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Effective controls for ethylene oxide—a case study

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The National Institute for Occupational Safety and Health (NIOSH) has studied the control of ethylene oxide (EtO) exposures associated with hospital sterilizers to determine which combinations of control measures are most effective. This case study describes the evaluation of controls at one hospital. The hospital had a gas sterilizer which used a mixture of EtO (12 percent by weight) in Freon-12®. The sterilizer was retrofitted with the manufacturer's control system consisting of a ventilated air gap, local exhaust ventilation above the sterilizer door, and cycle modifications for additional end-of-cycle air flushes. Personal and area samples for EtO were collected with charcoal tubes for laboratory analysis (NIOSH method #1607) and in gas sampling bags for on-site analysis with a portable gas chromatograph. The area in front of the sterilizer was also monitored with an infrared analyzer. All full-shift personal exposures and area concentrations were less than 0.05 ppm. Infrared monitoring showed no potential exposure in front of the sterilizer due to the purge cycle or opening the door a few inches for 15 minutes prior to transferring the load to an aerator. The EtO emitted during the post-sterilization chamber evacuation cycles was controlled by isolating all but the front of the sterilizer in an adequately ventilated recess room. The ventilation rate compared favorably with three design criteria. The airflow created by the slot hood above the sterilizer door controlled emissions from the sterilizer when the door was opened a few inches, consistent with a design equation for a flanged slot. General ventilation was not an important factor in this control strategy. Additional control measures were needed to deal with possible occasional and/or incidental exposures to potentially high concentrations of EtO. **Mortimer, V. D.; Kercher S. L.; O'Brien, D. M.** Effective controls for ethylene oxide—a case study. *Appl. Ind. Hyg.* 1:15-20; 1986.

Introduction

Ethylene oxide (EtO) has been used as a sterilant for many years, yet only within the past decade has there been increasing concern about the health effects of EtO exposure for those working with this chemical. In June of 1984, OSHA promulgated a new EtO standard that has a permissible exposure limit (PEL) of one part EtO per million parts of air (ppm), measured as an 8-hour time-weighted average (TWA).[1]

In response to the need to control EtO exposure to levels below 1.0 ppm, the Engineering Control Technology Branch (ECTB) of NIOSH is studying the control of EtO from sterilizers in the hospital setting. The goals of this study are to evaluate and document effective controls and to disseminate recommendations for controlling occupational ethylene oxide exposure. Information to support recommendations has been obtained from field surveys in selected hospitals, including monitoring EtO exposures and assessing control effectiveness. To date, surveys have been conducted in eight hospitals. This case study reviews the control system of one of the surveyed hospitals, which is representative of an effective control strategy.

Process description

Medical instruments and other items which cannot be sterilized by steam are gas sterilized. EtO is the most commonly used gas, and it is often supplied in a 12:88 EtO to Freon mixture or, less commonly, in a 10:90 EtO to carbon dioxide mixture. These mixtures are nonflammable. Prior to sterilization, the items are cleaned and sealed in packs made of plastic or paper which allow the diffusion of gases and vapors.

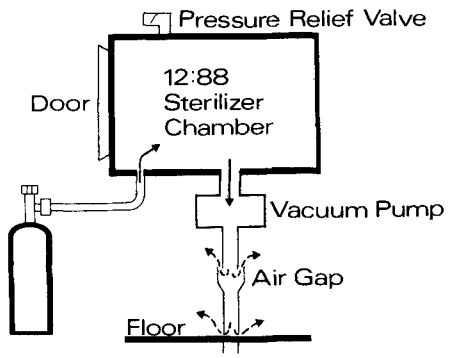

Figure 1—Schematic of sterilizer.

A typical sterilizer is depicted in Figure 1. It consists of a pressure/vacuum chamber connected to the gas supply cylinder and is evacuated through a water-sealed vacuum pump. A sterilization cycle consists of the following phases: initial vacuum to evacuate most of the air in the chamber, humidification, filling the chamber with EtO, a dwell period during which the actual sterilization takes place, and, finally, evacuation of most of the EtO in the chamber before opening the door. After sterilization, the load must be aerated to remove all residual EtO before the items can be used for patient care. Sterilization temperatures range from 37°C to 60°C. Most aeration cabinets operate at 49°C.

