IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

EUCLID GENERAL HOSPITAL
EUCLID, OHIO

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
Division of Physical Sciences and Engineering
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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 THIS STUDY

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 urging of workers' groups, OSHA began the rule-making 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 selected engineering controls which hospitals have implemented, and then to disseminate useful information and practicable recommendations on effective methods for controlling occupational ethylene oxide exposure.

BACKGROUND FOR THIS SURVEY

Euclid General 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, 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 was conducted in the CS Department on August 1, 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 has been provided in critical areas. The sterilizer had been modified to include a pulse-purge phase at the end of the cycle. 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 department Director provides education and training on proper work practices and the hazards of exposure to EtO. A continuous EtO monitor and alarm system provided warning for the workers if a severe leak or emergency situation should arise. Euclid General Hospital had a renovated ventilation system in the Central Service (CS) Department and had a local exhaust system to control EtO emissions. In addition, the hospital staff were very conscientious about EtO control and had made every effort of follow the guidelines of the American Hospital Association and the Health Industry Manufacturers Association for the safe and controlled use of EtO in sterilization operations.

This in-depth survey of the Central Service Department of Euclid General Hospital was conducted on September 24-28, 1984 to evaluate its operations and

associated controls for EtO exposure. This report documents the information pertinent to that evaluation.

POTENTIAL HAZARDS AND EXPOSURE GUIDELINES

Workers exposed to EtO may experience both acute and long-term health effects. EtO is a central nervous system depressant, and in air can cause acute irritation to the eyes, upper respiratory tract, and skin at concentrations of several hundred to 1,000 ppm. Exposure to high concentrations may also cause headache, dizziness, nausea, and vomiting. Dilute (1 percent) aqueous solutions can cause blistering of human skin 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 mononuclear cell 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 recess room and/or perhaps to the workroom atmosphere.

Opening of the Sterilizer Door

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

Transferring the Sterilized Load

Some of the EtO used in sterilization remains on the sterile items and wrapping material and inside the package after the sterilization cycle is complete. This EtO will be given off exponentially until equilibrium is reached with the surrounding air; and, depending on the composition of the items and their packaging, these off-gassing items can provide 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 accidentally discharged, a large quantity of EtO would be released. This could result in dangerous concentrations in the vicinity ot the cylinders and in the surrounding work area.

Pressure Relief Valve

Another possible source of EtO is the sterilizer safety valve. If the sterilizer becomes overpressurized during the cycle, this emergency relief valve releases EtO gas. If not controlled or remotely vented, this release may contribute a significant quantity of EtO to the workplace atmosphere.

Maintenance

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

HOSPITAL AND PROCESS DESCRIPTION

HOSPITAL AND CENTRAL SERVICE DEPARTMENT DESCRIPTION

Euclid General Hospital is a not-for-profit, acute care facility with 345 beds. Services which the hospital provides include: general surgery, orthopedic surgery, neurosurgery, cardiovascular catheterization, and infant delivery. The hospital also provides an in-patient rehabilitation unit for patients recovering from severe physical trauma.

The original structure was constructed in the early 1950's, and occupied in the fall of 1952. Since then several additions have been made. The CS Department is located on the second floor of the south wing. The decontamination room is located in the old section of the building while the adjoining clean room is located in a section of the hospital built in 1977.

Ethylene oxide gas sterilization operations for the hospital are conducted only in the Central Service (CS) Department. This department performs EtO sterilization for surgery, obstetrics, anesthesiology, respiratory therapy, the catheterization laboratory, x-ray, and emergency.

The CS Department employs 29 persons distributed over 3 shifts. On the day shift, only one person is assigned to operate the sterilizers and process loads in the sterilization room (known as the clean room). The others spend their time in the following areas: three or four are assigned to decontamination, five are in the preparation and packaging room, and three or four are in the linen room. Additionally, four employees work from 0900 to 1730 or from 1000 to 1830 in floating assignments. The department director,

assistant director, and secretary spend most of their time in offices or moving between the different areas of the department. During the evening shift, one person is assigned to each of the following areas: decontamination, preparation and packaging, linen, and operation of the sterilizers. The night shift employs one person in decontamination and one person in the linen 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 and sterile 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 (two steam, and one EtO) and an aerator that are recessed along one wall.

EQUIPMENT AND PHYSICAL DESCRIPTION

The EtO gas sterilizer is a Sybron-Castle, Sentry Model 400, purchased in 1973. Its internal chamber size is 20-inches by 20-inches by 38-inches, a volume of approximately 9 cubic feet.

