APPENDIX B:

HAZARD AND OPERABILITY STUDY OF AN ETHYLENE OXIDE STERILIZER

INTRODUCTION

The main body of the present report summarizes a 1984-86 study by NIOSH researchers on controls for continuous or routine emissions of ethylene oxide from sterilizer installations in hospitals. The goals of this study were to evaluate and document effective engineering controls used by the hospitals that were studied. This study involved conducting a series of walk-through surveys to identify hospitals for further study, and week-long industrial hygiene sampling at six facilities that were thought to represent state-of-the-art control. This approach is effective in evaluating the efficacy of controls currently in use, but is less useful for identifying possible causes of infrequent and potentially catastrophic releases. Unless process or work practice failures were observed during the survey (which is unlikely), they may not have been considered in this type of study.

As a follow-up to the field study, a second study was conducted to evaluate the potential for a catastrophic or nonroutine releases of EtO. A hazard and operability study (HAZOP), a form of process hazard analysis, was conducted on an EtO sterilizer supplied by compressed-gas cylinders. This sterilizer is similar to most of the sterilizers that are currently used in hospitals. The sterilizer installation, equipment, and operational procedures were reviewed and recommendations were developed both specifically for the studied installation and for the generic installation of any EtO sterilizer.

The success of a HAZOP study depends upon the the knowledge and experience of the personnel involved and on the completeness of the information that is available. A team is assembled drawing from all the areas of interest. In the case of the sterilizer HAZOP, the equipment designers, a manufacturers service representative, the hospital engineering supervisor, and the hospital maintenance supervisor provided the technical expertise on the sterilizer equipment, installation, and procedures. In addition, a team leader and recording secretary were provided on a consulting basis (Technica, Inc., Columbus, Ohio). The team leader was responsible for carrying out the HAZOP in a systematic manner.

The HAZOP technique involves studying the operation as a series of separate systems (called nodes). Using the set of guidewords listed in Table B-1, the team leader guides the group through each segment of the operation. Guidewords from the first part of the list relate to deviations in process parameters, such as too much pressure or no flow. For each guideword, the team attempted to identify a cause, or a series of causes. If no cause could be identified, the team moved on to the next guideword. If a cause was found, the team

discussed the consequences and plausibility of the deviation. If there were no significant consequences, the team proceeded to the next item. For items with both a plausible likelihood and a significant consequence, recommendations were formulated to eliminate or reduce the likelihood of the process deviation. In some cases, notes for additional study or later action were made. A similar procedure was used for guidewords from the second part of the list in Table B-1. These guidewords are not related to process deviations, but rather to specific subject areas or conditions of operation.

PROCESS DESCRIPTION

The process under study is sterilization of hospital equipment using an ethylene oxide sterilizer. The sterilizer consists of a jacketed chamber and associated pumps, pipes, filters, valves, etc.

The actual equipment layout of the sterilizer at the facility of interest is divided into two containment areas: a loading/unloading area, which incorporates the fronts of two aerators and two sterilizer/aerators; and an equipment area, which contains the aerators, piping, ethylene oxide tanks, and the sterilizer/aerators. The sterilizer chambers are fitted with a safety valve which, depending on the machine design, relieves the chamber at 15 psi or 40 psi; and a jacket safety valve (on steam-heated units), as shown in Figure B-1.

The sterilization process begins with a mixture of liquid ethylene oxide and Freon 12 that passes through a steam-heated heat exchanger and is gasified. The gaseous mixture is fed into a preheated chamber, which contains the materials to be sterilized. The materials remain in the gaseous environment for the required amount of time for proper sterilization. Then, the ethylene oxide/Freon mixture is removed from the chamber by a sequence of exhaust and aeration cycles. A final air wash of the chamber is done to complete the process.

The vented gases leave the chamber through a ventilation system where they mix with air to give an acceptable concentration of ethylene oxide before they are exhausted to atmosphere.

Aqueous effluent from the sterilizer passes to a disengaging funnel, so that any dissolved ethylene oxide which outgasses from the water can be directed to the ventilation system before the liquid effluent passes to the drain.

To aid in understanding the equipment layout, the following definitions were developed:

(i) Equipment Room - Room where ethylene oxide sterilizer, tanks, and piping are located.

(ii) Loading Room - Contained room in which the sterilizer loading/unloading takes place.

The layout of the sterilizer is shown in Figure B-1. An overall piping and instrumentation diagram is given in Figure B-2.

The EtO sterilizer system that was evaluated in the HAZOP study was divided into the following components, or nodes, for purposes of the HAZOP:

- Layout of the EtO sterilizer facility (Figure B-1)
- Storage, transport, and changing of the EtO/Freon supply cylinder (Table B-2, Figure B-3)
- EtO piping from the cylinders to the sterilizer (Table B-3, Figure B-4)
- Introduction of EtO/Freon into the EtO sterilizer (Table B-4, Figure B-2)
- Operation of the EtO sterilizer (Tables B-5 and B-6, Figure B-2)
- Utilities and process lines to and from the EtO sterilizer (Tables B-7, B-8, and B-9, Figure B-2)
- Reliability of the dilution ventilation system (Table B-11, Figure B-5)
- Reliability of the EtO area monitoring system (Tables B-12 and B-13, Figure B-6)

These nodes are discussed in the remainder of Appendix B.

LAYOUT OF THE ETO STERILIZER FACILITY

The design intention is to assure a safe working area, and to minimize the chances of EtO exposures. General recommendations for this are as follows:

- Ethylene oxide equipment should be isolated from other hospital equipment and should be in a separately enclosed area (containment room). Minimum size and layout should be such that staff and maintenance personnel should have adequate room for working, especially for transportation of ethylene oxide tanks. The ethylene oxide sterilizer and equipment should not be installed in or adjacent to patient areas.
- If the machine control panel cannot be seen from outside the loading room, a remote control panel should be used.

STORAGE, TRANSPORT, AND CHANGING OF THE ETO/FREON SUPPLY CYLINDERS

The design intent is to safely store, transport, and install the EtO/Freon cylinders. Figure B-3 depicts the recommended piping and valving arrangements for the supply cylinders. General recommendations for installing new cylinders are as follows:

- Supply valve, tank valve, vent valve, and needle valve to vent should be labeled (see Figure B-3). The same labeling system should be used in the written operating procedures.

- Ethylene oxide piping from tank to sterilizer should contain a line to the exhaust ventilation system.

The HAZOP analysis for cylinder storage is given in Table B-2.

ETO/FREON PIPING FROM THE CYLINDERS TO THE STERILIZER

The design intent of this system is to transfer liquid EtO/Freon from the storage cylinders to the sterilizer unit. Figure B-4 shows the arrangement to perform this function. The HAZOP analysis for EtO transport is shown in Table B-3.

INTRODUCTION OF ETO INTO THE STERILIZER

The design intent of this system is to introduce vaporized EtO/Freon into the sterilizer. This system is a continuation of the EtO/Freon piping in the previous section. The HAZOP analysis is shown in Table B-4, which refers to Figure B-2.

OPERATION OF THE ETO STERILIZER

The design intent of the EtO sterilizer is to provide appropriate sterilization of the reusable hospital supplies without allowing the EtO to escape into the workplace in unacceptable amounts. Table B-5 shows a HAZOP analysis for the routine sterilizer operation. Also, the written operating procedures were reviewed in conjunction with this analysis, and safe practices for these procedures are given.

UTILITIES AND PROCESS LINES TO AND FROM THE STERILIZER

In addition to EtO, sterilizer operation also involves flows of air, steam, and condensate, as shown in Figure B-2. Consequences of deviation in these flows are considered in this section. Air is used as a vacuum break in between the vacuum cycles that are used to remove the EtO. Table B-7 shows the results of a HAZOP analysis for this air.

Table B-8 shows the results of a HAZOP analysis for the steam supply to the sterilizer. The design intent is to provide humidification and some heating during the sterilization cycle.

Table B-9 shows the results of a HAZOP analysis for the drain line from the sterilizer. The design intent is to depressurize and evacuate the sterilizer. For later machines, an interlock prevents a high discharge rate through the use of a flow restricter. When the chamber pressure is below atmospheric, a bypass valve opens around the restricter.

A HAZOP analysis of the steam supply to the heat exchanger and sterilizer jacket and of the condensate line from the heat exchanger and sterilizer jacket

showed no issues of concern. The cooling water supply and drain also showed no concerns.

The HAZOP of the pressure relief valve on the sterilizer and of the gas temperature recorder/indicator is shown in Table B-10. The design intent of these items is to maintain proper conditions of temperatures and pressure for sterilization.

RELIABILITY OF THE DILUTION VENTILATION SYSTEM

The dilution ventilation should be designed in conjunction with the sterilizer equipment. The design intent is to remove EtO that has escaped into the work area and to vent excess heat from the sterilizer. General recommendations are as follows:

- The equipment room ventilation, loading room (room in which the sterilizer loading/unloading takes place), ventilation, and machine exhaust should be routed to a dedicated ventilation system, separate from other systems. It should be sized to maintain a negative pressure in equipment room relative to loading room, and a negative pressure in loading room relative to all other areas, if for example, a tank hose were to rupture; (this corresponds to a 5.4 lb/s release). A recirculation ventilation system is not safe for ethylene oxide areas.

- Final exhaust fan should be outdoors to keep a negative pressure in the indoor ducts.

- The loading room ventilation should maintain a pressure lower than that in surrounding areas not containing ethylene oxide. The equipment room ventilation should maintain a pressure below that of the loading room. It is suggested to have separate containment rooms (one for the equipment room, and a second for the loading/unloading room). Where separate loading and unloading rooms are provided, these should both be maintained at a lower pressure than surrounding areas. Efficient ventilation would require a high level supply inlet because of thermal stratification (exhaust above supply).

Table B-11 gives the HAZOP analysis for the dilution ventilation system.

ETO AREA MONITORING SYSTEM

The facility that was evaluated used a fixed-point gas chromatograph which rotated between a series of lines that drew air from various locations in the sterilizer area.

A HAZOP analysis was done on the transport lines for potentially EtO-laden air from the work areas to the GC. This is shown in Table B-12.

A HAZOP analysis was also done on the line that conducts inert carrier gas from the carrier gas tank to the GC column (Figure B-5). This is shown in Table B-13.

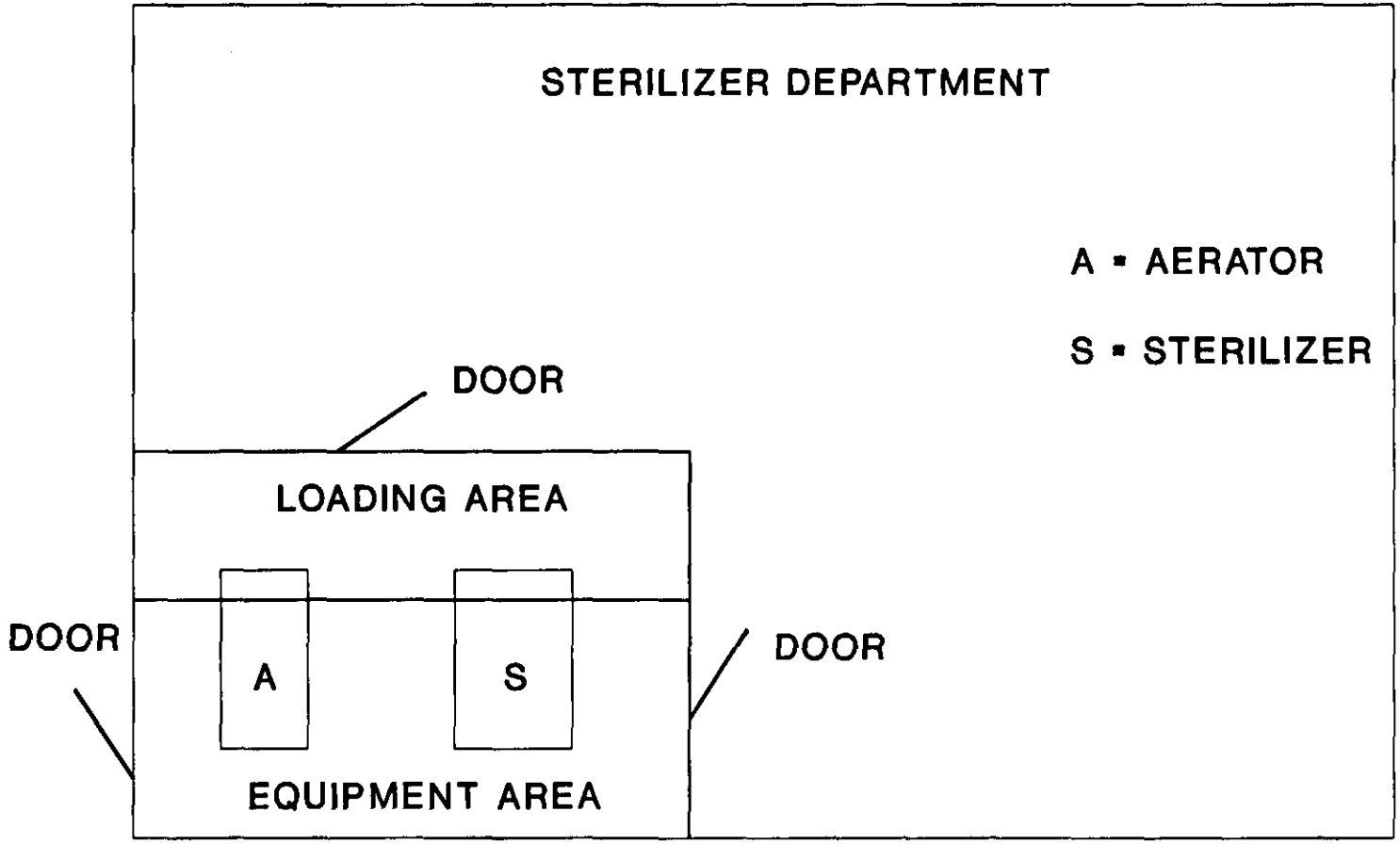

Figure B-1. Layout of the EtO Sterilizer Evaluated in the HAZOP.

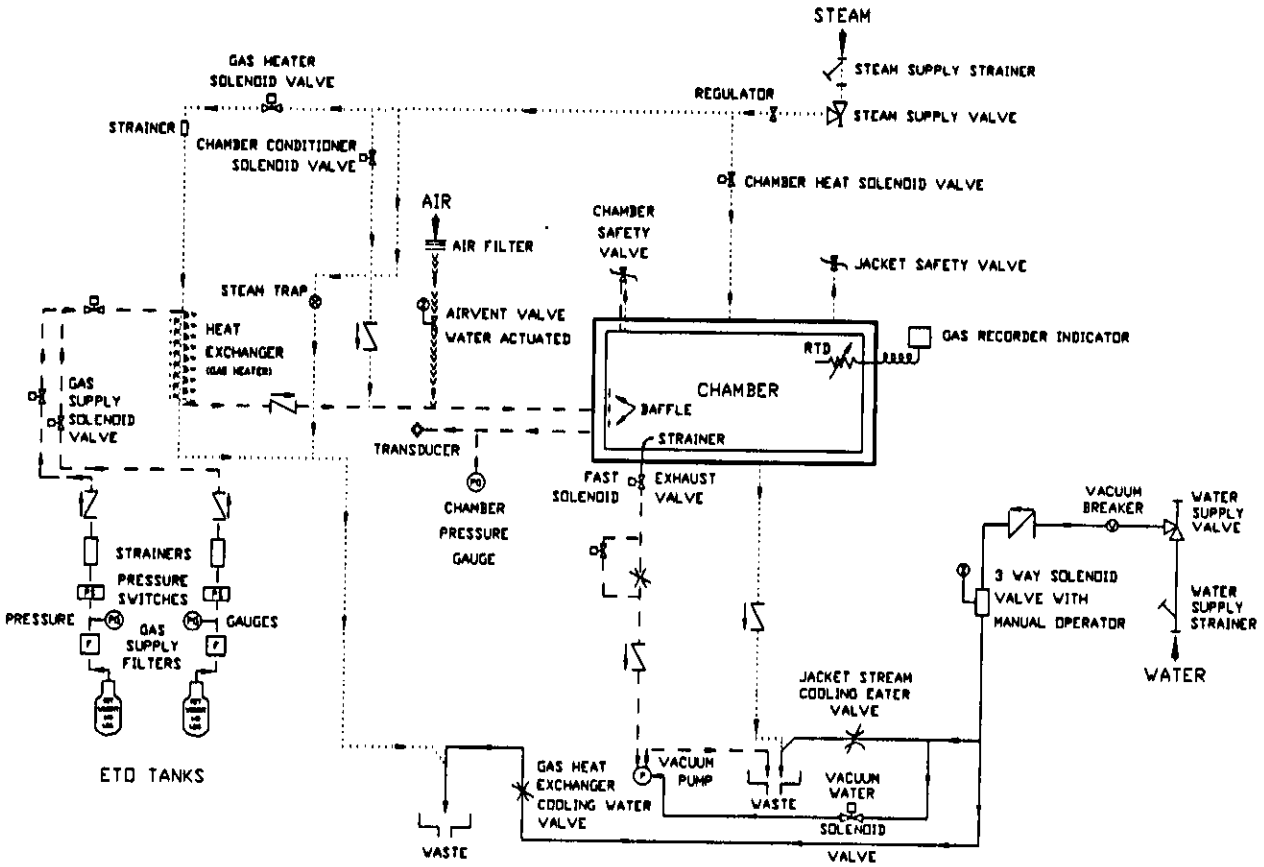

Figure B-2. Piping and Instrumentation Diagram for the EtO Sterilizer Evaluated in the HAZOP.

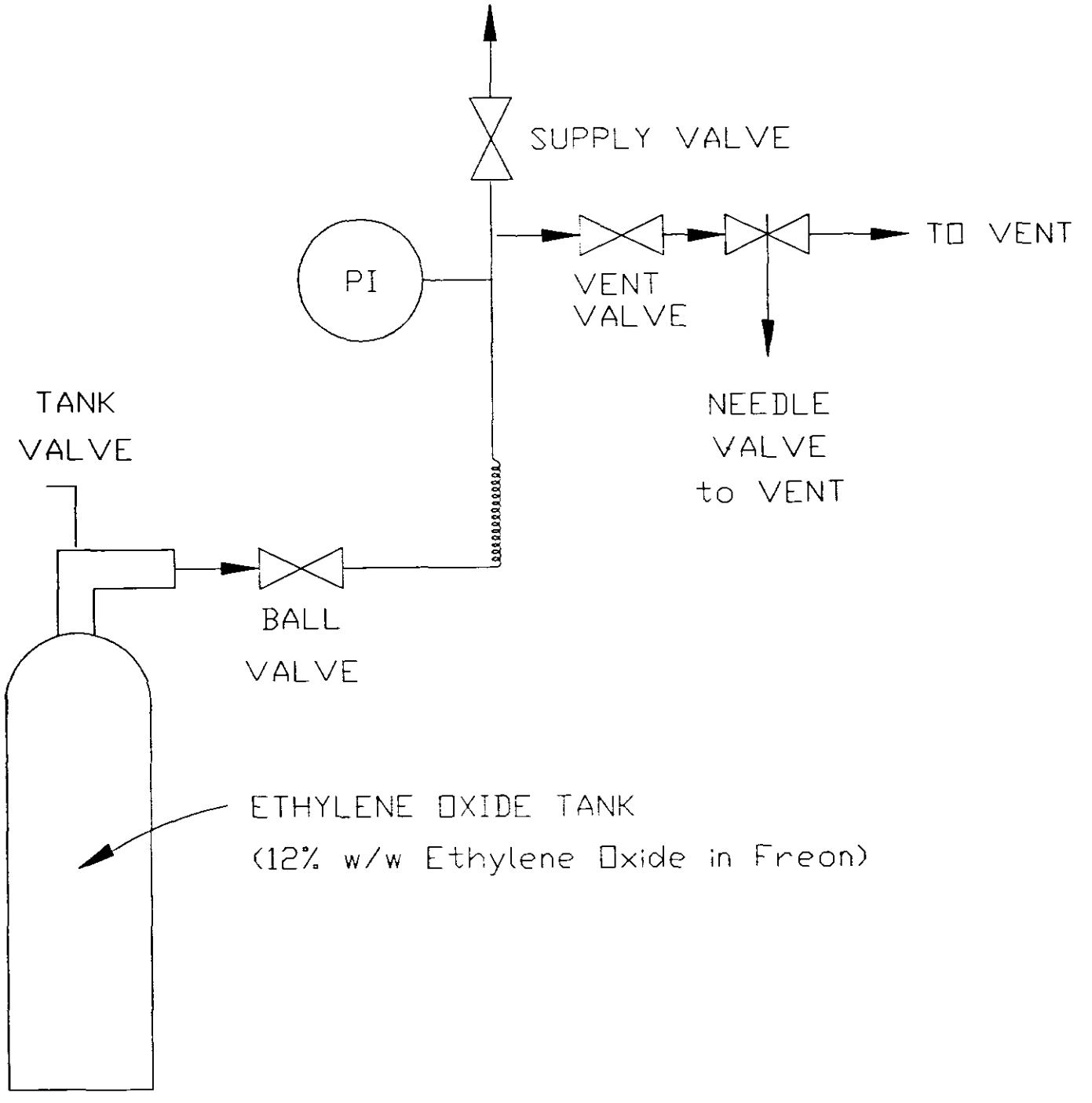

Figure B-3. Labeling of Valv on the EtO Supply Line.

