



## **Instructions for Michigan State University Staff: 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 (VHP) 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. MSU Staff must follow these instructions to set up the MSU Decontamination System in a room authorized for decontamination of compatible N95 respirators by healthcare facility Operator Teams.

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. 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 (<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).**

## **PREPARATION OF DECONTAMINATION CHAMBER BY MSU STAFF FOR VHP DECONTAMINATION**

### **Materials Needed:**

- HaloFogger FLX (one per room)
- HaloMist fluid to refill HaloFogger reservoir
- Chemical H<sub>2</sub>O<sub>2</sub> indicator strips to be placed throughout room (~5 per cycle)
- 6-log *Geobacillus* biological indicators to be placed throughout room (~4 per cycle)
- Masking tape (2" wide, Granger)
- Plastic sheeting for covering of exhaust vents
- String
- Tape measure
- Step ladder
- Hygrothermometer for recording environmental parameters
- Gloves/splash goggles
- Drager H<sub>2</sub>O<sub>2</sub> meter
- MSU Biological Indicator Culture Form for VHP Decontamination which should be completed

### **PROCEDURES**

#### **I. Preparing a Decontamination Chamber for VHP Decontamination**

1. Ensure supply air shutdown to the housing rooms, in conjunction with campus Facilities Services.

2. Cover the room exhaust vent by measuring vent size with tape measure and cutting plastic sheeting to fully cover vent area.
3. Adhere plastic sheeting over vent using masking tape.
4. Attach a string (minimum of 10 feet in length) to the sheeting by making a hole in the corner of the plastic, threading string through the hole and reinforcing with masking tape.

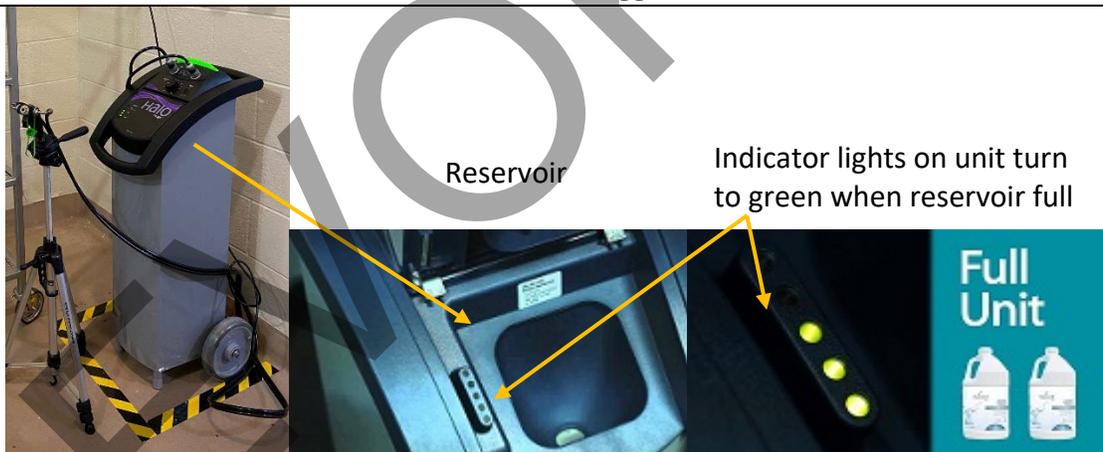
NOTE: This string will be run through the door jamb and pulled once gassing is complete. This allows air to exit the space through the exhaust vent without personnel entering and removing the plastic.

5. Place biological indicators and chemical H<sub>2</sub>O<sub>2</sub> indicators in corners of the room away from the fogger location and across the storage racks on which N95s will be placed. Biological and chemical indicators must be placed at different heights to ensure gas reaches places like high ceilings.

## II. Setting up the Halo fogger

1. Make sure unit is plugged in and power indicator light is green.
2. Confirm unit has HaloMist by referring to the indicator lights on front of the unit.
3. To add HaloMist to the reservoir, wear splash goggles and nitrile gloves.
4. Lift the front cover of the unit and pour liquid into the reservoir until indicator lights turn green.

NOTE: If empty, the indicator light will be red. To fill from empty, the unit requires two gallons of HaloMist. Yellow light indicates the fogger will need more HaloMist soon. Green lights indicate there is sufficient HaloMist in the fogger.



5. Attach the fogger hoses and nozzle.
  - a. Attach hoses in the appropriate orientation. You will hear a click when the connection is made. Attach nozzle to a tripod stand.

NOTE: Hoses have symbols which match up to decals on the unit.

- b. Ensure that the nozzle is pointed at least six feet away from the nearest object and pointed towards a corner.
  - c. Set the **FOG TIME** based on the room assignment (see Table below).
  - d. Tape one chemical indicator, with sensor tip facing toward hallway, on inside of viewing window frame.

Room Number	Floor Size (sq ft)	Room area (cubic ft)	Fog Time (mins)	Fog Dwell time (mins)	Exhaust time (mins)	N95 Respirator capacity per cycle
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10	202	1818	15	240	90	500
11-13	202	1818	15	240	90	700
14-15	292	2628	18	240	90	1000
16-18	202	1818	15	240	90	700

6. Exit the room, ensure string is running through the top of the door jam and out into the hallway. Use tape to seal the entire door and secure the string running through the top the door jam. Close room door and write '**READY**' on white board for room to signify that the room is ready for the next healthcare team to schedule use.

REVOKED

# POST-VHP CYCLE ACTIONS BY MSU STAFF

## STEP 1: ENTER BLDG AND DON PPE

Once the appropriate FOG AND DWELL phases are complete, MSU staff enter BLDG J through door 'S', don routine PPE (N95, disposable shoe covers, gowns, gloves, etc.) in Rm 1 and proceed through door 'D' to room(s) marked as 'CYCLE' by the Health team staff.

