IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

ST. FRANCIS/ST. GEORGE HOSPITAL
CINCINNATI, OHIO

REPORT WRITTEN BY.
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SIC CODE:	8062 (General Medical and Surgical Hospitals)
SURVEY DATE:	January 21-25, 1985
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INTRODUCTION

BACKGROUND FOR CONTROL TECHNOLOGY STUDIES

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

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

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 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

A preliminary survey was conducted in the Supply, Processing, and Distribution (SPD) Department of St. Francis/St. George Hospital on May 11, 1983. This preliminary survey indicated that the SPD Department had instituted engineering control technology for minimizing employee exposure to EtO and had developed a comprehensive program to protect its employees. The sterilizer, an AMSCO Model 2025, is equipped with AMSCO's Envirogard® system for worker exposure protection. This system includes a post-sterilization purge cycle and local exhaust of the drain, and sterilizer doors. Additional exhaust ventilation was provided above the aerator door and over the EtO cylinders.

Based on this information, it was determined that the hospital might fulfill the requirements of the study category specifying: a free-standing (not enclosed in a recess room) sterilizer using a 12:88 EtO and Freon 12 mixture, extra evacuation phases at the end of the sterilizer cycle, vented evacuation drain controls, and local exhaust ventilation other than just above the sterilizer door.

This in-depth survey of the Supply, Processing, and Distribution (SPD) Department of St. Francis/St. George Hospital was conducted on January 21-25, 1985 to evaluate its operations and associated controls for EtO exposure. This report documents the information pertinent to that evaluation.

POTENTIAL HAZARDS AND EXPOSURE GUIDELINES

Workers exposed to EtO may experience both acute and long-term health effects. EtO is a central nervous system depressant, and in air can cause acute irritation to the eyes, upper respiratory tract, and skin at concentrations of several hundred to 1,000 ppm. Exposure to high

concentrations may also cause headache, dizziness, nausea, and vomiting. Dilute (1 percent) aqueous solutions can cause blistering of human skin after prolonged contact, and allergic sensitization can also occur in some individuals.[1]

NIOSH has conducted animal toxicity studies to determine the possible long-term health effects of EtO exposure. The results of the NIOSH studies support the conclusions of other researchers that EtO is a mutagen and a carcinogen in animals. The studies showed an increase in sister chromatid exchanges and in chromosomal aberrations, evidence of mutagenic activity. The studies also showed an increase in the frequency of leukemia, peritoneal mesotheliomas, and cerebral gliomas. Adverse reproductive effects were also observed.[2]

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.[3]

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.[3]

In addition to the OSHA PEL of 1 ppm, the standard mentions an action level of 0.5 ppm, above which semi-annual monitoring is required. The American Conference of Governmental Industrial Hygienists has also adopted 1 ppm as an 8-hour time-weighted average Threshold Limit Value (TLV); however, they had allowed for an excursion limit such that short-term exposures should exceed 3 ppm no more than 30 minutes during a workshift and should never exceed 5 ppm. 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.

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 workroom atmosphere.

Opening of the Sterilizer Door

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

Transferring the Sterilized Load

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

SECONDARY EXPOSURE SOURCES

Other exposure sources may not be as readily apparent nor be encountered daily, but may also have the potential to cause significant exposures and/or contribute to the background concentration of EtO. Some of these sources may release EtO only when an accident occurs.

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 contribute to the background EtO concentration.

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 accidently discharged, a large quanity 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, EQUIPMENT, AND PROCESS DESCRIPTION

HOSPITAL AND SUPPLY, PROCESSING, AND DISTRIBUTION DEPARTMENT DESCRIPTION

St. Francis/St. George is a three-year-old hospital located in Western Cincinnati, which was built to consolidate two older facilities. The 6-story hospital occupies about 300,000 square feet of area and employs approximately 1,200 persons. St. Francis/St. George Hospital is a not-for-profit, acute care facility with 290 beds. Services which the hospital provides include. general surgery, orthopedic surgery, and neurosurgery.

Ethylene oxide gas sterilization operations for the hospital are conducted only in the Supply, Processing, and Distribution (SPD) Department, located on the first level. This department performs EtO sterilization for surgery, anesthesiology, respiratory therapy, the catheterization laboratory, x-ray, and emergency.

Sterilization is conducted to decontaminate medical supplies, surgical instruments, and other equipment. Most items are subjected to steam sterilization. However, heat sensitive items (e.g., telescopic instruments, plastic, and rubber goods) for which steam sterilization is impractical, are sterilized using EtO. This gas sterilant is capable of killing viable microorganisms, thus decreasing the incidence of bacterial infections. Ethylene oxide gas sterilization is conducted within the Supply, Processing, and Distribution (SPD) Department located on the first level. There are 41 persons employed in the sterilization area, distributed over 3 shifts. About one half of these employees are working in areas of potential EtO exposure (clean room and decontamination area). The layout of the SPD Department is diagramed in Figure 1. Of particular interest in this study are the clean room and the decontamination area which share a common wall. The gas sterilizer and the aerator are recessed in this wall, flush on the clean room side. The mechanical components of the sterilizer and aerator extend into the decontamination area and are enclosed in metal cabinets.

