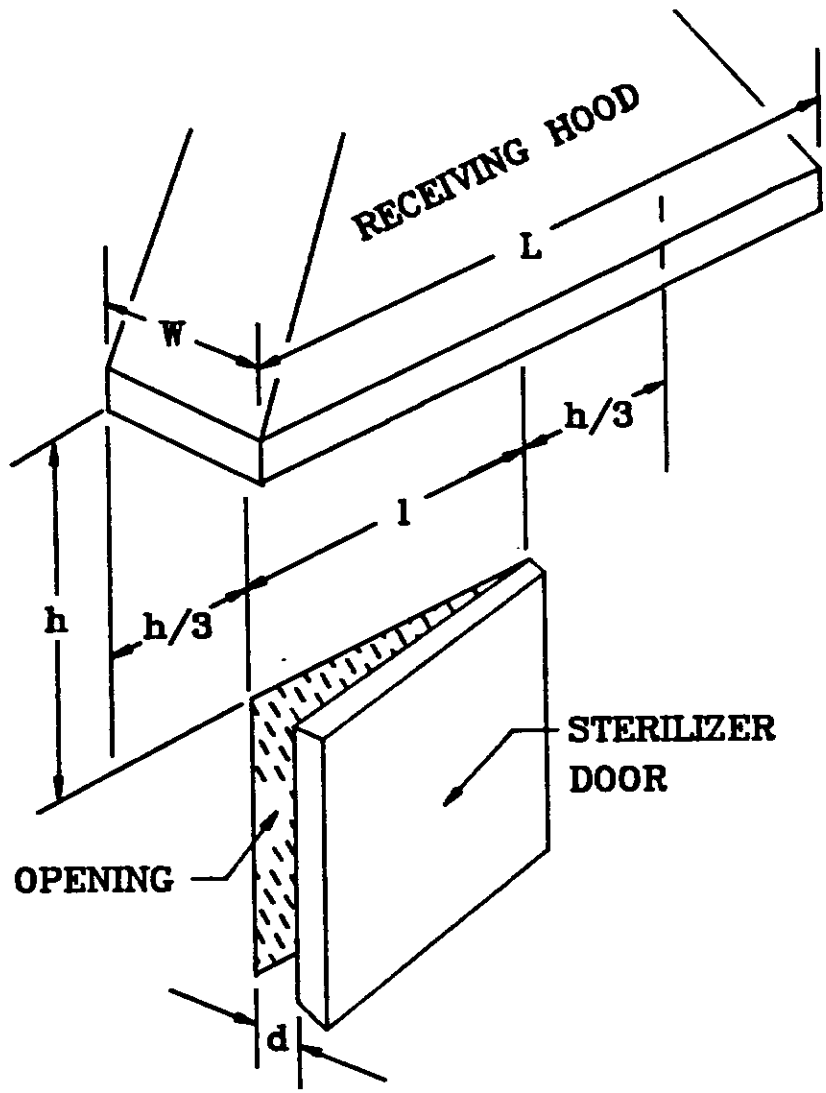

Figure 17. A canopy hood above the sterilizer door can be used to exhaust the EtO which rises in front of the sterilizer during the door-cracked period. (See text for a discussion of the appropriate values for the variables.)

sterilizer door, both the operator short-term exposure and the short-term area concentration in front of the sterilizer were significantly higher (although still within NIOSH recommended limits). This hospital did not use a door-cracked period.

VENTILATED AIR GAP ENCLOSURE

During the evacuation phase of a 12:88 sterilizer, 90 to 99 percent of the EtO in the chamber is discharged through the water-sealed vacuum pump. Surrounding the antisiphon air gap with a ventilated enclosure is an effective way to control the considerable quantity of EtO which passes through the sterilizer evacuation line from the water-sealed vacuum pump to the drain. Since the source can be completely enclosed, the required flow rate is that required to contain the EtO, i.e., the amount required to maintain a flow of air in through the openings of the enclosure when the vacuum pump is running. The openings are required to provide an escape for water which might back up from the floor drain and to allow air to enter the ventilation without causing a large pressure drop. On more than one survey in this study, an enclosure marketed by one of the sterilizer manufacturers, with two openings approximately 5 in^2 each, was observed to be effective when ventilated by approximately 50 cfm. One "homemade" enclosure drawing only 10 cfm through a small (approximately 1 in^2) opening did not prevent EtO from escaping.

