IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

BETHESDA HOSPITAL

CINCINNATI, OHIO

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SITE SURVEYED:	Bethesda Hospital, Inc.
SIC CODE:	8062
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Abstract

Controls for ethylene oxide (EtO) emitted from the gas sterilization of medical items were evaluated at Bethesda Hospital, Cincinnati, Ohio. EtO may have serious health effects, including carcinogenicity, and OSHA has established an 8-hour permissible exposure limit of 1 ppm. Personal exposures and area concentrations were sampled with charcoal tubes, gas bags, and/or an infrared analyzer. The full-shift exposures were controlled to less than 0.1 ppm with a combination of local exhaust ventilation, sterilizer cycle modifications, and work practices. Short-term exposures while transferring the load to the aerator did not exceed 5 ppm. The slot hood above the door was ventilated, and the door was not opened more than the capture distance of this hood (approximately 3 inches) during the 15-minute waiting period before pulling the load. EtO emissions from the drain during the purge were contained in an adequately ventilated recess room. Sensors, alarms, and procedures for handling emergency situations are recommended.

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INTRODUCTION

BACKGROUND FOR CONTROL TECHNOLOGY STUDIES

The National Institute for Occupational Safety and Health (NIOSH) is the primary Federal agency engaged in occupational safety and health research. Located in the Department of Health and Human Services (formerly DHEW), it was established by the Occupational Safety and Health Act of 1970. This legislation mandated NIOSH to conduct a number of research and education programs separate from the standard setting and enforcement functions carried out by the Occupational Safety and Health Administration (OSHA) in the Department of Labor. An important area of NIOSH research deals with methods for controlling occupational exposure to potential chemical and physical hazards. The Engineering Control Technology Branch (ECTB) of the Division of Physical Sciences and Engineering has been given the lead within NIOSH to study the engineering aspects of health hazard prevention and control.

Since 1976, ECTB has conducted a number of assessments of health hazard control technology on the basis of industry, common industrial process, or specific control techniques. Examples of these completed studies include the foundry industry; various chemical manufacturing or processing operations; spray painting, and the recirculation of exhaust air. The objective of each of these studies has been to document and evaluate effective control techniques for potential health hazards in the industry or process of interest, and to create a more general awareness of the need for and availability of an effective system of hazard control measures.

These studies involve a number of steps or phases. Initially, a series of walk-through surveys is conducted to select plants or processes with effective and potentially transferable control concepts or techniques. Next, in-depth surveys are conducted to determine both the control parameters and the effectiveness of these controls. The reports from these in-depth surveys are then used as a basis for preparing technical reports and journal articles on effective hazard control measures. Ultimately, the information from these research activities builds the data base of publicly available information on hazard control techniques for use by health professionals who are responsible for preventing occupational illness and injury.

BACKGROUND FOR THE STUDY OF ETHYLENE OXIDE STERILIZATION IN HOSPITALS

The present Control Technology Assessment of Ethylene Oxide Sterilization in Hospitals is the result of the research recommendations of the Feasibility Study of Engineering Controls in Hospitals completed in 1983. During the feasibility study, preliminary surveys were conducted at eight hospitals to assess the potential need for further research in the control of anesthetic gases, antineoplastic drug exposures, and ethylene oxide sterilization operations. Based on the feasibility study, a need for the evaluation and documentation of effective engineering controls for EtO sterilization was identified.

The health effects of ethylene oxide have been under intense study for several years. EtO exposure may cause irritation of the eyes, nose, and throat. Dermal exposure to aqueous solutions of EtO may cause burns and allergic sensitization. Animal toxicity studies have shown EtO to be a mutagen and a carcinogen. Studies of exposed workers have indicated increased mutagenic activity in human cells, an increase in the incidence of leukemia, and adverse reproductive effects. Many of these effects, both for exposed animals and humans, were observed at concentration levels lower than the former OSHA permissible exposure limit (PEL) of 50 parts EtO per million parts air (ppm), 8-hour time-weighted average (TWA). As a result of these studies and the urgings of workers' groups, OSHA began the rulemaking process to issue a new standard in early 1983. On June 15, 1984 OSHA issued a new PEL of 1 ppm (8-hr TWA) for ethylene oxide based on its determination that EtO is a potential human carcinogen.[1]

In response to the hospitals' need to control worker exposure to EtO to levels below 1 ppm, the Engineering Control Technology Branch (ECTB) of NIOSH is studying the control of EtO emissions from sterilizers in the hospital setting. The goals of this study are to evaluate and document selected engineering controls which hospitals have implemented, and then to disseminate useful information and practicable recommendations on effective methods for controlling occupational ethylene oxide exposure.

BACKGROUND FOR THIS SURVEY

As part of the feasibility study, a preliminary survey was conducted at Bethesda Hospital in April, 1983.[2] Bethesda Hospital had renovated the ventilation system in the Central Processing department and installed a local exhaust system to control EtO emissions at the sterilizer door and at the floor drain. In addition, the hospital staff were very conscientious about EtO control and had made every effort of follow the guidelines of the American Hospital Association and the Health Industry Manufacturers Association for the *safe and controlled use of EtO in sterilization operations.*

An in-depth survey of the Central Processing department of Bethesda Hospital was conducted on June 11-15, 1984 to evaluate its operations and associated controls for EtO exposure. This report documents the information pertinent to that evaluation.

POTENTIAL HAZARDS AND EXPOSURE GUIDELINES

Workers exposed to EtO may experience both acute and long-term health effects. EtO is a central nervous system depressant, and in air can cause acute irritation to the eyes, upper respiratory tract, and skin at concentrations of several hundred to 1,000 ppm. Exposure to high concentrations may also cause headache, dizziness, nausea, and vomiting. Dilute (1 percent) aqueous solutions can cause blistering of human skin, and allergic sensitization can also occur in some individuals.[3]

NIOSH has conducted animal toxicity studies to determine the possible long-term health effects of EtO exposure. The results of the NIOSH studies support the conclusions of other researchers that EtO is a mutagen and a carcinogen in animals. The studies showed an increase in sister chromatid exchanges and in chromosomal aberrations, evidence of mutagenic activity. The studies also showed an increase in the frequency of leukemia, peritoneal mesotheliomas, and cerebral gliomas. Adverse reproductive effects were also observed.[4]

The potential of EtO to cause mutagenic activity in humans has been examined by a number of investigators. The studies were conducted by examining blood lymphocyte cultures obtained from workers exposed to EtO in a variety of occupational settings. The results clearly demonstrate that EtO adversely effects human genetic material.[5]

Epidemiologic studies of humans occupationally exposed to EtO, show an increase in the frequency of leukemia and other malignant tumors. Taken along with the results of the animal studies, EtO must be considered a potential human carcinogen.[5]

In addition to the OSHA PEL of 1 ppm, the standard mentions an action level of 0.5 ppm, above which semi-annual monitoring is required. The American Conference of Governmental Industrial Hygienists has also adopt ed 1 ppm as an 8-hour TWA Threshold Limit Value (TLV); however, they had allowed for an excursion limit such that short-term exposures should exceed 3 ppm no more than 30 minutes during a workshift and should never exceed 5 ppm.[6] In its testimony to OSHA on the new standard, NIOSH recommended that a ceiling limit of 5 ppm not be exceeded for more than 10 minutes in a workday, and that the 8-hr PEL be set lower than 0.1 ppm to reduce the risk of occupational mortality to the greatest extent possible.[7]

PRIMARY EXPOSURE SOURCES

Hospital central service personnel may be exposed to EtO from several sources. Each source contributes to the ambient concentration of EtO but three may be directly responsible for most of the exposure on a daily basis.

