Instructions for Healthcare Facilities and Operator Teams: Emergency Use of the MSU System for Decontamination and Reuse of Compatible N95 Respirators with Vaporized Hydrogen Peroxide

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 in healthcare facilities to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic. Healthcare personnel 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 healthcare personnel 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 authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) 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;
  - Respirators containing exhalation valves;
  - Respirators containing antimicrobial agents;
  - 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.

NOTE: MSU staff within Campus Animal Resources are solely responsible for set up of the HaloFogger equipment and chemical and biological indicators within the MSU facility. MSU Staff are also solely responsible for verifying successful VHP exposure with chemical indicators, initiation of the post-cycle exhaust phase, and verifying successful decontamination with biological indicator results.

NOTE: Operator Teams are healthcare and safety personnel who work for the healthcare facility. They are trained by MSU in the preparation, transportation, and initiation of the decontamination of compatible N95 respirators using the MSU Decontamination System at the MSU facility in accordance with this EUA. Operator Teams previously have been trained in sterile technique, donning/doffing of PPE, and understanding of clean-to-dirty personnel traffic (e.g., sterile supply technicians, medical technicians).

Materials Needed and Supplied by the Healthcare Facility:

- Biohazard waste-size bags for batching of paper-bagged compatible N95 respirators
- Plastic carrying tote bin for vehicular transport of batched materials
- Permanent marker to mark decontamination cycle number on compatible N95 respirators as hash marks on the strap.
- Plastic clear bags for collection of decontaminated, compatible N95 respirators to visualize names and return to original user

Compatible N95 Respirator Marking and On-Site Collection:

1. Healthcare facilities must ensure that **chain of custody** is maintained to minimize risk of cross-contamination. HCPs will have already inspected and self-labeled their contaminated compatible N95 respirators using permanent marker with employee name prior to collection process.
2. The healthcare facility will create a collection site at the point of generation (i.e., hospital floor/unit) to gather compatible N95 respirators into individual paper bags, also individually labeled by staff. **NOTE: Paper bags are for compatible N95 respirators only.**

Figure 1. Chain of custody identification

3. Paper-bagged compatible N95 respirators are to be placed in biohazard containers (red bag style) that are tied closed, labeling with the originating area (e.g., healthcare unit number), placed into a secondary plastic bin with lid that fastens securely for vehicular transport to MSU. **NOTE: The healthcare facility is responsible for maintaining the chain of custody.**

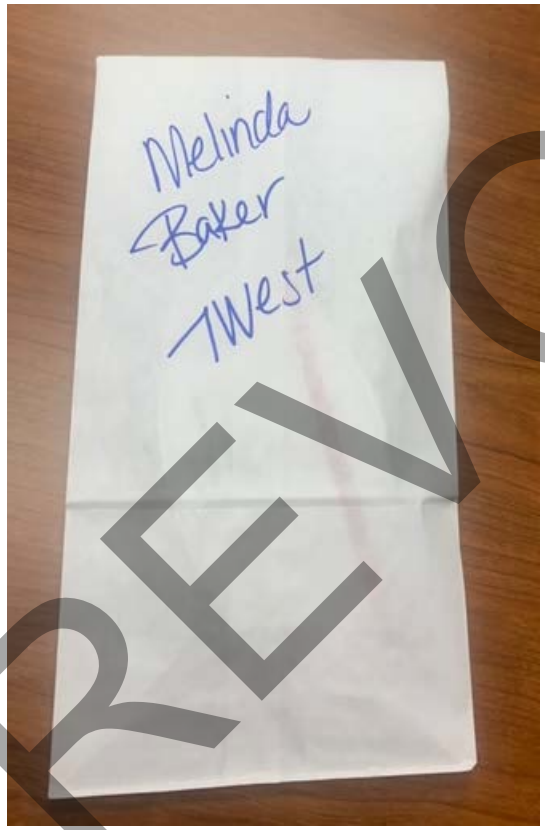


Figure 2. Chain of custody identification on paper-bagged compatible N95 respirator

Reuse Information:

Following decontamination, the healthcare facility will be provided with **decontaminated, compatible N95 respirators** that have been decontaminated using the MSU Decontamination System for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

The decontaminated, compatible N95 respirators will be redistributed to the healthcare personnel in their respective healthcare facilities.

Before reuse, the healthcare facility must inspect each returned, decontaminated, compatible N95 respirator for:

1. Numeric indication that the decontamination cycle number is 3 or less. **NOTE: Compatible N95 respirators are only to be decontaminated up to 3 times and then must be discarded after use. The Operator Team places a tick mark with permanent marker on the elastic band of each decontaminated compatible N95 respirator to indicate completion of each VHP exposure.**
2. Visible damage or soiling. **NOTE: Compatible N95 Respirators must be discarded and not reused if visually damaged or soiled.**