Two factors deserve special note. The first is that sterilizers which use the EtO mixture are fitted with a water-sealed vacuum pump to evacuate the chamber. During the evacuation phase, water (from the vacuum pump) and a small portion of the EtO, which becomes mixed with it, are released to the sewer drain. Plumbing codes require that there be an air gap in the water discharge line before it enters the floor drain. If not controlled, most of the EtO from the chamber escapes at this air gap when the pump is operating. Second, it is common for sterilizers of this type to be recessed into a wall so that only the

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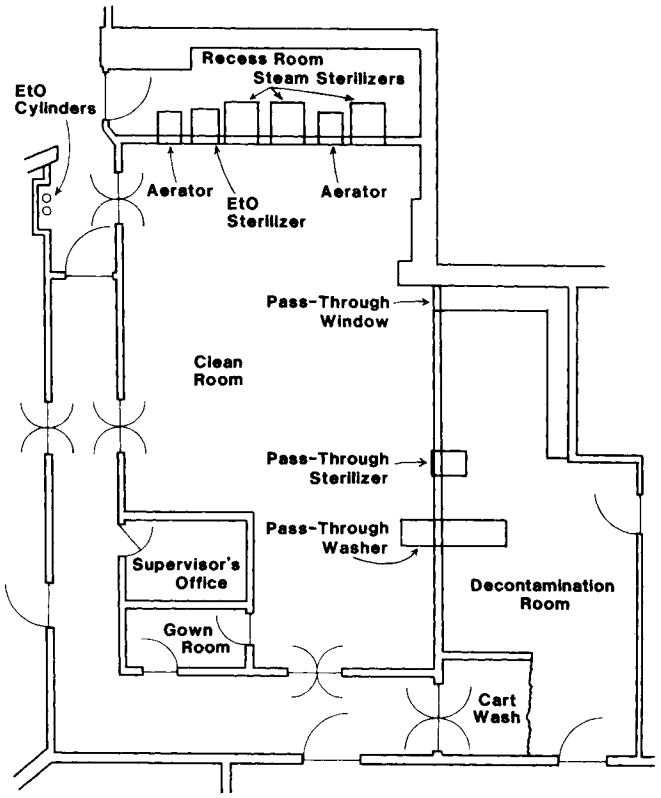

Figure 2—Layout of the Central Service Department showing the location of the recess room containing the gas sterilizer, three steam sterilizers, and two aerators.

front panel is visible, and the body of the sterilizer and usually the drain, plumbing, and supply cylinders are in a small room called a recess room. Since the room is usually small and quantities of EtO may be relatively large, the EtO concentrations in this room are potentially in the thousands of ppm.

All ethylene oxide sterilization for the hospital studied and its associated clinics and facilities was performed in the Central Service Department. The department had one EtO sterilizer, two aerators, and three steam sterilizers recessed into the wall at one end of the clean room, as shown in Figure 2. The rest of the clean room was used for instrument preparation, wrapping, and temporary storage of sterilized items. The general ventilation system had been updated during renovation of the department, beginning in 1979.

Two loads were routinely processed in the gas sterilizer on the evening shift and occasionally an additional load was processed during the day shift. Each cycle lasted approximately 3-1/2 hours followed by a 12-hour aeration period. Operators were instructed to open the door a few inches for 15 minutes to dissipate EtO remaining in the sterilizer before transferring the load to the aerator. For sterilization, items were inserted and removed using a three-shelved rack on a wheeled cart, but during the load transfer they were taken from the cart and placed on the aerator shelves by hand.

The gas sterilizer, a Medallion®-series model manufactured by the American Sterilizer Company (AMSCO, Erie, PA), had a chamber volume of approximately 0.25 m^3 (8.8 ft^3). The drain line from the sterilizer was fitted with a ventilated air gap enclosure. This air gap enclosure and a slot hood above the sterilizer door were ventilated as part of a package of controls called the Envirogard® system, supplied and installed by the sterilizer manufacturer. Another feature of this system was a modification of the cycle to add a 20-minute, door-locked air flush phase after the second exhaust vacuum phase. Additional repeating air flush phases would continue if the door was not opened within two minutes after the end-of-cycle buzzer sounded.