Uncontrolled Drain

During the evacuation phase of the sterilization cycle, most of the EtO in the sterilization chamber is removed through the vacuum pump and drain. For sterilizers which evacuate to an uncontrolled drain, much of the EtO used in

sterilization may be released into the recess room and/or perhaps to the workroom atmosphere.

Opening of the Sterilizer Door

In some situations, the most significant EtO emission source on a daily basis is the opening of the sterilizer door at the end of the sterilization cycle. In an uncontrolled system, warm, moist, EtO-laden air escapes from the sterilizer when the door is opened and may diffuse throughout the room. This source of EtO may release a significant quantity of EtO into the workroom air as a background concentration, and, depending on the work practices, may or may not provide a peak exposure for the sterilizer operator.

Transferring the Sterilized Load

Some of the EtO used in sterilization remains on the sterile items and wrapping material and inside the package after the sterilization cycle is complete. This EtO will be given off exponentially until equilibrium is reached with the surrounding air; and, depending on the composition of the items and their packaging, these off-gassing items can provide a significant EtO exposure source for the operator transferring the load to the aerator and contribute to the background levels of EtO in the workplace.

SECONDARY EXPOSURE SOURCES

Other exposure sources may not be as readily apparent, but may also provide important contributions to the background levels of EtO in the workroom air. Some of these sources may only intermittently release EtO.

Aeration

Post-sterilization aeration is essential for protection of the patients who will use the items and for controlling occupational exposure to EtO. While in the aerator the sterile items continue to off-gas. If the aerator cabinet is not vented out of the building or to a dedicated exhaust, it can become a major contributor to the background EtO levels.

Replacement of EtO Gas Cylinders

Ethylene oxide gas is supplied to many sterilizers from pressurized gas cylinders. When replacing empty EtO cylinders, the worker may be exposed to EtO vapors from residual EtO in the supply lines. Depending on the location and ventilation around the cylinders, the release of this trapped EtO may contribute to the background EtO concentration for the sterilizer operator operator and other workers. Cylinder changes are not usually performed on a daily basis.

If the contents of an EtO cylinder were accidentally discharged, a large quantity of EtO would be released. This could result in higher concentrations in the vicinity of the cylinders and in the surrounding work area than possible from any other source.

Pressure Relief Valve

Another possible source of EtO is the sterilizer safety valve. If the sterilizer becomes overpressurized during the cycle, this emergency relief valve releases EtO gas. If not enclosed and vented, this valve could be the source of a significant quantity of EtO.

Maintenance

Sterilizer part failures, maintenance operations, and repair work can also result in significant exposures to personnel. Of particular concern are plastic and rubber components which will absorb EtO and may even react with the gas; these parts can deteriorate over time. Valves, connections, and the front door gasket are potential sources of leaks, and occasional exposure. Maintenance personnel may be exposed by unknowingly entering the recess room to work on equipment when EtO concentrations are high, such as during or following a purge cycle.

HOSPITAL AND PROCESS DESCRIPTION

HOSPITAL AND CENTRAL PROCESSING DEPARTMENT DESCRIPTION

Bethesda Hospital, Inc. is a multi-institutional organization with two hospitals (Bethesda Oak, a 492-bed facility, and Bethesda North, a 271-bed facility), a 300-bed retirement home, two ambulatory care facilities, an out-patient service, nursing school, three medical office buildings, and a pharmacy. Of interest in this report is Bethesda/Oak Hospital in which the EtO sterilizers are located. The main building, now the north wing, was constructed in 1928. The south and west wings were added in 1959 and 1969, respectively. Further expansion of the facility occurred in the 1970's.

Ethylene oxide gas sterilization operations are conducted in the Central Processing department located in the sub-basement of the north wing. This department performs EtO sterilization for all Bethesda facilities including the Bethesda/North Hospital. Central Processing performs three main functions each located in separate rooms: decontamination, preparation and packing, and sterilization.

The layout of the Central Processing department is diagrammed in Figure 1. This study was conducted in the sterilization room--also known as the "clean room." The clean room, with an area of 1220 ft^2 and a volume of 9150 ft^3, contains three steam sterilizers, one EtO gas sterilizer, and two aerators recessed into the north wall. The aerator adjacent to the sterilizer is used routinely; the aerator located approximately 15 ft from the sterilizer is used only if the other aerator is full. The west side of the room is used for the temporary storage of freshly sterilized goods waiting to be delivered to surgery and other departments. Three work tables, a pass-through steam sterilizer, and a pass-through washer are located along the east wall.

Central Processing employs four workers and a supervisor in the clean room during the day (1st) shift. One of these workers moves between the clean room and the decontamination room throughout the day. During the evening (2nd) shift, three employees work in the clean room.

EQUIPMENT AND PHYSICAL DESCRIPTION

The EtO gas sterilizer is a Cryotherm, Medallion series, manufactured by the American Sterilizer Company (AMSCO). Its internal chamber size is 20 inches by 20 inches by 38 inches, approximately 8.8 cubic feet. The gas sterilizer has been modified with the AMSCO Envirogard® system, which adds a ventilated air gap (called a liquid/gas separator) to the sterilizer drain line, additional air flush(es) to the purge cycle, and ventilation to the slot in the front panel above the door.

The sterilizers may be accessed for maintenance via the small recess room located behind the north wall. This room is entered through a doorway off the hall and is locked to restrict access of unauthorized personnel. The backs of the sterilizers and aerators are open to the room. Steam and water from the sterilizers is dumped into an open floor drain which runs the length of the room.

