

# Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators

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## ABSTRACT

Disposable N95 filtering facepiece respirators (FFRs) certified by the National Institute for Occupational Safety and Health (NIOSH) are widely used by healthcare workers to reduce exposures to infectious biological aerosols. There is currently major concern among public health officials about a possible shortage of N95 FFRs during an influenza pandemic. Decontamination and reuse of FFRs is a possible strategy for extending FFR supplies in an emergency; however, the NIOSH respirator certification process does not currently include provisions for decontamination and reuse. Recent studies have investigated the laboratory performance (filter aerosol penetration and filter airflow resistance) and physical integrity of FFRs following one-cycle (1X) processing of various decontamination treatments. The studies found that a single application of some methods did not adversely affect laboratory performance. In the event that healthcare facilities experience dramatic shortages of FFR supplies, multiple decontamination processing may become necessary. This study investigates three-cycle (3X) processing of eight different methods: ultraviolet germicidal irradiation, ethylene oxide, hydrogen peroxide gas plasma, hydrogen peroxide vapor, microwave-oven-generated steam, bleach, liquid

hydrogen peroxide, and moist heat incubation (pasteurization). A four-hour 3X submersion of FFR in deionized water was performed for comparison (control). Following 3X treatment by each decontamination and control method, FFRs were evaluated for changes in physical appearance, odor, and laboratory filtration performance. Only the hydrogen peroxide gas plasma treatment resulted in mean penetration levels > 5% for four of the six FFR models; FFRs treated by the seven other methods and the control samples had expected levels of filter aerosol penetration (< 5%) and filter airflow resistance. Physical damage varied by treatment method. Further research is still needed before any specific decontamination methods can be recommended.

## INTRODUCTION

Properly fitting N95 filtering facepiece respirators (FFRs) certified by the National Institute for Occupational Safety and Health (NIOSH) are recommended for healthcare workers to reduce inhalation exposures to infectious aerosols, including 2009 influenza A (H1N1) virus<sup>1-3</sup>. The current global influenza pandemic of 2009 H1N1 heightens concern for effective respiratory protection for healthcare workers. N95 FFRs are certified by NIOSH regulations to have a minimum

filtration efficiency of  $\geq 95\%$  (or  $\leq 5\%$  penetration) against a polydisperse sodium chloride aerosol challenge<sup>4</sup>. The ability of these disposable devices to filter bioaerosols has been addressed in the literature<sup>5-10</sup>.

Shortages of FFRs during an influenza pandemic are likely due to an increase in global demand. The Institute of Medicine reports that a 42-day influenza pandemic outbreak may require over 90 million N95 FFRs to protect workers in the healthcare industry<sup>11</sup>. FFR stockpiling serves as a viable contingency plan<sup>12</sup>, but stockpiles are designed to alleviate a minor shortage and a severe pandemic would be likely to quickly exhaust stockpiled FFRs. Decontamination and reuse of FFRs may provide another solution by extending existing on-hand supplies. In general, NIOSH guidance states that FFR service life is limited by considerations of hygiene, physical damage, and excessive breathing resistance<sup>13</sup>. Currently, decontamination of disposable FFRs for purposes of reuse is not recommended, primarily because of concerns that decontamination would degrade the performance of the respirator. Additionally, NIOSH respirator certification does not currently include provisions for FFR decontamination and reuse. The Institute of Medicine suggested that simple decontamination techniques (e.g., bleach, microwave radiation, or ultraviolet light) should be researched in an effort to extend the service life of FFRs in the event of an influenza pandemic<sup>11</sup>.

Preliminary work on the decontamination of N95 FFRs has been published in recent years<sup>14-18</sup>. Some of this research has focused on whether commonly available decontamination methods were effective at rendering trapped viruses inactive, while other studies have investigated the effects of those decontamination methods on respirator performance. For example, Fisher et al. found that a sodium hypochlorite (bleach) concentration of 0.6% and microwave-oven-generated steam treatments of 45 sec and longer resulted in significant reductions ( $>4$  logs) of viable MS2 virus on FFR coupons<sup>16</sup>. Vo reported that sodium hypochlorite doses  $\geq 8.25$  mg/L for 10 min and UV irradiation dose  $\geq 7.20$  J/cm<sup>2</sup> (UV intensity = 0.4 mW/cm<sup>2</sup> and contact times  $\geq 5$  hr) deactivated all MS2 virus applied as droplets to whole, intact FFRs<sup>18</sup>. Viscusi et al.<sup>15</sup> evaluated laboratory performance (filtration efficiency and airflow resistance) of six N95 FFR models and three different P100 models following one-cycle (hereafter referred to as "1X") processing by five