Evaluation methods

Personal exposures and average concentrations of EtO at selected locations in the clean room were determined by sampling with charcoal tubes using NIOSH Method 1607.[2] Long-term personal samples were used to estimate 8-hour TWA exposures for the sterilizer operator and an instrument wrapper. Long-term area samples were located approximately 60 cm (2 ft) in front of the sterilizer, at a height approximately 150 cm (5 ft) above the floor and at the instrument wrapper's workstation in the clean room near the pass-through washer. Area samples indicated the exposure the worker would receive if the full shift was spent at the workstation monitored.

Short-term samples for the sterilizer operator and the area location in front of the sterilizer were collected, using both charcoal tubes and gas sampling bags (Tedlar®). The charcoal tube samples were collected for approximately 15 minutes, starting when the sterilizer door was opened and ending when the load transfer was complete. The gas bag samples were collected for shorter periods of time, usually less than one minute, to measure the concentration from a particular task or event.

Gas bag samples were collected during the evacuation phase at the area location in front of the sterilizer door and in the recess room both at breathing-zone height and near the ventilated air gap. Other gas bag samples were collected to determine representative concentrations associated with certain other tasks or events, as well as the approximate quantity of EtO in the chamber when the door was opened. All bag samples were analyzed on-site using a portable gas chromatograph with a photoionization detector.

TABLE I
Long-term charcoal tube samples, 8-hour TWA exposures

Sample location (ppm)	Average (ppm)	Range (ppm)	No. of samples
Sterilizer Operator	0.025*	0.01–0.04	6
Instrument Wrapper	0.014*	0.01–0.02	6
BZ over Door (Area)	0.025*	0.02–0.04	6
Wrap Table (Area)	0.017*	0.01–0.03	6

*One or more samples used in computing the average were less than the limit of detection for the analytical method.

Due to the variable nature of EtO release during the day, an infrared analyzer was used at the area location in front of the sterilizer door to continuously monitor the background EtO levels and to identify concentration changes which could be associated with certain events such as opening the door.

To assess the performance of the ventilation systems, air flow rates were measured using a hot wire anemometer and/or a Balometer® flow hood (Alnor Instrument Company, Niles, IL). Smoke tubes were used to determine capture effectiveness of the exhaust hoods and to assess air movement between rooms through doors and other openings.

Results

Worker exposures were well below the OSHA standard of 1 ppm as an 8-hour TWA. In fact, no concentrations were measured in excess of 0.05 ppm, 5 percent of the OSHA PEL. A summary of the results of the long-term sampling is presented in Table I. The limit of detection (LOD) for the analysis was 0.1 μg per sample. Averages were computed using the LOD value for those samples less than the LOD.

The average exposure of the sterilizer operator during load transfer was less than 0.5 ppm expressed as a 15-minute average. A summary of the results of the short-term sampling is presented in Table II. The bag samples identified in Table II represent shorter sampling times and are consequently higher than the charcoal tube measurements. However, their average concentration-duration products are all on the order of 2 ppm-minutes, as is shown in Table III along with the corresponding values for the long-term charcoal tubes.

The infrared analyzer used in front of the sterilizer door as a continuous monitor indicated that the load transfer was the major exposure source at this hospital. EtO levels did not exceed background concentrations except during the load transfer. A representative tracing of the infrared analyzer results is presented in Figure 3. Because of the slow response of the infrared analyzer to changes in concentration, this tracing only approximates the actual concentration profile. There was no significant instrument response during the purge cycles or during the period that the door was open a few inches prior to transferring the load. EtO concentrations in front of the sterilizer returned to background levels within five minutes after the load transfer.

TABLE II
Short-term charcoal tube and bag samples during load transfer

Sample location	Type of sample	Duration (min.)	Average (ppm)	Range (ppm)	No. of samples
Sterilizer Operator	Charcoal tube	16	0.12*	0.05 – 0.31	9
Sterilizer Operator	Bag	1	1.5	0.5 – 3.0	4
In front of Sterilizer	Charcoal tube	16	0.18	0.04 – 0.45	8
In front of Sterilizer	Bag	1	2.4	2.0 – 3.0	5

*One or more samples in computing the average were less than the limit of detection for the analytical method.