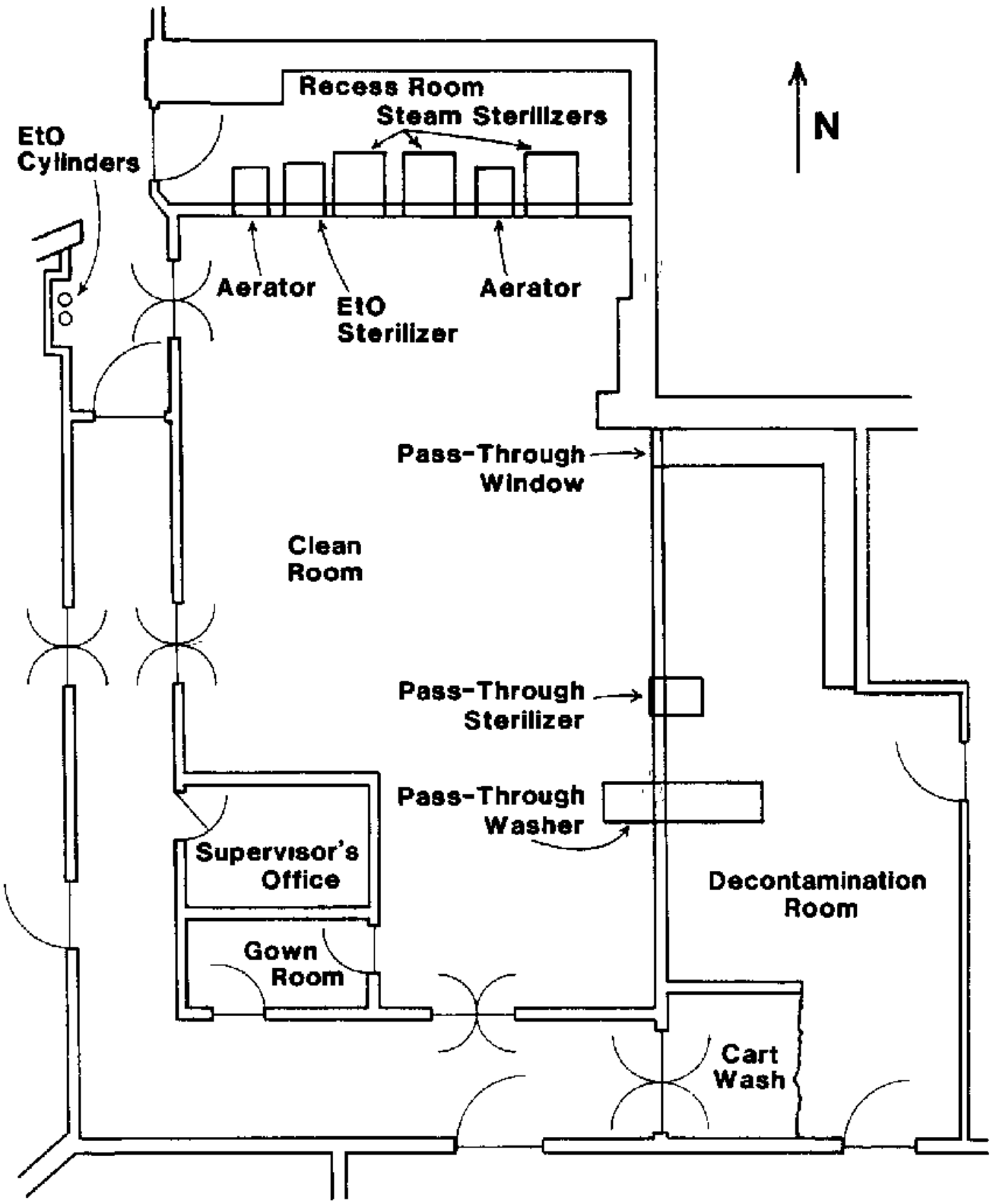

Figure 1. Central Processing Department.

The EtO sterilizer is supplied with gas from a cylinder. The cylinders are located in a niche in the hallway across from the north end of the clean room. Overhead copper piping connects the supply cylinder with the sterilizer gas inlet in the recess room.

Sterilizer Cycle Features

The cycle, which is 3 1/2 hours in duration, consists of several phases: initial vacuum, humidification, EtO charging, sterilization, two vacuum purges, and a twenty minute air flush period. At the end of an air flush period a buzzer sounds alerting the operator that the cycle is complete and the door may be opened. If the operator is delayed in opening the door more than 2 minutes, another air flush period begins, and the door may not be opened for 20 minutes.

Local Exhaust Ventilation

The Envirogard® system included the ventilation of the slot hood, 1 1/4 inch by 26 inches, located 2 inches above the sterilizer door. A 2-inch diameter flexible duct connects the hood to a fan rated at 300 cfm. The exhausted air is vented through a dedicated system to the outside.

A slot hood has been placed around the opening in the wall for the pass-through washer near the wrapping table. The air exhausted through this hood is returned to the main air handler.

General Ventilation

Additional ventilation above the sterilizers is provided by a row of five, 5 by 11-inch louvered vents located about 10 inches above the tops of the equipment control panels. These vents are open to the recess room, not attached directly to a ventilation duct.

Three exhaust vents in the ceiling close to the sterilizers and another vent above the wrapping table exhaust air from the clean room and return it to an air handler. Outside air may be mixed with this return air at the air handler. The percentage of recirculated air depends on a temperature and humidity controller.

The air from the air handler is suppled to three separate areas. The greatest portion goes back to the clean room. Smaller, approximately equal portions are supplied to the decontamination room and to the washroom and the supervisor's office.

PROCESS DESCRIPTION

Many of the items to be sterilized with EtO are prepared and packaged for sterilization in the using department. They arrive in the clean room ready for sterilization and are placed on a cart/rack. The sterilizer is cart-loaded with items for gas sterilization.

The department usually processes two EtO loads per day during the 2nd shift. Occasionally, extra items may need sterilization, requiring the 1st shift to process an EtO load. Items are removed from the aerator the following morning by the 1st-shift operator.

When the door is opened at the end of an air flush period, the operator opens it only a few inches and leaves the area for 15 minutes before returning to transfer the load from the sterilizer to the aerator.

To transfer the load, the operator pulls the rack from the sterilizer on to a wheeled cart, closes the sterilizer door, and pulls the cart to one of the aerators. The operator lifts the sterilized items off the rack and places them in the aerator and closes the door. The times that each shelf was loaded and the times when the items may be removed from the aerator are written on a piece of paper taped to the aerator door. Gas sterilized items are aerated for 12 hours.

The biological indicators are not placed in the aerator. After the aerator has been loaded and started, the biological indicator packs are opened. During our survey, the packs for the loads sterilized on the 1st shift were opened by the supervisor in her office. The 2nd-shift operator opened those from the 2nd-shift loads.

If an EtO supply cylinder empties during a cycle and an insufficient amount of EtO is supplied to the sterilizer, the cycle will automatically abort. Then a new cylinder must be connected, and the cycle restarted. The maintenance department is responsible for changing EtO cylinders.

The supply line is equipped with a coupler to allow quick connections to be made without the use of wrenches. The coupler is connected to the supply shut-off valve by 18 inches of flexible steel hose. The shut-off valve connects directly to the copper supply line for the sterilizer. The maintenance person closes the cylinder valve with a wrench, then closes the shut-off valve. The coupler is disconnected from the empty cylinder and connected to the full cylinder. There is no provision for purging the supply lines and the connecting hose prior to disconnecting the empty cylinder.

Preventive Maintenance

The Central Processing Department has a preventive maintenance contract with AMSCO for routine monthly visits. The AMSCO service representative inspects the steam sterilizers as well as the EtO sterilizer and aerators. The hospital maintenance personnel may also inspect and repair parts of the sterilizer, such as the door gasket.

Monitoring

Some personnel monitoring for EtO has been conducted, averaging once a year since 1979. As controls have been improved and more sensitive monitoring techniques have been used, measured EtO concentrations have dropped to less than 1 ppm for the operator's full-shift exposure. Diffusion badges were used on one occasion to monitor personal exposure for the sterilizer operator. Both samples, one worn for a full shift, the other only during the load transfer, were below the detection limit for the analytical procedure.

METHODOLOGY

Air movement and airborne ethylene oxide concentrations were measured to evaluate the effectiveness of the engineering controls. Table A-1 in Appendix A lists some of the major pieces of equipment used.

Processing the Test Load

In designing this study, it became obvious that conditions in each of the participating hospitals might be so different that meaningful comparisons could not be made unless some of the variables could be eliminated. Therefore, a test load was provided for processing at each hospital. The load consisted of a 15-inch length of latex rubber tubing in a peel-pac. The number of packages is adjusted to the volume of the sterilizer of interest to adsorb approximately 65 to 100 mg of EtO per liter of chamber volume. For the 8.8-ft^3 volume sterilizer, 66 packages were used. The rubber materials of this test load were chosen because EtO is absorbed into rubber during sterilization and off-gases more slowly than some other materials. This increased retention of EtO, provides a challenge to the control system and may aid in evaluating the effectiveness of the controls.

At this hospital, the test load was sterilized each morning from 8:00 a.m. to 11:30 a.m. for 3 days. No other loads were processed through the EtO sterilizer during the 1st shift. Sampling data from this test load provides the basis for comparison with the two regular (normal) loads processed during the 2nd shift.

MEASUREMENT OF CONTROL PARAMETERS

Sampling was conducted during two shifts for 3 days. Some samples were taken for each sterilizer load. An attempt was made to sample similar events (sterilizer to aerator transfer, etc.) to aid the comparison of sampling results. For this survey, some bag samples were taken only once or twice.

Charcoal Tube Sampling

To determine personal exposures and average concentrations of EtO at selected locations, air samples were collected using charcoal tubes. The samples were collected on 400 mg and 200 mg charcoal tubes (SKC No. 226-37) connected in series, and the sampling train was contained in a plastic holder. MDA pumps were fitted with limiting orifices and calibrated. The nominal flow rates were 20 milliliters of air per minute (mL/min) and 50 mL/min for the long-term and the short-term samples, approximately 4 hours and 20 minutes, respectively.

