OVERVIEW OF CONTROL TECHNIQUES

Engineering controls, work practice modifications, and maintenance procedures to limit worker exposure to EtO are applied to the primary emission sources. Control techniques may include isolation, equipment modification, exhaust ventilation, work practices, protective equipment, and both routine personal and continuous area environmental monitoring. Substitution was not found to be a viable alternative in this study.

SUBSTITUTION

Substitution of some other method which does not use EtO would eliminate the potential hazards from exposure to EtO. However, the substitute must perform satisfactorily to be acceptable, and it must be chosen carefully so that other, perhaps greater, hazards are not introduced into the workplace.

Steam is the preferred method for sterilizing certain medical items. However, a growing list of essential medical items cannot be subjected to the heat and moisture associated with steam sterilization.

Glaser listed a number of possible alternatives in the NIOSH Special Occupational Hazard Review;[4] and, in a later publication, he noted the evaluation of such alternative methods as gamma radiation, electron beam irradiation, and ultraviolet radiation as possible alternatives to EtO for certain applications. However, he also stated that hospitals have a present and future need for EtO sterilization, and he quoted from the April 1980 report of the Interagency Regulatory Liaison Group of the U.S. Government that, as of that date, there seemed to be no suitable alternative methods for sterilizing medical items and fumigating certain stored agricultural commodities.[37]

ISOLATION

Separating workers from EtO emissions sources by a physical barrier or large distances is one method to reduce worker exposure. The separation, or isolation, is most needed for the sterilization operations which may have relatively high EtO levels associated with them. However, isolation of the aeration process is also recommended.

Sterilization Operations

Glaser[4] and others[38-43] have recommended that sterilizer operations involving EtO should be isolated from all non-EtO work areas. Runnells suggested that the area be accessible only to sterilizing department personnel, and that the number of department personnel with direct access

should be restricted.[42] Halleck specified that the sterilizer should be located away from areas of heavy traffic.[43]

A common isolation technique is to recess the sterilizer (and aerator) in an equipment room so that the doors and the control panels are flush with the wall, and all of the mechanical components are behind the wall in the equipment room (mechanical access room). Often the EtO supply cylinders are also located in this room. When used in conjunction with local exhaust ventilation, this technique separates the workers from several potentially high EtO emission sources: the vacuum pump discharge line connection with the sewer drain, the overpressure relief valve, and the EtO supply cylinders.

Another option is to place the sterilizer (and aerator) in a separate room. This approach isolates several emissions sources from the workers during most of the shift. It also confines the EtO given off during the load transfer, preventing exposure to the other workers in the department. However, unless local exhaust ventilation is very carefully applied along with good work practices and controls for chamber concentrations, this method of isolation could serve to concentrate EtO emissions and thereby increase the operator's exposure during the load transfer.

Aeration

The Association for the Advancement of Medical Instrumentation (AAMI) has recommended that all sterilized items be aerated, preferably in an aeration cabinet designed for this function. Ambient aeration, at room temperature, even in a specified room or area, is a poor method which may eventually present problems with chronic exposure.[39]

Churinetz et al. described an aeration tunnel in an industrial facility through which the pallets of sterilized products move without human contact during the aeration process.[44] No such system is known to exist in a hospital; however, three of the major manufacturers of hospital sterilizers market units which permit in-chamber aeration after completion of the sterilization cycle. This isolates the load during aeration and eliminates the need to open the door and transfer the load after sterilization. This control option, however, effectively limits the number of loads which can be processed in a 24-hour period, since one sterilization cycle and one aeration cycle may occupy the unit for 15 to 18 hours.

EQUIPMENT MODIFICATION

Modification of the sterilizer cycle and the equipment may be used to control the EtO emissions. Reducing the chamber concentration by extending the EtO evacuation cycle(s) decreases the amount of EtO available for release into the operator's breathing zone when the door is opened at the end of the cycle. If unventilated, the antisiphon air gap in the discharge line of a water-sealed vacuum pump can emit large quantities of EtO. In addition, venting safety valves and chamber evacuation lines outside the building; installing, on large sterilizers, doors which can be opened from a remote locations; and providing interlocks so that the sterilizer doors can't be opened until the EtO concentration inside the chamber is safe should reduce EtO emissions/exposures.

Chamber Evacuation/Flushing

Glaser called for sterilizer design to assure effective displacement of EtO following sterilization.[4] He commented that is it desirable to have repeated air flushing prior to opening the door. Nevenheim concluded that sterilizer design could be improved by extending the final exhaust cycle, thereby reducing the amount of EtO released when the door is opened.[45] Possible modifications include multiple vacuums (pulse-purge), repeating air flushes, and in-chamber aeration. The use of a door-cracked period also reduces the chamber concentration.

Pulse Purge--
The cycles of some types of sterilizers can be modified to add a pulse-purge phase as the final vacuum. To begin this phase, a vacuum is drawn to about 10 inches Hg. A preset timer then controls the vacuum pump to provide 30 seconds of vacuum relief with incoming filtered air followed by 30 seconds of vacuum, through a differential vacuum of about 10 inches Hg. The sterilizer goes through approximately 30 pulse-purges in 30 minutes.

Samuels showed that adding a 15-minute "pulse-purge" period in the evacuation cycle reduced peak and short-term area EtO concentrations in front of the sterilizer immediately after door opening to less than half the levels measured when the standard vacuum cycle was used.[46] In other work, Samuels showed that a cycle purge on a table-top sterilizer was highly effective.[47] Peak exposures were reduced by a factor of 100 to 200. Short-term time-weighted average EtO concentrations were reduced by a factor of 20 to 50. In both studies, Samuels used a standard load consisting of 3.5 intermittent, positive pressure, breathing (IPPB) ventilator circuits per cubic foot of chamber capacity.

