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<b>[COVID-19] Decontamination of N95 Respirators: FDA Recommends Transition from Use of Decontaminated Disposable Respirators [ECRI Exclusive User Experience Network] [Update]</b>		

## Summary

Update Reason: This Alert provides new information regarding FDA's recommendations to transition away from crisis capacity conservation strategies for disposable respirators. For ECRI's previous coverage on this topic, see Special Reports [S0394](#) and [S0394 01](#).

## Problem

1. Healthcare facilities dealing with COVID-19 have faced shortages of single-use N95 respirators.
2. Extended use and reuse of single-use N95 respirators may increase healthcare worker exposure to the virus, as compared to using new N95 respirators for each patient interaction.
3. Many facilities have decontaminated single-use N95 respirators using various methods, including UV light, in order to prolong the usable life of N95 respirators and alleviate crisis capacities of PPE.
4. FDA now recommends that healthcare personnel and facilities transition away from crisis capacity conservation strategies for disposable respirators, such as decontaminating or bioburden reducing for reuse.

### ECRI Recommendations:

If your facility is not currently facing crisis capacities of N95 respirators:

1. Follow CDC guidance for conventional or contingency capacity strategies for appropriate management of N95 respirators, as appropriate to your facility's situation.
2. Do not use UV light or other decontamination methods.

If your facility is facing crisis capacity shortages of N95 respirators:

1. Follow CDC and NIOSH guidelines for optimizing your N95 respirator supply, including administrative controls, and extended use and limited reuse of respirators as appropriate ([CDC 2020](#)<sup>1</sup>, [NIOSH 2018](#)<sup>2</sup>).
2. Consider whether your facility's needs can be met using the CDC's strategy for a five-day rotation schedule to reduce the risk of self-contamination when reusing N95 respirators.

If your facility is facing crisis capacities and chooses to decontaminate N95 respirators between reuses:

1. Determine what level of restriction on N95 reuse your facility is prepared to commit to (FDA<sup>3</sup>):
  1. No restrictions – Consider decontamination approaches that have:
    1. Received FDA Emergency Use Authorization (EUA) for decontamination of N95 respirators for multiple users (Tier 1), or
    2. Otherwise demonstrated an ability to achieve a greater than 6-log reduction of highly resistant organisms.
    3. Vaporized hydrogen peroxide decontamination approaches may meet this need.
  2. "Single-user" approach, meaning that the same person would wear the N95 before and after decontamination - Consider decontamination approaches that have:
    1. Received EUA for decontamination for single users (Tier 2), or
    2. Otherwise demonstrated an ability to achieve a greater than 6-log reduction of moderately resistant organisms.
    3. Vaporized hydrogen peroxide decontamination approaches may meet this need. Some UV disinfection devices may also have testing data to support this approach.

3. Single-user approach and continuing to follow CDC guidelines for reuse of N95 respirators – Consider decontamination approaches that have:
  1. Received EUA for decontamination consistent with these restrictions (Tier 3), or
  2. Otherwise demonstrated an ability to achieve a greater than 3-log reduction of moderately resistant organisms.
  3. UV decontamination may be reasonable to consider under these circumstances.

If your facility chooses to implement decontamination of N95s using a device or approach that has received an EUA:

1. Confirm that N95 models used in your facility are compatible with the selected decontamination method. For example, N95s with cellulose may be degraded by vaporized hydrogen peroxide decontamination.
2. Follow the decontamination device instructions for use.

If your facility chooses to implement UV decontamination of N95s using a device that has not received an EUA:

1. Continue to follow CDC guidelines for limited reuse of respirators:
  1. Discard N95 respirators following use during aerosol generating procedures.
  2. Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
  3. Perform hand hygiene before and after touching or adjusting the respirator.
  4. Store used respirators properly, according to CDC guidelines, such as in a breathable paper bag.
  5. Assign only one wearer per respirator to reduce the risk of secondary exposure.
2. Consider developing a protocol for implementation of UV decontamination. The protocol may include:
  1. Before first use, label the respirator strap with the wearer's name.
  2. After use of a respirator, follow protocol for doffing. Avoid touching the interior surface.
  3. Place the respirator in a paper bag, marked to identify the wearer, for transport to a UV decontamination location.
  4. UV decontamination device operators should wear appropriate PPE (i.e., gloves, gown, respirator) when handling respirators. They should also take care to avoid touching the interior surface of the respirators.
  5. For decontamination using a purpose-built UV N95 decontamination device:
    1. Follow manufacturer recommendations for proper use of the device. Aim to achieve a UV dose of at least 500 mJ/cm<sup>2</sup>.
  6. For decontamination using countertop UV disinfection systems:
    1. Place the respirator in the device. Duckbill respirators that fold flat should be propped open to enable sufficient surface exposure.
    2. Follow the UV device manufacturer's recommendations for disinfection cycle time.
      1. Aim to achieve a UV dose of at least 500 mJ/cm<sup>2</sup>.
      2. Extended or multiple disinfection cycles may be required, since typical disinfection cycles (30 seconds to 2 minutes) are intended to deliver about 50 mJ/cm<sup>2</sup>. Discuss with the manufacturer whether long cycle options are available or can be enabled.
  7. For decontamination using UV room disinfection systems (towers):
    1. Hang respirators in the center of a clean, empty storage area. Place a UV room disinfection device 5 feet in front of the respirators.
      1. Space respirators appropriately. Do not allow them to touch one another.
      2. Be aware of the distance between each respirator and the UV device. If the distance increases beyond about 7 feet (about 45° angle from the UV device), longer cycle times may be required to achieve the desired dose.
      3. Ensure that each respirator has a clear line of sight to the UV device. Duckbill respirators that fold flat should be propped open to enable sufficient surface exposure. Attempt to limit shadowing that may reduce the UV dose that reaches the surface of the respirator.
    2. When enough respirators are present, run a disinfection cycle for at least 5 to 15 minutes (depending on the device), or as recommended by the UV device manufacturer. High-powered devices may achieve a 500 mJ/cm<sup>2</sup> dose in 5 minutes; lower-powered devices may require 15 minutes to achieve the recommended dose.

3. Move the device to the opposite side of the respirators, and repeat the cycle to ensure that the inside and outside surfaces of the respirator are disinfected.
8. Follow CDC protocol for donning reused respirators. Wear gloves, and perform hand hygiene before and after donning.
9. Inspect respirators before UV decontamination and before each reuse. Discard respirators that:
  1. Are soiled
  2. Are damaged (e.g., torn, discolored)
  3. Do not fit properly
  4. Are difficult to breathe through
  5. Have reached the maximum number of uses recommended by the N95 respirator manufacturer or were used a maximum of 5 times ([NIOSH 2018](#)).

