

N95DECON

A scientific consortium for data-driven study of N95 filtering facepiece respirator decontamination

APIC and N95DECON suggested guidance for infection prevention and workflow for UV-C decontamination of N95 FFRs during COVID-19

Introduction and Background

In efforts to provide guidance on decontamination methods, the Association for Professionals in Infection Control and Epidemiology (APIC) has collaborated with researchers at <u>N95DECON</u>—a consortium of scientists, engineers, clinicians, and students that disseminate data-driven studies of N95 filtering facepiece respirator (FFR) decontamination—in the review of Ultraviolet-C (UV-C) decontamination methods. This guidance resource is the result of APIC Infection Preventionist members compiling best available practices for infection prevention and control in the decontamination of N95 respirators using UV-C during the COVID-19 pandemic.

Caveat for Reuse During the COVID-19 Crisis

Both APIC and N95DECON affirm that the guidance related to UV-C decontamination of N95 respirators and its accompanying infection prevention and control recommendations are to be implemented ONLY during severe disruption to the N95 respirator supply chain following global pandemics, natural disasters, or man-made disasters. Healthcare facilities with adequate supplies of N95 respirators should not utilize decontamination methods, but rather follow the CDC/NIOSH and manufacturer's instructions for use. We consider well-resourced and reduced-resource settings. In some reduced or low resourced settings, UV-C may not be feasible owing to insufficient N95 respirator supply, infrastructure (electrical), or other resources.

UV-C Germicidal Light Safety Considerations

All UV light sources are hazardous to human health (HHS, 2020). The germicidal component of the UV spectrum is required for effective N95 decontamination (UV-C at wavelengths near 260 nm); UV-A and UV-B are not suggested for N95 decontamination (Kowalski, 2009). Healthcare personnel (HCP) should don skin protection (gown/lab coat, long pants, closed-toe shoes, gloves) and eye protection (UV-C protective glasses, UV-C blocking face shield) before operating any UV-C equipment. After UV-C treatment, N95 respirators should continue to be treated as still **biohazardous** and potentially contaminated with SARS-CoV-2 and other pathogens. Appropriate infection control practices, PPE, and hand hygiene must be used to reduce the risk of fomite-mediated contact transmission.

Suggested Guidance

Designating a room for decontamination

Facilities may designate a room or enclosure to conduct N95 respirator UV-C decontamination that has the following required features:

- Reprocessing area should be large enough to accommodate a UV-C source, N95 respirator mounting system, UV-C detector(s), and any other equipment necessary for UV-C operation.
- Major surfaces in the reprocessing area should be reflective to UV-C. Walls and ceiling should be coated with UV-C reflective materials (e.g., UV-reflective paint, aluminum foil, Tyvek®) (Jelden et al., 2017).
- Reprocessing area should have a closing door through which HCP can safely pass the necessary equipment.
- Windows in the reprocessing area should be covered with UV-C-blocking material.
- Area around the reprocessing area should clearly display hazard signage to indicate (1) carcinogenic UV-C light is in use, (2) biohazards are present (i.e., virus), and (3) access is limited to authorized personnel only.

Whenever possible, two separate ante rooms or staging areas should be utilized for (1) drop-off of contaminated respirators and (2) pick-up of decontaminated respirators. To avoid cross-contamination, the same areas (i.e., surfaces, containers) should not be used to store both contaminated and decontaminated respirators, even if handling is not simultaneous. Avoid difficult-to-decontaminate enclosures or rooms (e.g., carpeting, fabrics).

<u>Considerations for low-resource settings</u>: Designate three (3) distinct spaces to function as: (1) drop-off area for contaminated respirators, (2) reprocessing area for UV-C decontamination of respirators, and (3) a pick-up area for decontaminated respirators. At minimum, these designated spaces or enclosures can be separated with a simple barrier. Ideally, utilize 3 separate enclosures, each large enough to provide adequate space to ensure HCP safety and to contain equipment.