Closed-door Air Flush--
Other sterilizers, both those which use the 12:88 gas mixtures and those which use pure EtO, can be modified to include a repeating air flush phase following either 1 or 2 vacuums. Following the final vacuum, the chamber begins to fill with filtered air to an absolute pressure of about 2 inches Hg. The filtered air continues to flush through the chamber for 20 minutes, at which point an end-of-cycle buzzer sounds. If the sterilizer door is not opened within about 90 seconds, the air flush repeats, and the door cannot be opened until the 20-minute phase is complete.

Barron et al. presented a graph showing that two vacuum cycles reduced EtO concentrations in the chamber from almost 200,000 ppm to approximately 6,000 ppm, and two additional 20-minute closed-door air flush periods further reduced the in-chamber EtO concentrations to approximately 500 ppm.[48] This study used a load consisting of AAMI test packs. Roy recommended modifying the sterilizer process controller to include a 30-minute closed-chamber "post-vacuum" air flush.[49] Barbi presented evidence that two 30-minute vacuum cycles or four 15-minute cycles were better than one 60-minute cycle. However, the fact that the four 15-minute cycles were slightly worse than the two 30-minute cycles suggests that the vacuum must be held for a certain minimum time to gain the full effect.[50]

In-Chamber Aeration--
Most sterilizer manufacturers offer models which feature in-chamber aeration. While the other cycle modifications discussed above reduce the chamber concentration at the end of the cycle, the operator still must transfer the load to an aerator. With in-chamber aeration, the load transfer is eliminated. Specific in-chamber aeration cycles differ with sterilizer models, but the principle is the same. Following the normal sterilization cycle, fresh, filtered air is drawn across the load and exhausted from the chamber for the same period of time the load would have stayed in an aerator. The disadvantage with such a system is that the sterilizer/aerator can only process one load in a 15-hour period.

Door-Cracked Period--
The door-cracked period is a chamber-concentration reduction procedure which can be used with any sterilizer, and it is recommended by most sterilizer manufacturers; however, local exhaust ventilation must be provided above the sterilizer door. By opening the door a few inches and allowing the door to remain open for 15 to 20 minutes, the warm air containing EtO rises out of the chamber along the top of the door. Cooler air from the room is drawn into the opening along the bottom of the door, thus creating a natural convection current. This process reduces the chamber concentration before the operator contacts the load for the transfer to an aerator.

Antisiphon Air Gap

Roy reported that using a vented liquid/gas separator (antisiphon air gap) reduced EtO concentrations from 120 to 30 ppm in the vicinity of the drain during the evacuation cycle. He went on to state that exhaust ventilation alone would have been sufficient.[49]

Corn reported that a liquid/gas separator added to the drain of a large sterilizer reduced measured concentrations in the drain area by a factor of 10.[38] AAMI has recommended some control for the drain, and mentions a vented liquid/gas separator or a local exhaust ventilation system near the drain as two effective methods.[39] AAMI also has stated that sponge absorbers should be prohibited because they are ineffective and potentially dangerous.

Power Door

Lathan and Glaser stated that the greatest potential occupational exposure to EtO occurs when the sterilizer door is opened at the completion of the sterilization cycle.[51] Doors which open automatically at the conclusion of the cycle would obviate the need for the operator to be in the vicinity of the door when it opens. However, this would increase the ambient concentration if ventilation was inadequate to control the escaping EtO. Some industrial sterilizers and a few hospital sterilizers are reported to have automated door opening.[4,49]

Interlocks

Glaser reported some sterilizer doors could be opened (especially during a malfunction) during the sterilization cycle and/or the evacuation cycle.[4] Halleck stated in 1982 that sterilizers were fitted with door interlocks to prevent opening the door before excess EtO had been vented from the chamber and the pressure had reached an equilibrium with the ambient pressure, and that these interlocks have been redesigned to provide better control of door opening.[43] Churinetz *et al.* describe an interlock system on a storage room which did not allow the door to be opened until a high-flow ventilation system had reduced the concentration to an acceptable level.[44]

Safety Valves

Roy recommended that check valves be installed in the gas lines near the tank to reduce the release of gas from the line during the cylinder changing operation.[49] He mentioned that a manual valve is an alternative, but it is less desirable because it requires a conscious effort to perform the extra step of closing it, whereas the check valve functions automatically. Check valves are not recommended unless a safety relief valve is used.

Halleck emphasized the importance of shutoff valves in the gas lines to prevent gas from escaping during cylinder changing operations.[43] Corn recommended the check valves for the gas line termination at the cylinder and suggested using a purge system when changing in-line filters.[38]

Aeration

Aeration is normally accomplished at elevated temperature because this requires less time to reduce the concentration of residual EtO.[39,49] Ikeda has shown that the use of ultrasonic vibration during the aeration period further reduces the final concentration of residual EtO attained.[52]

Barbi reported that maximum offgassing of EtO is obtained when the sterilized load is kept at a pressure below the vapor pressure of the EtO/water solution for some time rather than returning immediately to atmospheric pressure, and that residual EtO concentrations decrease exponentially with aeration temperature.[50] This indicates that the aeration should be conducted at the highest temperature possible. He proposed a system for heated aeration at a sustained vacuum while maintaining approximately four chamber air changes per minute.

LOCAL EXHAUST VENTILATION

Local exhaust ventilation (LEV) can applied to all EtO emission sources. The goal is to capture and control the EtO before the gas can reach the operator's breathing zone or contaminate the workroom atmosphere. All LEV should be part of a dedicated system exhausted directly outside the building. The four EtO emission sources best controlled by LEV are the sterilizer door during the door-cracked period, the connection of the discharge line from a water-sealed vacuum pump to the floor drain, the connection of the EtO supply lines to the gas cylinders, and the overpressure relief valve on sterilizers which are

pressurized. Glaser[4], AAMI[39], and others[38,40,43,47,49,51,53-57] have specified the need for effective ventilation around sterilizer operations. The 1981 AAMI EtO ventilation guidelines have recommended contacting the manufacturer concerning the proper venting of sterilizers and aeration cabinets. They also recommended local exhaust ventilation but gave no details.[39]

Lathan and Glaser reported peak and short-term average concentrations in front of a number of sterilizers.[51] The concentration values varied considerably and did not seem to be related to sterilizer size or to the average number of cycles per day. They mentioned that the risk of EtO exposure for operators can be reduced by proper ventilation, but no ventilation information was given for the various sterilizers.

