Vaporized Hydrogen Peroxide Sterilization & Reuse of Filtering Facepiece Respirators: Project Safety Considerations and Outcomes

Thomas R. Block CIH MPH

Presentation Objectives

- 1. Identify factors contributing to study origin
- 2. Define study
 - 'Benchmarks'
 - Design elements & equipment
 - Challenges
- 3. Study outcomes
 - Proof of concept
 - Benchmark comparison
- 4. Bonus (time permitting): PAPR fabrication

Disclaimers

<u>Presentation:</u> <u>Opinions:</u> <u>Publications:</u> <u>General overview:</u> <u>Study specifics:</u> Based upon my observations and role My own Collaborative effort Fit within allotted time Available in publications (citations and links in conference handouts)

Rutgers University EHS Department

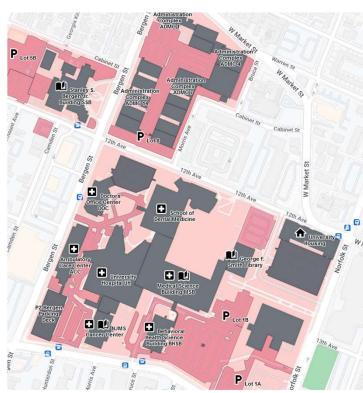
Primary Office: Piscataway NJ

- Biosafety, hazardous materials, occupational health & safety, health physics professionals
- Supports main campus students, faculty, staff activities for academic research & clinical functions, plus satellite campuses (Newark, Camden)
- Supports research extension facilities, clinical support staff, and county cooperative extension offices throughout state

RBHS Newark:

- 3 Biosafety staff
- 3 Health/Safety Specialist Staff (1 Staff RU Newark)

RBHS – Newark Campus



https://maps.rutgers.edu/lat=40.741221&lng=74.186583

- Urban campus near Newark Penn Station (Amtrak, NJ Transit, PATH)
- 'University Heights' 4 Campuses
 - RBHS (formerly UMDNJ)
 - NJ Institute of Technology (NJIT)
 - Rutgers Newark
 - Essex County College
- RBHS Newark
 - NJ Medical School (NJMS)
 - School of Dental Medicine (RSDM)
 - School of Health Professionals (SHP)
 - Cancer Research Center
 - International Center for Public Health (ICPH)

<u>Study Origins & Contributory</u> <u>Factors</u>

Prelude to 3-13-20

- January Concerns about 'novel virus' appearing in China Student abroad program modified, then cancelled
- February Respiratory protection supplies 'unavailable' Increased illness & fit test compliance observed
- March Increasing infection rates & 'hysteria' University 'closed 2 weeks' 3-13-20 Indefinite closure 3-30-20 Significant community infection prevalence

<u>'New Normal' on 3-16-20</u>

New Brunswick, Newark, Camden

- Support staff: Maintain essential operations (utilities, facilities, Public Safety)
 - Social distancing, barriers
 - Source control masking
 - Work from home 60%, on site 40% (facilities with private offices); all others remote
- Clinical staff: On-site (daily screening, masking) support critical community need
- Research: Initial 'pause' (reduced support staff); shut down 3-30-20

RBHS Newark

- Minimal support staff for essential operations, clinical (community) need
- Newark BSO's and HSS on site
 - > HSS: "All hands on deck" to fit test residents, essential clinical staff, research shut down
 - BSO's: daily review of IBC protocols (COVID research support)

1950 Defense Production Act (Amended 2018)

Presidential disaster declaration 3-26-20 (applicable 1-20-20 to 5-11-23)

Presidential authority to expedite and expand supply of materials and services from US industrial base to:

- Promote national defense
- Support emergency preparedness

Federal Priorities and Allocations System (FPAS)

- Priority-rated contracts & orders
- Preferential delivery to meet the delivery of items
- Place rated orders to ensure on-time delivery of materials and services
- Used to mitigate risks when delay in performance (MFR, logistics) could undermine program effectiveness

https://www.fema.gov/disaster/defense-production-act/federal-priorities-and-allocations-system

Disaster Declaration & DPA Consequences

Available fit test supplies don't match hospital supplies

- Hospitals given 'priority' to receive PPE
- Universities were not authorized to receive <u>any</u> shipments
 - > Residents & faculty supporting hospital staff encountered high variability of FFRP supplies
 - Medical and other students sent home
- Manufacturers needed to 'ramp up' production but new transportation and logistic requirements limited supply availability

