The Science Behind N95 Decontamination | Erin Kyle, DNP, RN, CNOR, NEA-BC
John D. Clay, PhD
Dr. Erin Kyle, DNP, RN, CNOR, NEA-BC, is the Editor-in-Chief, Guidelines for Perioperative Practice at AORN and is responsible for providing professional expertise regarding perioperative nursing practice on behalf of AORN. Dr. Kyle has authored several guidelines and serves as the staff liaison to AAMI and ASTM where she is active in sterilization and personal protective equipment standards development. During the COVID-19 pandemic Dr. Kyle worked as a team with AORN nurses to create, maintain, and deliver key clinical resources for AORN members including the web-based COVID-19 toolkit, the eBook Perioperative Care of the COVID-19 Patient, Virtual Clinical Updates and Town Halls, and a number of educational webinars about N95 decontamination. When organizations such as FDA sought perioperative nursing input in decisions and communications, Dr. Kyle served as AORN’s liaison to act as an advocate for worker safety during this health emergency.
Outcomes

Discuss how recommendations to manufacturer’s instructions for use is different during this health emergency relative to FDA Emergency Use Authorizations

Describe recommendations in the AORN Guidelines that can help users make sense of N95 decontamination

Discuss safety strategies for using N95 decontamination processes
It is critically important for the team in the room to be safe and protected and that is the highest priority.
N95 Respirator Decontamination is a **CRISIS CAPACITY** strategy and should only be used if no new N95s are available.

- [https://www.aorn.org/guidelines/aorn-support/covid19-faqs](https://www.aorn.org/guidelines/aorn-support/covid19-faqs)
Flowchart to Determine if an N95 FFR Crisis Capacity Strategy is Needed

Evaluate Adequacy of Current N95 FFR Inventory and Supply Chain
- Is your current N95 FFR inventory and supply chain equal to or greater than your PPE needs?
- Are there N95 FFRs available from local healthcare coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) that can cover your PPE needs based on your burn rate and ability to procure more PPE when needed?
- Use the Personal Protective Equipment (PPE) Burn Rate Calculator to help you plan and optimize the use of PPE during the response to coronavirus disease 2019 (COVID-19)

Evaluate Availability of Other Respirators in Your Inventory
- Are there NIOSH-approved respirators that meet or exceed the level of protection of N95 FFRs available in your inventory or from the supply chain to cover your PPE needs?
- Are there NIOSH-approved respirators available from local healthcare coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) that can cover your PPE needs?
- Other devices that can be used include N99, N100, P100, R100, R95, R80, and R50 FFRs, elastomeric respirators, and powered air-purifying respirators (PAPRs).
- The use of these devices is included in the conventional capacity strategies to conserve the supply of N95 FFRs.

Evaluate Extended Use of N95 FFRs
- Can extended use of N95 FFRs (using the same N95 FFR for more than one patient contact) cover your PPE needs based on your burn rate and ability to procure more PPE when needed?
- More information on extended FFR use and other contingency capacity strategies can be found here.

Yes

Yes

Yes

You are not operating at crisis capacity.
Follow conventional capacity strategies or if shortages are expected, contingency capacity strategies. Continue to monitor current respiratory protection needs and usage. More information on optimization strategies can be found here.

Check supply chain and other resources frequently (e.g., N99).

Apply crisis capacity strategies.
More information can be found at here.

FDA
Emergency Use Authorizations (EUA)
FDA “Clearance” versus “Authorization”

• Clearance – usual process - 510k or Premarket Approval (PMA)
• Emergency Use Authorization (EUA) – fewer restrictions, fewer validation and safety studies
  • Allowable only during public health emergencies
  • Additional uses for approved product, drug, or device
  • Could even be previously unapproved, or now need to be used in previously unapproved ways

FDA Guidance Document
Emergency Use Authorization of Medical Products and Related Authorities
In other words

**FDA Clearance** is more like a scheduled surgical case

Plenty of time to prepare

**FDA Emergency Use Authorization** is more like an emergency/trauma case (and you don’t have everything you need)

The best we can with what we have at the time
New and Improved FDA EUA Website

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe
We are using N95 decontamination - what to do with the IFU?