Korpella et al. reported peak concentrations of from 4 to 12 ppm EtO (varying somewhat with temperature and relative humidity of the cycle) for a 9-ft^3 sterilizer with the local exhaust fan shut off, while the concentration with the exhaust fan operating (at a capacity of 275 cubic feet of air per minute, cfm) was barely detectable.[56]

Sterilizer Door

Local exhaust ventilation may be applied along the top edge of the sterilizer door to capture the warm, EtO-laden air as it rises from the sterilizer chamber before the load transfer. The use of LEV in this location is particularly important when the door-cracked period is used at the end of the cycle. Any type LEV hood will have a defined capture control distance beyond which the LEV is not effective. This distance must be established for each application, and the sterilizer door must not be opened beyond that point during a door-cracked period.

AAMI has specified the area around the sterilizer door as the prime area for local exhaust ventilation (LEV).[39] A number of other references have recommended ventilation above the sterilizer.[38,46,48,49,56] Samuels presented data showing the benefits of installing LEV at the door of a table-top sterilizer.[55] A sidedraft hood with a baffle above the door was fabricated and set up for 150 ft/min airflow across the face of the open chamber. Peak EtO concentrations were reduced by a factor of 10 to 20, and short-term TWA concentrations of EtO were reduced by a factor of 2 to 40. Time-weighted average area concentrations of EtO, measured with a charcoal tube method, were reduced from 100 to 300 ppm to below detectable limits, and the 20-minute TWA operator exposure to EtO was reduced from over 5 ppm to less than 2 ppm.

Roy prescribed a canopy hood above the door with a design airflow of 100 cfm per square foot (cfm/ft^2) of door area.[49] He stated that it should be mounted as close to the door opening as possible and include a side baffle along the door opening opposite the hinge. He mentioned that sidedraft or downdraft hoods may be necessary in some situations. Although he did not give design values for these configurations, he cited a particular example where, originally, 300 cfm were required for a downdraft hood to control a 10-inch diameter (0.55 ft^2) door opening. When this hood was replaced with a

baffled sidedraft hood, 125 cfm/ft^2 proved to be effective. He stated these guidelines were found to be applicable for sterilizers ranging from table-top units to moderate size (70 ft^3) freestanding or wall-mounted sterilizers.

Nusbaum has maintained that the ventilation should be placed below the door at floor level.[54] He presented a table which specifies 1,000 cfm for sterilizers with a volume of less than 150 ft^3, up to 4,000 cfm for sterilizers greater than 1,000 ft^3 volume when downdraft ventilation is employed. He recommended doubling these flow rate values for ventilation above the door.

Markinson discussed the installation of a ventilation duct in the rear wall of a large industrial sterilizer. The duct was connected to a roof-mounted centrifugal fan with a capacity of 3,000 cfm. The fan was turned on by a microswitch when the door was opened.[57]

Drain

A sterilizer using the 12:88 gas mixtures is evacuated through a water-sealed vacuum pump. On the discharge side of the pump, water and EtO are released to a sewer drain. Because plumbing codes require an air gap between the sewer drain and any incoming line, all of the EtO from the chamber is released at the air gap. This air gap may be enclosed and local exhaust ventilation applied to capture the EtO. In situations where the vacuum discharge empties into an open floor drain, the floor drain may be enclosed with a capture box or exhaust hood.

AAMI[39] and others[4,43,48,49,51,54] have recommended ventilation for the drain area. Nusbaum has specified that ventilation be located 4 inches above an open floor drain pulling from 200 to 500 cfm for sterilizers ranging from less than 150 to greater than 1,000 cubic feet.[54]

Supply Cylinders

The 12:88 gas mixture is often supplied in 140-pound cylinders. The cylinders are connected to the sterilizer chamber with copper piping. Whether the cylinders are located in the mechanical access room or in the workroom, local exhaust ventilation can be supplied over the cylinder valves. The LEV may be either a hood or a flexible exhaust duct which can be moved over the valves during a cylinder change operation. A hood over the cylinders has the advantage of also controlling emissions resulting from a chance leaky connection.

AAMI[39] and others[49,51,54] have recommended ventilation of the area in which the gas cylinders are located and stored as a safety measure in case of leaks, and to control emissions during the cylinder changing operation.

Nusbaum recommended a separate 4-inch diameter duct for the EtO cylinder area, if the cylinders are not situated close to the floor drain ventilation or the sterilizer door ventilation.[54] He stated this branch duct should be sized to handle 300 cfm.

Roy suggested three possible alternatives.[49] The most effective one is to place the gas cylinders in a cabinet ventilated at a rate of 150 cfm per pair of cylinders. A second alternative is to use a slot hood above the cylinders, for which he recommended a ventilation rate of 100 cfm per cylinder. The third possibility is to install a flexible duct/flanged hood drawing 250 cfm which could be used for the cylinders and be available for maintenance operations and emergency situations.

Overpressure Relief Valve

Sterilizers which use the 12:88 gas mixture are pressurized to about 10 psig during the dwell period when the actual sterilization takes place. As an equipment safety feature, these sterilizers are fitted with an overpressure relief valve. If the chamber should become overpressurized, the valve would open and release EtO until the pressure returned to an acceptable level. The quantity of released EtO can be significant. Such an event can be controlled by installing a local exhaust hood over and around the valve.