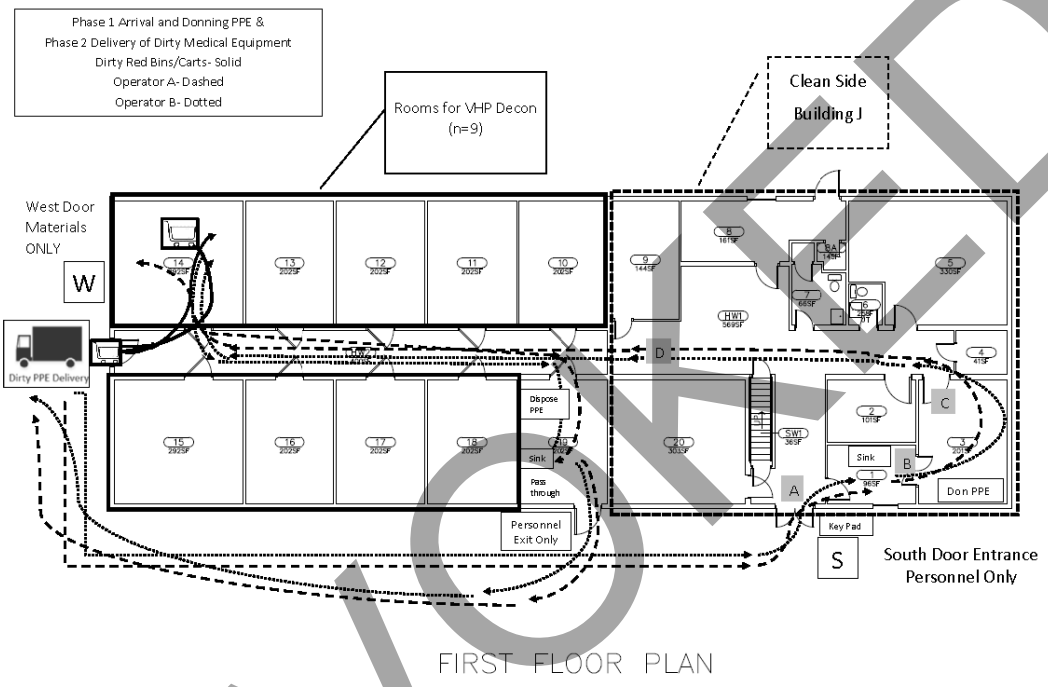
Transfer of Compatible N95 Respirators to MSU Decontamination Facility by Operator Teams:

IMPORTANT NOTE:
Operator teams must bring their own fit-tested N95 respirators to the MSU facility for personal use; additional PPE will be available at the MSU facility.

1. To initiate potential agreement and schedule availability for vaporized hydrogen peroxide decontamination of compatible N95 respirators, the healthcare facility must contact the Director of Campus Animal Resources (CAR) through email to carinfo@msu.edu.
2. Operator Teams that are transferring the collected compatible N95 respirators to the facility for decontamination must bring their own N95 respirators, for which they have been fit-tested, to the site for personal use; additional PPE (disposable shoe covers, gowns, gloves, etc.) will be available at the facility.
3. Building J at MSU is divided into designated soiled and clean sides with designated ingress and egress routes. Operator teams are not to deviate from the procedures on which they will be trained by MSU staff, so that the facility remains pathogen-free for all persons and capable of safely processing compatible N95 respirators from hospitals for decontamination and return.

PROTOCOL FOR VAPORIZED HYDROGEN PEROXIDE EXPOSURE OF COMPATIBLE N95 RESPIRATORS AT MSU BLDG J BY OPERATOR TEAMS

NOTE: Operator Teams are to work in teams of two (Operator A and Operator B)



FIRST FLOOR PLAN

Figure 3. Floor plan of the MSU facility for decontaminating compatible N95 respirators.

STEP 1: PLACE MATERIALS INSIDE OF BUILDING

- **Park at WEST end of BLDG J, outside of door 'W'; leave contaminated N95 respirators in vehicle with Operator B.**
- **Operator A will walk around building on the outside, to enter through main card accessible 'S' SOUTH door of BLDG J.**
- **Immediately after entry through door 'S', turn right through door 'A' into Rm 1. After washing hands (Rm 1) and donning clean PPE (Rm 3 - N95, gown, double layer of gloves, eye protection), Operator A will exit Rm 3 through door 'C' to central hallway and proceeds left through door 'D'. DO NOT RE-ENTER through door 'D'.**
- **Operator A will get a cart from assigned room and walk down main hallway to open WEST DOOR. Operator A must hold 'W' door open while standing inside facility and Operator B will place sealed transport container of contaminated N95 respirators on wheeled cart.**
- **Operator B will then enter through SOUTH DOOR to wash hands and don clean PPE (N95, gown, double layer of gloves), then walk down main hall to meet with Operator A.**

STEP 2: PLACEMENT OF CONTAMINATED N95 RESPIRATORS WITHIN ASSIGNED ROOM

Operators enter the assigned room, leave the sealed transport container in the cart in the middle of the room and close the room door.

NOTE: All housing rooms are negative airflow to the main hallway, such that air will flow into the rooms and contain potential pathogens away from the hallway space.

STEP 3: PREPARING TO UNPACK CONTAMINATED COMPATIBLE N95 RESPIRATORS

Operators stand on either side of the transport container and position themselves adjacent to separate storage racks so there is no contact between Operators and no crossover of both Operators placing materials on the same rack simultaneously.

