MALFUNCTION ABATEMENT PLAN
FOR
ETHYLENE OXIDE STERILIZERS AND
ASSOCIATED EMISSION CONTROL SYSTEMS

Royal Oak Hospital
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Royal Oak, Michigan

Beaumont Health – Royal Oak Hospital
EtO Sterilizers Malfunction Abatement Plan

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1.0 Purpose / Scope

The purpose of this Malfunction Abatement Plan (MAP) is to establish appropriate practices and procedures to maintain proper operation of the ethylene oxide (EtO) sterilizers and associated acid scrubber emissions control devices at the Beaumont Health (Beaumont) Royal Oak Hospital. This MAP specifies the operational, auditing, and maintenance procedures that will be followed to ensure that the sterilizers and associated emissions control systems are properly operated and maintained.

Conditions in the Renewable Operating Permit (ROP) require that the facility develop a MAP for the sterilizers and submit it to the State of Michigan Department of Environmental Quality, Air Quality Division (MDEQ-AQD) Southeast Michigan District Supervisor for approval.

A copy of the most recent Malfunction Abatement Plan must be maintained on file at the Beaumont Royal Oak Hospital.

Plan revisions are documented using the revision history log in Attachment A.

2.0 Supervisory Personnel

The Manager, Biomedical Engineering is responsible for the operation of the sterilizers and associated emission control devices and for ensuring that this MAP is maintained, implemented and revised as necessary.

The Biomedical Equipment Technician II is responsible for scheduling preventative maintenance and responding to equipment malfunctions.

Attachment B provides a list of supervisory personnel and contact phone numbers.

3.0 General Process Description

The medical sterilizers are manufactured by the 3M corporation. Two (2) of the sterilizers are Model No. Steri-Vac 8XL Gas Sterilizer units and two (2) are Model No. Steri-Vac 5XL Gas Sterilizer units. The four units are charged with 3M Steri-Gas™ Ethylene Oxide Gas Cartridges. After the units are loaded and the EtO cartridge is inserted operation of the units is fully automated.

Emissions from the sterilizers are controlled with three (3) Advanced Air Technologies Safe-Cell System Model 2002 acid scrubbers and dry bed chemical filters. The three (3) Advanced Air Technologies Safe-Cell System Model 2002 acid scrubbers have sufficient capacity to control emissions from all four (4) units (i.e., four (4) sterilizers may operate simultaneously).

The sterilizers exhaust the chamber to the control device using a venturi and compressed air (i.e., no pumps are used to exhaust the chamber). All of the exhaust (i.e., from the preconditioning, sterilization and exhaust phases) is directed to the control device. No water is directed to the sanitary drain.

4.0 Monitoring

This section presents operating variables that are monitored to verify proper operation of the sterilizers and acid scrubber control systems and the normal operating range for each variable. If monitored parameter values are outside of the acceptable ranges specified in this section, refer to the Corrective Action Procedures section in this MAP or contact the Biomedical Equipment Technician II.

4.1 Sterilizer Chamber Temperature

The required chamber temperature is determined based upon the sterilization cycle which is initially selected. The chamber temperature is required to be maintained within 3 ^{o}C of the selected cycle temperature. If at any time the temperature deviates more than 4 ^{o}C from the setpoint the sterilization cycle automatically stops.

4.2 Sterilizer Chamber Vacuum

During the sterilization cycle the chamber is maintained at a negative pressure relative to the room in order to prevent gas from the chamber from escaping into the sterilization room. In the event that a chamber leak is detected and room air infiltrates the chamber the sterilization cycle automatically stops. The sterilizer room is equipped with EtO alarms and the facility has a response plan in place should an EtO alarm be triggered.

The chamber vacuum is also required to puncture the EtO cartridge. The sterilizer uses the vacuum in the chamber to provide the force required to puncture the cartridge. This can only occur if the chamber pressure is below 160 mbars.

4.3 Acid Scrubber Exhaust Fan and Recirculation Pump Flows and Liquid Level

The acid scrubber exhaust fan flow is monitored using a differential pressure gauge. The differential pressure (exhaust flow) is required to be maintained within 1-inch of water column of the correct air flow rate determined during the initial setup. This ensures that the acid scrubber is properly exhausting the treated gas to the atmosphere.

The acid scrubber fluid recirculation pump is monitored using flow meters. The acid scrubber fluid recirculation flow rate should be kept at approximately 3 to 4 gallons per minute.

The acid scrubber liquid level is monitored using a limit switch. The liquid level in the acid scrubber decreases due to evaporation of the acid scrubber solution. The acid scrubber solution and should be maintained at a depth of approximately 27 inches.