different decontamination methods: ultraviolet germicidal irradiation (UVGI), ethylene oxide (EtO), hydrogen peroxide gas plasma (HPGP), microwave oven irradiation (dry method, without water to generate steam), and bleach. In that study, the dry microwave treatment caused melting of one N95 model and one P100 model, but did not negatively affect the laboratory performance of the other seven respirator models. Additionally, that study assessed potential health risks to the wearer and potential concerns for timely decontamination processing of large volumes of FFRs by hospitals. The other four decontamination methods did not affect laboratory performance for any of the nine investigated respirator models. The research described above focusing on 1X processing suggests that a single application of some decontamination methods followed by reuse may be possible. However, situations may arise that call for more than one decontamination and subsequent respirator use to further extend supplies.

The primary concern with multiple decontaminations is that it would be more likely than just a single decontamination to degrade the performance of the FFR. One of the most sensitive components of the FFR is the filter medium. In 1995, when 42 CFR 84 replaced 30 CFR 11 as the certification regulation for all non-powered, air-purifying particulate filter respirators, respirator manufacturers began to incorporate electrostatically enhanced filter media into their products as opposed to the older mechanical-type filtration media<sup>4</sup>. Electrostatic (or electret) filters collect particles by mechanical (nonelectrostatic) mechanisms, but also utilize a static charge on the filter fibers to enhance filtration without significantly increasing the filter's airflow resistance<sup>19-21</sup>. Although the filtering efficiency of stored electrostatic filters remains very stable for years<sup>12</sup>, their performance can decrease upon exposure to industrial aerosols, chemicals, and temperature<sup>22-25</sup>. For example, in a study of multiple intermittent aerosol exposure, N95 FFR filtration efficiency was reduced to levels  $< 95\%$  by intermittent loadings of 5 mg sodium chloride aerosol, one day a week over a period of several weeks<sup>20</sup>. Thus, an evaluation of the effects of multiple processing on FFRs is prudent given that it may become a necessity in the event of a dramatic FFR supply shortage and that multiple processing is likely to be more aggressive than a single treatment in terms of degrading filtration efficiency and/or causing physical damage.

In this study, three-cycle processing (hereafter termed “3X”) of eight decontamination methods on six FFR models was performed. It was hypothesized that filtration performance, physical integrity, and filter airflow resistance of FFRs after 3X decontamination would be similar to those from control FFRs and FFRs after 1X decontamination (e.g.,  $\leq 5\%$  filter penetration).

## EXPERIMENTAL DESIGN

To be consistent with previous research conducted in our laboratories, the same six N95 respirator models used by Viscusi et al.<sup>15</sup> in their evaluation of five decontamination methods were used in this study. The six models [three N95 FFR models (N95-A, N95-B, and N95-C) and three surgical N95 respirator models (SN95-D, SN95-E, and SN95-F)] also constitute a random sampling from N95 FFR models present in the U.S. Strategic National Stockpile. Surgical N95 respirators are NIOSH-approved N95 respirators that have also been cleared by the U.S. Food and Drug Administration (FDA) for use in the healthcare setting<sup>26</sup>. All respirators were purchased and verified to be from the same respective manufacturing lot at the beginning of the study to minimize any lot-to-lot variation as well as to ensure consistency during FFR filtration performance testing. FFRs used in this study consisted of electrostatically charged polypropylene filters (electret filter media).

