances.