CONCLUSIONS

EtO exposures from hospital sterilizers can be controlled to not exceed a ceiling limit of 5 ppm and to average less than 0.1 ppm for a full shift. All but one of the hospitals surveyed in this study had short-term exposures less than 2 ppm and full-shift exposures less than 0.1 ppm.

The extent of control needed by a hospital will depend on a number of factors such as the composition and size of the sterilized load, the location of the sterilizer and the time constraints on sterilization, the type of sterilizer and the types of controls selected, and the level to which EtO exposures are to be controlled. In-chamber aeration, which substantially eliminates any exposure, is the best control. When it is not possible to fully use in-chamber aeration, the results of this study suggest that cycle modifications, local ventilation above the sterilizer door, and a ventilated enclosure around the sterilizer drain are the next most effective techniques for reducing exposures. Other controls -- such as a well-ventilated equipment room, cylinder station ventilation, and sterilizer isolation rooms -- provide additional benefit. In this study, general ventilation did not seem to be as important as other control techniques in controlling EtO exposures. EtO and ventilation sensors and alarms and proper emergency response procedures are essential to every control system.

CYCLE MODIFICATIONS

In-chamber aeration resulted in EtO emissions/exposures below detectable limits. When in-chamber aeration was not used, pulse-purge cycles and deep-vacuum purges were effective in reducing the emission of EtO from the sterilizer and the exposure to the operator during the load transfer. A 15-minute door-cracked period reduced the concentration in the chamber before the door was fully opened by an average of 70 to 99 percent, regardless of the purge cycles which preceded it. Closed-door air flushes were observed to not be as effective as the vacuum purge cycles.

STERILIZER DOOR VENTILATION

Local exhaust ventilation above the sterilizer door will capture EtO emitted from the partially open sterilizer door if the flow rate is adequate for the exhaust hood's location. The further above the door that the hood is located, the larger the hood needs to be to allow for spreading of the plume as it rises. Without local exhaust ventilation above the sterilizer door, the EtO in the chamber at the end of sterilization will disperse throughout the room.

VENTILATED AIR GAP ENCLOSURE

If the discharge line of the sterilizer is not adequately controlled, a considerable quantity of EtO may be emitted during the evacuation cycle. Even if a ventilated enclosure is installed around the antisiphon air gap, if the junction with the floor drain or other openings in the line are not sealed, EtO may still escape. One possible route for EtO emission is a line connecting the leak cups on the water-sealed vacuum pump to the drain.

SINGLE-DOSE CARTRIDGE STERILIZERS

The sterilizers which use single-dose cartridges and operate below atmospheric pressure do not have liquid drain junctions. However, hospital personnel could be exposed if the discharge lines (which are pressurized above atmospheric pressure during the purge cycles) leak or if the outlet is not properly terminated outside the building. Also, if the cartridge-well is outside the sterilizer and the single-dose cartridge is not seated properly or there is some malfunction, workers could be sprayed and exposed to the EtO vapors.

EtO DISCHARGE LOCATION

The odor of EtO cannot be detected until concentrations reach approximately 700 ppm. Thus, workers may unknowingly be exposed. Such exposures may result from the reentry of EtO into buildings through heater or air conditioning intake vents. A small quantity of EtO can cause a potentially harmful concentration in the average size office or hospital room.

STERILIZER ISOLATION ROOMS

Enclosing the sterilizers in a separate room should result in low personal exposures and area concentrations in the areas outside the enclosure or containment zone. However, it may expose the sterilizer operators to higher concentrations when in the isolation room. A sterilizer isolation room cannot be used as a substitute for other controls.

MECHANICAL ACCESS ROOM/STERILIZER CABINET VENTILATION

Sterilizers supplied by compressed-gas cylinders are often recessed into a separate room (called a mechanical access room, equipment room, or recess room) which may or may not enclose all the potential EtO emission sources. These rooms are usually ventilated. This type of sterilizer may also be enclosed in a cabinet, which is usually not ventilated. There is always the possibility of incidental release of EtO in the enclosure. If the enclosure is inadequately ventilated, air containing EtO may escape into areas where employees work. Heat sources inside the enclosure tend to disrupt otherwise adequate ventilation.

Even if the mechanical access room ventilation is adequate, EtO released in the room could still be a problem for workers who must be in the room. Workers performing maintenance on other equipment in the mechanical access

room may be unaware of the potential for exposure to EtO during the purge cycle or if the overpressure relief valve should open.

SUPPLY CYLINDERS

A leak from the EtO supply lines or cylinders could release a considerable quantity of EtO. During the cylinder change operation, liquid EtO from the pressurized supply lines could spray the worker changing the cylinder when supply line is disconnected, creating both a skin hazard and an inhalation hazard.

RELIEF VALVE

For a 12:88 sterilizer, if the overpressure relief valve opens (at a set-pressure of 15 psig) approximately 100 gm of EtO could be released, enough to create a concentration of over 2,000 ppm in a 1,000-ft^3 room. This would create a hazardous situation.

DEDICATED EXHAUST

When an auxiliary fan is added to the sterilizer exhaust system to push air into the main exhaust duct, and a "dedicated" exhaust is not used -- i.e., there are other vents in the exhaust duct (which is almost always the case) -- EtO could be forced out of vents not exhausted by the auxiliary fan if the roof fan should fail and the auxiliary fan keeps running. This could expose hospital personnel in areas far removed from the sterilizers because their area (or an adjacent one) is served by the exhaust system from the sterilizer room.

VENTILATION ALARMS

Workers could be exposed to EtO if a sterilizer goes through an evacuation cycle, a load transfer procedure, or an in-chamber aeration cycle when the exhaust ventilation is not operating properly. The sterilizer should not be operated if the ventilation system is not functioning properly. Various sensors are available which could be installed to set off an alarm if flow decreased appreciably. However, such a system would require periodic maintenance and checking because lint, which is often present in the central service area from folding the linens, can interfere with the proper operation of flow sensors.

GENERAL VENTILATION

In this study, the volume of nonrecirculated air exhausted per hour relative to the room volume, usually referred to as "room air changes per hour," was not shown to be as important in controlling routine emissions of EtO as other engineering controls. However, if a large quantity EtO were released, a high rate of ventilation would be helpful in clearing the room, provided that all air is exhausted directly outside the building and not recirculated to any areas of the hospital. Typical ventilation rates found to be adequate are shown in Table 15.

Table 15. Typical Ventilation Rates Found to be Effective for Access Rooms.

Type of Equipment	Exhaust Volume cfm
Small (> 10. cu.ft.) electrically heated gas sterilizers	100
Large Steam-heated gas sterilizers and steam sterilizers	250
Aerators and instrument washer units	175

WORK PRACTICES

Exposures to emitted EtO may be lessened by limiting the closeness to the sources and/or the duration of the contact. Holding a load close to the breathing zone resulted in an elevated exposure. A 15-minute door-cracked period prior to transferring the load from the sterilizer to the aerator was effective at reducing the quantity of EtO in the chamber which could potentially expose workers.

EtO ALARMS

Implementing controls for emissions and exposures will reduce the likelihood and severity of exposures; however, the potential for an exposure can never be completely eliminated. The possibility of exposures above recommended limits due to accidents or malfunctions will always exist. Accidents can happen, and may involve the release of large amounts of EtO. Because the odor of EtO cannot be detected at concentrations much less than 700 ppm, workers can be exposed to potentially harmful amounts of EtO without knowing it, and sensors and alarms are needed to warn of elevated EtO concentrations. Relatively inexpensive EtO sensors and alarm systems are available which could alert workers to an emergency situation involving the presence of a high concentration (greater than 20 ppm) of EtO. Other more sophisticated (and more expensive) systems have been developed which could detect elevated concentrations on the order of 1 ppm or less.

EMERGENCY PROCEDURES

Hospital personnel could be overexposed if a large, uncontrolled release of EtO occurred. Most hospitals surveyed had developed emergency response plans, although only a few had rehearsed the plan to make sure everyone knew what to do.

ROUTINE MONITORING

NIOSH Method 1607 utilized with personal sampling pumps operated at flow rates of 10 mL/min (for 8 hours) and 50 mL/min (for 5 to 20 minutes) proved adequate for a 0.1 ppm 8-hour TWA and a 5 ppm STEL, respectively. From 0 to 94 percent of the air samples collected for EtO on charcoal tubes (NIOSH Method 1607) in this study were below the limits of detection (LODs) of the method. Limits of detection varied from 0.1 to 1.4 µg per sample, depending on the sample lot, the method of determining the LOD, and the laboratory performing the analysis. Method 1614 was issued in 1987, replacing Method 1607 utilized in this study. This method is a modification of OSHA Method 50. In addition to a larger sample capacity, the new method is more convenient to use, utilizing a single sorbent tube with an integral backup section in place of the two separate, larger tubes used with Method 1607.

RECOMMENDATIONS

When EtO is used, the control strategy should principally depend on the containment of EtO within sealed containers, equipment, and piping. Where exposures may occur, such as in the unloading of sterilized loads, a combination of local ventilation, good work practices, and personal protective equipment is needed to control exposures. The dilution ventilation system should be designed to reduce the potential for widespread exposures to EtO, and anticipated discharge points should also be designed to avoid additional exposures. Maintenance of equipment and controls and monitoring to assure proper performance and provide timely feedback of control effectiveness are also very important. The implementation of a good respiratory protection program and the labeling and posting of hazards are other components of a complete system of controls. All of these items are discussed in more detail in the following text and have been included in NIOSH's Current Intelligence Bulletin 52.[74]

EXPOSURE SOURCES AND SPECIFIC CONTROL METHODS

Sterilizer Area

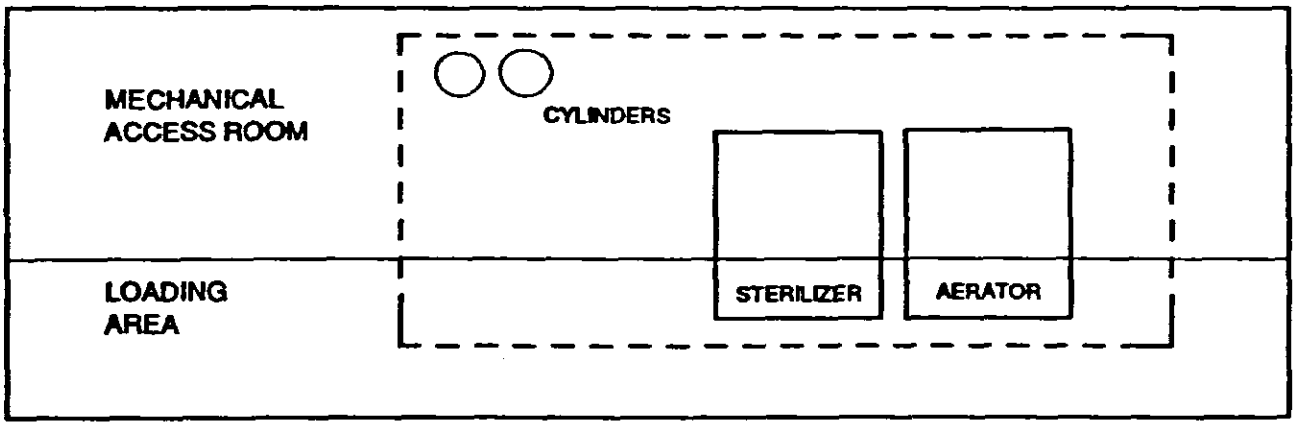
Exposure Source--
Sterilizer leaks can occur from the failure of gaskets, valves, or other equipment as well as from other sources described in this report. The layout of the sterilizer system can significantly affect the potential for EtO exposure if a leak should occur.

Control Methods--
If a sterilizer is supplied by a gas cylinder (Figure 19), the sterilizer, cylinder, and associated piping should be contained in a mechanical access room (also called the equipment room or recess room). Access to the front of the sterilizer should be gained through a separate loading room. The loading room should not be routinely occupied when the sterilizer is operating. A window should allow direct observation of the loading area and control console. Sterilizers using cartridges should also be located in separate, ventilated rooms or in laboratory hoods that are appropriate for controlling EtO exposure.