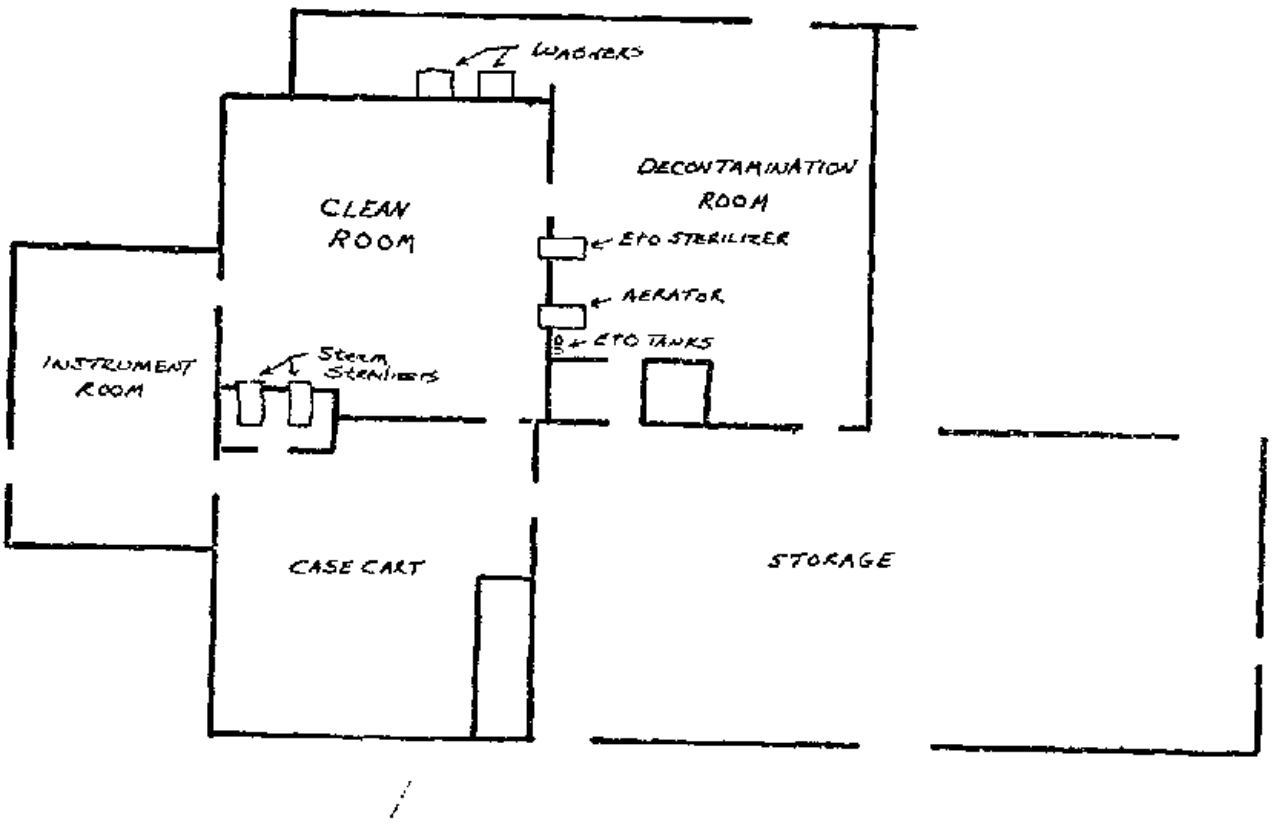

Figure 1. Layout of the Supply, Processing, and Distribution (SPD) Department.

EQUIPMENT AND PHYSICAL DESCRIPTION

The gas sterilizer, an American Sterilizer Company (AMSCO) Eagle Model 2025, has a chamber size of 20 x 20 x 38 inches. This unit is of the pass-through variety, and is equipped with a microcomputer-programmed control feature that carries sequential instructions for each cycle. This feature is designed to assure sterilization cycle accuracy and alerts the operator in the event of a malfunction. An illuminated front control panel provides the following information for the operator:

1. Status of the sterilizer operation: conditioning, sterilization, exhausting, or complete; visual and/or audible alert in the event of an unlocked door, temperature drop, gas leak, or power failure.

2. Sterilizer TIME: digital readout and countdown in hours and minutes.

3. CYCLE Selector: activates and visually displays the cycle for each load-type.

The EtO sterilizer is enclosed in a metal cabinet; drain and mechanical components of the sterilizer are separated from the clean room by a concrete wall. Only the door and control panel of the sterilizer are in the clean room. The sterilizer is equipped with AMSCO's "Envirogard" system for worker exposure protection. This system includes a post-sterilization purge cycle and a local exhaust ventilation system. The sterilizer cycle includes two deep vacuums (26 in. Hg) and a 20 minute air flush to minimize the concentration remaining in the chamber at the end of the cycle.

The aerator is an AMSCO Model 171GA1 with a chamber measuring 24 x 36 x 36 inches. It is located next to the gas sterilizer. Like the sterilizer, the aerator is enclosed in a metal cabinet; mechanical components of the aerator are separated from the clean room by a concrete wall. Only the door and control panel are in the clean room.

Ethylene oxide is supplied by two gas cylinders located in the decontamination area. EtO is supplied premixed with a halocarbon, dichlorodifluoromethane (Freon 12) to render it nonexplosive. The two cylinders are located under a canopy hood next to the aerator cabinet.

Sterilizer Cycle Features:

The sterilizer provides for both "hot" (140°F) and "cold" (105°F) sterilization cycles. The "hot" cycle lasts about 2 hours and 45 minutes; it includes an initial vacuum (26 in. Hg), humidification, EtO charging (8 psig for 1 hour and 45 minutes), 2 post vacuums (26 in. Hg), and a repeating 20-minute chamber air flush. The "cold" cycle lasts about 7 hours; it includes an initial vacuum (26 in. Hg), humidification, EtO charging (8 psig for 6 hours), 2 post vacuums (26 in. Hg), and a repeating 20-minute chamber air flush. 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 dual-load system will switch to a full tank and continue the cycle uninterrupted.

Local Exhaust Ventilation

The Envirogard® system provides local exhaust at two points: above the sterilizer door and at the exit drain. A 3/4 x 24 inch slot hood is located above the door on each side of the sterilizer. Hot EtO-laden air from the chamber is drawn by a blower (located in an enclosure above the sterilizer) through two, two-inch flexible exhaust ducts to a dedicated exhaust vent (shared with the aerator, aerator door hood, and tank canopy) to the outside of the building. The measured airflow is approximately 50 - 60 cfm for each door.

The drain area beneath the sterilizer unit is exhausted via the same blower assembly. Ventilation is required here to collect EtO removed from the sterilizer chamber. At the end of the sterilization cycle EtO gas is drawn by vacuum from the chamber by a water sealed vacuum pump which discharges to the exit drain. An enclosing hood surrounds the drain air break except for two 2 inch x 2 inch vent holes. Indraft through these openings measured 400 fpm, for an exhaust rate of about 22 cfm. The metal cabinet serves as a ventilated enclosure for the gas sterilizer. Exhaust ventilation for this cabinet is provided by the drain hood, located within this enclosure.

Hospital personnel designed and installed an exhaust hood over the aerator door. This hood consists of a Plexiglas® and sheet metal canopy measuring 10 inches deep by 30 inches wide. The vent is connected to the dedicated system which exhausts the Envirogard® system, the tank hood, and the aerator cabinet. The hood is designed to capture EtO laden air rising when the aerator door is opened.

Since leaks or gas cylinder changing operations can result in a significant EtO release, the gas cylinders are ventilated with a 13 inch deep by 30 inch wide canopy hood. Airflow for this hood measured 330 cfm.

General Ventilation

A constant-volume dual-duct heating/air conditioning system supplies air to all hospital departments. At the time of the survey (heating season), supply air was comprised of approximately 25 percent fresh (outdoor) air, and 75 percent recirculated air.

PROCESS DESCRIPTION

The sterilization process is conducted as follows: contaminated materials are plastic-bagged at the site of use and placed on metal carts in "soil rooms" on each of the five hospital floors. These items are delivered to the decontamination area of SPD via a small lift designed for this purpose. Heat-sensitive items are processed by hand or machine washing. Non-heat sensitive items are initially decontaminated by washing and steam sterilization.

Prior to sterilization, the materials are properly wrapped or packaged and labeled. Non-heat-sensitive items are terminally sterilized in steam sterilizers. Heat-sensitive items are cleaned in the decontamination area and

transferred to the clean room. There they are packaged, labeled, and loaded into wire baskets. The wire baskets are loaded into the EtO sterilizer from the clean room side and are gas sterilized. The door on the decontamination side of the "pass-through" sterilizer is not utilized.

Transferring the load

At the end of the sterilization cycle a buzzer sounds alerting the operator that the door may be opened. The operator first opens the aerator, removes and puts on a pair of cotton gloves, opens the sterilizer door and transfers the wire baskets one-by-one from the sterilizer to the aerator. The operator takes off the gloves, placing them in the aerator, then closes both the aerator and sterilizer doors. Last, the aerator door is labeled with the time of the load. After aeration for 12 hours, sterile items are stored or delivered as needed to surgery or other hospital departments.

Typically, the SPD Department runs two or three "cold" sterilization cycles per day. Sterilization cycles are only started if space will be available in the aerator at cycle completion. The "hot" cycle is not routinely used.

Replacing an EtO Supply Cylinder

Ethylene oxide gas is supplied by two gas cylinders located in the decontamination area. A dual-load system is used where the second tank acts as a reserve gas supply when the first is empty. This system automatically switches from an empty tank to a full one without requiring operator intervention. The maintenance department is responsible for changing EtO cylinders.

Preventive Maintenance

The SPD Department has a preventive maintenance contract with the sterilizer manufacturer with routine evaluations. The maintenance protocol specifies the evaluation of the EtO sterilizer and aerator 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 also check for leaks or provide minor service as requested by the SPD Supervisor.

Monitoring

The SPD Department has twice requested evaluation by the Industrial Commission of Ohio (ICO). On their initial visit EtO was detected coming out of the canopy hood located above the aerator door while the sterilizer was in the exhaust (purge) cycle. Hospital maintenance personnel were able to determine that the main exhaust fan was not operating due to a broken belt. A exhaust fan mounted on the sterilizer (part of the Envirogard®) vented to the same duct shared with this hood, the canopy above the tanks, and the aerator. Therefore, the ICO concluded that EtO could enter the SPD department via the exhaust duct system, if the main exhaust fan was inoperative. They recommended the installation of a flow monitor and alarm in the main exhaust

duct. The hospital followed these recommendations, installing a sail switch in the main exhaust duct connected to an alarm. The hospital also has both a monitoring and maintenance contract with AMSCO. Personal exposure monitoring is done on a semi-annual basis by AMSCO.

Work Practices

Work practices may have an important effect on the potential exposure an employee may receive. Work practices for EtO handling and sterilizer operation are specified in a procedure/policy manual. Hazard information and sterilizer operation instructions are posted beside the sterilizer. Employee education on the hazards of EtO exposure and its proper handling is an important part of the department's control program. New employees are given on the job training. Department personnel are provided with in-service training from the sterilizer manufacturer. Selected personnel have also attended seminars on ethylene oxide.

METHODOLOGY

To evaluate the effectiveness of the engineering control measures, both short- and long-term concentrations of ethylene oxide were determined and 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 in the Appendix.

MEASUREMENT OF CONTROL PARAMETERS

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

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 connected in series, and the sampling train was contained in a plastic holder. MDA pumps were calibrated at approximately 10 or 20 milliliters of air per minute (ml/min) for long-term (8 hours) air samples and 50 or 100 ml/min for short-term (15 minutes) samples.

Personal long-term samples were used to estimate time-weighted average exposures for the sterilizer operator and an instrument wrapper. Area samples indicate the effectiveness of the engineering controls by measuring the EtO which is in the workplace air near potential exposure areas. Long-term area samples were located at a fixed location approximating the operator's breathing zone in front of the sterilizer and 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 at the sound of the buzzer until she had finished transferring the load to the aerator and walked away from the sterilizer.

