N95 Respirator Decontamination Procedure

Forward

Prior to developing this procedure for the decontamination of N95 respirators, the University of Iowa Hospitals and Clinics (UIHC) carefully considered the extraordinary situation that has been created by the COVID-19 pandemic outbreak. Critical shortages of personal protective equipment (PPE) threaten health care workers in the State of Iowa, throughout the United States and around the world. The U.S. supply chain is presently unable to supply adequate numbers of N95 respirators to all healthcare systems so that they can protect the country’s healthcare workforce. Given the existence of state and national disaster declarations and the critical role that UIHC plays within this state and the region, it was our assessment that extraordinary and unconventional steps must be taken to prudently extend the useful life of critical PPE such as N95 respirators in order to preserve the health, well-being and availability of our institution’s healthcare workforce.

At the UIHC, a number of innovative techniques have been adopted since the 2014-15 West Africa Ebola Outbreak to enhance our ability to disinfect environmental surfaces. One of those techniques involves the delivery of an ionized hydrogen peroxide mist/fog that is generated by passing a low concentration source liquid (7.8% H2O2) through a 17,000v cold plasma arc. This ionized disinfecting mist, which appears to behave like a gas, is applied to environmental surfaces with two types of delivery devices which have been brought to the healthcare market by TOMI Environmental Solutions, Inc. under the trade name SteraMist®. This technology is EPA-registered as a hospital disinfectant under the name “Binary Ionization Technology (BIT) Solution”, and appears on EPA lists K, L, G and M. Our initial investigation found evidence to suggest that the speed of its antimicrobial effect, the relative lack of damage done to materials and surfaces, the fact that it dissipates fairly quickly into water vapor and oxygen after application leaving no toxic residue or odor behind, and the portability of the proprietary delivery systems could make adoption of this technology exceptionally useful.

UIHC subsequently tested this product in collaboration with the State of Iowa Public Health Hygienic Laboratory (SHL) in February of 2018, utilizing chemical indicators (CI), biological indicators (BI), (Mesa Labs Apex Line 1.0x10^6 min. G. stearothermophilus for gaseous hydrogen peroxide), and enzyme indicator (EI) technology from Protak Scientific produced by Public Health England (PHE) of the United Kingdom. After treatment of a test room with the SteraMist® product per the manufacturer’s protocol, with the various indicators distributed throughout the space, SHL laboratory technicians incubated the BIs for seven days. Test results indicated 6-log kill on all exposed BIs within the room that received exposure to at least 12-25ppm as indicated by the CIs. This finding was corroborated by test results from the EIs read on the same day of testing.

UI Health Care acquired this technology in March of 2018, intending it to be used for terminal disinfection of our CDC/NETEC-verified biocontainment unit, (one of two in DHS Region VII), following the care of any “Special Pathogen” patient(s). Since that time, we have successfully utilized this technology to address a number of difficult disinfection situations within our institution. Our experience with SteraMist® has demonstrated that this technology had the potential to be
successfully utilized for the purpose outlined in this document. We contacted the manufacturer for guidance and advice, and learned that a treatment protocol had been developed for this purpose that had been successfully tested on N95 respirators inoculated with SARS-CoV-2 virus. Complete inactivation of the virus was reported, and the protocol was subsequently operationalized by health authorities in Hong Kong.

UI Health Care modified and expanded the direct-spray protocol used by the authorities in Hong Kong by adding meticulous tracking and safety processes that were developed based upon proven concepts authored by colleagues at the University of Nebraska Medicine. We designed and constructed a rolling “spray rack” system that could securely and safely hold N95 respirators in a “bloomed” position during treatment. An efficient “drying booth” was constructed in which to hang treated N95 respirators to dry that vented off-gassed hydrogen peroxide directly and safely to the outdoors. The logistical processes required to operationalize this program were effectively tested by two teams of inhouse Central Sterilizing Services (CSS) technicians and quality control staff. Meticulous documentation methods were developed by the CSS team to track each used N95 respirator from the individual health care provider (HCP) who used it, through the treatment process, and then back to the HCP in their home unit/department. Appropriate ongoing quality control measures and daily analysis of safety and productivity were incorporated into the CSS workflow.

