



WARNING » BATTELLE N95 DECONTAMINATION SYSTEM IS NOT SAFE AND MAY NOT WORK

National Nurses United (NNU), the largest labor union for registered nurses in the United States, has examined the available evidence and warns that decontaminating and reusing N95 filtering facepiece respirators is unsafe.

Given reports of shortages of personal protective equipment (PPE), many hospitals and other health care employers have turned to reusing N95 filtering facepiece respirators designed for one-time use, including implementing decontamination methods to reuse respirators multiple times. And many employers are implementing N95 decontamination processes as an ongoing normal practice. This is unacceptable.

NNU has evaluated the available evidence on decontamination methods and determined that **NO METHOD IS BOTH SAFE AND EFFECTIVE.** For an N95 decontamination method to be safe and effective, it must meet three criteria »

1. It must effectively inactivate the pathogen.
2. It must not degrade the performance of the respirator including filtration, structural integrity, and face seal.
3. It must not introduce an additional hazard to the worker wearing the respirator.

Battelle's Critical Care Decontamination System was the first N95 decontamination method to be issued an emergency use authorization by the U.S. Food and Drug Administration (FDA). The U.S. federal government has issued a \$400 million contract to make Battelle's systems available across the country.¹

Battelle's process uses vaporized hydrogen peroxide to "decontaminate" N95 respirators. Tens of thousands of N95s are placed inside a container and hydrogen peroxide is vaporized into the container. The N95s remain in the chamber for a period of time. They are then removed and returned to the originating health care facility.²



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National Nurses United has reviewed documentation from Battelle and expresses the following concerns that Battelle's process has not been shown to be safe nor effective »

1. Does Battelle inactivate SARS-CoV-2 as well as other pathogens of concern in health care?

- » Battelle provides insufficient evidence to fully answer this question.
 - › Battelle states that they have verified their process on SARS-CoV-2 but the tests they used are insufficient. They tested their method on small cut-outs of the N95 filter material. This means they did not test the efficacy of their method on the straps, nose clip, folds and seams, foam, and other parts of a whole N95.
 - › Battelle cites several additional studies to show the efficacy of their process on other pathogens, but many of these studies actually used a different method (STERIS) and may not be fully comparable to Battelle.
 - › While hydrogen peroxide likely kills SARS-CoV-2 under some conditions, it is not clear whether Battelle's method kills SARS-CoV-2 present in and on N95 respirators.
- » We have several concerns about Battelle's methodology:
 - › Are hydrogen peroxide levels even throughout the chamber? Battelle put chemical indicators in 4 corners and 1 in center during their validation tests, according to their technical bulletin, but that may be insufficient given the size of these operations.
 - › Battelle's photos show inconsistent placement of the N95 respirators. Other studies have found the orientation of the N95s to be important to whether the hydrogen peroxide reaches all surfaces.³ Battelle states

that placement is not a factor, but does not seem to have evaluated this part of their process.

- › How well does Battelle's method inactivate pathogens trapped within the N95 filter media? Battelle has not evaluated this.

2. Does the decontamination method impact fit, filtration, structural integrity, performance of N95s?

- » Battelle has not evaluated the impact of their decontamination method on N95 respirators that have been previously used. They are currently experimenting on nurses and other health care workers without their consent.
 - › What is the impact of Battelle's method on an N95 that has been worn for several hours or several shifts? In their studies to show that their method was safe, Battelle tested only new and unused N95 respirators. This data does not reflect the ways that Battelle's method will be used in the real world.
 - › Each time a respirator is put on and taken off we know there is some degradation. Straps, nose clips, and other parts can fail with repeatedly putting on and taking off an N95. Decontamination may degrade already-used N95s to the point that they no longer provide protection.
 - › Battelle states that they are currently gathering real-world information. It is concerning to us that this data was not gathered before Battelle started selling their system. This means, in effect, that Battelle is experimenting on health care workers without their consent.