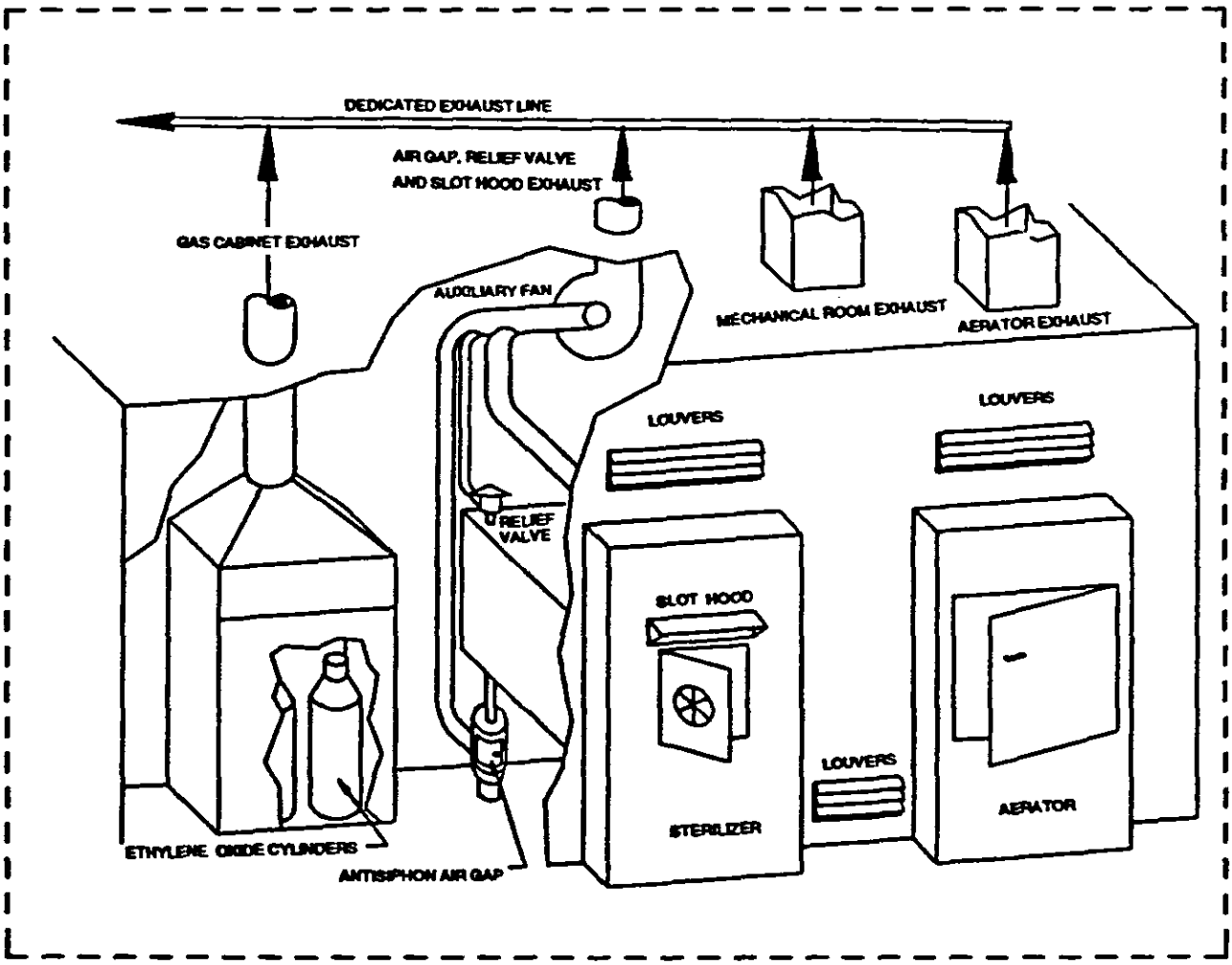
Operation of Sterilizers

Supply Cylinders--

Exposure source--Compressed-gas supply cylinders are potentially large sources of EtO exposure. A typical large supply cylinder of the 12:88 gas mixture contains 7,000 g of EtO. The supply line from such a cylinder contains liquid EtO under pressure. If this line is not properly purged before disconnection, the worker may be exposed to EtO from residual liquid or vapor in the supply line.



OVERHEAD VIEW OF STERILIZER AREA



CUT-AWAY VIEW OF STERILIZER AREA

Figure 19. Gas-cylinder-supplied EtO sterilizer with isolated loading area and mechanical access room.

Control methods--To control the inhalation hazard, local exhaust ventilation should be provided above the supply cylinders where they are connected to the sterilizer supply line(s), or the supply cylinders should be enclosed in a ventilated cabinet.

To protect workers who must disconnect the supply cylinder, a three-way vent valve should be installed on the supply line where it connects to the cylinder shut-off valve. This three-way valve should direct residual EtO from the supply line to a dedicated exhaust ventilation system or to the ventilated enclosure around the evacuation line and drain air gap.

The EtO supply line from the tank to the sterilizer should also contain a pressure gauge. The supply valve, tank valve, and vent valve should be labeled; these labels should be consistent with the written operating instructions. When changing the supply cylinder or disconnecting any portion of the supply line, workers should wear a full-face shield, protective gloves, and other protective clothing as required by OSHA (29 CFR 1910.1047)[75] to protect any area of the body that may come in contact with liquid EtO. For maximum protection, the gloves should be made of nitrile or butyl rubber.