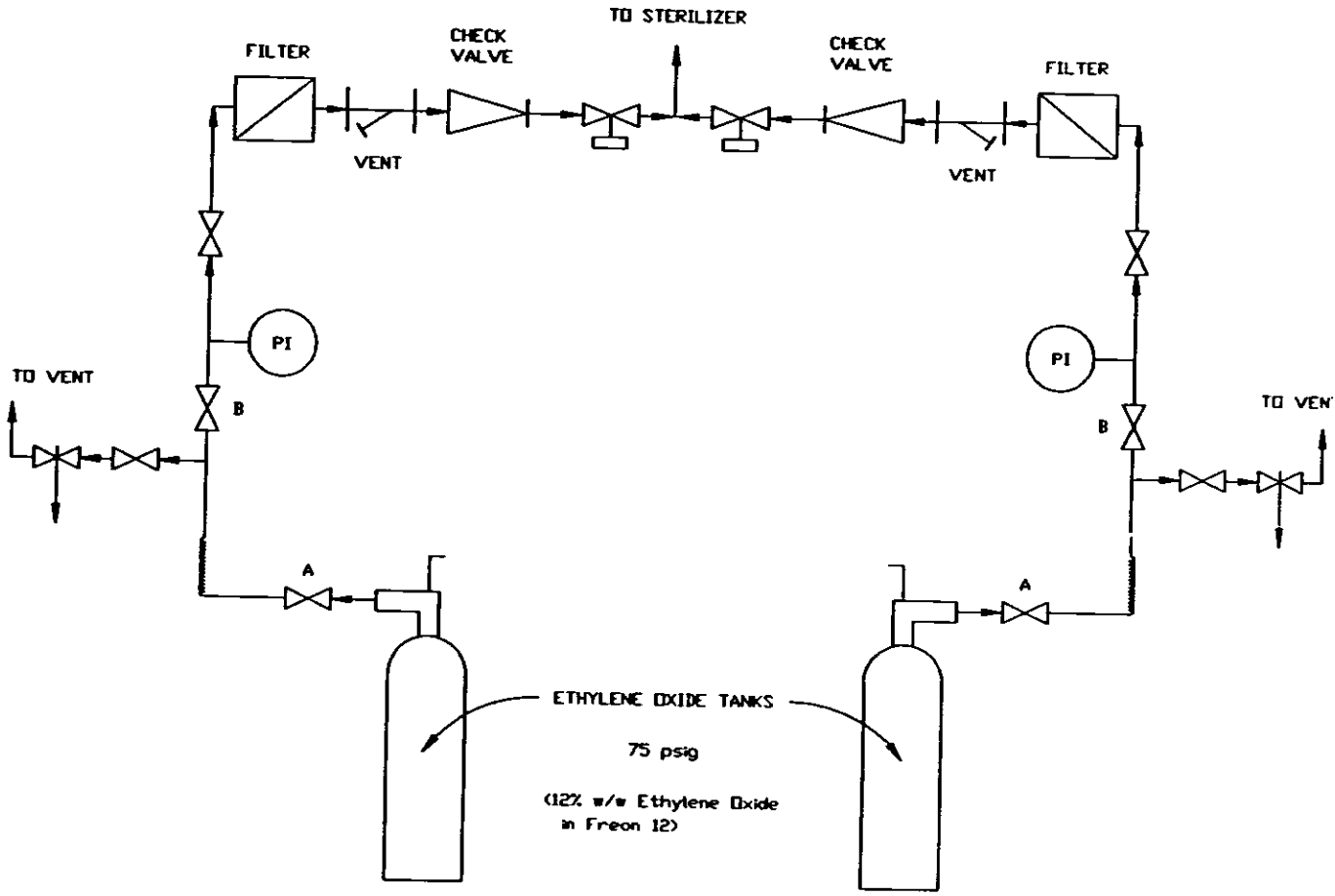

Figure B-4. Piping for Transport of EtO/Freon from the Supply Cylinders to the Sterilizer.

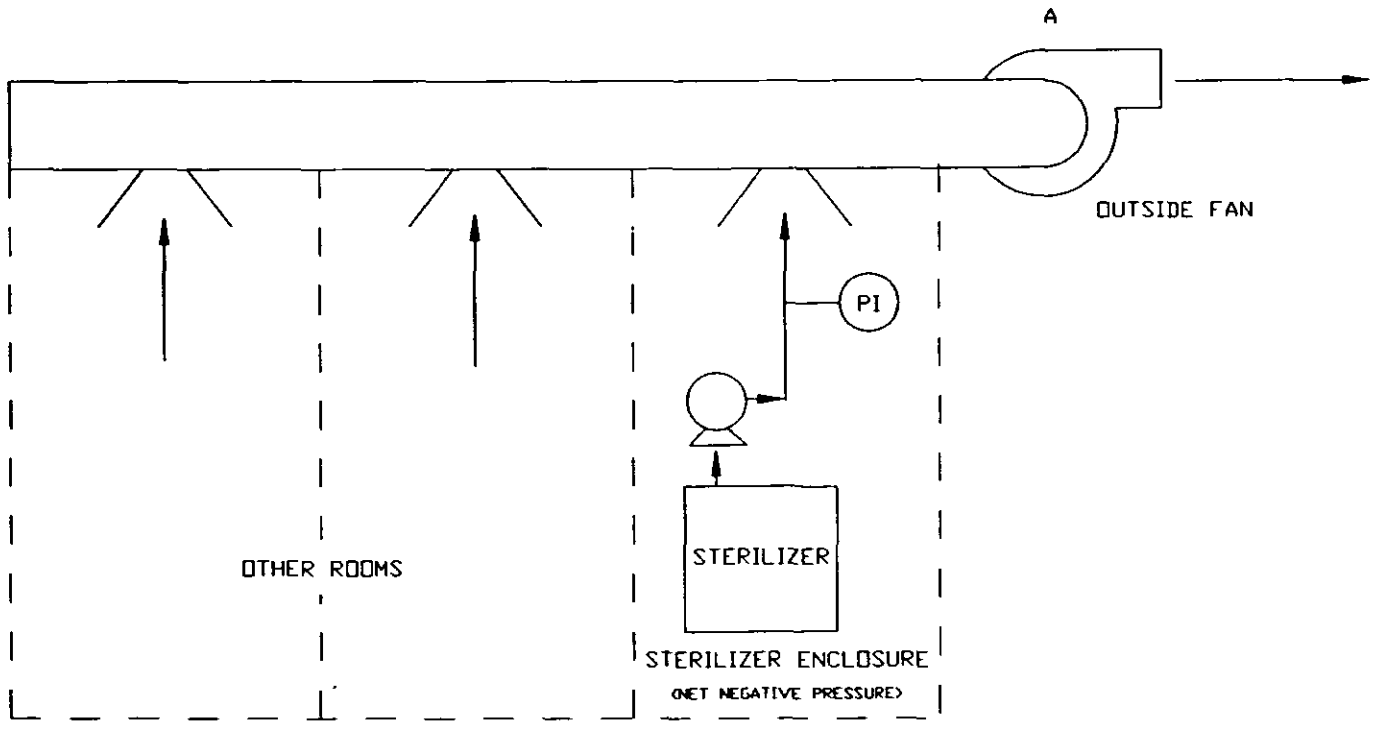

Figure B-5. Schematic of a Dedicated Dilution Exhaust for the EtO Sterilizer.