Two sequential long-term samples were used to estimate the full-shift time-weighted average (TWA) exposures for the sterilizer operator and an instrument wrapper. This same scheme was used to determine the TWA concentration at approximately breathing-zone height in front of the sterilizer and above a work table near the sampled instrument wrapper. Short-term samples were taken for the sterilizer operator and at the area location in front of the sterilizer from the time the sterilizer door was cracked open following the air flush period until the load was transferred to the aerator. The samples were then analyzed according to NIOSH Method 1607.

Gas Bag Sampling

Short-term personal and area samples were collected in Tedlar® gas bags (SKC No. 231) to coincide with certain events load transfer from sterilizer to aerator, cylinder change operation, etc. The collection times ranged from 15 seconds for the samples from inside the sterilizer chamber to 1 - 2 minutes for the load transfer operation. These bag samples were analyzed immediately using a portable gas chromatograph.

Infrared Analyzer Monitoring

Due to the sporadic nature of EtO release during the day, an infrared (IR) analyzer was used to monitor the EtO concentration at the area location in front the the sterilizer. This produced a a continuous record of the EtO concentration which could be used to identify any significant emissions of EtO into the breathing zone in front of the sterilizer associated with certain events.

Since the EtO sterilizer is adjacent to steam sterilizers, this location was occasionaly subjected to high humidity levels. Laboratory experiments showed the instrument responded to an increase in the humidity of the sampled air by indicating a higher concentration of EtO than was actually present. The magnitude of the response (at the 3.3 um wavelength) was approximately 3 ppm EtO for a 10-percent rise in relative humidity. To compensate for this effect, the IR analyzer was integrated with a humidity-temperature monitor and a computer. The computer corrected the IR output for the humidity effect and provided a continuous printout of the measured EtO concentration, the corrected EtO concentration, the air temperature, and the relative humidity. A chart recorder was also used to provide a continuous graphic record of changing humidity levels and measured EtO concentrations.

Airflow Measurements

The airflow velocities in the ducts supplying air to the Central Processing department were measured using a hot-wire anemometer. Within the department, supply airflow volumes were measured at the ceiling diffusers using a Balometer® flow hood.

The ventilation system in the department was evaluated by measuring the airflow through the various inlet and outlet vents. Most of the vents were measured using the Balometer®. For those vents which could not be fitted with this device, the airflow was estimated using a hot-wire anemometer or a smaller flow hood fabricated out of cardboard.

The average airflow through the slot hood over the sterilizer door and hood for the pass-through washer was determined by a multi-point measurement of air velocity with a hot-wire anemometer.

Smoke tubes were used to qualitatively evaluate the air supply and ventilation system. Airflow patterns around selected supply diffusers, return air grilles, smoke-relief grilles, wall louvers, and the slot hoods were sketched. Airflow patterns at the doorways, pass-through windows, and other openings into the department, were also evaluated using smoke tubes.

Work Practice Observations

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 his own exposure. To evaluate this effect, observations of the operator's work practices during his EtO sterilizer activities were made. An activities data sheet was completed for each sterilizer load processed including estimates of the time spent on each activity. Notes were made to aid the association of the sampling results with specific activities, particularly for air bag samples. Photographs of each step of the sterilizer activities were taken.

RESULTS

The test load was run during the morning of the three days on which samples were taken. It was the only load run during the 1st shift. Two normal loads were run during the 2nd shift on each of the three days. For purposes of identification in this report, the first normal load is referred to as N1 and the other one, N2.

AIR SAMPLING RESULTS

All personal exposure and selected area concentrations sampled with charcoal tubes were less than 0.5 ppm, the results are presented in Table A-2. In fact, approximately half of the samples (33 of 65) were below the limit of detection for the analytical procedure, 0.1 µg per sample. The results below detectable limits were evenly distributed between the long-term samples (25 of 48) and the short-term samples (8 of 17). The average detection limits for these two groups of samples are 0.015 ppm and 0.072 ppm, respectively. One sample (No. 77) was invalidated because of a pump problem.

Since two long-term samples were taken to cover a single shift, the actual time-weighted average exposures must be calculated by dividing the sum of the quantity of EtO on the charcoal tubes by the total volume of air drawn through the two tubes. The recalculated results are shown in Tables 1 and 2, and a summary of the charcoal tube results, averaged over the 3 days of the survey, is presented in Table 3. Note that the results for the test load do not differ significantly from those for the normal loads.

Table 1. Full-shift time-weighted average exposures.

Worker	Date mo/dy/yr	Shift	Load	Duration minutes	Concentration ppm
Sterilizer Operator	6/12/84	1st	Test	409	0.043
		2nd	Norm	431	0.032
	6/13/84	1st	Test	419	< 0.015
		2nd	Norm	401	0.016
	6/14/84	1st	Test	384	< 0.034
		2nd	Norm	488	< 0.012
Wrapper	6/12/84	1st	Test	388	< 0.013
		2nd	Norm	390	< 0.014
	6/13/84	1st	Test	395	< 0.025
		2nd	Norm	335	< 0.016
	6/14/84	1st	Test	421	< 0.014
		2nd	Norm	431	< 0.013

Table 2. Full-shift time-weighted average area concentrations.

Location	Date mo/dy/yr	Shift	Load	Duration minutes	Concentration ppm
In front of Sterilizer	6/12/84	1st	Test	325	< 0.016
		2nd	Norm	477	0.031
	6/13/84	1st	Test	410	< 0.018
		2nd	Norm	475	0.016
	6/14/84	1st	Test	484	0.042
		2nd	Norm	483	< 0.014
Wrapping Table	6/12/84	1st	Test	432	< 0.011
		2nd	Norm	430	< 0.021
	6/13/84	1st	Test	394	< 0.014
		2nd	Norm	443	< 0.022
	6/14/84	1st	Test	432	0.030
		2nd	Norm	464	< 0.011

Table 3. Average charcoal tube results for survey.

Description	Load	Number of Samples	Average EtO Concentration, ppm	Standard Deviation
Sterilizer Operator full-shift	Test	3	< 0.031	0.014
	Norm	3	< 0.020	0.011
Wrapper full-shift	Test	3	< 0.017	0.007
	Norm	3	< 0.014	0.002
In front of Sterilizer full-shift	Test	3	< 0.025	0.014
	Norm	3	< 0.020	0.009
Wrapping Table full-shift	Test	3	< 0.018	0.010
	Norm	3	< 0.018	0.006
Sterilizer Operator load transfer (approx 20 min.)	Test	3	< 0.009	0.007
	Norm	6	< 0.014	0.011
In front of Sterilizer load transfer (approx 20 min.)	Test	3	0.016	0.011
	Norm	6	< 0.020	0.020

Gas Bag Sampling

The results of the samples collected in gas bags and analyzed on site with the portable gas chromatograph are given in Table A-3; selected results, averaged over the 3 days of the survey, are presented in Table 4. All personal samples were less than 3 ppm for periods of approximately 1 minute. Exact collection times were not recorded.

Table 4. Average gas bag results for survey.

Description	Load	Number of Samples	Average EtO Concentration, ppm	Standard Deviation
Sterilizer Operator load transfer (approx 1 min.)	Test	1	0.5	___
	Norm	3	1.83	1.26
In front of Sterilizer load transfer (approx 1 min.)	Test	2	2.5	0.71
	Norm	3	2.33	0.58
Inside sterilizer chamber door first opened following final purge cycle	Test	1	460	___
	Norm	2	550	212

Infrared Analyzer Monitoring

EtO was not detected with the IR analyzer during the purge or the door-cracked periods, only during the load transfer. A typical output curve of the IR analyzer is illustrated in Figure 2. Selected values which characterize the output of the IR analyzer (also shown on Figure 2) are presented in Table A-4. The time of the peak represents the time that the concentration of EtO at the sampling location started to decrease. Since the response of the instrument is slower than the time course of the transient presence of EtO, the more accurate concentration value is the integrated output or concentration-time product, ppm-min, represented by the area under the curve. The actual peak concentration may be as much as 50 percent greater than the measured value.