Available FFPR didn't fit medical professionals

- Size
- Manufacturer

Consumption of FFRP driven by:

- High community infection and prevalence rates
- IC practices based on prepandemic assumption of adequate supplies

<u>Study Design, Benchmarks, &</u> <u>Challenges</u>

Project Inspiration & Design

Annual BSL 3 shut downs ensure worker protection and containment

- Experiments completed, organisms secured
- Vendor dispenses sterilant at high concentrations, for prescribed time, within facility and HVAC system
- BSO staff verify facility safety for support staff and vendor entry
- HVAC PM and HEPA filter replacement
- Facility maintenance to prevent fomite accumulation, facility degradation, and to ensure quality research results

<u>Concept:</u> Utilize same approach to sterilize & reuse disposable FFRP

Project Needs

- 1. Identify benchmarks
- 2. Access sterilization equipment, supplies, operator training
- 3. Identify staffing
- 4. Select appropriate location
 - Isolated HVAC system with HEPA filtration
 - Restricted access
 - Available lab support space (daily bump tests, culture BI's)
- 5. Identify respirator (source) supplies
- 6. Determine containment monitoring equipment, acquire equipment
- 7. Establish processing procedures
- 8. Define successful outcomes (efficacy)

FFPR Reuse 'Benchmarks'



Description

We at 3M have been studying ways to sterilize or disinfect filtering facepiece respirators for years. There are at least four key aspects of successful disinfection of respirators, and most studies do not take all four into consideration. The disinfection method must

- be effective against the target organism, such as the virus that causes COVID-19;
- not damage the respirator's filtration;
- not affect the respirator's fit; and
- be safe for the person wearing the respirator (e.g. no off-gassing of chemicals into the breathing zone).

If the filtration is damaged or the respirator does not fit, it will not help reduce exposure to airborne particles at the level indicated, such as N95, FFP2, etc.

As of March 27,2020, no disinfection method has met all four of these key criteria, and without all four, the method is net acceptable. 3M is now working with several major sterilization and disinfection companies and consulting with external experts to develop an effective disinfection method. We are working as quickly as possible and are hopeful that we will find an effective method soon.

Background

Filtering facepice respirators (FFR), such as those that meet the filtration efficiency requirements for classification as such as N95, FFP2, MNS5, and similar, are commonly used to help provide respiratory protection in a variety of workplaces, including healthcare settings. A common infection prevention practice employed by healthcare organizations is to utilize FFRs as one-time-use items when worm in the presence of infected patients.¹ In the face of a global pandmenti and associated FFR shortage, SM has received numerous questions concerning potential methods to disinfect FFRs, including questions relating to studies that have evaluated the effectiveness of various disinfection methods on FFRs. In an attempt to respond to urgent requests we are receiving from customers and organizations around the world, we have prepared this bulletin to provide information concerning a few methods that have been suggested to potentially help disinfect FFRs.

Based on currently available data, 3M does not recommend or support attempts to sanitize, disinfect, or sterilize 3M FFRs.

We note, however, that the U.S. Centers for Disease Control and Prevention (CDC) has published guidance on managing respirators during pandemics including the reuse and extended use of respirators at https://www.cd..oov/inabi/toisigs/howcontrol/srcommendedguidanceexture.html

3M Disinfection Method Considerations

- 1. Must be effective against target organism
- 2. Must not damage the respirator's filtration
- 3. Must not affect fit
- 4. Must be safe for person wearing processed FFRP (no off-gassing)

Fulfilling Project Needs

Vendor agreed to rent equipment, train operator

Project support personnel

- Infectious disease researchers (5)
- Essential service staff BSO's, EHS specialists (safety officer (SO) + deputy), HVAC
- IBC project review
- "Retired" BSL 3 containment facility available
 - Existing infrastructure operable
 - Restricted access, support spaces nearby

SO identified respirator supplies, containment/monitoring equipment BSO's familiar with decontamination and safety validation procedures Collaboration between researchers, BSO's, SO defined outcome efficacy

Study Safety & Design Considerations

- 1. Equipment & reagent
- 2. Confirm FFRP sterilization efficacy
 - a. Chemical contact indicators
 - b. Biological growth indicators
- 3. Identify FFRP for evaluation
- 4. Evaluate respirator fit and reuse
 - a. QNFT of sterilized respirators to confirm integrity & fit
 - b. Quantify cycles before failure of FFRP
- 5. Study goals
 - a. Research paper publication
 - b. Create FFRP supplies for clinical staff