Currently no standardized methods exist for the biological decontamination of contaminated FFRs. All of the methods selected for this study are likely to render some viruses and other biological organisms inactive under these conditions, but it is still necessary to demonstrate effectiveness for contaminated FFRs. The experimental conditions and parameters for the eight decontamination methods are summarized in *Table 1*. All FFRs were removed from their original packaging for testing. For a control set, three samples of each FFR model were submerged for four hours in deionized water, hung on a laboratory peg board and dried for a minimum of 16 hr with the aid of a fan before the treatment was repeated; three cycles of water submersion and drying were performed to be consistent with the three treatment cycles which were performed for the decontaminated FFR. The eight decontamination methods selected for this study include four methods (UVGI, EtO, HPGP, and bleach) which were evaluated in the previous study<sup>15</sup>, plus four new promising low-temperature decontamination methods: liquid hydrogen

peroxide (LHP)<sup>14</sup>, microwave-generated steam (MGS)<sup>16</sup>, moist heat incubation (pasteurization) (MHI), and hydrogen peroxide vapor (HPV)<sup>27</sup>. The moist heat conditions were based in part on previous research that found that 80°C dry heat exposures did not affect respirator performance<sup>14,15</sup>.

All laboratory experiments were conducted under standard laboratory conditions ( $21 \pm 2^\circ\text{C}$  and relative humidity of  $50 \pm 10\%$ ) on triplicate sets of FFRs for the controls and UVGI, MGS, bleach, LHP, and MHI treatments. The EtO and HPGP treatments were performed off site at a university medical center on three consecutive days. The HPV treatments were performed by BIOQUELL (UK), Ltd. at one of their facilities. The EtO, HPGP, and HPV methods each evaluated a set of six FFR samples.

Following treatment, the decontaminated and control FFRs were evaluated for changes in physical appearance, odor, and laboratory performance (filter aerosol penetration and filter airflow resistance). A Model 8130 Automated Filter Tester (AFT) (TSI, Inc., St Paul, MN, USA) was used to measure initial percent filter aerosol penetration (%P) and filter airflow resistance (pressure drop in mm H<sub>2</sub>O column height pressure) for all post-decontamination and control FFR samples. The TSI 8130 AFT delivers a solid polydisperse sodium chloride (NaCl) aerosol that meets the particle size distribution criteria set forth in 42 CFR 84 Subpart K, Section 84.181 for NIOSH certification<sup>4</sup>. The NaCl aerosol has a count median diameter (CMD) of  $0.075 \pm 0.020 \mu\text{m}$  and a geometric standard deviation (GSD) of less than 1.86. The mass median aerodynamic diameter (MMAD) of this aerosol is approximately 300 nm. All tests were conducted with a continuous airflow of  $85 \pm 4 \text{ L/min}$  and in a similar manner to be consistent with previous studies<sup>12,14,15,28</sup>.

## RESULTS AND DISCUSSION

For each FFR model/decontamination treatment combination and controls, the mean and standard deviation of initial filter aerosol penetrations (%P) and the mean and standard deviation of the initial filter airflow resistances are summarized in *Table 2*. All control and decontamination treatment groups, with the exception of 3X HPGP, had mean  $\%P \leq 4.01\%$ , which is similar to penetration levels found in untreated and 1X treated respirators from previous studies<sup>14,15</sup>. For example, %P for the untreated FFRs from the same six models used