The average concentration measured with the IR analyzer, averaged over the 3 days of the survey, are presented in Table 5. Two different averages have been calculated: one for the duration of the short-term charcoal tube sample (assuming no additional accumulation of EtO during the balance of the period) and one for just the duration of the IR response peak.

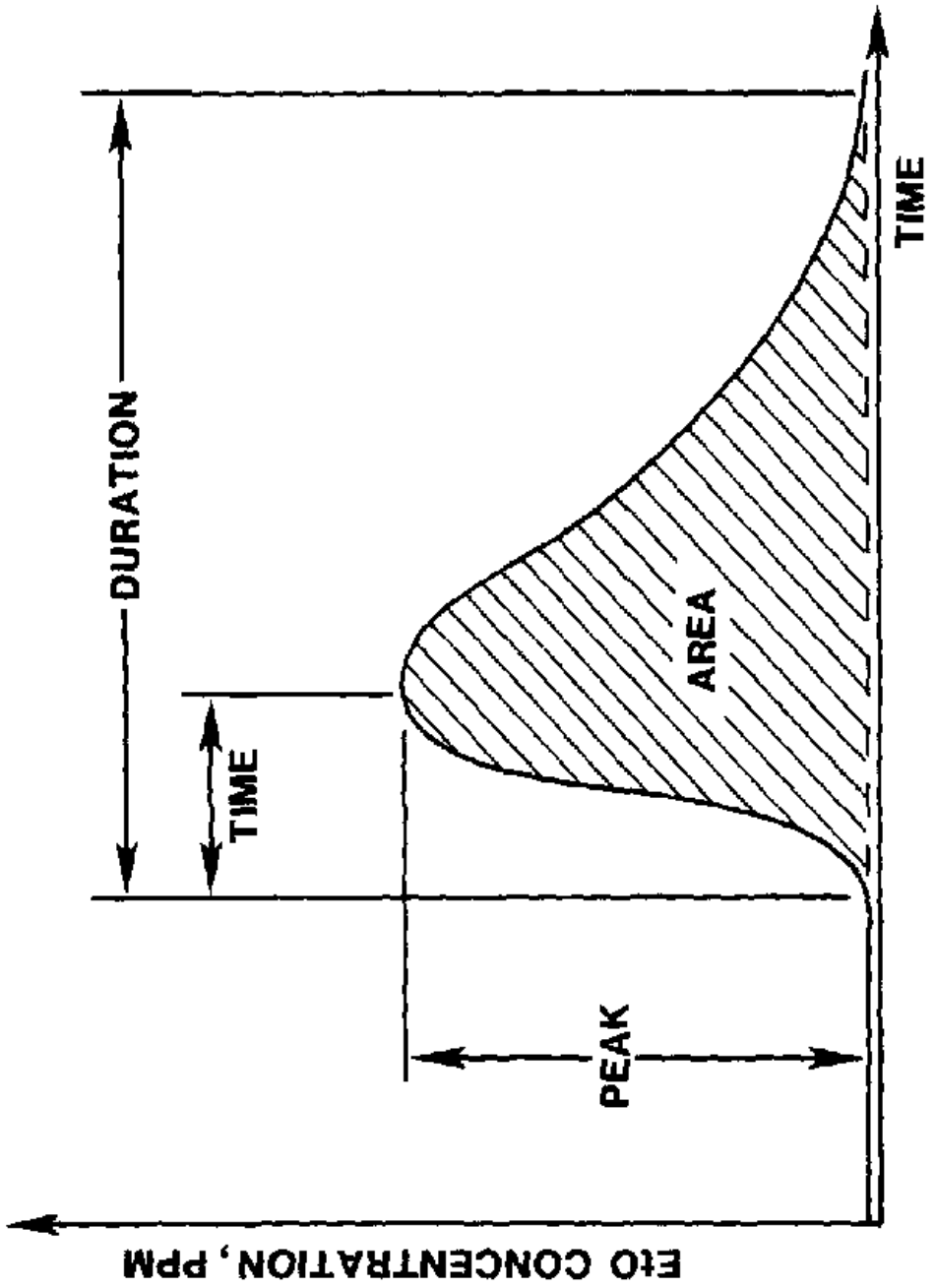

Figure 2. Typical response of infrared analyzer in front of EtO sterilizer during the end-of-cycle activities.

Table 5. Average infrared analyzer results for survey.

Description	Load	Number of Samples	Average EtO Concentration, ppm	Standard Deviation
In front of Sterilizer load transfer (approx 20 min.)	Test	3	0.32	0.22
	Norm	6	0.38	0.12
In front of Sterilizer load transfer (duration of IR response peak)	Test	3	1.72	0.26
	Norm	6	1.81	0.72

VENTILATION MEASUREMENTS

On the first day of the survey, it was noted that air was flowing into the clean room through the doorways and the smoke relief grilles in the ceiling. While discussing this situation with Bethesda Hospital personnel and learning about the operation of the air handler control system, a change was made in the set point of the recirculation controller. This changed condition, which did not noticeably affect the airflow situation, was maintained during the first two days of sampling. By the final day of sampling it had been determined that the best operation condition for this system would be to minimize the air being returned to the air handler from the clean room.. This condition was fully in effect for the second shift on June 14. This final change did not completely remedy the airflow imbalance, but it did substantially reduce the air flowing into the clean room. A summary of the results for these two conditions is shown in Table 6, compared with the design values taken from the ventilation drawings. The full table of ventilation measurement results is appended to this report as Table A-5.

Table 6. Comparison of general ventilation values.

	Values on 6/13/84	Values on 6/14/84
Air supplied to the clean room	1890	1295
Air exhausted from the clean room	2605	960
Percent recirculation of exhausted air	71	6

The renovation plan drawing does not specify values for the vents above the sterilizer and aerators, (exhaust) vents 8 - 13 along the recess room wall in Figure 3. The air volume exhausted through the slot above the EtO sterilizer door was estimated to be 120 cfm, with an average slot velocity of 530 ft/min. Measurements during this survey indicated exhaust rates for the vents in the recess room wall above the bank of sterilizers and aerators ranged from 25 to 60 cfm for the vent furthest to the EtO sterilizer up to between 100 and 130 cfm for the vent closest to the EtO sterilizer, with the higher values corresponding to the minimal recirculation.