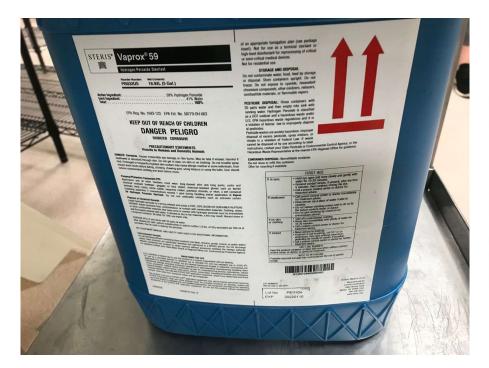
Safety Considerations - Equipment

Vendor provided ID researcher:

- Equipment & operational training
- Laptop for remote operation and monitoring processing room
- Equipment (stationary fans) & layout recommendations
- Identified direct reading monitoring equipment (leak detection)



Hydrogen Peroxide



SAFETY DATA SHEET

1. Identification of the Substance and Company

VAPROX® HC Sterilant (59% Hydrogen Peroxide) Use: For use with STERIS Amsco® V-PRO® 1, V-PRO® 1 Plus, V-PRO® 60 Sterilizer and V-PRO® maX Low Temperature Sterilization Systems

NEPA 704 HAZARD RATING Product No. PB007, PB028 SDS No. A124 HEALTH: FIRE: REACTIVITY: Prepared by: M. Ebers

asksteris msds@steris.com Date Created: May 16, 2006 Date Revised: July 25, 2014

STERIS Corporation, P. O. Box 147, St. Louis, MO 63166, US Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC) Telephone Number for Information: 1-800-548-4873 (Customer Service-Healthcare Pro

STERIS Limited, Chancery House, 190 Waterside Road, Hamilton Industrial Park, Leicester, LES 102, UK Emergency Phone No: +44 (0) 1895 622 639 Product/Technical Information Phone No: +44 (0) 116 276 8636

Hazards Identification: Harmful if inhaled. Harmful if swallowed. Causes severe skin burns and eye damage May intensity fire; oxidizer.

Hazardous Component(s)	% By WL	CAS No.	EU No.	Pictogram(s)	Hazard Code(s)	Oral LD so	Inhalation LC ₃₀
Hydrogen peroxide	59	7722-84-1	231-785-0	Flame over circle, Corrosion	H332, H302, H314, H272	225 mg/kg (rat) 50% solution	>0.17 mg/ (rat) 50% solution

4. Find Ad Maximum: Dip Conduct Trach regis immediately with water for already 15 model, out interdial detained, Sale Conduct Thrankin immediately with water for a track shall be model or advantage of the share of borecast of borecast years and borecast of the share of the model at the detained and these and borecast years and share of the share of the model at the detained at the share of the detained at the share of the share of the share of the share of the detained at the share of the share of the share of the share of the detained at the share of the share of the share of the share of the detained at the share of the share of the share of the detained at the share of the share of the detained at the share of the share of the detained at th

a crue capating Measures: Countinous of Remarket/Tush Point/Auto-Ignition Temperature: Non-combustle Upper Eliminable Limit: NA Special Hazards' Hydrogen peroxide will not hum but decomposition will generate oxygen that increases the esposise limit, enhances the burning rate and may initiate fire in combustion makenias. May react with soft metalls hydrogen peroxide must be immodiately and thoroughly autobal with water. If hydrogen peroxide must be immodiately and thoroughly autobal with water. I hydrogen peroxide must be immodiately and thoroughly autobal with water. If hydrogen peroxide is allowed to dry Exploribality Data 1, 10

Exprosatory Usate: No: Extinguishing Media: Vider or water fog. Do not use carbon dioxide or dry chemical fire extinguishens. Special Fire Fighting Procedures: Flood with water. Vicer tail protective cohing (rubber suit and boots including splash popular and self-contained lowerithing apparatus). In case of the, use water or water fog fire extinguishes only. Hazardowa Combustion Products: Contamination may cause rapid decomposition, oxygen pas release and

STER1S' -

7. Handling and Storage: 7.1 Handling: Read and observe all labeled use instructions. 7.2 Storage: Store in a cool dry area in the upphip position and away from combustibles. Never return unuse peroxide to original container: Utenaits used for handling peroxide should be made only of compatible material such as glavas, stainless steel, altimitum or plastic.

such as glass, stanless steel, aluminum or plastic.