1. FDA – **cleared** medical device outside the context of the declared health emergency (conventional N95 use)
   ✓ Adhere to the IFU

1. FDA – **authorized** medical device in a declared health emergency (N95 decontamination)
   ✓ Follow the instructions on the FDA EUA
### COVID-19 EUAs - N95 Respirator Decontamination

<table>
<thead>
<tr>
<th>Date</th>
<th>Company/Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2</td>
<td>Battelle</td>
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<td>April 11</td>
<td>ASP - STERRAD</td>
</tr>
<tr>
<td>April 20</td>
<td>Sterilucent</td>
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<tr>
<td>May 21</td>
<td>STERIS Steam</td>
</tr>
<tr>
<td>June 13</td>
<td>Technical Safety Services VHP</td>
</tr>
<tr>
<td>August 20</td>
<td>Nova2200</td>
</tr>
<tr>
<td>April 9</td>
<td>STERIS VPRO</td>
</tr>
<tr>
<td>April 14</td>
<td>Stryker - STERIZONE</td>
</tr>
<tr>
<td>May 7</td>
<td>Duke</td>
</tr>
<tr>
<td>May 27</td>
<td>Stryker Sustainability Solutions VHP</td>
</tr>
<tr>
<td>July 24</td>
<td>Michigan State University</td>
</tr>
</tbody>
</table>

AORN Guidelines & Guidance Documents – Pulling it all together

1. Guidelines for Perioperative Practice
   • Transmission-Based Precautions
   • Sterile Technique
   • Smoke Safety
   • Sterilization

2. COVID-19 Tool Kit & FAQs

3. Guidance Documents
   • Roadmap
   • Guidance for Health Care Industry Representatives
   • Statement regarding PAPRs in the OR

4. Care of the Perioperative COVID-19 Patient
   • Complete guide for the perioperative care during COVID-19 Pandemic
Guideline for Transmission-Based Precautions

Respiratory protection recommendations

• 2.7 – wear a NIOSH-approved, fit-tested surgical N95
• 2.7.1 – wear respiratory protection before entering room for airborne precautions
• 2.7.5 – facial hair should not cross under the seal of a fit-tested N95
• 4.2.1 – wear a NIOSH-approved, fit-tested surgical N95 before performing aerosol-generating procedures
Guideline for Sterile Technique

• 1.4 – an interdisciplinary team should determine if PAPRs may be used for respiratory protection in the presence of a sterile field

• 1.4.1 – create a standardized procedure for perioperative PAPR use and protection of the sterile field from contamination
Guideline for Surgical Smoke Safety

• 1.4 – wear respiratory protection as secondary protection against surgical smoke
• 1.4.1 – wear a fit-tested surgical N95 during higher-risk aerosol-generating procedures and procedures for patients with known or suspected aerosol transmissible diseases
• 1.4.2 – team may use a surgical N95 in conjunction with smoke evacuation for disease transmissible cases
• 2.1 – evacuate all surgical smoke
Guideline for Sterilization - Chemical sterilant exposure risks and limits

<table>
<thead>
<tr>
<th>Sterilant</th>
<th>OSHA exposure limits (8-hr work shift in 40-hr work week)</th>
<th>WHO – IRAC, ACGIH Carcinogenic?</th>
<th>Health effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen peroxide</td>
<td>1 ppm</td>
<td><em>Animals</em> – yes, <em>Humans</em> – not classifiable</td>
<td>Corrosive at high concentrations (&gt;10%); Bleaching, burns, blisters with skin contact; upper airway irritation &amp; burning, tightness in chest; permanent lung damage with severe inhalation injury</td>
</tr>
<tr>
<td>Ozone</td>
<td>0.1 ppm</td>
<td>Not classifiable</td>
<td>Headache, dryness of mucous membranes, reduced pulmonary function values</td>
</tr>
<tr>
<td>Peracetic Acid</td>
<td>0.4 ppm</td>
<td><em>Animals</em> – yes, <em>Humans</em> – not classifiable</td>
<td>Irritation, ulcers (skin); eyes lacrimation; extreme discomfort to mucous membranes</td>
</tr>
<tr>
<td>Ethylene Oxide</td>
<td>1 ppm</td>
<td>Carcinogenic in humans</td>
<td>Nausea, vomiting, neurological disorders, damage to CNS, liver, kidneys, respiratory distress</td>
</tr>
</tbody>
</table>
AORN COVID-19 Tool Kit & FAQs