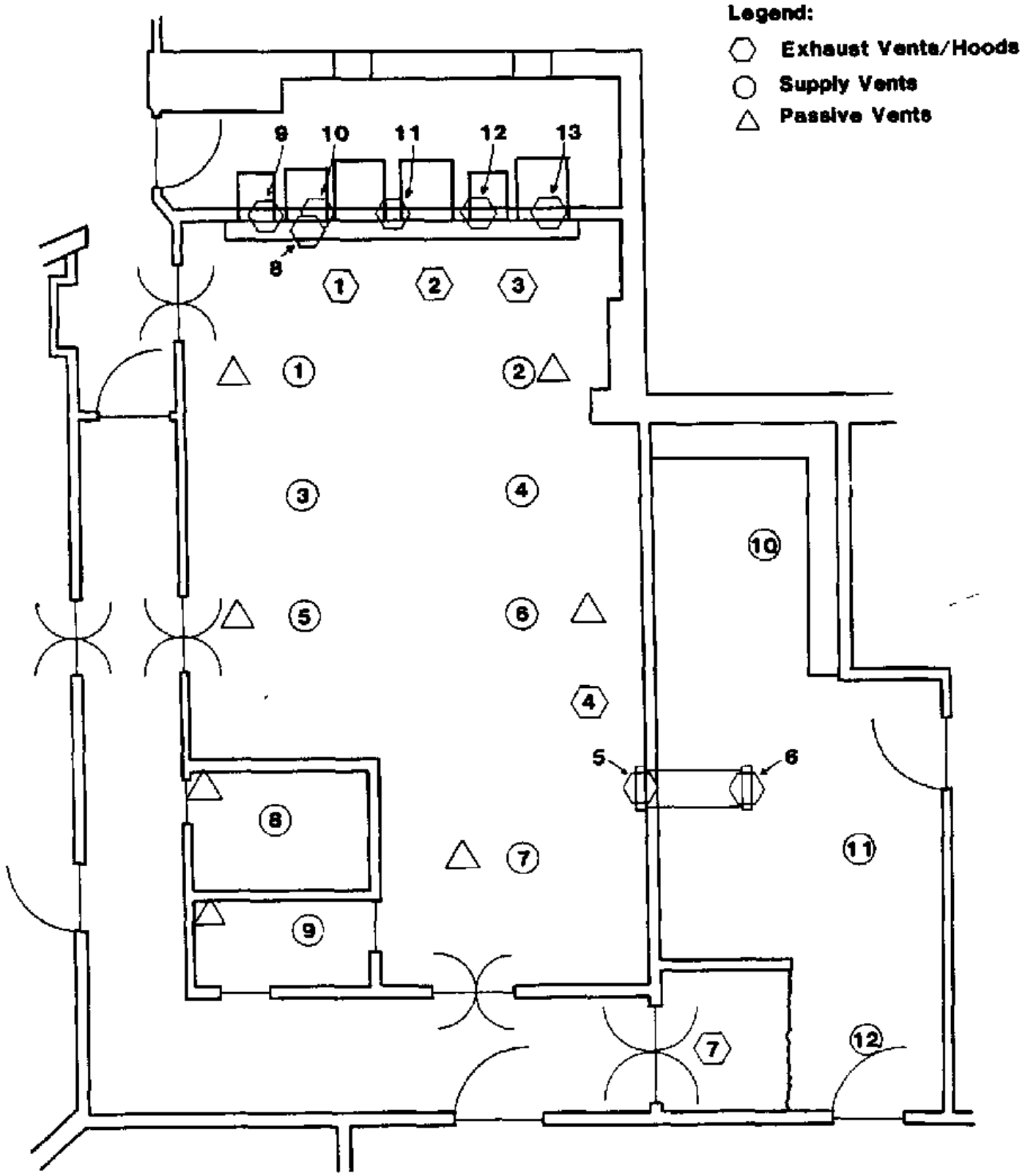

Figure 3. Location of the ventilation inlets and outlets.

CONTROL TECHNOLOGY

At this hospital, 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.

DRAIN CONTROLS

Worker exposure from the drain was controlled primarily by isolating all of the sterilizer except the front panel in a ventilated recess room. Samples collected at the area location in front of the sterilizer door during the evacuation period were less than 0.2 ppm, indicating that the ventilation of the recess room was effective in containing the EtO.

Drain Ventilation

Within the recess room the drain is somewhat controlled by a ventilated air gap, called a liquid/gas separator (LGS). Bag samples collected in the recess room during the evacuation phase of the cycle at breathing zone height were approximately 20 ppm compared to less than 2 ppm near the LGS underneath the sterilizer. Sampling above the open flow drain with an IR analyzer indicated EtO levels around 100 ppm. It seems that EtO was escaping from the open drain and elevating the breathing-zone concentrations in the recess room. The manufacture of the sterilizer recommends that the hospital enclose (seal) the drain when the Envirogard® system is installed.

DOOR CONTROLS

The control of emissions when the sterilizer door is opened involves reducing the quantity of EtO remaining in the chamber, and capturing as much of the air escaping from the sterilizer as possible. 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.

This department follows the work practice of opening the door a few inches at the end of the cycle and leaving the area for 15 minutes before unloading the sterilizer. With this practice, the distance which the door is opened is an important factor in controlling the EtO released along the top edge of the opening.

The slot hood over the sterilizer door provided control when the door was opened only a few inches. Making the airflow visible with a smoke tube showed that when the door was closed, air was captured by the slot hood out as far as 3 inches from the front of the sterilizer. With the hot air rising from the open doorway, this capture distance would be somewhat less, but opening the door an inch or two should be adequate. Much beyond this, air from in front of the sterilizer rises towards the ceiling where it may be exhausted by the vents in the recess room wall or the ceiling exhaust vent in front and slightly to the right of the gas sterilizer.

CONTROLS DURING LOAD TRANSFER

The primary controls are reducing the quantity of EtO remaining in the load and keeping the worker's breathing zone away from areas of high concentrations of EtO. Keeping the load in the sterilizer with vacuum purges and/or air flushes reduces the quantity of EtO in the load. AMSCO has 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.[8] The capture zone of the slot hood is not large enough to control emissions from the load as it is pulled from the chamber to be transferred to the aerator.

The sterilizer operators were trained to pull the load, rather than push it. They performed the load transfer quickly, minimizing the time during which they might be exposed to EtO. The short-term exposures measured were from 0.5 to 3 ppm for just the transfer, which lasted approximately a minute, and less than 0.4 ppm for the entire procedure including the 15-minute waiting period. Short-term concentrations at the area location in front of the sterilizer during the load transfer procedure ranged from 2 to 3 ppm. These data indicate that short-term exposures during the load transfer can be controlled to low levels.

GENERAL VENTILATION

More air is exhausted through the vents in the recess room wall above the sterilizers and aerators when less air is returned to the air handler for recirculation. When approximately 70 percent of the supplied air is recirculated from the clean room, the average flow rate through the recess room wall vents from the clean room is 70 cfm, ranging from 25 to 100 cfm. When only about 6 percent of the air supplied to the department is recirculated from the clean room, the average flow rate is 110 cfm, with individual values ranging from 60 to 120 cfm.

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" increased from four to eight.

For an emergency situation involving the release of a large quantity of EtO, a high rate of nonrecirculated ventilation would be helpful in clearing the room. In this case, increased "room air changes per hour" would be desirable, provided that the air was exhausted directly from the building.

CONCLUSIONS AND RECOMMENDATIONS

Control of the full-shift exposures, as measured with charcoal tubes, is excellent. All values are less than 0.1 ppm, including the area locations. Likewise, short-term exposures are well controlled, not exceeding 5 ppm for the short period (less than 1 minute) during which the load is transferred to the aerator. EtO emissions from the drain during the purge and from the door during the 15-minute waiting period are controlled so as to not create an exposure problem.

Although the exposures to the sterilizer operators are low, it should be possible to reduce them even more by not manually lifting the items from the sterilizer cart into the aerator. This would involve using a second cart and pulling it down to the other aerator. If more than two loads were run in a 12-hour period, it would still be necessary to manually move items into an aerator; however, the results from this survey have shown that this would not overexpose the worker if the transfer was completed within a minute or two and the items were kept at arms' length as much as possible.

EtO levels can get relatively high in the recess room during the purge cycles. Approximately 20 ppm at breathing-zone height was measured using the gas chromatograph and over 100 ppm down near the floor drain was measured with the IR analyzer. This room is clearly an area to be avoided during and for some time after the EtO evacuation cycles. Yet, there is no device to warn people to leave or not to enter the recess room when the EtO levels are high. A monitor which would measure the EtO concentration and signal when it was above preset limits would be best. It may be sufficient to install a light which would come on at or before the start of the first vacuum purge cycle and remain on until such time that the EtO concentration in the room is sure to have returned to a safe level. Any warning device should be located both inside and outside the room to warn those who may already be in the recess room as well as those who may want to enter it. If a monitor is installed, it is recommended that the limits be 3 ppm and 5 ppm, if available.