Gas Bag Sampling

Personal and area bag samples were collected using DuPont pumps calibrated at approximately one or five liters per minute (L/min) during certain events: load transfer from sterilizer to aerator, sterilizer chamber concentration at the end of the cycle, drain area, and atop the sterilizer cabinet (decontamination side) during chamber purge, and others. Each event was not sampled every cycle, and there were some differences in the way the samples were collected from cycle to cycle to help answer some other questions about the emission of EtO other than how much is present at some point and time. For the same reason, other specific samples were collected once or twice. These bag samples were analyzed on site using a portable gas chromatograph.

Infrared Analyzer Monitoring

Due to the sporadic nature of EtO release during the day, it seemed desirable to have a continuous record of the EtO concentrations in the breathing zone in front of the sterilizer. An infrared analyzer was used to monitor the EtO concentration at the area location in front of the sterilizer. This identified any significant emissions of EtO into the breathing zone in front of the sterilizer associated with certain events.

Peak concentrations cannot 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-constant of 1 minute and a 90-percent response time of approximately 3 minutes. Thus, short concentration peaks (such as those associated with the load transfer) may be underestimated by the IR analyzer, although the concentration-time product (ppm-min.) may be closely approximated.

Since the clean room also contains steam sterilizers, the potential exists for fluctuating humidity. Laboratory experiments showed the infrared analyzer responded to an increase in the humidity of the sampled air by indicating a higher concentration of EtO than 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 integrated with a humidity-temperature monitor. The IR analyzer and the humidity-temperature monitor were attached to a dual-pen strip chart recorder to provide a continuous graphic record of changing humidity levels and measured EtO concentrations.

Air Flow Measurements

The volumetric air flow for exhaust hoods was determined by measuring air velocities across hood (or slot) faces and multiplying the average result by the hood (slot) area. General ventilation supply air and exhaust flow volumes were measured at the ceiling diffusers/exhaust vents using a velometer flow hood. Smoke tubes were used to qualitatively assess airflow patterns and the results recorded on videotape.

Work Practice Observations

The work practices of the sterilizer operator may have a very important effect on the amount of EtO released into the workplace air and on his own exposure. To evaluate this effect, observations of the 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-pac". The number of packages is adjusted to the volume of the sterilizer of interest, corresponding to a 30 percent load level. For the 9-ft^3 volume sterilizer, 66 packages were used. The rubber materials of this test load were chosen because EtO is absorbed into rubber during sterilization and off-gases more slowly than some other materials. This increased retention of EtO, provides a challenge to the control system and may aid in evaluating the effectiveness of the controls.

The test load was sterilized on the first shift (day) on the first day of the study and on the second (evening) shift for remaining two days. One normal load was also processed through the EtO sterilizer during these shifts. Sampling data from this test load provides the basis for comparison with similar loads processed in other hospitals.

MEASUREMENT RESULTS

AIR SAMPLING

The results of the analysis of the charcoal tube samples is reported in Table A-2 in the Appendix and summarized in Table 1. All 8 hour twa samples collected in the clean room were below 0.05 ppm. Samples collected atop the sterilizer cabinet in the decontamination area were about an order of magnitude greater, averaging 0.3 ppm. Even in this area all samples were

Table 1 Results of Charcoal Tube Air Samples for Ethylene Oxide (Summarized).
St. Francis/St. George Hospital
Cincinnati, Ohio

Worker/Location	Ethylene Oxide Concentration (ppm)	
	Average	Standard Deviation
Sterilizer operator (full shift)	0.04	0.01
Above sterilizer door (clean side - full shift)	0.05	0.02
Wrapper (full shift)	0.02	0.01
Work table (full shift)	0.02	0.01
Decontamination area (full shift on sterilizer cabinet)	0.30	0.07
Sterilizer operator (load transfer only)	1.9	0.96
Above sterilizer door (load transfer only)	2.4	1.5

below the OSHA action level of 0.5 ppm. Short term charcoal tube samples collected during load transfer operations averaged 1.9 and 2.4 ppm, for the operator and a location above the sterilizer door, respectively. The limit of detection for these analyses was 0.1 ug EtO/sample.

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. Results of these measurements are reported in Table 2. Responses to ordinary load transfer operations generated peak concentrations ranging from 1 to 8.5 ppm, lasting from 1 to about 6 minutes. A single peak concentration of 23 ppm was recorded during the load transfer operation on the final day of the survey. This value was the result of a temporary baffle (discussed later in this report) installed above the sterilizer.

A number of samples were taken in gas collection bags and analyzed with a portable gas chromatograph (GC). The results of all the useable samples are given in Table 3. Average exposure of the operator during load transfer was 0.9 ppm as determined by the GC. Average concentration above the sterilizer door was slightly higher, 1.3 ppm. The lower exposure of the operator relative to the above the door concentration can be attributed to the operator's activities: unloading the sterilizer does not require the operator to remain directly in front of the sterilizer during load transfer. The concentration of EtO remaining in the sterilizer at the cycle end ranged from 320 to 1240 ppm. The operator's exposure was not correlated with the EtO remaining in the sterilizer. The operator's exposure may be related to positional or load factors not identified in this study. Ethylene oxide concentrations within the sterilizer cabinet at the drain area during the sterilizer purge averaged 2.5 ppm, indicating successful containment of the EtO by the drain hood. Concentrations atop the sterilizer cabinet in the decontamination area averaged 1.3 ppm during the purge.

Charcoal tube, gas chromatograph, and MIRAN sampling data for load transfer operations are compared in Table 4. The MIRAN infrared analyzer measurements are higher than those obtained with the GC by as much as an order of magnitude. This discrepancy is unexpected. The sensing cell of the MIRAN has a volume of about 5 liters and the MIRAN sampling pump a flowrate of 5 lpm. This results in an instrument response time of approximately 3 - 5 minutes. Thus, short concentration peaks (as those associated with the load transfer) may be underestimated by the MIRAN.

Table 2. Average Peak Ethylene Oxide Concentration as Determined with the MIRAN Infrared Analyzer.

