IN-DEPTH SURVEY REPORT

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

SHRINERS HOSPITALS FOR CRIPPLED CHILDREN
BURNS INSTITUTE - CINCINNATI UNIT
CINCINNATI, OHIO

REPORT WRITTEN BY
Sharon L Kercher

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
Division of Physical Sciences and Engineering
Engineering Control Technology Branch
4676 Columbia Parkway
Cincinnati, Ohio 45226

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HOSPITAL SURVEYED	Shriners Hospitals for Crippled Children Burns Institute - Cincinnati Unit 202 Goodman Avenue Cincinnati, Ohio 45219
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SURVEY DATE	March 18-22, 1985
SURVEY CONDUCTED BY	Sharon L Kercher Vincent D Mortimer, Jr.
EMPLOYER REPRESENTATIVES CONTACTED	Ronald Hitzler, Administrator Steve Goetz, Director, Materials Management Darlene Hardwick, R N , Supervisor, Supply, Processing and Distribution Matthew Maley, Manager, Environmental Control
EMPLOYEE REPRESENTATIVES CONTACTED	No Employee Organization
ANALYTICAL WORK PERFORMED BY	Utah Biomedical Testing Laboratory Salt Lake City, Utah

I INTRODUCTION

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 or 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 CONTROL TECHNOLOGY STUDIES

The present Control Technology Assessment of Ethylene Oxide Sterilization in Hospitals is the result of the research recommendations of the 1983 Feasibility Study of Engineering Controls in Hospitals. 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

Shriners Burns Institute expressed an interest in participating in the study and supplied information about the Supply, Processing, and Distribution (SPD) Department to NIOSH Based on this information, it was determined that the hospital might fulfill the requirements of a sterilizer system using 12/88 EtO/Freon mixture with extra evacuation phases at the end of the sterilizer cycle and local exhaust ventilation above the sterilizer door, and with in-chamber aeration

A preliminary survey was conducted in the Processing Department on January 15, 1985. Findings of this survey indicated the Processing Department had instituted engineering control technology for minimizing employee exposure to EtO and had developed a comprehensive program to protect its employees Local exhaust ventilation had been provided in critical areas. The sterilizer had a continuous fresh air purge phase following completion of the cycle and in-chamber aeration The sterilizer was recessed in a small room with dedicated ventilation. Proper work practices for employees were clearly outlined in a procedure and policy manual, and based on observation of the removal of a load from the sterilizer, the operator followed those procedures An in-service program had been given to the department by the sterilizer manufacturer after installation of the equipment in June 1984, providing information on operation of the new sterilizer and on the hazards and safe use of EtO. In addition, the hospital staff were very conscientious about EtO control and had made every effort to 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 Processing Department of Shriners Burns Institute was conducted on March 18-22, 1985 to evaluate its operations and associated controls for EtO exposure. This report documents the information pertinent to that evaluation

POTENTIAL HAZARDS, EXPOSURE GUIDELINES, AND EXPOSURE SOURCES

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 after prolonged contact, and allergic sensitization can also occur in some individuals [2]

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 mononuclear cell leukemia, peritoneal mesotheliomas, and cerebral gliomas Adverse reproductive effects were also observed [3]

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 [4]

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 [4]

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 [1] The American Conference of Governmental Industrial Hygienists has also adopted 1 ppm as an 8-hour time-weighted average Threshold Limit Value (TLV); however, they have 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 [5] In its testimony to OSHA on the new standard, NIOSH recommended that a ceiling limit of 5 ppm not be achieved 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.[6]

PRIMARY EXPOSURE SOURCES

Hospital central service personnel may be exposed to EtO from several sources. Each source contributes to the ambient concentration of EtO, however, two 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.

Removing the Sterile Load from the Chamber

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 This source is particularly important for loads which are transferred to an aerator For systems using in-chamber aeration, this potential exposure source is virtually eliminated although some EtO may still be in the sterilizer chamber at the end of the aeration cycle This air may also be drawn out of the chamber as the operator pulls the load from the chamber

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 exhaust is not vented out of the building or to a dedicated exhaust, it can become a major contributor to the background EtO levels.

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 liquid or gaseous EtO in the supply lines Depending on the location and ventilation around the cylinders, the release of this trapped EtO may contribute to background EtO concentration for the sterilizer operator and other workers

If the contents of an EtO cylinder were accidentally discharged, a large quantity of EtO would be released This could result in dangerous concentrations in the vicinity of the cylinders and in the surrounding work area

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 controlled or remotely vented, this release may contribute a significant quantity of EtO to the workplace atmosphere

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 during or following a purge cycle

HOSPITAL AND PROCESS DESCRIPTION

HOSPITAL AND PROCESSING DEPARTMENT DESCRIPTION

Shriners Burns Institute is a not-for-profit, private hospital with a 30-bed capacity, specializing in the treatment of burned and crippled children The hospital is a four-storied structure, with surgery, patient rooms, and the Processing Department located on the third floor

The Processing Department occupies three rooms: a decontamination and solutions storage room, a supply room/office; and the processing/sterilizing room, hereafter referred to as the clean room The hospital's two surgical suites are adjacent to the clean room and surgery personnel occupy one end of the clean room to process and supply surgical needs.

The layout of the Processing Department is diagrammed in Figure 1. One end of the room, occupied by surgery, contains a pass-through washer/sterilizer, ultrasonic cleaning equipment, and a steam sterilizer Items are supplied to one surgical suite through a pass-through window and are carried to an open door into the other suite Four to eight surgery personnel may be in the room at various times during the day shift

Evaluation of the clean room was focused on the area occupied by Processing Department personnel This end of the room contains storage cabinets, a work table, a steam sterilizer, and an EtO sterilizer The sterilizers are recessed into one wall of the clean room, isolating all but the front panels of the units in a separate, ventilated recess room

The Processing Department employs two workers and one supervisor on the day shift (0630 to 1500) The department is not staffed during the evening and night shifts One person from the Housekeeping Department cleans during the evening shift.