## STEP 2: VERIFY VHP EXPOSURE WITHIN ROOM AND START CYCLE 'EXHAUST' PHASE

- Verify that chemical indicator strip placed on viewing window into room has turned from white to black after VHP exposure.
- Remove masking tape from around the door frame and gently pull string toward the hallway to peel back edge of plastic sheeting from exhaust vent within room.
- Verify exhaust vent has been exposed while looking through viewing window; this allows air changes to return to 10-15/hour.
- Write 'EXHAUST' on room door and time started (EXHAUST PHASE MUST BE  $\geq$ 90 min).
- Exit through passthrough door, remove routine PPE, discard PPE according to posted signage, and return to BLDG at end of Exhaust phase.

**IMPORTANT:** During building visit to start EXHAUST cycle; MSU Staff must remove one 6-log Biological Indicator (BI) from facility refrigerator, leaving it unopened, as the control(+). This allows the control BI to warm to room temperature prior to collection of exposed BIs from VHP cycle room.

**NOTE:** If a viewing window indicator remains 'WHITE' - assume that the room has not been exposed to VHP. The fogger cycle will need to be run again. MSU staff will exit through the pass-through, door, return to door 'S' and follow full PPE donning instructions in Rm 1 and 3 to include N95 respirator. They will then enter housing room to assess HaloFogger and reinitiate VHP cycle, including restart to machine and sealing of door with masking tape.

## STEP 3: RE-ENTER BLDG, DON PPE AND PROCEED TO ROOMS

Once the appropriate FOG/DWELL/EXHAUST phases are complete, MSU staff enter BLDG J through door 'S', don routine PPE, retrieve handheld Drager H<sub>2</sub>O<sub>2</sub> sensor from docking station, and pick up the control (+) BI that was left to warm to room temperature. Next, proceed through door 'D' to 'CYCLE' rooms.

#### **STEP 4: REMOVE TAPE, DETECT VHP LEVEL, COLLECT BIOLOGICAL INDICATORS**

MSU staff will remove masking tape from assigned room door and stand at door way to decontaminated room with Drager H<sub>2</sub>O<sub>2</sub> reader for detection of VHP ppm.

**NOTE: To deem the area safe for personnel entry, the H<sub>2</sub>O<sub>2</sub> levels must be <1.0ppm. If the level is higher than 1.0ppm, the door should be closed and more time should be allowed for evacuation of VHP.**

After room as been deemed safe for entry, MSU staff will enter and verify that all chemical indicators throughout the room have turned black and collect biological indicator disks without disturbing or contacting the decontaminated N95 respirators.

Petri dishes containing the BIs should be enclosed and taped shut to maintain sterility during transport to laboratory.

#### **STEP 5: EXIT PROCEDURES**

MSU staff will leave room and close door, then update signage on outside of door to state 'TEST' with date and time to indicate that biological indicators have been collected.

MSU staff will return Drager unit to charging station and verify that control (+) BI pouch has been gathered, along room BIs. The BIs will then be taken immediately to the laboratory in an adjacent building for culturing up to 7 days.

## STEP 6: BIOLOGICAL INDICATOR CULTURE

The control (+) BI will be cultured last and the control (-) media tube remains unopened. BI disks are placed into labeled media tubes using aseptic technique within the Biosafety Cabinet in the laboratory.

All samples are to be incubated at ~60°C and results recorded on the “**MSU Biological Indicator Culture for VHP Decontamination**” data sheet daily up to 7 days assessing for turbidity and color changes to media.

Following confirmation of **no growth** of BIs, the healthcare facility and Operator Team will be notified to schedule return to the MSU campus for retrieval of decontaminated N95 respirators.

**QUESTIONS OR CONCERNS ABOUT VHP CYCLE PROCEDURES OR BIOLOGICAL INDICATORS?**  
MSU staff should contact the main Campus Animal Resources line to reach the Director or Facility Supervisors; emails can be sent to [carinfo@msu.edu](mailto:carinfo@msu.edu).

**If there is an emergency, call 911 immediately.**

**MSU Biological Indicator Culture for VHP Decontamination**

Date: \_\_\_\_\_

Health Site: \_\_\_\_\_ (abbrev = \_\_\_\_\_)

BLDG J Room #: \_\_\_\_\_

Room Temp (°F) / Humidity (%): \_\_\_\_\_ °F / \_\_\_\_\_ %

Incubator Temp (°C) \_\_\_\_\_ °C

Biological Indicator Type (Spor dex/Apex/other): \_\_\_\_\_

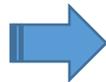
**RECORD DAY** as: **NEG** (if purple) or **POS** (if yellow/turbid) for each sample tested

<b>Sample #</b>	<b>BI location in Room as facing into doorway</b>	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Left side /lower shelf							
2	Left side/upper shelf							
3	Left rear/lower shelf							
4	Left rear/upper shelf							
5	Right rear/lower shelf							
6	Right rear/upper shelf							
7* - only in Rm 14 or 15	Middle back/center shelf							
8* - only in Rm 14 or 15	Middle front/center shelf							
9	Right side/lower shelf							
10	Right side/upper shelf							
Control (+)	New BI added-yellow							
Control (--)	No BI added-purple							

Blue-shaded samples are standard locations (#2, 3, 5, 10) for Rms 10-13,16-18 due to rack positioning

**Label media tubes at time of collection with:**

Health site abbreviation:  
Rm# - Sample #  
Mth-Day-20



\_\_\_\_\_  
\_\_\_\_ --  
\_\_\_\_\_  
\_\_ / \_\_ / 20

**TEST TUBE RACK COLOR/DESCRIPTION:**

\_\_\_\_\_