IN-DEPTH SURVEY REPORT

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPTIALS

AT

Bronson Methodist Hospital
Kalamazoo, Michigan

REPORT WRITTEN BY
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SURVEY DATE:	February 25 - March 1, 1985
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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 THIS PROJECT

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 (EtO) 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), expressed as an 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-hour TWA) for ethylene oxide based on its determination that EtO is a potential human carcinogen.(1) NIOSH recommends exposure be limited to less than 0.1 ppm (8-hour TWA) with a ceiling limit of 5 ppm for a period not to exceed 10 minutes in an 8-hour shift.(2)

In response to the hospitals' need to control worker exposure to EtO to levels below 1 ppm, the Engineering Control Technology Branch 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 effective engineering controls which select 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

Bronson Methodist Hospital expressed an interest in participating in the study and supplied information about the Central Service (CS) Department to NIOSH. Based on this information, it was determined that the hospital might fulfill the requirements of the category specifying: a sterilizer using a 12:88 EtO and Freon 12 mixture, no extra evacuation phases at the end of the sterilizer cycle, vented evacuation drain controls, and local exhaust ventilation other than above the sterilizer door.

A preliminary survey(3) was conducted in the CS Department on July 31, 1984. Findings of this preliminary survey indicated the Central Service 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 the drain area and over the sterilizer. An auxiliary exhaust system activated by an EtO sensor had also been installed. Proper work practices for employees were clearly outlined in a procedure and policy manual, and based on observation of the transfer of a load from the sterilizer to the aerator, the operator followed those procedures. The CS manager provided an in-service program every 3 months 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 Central Service Department of Bronson Methodist Hospital was conducted on February 25 - March 1, 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.(4)

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.(5)

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.(6)

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.(6)

In addition to the OSHA PEL of 1 ppm, the standard mentions an action level of 0.5 ppm, above which semiannual 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, it has 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.(7) 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.(2)

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-gasing items can provide an EtO exposure source for the operator transferring the load to the aerator and may contribute to the background levels of EtO in the workplace. EtO-laden 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 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 liquid or gaseous EtO in the supply lines. This may permit worker exposure to the EtO and may contribute to background EtO concentration levels, however, cylinder changes are not usually performed on a daily basis.

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, EQUIPMENT, AND PROCESS DESCRIPTION

HOSPITAL AND CENTRAL SERVICE DEPARTMENT DESCRIPTION

Bronson Methodist Hospital is a not-for-profit, acute care facility with 464 beds. Services which the hospital provides include: general surgery, oncology, eye surgery, cardiovascular catheterization, burn treatment, a trauma center, obstetrics, and neonatal care. The Central Service Department is located on the fourth floor of the building. The department is near the Labor and Delivery Department.

Ethylene oxide gas sterilization operations for the hospital are conducted in the Central Service Department and in the Surgery Department. The CS Department performs EtO sterilization for obstetrics, neonatal care, respiratory therapy, the catheterization laboratory, isolation cases, x-ray, and emergency. The Surgery Department sterilizes its own instruments and equipment. EtO sterilization operations conducted in the Surgery Department were not evaluated during the survey.

The CS Department employs 15 persons distributed over 3 shifts. The number of employees working on the day (1st) shift varies from four to six depending on the product volume to be processed on a particular day. Typically, one person works in the decontamination room and three to five others work in the sterilization and packing room (hereafter referred to as the clean room). Only one person is assigned to operate the sterilizers and process the loads. The department manager and one of the supervisors spend most of their time in offices or moving between the different areas of the department. During the evening (2nd) shift, four persons are in the department. One or two persons are assigned to decontamination, and two or three persons work in the clean room. The night (3rd) shift employs one or two persons as needed rotating between decontamination and the clean room.

The layout of the CS Department is diagrammed in Figure 1. Of particular interest in this study is the clean room which serves three functions. One end of the room is used to store clean supplies. Another part of the room serves as a processing area where cart loads are prepared for sterilization and where sterile loads cool before storage or distribution. A third area of the room is occupied by a bank of sterilizers (one steam, and one EtO) and two aerators that are recessed along one wall.

The sterilizers may be accessed for maintenance through a small recess room located behind the sterilizers. This room is entered through a doorway off the sterile storage room and is marked as a hazard area and restricted to authorized personnel only. The backs of the sterilizers and aerators are open to the room. Steam and water from the sterilizers are emptied into closed drains.