AAMI has specified the area near the sterilizer chamber pressure relief valve as an area to consider when installing LEV.[39] Roy cautioned that the chamber emergency valve be connected to a vent line which should be hooked up to the existing exhaust ventilation.[49]

Inspection Table Ventilation

Nusbaum, in discussing controls for industrial facilities, recommended that the tables where test packages are removed and inspected should be ventilated.[54]

The ventilation systems may not continue to provide adequate control if it is not properly maintained, and, even if regular preventative maintenance is performed, some part of the ventilation system may malfunction. Nusbaum suggested that alarms be provided to alert personnel that the ventilation has failed.[54]

AAMI allowed for other means as well.[39] Two such methods would be visual indicators that the system is working or an interlock which would not allow the sterilizer to be operated without the ventilation fan being in operation. Just as with the sterilization equipment, any malfunctions should be repaired immediately.

Aerator Ventilation

Glaser[4] and others[38,39,49,58] have discussed ventilation of the aerators. Roy has given the guideline of 150 cfm for ventilation at room temperature in an aerator constructed from an office storage cabinet.[49] He specifies that ventilation to a dedicated exhaust is essential.

GENERAL VENTILATION

General ventilation standards for hospitals are set by each state's department of health. About 50 percent of the states have formally adopted one of three

standards: the Hill-Burton, the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE), or the National Fire Prevention Association (NFPA). Most adhere to the Hill-Burton standard, which was originally mandated in 1946 with the passage of the Hill-Burton Act which authorized federal funding for the construction of hospitals. The remaining states either have adopted their own standards or informally apply one of the aforementioned. However, any hospital whose construction is federally funded must comply with the Hill-Burton standard (unless the state applies a more stringent standard).[59]

Each of these standards specifies ventilation requirements for various sections of the many areas in the hospital. Table 1 is a comparison of two of the standards with respect to the sterilization department. The NFPA does not specify any requirements for ventilation in the central service area and is omitted from Table 1.

Glaser[4] and others[39,40,47,53,54,55,58] have stressed the importance of locating the sterilizer (and the aerator) in a well-ventilated area. Recent recommendations have concurred that, at a minimum, in each hour a ventilation volume equal to ten times the room volume should be removed from the room and replaced with unrecirculated air.[4,38,39,54] This minimal rate is referred to in the references as ten room air changes per hour. To apply this recommendation, a hospital would have to exceed the ventilation requirements of most state standards. Samuels reported that approximately 46 percent of 171 hospitals responding to a survey questionnaire stated that air change rates in their sterilization departments were fewer than ten per hour.[60]

Gunther et al. mentioned that the ambient concentration of EtO will be halved (theoretically, assuming perfect mixing) in the period of time required to exchange an amount of air equal to the volume of the room (6 minutes for the case of 10 room air changes per hour).[61] Samuels has reported that within 15 minutes, the ambient EtO concentrations when the air is changed 10 times per hour can be reduced to approximately one-half that concentration when the air is changed 20 times per hour.[60] The real-life situation may approach this theoretical performance if the general ventilation has been properly designed and adequate make-up air is provided.

Glaser[4] and Churinetz[44] have suggested that the storage room for sterile items should also be ventilated. No design values, other than the ten air changes per hour, are known for this specific application.

Churinetz described a high/low ventilation system for the sterile items quarantine area of an industrial facility. It features a normally low rate of ventilation (about four air changes per hour). If EtO sensors detect a rise in concentration above a preset limit, the high-flow ventilation, which delivers about 50 air changes per hour, is activated. Another feature is the red light/green light system. The room cannot be entered until an employee manually activates the high-flow system. When the concentration has been reduced to an acceptable level, the green light comes on indicating that the room is safe to be entered.[44]

Table 1. Ventilation standards.

	Hill-Burton*			ASHRAE**		
	Outdoor Air Changes/Hr.	Total Air Changes/Hr.	Recir-culation	Outdoor Air Changes/Hr.	Total Air Changes/Hr.	Recir-culation
Sterilizer Equip. Rm.	Optional	10	No	Optional	10	No
Central Service						
Soiled Room	2	6	No	2	6	No
Clean Work Room	2	4	Optional	2	4	Optional
Unsterile Storage	2	2	Optional	Optional	2	Optional

* Standard entitled "Minimum Requirements of Constructing and Equipment for Hospital and Medical Facilities," issued by the U.S. Government as the 1974 Hill-Burton Standard.

** ASHRAE standard 62-73, "Standards for Natural and Mechanical Ventilation," published by the American Society of Heating, Refrigerating and Air Conditioning Engineers, Inc.[59]

WORK PRACTICES

The work practices of the sterilizer operator can be very important in reducing personal exposure to EtO particularly during the load transfer. The goal of work practice controls is to minimize the transfer time from the sterilizer to the aerator and to maximize the distance between the operator and the sterile load.

Certain work practices can affect the emission of EtO into the workplace air and the exposure of workers to ambient EtO. Probably the most significant is opening the sterilizer door at the end of sterilization. Others involve how the load transfer is performed and other tasks which bring workers in contact with EtO emission sources. Informing workers about the hazards and ways to reduce exposure is essential.

Allowing the load to stay in an unventilated sterilization chamber with the door closed causes the chamber concentration of EtO to increase as the sterilized items offgas the residual EtO. AAMI, Samuels, and Corn have recommended transferring the load to the aerator within minutes after the completion of the post-cycle purges.[38,39,46,47]

Many references recommend opening the door slightly (a few inches), and leaving the area for 15 minutes before unloading the sterilizer. However, if this procedure is to be followed, there should be adequate local exhaust ventilation to eliminate the escaping EtO.[2,4,37,43,50,51,53,54,56,61]

There are numerous other procedures recommended by one or more references. Many of these references have stressed the importance of informing the employees about the health hazards of exposure to EtO, and instructing them on proper use and operating procedures (such as routinely cleaning the door gasket and pulling the cart containing the sterilized load instead of pushing it during transfer from the sterilizer to the aerator). This training should then be reinforced on a regular basis.[1,2,4,37,41,44,48,50,59,62,63]

MAINTENANCE

With regard to exposure potential, maintenance is important in two different ways. First, if equipment (including the exposure controls) is not maintained, EtO may be emitted through leaky gaskets or not captured as expected by local exhaust ventilation. Second, workers performing maintenance on gas sterilizers or other equipment in the area may be exposed to EtO.