8. Eponeurs ControlPerional Protection: 16.1 Cocupational Exposure Limits Hydrogen peroxise: ACOH
2.1 Provide Text - ImpRinkpatro Hydrochics: 16.1 Cocupational Exposure Limits Hydrogen peroxise: ACOH
2.2 Peroxol Protection: Chemical applications uses cells (Self-Contained Beathing Appartual),
Explained Face Text Provide Self and the Self application of the Self and Hydrogen application of the Self and Hydrogen applications for the AMSCO U-VERO, V-PRO, V

10. Stability and Reactivity Hazordose Polymerization: Nill ind occur. Newspatible Materials: Cynates heuwatert drommin composide, india dud, potasam permanganate, oddarse, nickores, monistelle naraterial, minnate vargonz, ablask, cooper, dit, dud, no, heavy netista and their sata and organic materials especially viny monomen. Conditions to Arvide Canditions of Reactivity: Unsatable with heat and contamination; liberation of oxygen gas may result in dangerous pressures. Hazardous Decomposition or Byproducts: Contamination may cause rapid decomposition, oxygen gas release and dangerous pressures.

11. Toxicological Information
 11.1 Acute (Primary Routes of Exposent)
 11.1 Acute (Primary Routes of Exposent)
 11.1 Acute (Primary Routes of Exposent)
 11.1 Acute (Primary Context)
 11.1 Acute (Primary Context

11.2 Long Term Exposure: None known. Carcinopenicity: LARC, NTP and OSHA do not list this product or its ingredients as carcinopens. AC hydrogen perouds as a "Confirmed Animal Carcinopen with Unknown Relevance to Humans" A3. Reproductive Toxicity/Teratogenicity/Mutagenicity/Toxicologically Synergistic Products: ND ens. ACGIH lists

35% aqueous hydrogen peroxide solution dispensed to achieve between 400 – 800 ppm concentration for 3 hours

Verify Operation & Containment

Operator responsibility:

- Monitor VHP concentration within containment facility
- Assess processing room containment integrity
- If containment failure, then:
 - ➤ Terminate process
 - > Quantify ambient concentrations (emergency response, safe entry)

External (containment) parameters:

- 1. Relative room pressure
- 2. Hydrogen peroxide concentrations

Post Sterilization Verification

Two challenge methods used within processing room at specific locations:

- Chemical indicators colorimetric test (Sterrafin VHP Process indicators; violet → yellow) provides instant, visual confirmation of chemical concentrations at placement areas
- Biological indicators challenge test organisms (Spordex VHP biological indicator discs) placement in room and within enclosed control respirators
 - Cultured and incubated @ 37° C
 - Evaluated after 24 hr and 7 days
 - Growth/no growth

Respirator Stock

<u>Initial plan</u>: Use FFRP discards from failed hospital fit tests (unlimited supply). However, concerns regarding:

- Variability in manufacturers, models, sizes, construction (supply chain)
- Potential COVID contamination by clinical staff from facial contact (unknown COVID infection status); additional processing procedures & PPE?
- Visual damage noted to some FFRP before treatment
- 'Aesthetic' issues (cosmetics, creams)

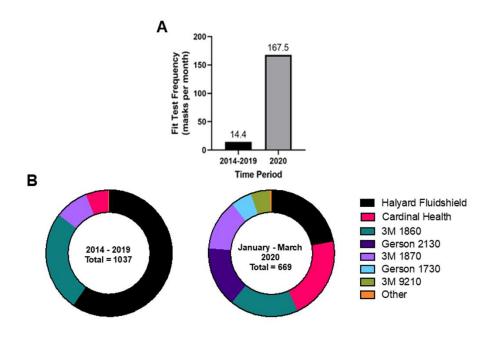
Final Plan: Used 'preferred' respirator models for clinical applications

- FDA fluid resistant models, small and regular sizes
- Existing performance history by residents, faculty, clinical support staff

Respirator Selection Criteria

Review 2013 – 2019 resident & medical student fit test records, identify:

- Models available & in use at UH and RWJUH
- Fluid resistant, comfortable FFRP
- Models becoming 'somewhat more available' over time
- Models sought by university procurement team



Graphic source: Alland research group

Filtering Facepiece Respirators Selected

3M

- 'Round' shape, Models 1860, 1860S
- 'Oval' shape, fold flat, Models 1870, 1870+, 9210

Cardinal Health

• 'Round' shape, Small and Medium/Large sizes

Gerson

• 'Rectangular' pleated shape, models 2130 and 1730

Halyard

• 'Duck bill' 46827 (small) and 46727 (regular)