TABLE I. FFR Treatments

| Treatment                                    | Experimental Conditions and Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ultraviolet germicidal irradiation (UVGI)    | UV Bench Lamp (UV-C, 254 nm, 40 W), Model XX-40S (UVP, LLC, Upland, CA). 45-min exposure at intensity 1.8 mW/cm <sup>2</sup> (note: one 45-min continuous exposure constitutes the 3X cycle). Test tube racks were placed beneath both ends of the lamp to lift the lamp ~ 25 cm from the working surface of a laboratory hood. The UV intensity was reported as the mean of 27 measurements over the rectangular area used at the surface of the hood using a UVX Digital Radiometer with a model UVX-25 Sensor (254 nm filter) (UVP, LLC, Upland, CA). Only the exteriors of the FFRs were exposed. The duck bill and flat fold style FFRs were placed over beakers to facilitate exposure to the FFR surface.                                                                                                                                                                                                                                                                                                                                                                                                          |
| Ethylene oxide (EtO)                         | Amsco® Eagle® 3017 100% EtO Sterilizer/Aerator (STERIS Corp., Mentor, OH) on HI-TEMP setting (55°C); 1-hr EtO exposure (736.4 mg/L) followed by 12-hr aeration. Samples were packaged in Steris Vis-U-All Low Temperature Tyvek®/polypropylene-polyethylene Heat Seal Sterilization pouches (six samples per pouch with a chemical indicator strip). All samples were physically accommodated by a single EtO cycle. Samples were processed at a university medical center (one treatment per day in three consecutive days). The same pouch was used for all three treatments.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Hydrogen peroxide gas plasma (HPGP)          | STERRAD® 100S H <sub>2</sub> O <sub>2</sub> Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA), 59% H <sub>2</sub> O <sub>2</sub> , cycle time ~55-min (short cycle); 45°C–50°C. Samples were packaged in Steris Vis-U-All Low Temperature Tyvek®/polypropylene-polyethylene Heat Seal Sterilization pouches (six samples per pouch with a chemical indicator strip). Samples were processed at a university medical center (one treatment per day in three consecutive days). The same pouch was used for all three treatments.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Hydrogen Peroxide Vapor (HPV)                | Room Bio-Decontamination Service (RBDS™, BIOQUELL UK Ltd, Andover, UK), which utilizes four portable modules: the Clarus® R HPV generator (utilizing 30% H <sub>2</sub> O <sub>2</sub> ), the Clarus R20 aeration unit, an instrumentation module and a control computer. The Clarus® R was placed in a room (64 m <sup>3</sup> ). The HPV concentration, temperature and relative humidity within the room were measured by the instrumentation module and monitored by a control computer situated outside the room. Room concentration= 8 g/m <sup>3</sup> , 15- min dwell, 125-min total cycle time. FFRs were hung on a string stretching across the length of room. Following HPV exposure, the Clarus R20 aeration unit was run overnight inside the room to catalytically convert the HPV into oxygen and water vapor. The treatments were performed in three consecutive days (one treatment per day). Biological indicators containing <i>Geobacillus stearothermophilus</i> spores were placed in five separate locations inside the room and a 6-log spore reduction was measured following the 3X treatment. |
| Microwave oven generated steam (MGS)         | Commercially available 2,450-MHz, Sharp Model R-305KS (Sharp Electronics, Mahwah, NJ) microwave oven with revolving glass carousel, 1,100 W (manufacturer rated); 750 W/ft <sup>3</sup> experimentally measured; 2-min total exposure duration at a power setting of 10 (maximum power). Two pipette tip boxes placed side-by-side (each 11.7 cm x 8.0 cm x 5.0 cm) filled with 50 mL room-temperature tap water (~ 20°C). FFR is placed outer-side down on top of pipette-tip boxes. FFR samples dried 1 hr between each exposure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Bleach*                                      | 30-min submersion in 0.6% (one part bleach to nine parts of deionized water) solution of sodium hypochlorite (original concentration = 6% available as Cl <sub>2</sub> ). Manufacturing specification: 6.00 ± 0.06% (w/w) available chlorine; Cat No. 7495.7-1, CAS No. 7732-18-5 (Ricca Chemical Company, Pequannock, NJ).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Liquid hydrogen peroxide* (LHP)              | 30-min submersion in 6% (one part hydrogen peroxide to four parts of deionized water) solution of hydrogen peroxide. Manufacturing specification: 30% hydrogen peroxide; Cat No. H325-500, CAS Nos. 7722-84-1, 7732-18-5, 12058-66-1 (Fisher Scientific, Fair Lawn, NJ).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Moist heat incubation / pasteurization (MHI) | 30-min incubation at 60°C, 80% RH in a Caron model 6010 laboratory incubator (Marietta, OH). Following the first incubation, the samples were removed from the incubator and air-dried overnight. Following the second and third incubations, samples were removed from the incubator and air-dried for 30 min with the aid of a fan.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

\*Liquid submersion methods. Following each exposure, FFRs were hung on a laboratory peg board and dried for a minimum of 16 hours with the aid of a fan before repeating the treatment or performing the laboratory aerosol filtration test.

in the study ranged from 0.335% (SN95-E) to 1.57% (SN95-D)<sup>15</sup>. In this study, the 3X HPGP treatments resulted in mean penetration levels > 5% for four of the six FFR models. For bleach, the 3X treated samples of model SN95-D showed a much larger mean %P (4.01%) compared to 1X bleach-treated samples tested previously [%P (n=3) for 1X = 0.561] for the same model<sup>15</sup>. The 3X and 1X bleach treatment mean %P values were similar for the other five models. The UVGI and EtO treatments had similar mean %P to 1X treated samples tested previously for the same six models<sup>15</sup>. As expected, the control FFRs had expected levels of filtration efficiency (all models had mean %P ≤ 2.12), implying that high humidity conditions (as demonstrated by complete submersion in deionized water) should have little or no effect on filtration efficiency of FFRs utilizing electrostatic media.