AAMI[39] and a number of others[4,38,40,42,47,49,55,57,63] have stressed the importance of a preventative maintenance program. Even if the equipment was properly designed and installed, inadequate maintenance can cause or allow the emission of EtO into the workroom air and may cause high exposures for maintenance personnel. The maintenance procedures, including preventative maintenance, and schedules may vary for each hospital, and are extremely important in reducing exposure of employees to airborne concentrations of EtO.

Leaks have most often been cited as a major source of potential high exposures. Regular checks of valve, tubing and piping connections, and door

gaskets should be conducted, so if a leak does occur, it can be fixed before it releases much EtO into the workplace.[4,38,43,45,49,57,63] Roy suggested using a "Freon® torch" leak tester used by refrigerator and air-conditioning repairmen to locate leaks for systems using EtO mixed with dichlorodifluoromethane.[49] However, the use of a "Freon® torch" leak tester would be a fire/explosion hazard if mistakenly used near a sterilizer which uses 100 percent EtO.

Maintenance workers should wear, or have available, the proper personal protective equipment to prevent skin and inhalation exposures. They should know the potential sources of EtO and what to do to avoid exposure while performing maintenance tasks.

MONITORING

Routine monitoring of the work environment is needed to ensure that the engineering control measures, and work and environment maintenance practices continue to perform effectively. Monitoring can be performed through conventional air sampling and by real-time environmental or equipment function sensors.

Air Sampling Methods

NIOSH recommends two sampling methods for EtO: Methods 1614[65] and 3702.[66] Method 1614 involves collection of EtO on HBr-coated charcoal tube (using a 100 mg front/50 mg backup charcoal tube), and measurement of a derivative of EtO (2-bromoethyl heptafluorobutyrate) by gas chromatography using an electron-capture detector. Method 1614 was issued in 1987, replacing Method 1607[64] which was utilized in this study. This method is a modification of OSHA Method 50.[67] The limit of detection of this method is 1 µg EtO per sample, corresponding to an 8-hour TWA exposure of approximately 0.02 ppm or a 10-minute exposure of about 0.4 ppm.

NIOSH Method 3702 describes a direct-reading technique utilizing a portable gas chromatograph with a photoionization detector. Samples are collected by drawing air directly into a syringe with subsequent injection or collection in a gas sampling bag. Use of a sampling bag can allow sampling times ranging from as low as a few seconds to an 8-hour TWA. The range of this method is 0.01 to 1,000 ppm.

Both NIOSH methods can be used to determine compliance with either the NIOSH recommended 8-hour time-weighted average (<0.1 ppm) or the OSHA limit of 1 ppm. Similarly, both NIOSH methods can be used to support either the NIOSH recommendation for a ceiling concentration of 5 ppm over a period of no more than 10 minutes or the OSHA excursion limit of 5 ppm over a period of no more than 15 minutes.

Air Sampling Strategies

NIOSH's Occupational Exposure Sampling Strategy Manual[68] suggests that the most reasonable sampling strategy, for the most efficient use of sampling resources, is to sample the employee presumed to have the highest exposure

risk. If there are a number of work operations as a result of different processes where there may be exposed employees, then a maximum risk employee should be selected for each operation. Samples taken for comparison with ceiling standards are best taken in a nonrandom fashion. That is, all available knowledge relating to the area, individual, and process being sampled should be utilized to obtain samples during periods of maximum concentrations of the substance.

In the preamble to their final rule on occupational exposure to ethylene oxide,[35] OSHA lists required monitoring activities for various exposure scenarios. These scenarios are described in Table 2. NIOSH[69] took a stronger position in comments to the Department of Labor opposing a recommendation to forego sampling under certain conditions: "The control of high concentrations of EtO over short periods of time depends on a number of actions, including good work practices and engineering controls. Initial and routine monitoring is needed to ensure that these work practices and engineering controls are still effective. The OSHA proposal assumes that if, at some point in time, exposures are below the PEL, then they will remain there."

Real-Time Monitoring Systems

Real-time monitoring devices are an integral part of a control system for EtO. These systems may be divided into two categories: (1) devices that directly monitor the sterilizer or its associated ventilation hardware; and (2) devices that indirectly monitor the performance of the control hardware by measuring the level of EtO present in the work environment.

Sterilizer and Ventilation Monitors--
This category includes rather unsophisticated sensors to directly monitor the sterilizer and indicate its operational status. An example of such a device is a mechanical sail switch. Sail switches determine the presence or absence of air flow in the exhaust ventilation ducts serving the sterilizer and the aerator. These sensors may be connected to a warning light or other alarm to alert the operator to this condition, or may be interconnected to the electrical control system of the sterilizer to prevent its operation without the presence of exhaust ventilation. Another example of this type of sensor are status alarms in areas remote from the sterilizer control panel such as mechanical access rooms, to indicate that the sterilizer is in an exhaust or purge cycle (when mechanical access room concentrations may be at their highest).

EtO Sensors--
The second category of monitoring devices are gas sensors which monitor worker exposure. These devices range from relatively simple and low-cost combustible gas sensors to relatively complex and expensive infrared spectrometers and gas chromatographs.

One combustible gas sensor observed in two hospitals consisted of a metal oxide sensor which increases in electrical resistance on contact with hydrocarbons. Output is nonlinear, but the device is factory calibrated as a dual set-point alarm, typically 20 and 50 ppm EtO. Since the device is not

Table 2. Sampling frequencies recommended by OSHA.