In some hospitals, even though ventilated enclosures had been installed, EtO escaped via other routes. One route was the junction of the floor drain and the discharge line from the ventilated enclosure. Another route was the lines connecting the leak cups on the water-sealed vacuum pumps to the floor drain. Table 12 shows that average mechanical access room concentrations are related to the drain controls (including secondary leaks) and are seemingly unrelated to the general ventilation for the mechanical access room. A statistical model (SAS® PROC GLM) showed that the mechanical access room concentrations for the unventilated drain air gap were significantly (R^2=.96, F=134, Pr=0.0001, df=20) greater than for the ventilated enclosure with an unsealed drain and that the concentrations for the unsealed drain were significantly greater than for the sealed drain.

SUPPLY CYLINDERS

The compressed-gas cylinders are a potential source of tremendous magnitude because they may contain as much as 7,000 grams of EtO, and the supply line from compressed gas cylinders contains liquid EtO under pressure. If this pressure is not relieved, the liquid EtO can spray the worker changing the cylinder and cause skin burns and/or irritation. To protect the maintenance worker changing the EtO supply cylinders, the supply line should be fitted with a valve to allow the contents of the line to be vented outside the building instead of into the space around the cylinders. It is acceptable and convenient to vent this valve to the ventilated enclosure for the sterilizer drain.

Even if the worker is not sprayed, the emitted EtO is an inhalation exposure hazard. Local exhaust ventilation is needed to capture EtO which might escape from the supply line connection to the EtO cylinders either during the

Table 12. Sterilizer discharge line/drain controls

Hospital	Drain Controls	Ventilation/ Room Volume ratio	Mechanical Access room Concentration ppm
C	Sealed Ventilation	4	0.28
D	Sealed Ventilation	45	0.32
C*	Unsealed Ventilation	4	2.3
I	Unventilated	8	9.1

* Same hospital.

cylinder change operation or due to a leaky connection. If designed with a hinged Plexiglas® panel, as illustrated in Figure 18, the worker's face will also be protected from EtO which might spray from the supply line when disconnecting it. The flow rate should be at least 100 cfm per square-foot of open area with the hinged panel in the down position.

One hospital placed the cylinders in a well-ventilated mechanical access room, with local exhaust ventilation above the cylinders. A cylinder change was sampled in this hospital. During the approximately 8 minutes required to complete the change, the concentration above the cylinders was approximately 1 ppm. The samples taken to determine the exposure of the person changing the cylinder were indistinguishable from the field blanks. During a cylinder change with neither ventilation nor a venting valve to relieve EtO trapped under pressure in the supply line, EtO sprayed from the connection point when the supply line was disconnected from the cylinder and the area concentration was measured to be approximately 100 ppm.

A respirator will be needed in case of an emergency situation when working with the EtO supply lines or cylinders. For situations where the worker encounters an unknown concentration of EtO or in an emergency situation, NIOSH recommends a compressed air, open circuit self-contained breathing apparatus with full facepiece.[70] Nitrile- or butyl-rubber gloves and a face shield will protect the worker from a possible spray of liquid containing EtO when the supply line is disconnected.

RELIEF VALVE

Sterilizers which are pressurized during the sterilization dwell period are fitted with overpressure relief valves. The valve is designed to open if the pressure inside the chamber exceeds a set limit, releasing the contents of the chamber to relieve the overpressure condition. The only time the chamber is pressurized is during the sterilization dwell period. For an 8.8-ft^3 sterilizer, approximately 50 grams of EtO could be emitted from the relief valve if it opened to relieve an overpressure condition.

MECHANICAL ACCESS ROOM/STERILIZER CABINET VENTILATION

With adequate (secondary) ventilation of the sterilizer enclosure (mechanical access room or sterilizer cabinet), EtO leaks inside the enclosure would not expose the sterilizer operator or other workers in the clean room. However, if this discharged EtO is not controlled, it can be reintroduced into the workroom air and increase the amount the workers are exposed to.

Ventilation for the enclosure around the body of the sterilizer, whether it be a cabinet or an equipment room (mechanical access room) is not as simple as merely applying exhaust ventilation at some point and expecting pressure differentials to control EtO emissions. The presence of the hot equipment complicates the airflow patterns.