Load	Peak ppm	Duration minutes	Total ppm-minutes	Average ppm
01/22 - Day - Normal	5.0	4.5	11.3	2.5
01/22 - Day - Test	3.5	4.0	7.0	1.8
01/22 - Evening - Normal	1.0	0.0	0.0	1.0*
01/23 - Day - Normal	4.0	4.0	8.0	4.0
01/23 - Evening - Normal	1.0	6.0	3.0	0.5
01/23 - Evening - Test	7.0	2.5	8.8	3.5
01/24 - Day - Normal	8.5	5.0	21.3	4.3
01/24 - Evening - Normal	1.0	1.5	1.5	1.0
01/24 - Evening - Test	23.0	2.0	23.0	12.0

*indicates less than stated concentration.

Table 3. Ethylene Oxide Concentration as Determined by Gas Chromatography.

Location/Activity	Ethylene Oxide Concentration (ppm)									Average
	01/22			01/23			01/24			
Shift:	1	1	2	1	2	2	1	2	2	
Load:	Norm	Test	Norm	Norm	Norm	Test	Norm	Norm	Test	
Operator (load transfer)	0.2	0.9	0.5	0.9	0.5	1.2	1.0	0.1*	2.6	0.9
Operator (loading sterilizer)	-	-	-	-	-	-	-	-	0.6	0.6
Above sterilizer door (unloading)	0.1	0.1*	0.9	1.4	0.7	1.7	3.8	0.4	2.9	1.3
Above sterilizer door (loading)	-	-	-	-	-	-	-	-	2.7	2.7
Sterilizer interior (cycle end)	-	790	1240	610	410	400	1240	320	510	690
Sterilizer interior (loading)	-	-	-	-	120	-	-	-	-	120
Drain area (during purge)	1.2	0.7	0.2	2.7	4.5	4.3	4.2	2.1	-	2.5
Decontamination room (purge)	-	1.1	0.1*	0.9	1.2	-	1.7	2.5	-	1.3
Drain cleanout (after purge)	-	-	-	-	-	-	-	0.2-	-	0.2
Below Sterilizer door (transfer)	-	-	-	-	-	-		0.7	-	0.7
Drain (cart wash area)	-	-	-	-	-	-	-	0.5	-	0.5

Table 4. Comparison of Charcoal Tube, GC, and MIRAN Sampling Data During Load Transfer.

Sample	Date	Shift	Load	Ethylene Oxide Concentration (ppm)		
				Charcoal	GC	MIRAN
Operator	01/22	1	Normal	1.3	0.2	--
	01/22	1	Test	1.3	0.9	--
	01/22	2	Normal	2.7	0.5	--
	01/23	1	Normal	1.3	0.9	--
	01/23	2	Normal	--	0.5	--
	01/23	2	Test	1.6	1.2	--
	01/24	1	Normal	2.5	1.0	--
	01/24	2	Normal	3.5	2.6	--
	01/24	2	Test	0.47	0.1*	--
	Average:			1.8	0.9	--
	Standard Deviation:			1.0	0.7	--
Over Door	01/22	1	Normal	2.0	0.1	2.5
	01/22	1	Test	2.5	0.1*	1.8
	01/22	2	Normal	1.6	0.9	1.0*
	01/23	1	Normal	1.9	1.4	4.0
	01/23	2	Normal	0.84	0.7	0.5
	01/23	2	Test	2.3	1.7	3.5
	01/24	1	Normal	3.3	3.8	4.3
	01/24	2	Normal	1.1	0.4	1.0*
	01/24	2	Test	5.9	2.9	12.0
	Average:			2.4	1.3	3.4
	Standard Deviation:			1.5	1.3	3.5

*indicates less than stated concentration.

VENTILATION MEASUREMENTS

The principal ventilation controls studied were the enclosing hood around the drain air break, the slot hoods above the sterilizer doors, and the canopy hoods above the aerator door and the EtO supply tanks. Measurements of volumetric flow rate and face velocity for the exhaust hoods are presented in Table 5. Measurements of volumetric flow rate for the supply air and exhaust of the SPD department are presented in Table 6. These measurements indicate that within the instrumental accuracy (+/- 5%), the exhaust and supply flows of the SPD department are balanced. Within the SPD department, the sterile areas (clean, instrument, and case cart rooms) have supply air slightly in excess of exhaust, while in the decontamination area the situation is reversed. This results in a general flow of air from the peripheral rooms into the decontamination area. Since the mechanical components of the sterilizer are located in the decontamination area, any failures likely to release large quantities of ethylene oxide would initially confine the hazard to this area.

WORK PRACTICE OBSERVATIONS

The exposure times are relatively short (less than 2 minutes) for both operators, considering that the baskets had to be transferred manually to the aerator. The operators were observed to turn their faces away from the sterilizer while unloading, increasing the distance of their breathing zone from the sterilizer. Work practices were not observed during a cylinder change operation, because no cylinder changes took place during this survey.

CONTROL EVALUATION

Control of the full-shift exposures, as measured with charcoal tubes, is excellent. No 8 hour twa exposure of the sterilizer operator and the instrument wrapper exceeded 0.05 ppm; average exposures measured were 0.04 ppm for the sterilizer operator and 0.02 ppm for the instrument wrapper. Long-term area samples averaged 0.02 ppm at the work table, 0.04 ppm at the sterilizer door, and 0.3 ppm atop the sterilizer cabinet in the decontamination area. Likewise, short-term exposures are well-controlled. Short-term charcoal tube results averaged 1.9 ppm for the sterilizer operator and 2.4 ppm for the sterilizer door location. Peak exposures measured in the breathing zone of the operator with a sampling bag/gas chromatograph did not exceed 2.6 ppm. The peak exposures were not only low, but the durations were short, lasting no more than a few minutes.