Control technology

Controls were in place to deal with the three major sources of EtO during each sterilization cycle: the drain during evacuation, the door after opening at the end of the cycle, and the load during transfer to the aerator. Ventilation was not the primary control in all cases. In fact, ventilation was probably not a factor in controlling exposures during load transfer.

Drain controls: Recess room ventilation

Of all the sources of EtO, the one with the potential to release the most EtO on a daily basis is the sterilizer discharge line to the floor drain. Although this hospital used a ventilated air gap, it discharged into an open floor drain. The manufacturer recommends sealing the floor drain junction when the Envirogard® system is installed. Breathing-zone concentrations in the recess room were elevated during the sterilizer chamber evacuation, and the concentrations measured above the open floor drain, approximately 3 m (10 ft) from the sterilizer, were even higher. Concentrations of 20 ppm were measured in the breathing zone around the sterilizer in the recess room. Sampling above the open floor drain with an infrared analyzer indicated EtO levels around 100 ppm. Apparently, EtO was escaping from the open portion of the drain and elevating the breathing-zone concentrations.

Consequently, worker exposures from the drain were controlled by what should be a secondary measure, isolating all of the sterilizer except the front panel in a ventilated recess room. Gas bag samples collected during the evacuation phase at the area location in front of the sterilizer door measured EtO concentrations less than 0.2 ppm, indicating that the ventilation of the recess room was effective in containing the EtO. Measurements of airflow going into the room through the vents indicated an exhaust flowrate for the recess room in excess of 28 m^3/min (1000 cfm).

Ventilation criteria

The ventilation for the recess room (sterilizer enclosure) at this hospital satisfied three independent design criteria. First, the ventilation rate was adequate to overcome the thermal air currents produced by heat generating equipment located within the recess room. Second, the volume of air drawn into the room was sufficient to limit the temperature rise to an acceptable level. Third, sufficient dilution ventilation was provided to purge the room of EtO within a specified time period following a sudden release, such as emptying the air in the sterilizer chamber containing EtO through the safety valve.

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 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

TABLE III
Average concentration-duration product, ppm-minutes*

Sample location	Long-term charcoal tube	Short-term charcoal tube	Short-term gas bag
Sterilizer Operator	12	1.9	1.5
In front of Sterilizer	12	2.9	2.4

*Calculated from the data in Table I and II.

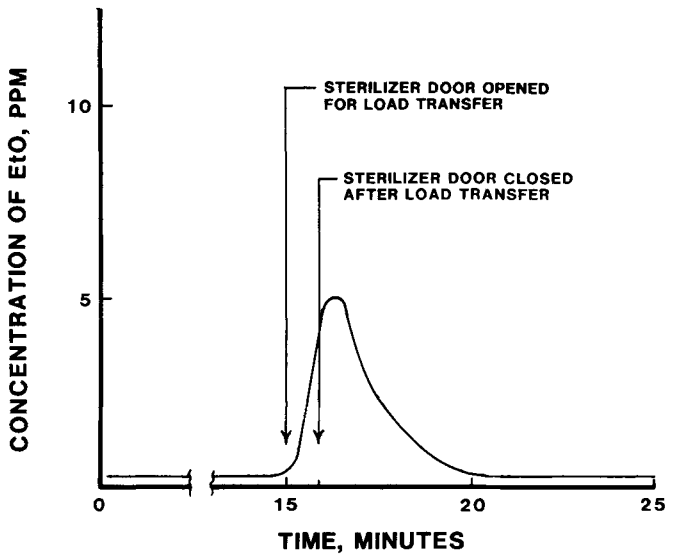

Figure 3—Typical EtO concentration in the breathing zone above the sterilizer door, as determined with an infrared analyzer. Time 0 corresponds to the opening of the sterilizer door a few inches at the completion of the sterilizer cycle. There was no instrument response until the load transfer began 15 minutes later.

leak out of the room.[3] For room temperatures not exceeding 93°C (200°F):

$$Q = 25.5(L\,H')^{1/3}\,(A)^{2/3}$$

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

In this situation, the height of the hot air column is taken to be the height of the recess room: 3 m (10 ft). The area of the vents was 0.46 m^2 (5 ft^2). Estimates of the heat released in the room were obtained from the equipment manufacturers and summed to obtain a value for H′, 1.9 cal/min (480 Btu/min). Using these values, the equation yields a design exhaust flow rate of approximately 27 m^3/min (970 cfm).