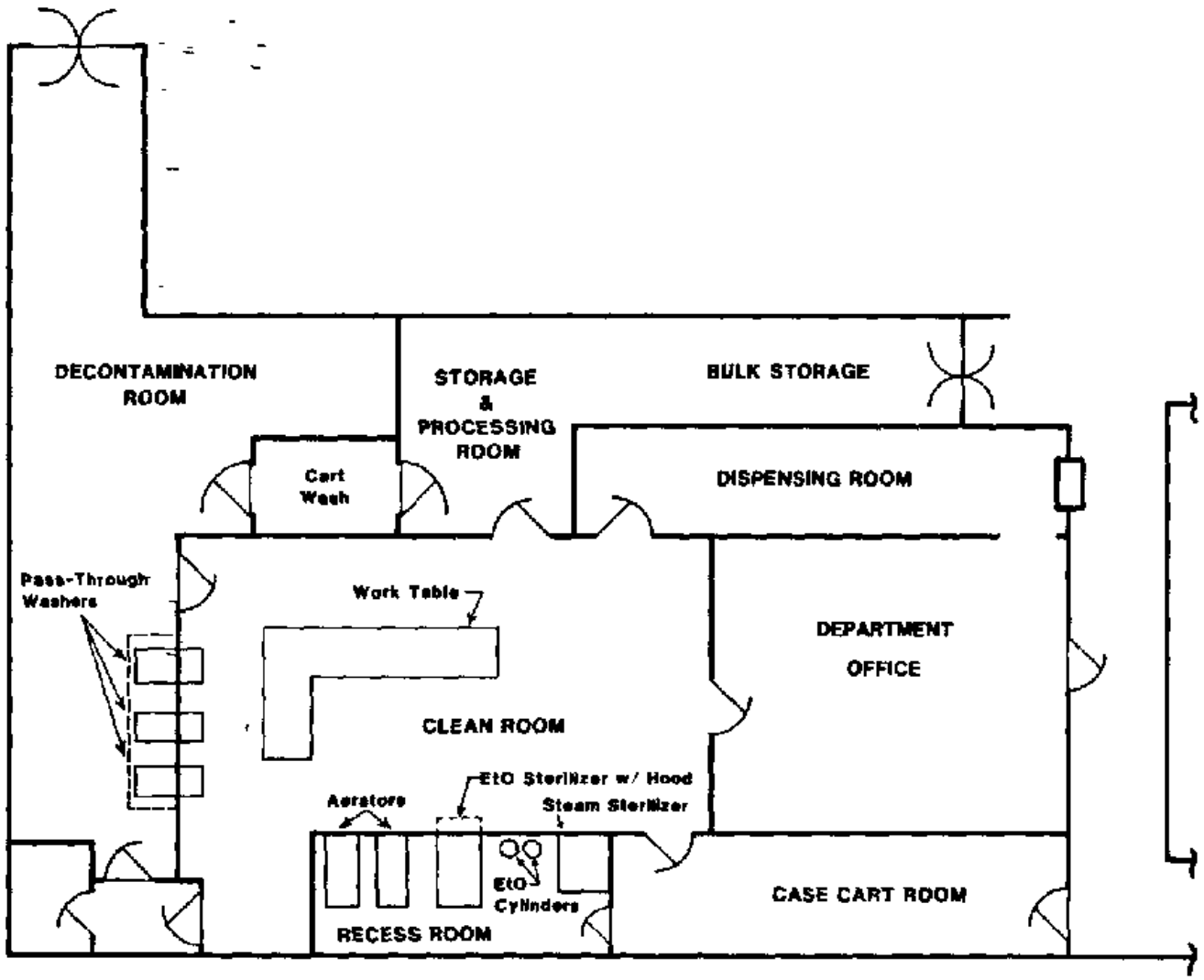

Figure 1. Central Service Department, Bronson Methodist Hospital.

EQUIPMENT AND PHYSICAL DESCRIPTION

The EtO gas sterilizer is an AMSCO (American Sterilizer Company) Medallion, Cryotherm. Its internal chamber size is 24 inches by 36 inches by 60 inches, a volume of approximately 30 cubic feet. The two aerators are AMSCO models each with an internal chamber size of approximately 30 cubic feet.

The sterilizer is supplied with an EtO/Freon 12 gas mixture in a 12:88 ratio by weight from gas cylinders. The cylinders are located in the recess room between the EtO and steam sterilizers.

Sterilizer and Aerator Cycle Features

The sterilization cycle is approximately 3 hours 30 minutes in length and consists of several phases: initial vacuum and humidification (about 30 minutes), EtO charging of the chamber and sterilization (about 2 hours 40 minutes), and two chamber evacuations (about 20 minutes). The sterilizer operates at 130°F.

Items are aerated for a minimum of 12 hours. Certain items may require up to 72 hours aeration time and are processed as specified by the manufacturer of the item. The two aerators are operated at 120°F.

Local Exhaust Ventilation

An architectural firm designed and installed an exhaust hood over the EtO sterilizer in 1981. This hood is constructed of sheet metal and measures 14 inches by 40 inches by 14 inches. Exhaust is provided by a rectangular vent in the wall, located inside the hood and measuring 6 1/2 inches by 22 inches. The vent is connected to the dedicated system which exhausts the recess room. The hood is located about 18 inches above the sterilizer door.

Local exhaust ventilation is also provided for the sterilizer drain. When the sterilizer chamber is evacuated, a mixture of water and EtO passes through the vacuum pump and into a drain. There the water and gas may separate, and the gases may escape to the recess room atmosphere. The hospital designed and installed a drain enclosure and connected the enclosure to the dedicated exhaust system. The sterilizer safety relief valve is also covered and vented through a duct connected to the same dedicated system.

General Exhaust Ventilation

The decontamination room is supplied by five air diffusers. Exhaust grilles are located over the pass-through washers, inside a canopy hood. Passive exhaust vents in the wall between the decontamination room and the clean room are also located over the pass-through washers. Doors between the decontamination room and the preparation/packaging area of the clean room are closed at all times.

The clean room has six supply air diffusers. Exhaust is provided by two louvered vents located above the tops of the steam sterilizer and the second aerator along the wall. These vents are passive and open to the recess room. Air flows from above the sterilizers into the recess room due to the negative pressure developed in the recess room by exhaust ventilation.

The CS Department recess room is exhausted by a dedicated system which was installed in 1976. During the exhaust phase of the sterilizer cycle, EtO levels in the recess room may become elevated. An auxiliary dedicated exhaust system (installed in 1984) is activated by an EtO sensor when the concentration exceeds 20 ppm. Vents for this exhaust system are located at the floor near the sterilizer drain, at the floor near the EtO supply cylinders, and near the ceiling of the room.

EtO supply cylinders are chained to the wall alongside the sterilizer in the recess room. Exhaust ventilation provided at this location is designed to exhaust any EtO which might escape during a cylinder change operation or in the event of a leaky cylinder connection. The architect's plan specified an enclosed cabinet exhausted at the floor at the back of the cabinet. The cabinet was not installed, however, the exhaust vent at the floor is part of the auxiliary exhaust system and may be manually activated during a cylinder change operation.

PROCESS DESCRIPTION

Heat- or moisture-sensitive items are sterilized with EtO gas. These items arrive in decontamination in enclosed carts delivered to the door by the using department, or picked up in the using department by CS personnel. The items are washed, dried, and either carted or carried into the preparation/packaging area of the clean room. Very small items are hand cleaned and treated with ultrasonics before passing into the clean room. The items may then be wrapped or heat-sealed in a peel-pak and carried to a table in front of the sterilizer bank. The sterilizer operator prepares the load for sterilization by arranging the items on a cart-rack, placing a biological indicator in the load, and completing the necessary record forms. The cart-rack is placed in the sterilizer, and the cycle is started at approximately 5:00 p.m. daily. If there are only a few items for EtO sterilization or in the event of an equipment malfunction (in either CS or Surgery), the CS Department may consolidate its load with Surgery's load, and only one load is run between the two departments.