DRAIN CONTROLS

An enclosing hood surrounded the air break with two 2 inch x 2 inch vent holes and the drain line was sealed at the floor. The velocity through these holes must be sufficient to overcome any transient room air currents, typically on the order of 25 to 50 fpm. An air velocity of 400 fpm was measured through these openings, which is more than adequate to meet this criteria. As a minimum, the volumetric exhaust flow rate of this hood must exceed the vacuum

Table 5. Local Exhaust Flow Rate Measurements (Gas sterilizer system)
Supply, Processing, and Distribution (SPD) Department
St. Francis/St. George Hospital
Cincinnati, Ohio

Exhaust hood	Slot or face velocity (fpm)	Flowrate (cfm)
Slot (3/4" x 24") above sterilizer door (clean side)	375	50
Slot (3/4" x 24") above sterilizer door (decontamination side)	460	60
Enclosing hood around drain air break (2 2" x 2" openings)	400	20
Canopy hood (10" x 30") above aerator door	240	440
Canopy hood (13" x 30") 8" above EtO cylinders	120	330

Table 6. Volumetric Flow Rate Measurements (Supply and Exhaust)
Supply, Processing, and Distribution (SPD) Department
St. Francis/St. George Hospital
Cincinnati, Ohio

Location	Supply (cfm)	Exhaust (cfm)
Case cart room	610	540
Clean room	1800	1900
Decontamination area	3700	4100
Instrument room	550	470

pump discharge rate if spillage is to be avoided. Examination of the slope of the chamber pressure curve on the sterilizer chart allowed estimation of the pump discharge rate at about 2 or 3 cfm. Measured exhaust flow rate was about 22 cfm, which exceeded this minimum requirement.

DOOR CONTROLS - STERILIZER

The control of emissions when the sterilizer door is opened involves reducing the quantity of EtO remaining in the chamber, and capturing as much as possible the air escaping from the sterilizer. The air flush period seemed effective in reducing the amount of EtO remaining in the sterilizer by an order of magnitude. Measurements of the chamber concentration immediately after the door was opened ranged from approximately 300 to 1200 ppm.

This department removes the load from the sterilizer immediately at the end of the cycle. Based on the air flow patterns observed with smoke tubes, the slot hood over the sterilizer door seemed to control emissions from the door out to a distance of about 3 inches. Measured air flow was 120 cubic feet per minute (cfm).

The American Conference of Governmental Industrial Hygienists publishes a handbook entitled: Industrial Ventilation - A Manual of Recommended Practice[4]. 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, fpm
X= distance from the sterilizer , ft.

For this particular process, the control velocity should be between 50 and 100 feet/min -- with the upper limit of the range recommended. In this case the volumetric flowrate is known (50 cfm). Solving the above equation for X, the capture distance, yielded 2 inches. Observation of chemical smoke indicated the slot hood was able to capture to a distance of about 3 inches. Smoke released at distances greater than 3 inches from the slot moved in a downward direction in front of the sterilizer due to the supply air diffuser. It was initially felt that this supply air may have interfered with the effectiveness of the slot hood located above the sterilizer door. To test this hypothesis a 10 inch by 30 inch wide cardboard baffle was temporarily installed immediately above the sterilizer to block the flow from the diffuser (day 3, test load only). This baffle increased the capture distance of the slot hood to about 6 inches; however, short term measurements of EtO were higher for this load transfer than for those without the baffle. Apparently the beneficial effect of the downward flow of clean air across the breathing zone of the operator more than compensates for the reduced capture distance of the slot hood.

STERILIZER CABINET EXHAUST

The drain exhaust constitutes the only ventilation of the sterilizer cabinet. Both long and short term samples indicate levels of EtO atop the sterilizer cabinet an order of magnitude greater than in the clean room. Although these levels are below the action level of 0.5 ppm, it does indicate that the drain exhaust, while more than adequate to contain drain emissions, may not be sufficient to contain other leaks which may occur within the cabinet, such as a major release at the safety valve.

ETO TANK HOOD

For the case of a canopy hood, the required exhaust volume is given by

$$Q = 1.4\ PDV$$

where:
Q = the volumetric air flow, cfm,
P = Perimeter of the work, ft.,
V = velocity of the air stream, fpm,
D = height above the EtO tanks, ft.

For the hood above the EtO tanks, the minimum control velocity (V) should be between 50 and 100 feet per minute (fpm). In this case the perimeter of the work area is about 4.7 feet, and the hood is located 6 inches above the tanks. Thus the recommended flowrate would be 330 cfm for a control velocity of 100 fpm. The measured flowrate was exactly 330 cfm.

DOOR CONTROLS - AERATOR

The hood above the aerator is also a canopy hood, which is modified by the presence of a side baffle extending the height of the door on one side and a wall perpendicular to the aerator on the other side. The above equation no longer represents the flow situation. Observation of chemical smoke demonstrated capture at distances of 18 to 24 inches from the aerator door at the measured volumetric flow rate of 440 cfm.

RECOMMENDATIONS AND CONCLUSIONS

This survey indicated that the Supply, Processing, and Distribution (SPD) Department has instituted engineering control technology for minimizing employee exposure to EtO and has developed a comprehensive program to protect its employees. Local exhaust ventilation has been provided in critical areas. Sampling results and ventilation measurements, verified the effectiveness of these controls.

Proper work practices for employees are clearly outlined in a procedure and policy manual, and based on observation of the transfer of loads from the sterilizer to the aerator, the operators follow those procedures.

Decontamination room personnel appear to be at potential risk in the case of an inadvertent release of ethylene oxide from the sterilizer safety

valve or other leaks occuring within the sterilizer cabinet. Fortunately, this condition can be remedied at relatively little cost to the hospital. Addition of sheet metal at the top of the sterilizer cabinet could provide relatively complete enclosure. Since the door on the decontamination side is never used for loading/unloading the sterilizer, a portion of the slot exhaust could be diverted for use at the safety valve.