Partnering with the leadership at the University of Iowa “Heartland Center for Occupational Health and Safety”, one of 18 NIOSH-funded centers in the U.S., an agreement to test the filtration efficiency of treated N95 respirators in their lab was established. An initial trial of six N95 respirators that had been treated per the original TOMI Environmental-developed direct spray protocol demonstrated a slight decline in respirator filtration efficiency. Upon recommendation of the test lab director, a cap of four total reprocessing cycles per N95 respirator was initially established to assure an adequate margin of safety for the HCP. It was hypothesized that the slight reduction of N95 filtration efficiency noted during initial testing could be due to either the technology’s ionized hydroxyl radical’s effect on the electrostatic charge of the N95 respirators, or possibly due to the proximity of the 17,000v cold plasma arc to the respirators during treatment. These potential effects have yet to be definitively proven or disproven.

After consultation with the company and a small number of prestigious U.S. academic medical centers who had similarly explored this technology for this same purpose, an additional trial of a larger number of test N95 respirators was conducted utilizing a modified treatment protocol that was applied to simulate three and subsequently six reprocessing cycles each on two groups of eight respirators, compared to six identical control respirators. Iowa’s NIOSH-funded center/lab then tested the N95 respirators for filtration efficiency, utilizing a nearly-identical test protocol to what is known to be utilized by NIOSH. Chemical indicators (CI) were employed to verify a minimum treatment exposure of 50-100ppm of hydrogen peroxide to the test respirators.

UI Heartland Center for Occupational Health and Safety laboratory analysis of the test N95 respirators indicated little to no degradation of the filtration efficiency in both test groups of eight respirators. Statistical analysis demonstrated no significant difference between the two test groups and the untreated control group. Based upon these laboratory results, it was determined that application of the newly-modified direct-spray protocol outlined in this document for up to six reprocessing cycles per N95 respirator would be reasonable and safe under current circumstances.
Reprocessing Procedure

*Important Note: Users of N95 respirators must not wear lipstick or other makeup when wearing an N95 respirator as it will contaminate the inside of the respirator, rendering it unable to be decontaminated using this method. Four visual examinations are included in the process map to assure the safety and efficacy throughout this procedure.*

**Process Map**

I. Central Sterilizing Service Staging & Provision of Collection Bins/ Supplies:

- Wash hands
- Collect “clean” staged case cart with “clean” bins, brown bags with labels
- Take clean case cart to point of use in participating unit/department.
- Provide materials in designated unit/department location for collection of used N95 respirators.

II. Health Care Provider (HCP) Instructions:

- HCP obtains new fit-tested N95 respirator from secure storage location in their unit/department.
- Using a black permanent marker, (Sharpie), HCP writes their first initial, last name, unit name/location, and date of first use on the outside/bottom edge of the N95 avoiding the top nose/bridge area and central/front filtration area.
- HCP carefully dons the respirator following the usual institution approved donning procedure ensuring the integrity of the respirator and proper fit.
- HCP uses the respirator in accordance with the institution’s extended use guidelines.
III. HCP Doffing:

- Remove the N95 respirator following the institution’s approved, safe doffing guidelines (e.g. be sure to use clean hands and not touch the front of the respirator; handle it only by the elastic straps, etc.).
- Place the used N95 respirator in a brown paper bag ensuring that the bag is correctly labeled with the HCPs full name, unit name/location in which to return it. *(Infection Control Note: brown paper bag must be used due to moisture build up during use that must be allowed to evaporate).*
- Place the brown paper bag in the designated “dirty N95 bin” in the drop off location within the unit/department.
- Note: if the HCP is a “float” staff member and will not return to the same unit/department for their next shift, mark the N95 and paper bag with the added word “FLOAT” in bold letters. They will then have to present to the last unit they worked in prior to their shift to retrieve their processed N95. Alternatively, they may present to the Decontamination Unit clean pickup area to personally retrieve their N95.

IV. In-house Courier Instructions:

- Donning gloves only, staff courier collects all used respirators (contained in brown paper bags) in a cart/tote. Once the cart/tote is loaded, staff courier will appropriately doff gloves, do hand hygiene with alcohol gel, then don new pair of gloves.
- Staff courier then safely transports the “dirty” case cart/tote to the Decontamination Unit next to the E.D. Ambulance Bay.
- Staff courier then unloads cart/tote in the designated “dirty storage” area in the Decontamination Unit.
- Staff courier then removes gloves and performs hand hygiene with alcohol gel.
- Staff courier then logs requested information on drop-off log; (name of staff courier, contact number, department/unit name and location, number of N95s dropped off, name of person to contact for pickup and their contact number).