Air does not always flow into a room with the same velocity at all openings. In fact, when heated processes are present in the room, air may actually flow out of vents and cracks in the walls near the top of the room if the

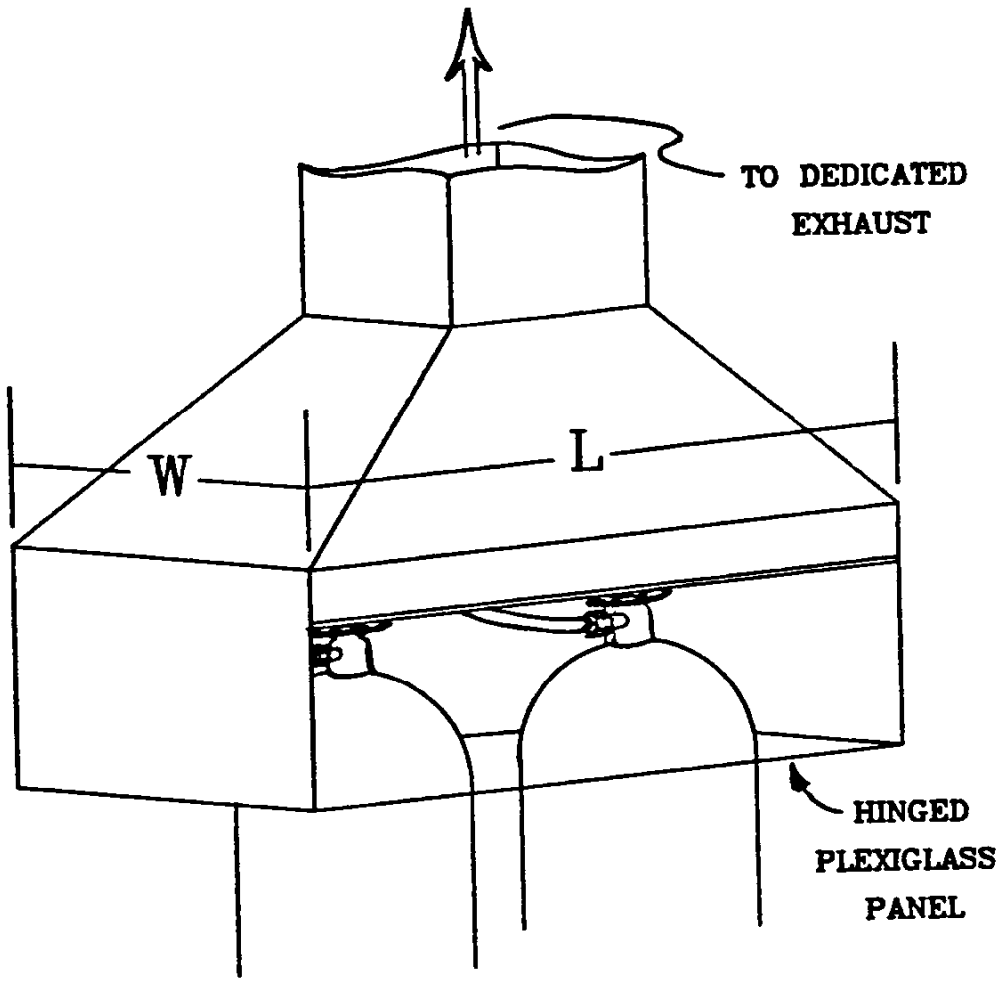

Figure 18. The recommended cylinder hood design features a hinged Plexiglas® panel which can be raised to remove the empty cylinder and slide in the new cylinder. In the down position, the panel protects the worker's face from spray while allowing the worker to see the connection point while the empty cylinder is being disconnected and then the new cylinder is connected to the supply line.

ventilation system does not exhaust enough air to handle the quantity of air rising to the ceiling due to thermal effects.

Using an equation for velocity of air flowing through an orifice at the top of an enclosure due to thermal head, a minimum exhaust flow rate can be calculated which assures that air does not leak out of the room.[71] For room temperatures not exceeding 93°C (200°F):

$$Q = 20(L\ H')^{1/3}(A)^{2/3}$$

where: Q = Minimum flow rate, ft^3/min;
L = Height of the hot air column, ft;
H' = Sensible heat released to the air stream, Btu/min;
A = Total area of vents, openings, and cracks, ft^2.

The height of the air column is taken to be a nominal room height (unfinished ceiling) of 10 feet. Because of the cube root, halving this value only reduces the flow rate prediction by 20%, so using the actual value is not critical. Small gas sterilizers are electrically heated and release only 100 to 200 Btu/hour into the mechanical access room. Steam sterilizers and steam-heated gas sterilizers release 2,500 to 5,000 Btu/hour. Aerators are in between these ranges at approximately 1,500 Btu/hour. Typically, 0.5 to 1.5 ft^2 of open area is present for each sterilizer. Even with these values, the solution of the equation is complicated. For simplicity, the equation has been solved using representative values for the different types of equipment and mechanical access room parameters. These results and some accompanying discussion are presented in the Recommendations for mechanical access room/sterilizer cabinet ventilation.