EQUIPMENT AND PHYSICAL DESCRIPTION

The EtO gas sterilizer is an Eagle Series, model 2027, manufactured by The American Sterilizer Company (AMSCO) Its internal chamber size is 20 inches by 20 inches by 38 inches, approximately 9 cubic feet

The EtO sterilizer is supplied with gas from a cylinder containing a mixture of EtO and Freon 12 in a 12:88 ratio by weight Two cylinders, connected in a dual-load system with the sterilizer, are located in the recess room The dual-load system automatically switches to a full cylinder should a cylinder empty during the cycle This allows the cycle to continue without interruption Access to the recess room is restricted The door is locked, and the key is kept by the supervisor The Maintenance Department has a key, but must notify the supervisor before entering the room.

Sterilizer Cycle Features

The cycle, which is about 3 1/2 hours in duration (at 130°F) consists of several phases· initial vacuum and humidification, about 1 hour, EtO charging

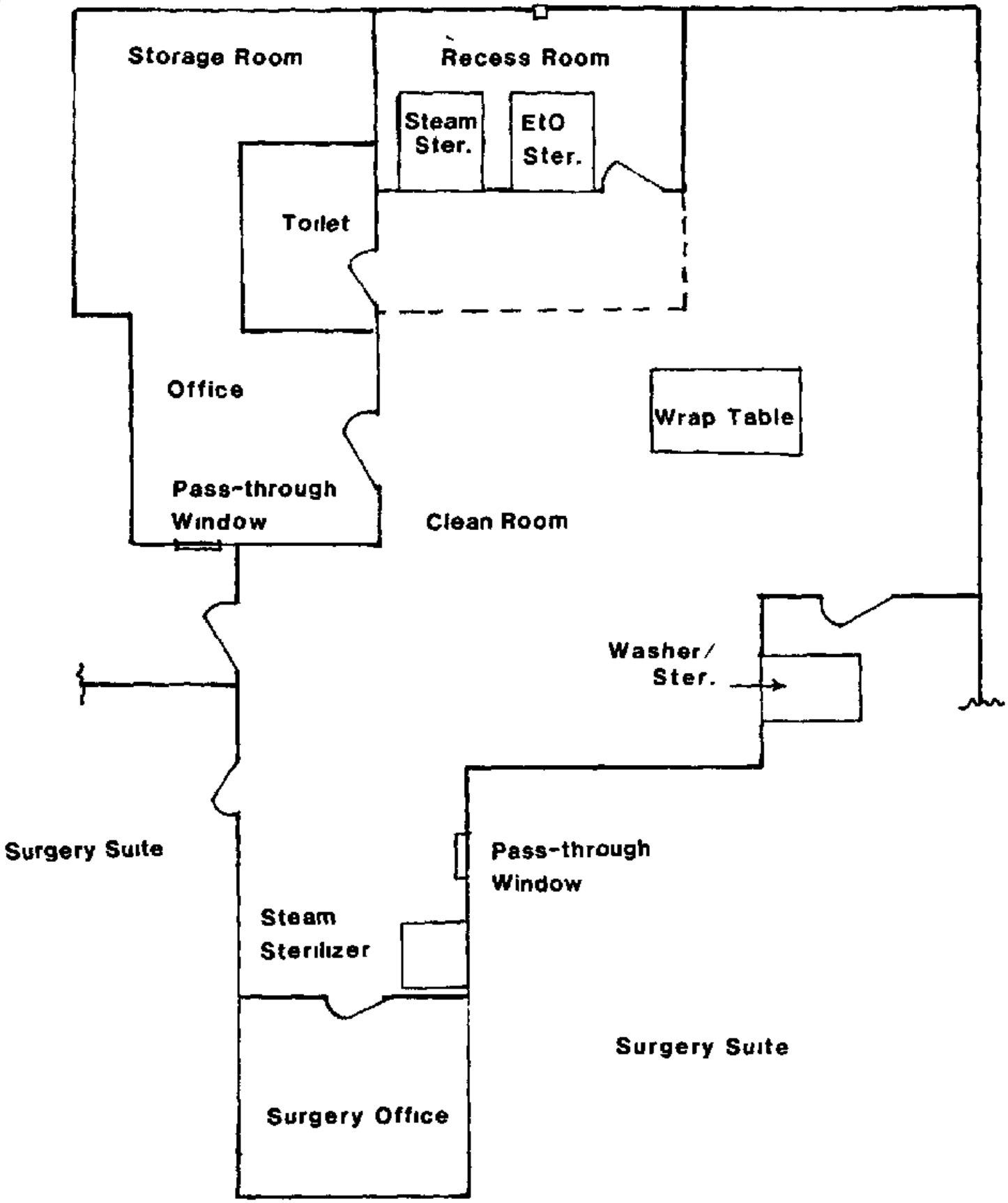

Figure 1. Processing Department, Shriners Burns Institute, Cincinnati, Ohio.

and sterilization, about 1 hour and 45 minutes; two vacuum purges, about 25 minutes; and a dynamic air flush; about 20 minutes This hospital always uses the in-chamber aeration feature Following the 20 minute air flush, another vacuum is pulled. The chamber is brought up to almost atmospheric pressure with an air flush for about 50 minutes, then another vacuum is pulled This alternating air flush/vacuum phase repeats once per hour for a minimum of 12 hours A buzzer signals the aeration cycle is complete and the load may be pulled. Without operator intervention, the aeration cycle will continue until the door is opened. During the survey, the sterilizer was operated at 130°F. The sterilizer/aerator may also operate at 100°F for loads which are particularly heat-sensitive

Local Exhaust Ventilation

The sterilizer is equipped with an exhaust system, Envirogard®, supplied by the manufacturer The system includes the ventilation of a slot hood measuring 5/8 inches by 24 inches located 2 inches above the sterilizer door Two, 2-inch diameter flexible ducts connect the hood to a fan rated at 500 cfm The air is exhausted directly to the outside through a flexible duct to a wall fan in the recess room

Local exhaust ventilation is also provided for the ventilated air gap, called a liquid/gas separator (LGS), attached to the sterilizer vacuum pump and a sealed floor drain as part of the Envirogard® system The LGS serves as an enclosing hood surrounding the drain airbreak except for two openings measuring approximately 2 by 2 1/2 inches The LGS is connected by 2-inch diameter flexible ducting to the same fan which provides the exhaust for the slot hood over the sterilizer door