Decontamination equipment and consumables

The following equipment and materials are suggested for UV-C decontamination of N95 respirators:

- **UV-C source:** System for generating UV-C germicidal wavelengths, validated with a UV-C specific sensor (see <u>Appendix: Guidelines for appropriate UV-C Sources</u> for technical details).
- **UV-C reflective surfaces:** Walls and ceiling should be covered with UV-C reflective materials (e.g., UV-reflective paint, aluminum foil, Tyvek®).
- UV-C-specific sensor: A sensor with peak detection response that matches the emission wavelength of the UV-C source (near 260 nm for high germicidal efficacy) should be used to validate that sufficient UV-C dose is applied to N95 respirators. (See <u>Appendix: UV-C measurement considerations</u> for more details.)
- **UV-C exposure field:** N95 respirator mounting system (e.g., heavy weight wire, utility, or metro cart) and/or N95 respirator mounting materials (e.g., clips), all composed of non-porous cleanable materials.
- **N95 respirator transport:** Paper bags, containers (e.g., to transport bags), decontamination wipes
- **N95 labeling:** Permanent markers (e.g., Sharpie®), not pens/pencils with sharp points (e.g., ballpoint)
- **PPE for HCP:** Face masks, gloves, hand hygiene products, UV-protective goggles, and faceshield. HCPs should don sufficient PPE to ensure no area of the body is exposed to UV-C light (i.e., gown/lab coat, closed-toe shoes, and long pants). Please see <u>PPE requirements</u> for more details.

Elastic straps on N95 respirators require chemical treatment for decontamination: The elastic straps on N95 respirators are not suitably decontaminated with exposure to UV-C (Heimbuch & Harnish, 2019; Mills et al., 2018). Each elastic strap should be decontaminated using a suitable alternate decontamination approach. To decontaminate the elastic straps, some US medical centers are wiping the straps with healthcare disinfectant wipes (e.g. PDI Super Sani-Cloth isopropanol-containing wipes) (Brickman et al., 2020). Use care to avoid 'erasing' any markings on the elastic strap during chemical decontamination.

Considerations for low-resource settings: Same recommendations as for higher-resourced settings.

Designated personnel engaged in UV-C reprocessing

Engaging with a multi-disciplinary team is advised for developing and implementing a respirator reprocessing program. Infection preventionists, environmental services, occupational health, nursing, respiratory therapy, building maintenance, and engineering personnel are recommended groups to be included in the program. Healthcare facilities might consider utilizing members of the sterile processing departments for implementation as many of these individuals have been trained on the fundamentals of device transport and infection control processes.

<u>Considerations for low-resource settings</u>: Same recommendations as for higher-resourced settings.

UV-C system training

Ensure all HCP and environmental services personnel that will be performing the decontamination process have completed training on basic infection prevention and control practices (see <u>APIC topic-specific</u> <u>infection prevention guides</u> for examples). All personnel that are responsible for operating UV-C sources must have adequate training on the technology or device instructions for use, safety features, and demonstrated competence. In addition, personnel should have completed the facility's education and training on the COVID-19 pandemic, SARS-CoV-2 transmission, and basic understanding of N95 respirators.

Considerations for low-resource settings: Same recommendations as for higher-resourced settings.

PPE requirements

Before and after UV-C decontamination, N95 respirators should be treated as **biohazardous** and potentially contaminated with SARS-CoV-2 or other pathogens. Appropriate infection control practices, PPE, and hand hygiene must be used to reduce the risk of contact transmission. All personnel operating, and proximal to, the UV-C decontamination process and/or reprocessing area should wear the following during transport and handling of the N95 respirators:

- A surgical/procedural mask
- Long pants and lab coat/gown that is laundered between each use
- Closed-toe shoes
- Gloves
- UV-C protective PPE, if entering, or proximal to, the reprocessing area (please double check the engineering controls of the UV-C source to assess risk of accidental illumination). In general, this involves skin and eye protection, including UV-blocking goggles, a UV-blocking face shield, and covering of any exposed skin.

In addition to donning sufficient PPE to reduce contact transmission of pathogens, full coverage of the HCP's eyes and skin is recommended, in case of unintentional UV-C source illumination (i.e., UV-C light is

unexpectedly activated). Hand hygiene must be performed after doffing any PPE after transport and handling of respirators.