Transferring the Load

At the end of the second evacuation, a buzzer sounds alerting the operator that the cycle is complete and the door may be opened. The operator turns the door handle so that the door will swing open when the pressure is released. Next the aerator door is opened, and the operator uses a heavy towel to protect the hand during contact with the cart. The sterilizer door is swung fully open, and the operator pushes the cart into the chamber, engages the cart-rack, and withdraws the cart-rack and cart. The sterilizer door is closed as the cart is pulled to the aerator. The operator then removes the

biological indicator from the load, and pushes the cart inside the aerator chamber. The cart-rack is disengaged and the cart withdrawn. The aerator door is closed and aeration times are taped to the outside of the door. The biological indictors are opened at the work table, then taken to the microbiology laboratory for incubation and analysis.

Cylinder Changes

The EtO sterilizer is supplied with gas from a compressed gas cylinder. If a cylinder empties during a cycle and an insufficient amount of EtO is supplied to the sterilizer, the cycle is interrupted. A new cylinder is needed about every 3 weeks. When a new cylinder is needed, the Central Distribution delivers one to the department, and a person from maintenance connects the new cylinder.

Preventative Maintenance

The CS Department has a preventive maintenance contract with MidWest Medical Company for routine quarterly evaluations. The maintenance protocol specifies the evaluation of the EtO sterilizer and aerators for mechanical function and leak testing. The service person also inspects the sterilizer door gasket and replaces it as needed. The EtO cylinders, supply lines, drain pipes, and floor drain are regularly leak-tested. Any necessary repairs are made immediately. Hospital maintenance personnel are also trained to provide some service functions for the sterilizer and are the first ones notified if the equipment malfunctions or leaks are suspected.

Monitoring

The CS monitoring program has three components: continuous monitoring with an alarm system, environmental area monitoring performed by maintenance, and personal monitoring.

In 1984, three monitoring sensors were installed in the department: one in the recess room near the sterilizer, one over the sterilizer door, and one over the work table in front of the sterilizers. The sensors and alarm system are manufactured by Gas Tech (model 1565-6). The alarm station is mounted on the wall at the end of the bank of sterilizers, about 10 feet from the EtO unit. When EtO concentration levels reach 20 ppm an audible and visual alarm is triggered. If levels reach 50 ppm the audible alarm becomes continuous. Each of the sensors is on a separate alarm indicator so that the worker can visually identify which location has triggered the alarm. During the exhaust phase of the sterilizer cycle, the sensor in the recess room is routinely triggered at the 20 ppm level. The department policy manual instructs workers to leave the department if the alarms remain activated for an "unreasonable" length of time.

Environmental area monitoring was performed by the CS manager initially in 1981. Maintenance personnel have been trained and now perform monitoring for the department every six months. Monitoring is also performed whenever there is a change in the system or if any leaks are suspected. Monitoring is performed with an infrared analyzer. Personal monitoring is performed for the sterilizer operator semiannually using 3M Company passive diffusion badges.

METHODOLOGY

To evaluate the effectiveness of the engineering control measures, both short- and long-term concentrations of ethylene oxide were determined and ventilation control parameters (mainly air velocity and volumetric flowrate) were measured. The major pieces of equipment used in this evaluation are listed in Table A-1 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[8]. 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 with limiting orifices of 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 of approximately 100 mL/min to collect duplicate samples for the same personal and area locations during the load transfer procedure (short-term, 3-6 minutes). MDA pumps (limiting orifices of approximately 20 mL/min) were used to collect long-term samples for an instrument wrapper and the wrapping area location. Day and evening shifts were 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 the 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 sterilizer door was opened and the load was transferred to the aerator. Samples were collected both for the sterilizer operator and at the area sampling location in front of the sterilizer from the time the operator walked up to the sterilizer to open the door at the end of the cycle until the load transfer to the aerator was completed, and the operator left the sterilizer area.

Gas Bag Sampling

DuPont pumps were used to collect air samples in Tedlar* gas sampling bags (SKC No. 231). A short-term area sample over the sterilizer door was collected for 3-7 minutes during the load transfer procedure. A 2-6 minute sample was collected for the sterilizer operator while transferring the sterile load to the aerator. To estimate the potential concentration of EtO

to which the operator might be exposed a sample was collected from inside the sterilizer chamber prior to removal of the load. This sample was collected for 15 seconds. A series of three samples were collected in the recess room during the final vacuum phase of each cycle to estimate the EtO levels and the rate of purging for the recess room. All gas 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. A continuous monitor provided a measure of the background EtO levels as well as indicating higher concentrations which could be associated with certain events.

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 (such as those associated with the load transfer) 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.

The infrared analyzer sampling probe was located over the sterilizer door along side the charcoal tube area samples for three of the sampled cycles. During the other three cycles, the sampling probe was placed at various locations in the recess room.

Air Flow Measurements

The air flow velocities were measured for the hood above the EtO sterilizer using a hot-wire anemometer. The average velocity was used to calculate the exhaust air volumetric flow rate for the hood. Within the department, supply air and exhaust flow volumes were measured at the ceiling and wall 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.

During the preliminary survey, the EtO sensor alarm was activated in the recess room during the evacuation cycle. The drain was the suspected source of EtO. It was hypothesized that the exhaust rate of the ventilation duct over the drain was less than the exhaust rate of the vacuum pump as it released EtO/water to the drain. To test this hypothesis, a magnehelic pressure gage was inserted into the duct, and the pressure readings during the evacuation of the chamber were recorded.

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.

Processing the Test Load

In designing this study, it became obvious that conditions in each hospital participating in the study would be so variable as to preclude any meaningful comparisons between hospitals unless some of the variables could be eliminated. Therefore, a challenge test load was provided for processing at each hospital. The load consists of packages of rubber surgical tubing, an 8-inch length contained in each "peel-pak". The number of packages is adjusted to the volume of the sterilizer of interest, corresponding to a 30 percent load level. For the 30-ft^3 volume sterilizer, 225 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.