## Background:

1. In an April 9, 2021, [Letter to Health Care Personnel and Facilities](#), FDA states that it is recommending healthcare personnel and facilities transition away from crisis capacity conservation strategies for disposable respirators, such as decontaminating or bioburden reducing for reuse (see [Hazard H0684](#)).
  1. Based on the increased domestic supply of new respirators approved by the Centers for Disease Control and Prevention's (CDC's) National Institute for Occupational Safety and Health (NIOSH) currently available to facilitate this transition, FDA and CDC believe there is adequate supply of respirators to transition away from the use of decontamination and bioburden reduction systems.
  2. However, FDA is currently not revoking the emergency use authorizations (EUAs) for decontamination and bioburden reduction systems.
2. N95 respirator manufacturers state that their products are intended for single-use. Due to regulatory restrictions related to device labeling, manufacturers of single-use N95s cannot recommend decontamination of their products. However, some manufacturers have been investigating the compatibility of their products with various decontamination methods. Refer to the manufacturers of your N95 models for product specific information on compatibility and durability.
3. Decontamination of N95 respirators before reuse is not required, according to CDC guidelines for contingency and crisis strategies.
  1. Extended use is preferred over limited reuse, because it provides lower risk of self-inoculation or transmission due to touching of the respirator. (NIOSH<sup>2</sup>, Fisher<sup>4</sup>)
  2. Decontamination may reduce the risk of self-inoculation when limited reuse is required. Risk factors for self-inoculation include (Fisher 2014<sup>4</sup>):
    1. Number of pathogens on the surface of the respirator
    2. Pathogen survival on the respirator
    3. Transfer efficiency of pathogens from the respirator surface to the hands or skin of a healthcare worker
3. CDC states that:
  1. The first strategy to reduce contact transmission of pathogens is to issue each healthcare worker five N95 respirators, to be used in a five-day rotation cycle. This cycle should allow at least five days of downtime, exceeding the expected three-day persistence of SARS-CoV-2 on surfaces.
  2. "If supplies are even more constrained and five respirators are not available for each worker who needs them, N95 FFR limited reuse with FFR decontamination may be necessary." (CDC<sup>5</sup>)
  3. "Fit performance during limited reuse, including decontaminated FFRs, should be monitored by the respiratory protection program manager or appropriate safety personnel."
  4. "As soon as new supplies can meet the projected demand, all reuse and decontamination of respirators should be discontinued. FFRs should only be reused when operating at crisis capacity due to the inability of FFR supplies to meet the burn rate."
4. During an August 5 [ECRI webcast](#), approximately 37% of survey respondents reported using UV light to decontaminate N95 respirators in some capacity. Another 27% reported using hydrogen peroxide decontamination (but not UV light).
5. Effectiveness of UV decontamination:
  1. Studies have shown that UV decontamination may be effective against influenza strains on the surface of N95 respirators. (Mills<sup>6</sup>, Heimbuch<sup>7</sup>, Lore<sup>8</sup>, Heimbuch 2019<sup>9</sup>)
    1. These studies did not test all models of N95 respirators, but included many common models.

2. These studies did not assess the penetration of organisms into the N95 respirator, or the effectiveness of UV light at different layers.
2. Based on data available for other coronaviruses (Walker<sup>10</sup>, Weiss<sup>11</sup>, Duan<sup>12</sup>, Kariwa<sup>13</sup>), ECRI has calculated (Kowalski book<sup>14</sup>) that a dose of 18 mJ/cm<sup>2</sup> at 254 nm wavelength may be sufficient to achieve a 3-log reduction of SARS-COV-2 on smooth surfaces.
3. Based on data from Fisher<sup>15</sup>, UV light reaching the internal filter layers of N95 respirators, where airborne viruses are likely to be caught, may be dramatically reduced.
  1. Depending on the respirator model, 0.25% to 31% of UVC light may penetrate to the filter layers.
  2. A surface-dose of 59 mJ/cm<sup>2</sup> to 7,000 mJ/cm<sup>2</sup> may be sufficient to achieve a 3-log reduction in SARS-COV-2 at the internal filter layers.
4. CDC guidelines state that:
  1. "Pathogens captured by the FFR's electret filtering layer are not readily dislodged due to the attractive forces between the particles and the electret filtering media. Physical contact with the filtering layer by the wearer is unlikely due to its location within the FFR. The outer surface, the surface furthest from the wearer's face, presents the highest risk for pathogen transfer to the wearer."<sup>5</sup>
  2. "The most significant risk is of contact transmission from touching the surface of the contaminated respirator."<sup>2</sup>
  3. "...in microbial transfer and reaerosolization studies more than ~99.8% [of respiratory pathogens] have remained trapped on the respirator after handling or following simulated cough or sneeze."<sup>5</sup>
5. The FDA provides guidance on overall organism inactivation, but does not currently address questions regarding what level of pathogen inactivation is required at the surface versus at internal filter layers (FDA<sup>3</sup>).
6. ECRI previously recommended doses of ≥60-500 mJ/cm<sup>2</sup> based on calculated dose requirements and available device capabilities. Evolving guidance from the FDA and CDC suggest that a goal of ≥3-log reduction in organisms is appropriate, and that doses of ≥500 mJ/cm<sup>2</sup> have been shown to be effective. Lacking data demonstrating effectiveness at lower doses, we now believe that a recommendation of ≥500 mJ/cm<sup>2</sup> is achievable and in line with federal guidelines.
7. Recommendations from other organizations:
  1. [CDC](#):
    1. Does not make recommendations
    2. Previously referenced studies showing that (although this [web page](#) has now been archived, and ECRI believes that the studies referenced are still relevant and informative):
      1. N95 respirators exposed to UV doses of 500 to 950,000 mJ/cm<sup>2</sup> have passed filtration performance and fit tests.
      2. UV doses of 500 to 1800 mJ/cm<sup>2</sup> have demonstrated at least a 3-log reduction of various viruses relevant to the SARS-CoV-2 pandemic.
  2. [N95 Decon](#):
    1. Recommend a surface dose of at least 1000 mJ/cm<sup>2</sup> to achieve a >3-log reduction in SARS-CoV-2 analogues based on published literature.
    2. [Joint Guidance with APIC](#) including standard operating procedures (SOP) to guide implementation of a policy.
  3. University of Nebraska has developed a [protocol for UV disinfection](#) of N95 respirators. This protocol has been widely publicized by news media.
    1. This protocol originally recommended a UV dose of 60 mJ/cm<sup>2</sup>, but has since updated their recommendations to a UV dose of at least 300 mJ/cm<sup>2</sup>.
    2. The protocol also recommends use of white ("clean") paper bags for returning N95 respirators to service, and brown ("dirty") paper bags for used N95 respirators.
8. Respirator Degradation:
  1. Studies have shown that very high doses of UV exposure may degrade N95 respirators.
    1. The first signs of meaningful degradation are likely to be visible: weakening of materials (e.g., tears) and loss of elasticity of straps that may lead to poor fit. (Lindsley<sup>16</sup>)
    2. Filtration effectiveness and air flow resistance were slightly degraded, but typically not to a meaningful level. Most N95 respirators were still able to pass NIOSH requirements for 95%