V. Central Sterilizing Services Collection & Contamination Transportation:

- Don gloves (purple)
- Wipe exterior of “dirty” red biohazard bin and place inside case cart.
- Doff gloves
- Change cart label to dirty
- Transport to ED Ambulance bay.
- Collect empty dirty case cart with bins—Don gloves-wipe exterior of case cart
- Doff gloves
- Transport case cart with bins inside to CSS Main decontamination for reprocessing.
VI. iHP Decontamination of N95 Respirators (max. of six times per N95 is allowed):

- Decon Receiver Accepts Bins of “dirty” N95s in Ambulance Bay
- iHP Tech donned in supplied air-line/hood and appropriate contact PPE opens Decon Room door, receives N95s for processing.
- Open one brown bag at a time, remove N95s and visually verify name, unit/location and date is on respirator and different color tally marks. **If there is 6 (six) colored tally marks on the N95 discard it in trash.** Assure documentation of N95 data is entered into the log.
- iHP Tech visually inspects N95 for damage, and interior surface for obvious residual lipstick/makeup. If present, discard the N95 in trash and document contamination in log.
- iHP Tech carefully mounts N95s on spray rack, **inside of N95s facing forward:** must delicately “bloom/open” foldable respirators **maintaining structural integrity;** clip to rack in “bloomed” position to assure optimum surface area presented for spraying. **Do Not Clip To Nose Bridge Area or To Soft Foam Padding If Present, Could Damage Seal. Utilize “Side Wing” Structures To Secure to Rack If Present.**
- Fold empty brown back in half and discard in trash; continue emptying brown bags, inspecting and mounting N95s on spray rack until it is full.
- Randomly place one “Iodine Test Paper” chemical indicator (CI) strip on one clip of each row on rack.
- Thoroughly wipe empty bin with disinfecting wipes.

A. iHP Application Process

1. Activate “manual” mode on SteraMist Environmental Unit control panel. Assure Environmental Unit is adequately primed with BIT Solution (as indicted by CI strips). **[Note: per the**
manufacturer, use of the “Surface Unit” instead of the “Environment Unit” for BIT® solution application in accordance with this protocol will produce equivalent results].

2. Switch to “spray” mode.
3. Stand behind the red line in front of spray rack with applicator primed and ready.
4. Position the applicator gun nozzle over the red line (24” back from rack).
5. Aim applicator at first N95 on top row, **assure ~24” is maintained from N95s** at all times and that the applicator is positioned/aimed straight at the N95s.
6. Depress either applicator trigger button to activate sprayer and begin **slow constant sweep** across the row allowing ~1 second of spray contact per N95.
7. At the end of the row, spray back over the same row in the opposite direction using the same technique. This equals **one application cycle** for that row.
8. Repeat this process for each row of N95s on the rack as described above.
9. Repeat above double-pass application cycle process one more time for each row on the rack to achieve a total of **two total application cycles per row** or 4 single passes over each row.
10. Rotate the spray rack 180 degrees to expose the fronts of the N95 respirators.
11. Starting with the first N95 on the top row, complete **two application cycles** per row, or 4 total single passes per row as described in steps 5-9 above, until all N95s on the spray rack have been treated.
12. Note the color of the sentinel “Iodine Test Paper” CI on each row, verify dark purple color achieved per scale on the CI container (50-100ppm). If dark purple color not achieved, reapply one application cycle to the row and reassess CI color.
13. This completes the iHP application process for that batch.

Note: the N95s respirators will be damp/moist after processing. Clean gloves must be worn to handle them.

