PPE Requirements for Technicians

Any technician or person handling contaminated PPE as well as equipment being used for the decontamination process must wear PPE in compliance with CDC COVID-19 Protocol. In the case of any obstacles to compliance with this policy due to limited PPE availability, questions regarding compliance and safety must be directed to CURIS Systems and solutions must be vetted according to CDC guidelines before implementation. It is important to note that the transmission method of COVID-19 both in the air and on touched surfaces is not completely understood and therefore implementation of these procedures should be treated with the utmost level of care for your own safety and protection.

Prior to service:
-Technician must be trained in Proper PPE use and removal
-Technician must be fit tested for PPE

Technician MUST wear the following when in contact with contaminated PPE

-A long sleeve fluid-resistant or impermeable gown

-Nitrile Gloves

-Respiratory Protection: Preferred form is a P100 full face piece respirator, a P100 half face respirator, or an N95 respirator

-Eye protection: In absence of a full face piece respirator, eye protection should be worn in the form of safety goggles or a face shield

Upon leaving the space with contaminated gear the above PPE should be be considered contaminated and removed. This gear should then be disinfected or set aside & contained for inclusion in a future fogging disinfection

When retrieving decontaminated PPE from site Technician MUST wear new or decontaminated

-Nitrile Gloves

-Respiratory Protection

and additionally MAY wear

-A long sleeve fluid-resistant or impermeable gown

-Eye Protection

It is recommended the PPE worn by any technician handling contaminated items be included in a decontamination fogging. Ideally having three or more sets of gowns and N95 masks (if in use) per technician would allow for a rotation as follows;
1) PPE worn while handling Contaminates —-> to be set aside for decontamination post use
2) PPE worn while handling decontaminated items
3) PPE contaminated during the previous cycle actively being included for decontaminated in this cycle

Reusable Full or partial face piece respirators and eye protection may be wiped with a decontaminate and reused once dry.

PPE Protocol Relevant Resources

As each facility differs in the area being used for decontamination, the below list is to be used as a partial resource to government guidelines. For this use, a site being used to decontaminate PPE should be considered a Healthcare Facility.

OSHA COVID-19 Control and Prevention: https://www.osha.gov/SLTC/covid-19/controlprevention.html

CDC Hand Hygiene in Healthcare Setting: https://www.cdc.gov/handhygiene/

CDC Guide to Wearing and Removing PPE: https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf

CDC Infection Control in Healthcare Facilities https://www.cdc.gov/sars/guidance/I-infection/healthcare.html
**The guidelines for Textiles should be followed if transporting PPE to a separate decontamination site.

"5. Personal protective equipment (PPE)
Gloves, gown, respiratory protection, and eye protection (as needed) should be donned before entering a SARS patient's room or designated SARS patient-care area… Removal of PPE in a manner that prevents contamination of clothing and skin is a priority.

- Gown and gloves – Wear a standard isolation gown and pair of nonsterile patient-care gloves for all patient contacts…
- Respiratory protection – Wear a NIOSH-certified N-95 filtering facepiece respirator for entering an AIIR or designated SARS patient-care area.3 If N-95 or higher level of respiratory protection is not available, then wear a snug-fitting surgical mask to prevent nose and mouth contact with large respiratory droplets. Discard respirators upon leaving the patient room or area.
- Eye and face protection — It is not yet known whether routine eye protection is needed to prevent SARS-CoV transmission. Routinely wear eye protection when within 3 feet of a patient with SARS-CoV… Corrective eyeglasses or contact lenses alone are not considered eye protection.
- Use safe work practices when wearing PPE:
    - Avoid touching the face with contaminated gloves
    - Avoid unnecessary touching of surfaces and objects with contaminated gloves

7. Textiles

- Place soiled linen directly into a laundry bag in the patient's room. Contain linen in a manner that prevents the linen bag from opening or bursting during transport and while in the soiled linen holding area
- Wear gloves and gown when directly handling soiled linen and laundry (e.g., bedding, towels, personal clothing) as per Standard and Contact Precautions. Do not shake or otherwise handle soiled linen and laundry in a manner that might aerosolize infectious particles.
- Wear gloves for transporting bagged linen and laundry.
- Perform hand hygiene after removing gloves that have been in contact with soiled linen and laundry.

10. Environmental cleaning and disinfection
Environmental services personnel should wear PPE as described in Section III.D.5 above. These staff should be trained in proper procedures for PPE use, including removal of PPE, and the importance of hand hygiene."