A 2-inch diameter flexible duct, connected to the same Envirogard® fan, has been located over the EtO cylinder valve connections This duct is capped except during cylinder changes

The Envirogard® fan is manually operated by a switch located under the sterilizer behind the lower front panel The operator activates the Envirogard® system when the sterilizer is loaded and turns off the system after the load is aerated and removed from the chamber The system is also activated during cylinder change operations

General Ventilation

The department is supplied with air from an intake on the east side of the building Air is exhausted directly outside in this "once through" system In the clean room and adjacent areas, there are a total of seven supply diffusers and four exhaust vents, refer to Figure 2 One of the exhaust vents is located in the ceiling between the steam sterilizer and the EtO sterilizer A 2-foot plastic ceiling baffle surrounds the sterilizer area, 4 1/2 feet out from the sterilizers and 11 1/2 feet along the recess room wall

The recess room is exhausted to the outside by a fan in the west wall A sail-switch is located on the positive side of the fan Vents for the general ventilation system in the room have been sealed off. A passive air intake

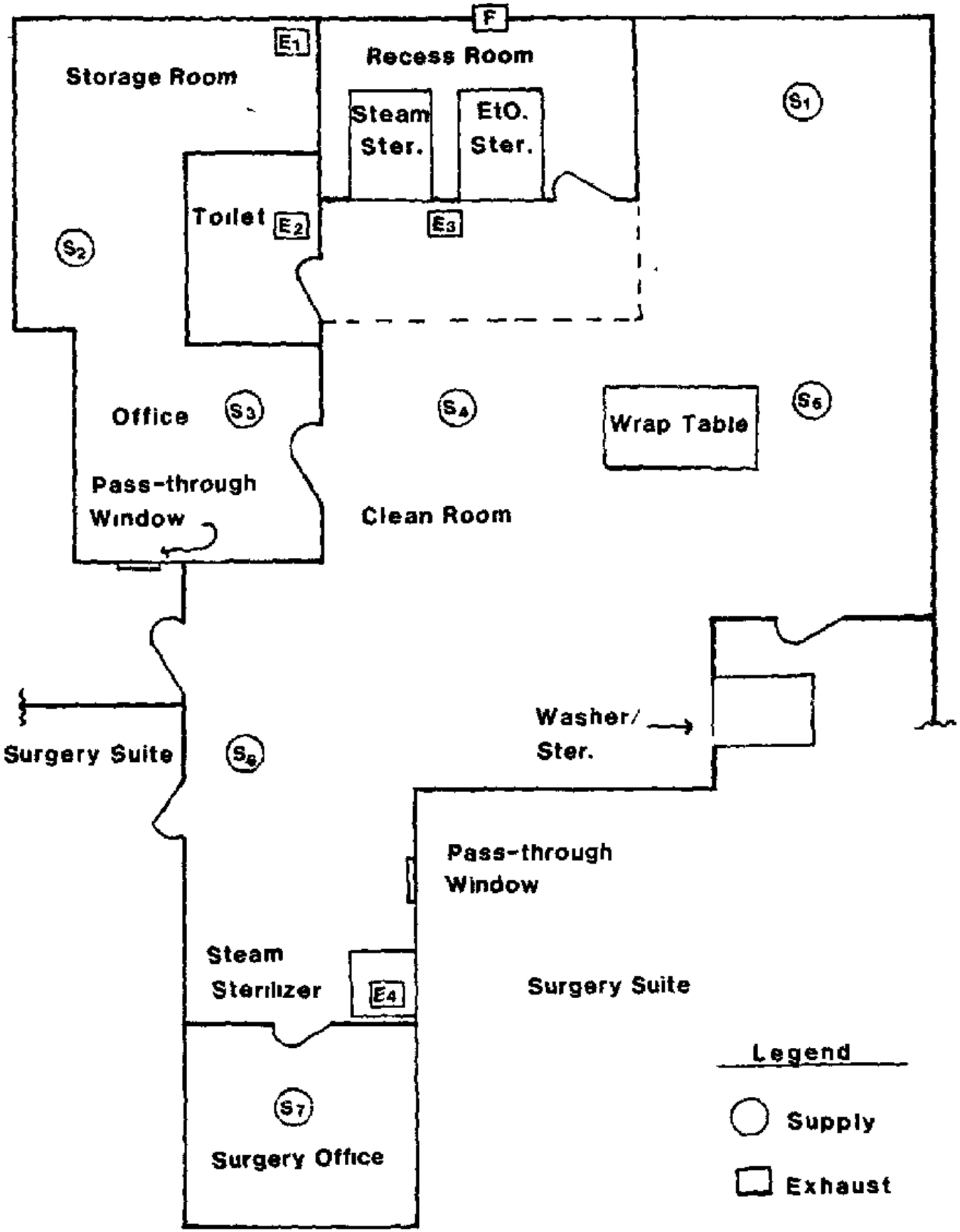

Figure 2 Location of the ventilation inlets and outlets

duct for the recess room passes through the north wall of the recess room through a corner of the clean room and to the outside through the west wall A positive pressure in the recess room relative to the outdoors prevents outside air from entering through the duct, thus make-up air for the room is supplied from the clean room through cracks under the recess room door and around the sterilizers.