Newly Sterilized Loads--

Exposure sources--Direct contact with EtO may occur when the operator transfers a load from the sterilizer to the aerator. A typical charge of EtO produces concentrations greater than 200,000 ppm in the sterilizer during the sterilization cycle. Grab samples taken during surveys showed concentrations up to approximately 4,000 ppm in the chamber when the door was first opened.

High EtO concentrations (10 to 100 ppm) can build up around newly sterilized, unaerated loads. Workers may therefore increase their exposures significantly by close contact with such loads for more than a few seconds (unloading requires 1 to 2 minutes).

Control methods--For maximum protection, the concentration of EtO in the sterilizer chamber should be as low as possible before the worker opens the door and removes the load. To eliminate or greatly reduce exposure to newly sterilized loads, in-chamber aeration should be used if available. If it is necessary to transfer the load to achieve aeration, workers should run as many post-sterilization EtO-reduction cycles as time allows. To further reduce the chamber concentration of EtO before load transfer, a ventilated exhaust hood should be installed above the sterilizer door, and the door should be opened for 15 or 20 minutes to the latched position or to a distance of 2 inches, whichever is less.

Workers should spend minimal time in the loading area during the entire sterilization cycle and should be kept away from the area during the door-latched phase. Any handling of a newly sterilized load should be done carefully but as quickly as possible to minimize EtO exposure. The operator should maintain an arm's length distance from the load if possible. A cart should be used to transfer the load, and instead of pushing the load (which may force EtO into the breathing zone), the cart should be either pulled or pushed from the side.

Ventilation

Dedicated Exhaust System--

Exposure sources--Ventilation is the principal means for controlling EtO emissions. If the primary EtO exhaust system involves ductwork that has inlets in other rooms of the building, EtO could be spread to these areas. Some sterilizers are fitted with an auxiliary fan to exhaust EtO from the primary emission points around the sterilizer and push the exhausted air into the ventilation system. For sterilizers that use an auxiliary fan, EtO may be forced out other inlet grilles in the ventilation system if the main fan does not have sufficient capacity for the additional exhaust flow from the sterilizer fan.

Significant EtO exposures may occur if the ventilation system fails or if its performance deteriorates significantly. Without reliable ventilation system monitors and alarms, the sterilizer operator may be unaware of a malfunction. An accidental release of a large quantity of EtO could contaminate other areas of the facility through the general ventilation system.

Control methods--EtO exhaust should be vented to a dedicated exhaust ventilation system -- that is, a system composed of local exhaust ducts that serve the sterilizer area only (i.e., the area containing the sterilizer, EtO cylinders, aerator, etc.) and route EtO directly to the outside of the building by maintaining a net suction on all of the exhaust ductwork. The exhaust system should be designed so that prevailing winds will not carry the exhaust into populated areas or into the open windows, doors, or air intakes of buildings.[76] If such a system has not yet been installed, and if the system uses one or more auxiliary fans, each grille in the system should be checked under all operating conditions with a smoke tube or other directional-flow indicator to ensure that air is drawn into the exhaust system and not pushed out while auxiliary fans are running.

Flow sensors and alarms should be installed to warn workers of fan failure or degraded performance. The sterilizer should not be operated if the exhaust system is not functioning properly, and the sensor and alarm systems should be checked as recommended by the manufacturer to ensure that they are operating.

Local Exhaust for Sterilizer Door--

Exposure source--Local exhaust ventilation above the sterilizer door will capture most of the EtO emitted from the partially open sterilizer door if the flow rate is adequate for the location of the exhaust hood. However, when the sterilizer door is first opened, the hot air (100° to 130°F, or 37.8° to 54.4°C) rises and entrains room air. Some EtO may escape if the ventilation hood does not exhaust all of the air rising from the open sterilizer door.

Control method--The local exhaust ventilation hood should be located as close as possible to the top of the sterilizer door. The greater the distance above the door, the larger the hood will need to be and the more air it will need to draw. The hood should be designed to control the EtO under worst-case conditions, which occur when the door is first opened. Any test of the hood's

capacity for containing EtO (e.g., workplace monitoring) should therefore be conducted when the sterilizer door is first opened.

To prevent contamination of other areas of the hospital, the ventilation system serving the EtO sterilizer room should have a dedicated exhaust system.