At the time of the survey, there was no way of knowing if a large quantity of EtO had accidentally been released. Sensors should be installed at the primary workstations in the clean room and/or at the potential major sources of EtO--e.g. the hallway where the supply cylinders are located, the recess room, and in front of the sterilizer. Commercially available sensors with alarm limits of 20 and 50 ppm would be acceptable for this purpose. The alarm should be audible throughout the department, with a visible indicator away from where the high concentrations are expected. An emergency evacuation and response plan should be developed and rehearsed.

Finally, devices should be installed on the ventilation systems exhausting air from the recess room and the Envirogard® system to warn if the systems malfunction. The indicators should be visible to the sterilizer operator in the clean room, and the EtO sterilizer should not be run unless both ventilation systems are fully operational.

To insure the continued quality and effectiveness of the engineering controls, personal exposure monitoring should be continued. At a minimum, the

sterilizer operator should be monitored for a full shift at least once per year. Additional monitoring would be desirable and may be required by the OSHA standard.

To protect the maintenance worker changing the EtO supply cylinders, face shields and gloves should be required for protection in case of an accident. Respirators should be available to handle emergency situations and may be desirable for routine cylinder changes. 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 (SCBA) with full facepiece.[9]

REFERENCES

1. Federal Register, Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910: Occupational Exposure to Ethylene Oxide. 49(122):25675-25676, June 14, 1984.

2. Preliminary Survey Report, Control Technology for Engineering Controls in Hospitals, Bethesda Hospital, Cincinnati, Ohio., August 13, 1983. NIOSH Report CT/143.18A.

3. Patty's Industrial Hygiene and Toxicology. Vol. II. Fasset, D.W., Irish, D.D. eds. New York: John Wiley and Sons; 1963: pp. 1629-1630.

4. Lynch, D.W. et al. Effects on Monkeys and Rats of Long-Term Inhalation Exposure to Ethylene Oxide: Major Findings of the NIOSH Study. Inhospital Ethylene Oxide Sterilization: Current Issues in EO Toxicity and Occupational Exposure. AAMI Technology Assessment Report, No. 8-84, 1984.

5. Landrigan, P.J.; Meinhart, T.J.; Gordon, J.; Lipscomb, J.A.; Lewis, T.R.; Leman, R.A. Ethylene Oxide: An Overview of Toxicologic and Epidemiologic Research. Am. J. Industrial Med. Vol. 6; 1984: pp. 103-116.

6. Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment with Intended Changes for 1983-84. American Conference of Governmental Industrial Hygienists, 1983.

7. NIOSH Policy Statement, Recommended Exposure Levels for Ethylene Oxide. DHHS, CDC, NIOSH, June 27, 1984.

8. Barron, W. R.; Gunther, D. A., Durnick, T. J.; and Young, J. H. Sterilizer Modifications to Minimize Environmental Ethylene Oxide. American Sterilizer Company, Erie, PA, Pub. No. DB-3005; 1981: p. 7.

9. Ronk, R., White, M. K., Linn, H. Personal Protective Equipment for Hazardous Materials Incidents: A Selection Guide. Morgantown, WV: U.S. Dept. of Health and Human Services, NIOSH Pub. No. 84-114; 1984: pp. 47-50, 71, 73-75, 85.

Appendix. Survey Data

SURVEY. Bethesda Hospital, Cincinnati, Ohio. June 12-14, 1984.

Table A-1. Equipment used on field survey.

Item	Model	Used for
Infrared spectrometer	Miran 1A	continuous area sampling
Infrared spectrometer	Miran 103	selected area sampling
RH and Temp. Monitor	General Eastern 400-C/D	RH and temperature
Strip chart recorder	Varian 9176	record of continuous EtO conc. and RH
Computer	Apple *II*-plus	correction and storage of EtO, RH, and temp data
Printer	Prism 132	print EtO and RH data
Hot-wire anemometer	Kurz 441	air velocity
Velometer Flow Hood	Alnor Balometer	airflow
Gas Chromatograph	Photovac 10A10	analysis of bag samples
Personal sampling pump	MDA 808	personal and area TWA smpl
Personal sampling pump	DuPont P-4000	collection of bag samples
Smoke tubes	Draeger 4351	airflow patterns

Table A-2. Charcoal tube sample results.

SURVEY: Bethesda Hospital, Cincinnati, Ohio. June 12-14, 1984.

SAMPLE DESCRIPTION	TERM	DAY	SHIFT	SAMPLE NO.	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Operator	Long	6/12	1st	140	303	5.309	0.34	0.036	10.8
Sterilizer Operator	Long	6/12	1st	64	106	1.869	0.21	0.062	6.6
Sterilizer Operator	Long	6/12	2nd	131	226	5.086	0.32	0.035	7.9
Sterilizer Operator	Long	6/12	2nd	139	205	4.686	0.24	0.028	5.8
Sterilizer Operator	Long	6/13	1st	91	293	5.074	< 0.10	< 0.011	< 3.2
Sterilizer Operator	Long	6/13	1st	97	126	2.203	< 0.10	< 0.025	< 3.2
Sterilizer Operator	Long	6/13	2nd	69	170	3.757	0.10	0.015	2.5
Sterilizer Operator	Long	6/13	2nd	149	231	5.036	0.16	0.018	4.1
Sterilizer Operator	Long	6/14	1st	123	303	5.257	0.30	0.032	9.6
Sterilizer Operator	Long	6/14	1st	72	81	1.362	< 0.10	< 0.041	< 3.3
Sterilizer Operator	Long	6/14	2nd	129	276	5.903	< 0.10	< 0.009	< 2.6
Sterilizer Operator	Long	6/14	2nd	78	212	4.471	0.13	0.016	3.4
Wrapper	Long	6/12	1st	108	249	5.327	< 0.10	< 0.010	< 2.6
Wrapper	Long	6/12	1st	146	139	2.971	< 0.10	< 0.019	< 2.6
Wrapper	Long	6/12	2nd	87	212	4.431	< 0.10	< 0.013	< 2.7
Wrapper	Long	6/12	2nd	88	178	3.757	< 0.10	< 0.015	< 2.6
Wrapper	Long	6/13	1st	65	156	3.111	0.25	0.045	7.0
Wrapper	Long	6/13	1st	138	239	4.761	< 0.10	< 0.012	< 2.8
Wrapper	Long	6/13	2nd	115	135	2.895	< 0.10	< 0.019	< 2.6
Wrapper	Long	6/13	2nd	156	200	4.214	< 0.10	< 0.013	< 2.6
Wrapper	Long	6/14	1st	137	258	4.777	< 0.10	< 0.012	< 3.0
Wrapper	Long	6/14	1st	126	163	2.951	< 0.10	< 0.019	< 3.1
Wrapper	Long	6/14	2nd	70	246	5.002	< 0.10	< 0.011	< 2.7
Wrapper	Long	6/14	2nd	119	185	3.678	< 0.10	< 0.015	< 2.8
Sterilizer Operator	Short	6/12	1st	75	23	1.074	< 0.10	< 0.052	< 1.2
Sterilizer Operator	Short	6/12	2nd	90	20	0.983	< 0.10	< 0.056	< 1.1
Sterilizer Operator	Short	6/12	2nd	93	18	0.839	0.20	0.132	2.4
Sterilizer Operator	Short	6/13	1st	124	21	1.082	< 0.10	< 0.051	< 1.1
Sterilizer Operator	Short	6/13	2nd	145	5	0.279	< 0.10	< 0.199	< 1.0
Sterilizer Operator	Short	6/13	2nd	114	18	0.904	< 0.10	< 0.061	< 1.1
Sterilizer Operator	Short	6/14	1st	159	29	1.461	0.44	0.167	4.8
Sterilizer Operator	Short	6/14	2nd	147	20	1.020	< 0.10	< 0.054	< 1.1
Sterilizer Operator	Short	6/14	2nd	120	15	0.760	0.46	0.336	5.0
Above Sterilizer Door	Long	6/12	1st	103	135	2.920	< 0.10	< 0.019	< 2.6
Above Sterilizer Door	Long	6/12	1st	92	190	3.995	< 0.10	< 0.014	< 2.6
Above Sterilizer Door	Long	6/12	2nd	80	266	5.734	0.38	0.037	9.8
Above Sterilizer Door	Long	6/12	2nd	136	211	4.528	0.19	0.023	4.9
Above Sterilizer Door	Long	6/13	1st	122	294	5.511	0.15	0.015	4.4
Above Sterilizer Door	Long	6/13	1st	148	116	2.164	< 0.10	< 0.026	< 3.0
Above Sterilizer Door	Long	6/13	2nd	107	245	5.366	0.11	0.011	2.8
Above Sterilizer Door	Long	6/13	2nd	160	230	5.041	0.19	0.021	4.8