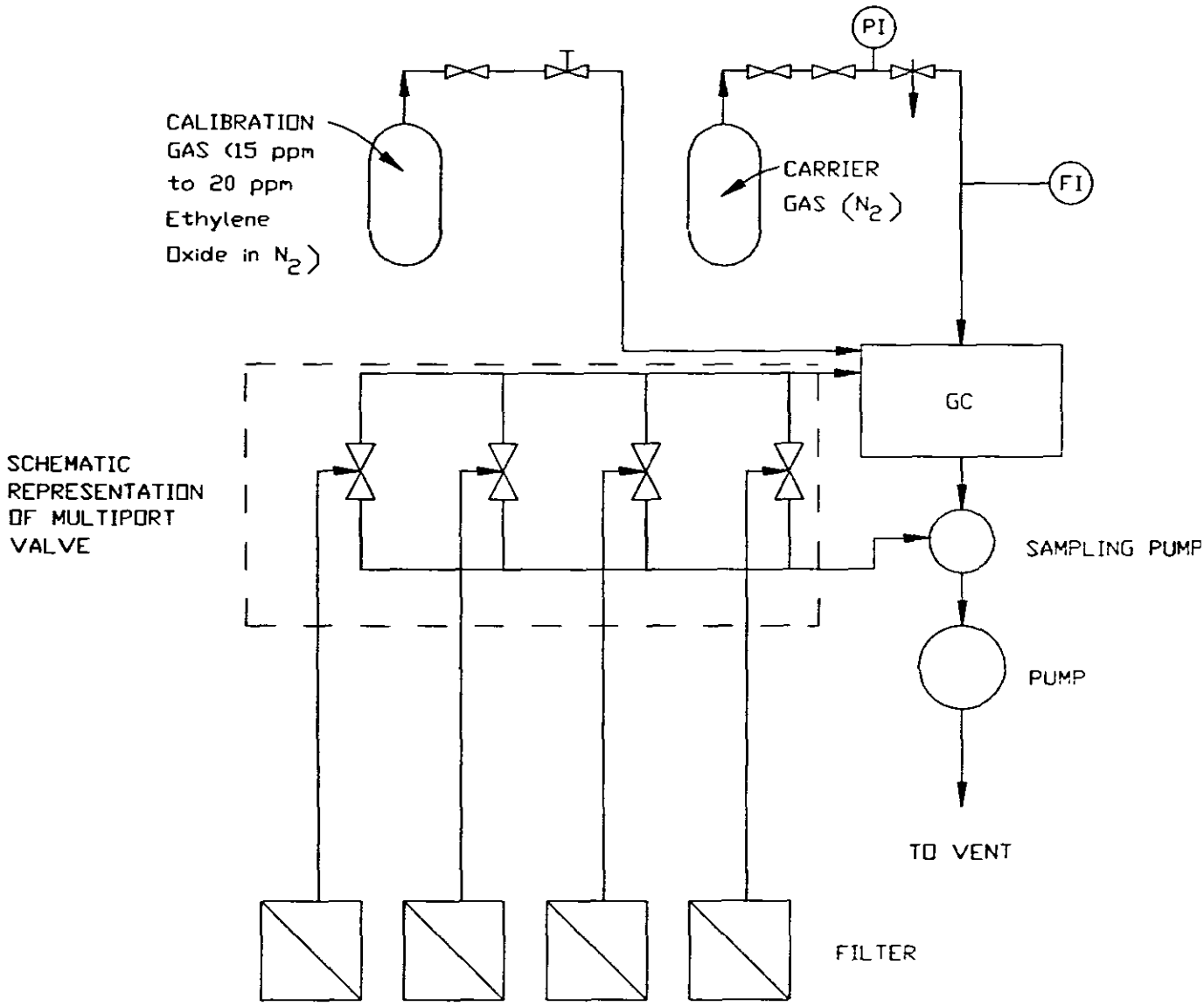

Figure B-6. Schematic of Area Monitoring System for EtO.

Table B-1. HAZOP Guideword List.

PART I - Process Parameters	
Flow	No Flow
	Reverse Flow
	More Flow
	Less Flow
Level	More Level
	Less Level
Pressure	More Pressure
	Less Pressure
Temperature	More Temperature
	Less Temperature
Viscosity	More Viscosity
	Less Viscosity

PART II - Other Items
Composition Change
Contamination
Pressure Relief
Instrumentation
Sampling
Corrosion/Erosion
Service Failure
Abnormal Operation
Maintenance
Static Electricity
Spare Equipment
Safety

Table B-2. HAZOP Analysis of EtO/Freon Supply Cylinders

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
SAFETY	High temperature.	High pressure.	Store tanks in well ventilated area below 100°F. Follow storage regulations of pressurized ethylene oxide gas (use of caps, etc.). Allow ethylene oxide tanks to achieve room temperature before use.
	Faulty or damaged cylinder.	Ethylene oxide release.	Develop a transportation route to avoid patient areas, and transport one tank at a time using a cart with a holding strap. Check for leaks from tanks using a halogen leak detector, or other appropriate leak detector, before transporting to equipment room, after transporting, and after connecting to piping. If ethylene oxide tank is dropped, assume leaking. If an audible or visible leakage, assume a severe leak and leave area immediately.

Table B-3. HAZOP Analysis of Piping and Valves for EtO Transport from the Storage Cylinders to the Sterilizer Unit (Refer to Figure B-4).