• FAQ: We have a shortage of surgical masks and/or respiratory protection, what should we do?
  • See the FAQ for details specific to
    • Conventional Capacity
    • Contingency Capacity
    • Crisis Capacity
    • When No Facemasks or Respiratory Protection are Available
Joint Statement: Roadmap for Maintaining Essential Surgery during COVID-19 Pandemic

• Updated August 10, 2020
• Joint Statement
  • American College of Surgeons
  • American Society of Anesthesiologists
  • Association of periOperative Registered Nurses
  • American Hospital Association
Perioperative Care of the COVID-19 Patient - eBook

- eGuideines+
- Comprehensive guide to patient care COVID-19 in surgical & other invasive procedures
- Chapters include
  - Resuming Operations
  - Preoperative Patient Assessment & Testing
  - Transport to the OR
  - OR
  - Postoperative Protocol
  - Cleaning the OR
  - Restoring a Dedicated COVID-19 OR to normal use
  - Perioperative Staff Self-Care

AORN Hot Topic Virtual Forum
COVID-19 N95 Decontamination
Sponsored by Battelle
It can be done
NPPTL Respirator Assessments to Support the COVID-19 Response

Respirator Assessments to Support COVID-19 Response

- Beyond Shelf Life/Stockpiled Respirator Assessment Request
- Beyond Shelf Life/Stockpiled Assessment Results
- International Respirator Assessment Request
- International Assessment Results
- Decontaminated Respirator Assessment Request
- Decontaminated Assessment Results

https://www.cdc.gov/niosh/npptl/respirators/testing/default.html

AORN HOT TOPIC VIRTUAL FORUM
COVID-19 N95 Decontamination
Sponsored by BATTELLE
It can be done
N95 Decontamination Resources

CDC - Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies

FDA - Emergency Use Authorization of Medical Products and Related Authorities
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#publication

FDA - Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency
https://www.fda.gov/media/136449/download

FDA - Emergency Use Authorizations
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe

FDA - Emergency Use Authorization Letter example
https://www.fda.gov/media/136529/download

FDA - Final Report for the Bioquell HPV Decontamination System for Reuse of N95 Respirators (2016)
https://www.fda.gov/media/136386/download

NIOSH – The National Personal Protective Technology Laboratory (NPPTL) Respirator Assessments to Support the COVID-19 Response
https://www.cdc.gov/niosh/npptl/respirators/testing/default.html

ECRI - CLINICAL EVIDENCE ASSESSMENT March 2020 ECRI Safety of Extended Use and Reuse of N95 Respirators

FDA – FAQs on Emergency Use Authorizations for Medical Devices During the COVID-19 Pandemic

FDA - Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff
https://www.fda.gov/media/136533/download

ECRI - CLINICAL EVIDENCE ASSESSMENT March 2020 ECRI Safety of Extended Use and Reuse of N95 Respirators
Get your questions answered

- AORN’s dedicated webpage to COVID 19
  https://www.aorn.org/covid19support

- Clinical Consult Line
  Open to members
  Tu-Wed 9am-1pm MST
  (800) 755-2676

- ORNL-COVID 19 - Members only
Thank You!
About Battelle

- Nonprofit, charitable trust formed in 1925
- Our mission: To translate scientific discovery and technology advances into societal benefits
- World’s largest, independent, not-for-profit research and development organization
Battelle’s Broad Experience in Healthcare

Battelle helps to advance science and technology to impact public health, improve patient outcomes, support clinicians, and drive critical research.
Battelle CCDS™ History

• Initial decontamination studies were performed in response to the Ebola outbreak
  • 2015-16 FDA study - vapor phase hydrogen peroxide (VPHP) proved to effectively decontaminate N95 respirator masks
  • Decontamination efficacy proven with *G. stearothermophilus* (spore former) as biological challenge
  • Filtration efficiency, inhalation resistance, and strap elasticity retained through 20 decontamination cycles relative to factory-fresh (new) FFR
  • 2020 pandemic - proved VPHP efficacy against SARS-CoV-2 in our BSL 3 laboratories

**CCDS™ is Based on Proven Science**
CCDS™ Overview

• Self-contained, mobile decontamination system for N95 FFR
• Designed to help address the PPE shortage in the U.S.
• Vapor phase hydrogen peroxide (VPHP) used to inactivate SARS-CoV-2 and numerous other pathogens
• Functional performance of N95 FFR retained through 20 decontamination cycles
• Safe for users, with $[\text{H}_2\text{O}_2] < 1\text{ppm}$
CCDS™ Process Details

