

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Michigan State University (MSU) Decontamination System, operated by the MSU Animal Care Program, that delivers vaporized hydrogen peroxide from Halosil HaloFogger FLX machines for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel (HCP) in healthcare facilities to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic. HCP must follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the MSU Decontamination System.

The MSU Decontamination System is authorized to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, for a maximum of 3 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 pandemic. The MSU Decontamination System has not been FDA approved or cleared for this use. FDA authorized the MSU Decontamination System for emergency use for the duration of the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3b(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (<u>https://wwwn.cdc.gov/niosh-cel/</u>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

- The MSU Decontamination System is not authorized for use with the following:
 - Respirators containing cellulose-based materials;
 - o Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - o Respirators containing duck-billed design; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- All compatible N95 respirators used in the MSU Decontamination System must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).

- Compatible N95 respirators that are visually soiled or damaged will not be collected for decontamination and must be discarded.
- Compatible N95 respirators may be decontaminated up to 3 times.
- If there is any breakdown of elastic bands or failure of form fit-testing after decontamination, do not use the respirator and discard.
- Any compatible N95 respirators with illegible markings to indicate the number of decontamination cycles completed must be discarded.
- Decontaminated, compatible respirators are not sterile.

Materials Needed:

- Paper bags that can be closed over for individual compatible N95 respirator placement after shift work
- Permanent marker to mark name and healthcare unit/station on compatible N95 respirators

Compatible N95 Respirator Marking, Collection, and Return:

- 1. Discard the mask if it has been decontaminated 3 times (which is after the 4th use).
- 2. Maintain **chain of custody** on your compatible N95 respirator to minimize risk of crosscontamination.



identification of compatible N95 respirators.

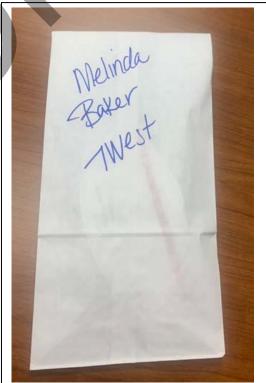


Figure 2. Chain of custody identification on paper-bagged compatible N95 respirator.

- 3. Label with your name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside OR inside of each N95 respirator, as shown above.
- 4. Confirm that the labeling is legible, and that there is no visible damage or soil/contamination prior to bagging the compatible N95 respirator.
- 5. Place your respirator in the paper bag provided by your healthcare facility and fold it. Place the bagged respirator at the healthcare facility's designated collection station. **NOTE: Paper bags** are for compatible N95 respirators only. Do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.
- 6. After receiving your decontaminated, compatible N95 respirator, please check to ensure that the respirator returned to you has your name and/or appropriate identifier on it. You must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.

If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator after exceeding 3 decontamination cycles. The Operator Team who completed the decontamination for your healthcare facility already placed a tick mark (maximum 3 times) with permanent marker on the elastic band of the decontaminated compatible N95 respirator to indicate completion of each VHP exposure.