

New Mexico Medical Advisory Team (MAT) Assessment

MAT Workgroup Name: Clinical Workgroup

Date: May 15, 2020

Question or Request: The COVID-19 pandemic requires wearing of isolation gowns, examination gloves, goggles/face shields, and procedural/surgical masks (face masks) or N95 respirators. Face masks, face shields, and N95 respirators are the most vital elements of this PPE ensemble as transmission of the SARS-CoV-2 virus occurs primarily by droplets. Studies have confirmed the acceptability of multiple methods for reprocessing of disposable N95 respirators which can be reasonably expanded to include face masks and face shields. The PPE Subgroup recommends the Governor to issue the following directive:

- **The most reliable and safest reprocessing methods of reprocessing PPE are vaporized hydrogen peroxide (VHP) and Ultraviolet (UV) radiation.**
- **New Mexico Hospitals and Healthcare Facilities/Services should seek to utilize these methods for reprocessing and extending the useful life of their disposable PPE.**

Recommendation/s in bullet form:

- Multi-user reprocessed PPE items should be retained as reserve supplies for use if/when supplies of new/unused PPE items become completely unavailable. Once put into use, specified limits of reprocessing cycles to ensure integrity of the items should be observed.
- Single-user reuse reprocessed PPE items may be used on demand within the specified limits of reprocessing cycles to ensure integrity of the items
- Collection and reprocessing of face masks, face shields, and disposable N95 respirators with large batch VHP or UV should commence as soon as possible to preserve vital PPE supplies.
- All methods of conservation for new PPE items during initial use should be maximized to extend the service life of these items in accordance with Centers for Disease Control and Prevention (CDC) and National Institutes of Occupational Safety and Health (NIOSH) guidance.

Reprocessing Options

Strong Evidence with FDA Emergency Use Authorization

Food and Drug Administration Emergency Use Authorization (FDA EUA) has been granted to the Battelle Critical Care Decontamination System (CCDS - <https://www.battelle.org/inb/battelle-critical-care-decontamination-system-for-covid19>) for disinfection of disposable N95 respirators. CCDS uses VHP in a portable shipping container configuration that the New Mexico National Guard has procured for use beginning May 1, 2020 in Rio Rancho, NM at the Santa Ana Star Center. The VHP system is an automated pressurized canister system that creates the vapor by pushing liquid hydrogen peroxide through a nozzle. The vapor then circulates into all spaces of the room. The racked items in the room are exposed to the vapor in two ways: 1) the vapor contacts surfaces of the items and the hydrogen peroxide in the vapor acts on the biologic contaminants to destroy them, and 2) the vapor penetrates porous materials also destroying any biologic contaminants that may have penetrated the material. Essentially, wherever air can go, VHP can go. Items must be bagged and shipped (details in the web link) for reprocessing and then are returned to the sender. The number of cycles an item can be reprocessed is limited to 20, the maximum number of items per cycle is 20,000, and reprocessed items are designated for multi-user reuse.

STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems Non-Lumen Cycle has been granted FDA EUA for small batch VHP processing of disposable N95 respirators and serves as another acceptable alternative for hospitals generating less volume for reprocessing and already having one or more of these devices. The number of cycles is limited to 10 (ten), the maximum number of items per cycle is 10 (ten) items (in sterilization pouches), and reprocessed items are intended for single-user reuse.

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FDA EUA has been granted to STERRAD using the 100S, NX, and 100NX models for small batch VHP processing of disposable N95 respirators and serves as an acceptable alternative for hospitals generating less volume for reprocessing and already having one or more of these devices. The number of cycles is limited to 2 (two), the maximum number of items per cycle is 10 items (in sterilization pouches), and reprocessed items are intended for single-user reuse.

FDA EUA has been granted to Strkyer Instruments using the STERIZONE VP4 Sterilizer for small batch VHP processing of disposable N95 respirators and serves as another acceptable alternative for hospitals generating less volume for reprocessing and already having one or more of these devices. The number of cycles is limited to 2 (two), the maximum number of items per cycle is 20 (twenty) items (in sterilization pouches), and reprocessed items are intended for single-user reuse.

FDA EUA has been granted to Sterilucet Sterilization System Flexible Cycle for small batch VHP processing of disposable N95 respirators and serves as another acceptable alternative for hospitals generating less volume for reprocessing and already having one or more of these devices. The number of cycles is limited to 10 (ten), the maximum number of items per cycle is 12 (twelve) items (in sterilization pouches), and reprocessed items are intended for single-user reuse.

Strong Evidence *without* FDA Emergency Use Authorization

Large batch VHP disinfection of PPE items can be performed using commercial medical-grade hospital room disinfection VHP systems following the manufacturer's instructions for use and by placing items on wire racks in a room with the VHP system. This process is primarily performed in hospitals already using VHP technology for room disinfection. Though specific products do not have FDA EUA, CDC and scientific literature do validate its use. The Bioquelle system utilized by the Battelle CCDS would be expected to perform similarly in a hospital setting. The number of cycles is limited to 20, the number of items per cycle is limited only by available space (run time may require adjustment for materials in the operating space for each run), and reprocessed items may be worn by a different user from the original user (called multi-user reuse).

Ultraviolet disinfection of PPE items is performed similarly to large batch VHP methods except that items must be suspended (hanging) vertically from the wire racks. The UV system is operated per its manufacturer's instructions for use, aligning the UV exposure with the PPE items to maximize surface exposure of the items to the UV source. Since UV only disinfects what it is directly exposed to (called "line of sight"), parts that are not directly exposed are not disinfected (called "shadowing"). To ensure complete disinfection of the PPE items inside and out, the UV system is operated at least 3 times with rotation of the racks approx. 120 degrees (1/3 of a complete rotation) each time. By doing this, all surfaces of the PPE items will be exposed to UV and each item will be entirely disinfected. This process can be performed at each hospital possessing UV room disinfection technology. The number of cycles is limited to 20, the maximum number of items per cycle is based on avoidance of line of sight overlap, and reprocessed items are intended for single-user reuse.

