BTEC Inc.

EtO Sterilizer Malfunction Abatement Plan

Prepared for:

The University of Michigan

Ann Arbor, Michigan

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APPENDIX

1.0 Introduction

On May 3, 2013, The Air Quality Division (AQD) of Michigan's Department of Environmental Quality issued Permit No. 30-13 to The University of Michigan (UM) for the installation of six ethylene oxide (EtO) sterilizers with emissions controlled by six abators. The equipment is to be installed at The UM Health System (UMHS), located at 1500 East Medical Center Drive in Ann Arbor, Michigan.

Regarding the EtO sterilizers, Permit No. 30-13 specifies that *"The permittee shall not operate any sterilizer associated with FGSTERILIZERS unless a malfunction abatement plan (MAP) as described in Rule 911(2), has been submitted within 60 days of permit issuance, and is implemented and maintained. If at any time the MAP fails to address or inadequately addresses an event that meets the characteristics of a malfunction, the permittee shall amend the MAP within 45 days after such an event occurs. The permittee shall also amend the MAP within 45 days, if new equipment is installed or upon request from the District Supervisor. The permittee shall submit the MAP and any amendments to the MAP to the AQD District Supervisor for review and approval. If the AQD does not notify the permittee within 90 days of submittal, the MAP or amended MAP shall be considered approved. Until an amended plan is approved, the permittee shall implement corrective procedures or operational changes to achieve compliance with all applicable emission limits."*

The purpose of this document is to summarize the malfunction abatement plan for the EtO sterilizers and associated abators. Section 2.0 of this document provides a description of the equipment. Section 3.0 summarizes the preventative maintenance program for the abators and Section 4.0 summarizes abator operating variables. Section 5.0 summarizes corrective procedures.

2.0 Process Description

All sterilization equipment at UMHS is operated and maintained by the UMHS Central Sterile Processing Department (CSPD). The CSPD receives reusable medical instruments, implants, and other items which requires sterilization. EtO sterilization is the most universally specified method where low temperature, pressure and moisture-sensitive processing is needed, whereas steam sterilization uses high pressure and temperature.

Items to be sterilized using EtO are prepared by wrapping them with materials that will allow penetration of the EtO while keeping the items separated from one another and ensuring that the supplies remain sterile until use. Once wrapped and placed on trays or carts, the items will be placed inside the sterilization chambers.

UMHS installed six new EtO sterilizers with emissions controlled by six catalytic oxidizers as follows:

- UM installed two new Model 5XL sterilizers manufactured by 3M. These sterilizers are designated Units 11 and 12. Model 5XL sterilizers have a chamber capacity of 4.8 cubic feet and process loads using 100% EtO sterilant gas. Exhaust from each sterilizer's compressed air venturi vacuum system are routed through a 3M Model 50 EO Abator. These abators are designated 11 and 12.

- UMHS installed four new Model 8XL sterilizers manufactured by 3M. These sterilizers are designated Units 13 through 16. Model 8XL sterilizers have a chamber capacity of 7.9 cubic feet and process loads using 100% EtO sterilant gas. Exhaust from each sterilizer's compressed air venturi vacuum system are routed through a 3M Model 50 EO Abator. These abators are designated 13 through 16.

Throughout the sterilization cycle, the sterilizer operates under vacuum. At standby, it is at atmosphere; at humidification it is at 160 to 100 mbars vacuum; at gas exposer it will vary, depending on the load, the average is 500 mbars vacuum; at final pumpdown it is 160 - 100 mbars vacuum; and at aeration it is at 80 mbars below atmosphere. Once the cycle is started, the chamber will not be above atmospheric pressure; it will always be in a vacuum condition.

Exhaust from the 3M Model 50 EO abators will be routed to the ambient air through a hospital rooftop exhaust stack.

3.0 Preventative Maintenance Program

3.1 Identification of Supervisory Personnel

Overall supervision of UMHS CSPD is provided by:

Name: Jania Torreblanca
Title: CSPD Manager
The University of Michigan Hospital
Central Sterile Processing Department
1500 East Medical Center Drive
Ann Arbor, Michigan 48109
(734) 936-6266 X34008

The employee directly responsible for inspection, maintenance, and repair of the catalytic oxidizer system is:

Name: Kris Carlisle
Title: Foreman, Hospital Maintenance
The University of Michigan Hospital
1500 East Medical Center Drive
Ann Arbor, Michigan 48109
(734) 232-1553

3.2 Description of Items to be Inspected

The items to be inspected to ensure proper operation of the sterilizers and abators will be (1) the Chemdaq mechanical and gas storage room EtO area monitoring system, (2) abator operating indicator lights, and (3) sterilizer and abator monitoring system data printouts. The EtO area monitoring system verifies that there are no EtO leaks from the sterilizers, the abators, or other components of the system. The abator operating indicator lights are pre-set by the manufacturer and indicate the proper operation of the abator (see Appendix A). The sterilizer and abator monitoring system printouts summarize various operating data relevant to the proper operation of the sterilizers and abators.