Ventilation Systems for Sterilizer Enclosures and Mechanical Access Rooms--

Exposure sources--Sterilizers that are supplied by compressed-gas cylinders are often recessed into a wall of the sterilizer room. The sterilizer door is usually located in the sterilizer room, but the gas cylinders, drain enclosure, and other potential emission points of EtO are in an adjacent mechanical access room. Workers who must enter the mechanical access room should not be at excess risk of EtO exposure unless engineering controls are absent or operating improperly, or unless an accident occurs. If the ventilation malfunctions, workers are at greatest risk during the purge cycle of the sterilizer, when EtO-laden air is vented from the chamber. If the mechanical access room becomes contaminated, EtO may also escape into work areas through any vents or openings in the walls.

All sterilizers should be located in one mechanical access room with the loading area in an adjacent room. However, the NIOSH survey indicated that some sterilizers were not recessed but were free-standing and enclosed in a cabinet. EtO leaks inside these cabinets (which are not usually ventilated) can also lead to worker exposure.

Control methods--Exhaust ventilation should be such that the net flow of air is from the mechanical access room to the loading room, with a net flow of air into both rooms. In the mechanical access room, air should enter all openings in the upper portion of the enclosure with a face velocity of at least 50 to 100 feet/minute. This velocity should be measured when all equipment in the enclosure is at operating temperature. Also, the ventilation should be sufficient to keep the temperature below 100°F in the area where the EtO cylinders are located. To take advantage of the fact that heated air from the equipment will rise, the room exhaust should be located near the ceiling and the EtO supply should be located near the floor.

To alert workers that a purge cycle is in progress, a warning light should be placed at each entrance to the mechanical access room, and a flashing or revolving light should be placed inside the room. Workers should not enter the mechanical access room during the purge cycle without the appropriate respiratory protection. If a sterilizer is enclosed in a cabinet, the cabinet should be vented to a dedicated exhaust system.

Waste Discharges

Discharges From Buildings--

Exposure source--When EtO is discharged from buildings, high concentrations can be carried for some distance on prevailing winds. Such EtO emissions can directly expose people downwind of the discharge, or they can enter the intakes of building heating, ventilation, and air conditioning systems.[77]

Control method--The exhaust ventilation discharge should be designed so that prevailing winds will not carry EtO into populated areas, open windows, doors, or air intakes for the heating, ventilating, or air conditioning systems of any buildings. The ASHRAE Handbook[76] contains detailed data on the design of ventilation systems. Any environmental release of EtO must comply with Federal, State, and local regulations.

Vacuum Pump and Sewer Drain Discharges--

Exposure sources--During the evacuation phase for sterilizers that use compressed-gas cylinders, 90% to 99% of the EtO in the chamber is discharged into a drain through the water-sealed vacuum pump. Even if the drain air gap between the sterilizer evacuation line and the sewer drain pipe is enclosed and ventilated, significant quantities of EtO may be emitted if the ventilation flow rate is inadequate or if the plumbing from the vacuum pump to the trap in the sewer drain line is not sealed. Another potential source of EtO is leakage from a small drain line connecting the leak-cups of the water-sealed vacuum pump to the floor drain.

Control methods--A ventilated enclosure should be placed around the air gap between the sterilizer evacuation line and the drain. Consult the sterilizer manufacturer for the proper exhaust ventilation rate. The vacuum pump discharge line should be installed to prevent water spillage. An air gap must be maintained between the discharge and the drain to avoid siphoning. The air gap should be partially enclosed, baffled, and ventilated. The floor drain junction should be sealed, as should all other connections of the sterilizer evacuation line and the drain line (except the openings into the ventilated enclosure).

Discharge Line From a Single-Dose Cartridge Sterilizer--

Exposure source--Sterilizers that use single-dose cartridges may contain greater than 400,000 ppm EtO in the chamber during sterilization, depending on the quantity of EtO used and the volume of the chamber. During the evacuation phase, more than 55% of the EtO in the chamber will pass through the discharge line. Because this line is pressurized from the venturi vacuum pump to the discharge point, EtO could be forced out if there were any openings in the line.

Control methods--As prescribed in the written maintenance procedures, periodic checks should be made to ensure that there are no leaks in the discharge line.

Discharges From Sterilizer Pressure-Relief Valve--

Exposure source--Pressurized sterilizers are fitted with pressure-relief valves. If this valve opens during the sterilization dwell period, EtO is emitted from its discharge point. Also, as air flows into the sterilizer from a vent line at the end of the vacuum purge, the line can become a leak point during the pressurization cycle if failure occurs.