Table A-2. Charcoal tube sample results (continued).

SAMPLE DESCRIPTION	TERM	DAY	SHIFT	SAMPLE NO.	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Above Sterilizer Door	Long	6/14	1st	125	306	6.148	0.16	0.014	4.4
Above Sterilizer Door	Long	6/14	1st	134	178	3.673	0.58	0.088	15.6
Above Sterilizer Door	Long	6/14	2nd	158	274	6.040	0.18	0.017	4.5
Above Sterilizer Door	Long	6/14	2nd	135	209	4.687	< 0.10	< 0.012	< 2.5
Wrap Table	Long	6/12	1st	71	261	5.927	< 0.10	< 0.009	< 2.4
Wrap Table	Long	6/12	1st	121	171	3.881	0.10	0.014	2.4
Wrap Table	Long	6/12	2nd	86	234	5.130	< 0.10	< 0.011	< 2.5
Wrap Table	Long	6/12	2nd	99	196	4.249	0.26	0.034	6.7
Wrap Table	Long	6/13	1st	152	239	5.271	< 0.10	< 0.011	< 2.5
Wrap Table	Long	6/13	1st	162	155	3.350	0.12	0.020	3.1
Wrap Table	Long	6/13	2nd	130	246	5.026	0.26	0.029	7.1
Wrap Table	Long	6/13	2nd	155	197	3.997	< 0.10	< 0.014	< 2.7
Wrap Table	Long	6/14	1st	151	258	5.627	0.35	0.035	8.9
Wrap Table	Long	6/14	1st	110	174	3.779	0.15	0.022	3.8
Wrap Table	Long	6/14	2nd	161	280	6.152	< 0.10	< 0.009	< 2.5
Wrap Table	Long	6/14	2nd	157	184	3.995	< 0.10	< 0.014	< 2.6
Above Sterilizer Door	Short	6/12	1st	59	22	1.069	0.24	0.125	2.7
Above Sterilizer Door	Short	6/12	2nd	74	22	1.012	< 0.10	< 0.055	< 1.2
Above Sterilizer Door	Short	6/12	2nd	81	14	0.683	0.57	0.463	6.5
Above Sterilizer Door	Short	6/13	1st	102	20	1.093	0.15	0.076	1.5
Above Sterilizer Door	Short	6/13	2nd	77*	0	0.000	0	< 0.000	< 0.0
Above Sterilizer Door	Short	6/13	2nd	62	19	0.999	0.14	0.078	1.5
Above Sterilizer Door	Short	6/14	1st	150	29	1.382	0.72	0.289	8.4
Above Sterilizer Door	Short	6/14	2nd	142	22	1.176	< 0.10	< 0.047	< 1.0
Above Sterilizer Door	Short	6/14	2nd	144	14	0.752	0.48	0.354	5.0

* Problem with sample; resulting concentration not representative of a full-shift time-weighted average.

Table A-3. Samples analyzed by gas chromatography.

SURVEY: Bethesda Hospital, Cincinnati, Ohio. June 12-14, 1984.

Description of Sample	Shift	Load	Concentration ppm
Samples on 6/12/84			
Along top edge of open sterilizer door after opening	A	test	30.0
From drain in hall behind recess room	A	test	1.0
At sterilizer area sample location during unloading	A	test	2.0
Behind steam sterilizer in recess room between loads	A	none	0.5
Above EtO sterilizer in recess room during sterilization	B	N1	0.1
Above EtO sterilizer in recess room during purge	B	N1	20.0
At sterilizer area sample location during purge	B	N1	0.2
Along top edge of open sterilizer door after opening	B	N1	60.0
At sterilizer area sample location during unloading	B	N1	2.0
At sterilizer area sample location 5 min. after opening	B	N2	0.6
At sterilizer area sample location during purge	B	N2	<0.1
Above EtO sterilizer in recess room during purge	B	N2	20.0
Samples on 6/13/84			
Above items removed from aerator after 12 hr. aeration	A	N1+2	0.7
Along top edge of open sterilizer door after opening	A	test	60.0
Operator's breathing zone during unloading	B	N1	0.5
At sterilizer area sample location during unloading	B	N1	2.0
Along top edge of open sterilizer door after opening	B	N1	10.0
Inside sterilizer after opening	B	N1	10.0
Samples on 6/14/84			
Above Envirogard® drain in recess room during purge	A	test	2.0
Inside sterilizer after opening	A	test	460.0
At sterilizer area sample location during unloading	A	test	3.0
Operator's breathing zone during unloading	A	test	0.5
Inside sterilizer after opening	B	N1	700.0
Operator's breathing zone during unloading	B	N1	3.0
Operator's breathing zone during opening BI pack	B	N1	2.0
Inside sterilizer after opening	B	N2	400.0
Operator's breathing zone during unloading	B	N2	2.0
At sterilizer area sample location during unloading	B	N2	3.0
Operator's breathing zone during opening BI pack	B	N2	1.0

Table A-4. Infrared results.

SURVEY: Bethesda Hospital, Cincinnati, Ohio. June 12-14, 1984.

Date mo/dy/yr	Shift	Load	Peak ppm	Time min	Duration min	Area ppm-min
06/12/84	A	test	5	0.5	2.7	5.2
	B	1	3.3	1	3.7	6.1
	B	2	2.5	2	3.2	5.2
06/13/84	A	test	2.5	0.5	2.1	3.0
	B	1	5	1.5	4.3	8.8
	B	2	2	1.3	3.2	4.3
06/13/84	A	test	4	1.5	9.1	16.5
	B	1	9	1.3	3.7	11.6
	B	2	2	1	4.8	5.2

Table A-5. Ventilation measurements.

SURVEY: Bethesda Hospital, Cincinnati, Ohio. June 12-14, 1984.

	Design values	Values on 06/13/84	Values on 06/14/84
		Supply Vents	
1.	330	280	190
2.	330	300	205
3.	330	280	185
4.	330	270	190
5.	330	250	170
6.	330	260	180
7.	330	250	175
8.	200	210	160 *
9.	140	230	175
10.	250	190	175 *
11.	350	100	90 *
12.	150	160	150 *
		Exhaust Vents	
1.	570	200	10
2.	570	800	45
3.	570	350	25
4.	600	620	40
5.	415	160 *	160
6.	415	**	**
7.	670	480	**
8.	***	120 *	120
9.	***	100	130
10.	***	90	130
11.	***	60	120
12.	***	80	120
13.	***	25	60

* Value estimated from other measurements.

** Not measured.

*** Not specified on drawing (No. 403, April 24, 1979).