TABLE II. Filter Aerosol Penetration (%P) and Filter Airflow Resistance (mm H<sub>2</sub>O) for 3X Decontaminated and Control FFRs<sup>†</sup>

| FFR Model              | Treatment | Mean Initial Sodium Chloride Penetration (%P) | Mean Initial Resistance (mm H <sub>2</sub> O) |
|------------------------|-----------|-----------------------------------------------|-----------------------------------------------|
| <b>N95 Respirators</b> |           |                                               |                                               |
| N95-A                  | Control   | 0.62 ± 0.19                                   | 8.1 ± 0.3                                     |
|                        | UVGI      | 0.41 ± 0.24                                   | 7.9 ± 0.2                                     |
|                        | EtO       | 0.34 ± 0.03                                   | 8.0 ± 0.1                                     |
|                        | HPGP      | 1.71 ± 1.04                                   | 7.7 ± 0.3                                     |
|                        | HPV       | 0.50 ± 0.07                                   | 7.5 ± 0.2                                     |
|                        | MGS       | 0.08 ± 0.03                                   | 9.5 ± 1.0                                     |
|                        | Bleach    | 0.63 ± 0.12                                   | 6.9 ± 0.1                                     |
|                        | LHP       | 0.49 ± 0.02                                   | 6.2 ± 1.6                                     |
|                        | MHI       | 0.43 ± 0.37                                   | 7.5 ± 0.1                                     |
| N95-B                  | Control   | 0.88 ± 0.12                                   | 10.5 ± 0.4                                    |
|                        | UVGI      | 1.24 ± 0.22                                   | 10.3 ± 0.3                                    |
|                        | EtO       | 0.96 ± 0.13                                   | 12.0 ± 0.4                                    |
|                        | HPGP      | <b>7.30 ± 10.68</b>                           | 10.9 ± 0.2                                    |
|                        | HPV       | 0.82 ± 0.16                                   | 11.4 ± 0.7                                    |
|                        | MGS       | 1.33 ± 0.24                                   | 9.9 ± 0.3                                     |
|                        | Bleach    | 1.07 ± 0.22                                   | 10.6 ± 0.5                                    |
|                        | LHP       | 1.50 ± 0.80                                   | 11.0 ± 0.5                                    |
|                        | MHI       | 0.70 ± 0.07                                   | 9.9 ± 0.1                                     |
| N95-C                  | Control   | 2.05 ± 0.33                                   | 10.5 ± 0.0                                    |