filtration after exposure to very high UV doses. (Lore<sup>8</sup> 1800 mJ/cm<sup>2</sup>, Lindsley<sup>16</sup> 120,000 mJ/cm<sup>2</sup>)

2. The UV dose that ECRI and the other cited organizations recommend are unlikely to cause meaningful degradation, even after repeated cycles. (Lindsley<sup>16</sup>)
  3. Each respirator model is composed of different materials, and some models may be more susceptible to damage than those previously studied.
  4. When UV decontaminating and reusing N95 respirators, users should inspect the respirator for signs of damage or poor fit before each use. Damage and poor fit are expected outcomes of normal use, even without decontamination.
9. Consider the limitations of UV disinfection:
1. Each UV disinfection cycle increases the likelihood of material degradation.
  2. Each reuse increases the likelihood of exposure (e.g., through touching a contaminated respirator) and poor fit (e.g., due to physical damage or stress).
  3. Each subsequent reuse of a respirator provides diminishing returns.
    1. A single disinfection-and-reuse approximately doubles your supply of N95 respirators.
    2. A second disinfection-and-reuse gives you 50% more supply than a single reuse.
    3. A third disinfection-and-reuse gives you 33% more supply than reusing twice.
  4. Weigh the risks and benefits of disinfection-and-reuse.
10. In response to COVID-19, ECRI has seen the introduction of many products that are specifically designed for decontamination of N95 respirators.
1. These devices may have advantages for this purpose, including:
    1. High intensity UV light
    2. Reflective surfaces intended to reduce the risk of shadowing on the N95 surface
    3. Fast cycle times
    4. Relatively low cost, compared to tower systems
  2. They are frequently designed to deliver high doses and may reduce the labor of decontamination.
  3. However, these devices are new to market, and do not have a long history of use. Some manufacturers may not have experience or expertise in designing UV disinfection technologies. Review available evidence supporting use of the device before purchasing.

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## UMDNS Term(s)

Respirators, Air-Purifying, Particulate [20359]

## Geographic Region(s)

Worldwide

## Suggested Distribution

Infection Control, Risk Management/Continuous Quality Improvement, Materials Management

## Comment

- This alert is a living document and may be updated when ECRI receives additional information.