<u>Considerations for low-resource settings</u>: Alternative PPE must be worn if the above is not available (such as a face covering in place of a surgical/procedural mask). Note that eye and skin protection is critical when working near, or with, UV-C equipment, as all UV light is carcinogenic, and thus, exposure to the eyes or skin is hazardous

N95 respirator labeling for return to, and reuse by, original HCP

Return of reprocessed N95 respirator to the original user is suggested in order to maintain fit and filtration function (as N95 respirators conform to the face of the first user), and because not all pathogens may be effectively inactivated by the UV-C treatment (Mills et al., 2018; FDA, 2020).

To ensure that N95 respirators are returned to the original user, label the N95 respirators prior to reprocessing. Ideally, each respirator should be labeled prior to first donning by HCP.

Minimal labeling of each N95 respirator includes:

- First and last name of HCP
- Number or mark to indicate reprocessing cycle number just completed.

For marking, use of a permanent marker is suggested (i.e., not ballpoint pens, pencil, or any other writing utensils that might risk damaging, or poking any holes in, the N95 respirator). Labeling on the front of the facepiece is performed in other protocols (Lowe et al., 2020). If labeling on the elastic strap, use care to avoid 'erasing' markings on the elastic strap during the separate chemical decontamination process. Any N95 respirators damaged during the labeling process should be discarded.

Alternate labeling approaches: To limit the risk of damage to the respirator facepiece and to avoid shadowing of the porous N95 respirator facepiece material by the marker ink, the <u>University of Chicago's</u> <u>UV-C decontamination protocol</u> uses index cards to label and track N95 respirators (Brickman et al., 2020). In another approach, labels are marked on the elastic strap in lieu of the facepiece.

<u>Considerations for low-resource settings</u>: While there may be few N95 respirators in use or available, use of the same labeling protocols is recommended.

N95 Reprocessing Cycle Limits

Before reprocessing respirators, please note the specific model and manufacturer of each respirator. Based on the peer-reviewed literature, UV-C decontamination has resulted in \geq 3-log reduction of viral activity in some, but not all, N95 respirator models with a dose of 1.0-1.2 J/cm² (Mills et al., 2018). The N95 material (e.g., molded cup- or dome-shaped N95s may have rigid, thicker material that transmits less UV-C) (Fisher and Shaffer, 2011) and respirator shape (e.g., 'flat-fold' or 'duck-bill' N95 models may be more challenging to configure such that all surfaces are exposed to the marginally-acceptable dose) may both impact decontamination efficacy (Mills et al., 2018). Respirators models that have not shown \geq 3 log reduction in viral activity upon UV-C decontamination in the peer-reviewed literature should not be subject to decontamination.

Studies report that several models of N95 respirators maintain fit and filter performance over 10-20 cycles of UV-C exposure at doses of 1.0 - 1.2 J/cm² (Heimbuch & Harnish, 2019). However, other peer-reviewed

studies state that each don and doff cycle can reduce respirator fit, with some models demonstrating unacceptable fit after 5 cycles (Bergman et al., 2012). As a result, we suggest N95 respirators be reprocessed no more than 5 times, unless noted by the manufacturer, or unless additional fit tests are performed on each HCP after each reprocessing cycle. When re-donning respirators after each decontamination cycle, a user seal check should be performed (CDC, 2020).

Considerations for low-resource settings: Same recommendations as for higher-resourced settings.

N95 Collection from HCPs

Maintaining a clear separation of clean and soiled areas is critical. Facilities may choose a designated soiled utility room (ideal) or other designated enclosure for soiled respirator drop off that is away from medication or food preparation areas.

Individual labeled N95 respirators should be placed in a breathable transport unit (e.g., a paper bag). Do not use sealed plastic bags (e.g., Ziplock^(R)) as moisture can build up and support microbial growth. Each bag should hold a single respirator. Take care not to compress bags or respirator.