The EtO sterilizer is supplied with gas from a cylinder. The two cylinders are located in a vented, double-wall cabinet behind the aerator. They are connected to the sterilizer in a dual-load system through copper piping. This system automatically switches from an empty tank to a full one without requiring operator intervention.

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 hall and is locked to restrict access of unauthorized personnel. The backs of the sterilizers are open to the room, while the backside of the aerator is enclosed in a ventilated cabinet. Steam and water from the sterilizers are emptied into closed drains.

The aerator is a Sybron-Castle Model 4041 with internal dimensions 2-feet by 4-feet by 5-feet, a volume of approximately 40 cubic feet. All items are aerated at 135°F for a minimum 12 hours. Implants are aerated for 30 hours.

Sterilizer Cycle Features

The cycle is five and one-half hours duration, and consists of several phases: initial vacuum, humidification, and temperature adjustment to 140°F (about 30 minutes); EtO charging of the chamber and dwell period (about 4 hours); evacuation and pulse-purge (about 30 minutes).

The pulse-purge phase was added to the sterilizer cycle in 1982. This modification was purchased from the manufacturer. This phase is designed to reduce the amount of EtO remaining in the chamber and the sterile load after the evacuation phase. This may greatly reduce the potential exposure of the operator during the transfer of the load to the aerator. A pulse of fresh, filtered air is injected into the chamber immediately followed by a purging of the chamber through a vacuum of approximately 5 inches water. Each