Assessing Functional Filter Integrity

At the end of each contamination run, select respirators for:

- Visual inspection for damage to filter, nosepieces, and headbands
- Functional filtration integrity quantitatively assessed using the Porta Count Model 3038 on fit test subjects

Test subjects trained to properly don and doff FFRP, then assess

- QNFT performed on unused FFRP devices [8 cycles]
- QNFT performed on 'lightly used' respirators
 - Lightly used QLFT failure on test subject, VHP processed, then QNFT FFRP
 - Lightly used QNFT to second user that fit on unused devices (mimic anticipated conditions of reuse to extend supplies)

Benchmark Criteria:

Sterilization efficacy confirmed No filter damage No adverse effect on fit No off-gassing

Improving Workflow, Cosmetic Influences

Hanging FFRP on hooks prior to VHP processing \rightarrow time consuming

- Stack FFRP in piles of various depths to assess process efficacy; compare outcome to hanging individual FFPR on racks
 - ➢ Pile depth (stacks) 4, 6, 8, 10, 12 units
 - > Cl's and Bl's inserted into the middle of each pile to assess efficacy
- Individual, used FFRP (1 or 2) stored inside paper bags; FFRP taped shut, bags closed (worse case) to assess efficacy

Does cosmetic & cream presence on discarded FFRP's influence sterilization outcomes?

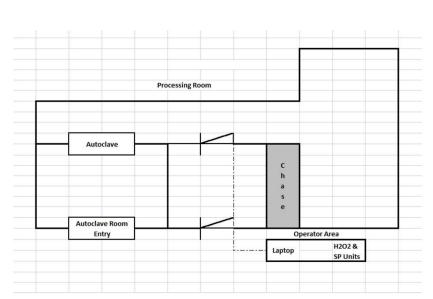
- Applied cosmetic and moisturizer layer to interior of FFRP
- Inserted CI's and BI's, folded and taped FFRP shut to assess process efficacy

Environmental Monitoring Challenges

Tubing from processing room door (through anteroom) to VHP operator table ~ 20 – 25 feet

Position static pressure & direct reading instrument next to laptop

Operator cognizant of pressure and VHP concentration changes (containment confirmation)



Processing Room & Operator Layout

Pressure Reading Instrument

- Position Tygon tubing at base of processing room door (at PC serial communication cord penetration), secure to floor
- Zero instrument after processing room & tubing secured
- Observe pressure changes



Drager VHP Instrument

Intended for area monitoring

- Inlet diameter 1"
- Sampling rate 500 cc/min

Preferred sampling location: next to processing room penetration for serial communication cable and pressure tubing

Challenges:

- Inlet adapter vs tubing diameters
- Sustain sampling rate in tubing to alleviate instrument 'fault'



Study Results

Positive Project Results

- 1. Equipment & methods used to sterilize rooms effective on FFRP
 - a. 90 minutes to achieve target concentration in processing room
 - b. All CI's turned yellow indicating optimal VHP exposure
 - c. All BI's had no growth 7 days post media inoculation
- 2. Surfaces of FFRP decontaminated when folded
 - a. Cl's inside control respirators turned yellow
 - b. BI's inside control respirators had no growth after 7 days
- 3. Improved workflow observed for stacks of 4, 6, 8
 - a. Confirmed with chemical & biological indicators
 - b. Increased processing: 250 units/rack (hung) vs 720 units/rack per pile (6)
 - c. Increased capacity [4250 hung vs 12,240 piled], decreased time [2 hrs vs 8.5 hrs]
 - d. Effective sterilization for FFPR folded inside bags (CI's and BI's)

Positive Results (Continued)

- 4. Confirmed cosmetic application on Halyard FFRP surface did <u>not</u> interfere with decontamination procedure
- 5. FFRP filters did not exhibit visual signs of degradation
- 6. Most FFRP continue to fit and function properly for at least 6 decontamination cycles

Negative Project Results & Limitations

- 1. Facility degradation after 8 runs
 - a. Visible deterioration to walls, floors, door sealants
 - b. Quantifiable leakage detected at processing room door
 - c. Off-gassing observed from porous surfaces/damaged areas
- 2. Quantifiable VHP off-gassing noted from FFRP immediately after reentry
- 3. Resilience to VHP process varies by FFRP manufacturer & model
 - a. Halyard exhibited observable downward trend
 - b. Functional integrity of 3M 1870 reduced after worn, processed, fit tested on second user
- 4. Fit test subject facial features, sizing not representative of general population
- 5. Clinical staff wanted 'their' FFRP sterilized & returned to them
- 6. Processing resources and concerns
 - a. Requires dedicated space, equipment, operator training, monitoring (area & process efficacy with CI's and BI's)
 - b. Labor intensive
 - c. Handling 'contaminated' PPE during rack loading activities
 - d. Achieved only 3 out of 4 3M benchmarks