Exposure Scenario	Required Monitoring Activity
Below the action level and at or below the EL.	No monitoring required.
Below the action level and above the EL.	No TWA monitoring required; monitor short-term exposures four times per year.
At or above the action level, at or below the TWA, and at or below the EL.	Monitor TWA exposures two times per year.
At or above the action level, at or below the TWA, and above the EL.	Monitor TWA exposures two times per year and monitor short-term exposures four times per year.
Above the TWA and at or below the EL.	Monitor TWA exposures four times per year.
Above the TWA and above the EL.	Monitor TWA exposures four times per year; monitor short-term exposures four times per year.

Note: EL = excursion limit (5 ppm for 15 minutes)

specific for EtO (hydrocarbons, hydrogen, halogenated organics, carbon monoxide, and steam also produce responses), the threshold of detection must be set high enough to prevent a continuous state of alarm from the interfering compounds. The nonspecific nature of the sensor, the high threshold, and the nonlinear response of this type of device do not permit exposure to be estimated, but do allow for the detection of gross problems. The nonspecific character does provide an advantage in calibrating the observed device: the manufacturer provides calibration gas in the form of an ethane/air mixture which provides the equivalent response to 20 ppm EtO. Thus, a nontoxic gas mixture can be used in place of a potentially toxic mix. The manufacturer's maintenance and calibration procedures should be followed on receipt of the instrument for this type of device, followed by calibration checks at monthly intervals for the first 6 months to establish an instrument performance log. Thereafter, calibration checks should be performed at 6-month intervals.

More advanced gas detection systems utilize infrared spectrometers and gas chromatographs. Since these systems are specific for EtO (although several potential interferences exist for the infrared systems), they can be used to estimate exposure to EtO if the monitoring points are representative of worker exposures. Both systems are relatively costly (elaborate computer-based systems approaching the price of a sterilizer) and may require specialized training to maintain and operate. These systems are similar to the portable infrared and gas chromatograph systems utilized in this study and described in more detail in the next chapter. Neither infrared nor gas chromatograph systems were used in any of the hospitals visited during the field study. A gas chromatograph system was in use in the hospital where the hazard and operability study was performed (Appendix B).

Gas detection systems equipped with set-point alarms and relay contacts can serve as master control devices. In addition to activating alarms, these relay contacts can be used to start auxiliary ventilation systems and to energize emergency gas shut-off valves.

THE EVALUATION OF CONTROL EFFECTIVENESS

HOSPITAL SELECTION

In this study, hospitals were considered in the final site selection only if at least one load per day was run, but not so many loads as to preclude running a standardized "test load." The test load was run to eliminate, as much as possible, the effects on EtO emissions/exposures due to the variability of load composition from one hospital to another, and one day to the next. Usually, the test loads were run early in the day or during the evening shift. Every effort was made to not disrupt or change the normal routine any more than necessary to gather the information we needed.

Preliminary surveys were conducted in 14 hospitals to identify potentially good control systems. The hospitals selected for in-depth study were representative of several combinations of controls deemed to characterize the majority of sterilization operations, although it is recognized that the selected control systems do not account for every type of EtO sterilization process.

Evaluation of different control systems was conducted during in-depth field surveys in eight hospitals. Table 3 is a matrix of the control system characteristics for each hospital and/or sterilizer studied. The hospitals were arbitrarily given a letter designation to identify them in the following discussion. The evaluation strategy for the sterilization process and control system for each hospital was designed to characterize and document the efficacy of the control system by focusing on the determination of worker exposures and area concentrations; characterization of the ventilation system and associated controls; and analysis of work practices.

AIR SAMPLING

NIOSH's Occupational Exposure Sampling Strategy Manual[68] suggests that the most reasonable sampling strategy, for the most efficient use of sampling resources, is to sample the employee presumed to have the highest exposure risk. If there are a number of work operations as a result of different processes where there may be exposed employees, then a maximum risk employee should be selected for each operation. Samples taken for comparison with ceiling standards are best taken in a nonrandom fashion. That is, all available knowledge relating to the area, individual, and process being sampled should be utilized to obtain samples during periods of maximum concentrations of the substance.

Personal EtO exposures and area EtO concentrations were determined using one or a combination of three methods: charcoal tube sampling, air bag sampling

Table 3. Control characteristics for sterilizers surveyed in this study.

Hospital / Sterilizer	Type of Sterilizer	Extra Chamber Evacuation*	In-Chamber Aeration	Local Exhaust Ventilation	Mechanical Access Rm./ Isolation	Discharge Control
A / 1	12:88	In-Chamber Aeration	Yes	Above Door	Mech. Acc.	Vent. Air Gap
B / 2	12:88	Air Flush + door-cracked period	No	Above Door	Mech. Acc.	Vent. Air Gap
C / 3**	12:88	Air Flush + door-cracked period	No	Above Door	Mech. Acc.	Vent. Air Gap
D / 4	12:88	Pulse/Purge cycle	No	Above Ster.	Mech. Acc.	Vent. Air Gap
E / 5	12:88	None	No	Above Ster.	Mech. Acc.	Vent. Air Gap
F / 7	100%	Air Flush + door-cracked period	No***	Above Door	Isolation	Venturi Vent.
F / 8	100%	Air Flush + door-cracked period	No	Above Door	Isolation	Venturi Vent.
G / 9	12:88	Air Flush	No	Above Door	Cabinet	Vent. Air Gap
H / 10	12:88	door-cracked period	No	Above Ster.	Isolation	Vent. Air Gap
H / 11	12:88	door-cracked period	No	Above Ster.	Isolation	Vent. Air Gap
I / 6**	12:88	door-cracked period	No	Other	Mech. Acc.	No

* In addition to one or two deep vacuums.