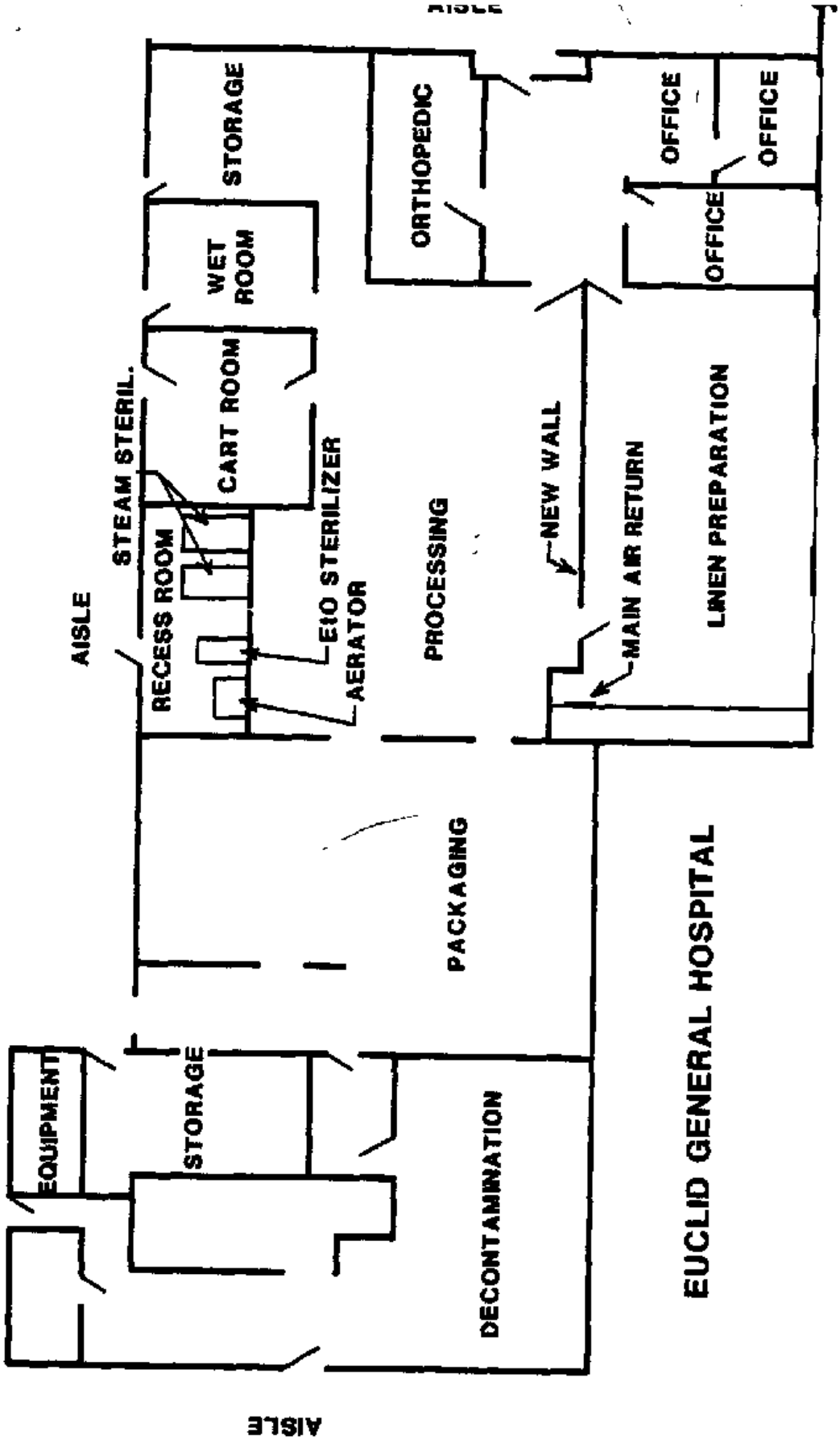

Figure 1. Layout of the CS Department.

pulse-purge takes about 1 minute. This process continues for approximately 30 minutes.

Local Exhaust Ventilation

Local exhaust of EtO emissions is provided by exhaust hoods above the sterilizer, at the drain, at the safety relief valve, and around the EtO cylinders.

The recess room serves as a ventilated enclosure for the gas sterilizer, aerator, two steam sterilizers, and the cylinders of EtO. The recess room is exhausted by a dedicated system through two open duct vents located in the wall near the ceiling. This spring, the fan exhausting the room was replaced. Hospital records indicate the new fan increased the exhaust capacity by 75 percent.

Hospital maintenance designed and installed an exhaust hood over the EtO sterilizer in 1984. This hood consists of a sheet metal canopy measuring 5 1/2 inches deep by 36 1/2 inches wide by 6 inches high. The vent is connected to the dedicated system which exhausts the recess room and the aerator. The hood is located about 17 inches above the sterilizer door. The hood is designed to capture EtO laden air rising as the sterilizer door is opened after the completion of the cycle.

Local exhaust ventilation is also provided for the ventilated air gap (purchased from Castle in 1982) at the attachment to the sterilizer drain. When the sterilizer chamber is evacuated, a mixture of water and EtO passes through the vacuum pump and is discharged to the drain. EtO is exhausted through a duct connected to the dedicated system exhausting the recess room.

The sterilizer safety relief valve is also exhausted through a duct connected to the same dedicated system.

The backside of the aerator located in the recess room is enclosed and vented to the dedicated exhaust system. This control provides exhaust for the EtO off-gassing from the sterilized goods in the aerator.

EtO supply cylinders are enclosed in a double-wall cabinet located behind the aerator in the recess room. Supplied air is provided for the cabinet to keep the cylinders cool in what may sometimes be a very hot environment. The cabinet is vented to the dedicated system to remove any EtO which might escape during a cylinder change operation or in the event of a leaky cylinder connection.

General Ventilation

A constant-volume single-duct heating/air conditioning system supplies air to the CS department and adjacent hospital areas. The CS Department was remodeled during July and August, 1984. The clean room and linen preparation areas were separated by a wall, and an additional recirculated air system was installed in the decontamination room.

The clean room has two supply air diffusers. Exhaust is provided by four louvered vents over the sterilizers, the canopy hood above the gas sterilizer, and four passive vents into a ceiling plenum. Each of the four louvered vents measure 7 by 17 inches and are located about 27 inches above the tops of the sterilizers and aerator along the wall. They serve to exhaust EtO and very hot air from the steam sterilizers into the recess room. These vents are open to the recess room. The recess room functions as an exhaust plenum: air flows from above the sterilizers into the recess room due to the negative pressure of the recess room with respect to the clean room. Four passive vents are open to the ceiling plenum. The linen preparation room was created during a remodeling by erecting a wall to separate the area from the clean room. The doors to this room are closed at all times. There are two supply air diffusers, the air return for the CS department, and one passive ceiling vent in this room.

PROCESS DESCRIPTION

The CS Department sterilizes medical supplies, surgical instruments and other equipment. Metal instruments and other items which can be steam sterilized are delivered to the decontamination room in covered or enclosed carts or through a dumbwaiter. These items are washed and enter the preparation and packaging room by cart through the gown room or through a pass-through washer. The items are dried, wrapped and packaged for terminal sterilization. Wrapped items are loaded onto carts in the processing area of the clean room and steam sterilized. The sterile items are either stored or delivered to the using department.