B. N95 Respirator Aeration/Drying

- Clean Receiver will receive the spray rack from the iHP Tech.
- Using clean gloves, the Clean Receiver will carefully remove each treated N95 from the rack and place in clean transport tote/container.
- Once container(s) are filled, the lid(s) will be sealed and containers placed in clean case cart for transport to high flow/negative pressure drying booth in LL BT.
- Upon arrival in the drying booth, don CAPR w/VOC activated charcoal filter and clean gloves. Activate the Drager H2O2 PPM monitor. [Note: OSHA safe limit is <1.0 ppm without PPE].
- Remove tote from clean case cart and hang N95s on drying line, carefully but securely clipping them to the line. **Avoid clipping to nose bridge area or on soft foam if present**. Utilize side wing structures to secure to line if present. (Note: off-gassing of residual H2O2 will continue until N95s are dry, appropriate PPE must be worn in Drying Booth. Monitor Drager detector for PPM).
- At least one hour of aeration drying time will be normally be required for each batch of N95s. Clean Receiver will monitor drying/off-gassing process with Drager H2O2 detector.
• Once completely dry and 0 ppm H2O2 emissions are noted, the N95s are ready for sorting/repackaging.

VII. Processed N95 Sorting/Repackaging for Return to HCP in Home Unit/Department

• Clean Receiver will collect N95s from drying line/rack, one owner at a time, and will place one blue tally mark with a blue Sharpie on the bottom of the respirator to visibly document the decontamination cycle.
• Visually inspect each N95 for obvious damage to mask itself or elastic straps. If noted, pull from reuse, discard and document on log.
• Deposit N95 for each owner in new white paper bag with their name and return location clearly marked on exterior of the white bag. Staple the bag shut. (Note: a white paper bag is used to allow any undetected residual moisture to evaporate following treatment and to visually distinguish it from unprocessed/contaminated N95s).
• Place white bags in “clean” case cart bin, sorted by unit/return location.
• Continue collecting reprocessed N95s in white bags labeled by owner and return location until all reprocessed/dry N95s are collected.
• Transfer “clean” bin to “clean” case cart.
• Complete required documentation in log: process finish time/date, number of N95s processed, other notes as required.
• Notify receiving unit(s) of pending delivery; notify transport “runner” to deliver reprocessed N95s to the appropriate unit/department.

VIII. Return Decontaminated N95 to HCP in Home Unit/Department:

• The Decontamination Unit will call the designated contact person provided on the log to notify them that their decontaminated N95s are ready for pickup.
• Designated unit/department staff courier dons gloves, brings clean cart/tote and retrieves decontaminated N95s from the Decontamination Unit’s designated clean pickup area. Staff courier logs their name and time of pickup on the Decontamination Unit log.
• Decontaminated N95s will be in a new, clean white paper bag displaying HCPs name and return location.
• The staff courier will drop off the processed N95s in the designated clean storage area in the unit/department and log the delivery time and number of N95s returned.
IX. HCP Reuse of Decontaminated N95s

- At the start of your next shift, the HCP will present to the clean storage area in the unit/department to pick up their decontaminated N95, assuring that their name is on the N95 contained within the new white paper bag before taking it. (Note: if the HCP is “float” staff, they should present to the clean pickup area of the unit that was documented on the original brown paper bag).

- The HCP will notice a tally mark in a different color (blue) that has been added to the front/bottom edge of their N95 respirator by a Decontamination Technician after it was processed. This is to track the number of times a particular N95 has gone through the decontamination process. **N95 respirators can be used up to seven times in total - the initial use when new, followed by up to six uses following the application of no more than six total decontamination cycles.**

- The HCP should inspect the N95 thoroughly prior to donning to assess for any obvious damage, failure of the elastic straps, etc. If damage is found, notify the unit/department supervisory staff before obtaining a new N95.

- The HCP dons the respirator per usual procedure ensuring the integrity of the respirator and proper fit. If proper fit cannot be verified, discard the respirator and obtain a new one.

- HCP uses the respirator following the institution-approved extended use guidelines.

- If the HCP finds that there is no decontaminated N95 available with their name on it, they will notify their unit/department supervisor. Situations that may result in no decontamination of N95s for a given HCW are:
  - The Decontamination Technician will inspect N95 respirators for residual lipstick/makeup contamination on the inside surfaces prior to processing them. If contamination is found, the N95 will be discarded, the unit/department leadership will be notified and a log entry will be made.
  - If obvious damage/defects are noted on any N95 submitted for decontamination, it will be discarded by the Decontamination Technician, the unit/department leadership will be notified and a log entry will be made.
  - A given N95 may have reached its maximum reuse cutoff identified for this technique.
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