Test loads were sterilized during the 1st shift for each of the three days of sampling. The department processed its normal load during the 2nd shift for the three days. Sampling data from these test loads provide the basis for comparison with similar loads processed in other hospitals.

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. A normal load was run during the 2nd shift on each of the three days. No other loads were run during the survey; however, a cycle abort occurred during the 2nd shift of the 3rd day because the EtO supply cylinder could only charge the chamber to 5 psi (gauge pressure). After the cylinder was changed, the cycle was restarted, and approximately 90 percent of the EtO originally charged in the chamber was evacuated by the initial vacuum draw of the new cycle.

AIR SAMPLING RESULTS

All full-shift personal exposures and selected area concentrations sampled with charcoal tubes were less than 0.5 ppm. The individual short-term samples for the operator ranged from approximately 0.4 to 6 ppm, and those for the area in front of the sterilizer, 0.8 to 14 ppm. Two samples (593 and 597) were invalidated because of a pump failure. The results are presented in Table A-2.

Approximately half of the valid samples (31 of 58) were below the limit of detection for the analytical procedure, which ranged from 0.29 to 0.50 ug per sample. Most of the results below detectable limits (25 of 31) were long-term samples with an average detection limit of 0.027 ppm.

Two side-by-side samples were taken for the operator exposures and for the concentrations in the area in front of the sterilizer. The average of each pair of full-shift samples is presented in Table 1; the short-term samples, in Table 2.

Table 1. Full-shift average concentrations.

Sample Description	Date mo/dy/yr	Shift	Load	Duration minutes	Concentration ppm
Sterilizer Operator	2/26/85	1st	Test	464	0.037
	2/26/85	2nd	Norm	497	0.027
	2/27/85	1st	Test	473	0.035
	2/27/85	2nd	Norm	489	0.031
	2/28/85	1st	Test	492	0.038
	2/28/85	2nd	Norm	469	0.041
In front of Sterilizer	2/26/85	1st	Test	489	0.029
	2/26/85	2nd	Norm	497	0.052
	2/27/85	1st	Test	495	0.112
	2/27/85	2nd	Norm	493	0.026
	2/28/85	1st	Test	513	0.067
	2/28/85	2nd	Norm	477	0.133

Table 2. Short-term average concentrations.

Sample Description	Date mo/dy/yr	Shift	Load	Duration minutes	Concentration ppm
Sterilizer Operator	2/26/85	1st	Test	5	1.273
	2/26/85	2nd	Norm	5	0.460
	2/27/85	1st	Test	4	1.796
	2/27/85	2nd	Norm	3	0.675
	2/28/85	1st	Test	4	1.766
	2/28/85	2nd	Norm	3	3.562
In front of Sterilizer	2/26/85	1st	Test	5	3.775
	2/26/85	2nd	Norm	6	1.299
	2/27/85	1st	Test	0	0.000
	2/27/85	2nd	Norm	5	1.410
	2/28/85	1st	Test	5	9.819
	2/28/85	2nd	Norm	4	1.970

A summary of the charcoal tube results, averaged over the 3 days of the survey, is presented in Table 3. Note that the full-shift results for the test loads do not differ significantly from those for the normal loads. However, for the short-term samples, especially those for the area in front of the sterilizer, the average for the test loads is substantially higher.

Table 3. Average charcoal tube results for survey.

Description	Load	Number of Samples	Average EtO Concentration, ppm	Standard Deviation
Sterilizer Operator	Test	3	0.037	0.002
full-shift	Norm	3	0.033	0.007
Wrapper	Test	3	0.021	0.005
full-shift	Norm	3	0.020	0.006
In front of Sterilizer	Test	3	0.069	0.042
full-shift	Norm	3	0.070	0.056
Wrapping Table	Test	3	0.032	0.028
full-shift	Norm	3	0.019	0.006
Sterilizer Operator	Test	3	1.61	0.29
load transfer (approx 4 min.)	Norm	3	1.57	1.73
In front of Sterilizer	Test	2	6.8	4.3
load transfer (approx 5 min.)	Norm	3	1.6	0.36

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 approximately equal to or less than 5 ppm for periods ranging from 2 - 5 minutes.

Table 4. Average gas bag results for survey.

Description	Load	Number of Samples	Average EtO Concentration, ppm	Standard Deviation
Sterilizer Operator load transfer (2-4.5 min.)	Test	3	4.63	0.80
	Norm	3	1.03	0.68
In front of Sterilizer load transfer (3.5-6.5 min.)	Test	2	15.7	11.3
	Norm	3	11.53	13.77
Inside sterilizer chamber door first opened following final purge cycle	Test	3	3400	588.8
	Norm	3	2522	667

Infrared Analyzer Monitoring

EtO was not detected with the IR analyzer during the purge, 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.

Representative concentrations measured with the IR analyzer at the area location in front of the sterilizer, averaged over the 3 days of the survey, are presented in Table 5. Two different sets of results have been calculated: one for the duration of the short-term charcoal tube samples and one for the duration of the IR response peak.