In some protocols (e.g., <u>UNMC</u>), individual HCPs are handed paper bags for storage of their contaminated respirators, which they can drop off at the designated drop-off point. To prevent confusion between contaminated and decontaminated respirators, different colored paper bags (e.g., brown for contaminated, and white for the newly decontaminated respirator) are used (Lowe et al., 2020). Some medical centers (e.g., the <u>University of Chicago's UV-C decontamination protocol</u>) staple each brown bag shut after drop-off of the decontaminated respirator (Brickman et al., 2020). Upon return of the decontaminated respirator in a white paper bag, a clean brown paper bag is also included for the next round of respirator decontamination (Lowe et al., 2020).

Considerations for low-resource settings: Same recommendations as for higher-resourced settings.

Transport to reprocessing

Ensure that the paper bags containing contaminated N95 respirators are placed in a container labeled "dirty", which is covered with a lid during transport. Do not stack bags on top of each other in the container; however, they can be placed side-by-side (see **Figure 2** below). Inspect N95 respirators and discard, regardless of indicated cycles, if you observe:

- Cosmetics or visible soiling (i.e., color or staining),
- Holes or punctures,
- Broken or missing elastic straps or metal nosepieces,
- Marks that indicate the respirator has exceeded reprocessing limits (see <u>N95 Reprocessing Cycle</u> <u>Limits</u> section),
- No name on respirator.



Figure 1: Transport systems. *Staff courier drops off contaminated N95s in individual brown paper bags using the transport cart* (Lowe et al., 2020).



Figure 2: Handling of respirators in paper bags. *Left: new white paper bags for the decontaminated N95 respirators are prepared (labelled with the name of the respirator's original user), each containing a new brown paper bag to be used for the next round of decontamination. Right: One decontaminated N95 respirator is placed into a new prepared paper bag after UV-C treatment (Lowe et al., 2020).*

Considerations for low-resource settings: Same recommendations as for higher-resourced settings

Placement and positioning of respirators for UV-C decontamination

General placement considerations are reviewed here, followed by two examples of placement configurations: the *Side-Mounting Approach* and *Taut-Strap Approach*. Before and after UV-C treatment, N95 respirators should be treated as **biohazardous** and potentially contaminated with SARS-CoV-2 and other pathogens. Appropriate infection control practices, PPE, and hand hygiene must be used to reduce the risk of contact transmission. General placement considerations include:

- In the designated staging/drop-off area, remove paper bags containing contaminated respirators from the cart one at a time, and then remove each N95 respirator from its corresponding paper bag.
- Ensure respirators do not touch each other during any part of reprocessing.
- Again, conduct inspection of the contaminated respirator, discarding if any of the criteria outlined in the **Transport to Reprocessing** section are observed.
- Treat transport bags as contaminated, and discard each after use into the appropriate waste stream (e.g., biohazard).

- Using a mounting fixture (e.g., clip), affix the respirator to the N95 mounting system (e.g., heavy weight wire, utility, or metro cart), minimizing clipped area as much as possible (e.g., position clip on periphery of respirator). The clipped area will block UV-C light, and therefore, will not be 'treated' with UV-C.
- The elastic straps on N95 respirators are not suitably decontaminated with exposure to UV-C. Each elastic strap should be decontaminated using a suitable alternate decontamination approach. To decontaminate the elastic straps, some US medical centers are wiping the straps with healthcare disinfectant wipes (e.g. PDI Super Sani-Cloth isopropanol-containing wipes) prior to UV-C exposure. Disinfectant wipe compatibility with the elastic strap material of each treated N95 respirator model should be tested to ensure that straps remain functional after treatment.
- Delicately "bloom" respirator, exposing as much outer surface as possible while preserving structural integrity. Do not turn inside out. Avoid touching the interior of the respirator to prevent contamination.
- Gently position elastic straps so that dangling straps will not create shadows on the respirator during exposure to UV-C.
- The number of respirators processed during each cycle depends on the size and uniformity of the UV-C illumination field (assessed with UV-C-specific sensors as described in <u>Appendix: Guidelines</u> <u>for appropriate UV-C Sources</u>) and the capability to affix the respirators to the mounting system without creating shadows on the respirators or touching the respirators to each other.
- For either mounting approach, the respirators should be sufficiently spaced from all neighboring respirators to ensure no touching (cross-contamination) and no shadowing of neighbors (see Figure 3 and Figure 4).
- Perform hand hygiene or replace gloves immediately after handling contaminated N95s.