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
NO FLOW	Closed valve in line or ethylene oxide tank is empty.	No hazard.	No safety issue.
REVERSE FLOW	Ethylene oxide tank is not present and valves A and B are open, and check valve fails.	Flow of trapped material into equipment room.	Written procedures should be placed near valve B indicating that the valve should not be open while changing ethylene oxide tanks.
HIGH FLOW (CONT-INUOUS RELEASE)	Broken line or hose due to an accidental break.	Damage to piping or other equipment. Chemical burns. Pool of ethylene oxide forms.	Instruction to operator must be to leave the room and initiate emergency procedures. Respirator equipment should be close by equipment room (room where ethylene oxide sterilizer, tanks, and piping are located). Equipment room should have two exits. All ethylene oxide tanks should be located in one general area.

(continued)

Table B-3 - continued

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
HIGH FLOW (CONT.)			Piping design should follow the code for medical gases and NFPA 99 codes (fire codes). NFPA code recommends that copper containing alloys are not suitable for ethylene oxide. This is the case if the ethylene oxide contains acetylene as a contaminant. Since all U.S. manufactured ethylene oxide now contains no acetylene, copper piping is considered here to be acceptable. This should specify hard copper tubing, silver solder joints, and adequate supporting. The piping diameter (1/4" min.) and routing should be chosen to minimize the liquid inventory. Piping should be labeled to identify it as carrying ethylene oxide. The ethylene oxide piping should not be adjacent to steam lines. Operators and maintenance staff should be trained in the hazards of ethylene oxide and Freon 12 according to OSHA regulations.

(continued)

Table B-3 - continued

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
HIGH FLOW (CONT.)			The atmosphere in the equipment room should be monitored to provide a gross leak alarm in the case of an accidental release. A suitable alarm concentration would be to a maximum of 100 ppm. The monitor should be tested periodically at the manufacturer's recommended frequency or every three months, whichever comes first. An organic vapor detector would be suitable. Alternatively, GC equipment could be used. The sampling point should be located in the approximate breathing zone in the loading area, near potential leak sources. The equipment room ventilation, loading room (room in which the sterilizer loading/unloading takes place), ventilation, and machine exhaust should be routed to a dedicated ventilation system, separate from other systems. It should be sized to maintain a negative pressure in equipment room relative to loading room, and a negative pressure in loading room relative to all other areas, if for example, a tank hose were to

(continued)

Table B-3 - continued

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
HIGH FLOW (CONT.)			rupture; (this corresponds to a 5.4 lb/s release). A recirculation ventilation system is not safe for ethylene oxide areas.
LESS FLOW		No hazard.	No safety issue.
MORE PRESSURE	Equipment room temperature increase warms tank.	Ethylene oxide leakage around tank valve. Polymerization in tank.	Vent should be sized to ensure that temperature in equipment room should be less than 100°F as specified by ethylene oxide gas distributor.
LOW PRESSURE			No safety issue.
HIGH TEMP. (NON-AMBIENT)	High room temperature.	High pressure.	Same as for more pressure.
	Steam leak onto tank.	Possible fusing of fusible plug.	When working on pressurized ethylene oxide system, (e.g., when changing cylinders, protective equipment should be worn, including face shield and gloves), facilities should be provided to allow rapid washing off of any spillage or splashing to the skin (e.g., a safety shower).

(continued)

Table B-3 - continued

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
COMPO-SITION	Composition in tank has pure ethylene oxide (no Freon 12).	Explosion or fire.	Inspection for correct labeling (usually by color and sticker) of newly arrived ethylene oxide and Freon tanks should be done. Tanks should be stored in an isolated area. Operator should ensure that the proper ethylene oxide and Freon tank is hooked up to sterilizer. A sign saying "Check tank label for proper ethylene oxide and Freon composition" should be posted in the storage room.
CONTAMI-NATION	Dirt contaminates process stream while making couplings.	Filter should remove.	No safety issue.
RELIEF (VENTING)	Blocked needle valve in vent line.	No depressurization of hose and line between valves A and B (see Figure 2).	A system of two isolation valves should be present on ethylene oxide inlet lines. Addition of a bleed between the two valves would reduce the consequence of leakage. Alternatively, addition of a pressure indicator between the valves would allow leak detection. Move or add the pressure indicator to position upstream of valve B. This configuration is shown in Figure B-4. The recommended configuration is shown in B-3.

(continued)

Table B-3 - continued

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
MAINT-ENANCE	Leak from valve stems, joints, etc.	Low concentrations of ethylene oxide in atmosphere.	Carry out regular check for leaks around fittings using an appropriate leak detector (i.e., a halogen or hydrocarbon leak detector).
SAFETY	Major leaks.	High concentration of ethylene oxide in area.	Develop a contingency plan for use when a major leak occurs. See Operational Procedure 9.
(SECURITY)	Unauthorized entrance into equipment room or access area.	Equipment misuse. Exposure to ethylene oxide.	Equipment room should be marked, and a locked door should be used if possible.
(HAZARDS OF PROCESS MATERIAL)			See recommendations for high flow.
(EMERGENCY EQUIPMENT)			See recommendations for high flow.

Table B-4. HAZOP Analysis of EtO Introduction into the Sterilizer (Refer to Figure B-2).

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
NO FLOW		No hazard.	No safety issue.
REVERSE FLOW		Not possible.	No safety issue.
MORE FLOW	Solenoid valve opens when chamber door is open.	Ethylene oxide transport through piping.	An interlock is required to ensure that the ethylene oxide inlet valve (or valves) cannot open unless the chamber door is locked.
	Regular wear on solenoid valves.	Leakage of solenoid valves.	A system of two isolation valves should be present on ethylene oxide inlet lines. Addition of a bleed between the two valves would reduce the consequence of leakage. In addition, the addition of a pressure indicator between the valves would allow leak detection. Move or add the pressure indicator to position upstream of valve B in Figure B-3.
MORE FLOW	Pressure switch fails.	- Relief valve on chamber lifts.	Chamber relief valve should be routed to the dedicated ethylene oxide ventilation system.
		- Failed door gasket.	Door gasket should be inspected before each use; replace when necessary.

