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Before and after: an evaluation of engineering controls for ethylene oxide sterilization in hospitals

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The control of ethylene oxide (EtO) emissions from a gas sterilizer in one hospital was evaluated before and after the installation of engineering controls. During the initial survey, full-shift personal exposures averaged 0.3 ppm and short-term exposures for the sterilizer operator averaged approximately 2 ppm for 20 minutes. The engineering modifications reduced full-shift personal exposures to less than the 0.1-ppm limit recommended by NIOSH and short-term exposures for the sterilizer operator to approximately 0.2 ppm for 20 minutes. Adding a ventilated slot hood above the sterilizer door and extending the sterilizer cycle to further reduce chamber concentrations before the door was opened reduced EtO concentrations in front of the sterilizer by more than 90 percent. Installing a ventilated enclosure around the air gap in the sterilizer discharge line and sealing its floor-drain junction reduced EtO emissions by approximately 97 percent; however, even with the required air gap enclosed and ventilated, an opening in the discharge line downstream of the vacuum pump can release a significant quantity of EtO. One potential problem which was not corrected was the control of EtO in the sterilizer recess room. **Kercher, S.L.; Mortimer, V.D.**: Before and after: an evaluation of engineering controls for ethylene oxide sterilization in hospitals. *Appl. Ind. Hyg. 2*:7-12; 1987.

Introduction

Hospitals and other health care facilities routinely use ethylene oxide (EtO) as an agent to sterilize heat-sensitive medical items. According to supplementary information published with the June 1984 amendments to the OSHA standard on EtO, the greatest potential for daily occupational exposure to EtO is associated with its use as a sterilant.[1]

Animal toxicity studies have shown EtO to be a mutagen and a carcinogen.[2] Studies of exposed workers have indicated increased mutagenic activity in human cells, an increase in the incidence of leukemia, and adverse reproductive effects, such as increased incidence of spontaneous abortion.[3,4] In June of 1984, OSHA reduced its permissible exposure limit (PEL) from 50 ppm to 1 ppm with an action level of 0.5 ppm.[1] NIOSH has recommended that the full-shift average exposure be less than 0.1 ppm. Additionally, NIOSH has recommended that workers not be exposed to concentrations greater than 5 ppm and that elevated exposures as high as 5 ppm should not be attained for more than 10 minutes during the workday.[5]

In response to the hospitals' need to control worker exposure to EtO to these low levels, the Engineering Control Technology Branch of NIOSH has studied the control of EtO emissions from hospital sterilizers. In-depth surveys were conducted in eight hospitals, representative of different types of sterilizers and control systems. This paper compares the results of two of those surveys conducted in the same hospital: one before and one after the installation of engineering controls.

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

Description

Ethylene oxide sterilization at this hospital was conducted only in the Supply, Processing, and Distribution Department. As is shown in Figure 1, the sterilization equipment was recessed into a room constructed between the clean room and the decontamination room to isolate the workers from the heat and noise while providing access to the equipment for maintenance. The EtO supply cylinder was also located in the recess room.

After being used in the hospital, the items to be resterilized were taken to the decontamination room where they were cleaned. Most of the sterilization activities, such as wrapping the items and loading and unloading the sterilizer, took place in a room referred to as the clean room.

This hospital usually processed one load per day in a sterilizer with an approximate chamber volume of 0.25 m^3 (8.8 ft^3) which used a mixture of 12 percent EtO and 88 percent Freon-12®. As is illustrated in Figure 2, the typical sterilization cycle for this type of ster-

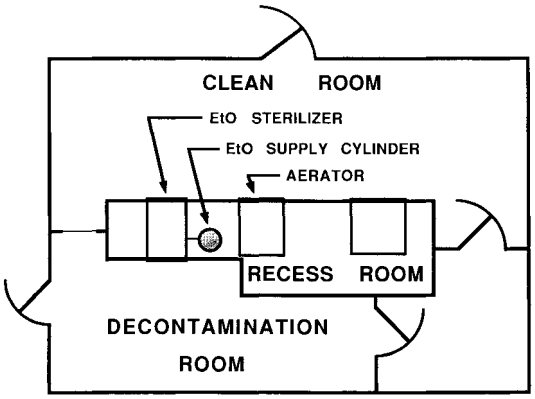

Figure 1—Schematic of the sterilization area.