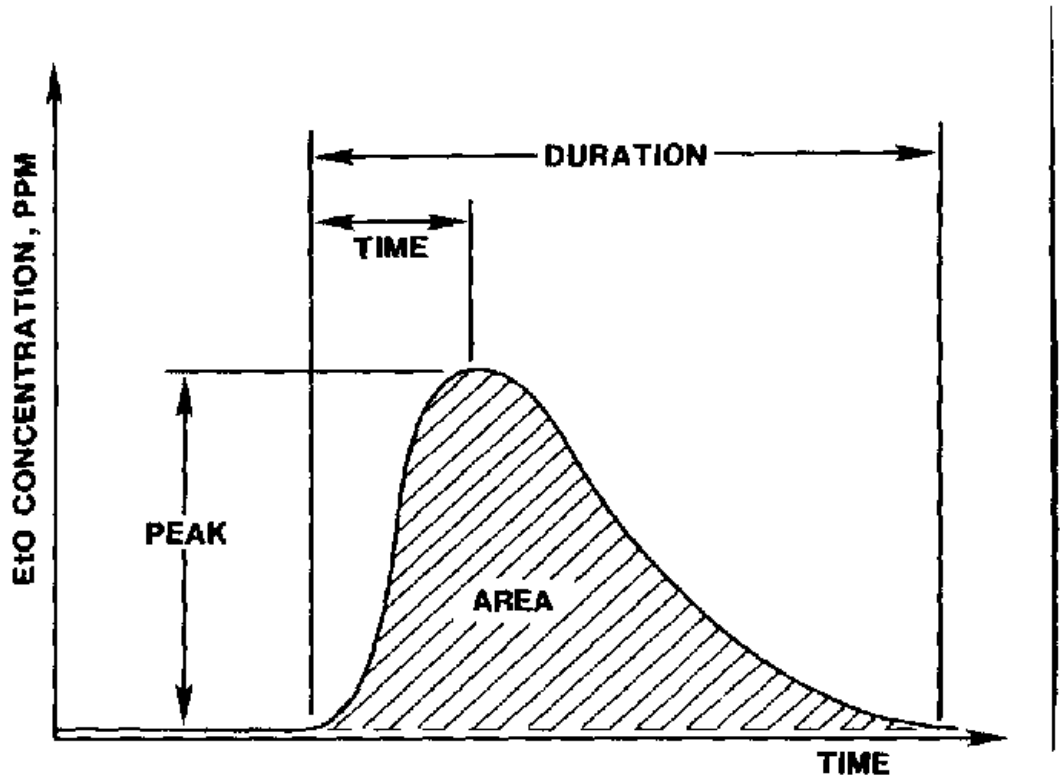

Figure 2. Typical response of infrared analyzer in front of EtO sterilizer during the end-of-cycle activities.

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 5 min.)	Test	2	5.54	2.03
	Norm	1	2.24	___
In front of Sterilizer load transfer (duration of IR response peak)	Test	2	2.82	0.37
	Norm	1	1.88	___

VENTILATION MEASUREMENTS

Generally, more air was supplied to the rooms of the Central Service Department than was exhausted; and air was observed, using smoke tubes, to flow out of the doorways of the department. The doorway airflow is shown in Figure 3 along with the identification of the ventilation inlets and outlets. A full table of the design values and measured values is presented in Table A-5.

All air exhausted from the department is exhausted directly out of the building. The return air duct and fan servicing this area also exhausts directly out of the building, rather than returning air to a supply air handler as implied by the labels.

The airflow into the hood above the sterilizer was measured to be approximately 550 cfm, sufficient to extend the capture distance of this hood out to over 1 ft from the sterilizer door. The measurements and observations were made with the door closed--with the door open and the hot load pulled out in front of the sterilizer, this capture distance would probably be less due to the momentum of the thermal rise.

The two vents of the auxiliary recess room ventilation system were measured to exhaust approximately 1500 cfm, almost twice as much as the main system exhausted from the recess room. The exhaust rates for the two vents in the recess room wall above the bank of sterilizers and aerators averaged about 70 cfm each, increasing to about 150 cfm when the auxiliary ventilation system came on.