Exhaust ventilation may be used to remove excessive heat if cooler air is available from surrounding areas. The volume of air required for a predetermined temperature rise is given by the following equation:

$$Q = 58\,H'/T$$

where: Q = the required exhaust air flow, m^3/min
H = Sensible heat released to the air stream, cal/min
T = the acceptable temperature rise, °C

Assuming that the recess room temperature should not exceed 38°C (100°F), the acceptable temperature rise would be approximately 17°C (30°F). Using the estimates of the heat release from the previous calculation, approximately 26 m^3/min (910 cfm) would be required.

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[4]:

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

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 three and ten to correct for incomplete mixing. Since this recess room was small, with good mixing due to thermal air currents, K was assumed to be three. The above equation can be solved for Q:

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

The initial concentration, C_1, can be estimated by assuming the entire sterilizer contents escape into the recess room. The volume of this recess room was approximately 70 m^3 (2500 ft^3). Assuming that a 0.25-m^3 (8.8-ft^3) sterilizer chamber charged with 160 grams of EtO suddenly released its contents to the room, the resulting recess room concentration would be approximately 1300 ppm. To reduce this concentration to 1 ppm in 30 minutes would require 50 m^3/min (1800 cfm), while 25 m^3/min (900 cfm) should accomplish the reduction in one hour.

These three considerations suggest that the minimum design value for the recess room exhaust would be 25 m^3/min (900 cfm). The actual recess room exhaust was in excess of 28 m^3/min (1000 cfm).

Door controls

The control of emissions when the sterilizer door is opened involves reducing the quantity of EtO remaining in the chamber in addition to capturing as much as possible the air escaping from the sterilizer. The air flush period seemed effective in reducing the amount of EtO remaining in the sterilizer by an order of magnitude. Measurements of the chamber concentration immediately after the door was opened indicated that only a few hundred milligrams of EtO remained rather than the few thousand milligrams predicted by assuming the cycle ended after two vacuum purges.

Work practices at this hospital involved opening the door a few inches at the end of the cycle for 15 minutes before unloading the sterilizer. The operator then moved away from the area where the peak EtO concentrations were likely to be present. With this practice, the distance which the door is opened can be an important factor in controlling the EtO released along the top edge of the opening. With a given flow rate and hood size, the capture distance of the hood is limited.

The slot hood over the sterilizer door provided control of EtO vapors escaping from the chamber when the door was opened a few inches at the end of the cycle. Based on the air flow pattern observed with smoke tubes, the slot hood seems to control emissions from the door to about 8 cm (3 in). Measured air flow was 3.4 m^3/min (120 cfm).

The relationship of control velocity, capture distance, and slot width to flow rate is given by the equation[5]:

$$Q = 2.6\,LVX$$

where: Q = the volumetric air flow, m^3/min
L = length of the slot, m

V = velocity of the air stream m/min

X = distance from the sterilizer, m

For this particular process, the control velocity should be between 15 and 30 m/min (50 - 100 ft/min)—with the upper limit of the range recommended. In this case the volumetric flowrate is known, 3.4 m^3/min (120 cfm), so the maximum capture distance can be estimated by solving for X. For a desired control velocity of 30 m/min (100 ft/min) and a slot width of 0.66 m (26 in), the capture distance calculated from the equation is about 6 cm (2.4 in), which agrees with the air flow patterns observed using the smoke tubes.

The equation may be used to predict what flow rate is needed to achieve a desired capture distance. In an existing system, the smoke tube method may be used to establish the maximum distance the door should be opened at the completion of the cycle. The fact that the sterilizer operators were generally consistent in opening the sterilizer door 8 cm (3 in) or less, rather than the 15 cm (6 in) usually recommended in the literature, may have contributed to the effectiveness of the slot hood in controlling emissions from the door.