While a cylinder change operation was not observed, the following points are suggested to ensure safety during this procedure. Installation of a bleed-off valve (leading to dedicated exhaust) is suggested to vent off any gaseous or liquid EtO remaining in the line. Gloves and a face shield should be worn during the cylinder change to protect from contact with liquid EtO. When not in use these goods should be stored under the canopy hood (above the tanks). Maintenance personnel responsible for tank changes should receive training similar to that of the SPD Department personnel.

Environmental monitoring of the department is an important part of the EtO control strategy and is suggested, even though the EtO levels are below the action level. It is recommended that periodic personal sampling be continued for the sterilizer operator over the full shift, and that representative decontamination room personnel also be included in the monitoring program. Additional monitoring may be required in order to comply with the OSHA standard. Without this data it is impossible to judge the continuing effectiveness of the control program.

Based on this survey, the SPD Department should be commended for a very sound program for EtO control.

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4. Committee on Industrial Ventilation, 1982. Industrial Ventilation: A Manual of Recommended Practice, Seventeenth Edition. Lansing, MI: American Conference of Governmental Industrial Hygienists, pp. 4-4,4-5.

APPENDIX

Table A-1. Equipment Used on Field Survey.

Item	Model	Used for
Infrared spectrometer	Miran 1A	continuous area sampling (above sterilizer door)
Infrared spectrometer	Miran 103	continuous area sampling (decontamination area)
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 GC	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

Table A-2.

Results of Charcoal Tube Air Samples for Ethylene Oxide
St. Francis/St. George Hospital
Cincinnati, Ohio

SAMPLE NO.	DESCRIPTION	DAY	SHIFT	FLOW mL/m	TIME min.	VOL. L	ANAL CODE	EtO ug	EtO ppm	EtO ppm-min
#339	Operator (L-T)	1/22	day	(10)	444	4.298	J	0.42	0.054	24.1
#370	Operator (L-T)	1/22	day	(20)	444	8.891	J	0.67	0.042	18.6
#385	Operator (L-T)	1/22	eve	(9)	482	4.364	J	0.34	0.043	20.8
#391	Operator (L-T)	1/22	eve	(20)	482	9.755	K	0.53	0.030	14.5
#382	Operator (L-T)	1/23	day	(10)	424	4.099	J	0.27	0.037	15.5
#387	Operator (L-T)	1/23	day	(20)	424	8.480	J	0.46	0.030	12.8
#410	Operator (L-T)	1/23	eve	(9)	494	4.440	K	0.34	0.042	21.0
#405	Operator (L-T)	1/23	eve	(20)	494	9.926	K	0.78	0.044	21.5
#418	Operator (L-T)	1/24	day	(10)	419	4.068	K	0.30	0.041	17.1
#431	Operator (L-T)	1/24	day	(20)	419	8.417	L	0.63	0.042	17.4
#454	Operator (L-T)	1/24	eve	(9)	494	4.488	L	0.37	0.046	22.6
#439	Operator (L-T)	1/24	eve	(20)	494	10.032	L	0.69	0.038	18.9
#331	Operator (S-T)	1/22	day	(56)	2	0.111	J	0.29	1.450	2.9
#345	Operator (S-T)	1/22	day	(60)	3	0.181	J	0.46	1.410	4.2
#369	Operator (S-T)	1/22	day	(57)	2	0.114	J	0.25	1.217	2.4
#362	Operator (S-T)	1/22	day	(62)	3	0.185	J	0.43	1.290	3.9
#398	Operator (S-T)	1/22	eve	(74)	2	0.147	K	0.79	2.983	6.0
#393	Operator (S-T)	1/22	eve	(76)	2	0.151	K	0.67	2.463	4.9
#380	Operator (S-T)	1/23	day	(58)	3	0.175	J	0.44	1.395	4.2
#414	Operator (S-T)	1/23	day	(60)	3	0.179	K	0.39	1.209	3.6
#409	Operator (S-T)	1/23	eve	(0)	0	0.000	K	0.10*	0.000	0.0
#397	Operator (S-T)	1/23	eve	(62)	4	0.247	K	0.76	1.708	6.8
#319	Operator (S-T)	1/23	eve	(0)	0	0.000	J	0.11	0.000	0.0
#427	Operator (S-T)	1/23	eve	(63)	4	0.253	L	0.69	1.514	6.1
#437	Operator (S-T)	1/24	day	(73)	3	0.220	L	0.93	2.346	7.0
#438	Operator (S-T)	1/24	day	(75)	3	0.226	L	1.10	2.701	8.1
#456	Operator (S-T)	1/24	eve	(65)	2	0.129	L	0.12	0.516	1.0
#441	Operator (S-T)	1/24	eve	(65)	2	0.129	L	0.86	3.700	7.4
#419	Operator (S-T)	1/24	eve	(66)	2	0.133	K	0.10*	0.417*	0.8*
#444	Operator (S-T)	1/24	eve	(66)	2	0.133	L	0.79	3.297	6.6

*indicates less than specified quantity

ANALYSIS CODE=J: February 12, 1985
ANALYSIS CODE=K: February 18, 1985
ANALYSIS CODE=L: February 22, 1985

Table A-2. (continued)

Results of Charcoal Tube Air Samples for Ethylene Oxide
St. Francis/St. George Hospital
Cincinnati, Ohio