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- » Battelle’s process may degrade N95 filtration, fit, and performance.
 - › Battelle maintains that their process does not degrade the N95 for up to 20 decontamination cycles. However, other studies have used methods similar to Battelle’s and found that N95 performance is impacted after two or three cycles.⁴
 - › Battelle uses a physical and visual inspection to determine whether respirators are impacted by the decontamination process. But you cannot tell just by looking if the N95 filter or fit has been degraded. This is like if a car mechanic just looked at the outside of your car and said it looks fine.
 - › N95 models vary in structure, material composition, characteristics, etc. Data from tests on specific N95 models may not apply to other models. So far, Battelle has only tested a few dozen models.
 - › Battelle’s own research showed degradation of N95s after decontamination:
 - » One model’s elastic straps were elongated and degraded (textured surface).
 - » Another model had a char-like odor after decontamination.
 - » A third had a hard, brown spot that appeared after decontamination. Battelle did not investigate and deemed this N95 good-to-go.
 - » Other models had bad fit testing results and wearers reported feeling air leakage around the nose (which means the N95 didn’t seal fully to the wearer’s face and therefore should not have passed a fit test).
 - › The methods that Battelle uses to test the filtration of N95 respirators after decontamination do not measure whether the N95 respirators filter very small particles in the size range of viruses (less than 100-150 nanometers).
- 3. Does wearing a decontaminated N95 pose a risk to the wearer?**
- » Yes.
 - » Hydrogen peroxide vapor is toxic and highly dangerous to breathe in.⁵ It is a colorless and odorless gas, which means that traces of off-gassing may not be detected by the wearer, making it difficult to protect themselves.
 - » The U.S. Agency for Toxic Substances & Disease Registry (ATSDR) states for hydrogen peroxide: “Detection of odor does not provide adequate warning of hazardous concentrations.”⁶
 - » Hydrogen peroxide residue on and in the N95 respirator may pose respiratory and skin hazards.
 - » Can hydrogen peroxide be trapped between layers of the N95? And can this result in off-gassing later? Battelle states that they conduct some tests during the decontamination process to ensure that off-gassing does not occur. But health care workers report headaches, odor sensitivity, and other symptoms when wearing decontaminated N95s.
 - » Symptoms of hydrogen peroxide exposure include »
 - › Headache, dizziness, nausea.
 - › Airway irritation.
 - › Hoarseness and shortness of breath.
 - › Sensation of burning or tightness in the chest.
 - › Skin irritation and burns.

Instead of turning to dangerous decontamination and reuse practices, employers should be proving nurses and other health care workers the safe workplaces they deserve.

Employers are legally and morally obligated to provide a safe and healthful workplace to employees. To prevent exposure to and transmission of COVID-19, health care employers must implement comprehensive precautions, based on the precautionary principle that states that we do not wait for scientific proof of harm before taking action to protect people's health.

- » Health care employers must implement engineering controls, including prompt screening and isolation procedures, designated COVID-19 units, and converting rooms, units, floors, or entire facilities to negative pressure, where possible. See NNU's model standards for hospitals for more information: <https://bit.ly/NNU-COVID19-SurgeStandards>.
- » PPE should be of the highest standard, based on the precautionary principle, and should include a powered air-purifying respirator (PAPR) and coveralls that include both head and shoe covering, and gloves.

- » Under no circumstances, should nurses and other health care workers be provided less than a minimum of N95 filtering face piece respiratory protection when caring for patients with suspected or confirmed COVID-19, in addition to other necessary PPE.

Where N95 respirators are truly not available, employers should turn to PPE designed to be reusable and decontaminated safely, including powered air-purifying respirators (PAPRs) and elastomeric respirators.⁷

ENDNOTES

- 1 <https://www.battelle.org/newsroom/news-details/battelle-lands-400m-federal-contract-to-decontaminate-n95-masks-for-hospitals-in-more-cities>
- 2 <https://www.battelle.org/inb/battelle-critical-care-decontamination-system-for-covid19>
- 3 Duke University https://www.safety.duke.edu/sites/default/files/N-95_VHP-Decon-Re-Use.pdf
- 4 Fischer et al. reported testing a vaporized hydrogen peroxide method at approx. 1000 ppm for 7 min and found that N95 fit factor was unacceptably impacted after 3 decontamination cycles. Battelle's process operates at 750-1000 ppm for 2.5 hours. Fischer, Robert et al. "Assessment of N95 respirator decontamination and re-use for SARS-CoV-2," *medRxiv*, April 24, 2020, <https://www.medrxiv.org/content/10.1101/2020.04.11.20062018v2>
- 5 <https://www.atsdr.cdc.gov/mmg/mmg.asp?id=304&tid=55>
- 6 <https://www.atsdr.cdc.gov/mmg/mmg.asp?id=304&tid=55>
- 7 The U.S. Occupational Safety and Health Administration wrote in their guidance document that "when disposable N95 filtering facepiece respirators are not available, consider using other respirators that provide greater protection and improve worker comfort," including "a R/P95, N/R/P99, or N/R/P100 filtering facepiece respirator; an air-purifying elastomeric (e.g., half-face or full-face) respirator with appropriate filters or cartridges; powered air purifying respirator (PAPR) with high-efficiency particulate resistance (HEPA) filter; or supplied air respirator (SAR)." U.S. Occupational Safety and Health Administration (2020), "Guidance on Preparing Workplaces for COVID-19," online at <https://www.osha.gov/Publications/OSHA3990.pdf>