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 chamber is cart-loaded with items for gas sterilization The chamber door is closed and the operator begins the cycle

The department usually processes one EtO load per day during the evening shift The cycle is started about 1430 and the employees leave at 1500 The sterilizer is set to automatically process the load through the aeration cycle. Items are removed from the chamber the following morning (about 0630) by the operator Chemical and biological indicators are removed from the load The sterile, aerated items are then labeled and prepared for picked-up by the using department

Replacing and EtO Supply Cylinder

The EtO cylinders are connected in a dual-load system so that an empty cylinder encountered during the sterilizer charge phase will automatically switch to the full cylinder A "Low Gas" indicator light and tape readout alert the operator to the condition, and the cycle continues uninterrupted

The operator calls maintenance for replacement of the empty cylinder Maintenance personnel bring the new cylinder to the recess room and check that the Envirogard® system is operating before entering the recess room The flexible duct over the cylinder valve is uncapped and positioned over the cylinder valve which is to be disconnected The cylinder valve is closed and the ball-type, shut-off valve is closed. The connector is cracked open to purge the line, and the maintenance person leaves the recess room for 3 to 4 minutes Upon returning to the room, the connector is opened fully and again the person leaves the room for 2 to 3 minutes The new cylinder is brought into the recess room and connected to the supply line hose The empty cylinder is removed Finally, the shut-off valve and the cylinder valve are opened The connections are leak-tested using a halogen detector The flexible ventilation duct is capped, the "Changeover Complete" button is pressed, and the person leaves the room A cylinder change is required about once each month

Preventative Maintenance

The Processing Department has a preventive maintenance contract with AMSCO for routine evaluations every 2 months The maintenance protocol specifies the evaluation of the EtO sterilizer for mechanical function and leak testing The service person also inspects the sterilizer door gasket and replaces it as

needed Air lines and water lines are checked Any necessary repairs are made immediately. AMSCO service personnel perform maintenance functions for the sterilizer

Education and Monitoring

An in-service on the operation and safe use of EtO was provided to the department by AMSCO in June 1984 after the new equipment was installed The department supervisor provides an in-service on EtO every six months One of the employees attended a seminar on EtO sponsored by the Society of Hospital Central Service Personnel. An in-service was also provided for the surgical staff sharing the clean room with the Processing Department

The maintenance personnel were provided with an in-service by AMSCO after the installation of the new equipment The Maintenance Department supervisor has a written policy on handling EtO and changing the cylinders. Training is provided for the department

Monitoring has been performed for the department on one occasion by GMA prior to the purchase of the Eagle sterilizer The department is interested in developing a routine monitoring program

METHODOLOGY

To evaluate the effectiveness of the engineering control measures, both short- and long-term concentrations of ethylene oxide were determined and ventilation parameters (mainly air velocity and volumetric flowrate) were measured The major pieces of equipment used in this evaluation are listed in Table I of the Appendix

MEASUREMENT OF CONTROL PARAMETERS

Charcoal Tube Sampling

To determine personal exposures and average concentrations of EtO at selected locations in the clean room, personal and area samples were collected using coconut shell charcoal tubes according to NIOSH Method 1607. The samples were collected on 400 mg and 200 mg charcoal tubes (SKC#226-37) connected in series, and the sampling train was contained in a plastic holder MDA pumps with limiting orifices rated at approximately 10 milliliters of air per minute (mL/min) and 20 mL/min were used to collect duplicate samples for the sterilizer operator and the area over the sterilizer door for long-term (8-hour) samples, and with limiting orifices rated at approximately 100 mL/min to collect duplicate samples for the same personal and area locations during the load removal procedure (short-term, 1-2 minutes) MDA pumps (limiting orifices rated at approximately 20 mL/min) were used to collect long-term samples for an instrument wrapper and the wrapping area location The day shift was sampled for three days

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

Short-term samples provided an estimate of the peak concentrations of EtO released when the sterile/aerated load was removed from the chamber Samples were collected both for the sterilizer operator and at the area sampling location in front of the sterilizer from the time the operator opened the sterilizer door to the time when the operator started to label the sterile items

Gas Bag Sampling

DuPont pumps were used to collect air samples in Tedlar® gas sampling bags (SKC #231) A short-term area sample over the sterilizer door was collected for 2-3 minutes during the unloading procedure A 1-2 minute sample was collected for the sterilizer operator while removing the sterile/aerated load from the sterilizer To estimate the effectiveness of the air flush phase in reducing the amount of EtO left in the chamber at the end of the aeration

cycle, a sample was collected in the sterilizer chamber when the door was opened for unloading These samples were collected for 15 seconds each Air bag samples were also collected during the vacuum purge phase at several locations around the drain in the recess room for 30 seconds each All air bag samples were analyzed on-site with a portable gas chromatograph

Infrared Analyzer Monitoring

Due to the cyclic nature of EtO release during the day, it was desirable to have a continuous record of the estimated EtO concentrations in the breathing zone in front of the sterilizer The sampling probe of the IR analyzer was located over the sterilizer door at the same location as the charcoal tube samples On March 20-21, the sampling probe was moved to a location near the sterilizer drain in the recess room for the vacuum purge phase The continuous monitor provided a measure of the background EtO levels in the clean room as well as indicating higher concentrations which could be associated with certain events (such as the sterilizer vacuum purge).

Peak concentrations may not be accurately measured with an infrared (IR) analyzer The sensing cell of the instrument has a volume of about 5 liters and the sampling pump a flowrate of 5 L/min This results in an instrument response time of approximately 3-5 minutes Thus, short concentration peaks may be underestimated by the IR analyzer.

Laboratory experiments showed the instrument responded to a known concentration of EtO and humidity by indicating a higher concentration reading than the EtO level which was present The sensitivity of the response at the 3 3 um wavelength was approximately 3 ppm EtO for a 10 percent rise in relative humidity To compensate for this effect, the IR analyzer was connected in series with a hygrothermograph These instruments were attached to a strip chart recorder to provide a continuous graphic record of changing humidity levels and EtO concentrations This arrangement allowed differentiation of the response of the infrared analyzer to EtO from relative humidity

Sampling for the Cylinder Change Operation

On March 21, an EtO cylinder emptied during the charge phase of the sterilizer cycle The dual-load system did not automatically switch to a full cylinder due to a closed supply line valve necessitating an immediate cylinder change operation During this activity, the maintenance person was sampled with charcoal tubes using the procedure previously described (duplicate samples at approximately 100 mL/min for 8 minutes), and an air bag sample was collected in the personal breathing zone The area over the EtO cylinders in the recess room was sampled with charcoal tubes (duplicate samples at a nominal rate of 100 mL/min for 8 minutes) An air bag sample was collected in the same location, and the IR sampling probe was moved to the area over the cylinders