Control methods--The pressure-relief valve and air vent line should be vented to the dedicated EtO ventilation system. Consult the sterilizer manufacturer

for the proper tubing size and exhaust ventilation rate required to handle any discharge from this valve.

Accidental Releases

Exposure Sources--

Accidental releases of EtO may occur from several sources, including cartridges, sterilizer discharge lines, and EtO supply cylinders. Single-dose cartridges usually contain 67, 100, or 134 g of EtO, depending on their size. An 8.8-foot^3 sterilizer uses a mixture of EtO (12% by weight) and dichlorodifluoromethane, and it discharges approximately 150 g of EtO into the drain during each purge cycle. A typical large supply cylinder for the 12:88 gas mixture contains 7,000 g of EtO.

Because the odor of EtO cannot generally be detected below approximately 700 ppm,[78] workers can be exposed to high concentrations of this compound without knowing it. A relatively small quantity of EtO in an average room can create concentrations that are many times the exposure limit. For example, 1 g of EtO can create a concentration of more than 20 ppm in a 10- by 10-foot room with an 8-foot ceiling.

Control Methods--

To control accidental releases, the sterilizer, gas cylinders, and associated piping should be contained in a mechanical access room. All exhaust from this room should be routed to a dedicated exhaust ventilation system, which is described in the following section. Access to the front of the sterilizer for loading should be gained through a separate, dedicated loading area.

A thorough review of the design and operation procedures using a form of process hazard analysis is useful for anticipating equipment and work practice failures that could lead to accidental releases.[79,80] A hazard and operability study (a form of process hazard analysis) of an EtO sterilizer system is described in Appendix B.

A written emergency response plan should be developed and practiced in anticipation of an accidental release. In the event of a known or suspected large release of EtO, the emergency response plan should be initiated. The area where the release occurred should be evacuated, and the appropriate personnel and departments should be notified (e.g., safety office, fire department, and maintenance crew). The area should be entered only by persons wearing pressure-demand, self-contained breathing apparatus until the problem is corrected and EtO concentrations return to acceptable levels. Sensors and alarms should be installed to detect and warn of accidental releases of EtO.

GENERAL CONTROL METHODS

Maintenance

Maintenance procedures and schedules vary among facilities, and therefore a written maintenance plan should be prepared for each facility that uses EtO sterilization equipment. The procedures should be developed by knowledgeable persons who consider the equipment manufacturers' recommendations, frequency

of use, and other circumstances that might affect the integrity of the equipment. The maintenance plan should also include regular checks of door gaskets, valves, tubing, and piping connections. Maintenance workers should wear the proper personal protective equipment to prevent skin or inhalation exposures, as required in 29 CFR 1910.1047. They should also be aware of potential sources of EtO and procedures for avoiding exposure during maintenance.

Monitoring

Routine monitoring of the sterilizer and associated equipment as well as the work environment is needed to ensure the continuing effectiveness of engineering control measures, work practices, and equipment maintenance. Workplaces can be monitored for contaminants by using (1) conventional air sampling methods, which determine average concentrations over a period of time, or (2) real-time monitoring devices, which measure actual concentrations at a specific point or interval in time.

Conventional Air Sampling--

Sampling methods--NIOSH recommends two air-sampling methods for EtO: Methods 1614[65] and 3702.[66] Method 1614 involves collecting EtO on a hydrogen-bromide-coated charcoal tube and measuring a derivative of EtO (2-bromoethylheptafluorobutyrate) by gas chromatography using an electron-capture detector. The detection limit of this method is 0.0006 ppm EtO per sample, and the working range is 0.05 to 4.6 ppm. This method is applicable to short-term (10-minute) samples.

NIOSH Method 3702 employs a direct-reading technique using a portable gas chromatograph with a photoionization detector. Samples are collected by drawing a known volume of air into a gas-sampling bag. Use of a sampling bag allows sampling times ranging from a few seconds to 8 hours. The working range of this method is 0.001 to 1,000 ppm in relatively noncomplex atmospheres such as those in the sterilizer areas of hospitals.

Sampling strategies--The most reasonable, efficient sampling strategy is to sample the worker with the highest risk of exposure.[68] A maximum-risk worker should be selected and sampled for each operation that poses a risk of EtO exposure. Samples should be obtained during periods of maximum EtO concentration for comparison with ceiling standards. Periods of maximum EtO concentration should be determined by using all available knowledge about the area, workers, and process being sampled.