PPE Protocol

SYNOPSIS: All PPE decontamination will be performed in an air tight room with the capacity to treat several hundred N95 masks simultaneously. The goal is to decontaminate the mask and filters to 99.9999% achieving a 6-log reduction within those critical media. Several levels of validation will be employed to test the efficacy of an absence microbial growth. In addition, the N95 filters will be tested to ensure continued efficacy of the filter media. Autonomous assurance reports will be generated from each lot treated with documentation as certification of the treatment.

1. Technician needs to be wearing PPE in compliance with CDC/WHO COVID-19 Protocol as described above.
2. Inspect room. Measure and record dimensions (cubic feet)
3. Take pictures for confirmation and documentation purposes
4. Confirm temperature and humidity are within limits. Record levels of each.
5. Place 2 fans (12-16cfm) inside room turned on and plugged in to CURIS integrated outlet (sequential port.) These fans will activate at the end of the pulse sequence
6. Clean for gross contaminates if possible
7. Chemical wipe down of fomites (other than PPE to be sterilized)
8. Place H202 Chemical Indicator strips in all four corners of the room
9. Place a Biological Indicator of Geobacillus Stearothermophilus 1 x 10^6 in the center of room
10. Program foggers using CURIS App and the Standard Technician Checklist information
11. Position PPE “fogging rack” in room
12. Insure proper position of PPE by securing edges of individual units to fogging rack
13. Inspect for and discard any N95 mask which has reached 30 rounds of decontamination and use
14. Insure proper spacing of PPE and provide distance of at least three inches between rows to allow for air flow during disinfection process
15. Upon leaving room technician must remove and contain contaminated PPE
16. Commence fogging with primary and secondary injection phases
17. Allow sequential fans to run for 20 minutes
18. Introduce room to fresh air (either from outside, through HVAC exhaust system, or using air scrubber) for 60 minutes & achieving 1ppm H2O2
19. Allow PPE to air dry
20. Recover all PPE upon completion of job
21. Recover Biological Indicator, Chemical test strips, blue tape, and signs
22. Mark each N95 mask indicating number of times it has been decontaminated
23. Select one unit of PPE for swab testing of bacterial load CFU
24. Select three N95 mask for NIOSH filter testing (after a passed test return these three masks to be decontaminated)
25. Store treated PPE in a sealed sterile bag
26. Issue completed report

Validation Testing = Risk Management

Treating the N95 is only the first step. Fighting something you can't see is impossible without implementation of proper validation methods. This proves whether the treatment was a success or a failure. Ensuring success in microbial disinfection is key to any decontamination process. This will need to be treated as a BSL 3 decontamination process due to the level of virulence involved with the organism being targeted. Our process includes multiple methods of validation as outlined below;

1. Biological Indicator in the center of the room: Geobacillus Sterathermopholis 1 x 10^6 – 99.9999%)
2. Chemical Indicators in each of four corners in room: Ensuring proper introduction of vapor to the space.
3. NIOSH Testing by batch testing two (2) units per batch to ensures integrity of filtration
4. Perform Colony Forming Units testing by testing one (1) unit per batch

Throughput for PPE Decontamination

1. Complete Fogging Procedure, including aeration is 2-4 hours
2. Capable booth capacity 200-300 masks
3. Two booths operating with continual capacity
4. BI for incubation: incubate for 24hrs for efficacy, keep for 7 days per FDA regulations

Resources:

CDC: Standard Respirator Testing Procedures https://www.cdc.gov/niosh/npptl/stps/apresp.html

Evaluation of Five Decontamination Methods for Filtering Facepiece Respirators https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2781738/

Relevant to HEPA filtration: Effectiveness of Aerosolized Hydrogen Peroxide in Simultaneous Decontamination of a Laboratory and a Biological Safety Cabinet https://www.dropbox.com/s/hzi92idcd3lbz9e/BAKER%20Inst.%20QUAD%20Harvard.png?dl=0

WHO: Surface Sampling of COVID-19: A Practicle "How-To" Protocol for health care and public health professionals The second table details potential exposure touch points when in a health care facility https://apps.who.int/iris/bitstream/handle/10665/331058/WHO-2019-nCoV-Environment_protocol-2020.1-eng.pdf

Peroxide Vapor (HPV) Decontamination of Reuse of N95 Respirators http://wayback.archive-it.org/7993/20170113034232/http:/www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMRegulatoryScience/UCM516998.pdf


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