4.4 Acid Scrubber Bypass

During normal operation of the sterilizers, an "Ok to Run" pilot light will be illuminated on the front of the sterilizer unit and a corresponding green light in the operator area will be illuminated. In the event of certain malfunctions, and in order to prevent damage to the sterilizer unit, a solenoid will be fired, which will open the bypass exhaust valve. The "Ok to Run" pilot light will turn off and a "Bypass Valve Active" pilot light will be illuminated. A corresponding red light in the operator area will be illuminated. The bypass exhaust will exhaust emissions from the sterilizer unit directly to the atmosphere. The following malfunction conditions will cause the bypass valve to activate:

- Loss of negative pressure in the dedicated hospital exhaust system;
- Malfunction of the acid scrubber exhaust fan;
- RP-1 selector switch on acid scrubber cabinet door not in Auto position; and
- Low liquid level alarm on acid scrubber.

Any occurrence of the activation of the bypass valve will be reported to the MDEQ along with an estimation of bypassed EtO emissions.

4.5 Canister Storage Cabinet Exhaust

The EtO canister storage cabinet exhausts to the atmosphere through the acid scrubber bypass exhaust stack. In the event of a malfunction that causes a canister leak of EtO into the general room area or if EtO is exhausted through the bypass exhaust stack, an alarm will be activated and appropriate personnel will be notified. The general room area and bypass exhaust air handler are each equipped with EtO alarms. When an alarm is activated the room air intakes are closed in order to create a negative pressure in the area and ensure all EtO is exhausted from the room.

Any occurrence of the activation of the EtO alarm associated with uncontrolled EtO emissions will be reported to the MDEQ along with an estimation of uncontrolled EtO emissions.

5.0 Periodic Inspections

5.1 Sterilizer Cycle Recorder Chart

The sterilizer is equipped with a thermal printer which prints out a summary of information regarding each sterilization cycle. These individual print outs are reviewed to analyze the sterilizer performance and to identify any error codes or caution messages which may need to be addressed.

5.2 Acid Scrubber Capacity Checks

On a periodic basis, based on the number of sterilization cycles run, the liquid level of the acid scrubber should be checked. A low level liquid alarm will occur if the capacity decreases by greater than 20%.

5.3 Acid Scrubber Solution Check

When the scrubber solution is nearing the practical capacity for EtO evacuations (approximately 292 kg of EtO exhausted through the unit), the scrubbing solution should be analyzed for ethylene glycol concentration (via ASTM D1123 by Karl Fischer Titration) in order to determine if the solution needs to be changed out. Beaumont is required by Permit to Install No. 205-02C to monitor the mass of EtO that is injected into each sterilization cycle (maximum amount of EtO which is subsequently exhausted to the acid scrubber).

The pH of the acid solution should be checked on a monthly basis to ensure that the scrubbing solution is within the acceptable range. If the pH of the scrubbing solution increases above 3.0, the scrubbing solution should be changed out.

6.0 Corrective Action Procedures

This section provides a general description of the corrective action procedures to be taken in the event of a malfunction.

6.1 Sterilizer Caution Messages and Error Codes

There are a number of sterilizer caution messages and error codes that can occur. Refer to the sterilizer operational manual for an explanation of individual faults, a detailed description of each fault is beyond the scope of this MAP. Most faults will cause a shutdown of the sterilization unit. If the cycle is shutdown prior to finishing the door will remain locked until the chamber has completed a purge cycle. A sterilizer caution message or error code must be reported to the Biomedical Equipment Technician II.

6.2 Low Sterilizer Chamber Temperature

The sterilizer chamber temperature is continuously monitored and automatically regulated by the sterilizer control system and will trigger an error code and automatic shutdown if a high or low temperature is measured. The error code will be displayed on the control screen.

In the event that a high or low sterilizer chamber temperature (deviates greater than 3 ºC from cycle setpoint) is observed, notify the Biomedical Equipment Technician II and inform staff that the unit may not be used until the problem is corrected and the sterilizer can maintain the proper temperature.

High or low sterilizer chamber temperature could be the result of:

- Actual heater failure or heater temperature controller failure.
- Failure of a temperature sensor.

6.3 Low Sterilizer Chamber Vacuum

The vacuum within the sterilizer chamber is monitored and regulated by the sterilizer control system. In the event that the chamber vacuum is lost an error code will be triggered and automatic shutdown of the unit will occur. The Biomedical Equipment Technician II should be notified to troubleshoot the problem.

Loss of chamber vacuum could be the result of:

- Loss of compressed air, air lines should be checked.
- Pressure sensor failure or bad door closed connection.
- Leak in the chamber or vacuum system failure.

6.4 Scrubber Low Exhaust Flow

The exhaust flow of the acid scrubber is monitored using a differential pressure gauge. In the event that the differential pressure (exhaust flow) is outside the specified limits a low flow alarm will be triggered. This will also trigger the scrubber bypass valve. The Biomedical Equipment Technician II should be notified to troubleshoot the problem.

Low exhaust flow could be the result of:

- Exhaust fan loss of power or switched off.

- Fan overload relay could be tripped and need to be reset.
- Exhaust blower could not be operating properly or dampers in the duct may have been shut.
- Sensing lines may be plugged or reactant filter may be plugged.