Air Flow Assessment

The air flow velocities were measured for the slot hood above the sterilizer door using a hot-wire anemometer The average velocity was used to calculate

the exhaust air volumetric flow rate for the hood Intake slots in the LGS were also measured with a hot-wire anemometer. Within the department, supply air and exhaust flow volumes were measured at the ceiling diffusers and at the ceiling exhaust vents using a velometer flow hood. Smoke tubes were used to qualitatively assess air movement patterns in the workroom and near local exhaust hoods, and the results were recorded on videotape

On the first day of the survey, the Environmental Control and Maintenance Departments expressed concern that air exhausted from the recess room through the wall fan might be entrained in the supply air intake for the ground and second floors This air intake is located approximately 15 feet below the wall exhaust fan for the recess room To investigate this possibility, a smoke generator was used in the recess room Smoke was exhausted from the room through the wall fan, and the resulting air patterns outside the building were observed and videotaped Gas bag samples were collected inside the air intake plenum during the purge phase of the sterilizer cycle for three days One gas bag sample was collected above a drain in the air handler room on the second floor where a halogen detector indicated a possible high concentration of EtO/Freon

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 personal exposure To evaluate this effect, observations of the operators' work practices during their 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 Each step of the sterilizer activities was videotaped to make additional analyses available

MEASUREMENT RESULTS

AIR SAMPLING

The results of the analysis of the charcoal tube samples are reported in Table II and summarized in Tables III and IV. The limit of detection (LOD) for the analytical procedure was 0.1 ug per sample The long-term personal samples for the sterilizer operators ranged from 0 01 ppm to 0.08 ppm for a full-shift exposure average of 0 03 ppm. The full-shift exposure average for the instrument wrapper was 0 06 ppm Averages are for one shift for three days All long-term area samples were less than 0 09 ppm

Short-term samples collected during load removal operations for the sterilizer operator ranged from 3 05 ppm to 6 46 ppm for an average exposure of 4 12 ppm Short-term exposures are best viewed in terms of the concentration-time product, ppm-minutes An exposure of 5 ppm, even for only 1 minute may seem unacceptably high while one of 0 25 ppm for 20 minutes may seem acceptable, even though both situations involve an exposure to the same quantity of EtO. The concentration-time product compensates for the different exposure time In terms of this product, operator exposures ranged from 4 to 8 ppm-min with an average of 6.5 ppm-min Results of the short-term charcoal tube samples collected on the maintenance person during an EtO cylinder change operation are an average EtO concentration of 0 43 ppm and 3 4 ppm-minutes For the area over the EtO cylinders during the change, the measured EtO levels averaged 1 42 ppm

The air sampling location in front of the sterilizer was also monitored continuously with an infrared analyzer, whose output was recorded on a strip chart recorder simultaneously with that of a hygrothermograph The average response to a load transfer operation generated a peak of approximately 1 ppm decaying to background levels within 10 minutes This peak was seen to begin at the time the load was pulled from the sterilizer An average 15 minute TWA concentration of 0 3 ppm was calculated from the tracings, refer to Table V

Gas bag samples were collected for the sterilizer operator and the sterilizer door area during the load removal. These samples were analyzed on site with a portable gas chromatograph The results are presented in Table VI. Charcoal tube, gas chromatograph, and MIRAN monitoring data collected during load removal operations are compared in Table VII

VENTILATION MEASUREMENTS

Measurements of volumetric flow rate for the supply air and exhaust of the CS Department are presented in Table VIII These measurements indicated that within the instrumental accuracy, the exhausted air volume exceeds the supply air volume for a net negative pressure in the department. Air flow patterns defined with smoke tubes support this conclusion.

Local exhaust ventilation was measured for the slot hood over the sterilizer door The exhaust flowrate was 65 cfm Approximately 12 cfm was measured at each of the intake slots of the LGS.

Air flow patterns of smoke exhausted from the recess room indicated that under certain climatic and wind conditions, it might be possible that the exhaust air could be entrained in the supply air plenum Results of the gas bag sampling over three days, yielded an EtO concentration average of 0 26 ppm

WORK PRACTICE OBSERVATIONS

During the survey, the work practices of two sterilizer operators were observed Among the operators, the specific order in which the tasks associated with the load removal were performed varied somewhat The operators performed the load transfer in less than 1 minute and spent less than 5 minutes removing the biological indicator and labeling the sterile, aerated products

CONTROL EVALUATION

In evaluating the control system, consideration is given to each component of the system the isolation of the sterilizer in the ventilated recess room, the ventilated air gap in the drain line, the exhaust slot hood over the sterilizer door, the use of in-chamber aeration, and the work practices While the individual components provide important aspects of control, many elements are interdependent and contribute to the overall effectiveness of the system

DRAIN CONTROLS

Worker exposures from the drain are controlled primarily by isolating all of the sterilizer except the front panel in a ventilated recess room MIRAN IA tracings of EtO concentrations in front of the sterilizer indicated no detectable EtO present during the purge phases Tracings of EtO concentrations in the recess room during the purge phases showed approximate EtO peak levels of 35 ppm These data indicate the ventilation of the recess room was effective in containing the EtO Exhaust ventilation for the recess room was estimated to be 1250 cfm. This estimate was obtained using an hot-wire anemometer for measurements at the negative side of the wall exhaust fan in the recess room

It can be shown that the ventilation for the recess room met 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 15 minutes following a sudden release, such as emptying the EtO/Freon 12 contents of the sterilizer chamber through the safety valve

Air Velocity Through Enclosure Openings

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 Hemeon[7] gives an equation to calculate the velocity of this airflow through an orifice at the top of an enclosure From this equation, a minimum exhaust flow rate can be calculated which assures that air does not leak out of the room For room temperatures not exceeding 200°F.