ilizer takes about 3 hours and consists of four phases: an initial evacuation, charging of the chamber with EtO, a dwell period during which sterilization takes place, and an end-of-cycle purge period with two deep vacuums. At the end of the cycle, the load was transferred to the aerator where the residual EtO would off-gas, making the items safe for patient use.

There are three major daily sources of EtO emissions. First, during the evacuation phase of the sterilization cycle, most of the EtO in the sterilization chamber is removed by a water-sealed vacuum pump and discharged at the sewer drain. Plumbing codes require that there be an air-gap between the sterilizer evacuation line and the drain. If this air-gap and/or other openings in the discharge line are not controlled, EtO may get into the workroom atmosphere.

The second source is opening the sterilizer door. Warm air containing EtO rises from the sterilizer when the door is opened, and, if not removed by local exhaust ventilation, the EtO will disperse throughout the room. This hospital followed the practice, recommended by the sterilizer manufacturer, of opening the door a few inches at the end of the cycle and leaving the area for 15 minutes to allow the EtO concentration in the sterilizer to decrease more before the sterilizer operator comes in contact with the load.

Third, the operator can be exposed to EtO when the sterilized items are removed from the sterilizer and transferred to the aerator.

Methodology

To assess the control of these EtO emission sources, personal exposures and area concentrations were sampled, ventilation airflow was evaluated, and work practices were observed. The sampling strategy was specifically designed to evaluate the control measures.

Personal long-term samples were used to estimate 8-hour time-weighted average exposures for the sterilizer operator and a worker in the same area who did not operate the sterilizer. Area samples were taken to assess the effectiveness of the engineering controls by measuring the EtO which was in the ambient air. Long-term area samples were collected at a fixed location approximating the operator's breathing zone in front of the sterilizer, at a work bench where the other sampled worker spent part of the shift, and (for the 1985 survey) on a work table in the decontamination room. Also, side-by-side samples were collected inside the recess room during each day shift for approximately a 4-hour period which included the chamber evacuation at the end of a cycle.

Short-term samples provided an estimate of the concentration of EtO released from the time the sterilizer door was opened until the load transfer to the aerator was completed. Samples were collected both for the sterilizer operator and at the area sampling location in front of the sterilizer.

TABLE I
Sampling strategy

Sample location	Long-term	Short-term
Operator exposure	CT[a]	CT, GC[b]
Other worker exposure	CT	—
Sterilizer door area	CT	CT, GC, IR[c]
Work table area	CT	—
Recess room area	CT	—
Decontamination area	CT	—
Chamber interior (door cracked)	—	GC
Chamber interior (15 min later)	—	GC

[a]Charcoal tubes
[b]Gas bag / portable gas chromatograph
[c]Infrared analyzer

Table I summarizes the types of samples collected and the three different methods used. Both full-shift and short-term samples were collected with charcoal tubes and analyzed according to NIOSH Method 1607.[6]

In addition to the charcoal tube samples, short-term samples for the sterilizer operator (1-2 minutes during load transfer) and the area in front of the sterilizer (15-20 minutes) were collected in Tedlar® gas bags and analyzed on-site with a portable gas chromatograph (Photovac, Inc., Thornhill, Ontario, Canada).[7] This method was also used