Heat- or moisture-sensitive items must be sterilized with EtO gas. These items arrive in decontamination by three routes: by dumbwaiter, 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 through the gown room into the preparation and packaging room. The items may then be wrapped or heat-sealed in a peel-pac and carried to a table in front of the sterilizer bank. The sterilizer operator prepares the load for sterilization by arranging the items in wire baskets, placing a biological indicator in the load, and completing the necessary record forms. The wire baskets are placed on the sterilizer shelves, and the cycle is started at 0800 daily except Sunday.

Transferring the Load

At the end of the pulse-purge phase 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 with a key, the door labeled with the times for the load, and the operator puts on cotton gloves. The sterilizer door is swung fully open, and the operator transfers the wire baskets one-by-one from the sterilizer to the aerator. The sterilizer door is closed, and the operator removes the biological indicator from the load. The aerator door is closed while the indicator is removed from the encasing syringe and placed in the incubator. The operator then reopens the aerator door and disposes the syringe in a waste container in the aerator. Tape labels of aeration times are placed on the appropriate shelves, and the door is closed.

Replacing an EtO Supply Cylinder

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. At the time of the survey, the dual-load system was not working properly, and a cylinder emptying during a cycle would have caused the cycle to abort. To avoid an aborted cycle, the sterilizer operator kept a count of how many loads had been processed from the cylinder before starting the load. About 26 to 32 loads can be processed on one cylinder. If a new cylinder is needed, the stock room brings one to the department, and a plumber from maintenance connects the new cylinder.

Preventative Maintenance

The CS Department has a preventive maintenance contract with the sterilizer manufacturer with routine quarterly 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 CS Director.

Monitoring

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

In 1983, two monitoring sensors were installed in the department, one in the recess room between the sterilizer and the aerator and the other on the wall over the sterilizer. The sensors and alarm system are manufactured by Gas Tech® (model 1565-6). The alarm station is mounted on a wall at the end of the bank of sterilizers, about 12 feet from the EtO unit. Each of the sensors is on a separate alarm indicator so that the worker can identify which location has triggered the alarm. Pilot lights indicate that each sensor is operating. When EtO concentration levels reach 20 ppm an audible (beeping tone) and visual alarm (a light at the alarm station is lit) are triggered. If levels reach 50 ppm a second light is activated. During the pulse-purge phase of the sterilizer cycle, the sensor in the recess room is routinely triggered at the 20 ppm level. Workers have been instructed to evacuate the area and to notify maintenance if the sensors indicate 50 ppm in the work room.

In 1984 a flow switch was installed in the exhaust duct leading from the recess room. If the exhaust flow decreases or stops, an alarm located next to the GasTech® monitor will be triggered.

Environmental area monitoring has been performed by Medical Instrumentation Systems - Hospital Shared Engineering Services, Inc. (MIS) four times since August 1981. Presently, MIS is scheduled to monitor the department every six

months. MIS monitors using an infrared analyzer and makes air flow measurements. The most recent report indicates EtO levels are low. The measurements are not in a form which can be directly compared with the OSHA standard.

Upon employment, each person receives a blood work-up and physical evaluation. Employees in the CS Department are monitored through bi-annual blood tests. The purpose of these tests is to detect early warning signs of leukemia.

Work practices

Work practices may have an important effect on the potential exposure an employee may receive. Work practices for every facet of EtO handling and sterilizer operation are specified in a procedure/policy manual. Hazard information and sterilizer operation instructions are posted beside the sterilizer.

A work practice which may limit the operator's exposure to EtO, is the removal of the load from the sterilizer immediately upon completion of the cycle. With the pulse-purge phase, the EtO in the chamber is theoretically at its lowest when the buzzer sounds at the end of the cycle. Any delay in opening the door and transferring the load allows the items to off-gas causing EtO concentration levels to build up in the chamber.

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. The CS Director provides an in-service program every 3 months using commercially available slides and tapes. The plumber assigned to change EtO cylinders for the department is also provided with instruction on EtO hazards and safe handling.

Workers are also separated from the sterilizer by distance. The load processing work station is located at least 25 feet away from the sterilizer, and the operator assigned to that task is mobile, so that approximately 30 per cent of the work day is spent at that station. Only the sterilizer operator routinely moves into the sterilizer area and then only for two to three minutes at a time. Other workers in the department are stationed in rooms other than the clean room and have no contact with the sterilizer.