- CCDS™ process consists of four phases
- Decontamination cycle successfully generates hydrogen peroxide micro-condensation through the 2.5 hour dwell phase
- Hydrogen peroxide results in > 6-log reduction as indicated by collocated chemical indicators
- Aeration step ensures $[\text{H}_2\text{O}_2] < 1 \text{ppm}$
CCDS™ Research Team Charter

• Perform due diligence testing on N95 respirators to build a data bank to support CCDS™ field operations

• Collaborate with industry and government to conduct independent, third party testing of N95 respirators decontaminated using the CCDS™ process
CCDS™: Due Diligence Research

- Performance testing on 25+ unique makes and models of FFR through multiple decontamination cycles
  - Filtration efficiency (> 400 tests to date)
  - Inhalation resistance (> 400 tests to date)
  - Strap performance (> 800 tests to date)
- Third party assessment (independent validation) of N95 FFR decontaminated using CCDS™
- Testing on high-wear respirators (worn through multiple shifts and double shifts) from hospital systems

Test results have confirmed a retention of functional properties for the N95 respirators after decontamination

AORN | HOT TOPIC VIRTUAL FORUM
COVID-19 N95 Decontamination

Sponsored by Battelle
Tests Conducted

• Initial Aerosol Filtration Efficiency
  • TSI 8130A CertiTester
    • Method and instrument used by NIOSH for N95 FFR certification
  • Aerosol challenge
    • ±0.075 μm diameter particles with ±0.02 μm tolerance
  • Pass/Fail criterion: >95%

• Inhalation Resistance
  • TSI 8130A CertiTester
  • Pressure drop at 85 L/min constant flow
  • Pass/Fail criterion: <35 mm H₂O
Tests Conducted

• H₂O₂ Off-Gassing
  • Battelle-developed method unique/specific to address “toxicity” concerns
  • Method better aligns with the airflow dynamics and conditions experienced by the FFR wearer than a static measurement
    • Q=32 L/min constant, T=22±3°C, and RH=50±5%
    • H₂O₂ concentration measured using electrochemical cell
      (i.e., Draeger PACIII or Xam-5100)
  • Pass/Fail criterion: [H₂O₂] < 1 ppm
    • Based on OSHA PEL
Tests Conducted

• Strap Testing
  • Mechanical property testing of straps as indicator of fit
  • Method developed by Battelle based on review NIOSH and 3M methods to evaluate N95 straps
  • Pass/Fail criterion: TBD
    • Strap testing is not required as part of NIOSH certification
    • Relationship between strap tension and respirator fit does not exist; therefore, there is no established pass/fail criterion

Strap Test Method

<table>
<thead>
<tr>
<th>Sample Quantity</th>
<th>Test top and bottom straps from 3 decontaminated respirators and 2 controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size</td>
<td>~13 cm total length, 10 cm grip separation</td>
</tr>
<tr>
<td>Crosshead Speed (Rate)</td>
<td>1 cm/s</td>
</tr>
<tr>
<td>Step 1</td>
<td>Stretch to 200% then return to start</td>
</tr>
<tr>
<td>Step 2</td>
<td>Stretch to 150% then return to start</td>
</tr>
<tr>
<td>Step 3</td>
<td>Stretch to 200% then return to start</td>
</tr>
<tr>
<td>Report</td>
<td>Report max stress at 200% strain (last cycle)</td>
</tr>
</tbody>
</table>
Representative Results (Honeywell Sperian N1105)

Aerosol Collection Efficiency @85 L/min

Inhalation Resistance @85 L/min

Strap Testing (Stress @200% Strain)

Strap Testing (Max Load to Achieve 200% Elongation)
Field Use Validation (MGH Results)

- Battelle has performed two different tests to characterize the functional performance of N95 respirators after multiple use cycles by actual healthcare workers, with decontamination after each use
  - MassGen Hospital (MGH) – Testing through 5 uses
  - Local Columbus Hospital (Ohio Health) – Testing for up to 9 uses

- These tests assess potential interactions of body oils and sweat with N95 FFR materials

MassGen research scientists led controlled evaluations of more than six decontamination technologies for N95 FFR evaluated through March 2020. Verification and selection of vaporized hydrogen peroxide as preferred method preceded introduction to Battelle CCDS™.
Field Use Validation (MGH Results)