If some ethylene oxide is released into the enclosure, the ventilation will reduce the concentration in time. The rate of decrease of concentration of a contaminant once further generation has ceased is given by the following equation:[72]

$$\ln \frac{C_2}{C_1} = - \frac{Q'}{kV} (t_2 - t_1)$$

where: C_2 = the concentration at time t_2;
C_1 = the concentration at time t_1;
Q' = the effective ventilation rate;
V = the volume of the enclosed space.

The effective ventilation rate, Q', is equal to the actual ventilation rate, Q, divided by a design distribution constant, K, which is a value between 3 and 10 to correct for incomplete mixing. Since most sterilizer enclosures are small with good mixing due to thermal air currents, K can be assumed to be 3. The equation can be solved for Q:

$$Q' = \frac{3V}{(t_2 - t_1)} \ln \frac{C_1}{C_2}$$

The initial concentration, C_1, can be estimated by assuming the entire sterilizer contents escape into the mechanical access room.

DEDICATED EXHAUST

At least one overexposure situation has been attributed to a nondedicated exhaust system.[36] At this hospital, the overexposure was sufficient to elicit acute exposure symptoms. It was later discovered that the fan belt for the roof fan might have broken about the same time the symptoms were first noticed. However, evaluation of the ventilation system showed that the roof fan was also inadequately sized to exhaust the air supplied by the two auxiliary fans and still maintain the required exhaust ventilation at all of the original vents. This caused air containing EtO to be forced out of some of the exhaust vents when both auxiliary fans were running.

EtO DISCHARGE LOCATION

The discharge lines for the single-dose cartridge sterilizers are usually soldered copper vented directly outside the building. In one installation, the outlet was in a courtyard near windows and air-conditioning intakes. The two models of this type of sterilizer now being used are charged with 100 or 134 grams of EtO during sterilization. Most of this EtO is discharge during the evacuation cycles, and an exposure hazard would result if the discharged airstream reentered the building.

The reentry of exhausted EtO can cause an exposure hazard. Although considerable dispersion of the EtO in the ventilation discharge would occur within a few hundred feet of the discharge point, not much dilution would occur in the first 10 feet or so, especially in areas of mild air currents. Using Sutton's equation for atmospheric diffusion,[73] it is predicted that a discharge of 100 grams of EtO over a 10-minute period would create a concentration of approximately 175 ppm at a distance of 10 feet from the discharge point along the axis of the discharge stream. If this discharge stream were to reenter the building, it would deposit approximately 1 gram in the space entered. Such a quantity would create a temporary concentration of 20 ppm in a room 20 by 20 feet with an 8-foot ceiling.

GENERAL VENTILATION

In general, room ventilation rates did not seem to be related to levels of EtO in this study, although this may be due to the overall low levels of EtO emission. On one survey, no difference was noted in the airborne EtO concentrations as the number of "room air changes per hour" was increased from four to eight by increasing the amount of outside air supplied to the room. Furthermore, EtO exposures were controlled to less than 0.1 ppm when the ratio of ventilation rate (ft^3/hour) to room volume (ft^3) was four rather than the often recommended ten.

Area concentrations are more indicative of the effectiveness of general ventilation than are personal exposures; however, the area concentration in front of the sterilizer includes the effect of end-of-cycle/load transfer EtO emissions, which are related more to local exhaust ventilation. Therefore, an

Table 13. Comparison of full-shift operator's exposures and area concentrations in front of the sterilizer with the ratio of the ventilation volume per hour to the room volume.

Hospital	Ventilation/ Room Volume ratio	Sterilizer Area Concentration* ppm	Operator exposure* ppm
B	8	0.02	0.03
C	9	0.04	0.04
I	9	0.31	0.20
G	12	0.03	0.03
F**	18	0.08	0.01
H**	41	0.38	0.04

* Geometric mean if more than one sample

** Gas sterilization equipment located in a separate room entered only to load, unload, and check on the operation of the sterilizers and aerators.