Workers on the evening and night shifts do not routinely process an EtO load. Department policy prohibits the processing of an EtO load on the night shift and on Sundays and holidays. These time constraints serve to isolate some of the workers from potential EtO exposure.

Employees are encouraged to wear cotton gloves when transferring items from the sterilizer to the aerator. After being worn for one transfer procedure, the gloves are also placed in the aerator with the load.

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 the Appendix (Table A-1).

MEASUREMENT OF CONTROL PARAMETERS

Sampling was conducted during two shifts for three days. Some samples were taken for each sterilizer load. An attempt was made to sample similar events (sterilizer to aerator transfer, etc.) during each shift to aid the comparison of sampling results.

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. Samples were collected in duplicate via a dual-train sampling manifold connected to a single sampling pump. MDA pumps were calibrated at approximately 10 and 20 milliliters of air per minute (ml/min) for long-term (8 hours) samples and 50 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 collected 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 to crack the door at the end of the pulse-purge phase until she had finished transferring the load to the aerator and walked away from the sterilizer.

In addition to the above sampling, area samples were collected in the sterilizer recess room for the purpose of sampling and analytical method comparison. Three methods were evaluated: NIOSH Method 1607, OSHA Method 50, and the 3M passive monitor. Three sets of samples were taken in triplicate each day; samples were collected for a four hour period which included the pulse-purge phase of the sterilizer cycle.

Gas Bag Sampling

Short-term personal and area samples were collected in gas bags (Fisher Scientific) using DuPont pumps calibrated at approximately 1 and 5 liters per minute (L/min) during certain events: load transfer from sterilizer to aerator, sterilizer chamber concentration at the end of the cycle, cylinder change operation, and others. These bag samples were analyzed immediately using a portable gas chromatograph.

Infrared Analyzer Monitoring

Due to the sporadic nature of EtO release during the day, 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.

Short concentration peaks 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 EtO sterilizer is adjacent to steam sterilizers, this location was subject to high humidity levels. 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 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.

Air Flow Measurements

The air flow velocities in the duct exhausting air from the hood above the sterilizer door and recess room were measured using a hot-wire anemometer. Air velocity was measured at eight points in the rectangular duct and the results averaged. The average velocity was used to calculate the exhaust air volumetric flow rate from the recess room. Within the department, supply air and exhaust flow volumes were measured at the ceiling and wall diffusers and exhaust vents using a velometer flow hood.

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 the operator's 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 Challenge 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 second (evening) shift for three days. No other loads were processed through the EtO sterilizer during this shift.

MEASUREMENT RESULTS

AIR SAMPLING

The results of the analysis of the charcoal tube samples are reported in Table A-2 in the Appendix. The majority of the charcoal tube samples (70 of 72) were below the limit of detection for the analytical procedure, 1.4 ug per sample. The remaining two samples were both below the limit of quantitation of the procedure, 4.7 ug per sample. This means that the 8-hour time weighted average (TWA) exposure of the sterilizer operator was less than about 0.2 ppm, and that of the equipment wrapper was less than 0.1 ppm. (The difference is due to different sampling conditions rather than to a difference in exposure.)

The air sampling location in front of the sterilizer was also monitored continuously with an infrared analyzer, whose output was recorded on a strip chart recorder simultaneously with that of a hygrothermograph. The average response to a load transfer operation generated a peak of approximately 2-3 ppm lasting for about 2 minutes, followed by an additional 2 minute period with a relatively constant concentration of about 1 ppm. An average 15 minute TWA exposure of 0.5 ppm with a relative standard deviation of about 100 percent was calculated from the tracings (See Table 1). The highest peak measured was approximately 3 ppm.

Table 1 Average Peak Ethylene Oxide Concentration as Determined with the MIRAN Infrared Analyzer.

Load	Peak ppm	Duration minutes	Total ppm-minutes	Average ppm
09/25 - Normal	2.4	3.0	3.3	1.1
09/25 - Test	3.0	2.0	4.4	2.2
09/26 - Normal	2.0	2.8	2.8	1.0
09/26 - Test	2.0	15.0	27.5	1.8
09/27 - Normal	1.0	2.5	1.3	0.5
09/27 - Test	2.0	4.0	4.0	1.0

A number of samples were taken in gas collection bags and analyzed with a portable gas chromatograph. The results of all the useable samples are given in Table 2. Charcoal tube, gas chromatograph, and MIRAN sampling data for load transfer operations are compared in Table 3. The MIRAN infrared analyzer measurements are lower than those obtained with the GC by as much as an order of magnitude. This discrepancy is expected, due to the slow response of the MIRAN described earlier.