Controls during load transfer

The primary controls involve reducing the quantity of EtO remaining in the load and keeping the worker's breathing zone away from areas of high concentration of EtO. Keeping the load in the sterilizer with vacuum purges and/or air flushes reduces the quantity of EtO. It has been reported that the two vacuum cycles remove 97 percent of the EtO in the chamber at the end of sterilization and that the first air flush removes 80 percent of the EtO remaining after the vacuum purge.[6]

The sterilizer operators were trained to pull the cart to the aerator, rather than pushing it, and they performed the load transfer quickly, minimizing their exposure to EtO. Their short-term exposures for just the load transfer, which lasted approximately one minute, ranged from 0.5 to 3 ppm and were less than 0.4 ppm for the highest 15-minute period. All short-term results, including area concentrations, were less than 10 ppm-minutes, approximately 2 percent of the 480 ppm-minutes allowed by the 1 ppm, 8-hr TWA.

General ventilation

The volume of nonrecirculated air exhausted per hour relative to the room volume, usually referred to as "room air changes per hour," is not very important in controlling routine emissions of EtO in a situation such as this where there are effective engineering controls. 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 with substantially less than the often recommended ten air changes per hour. For an emergency situation involving the release of a large quantity of EtO, a high rate of ventilation would be helpful in clearing the room, provided that all air was exhausted through a dedicated system and not returned to a supply air handler. The ventilation discharge points must be located so that exhausted EtO does not reenter the building through open windows, air conditioners, or other supply air intakes.

Conclusions and recommendations

Based on the sampling results, both the workers' short- and long-term exposures to EtO were well controlled. The system of controls at this hospital had many strong points, foremost of which was the adequately ventilated recess room which prevented EtO from the drain from reaching the area in front of the sterilizer even though it escaped from the drain into the recess room. The combination of two vacuum purges, a 20-minute air flush, and a 15-minute waiting period with the door opened a few inches reduced the concentration in the chamber to less than 0.1 percent of the concentration during sterilization. The ventilation above the sterilizer door captured EtO escaping from the sterilizer door—when opened a few inches—however, it may not have had much effect during the load transfer period.

Rather that relying on a "well-ventilated room" as a primary control, it is recommended that effective controls be installed at the major sources of EtO release. These controls include a ventilated enclosure for the drain air gap, additional cycle phases to reduce the concentration in the sterilizer before the door is opened, and work practices which minimize contact with the sterilized load. However, there is always the possibility of incidental release of EtO in the enclosure, so the ventilation should be sufficient not to allow any airflow out of the enclosure. The thermal effects equation will give an estimate of the flow rate needed.

Despite the ventilated air gap in the drain line, EtO escaped from the open drain in the recess room. Since elevated EtO concentrations occur in the recess room during the evacuation phase, a warning system should be present to alert workers not to enter the room for some time (which may be estimated from the rate-of-purging equations) after this phase is complete. Ideally, this warning system would alert workers whenever EtO concentrations in the recess room were too high for a person to enter without respiratory protection.

The sterilizer operator should be alerted when the ventilation system is not functioning properly. This could be achieved by installing a sail switch or differential pressure sensor in the exhaust duct which would set off an alarm if flow decreased appreciably. EtO organic vapor sensors are also available which alert workers to an emergency situation involving the presence of a high concentration of EtO.

To protect the maintenance worker changing the EtO supply cylinders, supply line purge systems and/or local exhaust ventilation above the cylinders should be installed. Face shields and gloves should be worn by the worker who changes the cylinder for protection in case of an accident. Respirators should be available to handle emergency situations and may be necessary for routine cylinder changes if the controls are inadequate. 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.[7]

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Still useful today. . . "Before welding or any other process of heating a metal is done, it should be determined if the metal contains or is coated with cadmium. A simple test is as follows: Apply a drop of 10 per cent solution of ammonium nitrate to the clean metal surface. Allow a few seconds for this solution to dissolve some of the metal. Blot with a piece of filter paper and then apply a drop or two of 5 per cent sodium sulfide on the wet portion of the filter paper. If it remains colorless, no cadmium is present. If a yellow color forms, cadmium is present."

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