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

where:

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

In this situation, the height of the hot air column is taken to be the height of the recess room The area of the cracks is estimated to be 1 ft^2

Estimates of the heat released in the room were obtained from the manufacturers of the equipment and summed to obtain a value for H' Using a height of 9 ft, a total area of 1 ft^2, and heat release rates of 2 5 Btu/min for the gas sterilizer and 160 Btu/min for the steam sterilizer, the equation yields a design exhaust flow rate of approximately 230 cfm

Temperature Rise

Exhaust ventilation may be used to remove excessive heat if a source of cooler air is available (from surrounding areas) The volume of air required for a predetermined temperature rise is given by the following equation from reference 7·

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

where·

Q = the required exhaust air flow, cfm;
H'= Sensible heat released to the air stream, Btu per min;
T = the acceptable temperature rise, °F

Assuming that the recess room temperature should not exceed 100°F, the acceptable temperature rise would be approximately 30°F Using the estimates of the heat release from the previous calculation, approximately 300 cfm would be required to limit the temperature rise in the recess room to 30°F

Rate of Purging

The rate of decrease of concentration of a contaminant once further generation has ceased is given by Mutchler(8)

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

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

Q', the effective ventilation rate, is equal to the actual ventilation rate, Q, divided by a design distribution constant, K, a value between 3 and 10 to correct for incomplete mixing Since sterilizer recess rooms are small and typically unoccupied, K will be assumed to be 3 The above equation can be solved for Q

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

In this equation, the desired time period for purging must be specified 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 600 ft^3 Assuming that a 9-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 5500 ppm. To reduce the recess room concentration to 1 ppm in 30 minutes would require 500 cfm, and 1050 cfm should accomplish the reduction in 15 minutes

Drain Ventilation

Bag samples were collected in the recess room during the evacuation phase of the cycle at the rear of the sterilizer and near the LGS EtO concentrations near the drain ranged from 32 ppm to 100 ppm and at the rear of the sterilizer were approximately 38 ppm Sampling above the drain with an infrared analyzer indicated EtO levels around 35 ppm Air flow measurements at the ventilated air gap show air flow into the LGS was about 24 cfm The ventilation rate for the LGS would seem to be sufficient to prevent EtO gas from escaping and entering the recess room A possible source of EtO is the leak cup from the drain line of the vacuum pump This opening is uncontrolled and seems to provide a escape route for the EtO Effective ventilation of the recess room by the wall fan limits the potential impact of this situation except for workers who might enter the recess room during the purge phase

CONTROLS FOR LOAD REMOVAL

The control of emissions when the sterilizer door is opened involves reducing the quantity of EtO remaining in the chamber, capturing as much as possible the air escaping from the sterilizer, and keeping the worker's breathing zone away from areas of elevated concentrations.

In-Chamber Aeration

The use of in-chamber aeration eliminates virtually all of the EtO present in the sterilizer chamber by the time the door is opened. Gas bag samples were collected inside the sterilizer chamber prior to load removal These samples ranged from 5 ppm to 11 ppm AMSCO reports EtO levels in the sterilizer chamber range from 1000 ppm to 2000 ppm at the end of the evacuation phase of the cycle when loads would be transferred to an aeration cabinet if the in-chamber aeration feature were not used [9] In-chamber aeration could potentially reduce the concentrations to which an operator might be exposed by as much as a factor of 200. Actual concentrations in the sterilizer chamber both at the end of the evacuation phase and following in-chamber aeration are highly variable and dependent on the type and quantity of items sterilized

Exhaust Ventilation for the Door

The slot hood over the sterilizer door was designed to capture EtO vapors escaping from the chamber when the door was opened a few inches at the end of the cycle This control is particularly important for sterilizers lacking the in-chamber aeration feature, since a common practice is to open the door a few inches at the end of the cycle and wait up to 15 minutes before transferring the load to an aerator Since this department has no aerator, the in-chamber aeration feature is always used The effectiveness of the slot hood in

capturing the residual EtO in the chamber escaping when the door is opened at the end of the aeration cycle can be evaluated by estimating the capture distance of the hood With a given flow rate and hood size, the capture distance of the hood is limited

The American Conference of Governmental Industrial Hygienists publishes a handbook entitled Industrial Ventilation - A Manual of Recommended Practice[10]. This manual discusses control velocities and capture distances with specific criteria and equations to aid in evaluation and design For the case of a slot hood, the required exhaust volume is given by

$$Q = 2\ 8\ LVX$$

where: Q = the volumetric air flow, cfm,
L = length of the slot, ft ,
V = velocity of the air stream, ft/min,
X = distance from the sterilizer, ft

For this particular process, the control velocity should be between 50 and 100 ft/min--with the upper limit of the range recommended In this case the volumetric flowrate is known (65 cfm), so the maximum capture distance can be estimated by solving this equation for X. For a desired control velocity of 100 ft/min, the maximum capture distance calculated from the equation is less than 1 inch For the existing conditions and the practice of in-chamber aeration, the slot hood does not provide any significant control

Work Practices

The sterilizer operators were trained to pull the load to the labeling area, rather than push it They performed the load removal quickly, minimizing their exposure to EtO Use of cart loading/unloading of the sterilizer, helped to minimize the worker's actual contact with the items. The short-term exposures estimated by charcoal tube sampling ranged from 3 to 6 ppm for a period less than two minutes Short-term concentrations at the area location in front of the sterilizer during the load removal procedure ranged from less than 1 ppm to 3 ppm These data indicate the short-term exposures during the load removal can be controlled to very low levels

CONTROLS FOR CYLINDER CHANGE OPERATIONS

Local exhaust ventilation and work practices contributed to the low concentrations of EtO generated by the cylinder change operation Local exhaust seemed very effective in controlling EtO released when the shut-off value was cracked opened. The maintenance worker uncapped the flexible duct located near the cylinders and placed the end of the duct over the top of the cylinder valves Exhaust for this duct is provided by the Envirogard® fan Charcoal tube samples collected over the cylinder yielded an average concentration of 1 42 ppm A gas bag collected at the same location estimated the concentration to be 0 1 ppm Within the limits of the infrared analyzer, no EtO concentrations above background noise were indicated.