- N95 FFRs received from MGH met the filtration requirement (≥95%) after up to 5 cycles
- Use/sweat followed by decontamination did not degrade collection efficiency
Field Use Validation (Ohio Health HCP Results)

- A total of five N95 FFRs received from local HCP were procured to assess functional performance after 8 and 9 cycles of use and subsequent decontamination.
- Use/sweat did not change functional performance.
Independent Validation of CCDS™

- **NIOSH**: completed testing of CCDS process and validated efficacy through 20 cycles of decontamination
- **3M**: validated the VPHP process through 20 cycles
- **CDC**: posted test results for the CCDS VPHP process that confirmed performance and fit
- **NIH**: study found the VPHP process is the most effective for decontamination
- **Massachusetts General Hospital**: research confirmed the safety of VPHP process
- **Duke**: validated the VPHP process and post-decontamination performance
CCDS™ Webinar Summary

• CCDS™ was developed to address the potential PPE shortfall, with an emphasis on N95 FFR

• The CCDS decontamination approach is based on sound science and the CCDS Research team continues to build a data repository to ensure that the process is safe and effective

• CCDS provides a proven, critical & ready solution for healthcare workers and first responders
More information about Battelle CCDS™ can be found at: www.ccdsfacts.org
Thank you
AORN Webinar Backup
**CCDS™ Marker Study**

- **Study performed to assess the impact of Sharpie markers on FFR**
- **Aerosol Collection Efficiency and Inhalation Resistance**
  - Seven FFR models tested maintained aerosol collection efficiency >95% through 20 VPHP decontamination cycles with black Sharpie writing on them
  - Inhalation resistance was unaffected by the Sharpie writing and VPHP decontamination cycles
- **Decontamination Efficacy**
  - Complete inactivation of SARS-CoV-2
CCDS™ Efficacy on Face Shields

- Battelle has demonstrated the ability to decontaminate other types of PPE, including face shields
- EUA amendment submitted to permit decontamination of face shields is under evaluation by FDA
CCDS™ Efficacy on KN95

- Battelle has evaluated the ability to decontaminate KN95 FFR
- EUA amendment was submitted to permit decontamination of KN95 FFR, but was rejected along with all other potential decontamination techniques
- Risk of counterfeit KN95 was too high
Biological Indicators (BI) versus Chemical Indicators (CI)

- Battelle’s CCDS™ process was developed and verified to decontaminate 6-log (no viable organisms left) *G. stearothermophilus* spores which are the industry standard biological indicator for VPHP processes and for medical device sterilization
- The spores were inoculated by direct liquid droplet (splash) and via aerosol delivery directly onto the N95 filter media
- After decontamination, samples were placed into liquid growth media providing a very conservative method of evaluation
- Samples were grown for 7 days and no viable microorganisms were present
- Other samples inoculated with SARS-CoV-2 virus and verified that the process results in no detection of viable virus after treatment
- BI correlated to CI performance through these tests
Fit Test Results

• Battelle has utilized strap elasticity as a measure of fit, similar to the approach advocated by 3M
• Other fit tests have been performed in support of CCDS™ and as part of the 2015-16 FDA study
• NIOSH has performed testing on manikin head forms as part of their testing
• Fit of a respirator is a dynamic phenomenon with numerous confounding factors that can contribute to a lack of acceptable fit
• In accordance with guidance from NIOSH about the proper use of N95 FFR, Battelle recommends that all users perform a seal check when donning a respirator (new and decontaminated)
• Failed seal check = different N95 FFR
Residual Hydrogen Peroxide

• Several health care providers have reported a rash, sore throat, or localized irritation when donning a decontaminated N95 FFR
• Hydrogen peroxide is an odorless material at concentrations below 30%
  • Equilibrium concentration of hydrogen peroxide vapor over a 30% solution is about 470 pm
• Since N95 FFR are not removed from the chamber until the concentration of hydrogen peroxide is below 0.8 ppm, it is not likely that any of the reports of irritation are due to residual hydrogen peroxide
Odor on Decontaminated N95 FFR