Only double-gloved hands are to contact the soiled compatible N95 respirators as they are removed from the transport container.

STEP 4: UNPACKING CONTAMINATED COMPATIBLE N95 RESPIRATORS

Operators alternate removal of one compatible N95 respirator at a time from transport container within assigned room; movements are to be steady and efficient without rushing. Operators are not to disrupt or touch any of the biological indicators or paper chemical indicators that were pre-placed in the room by MSU staff.

STEP 5: PROPER PLACEMENT OF CONTAMINATED COMPATIBLE N95 RESPIRATORS ON RACK

Contaminated compatible N95 respirators are to be inspected for holes, tears, and visible soiling prior to placing on racks. Those found to have holes, tears, and/or visible soiling must be discarded. Placement on racks are to be adjacent but not overlapping. The contaminated compatible N95 respirators are to be placed with DOMED surface UP and facing ceiling so the side that would be touching the face is touching the rack.

STEP 6: START HALOFOGGER DEVICE

When all contaminated compatible N95 respirators have been placed on racks, operators must:

- **Leave transport cart and container open to the room so it can be VHP decontaminated.**
- **Place container on top of a rack shelf.**
- **Review placement of respirators on racks to ensure proper placement.**

Operator A will open the room door while Operator B presses the START button on the HaloFogger device. Both Operators will then remove their outer layer of gloves and drop into the cardboard barrel and exit the room within 1 minute of pressing START. Ensure door is shut securely.

STEP 7: TAPE AROUND DOOR FRAME

Operator Teams then take provided tape and run one layer between doorframe and door on all four sides of door as a precautionary measure. Operator Teams will update signage on outside of door to state 'CYCLE' with date and state time.

STEP 8: EXIT PROCEDURE

Remove PPE and discard according to posted signage. Wash hands with soap and water. Exit Pass-through room through EXIT DOOR to the exterior of the building. Prior to departure in vehicle, email MSU (carinfo@msu.edu) that operators have left the building.

MSU Facility appearance after Operator Team prepares compatible N95 respirators for decontamination:

POST VHP CYCLE ACTIONS IN BLDG J BY OPERATOR TEAMS

NOTE: Operators Teams are to work in teams of two (Operator A and Operator B)

STEP 1: ENTER BUILDING AND DON PPE

Email MSU (carinfo@msu.edu) to obtain clearance from MSU to pick-up decontaminated compatible N95 respirators. This is after MSU confirms biological indicator results (72 hours). Only then can Operator Teams remove decontaminated N95 respirators from the facility. Operator Teams can return to pick up items once MSU verifies that all biological indicators are negative and contacts the healthcare facility.

Both Operators enter BLDG J through main card-accessible Door 'S' of BLDG J. Using social distancing practices, proceed one by one through steps below:

- **Immediately after entry through door 'S', turn right through door 'A' into Rm 1 and wash hands at sink. Without touching clean hands to surfaces or doors, exit Rm 1 through swinging doors 'B' into Rm 3 and don clean PPE (surgical mask and gloves only for equipment pick up).**
- **After donning clean PPE, exit Rm 3 through door 'C' and proceed left toward door 'D'.**
- **Once Operator passes through door 'D', DO NOT RE-ENTER back through door 'D'.**

MSU Facility appearance as Operator Team collects decontaminated N95s in plastic bags for return:

STEP 2: GATHER AND MARK COMPATIBLE N95 RESPIRATORS

Once in the room, Operator Teams close the door to the hallway and will gather decontaminated compatible N95 respirators piece by piece;

The Operator Team places a tick mark with permanent marker on the elastic band to indicate completion of each VHP exposure. The Operator Team will then place decontaminated compatible N95 respirators in clear plastic bagging to assist with visualization of original wearer's name to help with chain of custody return at originating site.

NOTE: Only 3 VHP cycles are permitted per compatible N95 respirator; discard compatible N95 respirators with more than 3 hash marks.

STEP 3: MOVING EQUIPMENT OUT OF BLDG J

Operator Teams will put decontaminated compatible N95 respirators into disinfected transport container within room and seal this container closed before leaving room. The transfer container will now be marked as decontaminated. Container must be placed on cart, cart wheeled to door 'W' (where materials were initially brought inside) and door opened to then place the transport container on the ground OUTSIDE on driveway. Do not step out of door 'W' and let it close, as it will lock Operator Teams outside of building.

Operator Teams return cart to original housing room, close room door and write 'EMPTY' with date and time on the signage to room.

STEP 4: EXIT PROCEDURES

Walk along main hallway towards door 'D'. DO NOT go through door 'D'. Before door 'D', turn right into pass-through room. Operators will exit facility through pass-through and dispose of PPE into labeled cardboard barrel before exit. Depart through pass-through exit door to exterior of the building to parked vehicle. Retrieve transport container from outside door 'W' and load decontaminated N95 respirators securely into holding location on-site.

STEP 5: FINAL STEPS

Transport container is to be bagged in clear plastic bag with sticker noting date/time of removal from facility. Before departing BLDG J parking area, Operator Teams are to alert MSU (carinfo@msu.edu) that they have left BLDG J.