Work practices and technique also limited the worker's EtO exposure. After cracking open the cylinder shut-off valve, the worker left the recess room and waited 3 to 4 minutes before returning to the cylinders This delay allowed EtO remaining in the line to be released and exhausted through the flexible duct After completing the cylinder change, the worker checked the connections for leaks using a halogen detector. This practice helped to insure the connections had been made properly and the recess room would not be contaminated with EtO from a leaky cylinder The average exposure measured with charcoal tubes was 0.43 ppm over 8 minutes for an average of 3.4 ppm-min A gas bag collected in the breathing zone estimated the exposure to be 0 1 ppm

EXHAUST ENTRAINMENT IN SUPPLY AIR

Analysis of the videotape of air patterns defined with smoke exhausted from the recess room indicates that under certain climatic and wind conditions exhaust air could be entrained in the supply air intake located directly below the wall exhaust fan Results of gas bags collected in the air handler plenum during the exhaust phase of the sterilizer cycle showed an average EtO concentration of 0.26 ppm. Wind conditions and temperatures were not documented for the sampled time periods Therefore, whether these EtO levels represent a typical situation or a worst case cannot be determined

The Maintenance and Environmental Control Departments reported having identified the presence of a gas which was presumed to be EtO/Freon 12 in a stairwell prior to January 1985 This gas was detected with a halogen detector. No evidence of this condition existed during the survey One possible explanation is the ventilation of the recess room as it existed prior to the installation of the wall fan The former system added the Envirogard® exhaust fan to an existing ventilation duct which did not have the capacity to handle the additional load. Thus EtO from the Envirogard® system was being emptied back into the recess room This condition would allow EtO levels to buildup in the room and, as per the discussion on air movement in heated enclosures, EtO-laden air could escape through cracks It is possible that the EtO found in the stairwell had traveled from the recess room along electrical conduit to the outlets in the stairwell The problem of insufficient recess room ventilation was identified for the hospital during the preliminary survey and had been resolved prior to the in-depth survey

CONCLUSIONS AND RECOMMENDATIONS

Control of the full-shift personal exposures, as measured with charcoal tubes, is excellent All values are less than or equal to 0 1 ppm All full-shift area concentrations are less than 0 1 ppm Likewise, short-term exposures are well controlled The OSHA permissible exposure limit of 1 ppm, 8-hour TWA was met as well as the "action level" of 0 5 ppm Both ACGIH and NIOSH recommendations for 8-hour TWA exposures and short-term excursion limits were met.

Engineering controls worked very well in limiting exposures and maintaining low EtO concentrations in the workroom air An adequately ventilated recess room which prevented EtO from the drain from reaching the area in front of the sterilizer was particularly effective The department policy of operating the sterilizer after the workers have left for the day also eliminates exposure opportunities (except for the potential presence of housekeeping in the area during the second shift) The use of in-chamber aeration effectively limits EtO exposures for the workers during load removal

To insure the continued quality and effectiveness of the engineering controls, a monitoring program should be established The program should provide for full-shift, personal sampling for the sterilizer operator at least once per year Additional monitoring may be required by the OSHA standard

The sterilizer operator should be alerted when the ventilation system is not functioning properly A sail-switch on the positive side of the recess room wall fan is a good indicator but is only visible if the operator opens the recess room door to check before starting a load A visual indicator over the sterilizer should be added An audible alarm could also be installed to alert workers if the sail-switch closes, thus indicating a failed ventilation system EtO organic vapor sensors are 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, 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 [11]

An exhaust duct for the recess room should be constructed to the roof to prevent entrainment of EtO in the supply air intake for the ground and second floors The required height of the stack above the roof can not be determined on the basis of this study An environmental consulting firm should make the necessary study of air movement on the roof to determine a safe height for the release of the EtO exhaust

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APPENDIX

TABLE I EQUIPMENT USED ON FIELD SURVEY

Item	Model	Used for
Infrared spectrometer	Miran 1A	continuous area sampling
Hygrothermograph	General Eastern	relative humidity and temperature
Strip chart recorder	Varian	record of EtO conc. and rel hum
Hot-wire anemometer	Kurz	air velocity
Velometer Flow Hood	Alnor	volumetric air flow
Gas Chromatograph	Photovac 10A10	analysis of bag samples
Personal sampling pump	MDA 808	personal and area TWA samples
Personal sampling pump	DuPont P-4000	collection of bag samples
Smoke tubes	Draeger	air flow patterns
Smoke generator	Roscoe	exhaust patterns for recess room

TABLE II CHARCOAL TUBE SAMPLING RESULTS
DAY SHIFT

SAMPLE DESCRIPTION	TERM	DAY	SAMPLE NUMBER	TIME min.	VOL. L	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Operator	Long	3/19	#636	470	9.531	0.43	0 025	11 8
Sterilizer Operator	Long	3/19	#656	470	4 291	0.65	0.084	39 5
Sterilizer Operator	Long	3/20	#662	482	9.623	0 17	0.010	4 7
Sterilizer Operator	Long	3/20	#667	482	4 333	0 43	0.055	26 5
Sterilizer Operator	Long	3/21	#675	458	9 321	0 18	0 011	4 9
Sterilizer Operator	Long	3/21	#678	458	4 197	0 16	0.021	9 7
Instrument Wrapper	Long	3/19	#657	450	4.284	0 86	0 111	50.1
Instrument Wrapper	Long	3/20	#643	483	4 675	0 41	0 049	23 5
Instrument Wrapper	Long	3/21	#659	525	5 022	0 28	0 031	16 2
Sterilizer Operator	Short	3/19	#654	2	0 077	0.53	3 820	7 6
Sterilizer Operator	Short	3/19	#658	2	0 080	0 44	3 053	6 1
Sterilizer Operator	Short	3/20	#616	1	0 061	0 71	6.460	6.5
Sterilizer Operator	Short	3/20	#629	1	0 059	0 44	4 139	4 1
Sterilizer Operator	Short	3/21	#625	2	0 077	0.57	4 108	8 2
Sterilizer Operator	Short	3/21	#661	2	0 074	0.42	3.150	6.3
Maintenance Person	Short	3/21	#670	8	0 508	0 28	0 306	2.4
Maintenance Person	Short	3/21	#673	8	0 530	0 53	0 555	4.4
Above Sterilizer Door	Long	3/19	#627	472	4 602	0 77	0 093	43 8
Above Sterilizer Door	Long	3/19	#628	472	9 462	0 50	0 029	13.8
Above Sterilizer Door	Long	3/20	#663	480	4 657	0 36	0 043	20 6
Above Sterilizer Door	Long	3/20	#666	480	9 575	0.26	0.015	7.2
Above Sterilizer Door	Long	3/21	#638	522	10 397	0 22	0 012	6 1
Above Sterilizer Door	Long	3/21	#640	522	5 057	0 34	0.037	19 5
Above Sterilizer Door	Short	3/19	#635	2	0 153	0 58	2 104	4 2
Above Sterilizer Door	Short	3/19	#637	2	0.172	0.62	2 001	4.0
Above Sterilizer Door	Short	3/20	#642	1	0 116	0 59	2 823	2 8
Above Sterilizer Door	Short	3/20	#665	1	0 131	0.51	2.161	2 2
Above Sterilizer Door	Short	3/21	#672	3	0 176	0 46	1 451	4.4
Above Sterilizer Door	Short	3/21	#681	3	0 198	0 17	0 477	1.4
Wrapping Table Area	Long	3/19	#611	481	5 322	0 68	0 071	34.1
Wrapping Table Area	Long	3/20	#644	480	5 280	0.40	0.042	20 2
Wrapping Table Area	Long	3/21	#660	524	5 759	0.24	0 023	12 1
Above EtO Cylinders	Short	3/21	#631	8	0 606	0 97	0.888	7 1
Above EtO Cylinders	Short	3/21	#674	8	0.540	1.9	1.953	15 6