|                                 |         |                    |            |
|---------------------------------|---------|--------------------|------------|
|                                 | UVGI    | 1.26 ± 0.25        | 11.1 ± 0.5 |
|                                 | EtO     | 1.29 ± 0.40        | 11.9 ± 0.5 |
|                                 | HPGP    | <b>4.64 ± 3.09</b> | 11.5 ± 0.8 |
|                                 | HPV     | 1.18 ± 0.20        | 11.8 ± 0.5 |
|                                 | MGS     | 1.25 ± 0.31        | 11.1 ± 0.6 |
|                                 | Bleach  | 1.38 ± 0.23        | 11.4 ± 0.3 |
|                                 | LHP     | 1.52 ± 0.38        | 11.0 ± 0.6 |
|                                 | MHI     | 0.90 ± 0.29        | 10.7 ± 0.2 |
| <b>Surgical N95 Respirators</b> |         |                    |            |
| SN95-D                          | Control | 2.12 ± 0.41        | 16.8 ± 0.8 |
|                                 | UVGI    | 1.59 ± 0.27        | 17.6 ± 1.4 |
|                                 | EtO     | 2.55 ± 0.72        | 16.9 ± 0.6 |
|                                 | HPGP    | <b>6.04 ± 5.14</b> | 14.4 ± 0.2 |
|                                 | HPV     | 2.35 ± 0.22        | 16.4 ± 0.6 |
|                                 | MGS     | 2.14 ± 0.22        | 14.4 ± 0.4 |
|                                 | Bleach  | 4.01 ± 0.47        | 12.1 ± 1.0 |
|                                 | LHP     | 3.35 ± 1.26        | 11.7 ± 0.1 |
|                                 | MHI     | 2.16 ± 0.10        | 15.0 ± 0.3 |
| SN95-E                          | Control | 0.63 ± 0.35        | 7.1 ± 0.2  |
|                                 | UVGI    | 0.34 ± 0.40        | 9.6 ± 0.6  |
|                                 | EtO     | 0.25 ± 0.09        | 9.5 ± 0.2  |
|                                 | HPGP    | 2.50 ± 3.15        | 9.0 ± 0.4  |
|                                 | HPV     | 0.44 ± 0.30        | 8.2 ± 0.5  |
|                                 | MGS     | 0.52 ± 0.35        | 8.8 ± 0.3  |
|                                 | Bleach  | 0.24 ± 0.06        | 8.9 ± 0.6  |
|                                 | LHP     | 0.12 ± 0.02        | 9.0 ± 0.2  |
|                                 | MHI     | 1.06 ± 0.56        | 7.9 ± 0.0  |
| SN95-F                          | Control | 0.64 ± 0.07        | 9.7 ± 0.3  |
|                                 | UVGI    | 0.66 ± 0.14        | 10.5 ± 0.7 |
|                                 | EtO     | 0.75 ± 0.16        | 10.5 ± 0.4 |
|                                 | HPGP    | <b>8.76 ± 8.78</b> | 10.0 ± 0.4 |
|                                 | HPV     | 0.52 ± 0.07        | 8.4 ± 0.4  |
|                                 | MGS     | 0.98 ± 0.39        | 10.1 ± 0.2 |
|                                 | Bleach  | 0.77 ± 0.13        | 10.2 ± 0.5 |
|                                 | LHP     | 0.97 ± 0.29        | 9.8 ± 0.5  |
|                                 | MHI     | 0.58 ± 0.07        | 10.1 ± 0.2 |

\*Bold font: mean initial penetration values > 5%.

<sup>†</sup>n=6 for EtO, HPGP, and VHP. n=3 for all other methods.

Of the 36 samples that underwent HPGP processing, nine samples had %P levels > 5%.



Interestingly, high penetration results for these samples were observed to be associated with the stacking order of the FFRs in the sample pouch (six FFR samples were stacked in a Steris Vis-U-All Low Temperature Tyvek®/polypropylene-polyethylene pouch along with a chemical indicator strip). We do not know conclusively that the HPGP was able to penetrate all FFR samples in the stack, however we do know that HPGP penetrated the pouch because of the color change of the chemical indicator strip. Of the six FFR models tested, the stacking order was documented for only three models (this is because the apparent stacking order phenomenon was not noticed until after several samples had been tested). Of these three models with known stacking order, N95-B, N95-C, SN95-D, six samples of 18 total samples (6 of 18 = 33%) had %P > 5%. These six samples were located either at the top, bottom, or one sample away from the top or bottom of the stack. This suggests that the samples physically located in the middle of the stack were shielded from the harsh processing conditions. Interestingly, no packing effects were observed in the previous study<sup>15</sup>, in which STERRAD® 100S 55 min short cycle (45°C–55°C) HPGP processing (1X) was performed off-site by a commercial vendor specializing in low-temperature decontamination. In that study<sup>15</sup>, each individual FFR sample was packaged in a Mylar/Tyvek® pouch (i.e., one FFR per pouch) along with a chemical indicator strip and changes in filtration performance were not statistically different from the controls. In that study, the chemical indicator strip also showed penetration of HPGP into the pouch. Both studies also used a hydrogen peroxide of similar concentration (59% and 58% for the 3X and 1X experiments, respectively). Aside from the differences in how the FFRs were packaged, no other differences between the methods were apparent.

Follow-up experiments were done at the HPGP conditions used here to better understand possible shielding effects; the only difference in equipment was that the follow-up experiments used a different brand of pouch (Converters® Low Temperature Sterilization Tyvek®/polyethylene terephthalate -- polyethylene pouch). Twenty-four respirators from two of the six models (N95-B and SN95-D) were packaged individually for 3X HPGP processing. In one set of experiments the same pouch was used for all three cycles, while in the other set of experiments a new pouch was used for each cycle. For N95-B, the mean %P after 3X HPGP

processing was 32.4% and 19.5%, respectively for the two conditions, while mean %P was 4.76% and 4.41% for SN95-D. Compared to the stacked processing (i.e., six FFR per pouch) there was a slight improvement in filtration performance (i.e., reduced %P) for SN95-D, but still half of the replicates had %P values > 5%. These results further suggest that those FFRs that receive the highest exposure to the 3X HPGP processing conditions (e.g., top or bottom of the stack) were most likely to experience the large degradation in filtration performance. However, additional studies are still needed to better understand which HPGP processing conditions cause changes to respirator filtration performance as the reported heating cycle of the method (45°C–55°C) does not reach temperatures known to affect filtration performance and similar effects were not observed for LHP or HPV.