Note for UV-C sources that irradiate from one side of the N95 respirator exposure field: If the reprocessing system uses a single UV-C source (i.e., illuminating N95 respirators from one side only), then the respirators must be "flipped" to expose the shadowed side of the respirator to the UV-C source. A preferred approach is to 'flip' (move) the entire N95 mounting system (e.g., heavy weight wire, utility, or metro cart) versus flipping individual respirators, which requires additional handling of individual respirators, which increases chances for cross-contamination and decreases processing throughput.

While a wide range of approaches are used for arraying and mounting the N95 respirators in the UV-C Exposure Field, we overview two common versions here: the *Side-Mounting Approach* and *Taut Strap Approach*.

Version 1: Side-Mounting Approach

To set up:

- Delicately "bloom" the 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.
- Hang respirator with clip on the bottom or side of the respirator, minimizing clipped area as much as possible. Ensure the straps are hanging towards the inside of the respirator and not resting on the front of the respirator
- Ensure respirators do not touch each other during any part of reprocessing.



Figure 3: Side-Mounting Approach for N95 respirators. *Two models of N95 respirator hung by the bottom or side edge for room-scale decontamination. Right image depicts strap placement between nose and chin panels, along the inside of the respirator (Children's Health Dallas, 2020).*

Version 2: Taut Strap Approach

To set up:

- Delicately "bloom" the respirator, exposing as much outer surface as possible while preserving structural integrity. Do not turn inside out.
- Hang N95 respirator on the decontamination rack by its straps. N95 respirator configuration may depend on the model (see examples below), and similar respirators should be grouped together (but not touching) in the same decontamination cycle.









Figure 4: Taut-Strap Approach for N95 respirators. *Example configurations for hanging four models of N95 respirator using the taut-strap approach. Respirators are hung on a metal frame containing strap placement fixtures and wheels for rack transport* (Brickman et al., 2020).

<u>Considerations for low-resource settings</u>: Same recommendations as for higher-resourced settings. If the UV-C processing unit is small, take special care to place the N95 respirators to avoid touching each other. Arrange the elastic straps out so that they do not touch or cover any part of the respirator.

Decontamination cycle and duration

Ensure that UV-C source irradiance at the location of the UV-C exposure field has been measured using a NIST-traceable, calibrated UV-C sensor (see <u>Appendix: Guidelines for appropriate UV-C Sources</u> for technical details). Calculate and note the <u>minimum exposure time</u> required to achieve a dose ≥ 1.0 J/cm² on each N95 respirator, as informed by published studies of SARS-CoV-2 surrogates (Heimbuch & Harnish, 2019; Mills et al., 2018; Lore et al., 2012). Consider adding a safety factor to account for any errors or uncertainties in dose measurement/calculation. Once the N95 respirators are in the reprocessing area and mounted in the UV-C exposure field, proceed with the following:

- Remove all transport materials from the reprocessing area.
- Ensure all HCPs have enough time to safely exit the reprocessing area, closing all doors, prior to activating the UV-C light. Special timing considerations should be made if reprocessing areas require HCPs to enter the enclosure.

- Seal doors to reprocessing area per UV-C source manufacturer's instructions.
- Following the manufacturer's instructions, initiate the UV-C exposure cycle for the minimum exposure time required to achieve a dose ≥ 1.0 J/cm² on each N95 respirator.
- Doff PPE and perform hand hygiene.

Considerations for low-resource settings: Same recommendations as for higher-resourced settings.

Detach and remove respirators from UV-C decontamination mounting system

UV-C decontamination of N95 respirators yields decontaminated -- but not sterile -- respirators. As such, processed respirators should be handled with caution, and even treated as if still contaminated. Removal of each N95 respirator from the exposure system should be performed so as to not introduce cross-contamination risks. For example, respirators should not touch each other, as cross-contamination should be assumed possible, and the mounting fixtures should be decontaminated using a process suitable for the fixture material (e.g., non-porous plastic or metal clips).