TABLE II CHARCOAL TUBE SAMPLING RESULTS
DAY SHIFT, CONTINUED

SAMPLE DESCRIPTION	TERM	DAY	SAMPLE NUMBER	TIME min	VOL. L	EtO µg	EtO ppm	EtO ppm-min
Field Blank		3/19	#652			0 72		
Field Blank		3/19	#653			0 44		
Field Blank		3/20	#669			0 59		
Field Blank		3/20	#671			0 51		
Field Blank		3/21	#679			1 3		
Field Blank		3/21	#680			0.20		
Quality Assurance Q1411			#655			7 6		
Quality Assurance Q1414			#664			9 1		
Quality Assurance Q1408			#646			5.0		

TABLE III FULL SHIFT TWA EXPOSURES/AREA CONCENTRATIONS
CHARCOAL TUBE RESULTS

Worker/Location	# Samples	Average Concentration, ppm	Standard Deviation
Operator	6	0 03	0 03
Wrapper	3	0 06	0 03
Sterilizer Door	6	0 04	0 03
Wrap Table	3	0.04	0 02

TABLE IV. SHORT-TERM CHARCOAL TUBE RESULTS

Worker/ Location	# Samples	Average Conc , ppm	Standard Deviation	Average Conc., ppm-min	Standard Deviation
Operator	6	4 12	1.13	6 47	1 29
Sterilizer Door	6	1 84	0.73	3 17	1 12
EtO Cylinders	2	1 42	0 53	11 35	4 25
Maintenance Person	2	0 43	0 13	3 4	1 0

TABLE V MIRAN IA MONITORING RESULTS

Date	Location of Samples	Peak ppm	Duration minutes	Average ppm	Total ppm-min	15 min ppm	TWA
3/19/85	Ster Door	1	10	0 5	5	0.3	
3/20/85	Ster Door	1	10	0 5	5	0.3	
	Recess Room During Purge	34	19	9.3	177	12	
3/21/85	Ster Door	1	10	0 5	5	0 3	
	EtO Cylinder During Change	-	-	-	-	-	
	Recess Room	35	15	12	177	12	

TABLE VI GC SAMPLING RESULTS.

Location/Activity	Ethylene Oxide Concentrations, in ppm 3/19/85	3/20/85	3/21/85	Average	Standard Deviation
Operator-load removal	0 2	0 2	0.2	0 2	0 0
Sterilizer Door-load removal	0 3	0 2	0 2	0 23	0.05
Sterilizer Chamber-before load removal	7.9	11	5	8	2.4
Sterilizer Chamber-before load insertion	3 6	21	22	15.5	8 4
Sterilizer Door-load insertion	--	0 2	--	0 2	--
Drain-during purge recess room	32	36	100	56	31
Recess Room-during purge rear of sterilizer	--	--	38	38	--
Air Handler Plenum	0 3	0.37	0 1	0 26	0 11
Drain-air handler rm 2nd. floor	0 2	--	--	0 2	--
Maintenance Man-cylinder change	--	--	0 1	0.1	--
Above Cylinders-during cylinder change	--	--	0 1	0 1	--

TABLE VII COMPARISON OF CHARCOAL TUBE, GC, AND MIRAN IA DATA DURING LOAD REMOVAL

Sample	Date	Shift	Ethylene Oxide Concentration, PPM Charcoal	GC	MIRAN IA
Operator	3/19/85	Day	3 44	0 2	--
	3/20/85	Day	5 30	0.2	--
	3/21/85	Day	3 63	0 2	--
	Average		4 12	0 2	--
	Standard Deviation		0 84	----	
	Mean Sample Time:		2 min	2 min	--
Over the Sterilizer	3/19/85	Day	2 05	0 3	0.3
	3/20/85	Day	2 49	0 2	0 3
	3/21/85	Day	0 96	0 2	0 3
	Average		1 83	0 23	0.3
	Standard Deviation		0 64	----	0 0
	Mean Sample Time		2 min	2 min	15 min

TABLE VIII. GENERAL VENTILATION DATA

Area	Grille No	Supply (CFM)	Exhaust (CFM)
Clean Room	S1	150	----
	S4	75	----
	S5	165	----
	S6	260	----
	E3	---	75
	E4	---	50
	Slot*	---	65
Recess Room	F	---	1250
Office and Storage	S2	165	----
	S3	125	----
	E1	---	12
Toilet	E2	---	20
Surgery Office	S7	30	----
Total		970	1472

*Slot over sterilizer door with Envirogard® operating