For all treatment and control groups, mean initial filter airflow resistance measurements were < 17.6 mm H<sub>2</sub>O. These results are similar to those found with untreated and 1X decontaminated FFRs reported previously<sup>15</sup>. EtO, HPGP, HPV, and UVGI decontamination were the only methods that did not cause any observable physical changes to the FFRs. In previous 1X HPGP treatments, FFRs exhibited slight tarnishing of metallic nosebands<sup>14,15</sup>; however, this effect was not observed in the 3X treatments. The specific reason for the difference in effects is unknown, however the samples were packaged differently for the 1X and 3X processes as described earlier in this section.

Two methods (MGS and MHI) caused all SN95-E samples to experience partial separation of the inner foam nose cushion from the FFR. Two of the SN95-D samples experienced a slight melting of the head straps following the first 2-minute cycle. Some concerns have been raised about possible sparking during microwave heating caused by the metallic FFR nose bands. In these experiments where water basins were placed in the microwave with the FFR, no sparking was observed. Sparking has previously been observed only one time in our laboratory when microwaving an FFR for one minute without using a water basin.

Bleach exposure caused various effects: for all FFR models, metallic nosebands were slightly tarnished and visibly not as shiny when compared with their as-received counterparts. For those models with staples (N95-B, N95-C, SN95-E and SN95-F)

staples were oxidized to varying degrees. Three models (N95-A, SN95-E, and SN95-F) had discolored (yellowed) inner nose pads. The nose pad of model SN95-E samples dissolved (only 50% remained). Discoloring of other areas of the FFR were observed in models SN95-F (bleeding of printed ink lettering), SN95-E (material adjacent to nose pad became yellowed), and SN95-D (area adjacent to nose clip discolored). Following air-drying between exposure cycles (at least 16 hr), all FFRs which were exposed to bleach were dry to the touch and all still had a characteristic bleach odor, which is consistent with previous findings<sup>15</sup>. For those models which had staples (N95-B, N95-C, SN95-E and SN95-F), liquid hydrogen peroxide treatment caused staples to oxidize to varying degrees; this effect was not observed following the 3X HPGP and HPV treatments.

The ability to safely decontaminate and reuse FFRs under emergency conditions, such as FFR supply shortages, is an emerging field of study necessitating further investigation. The findings from this preliminary study, while promising, are exploratory and the data presented here are applicable only to the FFR models tested under the specified treatment conditions. This study did not evaluate FFR filtration efficiency of actual bioaerosols following a decontamination treatment, which is a relevant concern. Additionally, this study did not evaluate the ability of each treatment condition to inactivate infectious biological organisms (such as H5N1 or 2009 H1N1 influenza virus) from contaminated FFR or evaluate the effect on fitting characteristics of decontaminated FFR after 1X and 3X decontamination. These topics will be the subject of future manuscripts by our research groups.

## CONCLUSIONS

This research investigated the effects of three cycles (3X) of decontamination processing on the laboratory performance and physical integrity of NIOSH-certified N95 FFR. All control and treatment groups, with the exception of 3X HPGP, had mean initial filter penetration of  $\leq 4.01\%$ . Only the 3X HPGP processing caused levels higher than expected of initial aerosol penetration ( $>5\%$ ) in 9 of 36 (25%) samples. These observations may be associated with the FFR stacking order inside the HPGP processing pouches, because those samples most exposed to processing conditions degraded the most. Initial airflow resistance values were as expected ( $\leq 17.6$  mm H<sub>2</sub>O) for all decontamination methods and control samples. Further research is

needed before any specific decontamination methods can be recommended for any specific FFR model.

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## DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health (NIOSH). Mention of company names or products does not constitute endorsement by NIOSH.

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