In addition, UMHS has a contract with 3M to conduct a semi-annual preventive maintenance program (see Appendix B).

3.3 Frequency of Inspections

With the exception of the semi-annual preventive maintenance program to be performed by 3M, all other inspections are conducted on a daily basis, Monday through Friday when in operation. Weekend and holiday usage of the sterilizers is minimal.

3.4 Identification of Major Replacement Parts

The UMHS has a maintenance/ repair service contract with 3M. Recommended preventative maintenance replacement parts will be provided by 3M on each equipment model.

4.0 Operating Variables

The two operating variables relevant to proper operation of the abators are catalytic chamber temperature and exhaust air flowrate. Proper values are ensured by the interlock system that serves the abators (see Appendix A).

5.0 Description of Corrective Procedures or Operational Changes

If the EtO sterilizer or abator show any signs of malfunction via the monitoring system printouts or the abator indicator lights, the units are taken out of service and reviewed or repaired. Before placing back into service, a biological load is run to ensure the unit is sterilizing and operating properly.

Appendix A - Indicator Light

Indicator	Normal Status	Malfunction
Abator On (Green)	ON/OFF	Indicates Abator is on. If OFF, check main disconnect to Abator.
Ready (Green)	ON	OFF indicates one of the following problems: 1. Low process temp 2. High process temp 3. Low air flow 4. Open RTD
Working (Green)	ON/OFF	ON indicates Abator is processing EO.OFF indicates no or low concentrations of EO.
Low Air Flow (Red)	OFF	ON indicates one of the following problems: 1. Plugged pre-filter (Must replace every 6 months or sooner) 2. Blocked Outflow 3. Blower Malfunction
Over Temperature (Red)	OFF	ON indicates system malfunction. After completion of cycle, shut down. Call for service. **DO NOT RESTART.**
Over Temperature (Red) Slow Flash (1 flash/second)	OFF	ON indicates high heater sheath temperature or open RTD.
Over Temperature (Red) Fast Flash (3 flash/seconds	OFF	ON indicates the temperature rate of rise too fast due to low airflow

Appendix B

Distribution Limited To Current 3M Approved Service Providers

Equipment Bulletin

14B

Subject: Donaldson 50 SCFM Abator PMA Procedure

Date: September, 19 2001

Machines Affected: All Abators

Condition: None

Cause: None

Solution: Perform routine maintenance every 6 Months.

PMA Procedure

1. Be certain that the sterilizers are turned off. Remove power from the abator at the breaker panel.
2. Open the abator control panel. Turn off the 30 amp circuit breaker in the abator.
3. Examine the wiring in the control panel for loose connections at the terminal strips.
4. Loosen the 4 fasteners that hold the top cover in place and remove the top cover.
5. Examine the top cover seal for damage or areas that do not seal. If damaged, replace the seal according to directions in the Abator Service Manual. (78-8069-7460-2)
6. Loosen the clamp on the prefilter and remove the filter. Replace it with a new filter. (78-8069-7459-4)
7. Examine the wiring for any signs of over heating.
8. Rebuild the solenoid valves annually or when the diaphragms are deformed , using kits 26-1017-3478-3 and 26-1017-3477-5.
9. Insert temp probe in the blower exhaust Rubber boot. Replace the top cover.
10. Restore power to the abator at the breaker panel and at the circuit breaker in the control panel.

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11. Perform an abator System Functional Check by installing an empty EO gas cartridge in the sterilizer and starting a Cool Cycle. a. Temperature Check – Ready Light – ON between 280-330 ^{0}F (138-165 ^{0}C). b. Airflow check – Air flow must be 55 +5, -0 scfm (94.2 +8.5 – 0 Normal M^3/hr.). Refer to the Service Manual for the procedure.	c. Airflow Fault – The Low Airflow Light will illuminate and the Ready light will go out. Refer to the Service Manual. 12. Be certain that the solenoid valves switch when the Ready light goes out. 13. Be certain that all the light bulbs work. 14. Remove the temperature probe from the abator. 15. Tighten the 4 fasteners to secure the top panel.