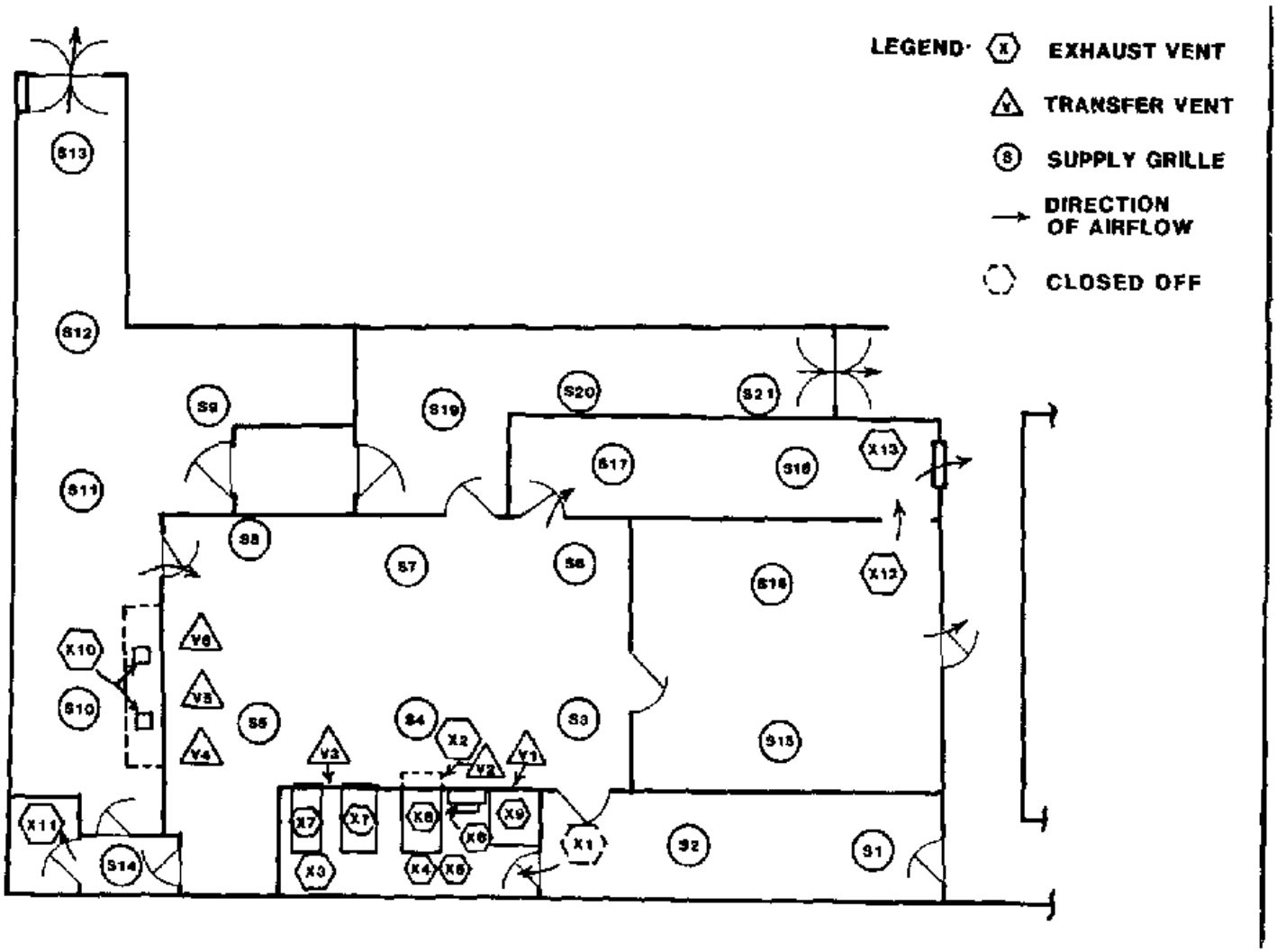

Figure 3. Location of the ventilation inlets and outlets.

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. IR monitoring at the area location in front of the sterilizer door showed no increased response (EtO concentration) during the evacuation period, 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; however, enough EtO is emitted during the purge to trigger the sensor in the recess room at the 50-ppm level. IR monitoring underneath the sterilizer during the purge peaked at over 100 ppm. One source is the drain exhaust duct itself. Pressure measurements in the drain exhaust duct revealed that during the purge phase, the duct becomes pressurized instead of exhausted. The exhaust capacity of this duct is not sufficient to accommodate the forced input from the vacuum pump as it evacuates the sterilizer chamber. Another contributory source may be a line to drain leakage from the input shaft of the water-sealed vacuum pump.

The auxiliary ventilation system, which comes on when the sensor in the recess room detects an EtO concentration greater than 20 ppm, exhausts a total of 1500 cfm from the recess room. This additional ventilation is capable of reducing the EtO concentration in the recess room to less than 1 ppm within 30 minutes following the end of the purge cycle. The plans called for a system continuously exhausting 1100 cfm, but the system functions well as 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 vacuum purges removed approximately 99 percent of the EtO that was in the chamber during the sterilization period. However, the concentrations in the chamber of approximately 3000 ppm indicate that as much as 5 grams of EtO remained in the chamber at the end of the evacuation cycle, enough to raise the concentration in the department to over 3 ppm if all this EtO were allowed to escape and disperse.

This department follows the work practice of unloading the sterilizer immediately after the end of the evacuation cycle. With this practice, the distance which the door is opened is not an important factor in controlling the EtO released from the chamber through the open door.

The hood over the sterilizer door provided good control of the area in front of the sterilizer. Making the airflow visible with a smoke tube showed that when the door was closed, air was captured by the hood out as far as 20 inches from the front of the sterilizer. With the hot air rising from the load of sterile items being removed from the sterilizer, this capture distance would be somewhat less. Such an arrangement can not be expected to control emissions from the cart of sterilized items as it is pulled from the sterilizer and moved to the aerator.

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 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.[9] The measured concentration in the chamber when the door was first opened at the end of the cycle agree with this estimate. However, a considerable amount of EtO still remains in the chamber and on the sterilized items.

The sterilizer operators were unable to pull the load, rather than push it. Because of the room configuration and the way the aerator doors were hinged, the load had to be pushed to the aerators. The location of the work table in the clean room made it difficult to maneuver the cart. This may have caused the operation to take longer and brought the operator into closer contact with the load than if there were fewer obstacles. The short-term exposures for the sterilizer operator averaged approximately 1 ppm for the approximately 4 minutes it took to transfer the normal load. Thus, despite the hindered transfer procedure, the short-term exposure levels were within NIOSH recommended limits.

GENERAL VENTILATION

Not much air is exhausted through the vents in the recess room wall above the sterilizers and aerators. The average flow rate through the recess room wall vents from the clean room is usually 70 cfm, although it does double when the auxiliary recess room ventilation system comes on.

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. 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 as it is at this hospital.

CONCLUSIONS AND RECOMMENDATIONS

Control of the full-shift exposures, as measured with charcoal tubes, is excellent. All values are less than 0.2 ppm, including the area locations. Likewise, short-term exposures are well controlled, not exceeding 5 ppm for the short period (less than 4 minutes) during which the normal load is transferred to the aerator. EtO emissions from the drain during the purge are controlled so as to not create an exposure problem in front the the sterilizer.

Although the exposures to the sterilizer operators are low, it should be possible to reduce them even more by removing some of the impediments to the load transfer. If the work table were moved and the aerator doors were hinged on the other side, the operator could have the aerator door open and pull the load from the sterilizer directly to a position in front of the aerator; and then, with one maneuver, push the cart into the aerator.

EtO levels can get relatively high in the recess room during the purge cycles. Over 100 ppm was measured down near the floor drain 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 clear warning for people to leave or not to enter the recess room when the EtO levels are high. A sensor was in place which measured the EtO concentration and signaled when it was above preset limits; however, the lowest level for which there was an alarm was 20 ppm, and the alarm indicator was visible only in front of the sterilizer. Lights should be installed 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. With the auxiliary system operating, 30 minutes should be sufficient time. These lights should be installed 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.

It is desirable to add the drain exhaust to the auxiliary exhaust system. This system should be set to operate during the evacuation phase of the cycle and when activated by the EtO sensor in the recess room. With the exhaust volume supplied by the auxiliary system, routine activation of the EtO sensors should be eliminated.

A differential pressure sensor has been installed on the main exhaust system (EF-7) servicing the Central Service Department. A similar device should be installed on the auxiliary ventilation system exhausting air from the recess room to warn if this system malfunctions. The indicators for both systems should be visible to the sterilizer operator in the clean room, and the EtO sterilizer should not be run unless the EF-7 system is working.

An emergency evacuation and response plan should be developed and rehearsed.