Final Thoughts

- 1. You think you're prepared realize you're not then it's too late
- 2. Stockpiling PPE is good, but you need excellent storage & management practices. Even then, an emergency rapidly depletes resources, with questionable replenishment capabilities

2020 NIOSH Beyond Shelf Life/Stockpiled Assessment Results N-95 respirators https://www.cdc.gov/niosh/npptl/respirators/testing/ExpiredN95results.html

- 3. Disposable PPE manufacturing is scalable upon demand; however, you're at risk to interruptions and shortages until demand initiates more production
- Government and manufacturers are working to incorporate more reusable textiles in PPE to address sustainability & supply chain issues
 → Europeans utilize 60 70% reusable (laundered) textiles in healthcare PPE

NAS Webinar March 4-5, 2024 "Reuseable Health Care Textiles for PPE Workshop" https://www.nationalacademies.org/event/41729_03-2024_reusable-health-care-textiles-forpersonal-protective-equipment-a-workshop

Publications

Russo, R, Levine C, Grady C, Peixoto B, McCormick-Ell J, Block T, et al. Decontaminating N95 Respirators during the COVID-19 Pandemic: Simple and Practical Approaches to Increase Decontamination Capacity, Speed, Safety, and Ease of Use. J Hosp Infect 2021; 109:52 – 57.

https://www.sciencedirect.com/science/article/pii/S019567012030570



Decontaminating N95 respirators during the COVID-19 pandemic: simple and practical approaches to increase decontamination capacity, speed, safety and ease of use

R. Russo^a, C. Levine^a, C. Grady^a, B. Peixoto^a, J. McCormick-Ell^{b,†}, T. Block^b, A. Gresko^b, G. Delmas^b, P. Chitale^a, A. Frees^b, A. Ruiz^b, D. Alland^{a,*}

^a Center for Emerging Pathogens, New Jersey Medical School, Rutgers University, Newark, NJ, USA ^b Rutgers Environmental Health and Safety, Rutgers University, Newark, NJ, USA

ARTICLEINFO	SUMMARY
-------------	---------

Article history: Received 21 August 2020 Background: The COVID-19 pandemic has caused a severe shortage of personal protective equipment (PPE), especially N95 respirators. Efficient, effective and economically feasible Levine, C, Grady C, Block T, Hurley H, Russo R, Peixoto B, et al. Use, Reuse, or Discard: Quantitatively Defined Variance in N95 Respirator Integrity following Vaporized Hydrogen Peroxide Decontamination during the COVID-19 Pandemic. J Hosp Infect 2021; 107:50 – 56.

https://www.sciencedirect.com/science/article/pii/S0195670120304679



Use, re-use or discard? Quantitatively defined variance in the functional integrity of N95 respirators following vaporized hydrogen peroxide decontamination during the COVID-19 pandemic

```
C. Levine <sup>a, b</sup>, C. Grady <sup>a, b</sup>, T. Block <sup>a, c</sup>, H. Hurley <sup>a</sup>, R. Russo <sup>a</sup>, B. Peixoto <sup>a</sup>,
A. Frees <sup>a, c</sup>, A. Ruiz <sup>a, c</sup>, D. Alland <sup>a, *</sup>
<sup>a</sup>Rutgers New Jersey Medical School, Newark, NJ, USA
```

^b Rutgers Biomedical and Health Sciences, Newark, NJ, USA ^c Rutgers Environmental Health and Safety, Newark, NJ, USA

ARTICLEINFO SUMMARY

Article history: Received 3 July 2020 Background: Coronavirus disease 2019 has stretched the ability of many institutions to supply needed personal protective equipment, especially N95 respirators. N95 decon-

<u>Acknowledgements</u>

Dr. David Alland – UH ID Chief and Director, ICPH
Dr. Jessica McCormick-Ell – RU BSO and study design
A Gresko, G Delmas, A Ruiz – RU BSO group
Dr. Alland's Research Group

R Russo, C Levine, C Grady, B Peixoto, P Chitale, H Hurley

A Frees – deputy safety officer (my backup)
Rutgers IBC members

All mentioned in journal articles

Thank You!





PAPR Fabrication