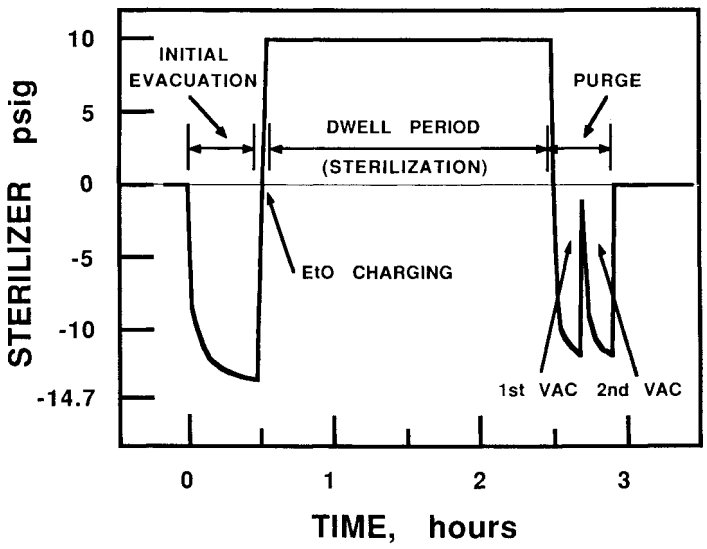

Figure 2—Basic sterilization cycle.

to determine the sterilizer chamber concentration at two specific times after the end of the cycle.

A Miran 1-A infrared (IR) analyzer (The Foxboro Company, Foxboro, MA) was used to continuously monitor the EtO concentration at the sampling location in front of the sterilizer (3.3 μm wavelength and 20.25 m path length). However, when interpreting its output, two factors must be kept in mind. First, the instrument does not fully respond to peak concentrations of short duration. Therefore, peak concentrations were used qualitatively. Second, the instrument responds to water vapor in the air by indicating a higher concentration of EtO than is actually present. To assess the effect of humidity on the IR analyzer response, a hygrothermograph and strip chart recorder were connected in series with the IR analyzer. Thus, any sudden change in humidity could be differentiated from true peaks of EtO concentration.

Within the sterilization area, ventilation airflow measurements at each accessible supply or exhaust grille were made with a Balometer® flow hood (Alnor Instrument Company, Niles, IL). The airflow through local exhaust ventilation openings was determined using a hot-wire anemometer.

Smoke tubes were used to qualitatively evaluate the supply and exhaust ventilation system. Air flow patterns at selected locations were observed and sketched. Air flow patterns above the sterilizer door were visualized with smoke tubes and recorded on videotape.

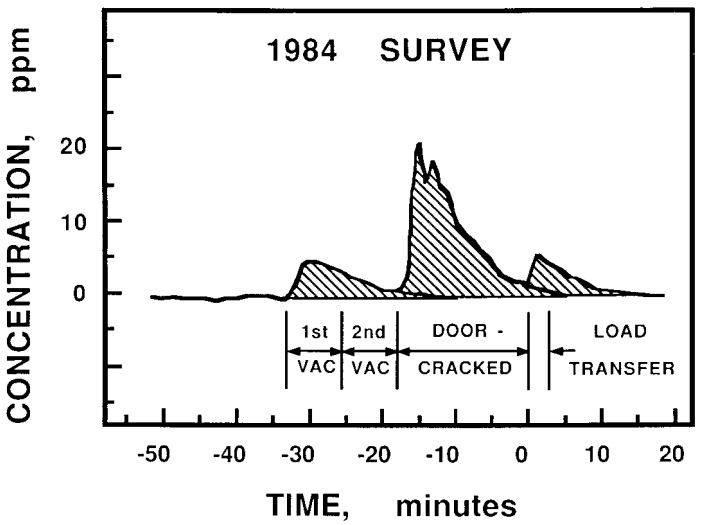

Figure 3—Typical infrared analyzer response for the area in front of the sterilizer from initial survey.

The work practices of the sterilizer operator may have a very important effect on the amount of EtO released into the workplace air and on personal exposure. To evaluate this effect, observations of the operator's work practices during EtO sterilizer activities were made using a video camera/recorder.