SAMPLE NO.	DESCRIPTION	DAY	SHIFT	FLOW mL/m	TIME min.	VOL. L	ANAL CODE	EtO ug	EtO ppm	EtO ppm-min
#363	Wrapper	1/22	day	(20)	436	8.887	J	0.73	0.046	19.9
#386	Wrapper	1/22	eve	(22)	477	10.520	J	0.34	0.018	8.6
#361	Wrapper	1/23	day	(20)	426	8.528	J	0.30	0.020	8.3
#420	Wrapper	1/23	eve	(22)	481	10.462	L	0.36	0.019	9.2
#434	Wrapper	1/24	day	(20)	424	8.482	L	0.31	0.020	8.6
#423	Wrapper	1/24	eve	(22)	493	10.643	L	0.37	0.019	9.5
#344	Decontam. room	1/22	day	(14)	449	6.392	J	4.00	0.347	155.9
#384	Decontam. room	1/22	eve	(13)	492	6.168	J	2.60	0.234	115.1
#392	Decontam. room	1/23	day	(15)	427	6.473	K	2.60	0.223	95.2
#404	Decontam. room	1/23	eve	(13)	495	6.246	K	3.50	0.311	153.9
#435	Decontam. room	1/24	day	(15)	443	6.699	L	4.70	0.389	172.5
#412	Decontam. room	1/24	eve	(13)	482	6.078	K	3.40	0.310	149.6
#324	Work table	1/22	day	(21)	451	9.571	J	0.41	0.024	10.7
#395	Work table	1/22	eve	(22)	477	10.307	K	0.18	0.010	4.6
#396	Work table	1/23	day	(21)	434	9.254	K	0.18	0.011	4.7
#381	Work table	1/23	eve	(22)	493	10.674	J	0.47	0.024	12.0
#432	Work table	1/24	day	(21)	429	9.120	L	0.47	0.029	12.3
#424	Work table	1/24	eve	(22)	493	10.838	L	0.33	0.017	8.3
#341	Sterilizer (L-T)	1/22	day	(10)	448	4.358	J	0.51	0.065	29.1
#371	Sterilizer (L-T)	1/22	day	(17)	448	7.677	J	0.75	0.054	24.3
#389	Sterilizer (L-T)	1/22	eve	(9)	478	4.126	K	0.21	0.028	13.5
#390	Sterilizer (L-T)	1/22	eve	(24)	478	11.606	K	0.65	0.031	14.9
#401	Sterilizer (L-T)	1/23	day	(10)	434	4.196	K	0.18	0.024	10.3
#383	Sterilizer (L-T)	1/23	day	(17)	434	7.392	J	0.46	0.035	15.0
#413	Sterilizer (L-T)	1/23	eve	(9)	493	4.258	K	0.40	0.052	25.7
#399	Sterilizer (L-T)	1/23	eve	(24)	493	11.975	K	0.94	0.044	21.5
#428	Sterilizer (L-T)	1/24	day	(10)	430	4.142	L	0.58	0.078	33.4
#452	Sterilizer (L-T)	1/24	day	(17)	430	7.296	L	0.95	0.072	31.1
#394	Sterilizer (L-T)	1/24	eve	(9)	491	4.235	K	0.37	0.048	23.8
#408	Sterilizer (L-T)	1/24	eve	(24)	491	11.912	K	0.99	0.046	22.6

*indicates less than specified quantity

ANALYSIS CODE=J: February 12, 1985
ANALYSIS CODE=K: February 18, 1985
ANALYSIS CODE=L: February 22, 1985

Table A-2. (continued)

Results of Charcoal Tube Air Samples for Ethylene Oxide
St. Francis/St. George Hospital
Cincinnati, Ohio

SAMPLE NO.	DESCRIPTION	DAY	SHIFT	FLOW mL/m	TIME min.	VOL. L	ANAL CODE	EtO ug	EtO ppm	EtO ppm-min
#329	Sterilizer (S-T)	1/22	day	(62)	2	0.124	J	0.46	2.059	4.1
#318	Sterilizer (S-T)	1/22	day	(59)	3	0.177	J	0.77	2.414	7.2
#359	Sterilizer (S-T)	1/22	day	(62)	2	0.124	J	0.42	1.880	3.8
#325	Sterilizer (S-T)	1/22	day	(59)	3	0.177	J	0.81	2.540	7.6
#388	Sterilizer (S-T)	1/22	eve	(70)	6	0.422	J	1.20	1.578	9.5
#346	Sterilizer (S-T)	1/22	eve	(70)	6	0.423	J	1.20	1.574	9.4
#400	Sterilizer (S-T)	1/23	day	(62)	4	0.248	K	0.77	1.723	6.9
#357	Sterilizer (S-T)	1/23	day	(62)	4	0.249	J	0.90	2.006	8.0
#421	Sterilizer (S-T)	1/23	eve	(68)	3	0.205	L	0.33	0.893	2.7
#422	Sterilizer (S-T)	1/23	eve	(64)	4	0.257	L	0.99	2.138	8.6
#406	Sterilizer (S-T)	1/23	eve	(68)	3	0.205	K	0.29	0.785	2.4
#411	Sterilizer (S-T)	1/23	eve	(65)	4	0.258	K	1.10	2.366	9.5
#436	Sterilizer (S-T)	1/24	day	(73)	3	0.220	L	1.40	3.532	10.6
#426	Sterilizer (S-T)	1/24	day	(74)	3	0.221	L	1.20	3.014	9.0
#416	Sterilizer (S-T)	1/24	eve	(79)	2	0.158	K	0.30	1.054	2.1
#447	Sterilizer (S-T)	1/24	eve	(64)	2	0.127	L	1.50	6.555	13.1
#403	Sterilizer (S-T)	1/24	eve	(79)	2	0.159	K	0.34	1.187	2.4
#429	Sterilizer (S-T)	1/24	eve	(64)	2	0.128	L	1.20	5.203	10.4
#402	Field blank	1/22	day				K	0.10*		
#407	Field blank	1/22	day				K	0.10*		
#350	Field blank	1/22	eve				J	0.21		
#417	Field blank	1/23	eve				K	0.10*		
#415	Field blank	1/23	eve				K	0.10*		
#367	Field blank	1/24	day				J	0.22		
#440	Field blank	1/24	eve				L	0.10*		
#349	Field blank	1/24	eve				J	0.14		
#446	Field blank	1/24	eve				L	0.10*		

*indicates less than specified quantity

ANALYSIS CODE=J: February 12, 1985
ANALYSIS CODE=K: February 18, 1985
ANALYSIS CODE=L: February 22, 1985