• Several health care providers have reported an objectionable odor when donning a decontaminated N95 FFR
• Battelle utilized GC/MS testing to characterize and quantify volatile materials from FFR decontaminated using CCDS™
• Numerous species detected at low levels (ppb and ppt)
  • All species well below safety limits (OSHA PEL and ACGIH TLV)
  • Identified acetaldehyde as the potential source of odor (odor detection limit = 50 ppb)
Soiling of N95 FFR

• The primary reason N95 FFR are rejected on receipt is due to soiling of the FFR
• Due to the unknown interactions of various sources of soiling on decontamination, all N95 FFR with visible soiling are rejected
Hydrogen Penetration through N95 FFR

- The ability of the VPHP to penetrate the full thickness of the N95 materials and affect a 6-log reduction of spores is a critical step to ensure the ability of the CCDS process to be effective.
- A targeted study was performed to demonstrate that hydrogen peroxide penetrates through the entire thickness of the N95 FFR and achieves a 6-log reduction.
  - CI encapsulated in the middle of an N95 FFR so that VPHP must penetrate through the N95 materials to reach the CI cards and elicit a color change commensurate with a 6-log reduction.
Common FAQs

1. Does the decontamination method effectively inactivate the SARS-CoV-2 virus and other pathogens?
   A: Yes. We have verified our process using the SARS-CoV-2 virus on over 25 makes and models of N95s. We were able to achieve complete inactivation of the SARS-CoV-2 viral load on the FFR materials. Research data related to inactivation of other pathogens using VPHP for bio-decontamination is attached to this document.

2. Was testing done on the full N95 respirators, including curves, seams, straps, etc.?
   A: Yes. Research was conducted on entire N95 masks using both a liquid inoculation as well as an aerosol inoculation where the spores were drawn into the FFR to develop the cycle. Results showed that VPHP renders SARS-CoV-2 non-infectious on all areas of the masks. In fact, zero viable SARS-CoV-2 was recovered in test samples post VPHP decontamination.

3. Has testing been done on the impact of decontamination on N95s that have been used by nurses for a full shift or even multiple shifts?
   A: Yes. Battelle is currently working with Massachusetts General Hospital and OhioHealth to test the impact of the CCDS™ process on N95s that had been used by nurses for a full shift and multiple shifts. Nurses use the N95s and send them to a CCDS location for decontamination. Those masks are then sent to our CCDS research team to evaluate. To date (through 10-12 cycles), there is no reduction in filter efficiency or head strap performance for high-wear masks.
Common FAQs (continued)

4. Is there sufficient off-gas time to remove residue which may pose respiratory, skin hazard or odor sensitivity?
A: Yes. Battelle developed the CCDS™ process with an established aeration cycle such that no measurable off-gassing of H2O2 could be detected, and to ensure that residual hydrogen peroxide is below the OSHA permissible exposure limit (PEL) after decontamination (<1ppm). Additional H2O2 off-gassing testing has shown that H2O2 off-gassing does not present a hazard to wearers. Hydrogen peroxide vapor has no smell and is imperceptible at concentrations below <200 ppm. After aeration, VPHP levels are well below this limit on our FFR at <.8 ppm. Further, this level is well below the odor detection limit and is also well below the levels where health effects are noted (per the Agency for Toxic Substances and Disease Registry (ATSDR), https://www.atsdr.cdc.gov/MMG/MMG.asp?Id=304&tid=55).

5. Other studies have examined decontamination methods (such as the ASP method that uses vaporized hydrogen peroxide) and found that N95 performance is impacted after just a few cycles.
A: The CCDS™ process (VPHP) is very different from ASP type process (hydrogen peroxide gas plasma) which is known to impact N95s in a negative way, which is why they can only use it for 2-3 cycles. The VPHP process that Battelle selected for the CCDS system should not be confused with hydrogen peroxide gas plasma which is common in most large hospital systems.

Research conducted by external organizations indicate that alternative decontamination approaches, including moist heat, microwave generated steam and UVGI resulted in substandard pathogen inactivation and damage to FFRs, making them unsuitable for reuse.
Research Reports on VPHP Effectiveness

Vapor phase hydrogen peroxide (VPHP) has been shown to kill a wide range of bacteria and viruses.


   https://journals.sagepub.com/doi/10.1177/153567601101600101

   https://journals.sagepub.com/doi/10.1177/153567601001500105

4. **MRSA**
   https://www.journalofhospitalinfection.com/article/S0195-6701(07)004094/fulltext?mobileUi=0