1984 Survey

The initial survey was conducted in 1984.[8] Other than a 15-minute door-cracked period, there were no effective controls for the three major EtO emission sources. The sterilizer discharge line emptied into an open floor drain in the recess room. The recess room was inadequately ventilated by a dedicated exhaust system such that air flowed out of, instead of into, the recess room through the grilles above the sterilizers. The slot built into the front panel of the sterilizer just above the door was unventilated other than being open to the recess room similar to the grilles. General ventilation was provided by supply and return air vents in the ceiling, but it was difficult to determine what effect it had on the control of EtO.

TABLE II
Comparison of sampling results before and after controls installation

		Before–1984	After–1985[a]	
Sample (period)[b]	Type[c]	Average ppm	Average ppm	Percent reduction
Operator (1)	CT	0.24	< 0.05	> 79%
Sterilizer door (1)	CT	0.51	< 0.06	> 88%
Other worker (1)	CT	0.37	< 0.09	> 76%
Work table (1)	CT	0.30	< 0.05	> 83%
Recess room–purge (2)	CT	9.2	< 0.28	> 97%
Chamber–door cracked (3)	GC	1750	560	68%
Chamber–15 min later (3)	GC	210	90	57%
Operator (4)	CT	1.9	< 0.22	> 88%
Operator–load transfer (5)	GC	2.4	0.56	77%
Sterilizer door (4)	CT	4.0	< 0.31	> 92%
Sterilizer door (4)	GC	5.2	< 0.23	> 96%

[a]1985 does not include data collected during unsealed drain condition.
[b](1) Full-shift, (2) 4-hour, (3) 15 seconds, (4) 15-20 minutes, (5) 1-2 minutes.
[c]CT = Charcoal tube; GC = Gas bag samples.

1984 Survey data summary

During this first survey, full-shift exposures for both workers averaged approximately 0.3 ppm (Table II). These EtO levels were higher than any other hospital surveyed in this study. Overall, the results indicated three areas where controls could be improved.

First, it is evident from IR analyzer response for the area in front of the sterilizer (Figure 3) that EtO was being released at the drain during the purge cycle and getting out of the recess room. Although ventilation measurements indicated that approximately 8.5 m^3/min (300 cfm) was exhausted from the recess room by the dedicated ventilation system, the use of smoke tubes confirmed that air flowed through the grilles out of the recess room into both the decontamination room and the clean room.

Second, the IR analyzer response also indicated that EtO was escaping from the sterilizer during the 15-minute door-cracked period and was not captured by

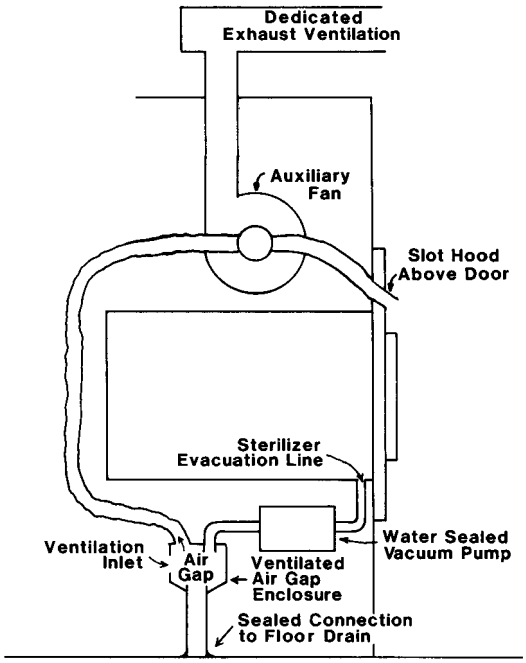

Figure 4—Ventilation controls added after initial survey.

the slot above the door. Again, smoke tube visualization showed that, although some air flowed into the recess room through the slot, most of the air rising from the sterilizer flowed past the slot and dispersed into the clean room.

Third, the IR analyzer response indicated that peak concentrations in the sterilizer area during load transfer operations may have exceeded 5 ppm. The sterilizer operator short-term exposures sampled with charcoal tubes averaged approximately 2 ppm, and the door area samples averaged 4 ppm, both over approximately a 20-minute period. Emissions during the load transfer might have been higher had it not been for the 15-minute door-cracked period.