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 (but expected high) concentration of EtO or in an emergency situation, NIOSH recommends a compressed air open circuit self-contained breathing apparatus (SCBA) with full facepiece.[10]

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Appendix Survey Data

Table A-1 Equipment used on field survey

SURVEY: Bronson Methodist Hospital, Kalamazoo, Michigan, February 26-28, 1985

Item	Model	Used for
Infrared spectrometer	Miran 1A	continuous 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
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 Bronson Methodist Hospital, Kalamazoo, Michigan, February 26-28, 1985

SAMPLE DESCRIPTION	TERM	DAY	SHIFT	SAMPLE NO	TIME min	VOL L	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Operator	Long	2/26	1st	550	464	4 616	< 0 33	< 0 040	< 18 4
Sterilizer Operator	Long	2/26	1st	543	464	9 390	0 60	0 035	16.5
Sterilizer Operator	Long	2/26	2nd	546	497	4 675	< 0 33	< 0 039	< 19 5
Sterilizer Operator	Long	2/26	2nd	589	497	10 318	< 0 29	< 0 016	< 7.8
Sterilizer Operator	Long	2/27	1st	599	473	4 680	< 0 29	< 0 034	< 16.3
Sterilizer Operator	Long	2/27	1st	603	473	9 520	0 62	0 036	17 1
Sterilizer Operator	Long	2/27	2nd	591	489	4 597	< 0 29	< 0 035	< 17.1
Sterilizer Operator	Long	2/27	2nd	615	489	10 145	< 0 50	< 0 027	< 13 4
Sterilizer Operator	Long	2/28	1st	607	492	4.946	< 0.29	< 0.033	< 16 0
Sterilizer Operator	Long	2/28	1st	619	492	10 060	0 80	0 044	21.7
Sterilizer Operator	Long	2/28	2nd	624	469	4 418	< 0 50	< 0 063	< 29 5
Sterilizer Operator	Long	2/28	2nd	496	469	9 750	< 0.33	< 0 019	< 8 8
Instrument Wrapper	Long	2/26	1st	547	456	10 389	< 0 33	< 0 018	< 8.0
Instrument Wrapper	Long	2/26	2nd	588	349	8 001	< 0 29	< 0 020	< 7.0
Instrument Wrapper	Long	2/27	1st	582	467	10 430	< 0 33	< 0 018	< 8.2
Instrument Wrapper	Long	2/27	2nd	604	482	11 338	< 0 29	< 0 014	< 6 8
Instrument Wrapper	Long	2/28	1st	617	477	10 772	< 0 50	< 0 026	< 12 3
Instrument Wrapper	Long	2/28	2nd	648	480	11 125	< 0 50	< 0 025	< 12.0
Sterilizer Operator	Short	2/26	1st	539	5 2	0 319	0.70	1 218	6 3
Sterilizer Operator	Short	2/26	1st	541	5 2	0 334	0 80	1 329	6.9
Sterilizer Operator	Short	2/26	2nd	586	5 9	0 365	< 0 29	< 0 441	< 2 6
Sterilizer Operator	Short	2/26	2nd	552	5 9	0 382	< 0 33	< 0 479	< 2 8
Sterilizer Operator	Short	2/27	1st	584	4 4	0 270	0 80	1 644	7 2
Sterilizer Operator	Short	2/27	1st	592	4 4	0 282	0 99	1 948	8.6
Sterilizer Operator	Short	2/27	2nd	605	3 8	0 233	< 0 29	< 0 691	< 2 6
Sterilizer Operator	Short	2/27	2nd	598	3 8	0 244	< 0 29	< 0.660	< 2.5
Sterilizer Operator	Short	2/28	1st	620	4 7	0 289	< 0 50	< 0 960	< 4.5
Sterilizer Operator	Short	2/28	1st	626	4.7	0 302	1 40	2 573	12 1
Sterilizer Operator	Short	2/28	2nd	639	3 1	0 193	2 00	5.751	17 8
Sterilizer Operator	Short	2/28	2nd	633	3 1	0 202	< 0 50	< 1 374	< 4 3
Above Sterilizer Door	Long	2/26	1st	579	489	4.710	< 0 33	< 0 039	< 19 0
Above Sterilizer Door	Long	2/26	1st	548	489	9 858	< 0 33	< 0 019	< 9 1
Above Sterilizer Door	Long	2/26	2nd	551	497	5 230	0 50	0 053	26 4
Above Sterilizer Door	Long	2/26	2nd	587	497	9 182	0 85	0 051	25.5
Above Sterilizer Door	Long	2/27	1st	608	495	4 720	1 00	0 118	58 2
Above Sterilizer Door	Long	2/27	1st	557	495	9.878	1 90	0 107	52 8
Above Sterilizer Door	Long	2/27	2nd	583	493	5 191	< 0 33	< 0 035	< 17.4
Above Sterilizer Door	Long	2/27	2nd	594	493	9 114	< 0 29	< 0.018	< 8 7