** Same hospital - before (6) and after (3) installation of controls.

*** Although this sterilizer was fitted with in-chamber aeration, all loads sampled during the survey were transferred to an aerator.

with on-site analysis by gas chromatograph, and real-time monitoring. Table 4 summarizes the types of samples collected and the associated methods.

Charcoal Tubes

To determine personal exposures and average concentrations of EtO at selected locations in the clean room, personal and area samples were collected using coconut shell charcoal tubes and analyzed according to NIOSH Method 1607.[64] The samples were collected on 400 mg and 200 mg charcoal tubes (SKC No. 226-37, SKC, Inc., Eighty Four, Pennsylvania) connected in series, and the sampling train was contained in a plastic holder. Personal sampling pumps (MDA Accuhaler® 808, MDA Scientific, Inc., Glenview, Illinois) with limiting orifices of approximately 10 milliliters of air per minute (mL/min) and 20 mL/min (one of each type orifice) were used to collect duplicate samples for the sterilizer operator and the area over the sterilizer door for long-term (8-hour) samples, and with limiting orifices of approximately 100 mL/min (samples in some hospitals used limiting orifices of approximately 50 mL/min) to collect duplicate samples for the same personal and area locations during the load transfer procedure (short-term, 15 to 20 minutes). MDA pumps with limiting orifices of approximately 20 mL/min were used to collect long-term samples for an instrument wrapper and the wrapping area location. Day and evening shifts were sampled for 3 days.

Personal long-term samples were used to estimate time-weighted average exposures for the sterilizer operator and an instrument wrapper. Area samples estimate the EtO which is in the workplace air near potential exposure sources. Given that the sterilizers and aerators are the primary sources for EtO release, long-term area samples were collected at a fixed location approximating the operator's breathing zone in front of each sterilizer. To estimate the effectiveness of the control system in preventing EtO contamination of the general workroom air, a long-term area sample was collected at a work table near the sampled instrument wrapper.

Short-term samples provided an estimate of the peak concentrations of EtO released when the sterilizer door was opened and the load was transferred to the aerator. Samples were collected both for the sterilizer operator and at the area sampling location in front of the sterilizer from the time the operator walked up to the sterilizer to crack the door at the end of the evacuation phase until the load transfer to the aerator was completed, and the operator left the sterilizer area.

Gas Bags/Portable GC

Personal sampling pumps fitted with an outlet nozzle (DuPont P-4000, DuPont Company, Wilmington, Delaware) were used to collect air samples in Tedlar® gas sampling bags (SKC No. 231, SKC, Inc., Eighty Four, Pennsylvania). A short-term area sample over the sterilizer door was collected for 15 minutes during the load transfer procedure. A 2- to 3-minute sample was collected near the operator's breathing zone while the sterilizer operator transferred the sterile load to the aerator. To estimate the effectiveness of the evacuation phase and/or air flush phase in reducing the amount of EtO left in the chamber at the end of the cycle, a sample was collected in the sterilizer

Table 4. Sampling strategy.

Sample Location	Long-Term Samples	Short-Term* Samples
Operator Exposure	Charcoal Tube	Charcoal Tube, Gas Bag
Other Worker Exposure	Charcoal Tube	------
Sterilizer Area	Charcoal Tube	Charcoal Tube, Gas Bag, and Infrared Analyzer**
General Area	Charcoal Tube	------
Mechanical Access Room Area***	Charcoal Tube	------
Decontamination Area****	Charcoal Tube	------
Chamber Interior (end of cycle)	-----	Gas Bag
Chamber Interior (end of door-cracked period)	-----	Gas Bag

* Period of time including the load transfer, usually 1 to 2 minutes or 15 to 20 minutes depending on the particular hospital and type of sample and whether or not a door-cracked period was used.

** The IR analyzer ran continuously, but its output was analyzed only during the (typically short-term) events which created elevated EtO concentrations

*** Partial-shift samples taken during three surveys.

**** Full-shift samples taken during one survey when it was suspected that EtO was escaping into the decontamination room from a poorly controlled mechanical access room.

chamber when the door was cracked open prior to the 15-minute waiting period or before the load was removed for those hospitals not using a 15-minute door-cracked period. Another sample was taken from the sterilizer chamber interior after the 15-minute waiting period, before the load was removed, to estimate the potential concentration of EtO to which the operator might be exposed. These latter two types of samples were collected for 15 seconds. All air bag samples were analyzed on-site with a portable gas chromatograph (Photovac 10a10, Photovac, Inc., Ontario, Canada) according to NIOSH Method No. 3702.[66]

Infrared Analyzer

Due to the sporadic nature of EtO release during the day, it was desirable to have a continuous record of the estimated EtO concentrations in front of the sterilizer. An infrared (IR) analyzer (MIRAN® 1A, Foxboro Company, South Norwalk, Connecticut) was physically located either beside the sterilizer, or outside the sterilizer room for the two hospitals with isolated sterilizers, and connected by flexible, plastic tubing to a sampling probe located in the breathing zone area in front of the sterilizer. The IR analyzer continuously monitored the background EtO levels as well as indicated higher concentrations which could be associated with certain events such as transferring the load from the sterilizer to the aerator.

Peak concentrations may not be accurately measured with an infrared analyzer. The sensing cell of the instrument has a volume of about 5 liters and the sampling pump a flow rate of 5 L/min. This results in an instrument response time of approximately 3 to 5 minutes. Short concentration peaks (such as those associated with the load transfer) may be underestimated by the IR analyzer. Thus the IR analyzer responses were used qualitatively, and actual concentrations were interpreted as being greater than the measured peak values.

Laboratory experiments showed the instrument responded to a known concentration of EtO and humidity by indicating a higher concentration reading than the EtO level which was present. The sensitivity of the response at the 3.3 μm wavelength was approximately 3 ppm EtO for a 10 percent rise in relative humidity. To compensate for this effect, the IR analyzer was connected in series with a hygrothermograph (General Eastern model 400C/D percent, General Eastern Corporation, Watertown, Massachusetts). The IR analyzer and the hygrothermograph were attached to a dual strip chart recorder to provide a continuous graphic record of changing humidity levels and EtO concentrations. This configuration allowed differentiation of the response of the IR analyzer to EtO from relative humidity.