6.5 Scrubber Low Fluid Recirculation Flow

The fluid recirculation flow of the acid scrubber is monitored using a flow meters. In the event that the recirculation flow is outside the 3 to 4 gallon per minute flowrate range a pump flow alarm will be triggered. The Biomedical Equipment Technician II should be notified to troubleshoot the problem.

A pump flow alarm could be the result of:

- Recirculation pump loss of power or not switched to the Auto position.
- Pump overload relay could be tripped and need to be reset.
- Ball Valve No. BV-1A should be open and Valve Nos. BV-1B and BV-1C should be closed.

6.6 Scrubber Low Fluid Level

The scrubber liquid level is monitored using a limit switch. In the event that the liquid level decreases to a point (about a 20% decrease of fluid weight) a low liquid level alarm will be triggered. This will also trigger the scrubber bypass valve. The Biomedical Equipment Technician II should be notified to troubleshoot the problem.

A low liquid level alarm is the result of the evaporation of the acid scrubber solution. Additional water should be added until the level is returned to a depth of approximately 27-inches.

7.0 Preventative Maintenance

7.1 Preventative Maintenance Schedule

Sterilizer preventative maintenance should be performed according to the schedule indicated below.

- Clean chamber walls and floor with warm water and mild soap (daily)
- Clean outer lip of chamber with warm water and mild soap (daily)
- Clean inside surface of chamber door with warm water and mild soap (daily)
- Clean outer surface of cabinet with warm water and mild soap (daily)
- Clean door gasket with warm water and mild soap (daily)
- Drain moisture and oil from the bottom of the compressed air filter reservoirs (daily)
- Replace the mist separator element (semi-annually)
- Replace the micromist separator (annually)

Acid scrubber preventative maintenance should be performed according to the schedule indicated below.

- Inspect scrubber for liquid leaks (weekly)
- Check and record scrubber recirculation pump flow meter reading (weekly)
- Check and record exhaust fan differential pressure gause reading (weekly)
- Check the number of sterilizer cycles and amount of EtO processed (weekly)
- Check reactant capacity as described Section 5.3 (as needed, dependant on amount of EtO processed)

Attachment C provides forms for recording preventative maintenance. As an alternative, preventative maintenance may be recorded in the facility's site-wide maintenance program.

7.2 Spare Parts Inventory

The manufacturers of the sterilizers and scrubber units do not recommend any spare parts be kept in inventory. Any maintenance that is required is to be performed on the units is to be done by a trained technician. Beaumont operates four sterilizers and three acid scrubbing units, therefore, the capacity exists such that a malfunctioning unit can be taken out of service until it is repaired.

8.0 Attachments

The following documents and materials are included as part of this Malfunction Abatement Plan:

Attachment A: Plan Revision History
Attachment B: Supervisory Personnel
Attachment C: Maintenance Checklist

ATTACHMENT A

PLAN REVISION HISTORY

Attachment A

Malfunction Abatement Plan
Revision History

Date of Revision	Actions / Reason for Revision
1/2/2014	Initial draft of Malfunction Abatement Plan.
2/27/2014	Updated to reflect changes to Permit to Install revision (PTI No. 205-02C)
3/16/2016	Updated to add EtO canister storage cabinet exhaust and update job titles.
8/7/2018	Updated supervisory personnel.

ATTACHMENT B

SUPERVISORY PERSONNEL

Attachment B

Malfunction Abatement Plan
Supervisory Personnel

Title	Name	Contact Numbers	
Manager Biomedical Engineering	Rocco Ottolino, MS, CCE	Office 24-hr	248-898-0312 312-720-6417
Biomedical Equipment Technician II	Jim Gibson	Office 24-hr	248-898-4464 248-544-8615

ATTACHMENT C

MAINTENANCE LISTS

EtO Sterilizer and Emission Control System
Weekly / Monthly Inspection Checklist

Date of inspection _____ Performed By: _____

1. Record the following operating parmeters (weekly / monthly)

Acid scrubber recirculation pump flow rate (weekly)	_____ gpm
Acid scrubber exhaust fan differential pressure (monthly)	_____ in. H_2O

2. Perform following sterilizer tasks (weekly)	OK	No	See Notes
Clean chamber walls, floor, lip, surfaces and gasket			
Drain moisture and oil from air filter reservoirs			

3. Perform following acid scrubber tasks (monthly)			
Inspect acid scrubber for leaks			
Check number of sterilizer cycles and amount of EtO processed since last fluid changeout.			

Other Notes / Corrective Actions

EtO Sterilizer and Emission Control System
Semi-Annual and Annual Preventative Maintenance

Enter date that maintenance / inspection was performed and by whom.

General Maintenance (Semi-Annually)

	1st Q	2nd Q	3rd Q	4th Q
Replace the mist separator element				

General Maintenance (Annually or As-Needed)

	1st Q	2nd Q	3rd Q	4th Q
Replace micromist separator (annually)				
Check reactant capacity (as-needed)				

Other Notes or Maintenance