Weak Evidence

Ultraviolet reprocessing of disposable N95 respirators can also be performed using table top UV disinfection devices. These devices allow in-the-moment reprocessing after extended use of these items with the added value of item retention by the original user. Items are disinfected with these devices following the user instructions while on the nursing unit: items are placed within the device (up to 6 items per run), the device is operated per instructions, then the items may be removed by their users and worn again while adhering to conservation guidance for the item(s). Presbyterian Healthcare Services is procuring such devices for strategic placement on hospital nursing units providing care to COVID-19 patients and PUIs.

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Moist Heat consisting of 60 deg Celsius and 80% relative humidity caused minimal degradation in the filtration and fit performance of tested disposable N95 respirators, however studies have not confirmed the disinfection efficacy.

Dry Heat (70 deg Celsius x 30 minute) appears in pre-print medical research citations and is typically accepted as effective at disinfecting. The remaining concern is degradation of the item from heat exposure. These pre-print citations suggest that 2-3 cycles of disinfection with dry heat may be acceptable, however these results have not been thoroughly validated by peer review.

Avoid/Not Recommended for Use

Other modalities in the evidence base that are not endorsed by CDC or granted EUA by the FDA include:

- Autoclave – substantial filter degradation
- Dry Heat (160 deg Celsius) – substantial filter degradation
- Isopropyl Alcohol – substantial filter degradation
- Soap – substantial filter degradation
- Dry Microwave Irradiation – substantial filter degradation

Bleach – filter performance remained intact but residual odor and chlorine off-gassing were significant and could pose risk to the user.

Disinfectant Wipes – performance was variable depending on active ingredient and type of respirator.

Ethylene Oxide (EtO) – performance remained intact with no visible degradation of respirators, however a residual chemical that does not completely off-gas poses a carcinogenic and teratogenic risk to the user. Additionally, cycle times are extensive to allow for sufficient off-gassing.

Assessment:

Studies have confirmed the acceptability of multiple methods for reprocessing of disposable N95 respirators which can be reasonably expanded to include face masks and face shields. The most reliable and safest reprocessing methods are vaporized hydrogen peroxide (VHP) based. These methods are currently in use at multiple New Mexico hospitals for disinfection of infectious disease patient rooms after discharge. These same devices for VHP disinfection may be employed without modification to disinfect N95 respirators on large scales.

The University of Nebraska has widely shared their protocol for single-user reuse UV disinfection of N95 respirators. Duke Health recently completed a study confirming the durability of materials and continued fit of disposable N95 respirators following 20 cycles of VHP reprocessing. Battelle Memorial Institute was recently granted Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for VHP reprocessing of disposable N95 respirators on a scale of up to 20,000 items per run in a portable system.

Large batch VHP is the more efficient and equally effective reprocessing method since it does not require multiple runs to accomplish complete disinfection and can process large quantities in a single run. Ultraviolet is an acceptable alternative or back-up process to VHP, though cannot typically accommodate as many items per run.

Hospitals and Healthcare facilities will need to develop a standard process with written guidance on collection, transport, inspection, racking, VHP or UV application, un-racking, re-inspection, and packaging PPE items, along with user instructions for the table top UV devices.

Studies have not been performed on reprocessing of disposable face masks (procedural/surgical) or disposable face shields and goggles. Experience with VHP suggests acceptability of including these two additional types of PPE as crisis standards of care should new/unused items become completely unavailable. The lack of studies to validate both fit and function of these two additional types of PPE must be emphasized and use of these reprocessed items should

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include a monitoring program, at least initially, to ensure workforce safety. These items should still be collected for later reprocessing or for contemporaneous reprocessing and storage as a reserve supply so that opportunity to retain them is not lost should data on effectiveness for these items become available during the COVID-19 pandemic.

Red flags and concerns:

- Reprocessing (as well as extended use and reuse) may cause degradation of materials; therefore, each reprocessed PPE item should be inspected for soiling and/or damage and checked for Fit prior to each use.
- Lack of confirmatory studies/data on reprocessing of face masks and face shields/goggles.
- The Duke Health methodology tested with *Geobacillus stearothermophilus* spores and their fit testing was performed on "two individuals with differing facial structures". These recommendations extrapolate data from related (but not specific) methodologies. Their study did not test on multiple individuals in real life situations nor were they tested with SARS-CoV-2. Similarly, the much discussed FDA document on UVGI (https://www.ara.com/sites/default/files/MitigateShortageofRespiratoryProtectionDevices_3.pdf) looked at "fit factor" with influenza, MERS and SARS (not SARS-CoV-2), and they used a "dummy" to look at "fit", not real people.
- Reusable P100 respirators are not disposable items and are not included in this guidance. The use of reusable P100 respirators does reduce the consumption of disposable N95 respirators so that available supplies of these items will last longer.

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Level of Consensus: Total

Resources/Reference:

- Centers for Disease Control and Prevention (CDC): <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>
- Centers for Disease Control and Prevention (CDC) and National Institutes of Occupational Safety and Health (NIOSH) guidance: <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>
- University of Nebraska UV Protocol: <https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf>
- Duke Health Reprocessing Study: https://absa.org/wp-content/uploads/2020/04/APB_919932.pdf
- Battelle Memorial Institute FDA EUA: <https://www.fda.gov/media/136529/download>