1985 Survey

In mid-1985, the hospital installed additional controls to reduce EtO emissions. The hospital chose a control system marketed by the manufacturer of the sterilizer.

The control system, shown in Figure 4, which was retrofitted to the sterilizer, included a ventilated enclosure around the drain air gap. To control emissions from the door during the door-cracked period, an auxiliary fan was added to ventilate the slot above the sterilizer door. To warn if the roof fan failed, a sensor with an indicator light was installed in the dedicated ventilation system. To reduce chamber EtO concentrations at the end of the cycle, the sterilizer cycle was modified to include at least one 20-minute air flush after the second deep vacuum.

1985 Survey data summary

In late 1985, a second survey was conducted to evaluate the effect of the installed engineering controls.[9] Workers' exposures had been reduced to less than 0.1 ppm. In fact, due to the low levels of EtO sampled relative to the capabilities of the laboratory analysis, most of the charcoal tube results (45 of 62) were less than the analytical limit of detection (LOD), so the actual averages may have been much lower than the results denoted in Table II with a "less than" symbol, indicating that the LOD was used for one or more of the values in the calculation of the average.

Despite the improved drain control, two problem areas were identified. During the first sampled load of the second survey, the IR analyzer response, as depicted in the top portion of Figure 5, showed an unexpected broad peak response during the purge cycle, indicating both that EtO was escaping from the drain and that the recess room ventilation was still inadequate since EtO was still reaching the area in front of the sterilizer. A gas bag sample collected inside the recess room during the purge showed the concentration to be approximately 5000 ppm. After this was observed, the drain was inspected, and an unsealed gap was found where the discharge line entered the floor drain. This gap was sealed for the remainder of the survey, and for subsequent loads the IR analyzer detected elevated EtO concentrations in front of the sterilizer only during the load transfer. Recess room concentrations sampled with gas bags averaged 60 ppm during subsequent purge cycles.

The manufacturer's control package included an auxiliary fan to ventilate the enclosed air gap in the drain line and the slot hood over the sterilizer door. Unfortunately, the capacity of the inadequate roof fan was not increased, so the net recess room ventilation dropped to 3.4 m^3/min (120 cfm).

Comparison of survey results

Referring to Table II, the average recess room concentration measured during

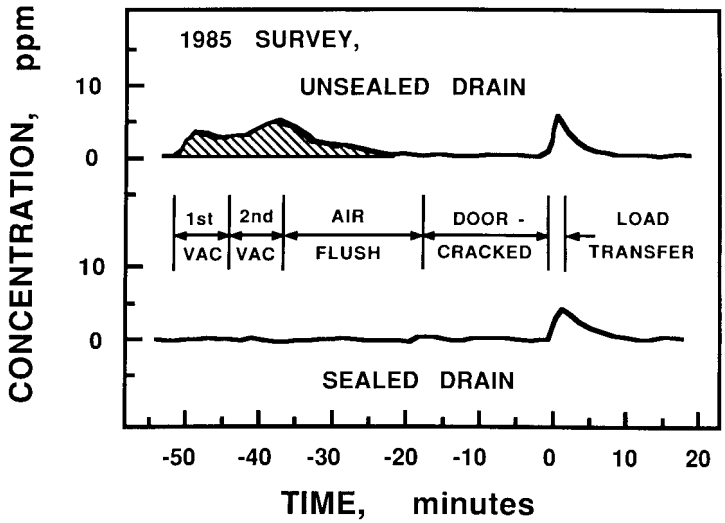

Figure 5—Infrared analyzer responses for the area in front of the sterilizer from follow-up survey for unsealed and sealed drain.

the first survey (9.2 ppm) and the average obtained for all loads except the first load of the second survey (0.28 ppm) indicates that emissions from the drain were reduced by approximately 97 percent due to sealing the floor drain junction and installing a ventilated enclosure around the air gap. The corresponding recess room concentration measured for the one load run during the second survey with the discharge-line/floor-drain junction unsealed was approximately 2.3 ppm. This indicates that even with the required air gap enclosed and ventilated, a small leak in the discharge line downstream of the vacuum pump can release a significant quantity of EtO.