"ambient" or background concentration is calculated by subtracting the quantity (ppm-min) of EtO collected by the sampler during the short-term sample from the (full-shift) total quantity sampled and dividing by the full-shift sample time minus the short-term sample time. As is shown in Table 13, the calculated ambient concentration in front of the sterilizer and the concentration to which the operator was exposed during the day were not well correlated to the general ventilation expressed as a ratio of cubic feet per hour divided by the room volume (ft^3) as well as to each other. In fact, not only was a low correlation (r^2-value less than 0.25) obtained from statistical modeling, but also what little correlation there was had a negative slope.

The general ventilation system of most of the hospitals survey recirculated some of the air exhausted from the sterilizer area. In a some cases, this recirculated air stream could not be shut off. In the event of an EtO emergency, it would be desirable to have all the air exhausted from the sterilizer area directly outside the building. If it were not, EtO could be spread throughout the hospital.

ISOLATION/SEPARATION

The ratio of the operator's ambient full-shift minus short-term exposure to the ambient concentration in front of the sterilizer could be indicative of the effect of separating the operator from the sterilizer during the (large) portion of the shift not spend unloading the sterilizer. The pertinent data to examine this relationship are shown in Table 14. Examining this data, it can be seen that the four sterilizers which were located in separate (isolation) rooms were among the five sterilizers with the lowest values of this ratio. Also, the four highest ratio values were for four of the five sterilizers with the highest chamber concentrations when the door was opened to remove the load. Using the SAS® procedure (PROC GLM®) to quantify the appropriateness of a general (linear) statistical model to fit the data, it was found that this ratio had the highest concentration (1^2=0.32) to the limiting of operator exposure of any of the factors investigated.

The data indicate that hospitals F and H, which had isolation rooms, had low operator short-term exposures. This is especially noteworthy in the case of hospital H, which had relatively high sterilizer area concentrations. However, it is not certain if this was because of or in spite of the isolation.

WORK PRACTICES

Load Transfer

Due to dispersion, the concentration of EtO decreases with increasing distance from the source and the passing of time. Although not directly proportional, it is expected that worker exposure increases with increasing time in contact with the load. However, no quantitative relationship was found between these factors in this study.

EtO seems to offgas from the newly sterilized load relatively slowly compared to the usually short time (30 seconds to 2 minutes) required to transfer a

Table 14. The relationship of the presence of a sterilizer isolation room and the chamber concentration when the door was opened for the load transfer to the ratio of the sterilizer operator's ambient exposure to the sterilizer area ambient concentration.

Sterilizer	Operator Exposure Area Concentration	Isolation Room	Door-Open Chamber Concentration, ppm
7	0.10	Yes	17
8	0.13	Yes	6
4	0.21	No	270
11	0.23	Yes	32
10	0.66	Yes	130
6	0.80	No	280
9	1.17	No	360
5	2.35	No	2800

load to an aerator. However, high concentrations can develop close to the load. Two samples taken above a load being transferred to an aerator at one hospital showed concentrations ranging from 100 ppm to less than 10 ppm as the distance from the load changed from a few (approximately 2) inches to approximately 1 foot. During the actual transfer of the load to an aerator, the local exhaust hood cannot be expected to control EtO emissions from the load. The operator's exposure can increase substantially if the operator comes in close contact with the load for more than a few seconds. During one survey, an elevated short-term exposure -- five to ten times higher than the average for that survey -- occurred when a basket of newly sterilized items was held on the operator's arm while the aerator door was opened. Although it was not shown that pulling the load or walking with the load to the side resulted in significantly lower exposures, such practices seem to make good sense.

The rate of offgassing and the amount of EtO given off will be even less if the EtO concentration in the chamber is lowered before the load is removed. Some hospitals followed the sterilizer manufacturers' recommended practice of opening the door a few inches at the end of the cycle and leaving the room for 15 minutes before unloading the sterilizer. Following this work practice, the average concentration inside the chamber before opening the door fully to transfer the load was approximately 90 ppm. Although this value was highly variable, ranging from 38 to 150 ppm, the average additional reduction of more than 85 percent from the concentration at the start of the waiting period indicates that the door-cracked period was effective.

Air Out Chamber Before Cleaning

The sterilizer chamber can retain a significant quantity of EtO. For Hospital G, in which the load was transferred without a door-cracked period, the concentration measured inside the chamber a few hours after the load transfer averaged over 200 ppm. At another hospital in which, although a door-cracked period was not used prior to load transfer, the door was left partially open overnight, the concentration inside the chamber prior to cleaning averaged 0.56 ppm, and the exposure to the operator while cleaning the sterilizer chamber averaged 0.27 ppm.