The long-term samples were collected for a full shift. The short-term samples were collected for just long enough to span the event and obtain a representative sample, usually 1 to 2 minutes or 20 minutes depending on the particular hospital and whether or not the door-cracked period was used. The mechanical access room and decontamination area samples were not collected at every hospital. Even though the IR analyzer monitored continuously, its output was analyzed only during events which created elevated EtO concentrations, so it is considered a short-term sampler for this study.

EVALUATION OF VENTILATION SYSTEMS

In evaluating the effectiveness of the sterilization department's overall control system, it was essential to adequately characterize the components of the ventilation system, both local exhaust ventilation and general dilution ventilation. Each component played a role in controlling the workers' EtO exposures.

Local Exhaust Ventilation

Local exhaust ventilation is important in limiting the amount of EtO which leaves the airspace immediately in front of the sterilizer chamber opening, as well as other areas such as around the drain and the pressure relief valve and above the supply cylinders. The list of possible determinant variables applicable to the effectiveness of a local exhaust ventilation system includes:

1. Hood design, dimensions, and location with respect to the source(s) to be controlled.
2. Airflow patterns around the hood and source(s) to be controlled.
3. Hood flow rate.
4. Hood face velocity.
5. Capture velocity around source(s) to be controlled.

In evaluating the local ventilation system, several measurements and observations were necessary. First, the exhaust hood was characterized by its shape, dimensions, and location with respect to the exposure source (chamber door or drain). Second, airflow patterns around and between possible source points and the ventilation hood(s) were observed using smoke tubes (Dräger 4351, National Dräger, Pittsburgh, Pennsylvania). Third, measurements were made of the hood face velocity, selected airflow velocities between the source and the hood, and ambient airflow velocities around the source. Finally, the system design specifications were checked.

General Ventilation

The proper use of general dilution ventilation can effectively reduce the ambient concentration resulting from EtO sources not controlled by other measures. Factors affecting the efficacy of general dilution ventilation as a control of employee exposure are the size and layout of the department, the location of supply air inlets and exhaust outlets, the airflow patterns within room, and the percent recirculation of air previously exhausted from the sterilizer area.

The determinant variables associated with an evaluation of general ventilation as a control are:

1. The volumetric flow rate and
2. The size of the room.
3. Airflow patterns in the room.

In assessing the general ventilation, a floor plan was drawn and the pertinent dimensions of the EtO sterilization area were measured, noting the location of

the air supply outlets and ventilation exhaust inlets. The volumetric flow rate for each supply or exhaust grille was measured using a velometer Flowhood® (Alnor Balometer®, Alnor Instrument Company, Niles, Illinois). If access to a particular grille was restricted, the volumetric flow rate was estimated by measuring the average velocity readings at each affected inlet or outlet and multiplying by the cross sectional area of the grille. These velocity measurements were taken using a hot-wire anemometer (TSI model 1650, TSI, Inc., St. Paul, Minnesota). The volumetric airflow rate through the local exhaust system was estimated by multiplying the average face velocity measurement and the cross sectional area of the hood.

The total volumetric flow rate exhausted from the room was computed by summing the individual local exhaust and general ventilation flow rates. This number was compared with the corresponding value for the total flow rate of air supplied to the room. In order to maintain a positive pressure with respect to areas outside the room so that air which may contain infectious agents does not enter the sterile supply room, there should be a slight (approximately 15 percent) excess of supply air. This excess also assures that the ventilation systems are working at peak capacity, not having to draw against a negative pressure. The pressure condition between the sterilizer room and the surrounding areas was checked using a smoke tube at the doorways to show if air was being pushed out of the clean room, indicating the desired positive pressure, or drawn into the room, indicating a net negative pressure.

Observations of the airflow patterns were made using standard smoke tubes. These tubes emit a thin trail of a chemical smoke when air is passed through them. The smoke follows the air currents; thus, it is possible to see both the direction and the speed of air movement. Visualizing and videotaping these patterns and the airflow between and around the various source points, workstations, ventilation openings, and other selected points in the room provided information on the potential exposure of employees with respect to their working in an airflow path between an exposure source and the exhaust.

Where possible, information on the system design, including duct sizing, fan ratings, and the provision for make-up air or recirculation, were obtained from engineering drawings or inspection. Finally, the system design specifications were checked.

EVALUATION OF WORK PRACTICES

Observations of the employees' work practices were an important part of characterizing the personal exposures. For a given situation with a certain potential exposure and a particular combination of control measures, the actual employee exposure varied considerably depending on how the worker performed the job.

Each load transfer was videotaped and analyzed to characterize the effect of the work practices on exposure. The following variables were determined:

1. Job tasks of each worker to be sampled.
2. Identification of high exposure tasks.
3. Workstation for each high exposure task.

4. Door opening procedure at the end of the cycle.
5. Method of inserting and removing items - basket and/or cart.
6. Time for transferring items from sterilizer to aerator.
7. Handling of transfer cart or basket - pull, push, or swing to aerator.
8. Amount of time in close contact with newly sterilized items.

Potentially high exposure tasks were identified. Certain tasks, such as opening the sterilizer door and handling the sterilized items, and other potentially high exposure situations were analyzed to determine if the manner with which each was performed contributed to an increased potential for exposure to or the emission of EtO. The use of personal protective equipment was noted. This analysis was included in the interpretation of the sampling results obtained from each survey.

ANALYSIS OF DATA

The data were eventually stored in computer files. Various statistical procedures were used to characterize and compare the data. The statistical analyses were applied using the appropriate SAS/STAT® Procedures for personal computers, Version 6 Edition (SAS Institute Inc., Cary, North Carolina).