Standard Operating Procedure SOP No. Microbiological Decontamination Procedure 8.054

DCR No.: 03026 Revision No.: 1 Effective: 3-5-99 Supersedes: 3-5-99 Revision Date: 11-15-03

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1 Purpose

1.1 To establish a method of decontamination for equipment used in biohazard facilities.

2 Scope

2.1 This procedure applies to Class II Biohazard Cabinets, as well as contaminated rooms and storage areas or any other biohazard equipment such as incubators.

3 Reference

- 3.1 NSF Standard 49, 2002, Annex G.
- 3.2 NIOSH Pocket Guide to Chemical Hazards, June 1997.

4 Definition

4.1 g/ft³: grams per cubic foot

5 Responsibility

- 5.1 Test and Balance (TAB) technicians shall record all measurements, quantities and times on Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III) in the Decontamination Information section and indicate that the test has been performed, Yes or No, on Form FN 8.057.1 (Biohazard Safety Cabinet Test Report Summary Sheet).
- 5.2 All test reports shall be saved in files, located in the TAB department of Therma.
- 5.3 All test equipment utilized shall be in calibration in accordance with National Environmental Balancing Bureau (NEBB) Standards and traceable to the National Institute of Standards and Technology (NIST).

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- 6 Materials Requirement
 - 6.1 Three electric frying pans
 - 6.2 Paraformaldyhyde
 - 6.3 Ammonium Bicarbonate
 - 6.4 Visqueen (when decontaminating Biohazard Safety Cabinets)
 - 6.5 Duct Tape

7 Equipment

- 7.1 Temperature and Humidity measuring instrument
- 7.2 Environmental Monitoring system capable of measuring a low limit of 0.010 ppm of Paraformaldehyde, and 20.000 ppm of Ammonium Bicarbonate
- 7.3 MSHA/NIOSH approved full face respirator with a high efficiency particulate filter

8 Procedures

- 8.1 Calculate the total volume of the equipment to be decontaminated in cubic feet by multiplying the height, width and depth measured in inches, and dividing the result by 144. (If additional ductwork to a gas tight damper is present, or if a plenum is set on top of the exhaust HEPA, the extra volume must be added to the volume of the equipment) Enter measurements and volume calculated on the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III).
- 8.2 Multiply the total volume of the equipment by 0.3 g/ft³ to determine the gram weight of Paraformaldehyde required. Record on the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III).
- 8.3 Determine the gram weight of Ammonium Bicarbonate by multiplying the gram weight of paraformaldehyde determined in 8.2 by 1.10. Record on the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III).
- 8.4 Using a scale, measure the appropriate amount of Paraformaldehyde and Ammonium Bicarbonate determined in 8.2 and 8.3 into separate electric frying pans set to 450 to 475° F. Spread the chemicals evenly over the frying pan surface.
- 8.5 Fill a third frying pan with water to a depth of 1 inch.

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- 8.6 Place frying pans in equipment to be decontaminated. Plug into switched electrical outlet that is external to the equipment to be decontaminated with the power off. Do not apply power to any of the flying pans yet.
- 8.7 Place a temperature and humidity sensor in the equipment to be decontaminated.
- 8.8 Close and seal the opening to the work area (the exhaust filter as well on Biohazard Safety Cabinets) with heavy gauge plastic film and tape.
- 8.9 Attach signs warning that equipment is undergoing decontamination to equipment undergoing decontamination, and on all doors which access the room where the equipment is located.
- 8.10 MSHA/NIOSH approved full-face respirator with a high efficiency particulate filter should be with technician, ready to wear if necessary.
- 8.11 Determine temperature and humidity inside the equipment. It should be 70°F or higher, and the humidity should be 60 to 85%. Use the frying pan with water to increase the temperature and humidity to the required levels. Shut off water frying pan when levels are reached.
- When the temperature and humidity reach the levels required in 8.11, turn on the frying pan with the Paraformaldehyde.
- 8.13 (When decontaminating a Biohazard Safety Cabinet, after 25% of the Paraformaldehyde has depolymerized, turn on the cabinet blowers for 10 to 15 seconds. Repeat after 50%, 75% and 100% of the paraformaldehyde has depolymerized.) Shut off Paraformaldehyde frying pan when all paraformaldehyde has depolymerized.
- 8.14 Monitor Paraformaldehyde levels around equipment using the Environmental Monitoring equipment. If levels meet 0.016 ppm, MSHA/NIOSH approved full-face respirator must be worn and the area evacuated of all personnel. Record highest levels reached (immediately after all Paraformaldehyde has depolymerized) on FN 8.057.4 Biohazard Safety Cabinet Test Report Details III.
- 8.15 Allow the cabinet to stand for a minimum of six hours, preferably overnight. Record actual decontamination time on the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III).

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- 8.16 When decontamination is complete, turn on the frying pan with Ammonium Bicarbonate. (If decontaminated equipment is a Biohazard Safety Cabinet, turn on the cabinet blower.) Shut off frying pan (and cabinet blowers if applicable) when all of the Ammonium Bicarbonate has dissipated.
- 8.17 Monitor Ammonium Bicarbonate levels around equipment using the Environmental Monitoring equipment. If levels meet 25.000 ppm, MSHA/NIOSH approved full-face respirator must be worn and the area evacuated of all personnel. Record highest levels reached (immediately after all Ammonium Bicarbonate has dissipated) on the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III).
- 8.18 Run flex duct to nearest exhaust inlet and attach temporarily with duct tape.
- 8.19 Allow decontaminated equipment to stand for at least 1 hour before opening seals. Record actual purge time on the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III).
- 8.20 Connect duct from 8.18 to plenum above exhaust filter on Biological Hazard Cabinet, or slit heavy gauge plastic, insert duct and seal with duct tape. Slit heavy gauge plastic at Biological Hazard Cabinet inlet opening, or at bottom of equipment opening, and allow equipment to ventilate.
- 8.21 Remove all tape, heavy gauge plastic and electric frying pans from equipment. Wipe decontaminated equipment surfaces with warm water and cloth.
- 8.22 Attach certification label to equipment indicating that equipment has been decontaminated with Paraformaldehyde, the date and the technician.
- 8.23 Indicate that the test has been performed, Yes or No, on Form FN 8.057.1 (Biohazard Safety Cabinet Test Report Summary Sheet).

9 Review and Approval

9.1 TAB technicians shall return the Form FN 8.057.1 (Biohazard Safety Cabinet Test Report Summary Sheet) and the Form FN 8.057.4 (Biohazard Safety Cabinet Test Report Details III) to the TAB Department for review.

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Document Approval

Non Simers	10/01/03
Test & Balance Supervisor	Date

Engineering Manager $\frac{|O/61/63|}{Date}$

Quality Assurance Manager

U-15-03

Date

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