The appearance in front of the sterilizer of EtO released in the recess room indicates that the measured recess room exhaust ventilation was insufficient. A large part of the problem was the effect of the heat generated by the equipment, drawing large quantities of air in through openings in the bottom portion of the room to replace the air rising to the ceiling due to the temperature-induced density gradient.[10]

Figure 6 compares typical IR analyzer responses from each survey illustrating the improved control of the EtO emissions during the 15-minute door-cracked period. During the first survey, with only the recess room exhaust drawing air through the slot above the door, EtO escaping from the sterilizer was not effectively controlled. During the second survey, the IR analyzer did not detect EtO in front of the sterilizer during any of the door-cracked periods.

Again referring to Table II, the improved control of emissions from the door is shown quantitatively by the short-term concentrations measured in front of the sterilizer. The results indicate that the potential for exposure working in front of the sterilizer was reduced to less than half a part per million. During the first survey, the short-term concentrations averaged 4 ppm, and for the second survey the average was less than 0.31 ppm, a reduction of greater than 92 percent.

Reducing the chamber concentration decreases the amount of EtO available for release into the operator's breathing zone when the sterilizer door is opened to pull the load. Figure 7 illustrates the effect of the air flush and the door-cracked period on the chamber concentration. With the addition of the air flush period to the cycle, the chamber concentrations were reduced an average of 60 percent. With just the door-cracked period, measurements indicate that sterilizer chamber concentrations were reduced approximately 85 percent. The total reduction with both an air flush and a door-cracked period was 95 percent.

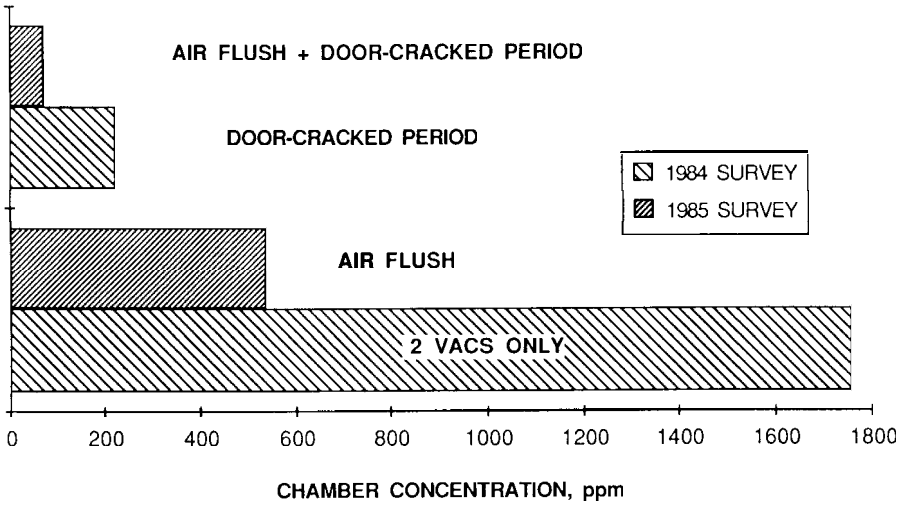

Figure 7—Effect of air-flush and door-cracked periods on chamber concentration.

The effectiveness of controls during load transfer is indicated by the substantial reductions in the operators' short-term exposures, as shown in Table II. The short-term samples collected in gas bags are the preferred indicator of effectiveness because they represent concentrations during only the load transfer activity. For the first survey, operators' exposures were 2.4 ppm (1-2 minute samples) compared to exposures for the second survey averaging 0.56 ppm, a reduction of 77 percent. For the charcoal tube samples, the operators' average exposure during the first survey was 1.9 ppm compared to the exposures measured during the second survey averaging less than 0.22 ppm.