Transfer each individual N95 respirator into an unused, uncontaminated paper bag. Prior to inserting the respirator into a clean paper bag, write the name of the HCP on the front of the bag. In addition, some protocols (e.g., <u>UNMC</u>) also include an additional paper bag for subsequent dropoff of a used respirator for future decontamination (Lowe et al., 2020).

<u>Considerations for low-resource settings</u>: Same recommendations as for higher-resourced settings.

Transport from reprocessing

Avoiding re- and cross-contamination of decontaminated N95 respirators is essential. Perform hand hygiene prior to moving paper bags to the clean transport container. Ensure that N95 respirators that have completed the reprocessing cycle are transported in uncontaminated container(s) labeled "clean", and covered while transported.

If a plastic bin was used to transport the contaminated N95 to the processing area, the bin must be decontaminated with the decontamination solution for appropriate contact time and allowed to air dry before the newly decontaminated N95 is placed in it for transport. Hand hygiene must be performed following reprocessing.

Considerations for low-resource settings: Same recommendations as for higher-resourced settings

Guidance references

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Appendix: Technical Considerations for Implementing UV-C Sources

All UV light is carcinogenic and hazardous to human health. HCPs working in proximity to the UV-C treatment system must wear skin protection (gown/lab coat, long pants, closed-toe shoes, gloves) and eye protection (UV-C protective glasses, UV-C blocking face shield) before operating any UV-C equipment. In addition, all PPE must also meet infection prevention standards, as outlined in the <u>PPE requirements</u> section of this document.

UV-C source considerations

As presented in detail by N95DECON, designers of UV-C decontamination systems are urged to consider:

- UV wavelength with germicidal capabilities: UV-C light is required, with high germicidal efficacy near 260 nm (EPA, 2006). UV-A and UV-B wavelengths are not suggested for N95 decontamination due to dramatically lower expected germicidal efficacy (Lytle & Sagripanti, 2005). Previously established protocols for UV-C decontamination have generally used low-pressure mercury low-ozone UV-C lamps (Lowe et al., 2020).
- UV-C dose level and uniformity: The UV-C source must have sufficient UV-C irradiance (mW/cm²) and uniformity over the treatment area to achieve a ≥ 1.0 J/cm² UV-C dose at all surfaces of exposed N95 respirators within the treatment period (Mills et al., 2018). All respirator surfaces must be exposed to the minimum (1 J/cm²) UV-C dose for the decontamination of viruses similar to SARS-CoV-2 to be effective. Use of two UV-C sources allows placement of the respirators in a plane of irradiation, with concurrent exposure of both the inside and the outside of the respirator to UV-C light, eliminating the need to 'flip' the respirators if only a single UV-C source is used (Lowe et al., 2020).

For additional details on critical technical considerations for UV-C sources, please see the N95DECON <u>UV-C Technical Report</u>.

UV-C measurement considerations

UV-C sources should be validated with a UV-C specific sensor, having a peak detection response that matches the emission wavelength of the UV-C source (near 260 nm for high germicidal efficacy; EPA, 2006). The sensor should be used to: (1) map the treatment area to identify locations with the lowest UV-C irradiance (mW/cm²) and (2) design and monitor the UV-C decontamination process to ensure that all areas of the treatment plane (including areas with the lowest UV-C irradiance) are dosed with UV-C \geq 1.0 J/cm² during each decontamination cycle. Ideally, the UV-C sensor should be calibrated by a national measurement laboratory (e.g., NIST) (Bolton & Linden, 2003; ASTM G130-12).

UV-C sources used in existing protocols

While not recommending specific models or vendors for UV-C assisted decontamination, information on existing, publicly available protocols may be useful:

- University of Nebraska Medical Center: <u>UV-C N95 Decontamination Protocol</u> which uses a <u>ClorDiSys</u> <u>Torch System</u>
- University of Chicago Medical Center: <u>UV-C N95 Decontamination Protocol</u> which uses a <u>Surfacide</u> <u>Helios</u>

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