Real-Time Monitoring Devices--
Real-time monitoring devices are an integral part of a control system for EtO. These devices include equipment-function sensors and environmental sensors.

Equipment-function sensors--Equipment-function sensors are used to directly monitor the operation of the sterilizer and exhaust ventilation systems. Examples of these sensors are sail switches that indicate the presence of air flow in the ventilation exhaust ducts, and alarms or warning lights that

indicate the sterilizer is in a purge cycle. Sensors should be connected to an audible alarm and a warning light to alert the operator to an equipment malfunction, or they may be designed to prevent sterilizer operation without the presence of exhaust ventilation.

Environmental sensors--Environmental sensors are gas sensors that monitor the atmosphere for the presence of EtO. These devices range from simple, low-cost, organic vapor sensors to complex gas chromatograph systems. Both the sterilizer room and the mechanical access room should be monitored and equipped with an alarm to warn workers of high EtO concentrations.

Monitors do not need to be specific for EtO; for example, an organic vapor detector would be suitable. Gas chromatographic equipment may also be used to monitor EtO concentrations in the work environment. Frequent manual calibrations are required on systems without self-calibration. To avoid confusion, cylinders containing EtO should be stored apart from cylinders containing other gases. The sampling or detection points should be located approximately at breathing zone height, near the EtO cylinders, near the sterilizer body, and in the loading zone. Sampling lines should contain a rotameter or other flow indicator and should be inspected for damage routinely. Monitors should be tested at intervals recommended by the manufacturer.

Respiratory Protection

Respirators are the least preferred method for controlling worker exposure to EtO. They should not be used as the only means of preventing or minimizing exposure during routine operations, but they may be used in the following circumstances; when engineering and work practices are not technically feasible, when engineering controls are in the process of being installed, when emergencies occur, or when certain maintenance operations are being performed (including those requiring confined-space entry).

A respiratory protection program should include an evaluation of the worker's ability to perform the work while wearing a respirator, regular training of personnel, periodic environmental monitoring, and respirator fit testing, maintenance, inspection, and cleaning. Respirators should be selected by a knowledgeable person who is in charge of the program. The program must be evaluated regularly, and at a minimum, it must comply with the requirements of the OSHA respiratory protection standard (29 CFR 1910.134).[75]

Workers should use only respirators that have been certified by NIOSH and the Mine Safety and Health Administration (MSHA). Table 16 lists the minimum respiratory equipment required to meet the NIOSH REL under given conditions. For additional information on the selection and use of respirators, consult the NIOSH Respirator Decision Logic[81] and the NIOSH Guide to Industrial Respiratory Protection.[82]

Labeling and Posting of Hazards

Workers must be informed of exposure hazards, potential adverse health effects, and methods for protecting themselves from exposure to EtO. This

Table 16. NIOSH recommended respiratory protection for EtO

Condition	Minimum respiratory protection*,#
Airborne concentration of <0.1 ppm	No respirator required
Airborne concentration of 0.1 to 5 ppm	Any air-purifying, full-facepiece canister respirator that provides protection against EtO and is equipped with an effective end-of-service-life indicator (ESLI), or Any self-contained breathing apparatus (SCBA) equipped with a full facepiece, or Any supplied-air respirator (SAR) equipped with a full facepiece
Airborne concentration ≥5 ppm, or planned or emergency entry into unknown environments	Any SCBA equipped with a full facepiece and operated in a pressure-demand or other positive-pressure mode, or Any SAR equipped with a full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary SCBA operated in a pressure-demand or other positive-pressure mode
Firefighting	Any SCBA equipped with a full facepiece and operated in a pressure-demand or other positive-pressure mode
Escape only	Any air-purifying, full-facepiece canister respirator that provides protection against EtO and is equipped with an effective ESLI, or Any appropriate escape-type SCBA

* Only NIOSH/MSHA-approved equipment should be used.
# The respiratory protection listed for any given condition is the minimum required to meet the NIOSH REL of 5 ppm (9 mg/m^3) for no more than 10 minutes/day or <0.1 ppm (0.18 mg/m^3) as an 8-hour TWA.

information must be communicated in accordance with OSHA regulations as stipulated in 29 CFR 1910.1047 (Ethylene Oxide)[75] and in 29 CFR 1910.1200 (Hazard Communication)[75]. In addition to the signs and labels required under these regulations, NIOSH recommends that signs outlining good work practices be posted (1) in front of sterilizers, (2) above EtO supply cylinders, and (3) at the entrance to mechanical access rooms.

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