(continued)

Table B-4 - continued

GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/RECOMMENDATION
LESS FLOW	General use.	- Longer time to pressurize. Fails after time limit.	No safety issue.
LESS PRESSURE	Steam vent line from heat exchanger is blocked.	Higher temperature in ethylene oxide and polymer forms.	No safety issue.
LOW TEMP. IN ETHYLENE OXIDE LINE	Hot chamber contains liquid ethylene oxide and Freon.	- No safety hazard if relief valve is adequately sized. - Rapid evaporation of ethylene oxide & Freon. - Overpressure in chamber.	Relief valve should be sized for maximum liquid feed rate to hot chamber, assuming all liquid will evaporate.
SERVICE FAILURE	Power failure during sterilization steps.	- Sequence stops. - Valves close.	Manual venting arrangement for power failure should not be used as this could lead to ethylene oxide exposure to operator. It is recommended that either the manual vent valve be disabled, or only used under careful management control.

Table B-5. HAZOP Analysis of Routine Sterilizer Operation.

STEP	GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/ RECOMMENDATION
WARMUP	SAFETY HAZARDS	Setting temperature higher than 130°F.	Contact burns - alarm sounds at 160°F.	No safety issue.
		Misreading of temperature (high or low).	Out of limits - won't start.	No safety issue.
		Misreading of pressure (high or low).	Out of limits - won't start.	No safety issue.
PREHEAT	SAFETY HAZARDS	Timer malfunctions.	No hazard.	No safety issue.
EVACUATION AND STEAM PULSING	SAFETY HAZARDS	Air or steam leakage into chamber.	Causes higher pressure or pumps work harder. No hazard.	No safety issue.
		Vacuum switch faulty.	- Pressure not achieved. No hazard.	
			- Overpressurize chamber possible, but no hazard.	
		Air in chamber during evacuation.	No hazard.	
		Faulty reading of pressure during evacuation.	Too long in cycle - alarm sounds. No hazard.	

(continued)

Table B-5 - continued

STEP	GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/ RECOMMENDATION
CHARGING WITH ETO	NO FLOW		Alarm from watchdog timer.	No unresolved safety issue.
	MORE FLOW	Leakage in heat exchanger (tubes).	Steam carries ethylene oxide gas to drain.	No unresolved safety issue.
		Reverse flow into steam line.	No real chance of leakage to steam.	No safety issue.
		Reverse flow into air line via leaking valve.	Ethylene oxide leak to equipment room.	Air inlet to chamber should not pick up air from equipment room, but from exhaust duct to reduce risk from reverse leakage of ethylene oxide.
	SAFETY HAZARD	Prior evacuation of air was not achieved; begins to charge with ethylene oxide and Freon.	No hazard to operators - not sure of sterility of load.	See Operational Procedure 2b.
STERILIZING PROCESS	SAFETY HAZARD	Leakage of ethylene oxide and Freon.	Notification by computer printouts and alarms if leakage is severe.	No unresolved safety issue.
EVACUATION	SAFETY HAZARD	Rapid depressurization of chamber.	Overloading of vent (exhaust) system at the plumbing gap.	Maximum exhaust rate of gas from chamber must not exceed ventilation system capacity.

(continued)

Table B-5 - continued

STEP	GUIDEWORD/ DEVIATION	POSSIBLE CAUSES	POSSIBLE CONSEQUENCES	ACTIONS/QUESTION/ RECOMMENDATION
EVACUATION AND AIR WASH	LEAKAGE OF ETHYLENE OXIDE	Faulty pressure switch allows cycle to step on without proper evacuation.	Open door when not actually safe to do so.	See Operating Procedures 2b and 2c. Also, an interlock is required to ensure that the ethylene oxide inlet valve (or valves) cannot open unless the chamber door is locked. Add a 20 min. air wash procedure if not already on system.

Table B-6. Safe Practices for Sterilizer Operating Procedures.

1. Loading

   a) Packaging must be freely permeable to ethylene oxide in both directions. All plastic bags are not suitable (e.g. "green bags").

   b) Loading carts or baskets should be used, to ease the unloading process. No load should be placed in the sterilizer which would require the operator to unload articles separately.

   c) Soiled goods should be cleaned before packaging. Goods sterilized by ethylene oxide should be only those which cannot be sterilized another way.

   d) Loading should not be so dense as to prevent complete circulation of gas around each package.

2. Unloading a Load Which Has Not Been Fully Aerated

   (Typical procedure for larger sterilizers.)

   a) Whenever possible, a load should be aerated in the sterilizer.

   b) On completion of cycle, check that cycle completed properly on the chart or print out. If not, follow procedure for an incomplete cycle.

   c) Open door 2-3 inches to allow local ventilation system to capture the chamber off-gas. Leave door in this position for 15 minutes. Operator should leave area during this time.

   d) Prepare aerator for loading before opening door.

   e) Open door. Unload cart to transport cart. Operator should draw cart out, moving backwards in front of cart. Operator should avoid entering chamber, and keep as much distance from load as possible.

   f) Ensure that upper cart locks onto transport cart.

   g) Biological indicators should normally be removed only after aeration. If biological indicator is to be removed from nonaerated load, this should be done with minimum operator contact with the load, and with air flow from operator to load. Incorrect practices in removal of biological indicators from a nonaerated load could give significant exposure to the operator.

   h) Where possible, pull load to aerator on cart, keeping distance between operator and load wherever possible. This ensures rising plume of

(continued)