Conclusions and recommendations

The results from these two surveys show that the engineering control modifications greatly improved the control of EtO emissions. Worker exposures were reduced 75 to 90 percent to values less than the 0.1-ppm full-shift exposure limit and the 5-ppm/10-minute ceiling limit recommended by NIOSH.

The greatest reduction in EtO emissions were obtained by controlling the discharge of EtO from the sterilizer vacuum pump. However, even after the drain air gap was ventilated, significantly higher levels of EtO were measured when the sterilizer discharge-line/floor-drain junction was not sealed.

The addition of a 20-minute closed-door air flush period before the door was opened reduced the chamber con-

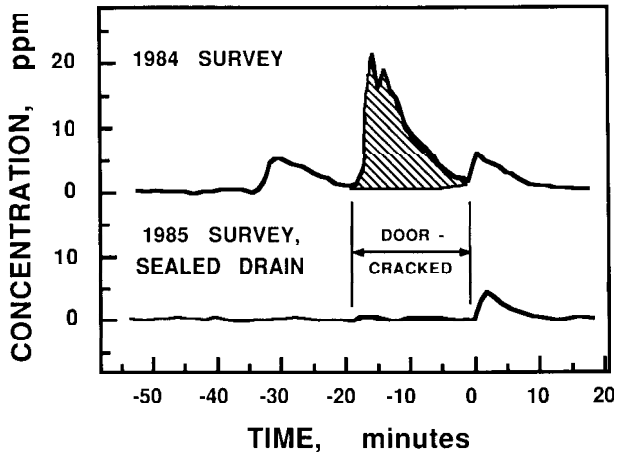

Figure 6—Comparison of typical infrared analyzer responses for the area in front of the sterilizer from initial and follow-up surveys.

centration by approximately 60 percent. A 15-minute waiting period with the door open a few inches yielded an 85 percent reduction.

EtO released into the recess room was not contained even though exhaust ventilation was provided. In fact, since the capacity of the roof fan for the recess room ventilation was not increased when the control system was installed, the net ventilation rate was reduced instead of being increased. On the plus side, a sensor and indicator light had been installed to warn if the roof fan failed.

These conclusions support the following recommendations:

1. Install a ventilated enclosure for the required air gap and seal all other openings in the sterilizer discharge line.
2. Use additional purge cycles to reduce the quantity of EtO in the chamber before the load is pulled. If proper ventilation is installed above the sterilizer door, before transferring the load to the aerator, open the sterilizer door a few inches (no further than the capture distance of the ventilation) for 15 minutes, or longer if time allows.
3. Install a sensor to detect exhaust ventilation failure and alarms to alert workers. If the dedicated exhaust system fails, stop the gas sterilizer operation until full ventilation is restored.
4. Since there is the potential for large quantities of EtO to be released into the recess room (via leaks or some other incidental discharge), provide enough exhaust ventilation for this room so that air always flows into, never out of, the room. However, this should be a secondary control, not a substitute for controlling the drain. Guidelines for ventilation of heated enclosures are presented in reference 10.

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ABIH 1987 dues and roster fees

The Board announces the following schedule of dues and fees for 1987.

Diplomates dues remain unchanged at $40.00 (U.S. funds).

Dues are used by the Board to support its services and provide support to the American Academy of Industrial Hygiene, as described in the 1985 ABIH Annual Report.

The payment of annual dues is required for annual roster listing and as part of the diplomate's certification maintenance. Beginning in 1987, a diplomate who fails to pay his/her annual dues will be recorded as not in good standing with the Board. As a condition of reinstatement the Board will require the payment of all lapsed dues and an administrative fee of $25.00 for each year that dues have lapsed.

The roster fee for Industrial Hygienists in Training is increased to $20.00 (U.S. funds). This is the first increase in that roster fee in the last ten years and is intended to reflect more accurately the services which the Board provides to IHITs, as described in the 1985 ABIH Annual Report.

1987 Dues and Fees notices will be mailed in early January, 1987 with returns to be no later than March 1, 1987. There will be no second notice.