Table A-2. Charcoal tube sample results, continued

SURVEY: Bronson Methodist Hospital, Kalamazoo, Michigan, February 26-28, 1985

SAMPLE DESCRIPTION	TERM	DAY	SHIFT	SAMPLE NO.	TIME min.	VOL L.	EtO µg	EtO ppm	EtO ppm-min
Above Sterilizer Door	Long	2/28	1st	623	513	4 947	0 50	0 056	28 8
Above Sterilizer Door	Long	2/28	1st	606	513	10 353	1.45	0 078	39.9
Above Sterilizer Door	Long	2/28	2nd	668	477	5 060	< 0 50	< 0 055	< 26 2
Above Sterilizer Door	Long	2/28	2nd	610	477	8 885	3 40	0 212	101.3
Wrapping Table	Long	2/26	1st	553	489	10.735	< 0 33	< 0 017	< 8.3
Wrapping Table	Long	2/26	2nd	595	492	11 055	< 0 29	< 0 015	< 7.2
Wrapping Table	Long	2/27	1st	596	495	10.747	< 0 29	< 0 015	< 7.4
Wrapping Table	Long	2/27	2nd	602	491	10.816	< 0 29	< 0 015	< 7.3
Wrapping Table	Long	2/28	1st	612	512	11 254	1 30	0 064	32 8
Wrapping Table	Long	2/28	2nd	651	482	10 709	< 0 50	< 0 026	< 12.5
Above Sterilizer Door	Short	2/26	1st	542	5.6	0 363	2 20	3 364	18 8
Above Sterilizer Door	Short	2/26	1st	585	5 6	0 346	2 61	4 187	23.4
Above Sterilizer Door	Short	2/26	2nd	556	6.7	0 437	1.10	1.397	9 4
Above Sterilizer Door	Short	2/26	2nd	555	6 7	0.416	0 90	1 201	8 0
Above Sterilizer Door	Short	2/27	1st	597	0	0 000	< 0 29	< 0 000	< 0.0
Above Sterilizer Door	Short	2/27	1st	593	0	0 000	< 0 29	< 0.000	< 0 0
Above Sterilizer Door	Short	2/27	2nd	618	5 0	0 327	1 20	2 037	10 2
Above Sterilizer Door	Short	2/27	2nd	600	5 0	0 312	0.44	0 783	3.9
Above Sterilizer Door	Short	2/28	1st	634	5 3	0 343	8 78	14.207	75 3
Above Sterilizer Door	Short	2/28	1st	614	5 3	0 327	3 20	5 431	28 8
Above Sterilizer Door	Short	2/28	2nd	613	4 4	0 286	1.40	2 717	12 0
Above Sterilizer Door	Short	2/28	2nd	621	4 4	0.272	0 60	1 224	5 4
Field Blank		2/26	1st	549			< 0 33		
Field Blank		2/26	1st	581			< 0 33		
Field Blank		2/26	2nd	532	80		< 0 33		
Field Blank		2/26	2nd	554	80		< 0.33		
Field Blank		2/26	2nd	580			< 0 33		
Field Blank		2/27	1st	590			< 0 29		
Field Blank		2/27	1st	601			< 0.29		
Field Blank		2/27	2nd	609	60		5.44		
Field Blank		2/27	2nd	632			< 0.5		
Field Blank		2/28	1st	622			< 0 5		
Field Blank		2/28	2nd	645	510		< 0 5		
Field Blank		2/28	2nd	649			< 0.5		
Quality Assurance Q1262				630			11 2		
Quality Assurance Q1407				641			5 37		
Quality Assurance Q1410				647			14 2		
Quality Assurance Q1412				650			3 4		

Table A-3 Samples analyzed by gas chromatography

SURVEY Bronson Methodist Hospital, Kalamazoo, Michigan, February 26-28, 1985

Activity and Location	2/26/85		2/27/85		2/28/85			
	Ethylene Oxide Concentrations in PPM							
	Test	Normal	Test	Normal	Test	Normal	Average	SD
Sterilizer Operator-breathing zone during load transfer	3 5	2	5 2	0 6	5 2	0 5	2 83	1 95
Over Sterilizer Door-during load transfer	---	31	27	1 7	4 4	1 9	13 2	13
Sterilizer Chamber Interior-before load removal	3200	3200	4200	2750***	2800	1615	2960	767
Recess Room-drain area during 1st vacuum	430	42			380	66*	229 5	176 6
Recess Room-safety valve during 1st vacuum		14	3 9		380		132 6	175
Recess Room-drain area after 2nd vacuum complete	0 5						0 5	--
Recess Room-drain during load transfer		53**					53	--
Recess Room-drain ___minutes after load transfer completed								
0 minutes				545			545	--
1		7					7	--
4		5					5	--
5	1			2 4			1 7	0 7
7				3 2			3 2	--
8				2 5			2 5	--
29	0 7						0 7	--
Recess Room-safety valve ___minutes after load transfer completed								
0 minutes				3 6			3 6	--
5			5 9				5 9	--
8			1 6				1 6	--
14			2 8				2 8	--
Recess Room-floor near front of sterilizer during 1st vacuum						302	302	--
Recess Room-floor near back of sterilizer during 1st vacuum						0 3	0 3	--
Sterilizer Chamber Interior-before loading for sterilization			7 7	26	20		17 9	7 6
Sterilizer Chamber Interior-2 hr after door closed upon completion of transfer		32					32	--

* During the evacuation of an aborted cycle
** Bag valve not fully open
***Line not purged during sample collection

Table A-4 Infrared results for area location in front of sterilizer

SURVEY. Bronson Methodist Hospital, Kalamazoo, Michigan, February 26-28, 1985

Date mo/dy/yr	Shift	Load	Peak ppm	Time min	Duration min	Area ppm-min
02/26/85	A	Test	6	1 5	9	23
	B	Norm	5	1	8	15
02/28/85	A	Test	8	1.7	12	37

Table A-5. Ventilation flow rates, cfm

SURVEY: Bronson Methodist Hospital, Kalamazoo, Michigan, February 26-28, 1985

	Design values 1974	Revised values 1976	Modification 1981	Measured values 1985
S-1	225	200	*	180
S-2	225	200	*	260
S-3	450	400	*	330
S-4	450	400	*	340
S-5	450	400	*	370
S-6	450	400	*	350
S-7	450	400	*	140
S-8	450	400	*	310
S-9	540	400	*	470
S-10	540	400	*	300
S-11	540	400	*	290
S-12	540	400	*	250
S-13	540	400	*	480
S-14	100	50	*	20
S-15	250	200	*	200
S-16	250	200	*	270
S-17	200	200	*	120
S-18	200	200	*	150
S-19	200	200	*	240
S-20	335	300	*	260
S-21	335	300	*	275
X-1	450	400	0	0
X-2	V-2	V-2	450	570
X-3	1200	1200	450	350
X-4	*	*	150	10
X-5	*	*	150	60
X-6	*	*	150	75
X-7	*	*	150	**
X-8	*	*	150	560
X-9	*	*	1100	960
X-10	2800	2100	*	1420
X-11	100	50	*	20
X-12	400	400	m	***
X-13	400	400	m	***
V-1	400	400	600	75
V-2	400	400	X-2	X-2
V-3	400	400	600	70
V-4	400	400	*	10
V-5	400	400	*	15
V-6	400	400	*	10

* Value not specified on drawing
** Not measured
*** Value not documented