Table 2 Ethylene Oxide Concentration as Determined by Gas Chromatography.

Location/Activity	Ethylene Oxide Concentration (ppm)						
	09/25		09/26		09/27		Average
	Norm	Test	Norm	Test	Norm	Test	
Operator wiping ster. interior	0.1	-	0.4	-	-	-	0.3
Aerator interior (unloading)	0.1	-	0.3	-	-	-	0.2
At safety release valve	1.5	-	-	-	-	-	1.5
Recess room (mid-cycle)	0.1	-	0.1	-	0.1	-	0.1
Recess room (pulse-purge)	0.8	4.0	2.4	5.2	4.0	5.6	3.7
Aerator interior (loading)	-	2.5	-	2.3	-	-	2.4
Operator (unloading)	2.2	1.8	3.7	2.3	0.4	0.2	1.8
Above sterilizer door (unloading)	10.1	5.4	5.1	2.2	4.1	0.6	4.8
Sterilizer interior (cycle end)	175	540	140	370	150	100	245
Ster. int. (15 m after unload)	-	-	-	3.1	-	-	3.1
Sterilizer interior (loading)	-	1.0	-	1.8	-	0.1	1.0
Above test load after aeration	-	-	-	0.2	-	0.5	0.4

Table 3 Comparison of Charcoal Tube, GC, and MIRAN Sampling Data.

Sample	Date	Shift	Ethylene Oxide Concentration (ppm) Charcoal	GC	MIRAN
Operator	09/25	1	2.6*	2.2	—
	09/25	2	1.3*	1.8	—
	09/26	1	1.4*	3.7	—
	09/26	2	1.1*	2.3	—
	09/27	1	1.3*	0.4	—
	09/27	2	1.3*	0.2	—
	Average:		NA	1.8	—
	Standard Deviation:		NA	1.3	—
	Sample Time:		(15 min)	(2 min)	(15 min)
Over Door	09/25	1	1.3*	10.1	1.1
	09/25	2	1.3*	5.4	2.2
	09/26	1	1.4*	5.1	1.0
	09/26	2	1.8*	2.2	1.8
	09/27	1	1.3*	4.1	0.5
	09/27	2	1.3*	0.4	1.0
	Average:		NA	4.6	1.3
	Standard Deviation:		NA	3.3	0.6
	Sample Time:		(15 min)	(15 min)	(5 min)

*indicates less than stated concentration.

The results of the analysis of the NIOSH/OSHA/3M comparison samples (charcoal tubes and passive monitors) is reported in Table A-3 in the Appendix and summarized in Table 4. The OSHA and 3M samples were in very close agreement. The NIOSH samples were consistently higher though well within 2 standard deviations of the other methods.

Table 4 OSHA/NIOSH/3M Comparison Summary.
(PPM EtO)

DATE	OSHA		NIOSH		3M Badge	
	AVG	SD	AVG	SD	AVG	SD
9/25	.304	.020	.493	.106	.185	.025
9/26	.224	.003	--	--	.142	.000
9/27	.251	.004	.334	.001	.141	.001

AVG = Average
SD = Standard Deviation

VENTILATION MEASUREMENTS

Measurements of volumetric flow rate for the supply air and exhaust of the CS department are presented in Table 5. These measurements indicate that within the instrumental accuracy the exhaust and supply flows of the CS department are balanced. Within the CS department, the general flow of air is from the peripheral rooms into the recess room or linen preparation area, through the clean room.

The air return vent located in the linen preparation room provides a very strong negative pressure with respect to the clean room. Since ceiling plenum is common to both the linen preparation and clean rooms, there is a net flow of air through this plenum from the clean room to linen preparation.

The principal ventilation controls studied were the canopy hood above the sterilizer door and the sterilizer enclosure (recess room). A volumetric flowrate of 150 cfm was measured for the canopy hood, while a flowrate of 1000 cfm was measured for the recess room.

Table 5 Volumetric Flow Rate Measurements (Supply and Exhaust)
Central Service Department
Euclid General Hospital
Euclid, Ohio

Location	Supply (CFM)	Exhaust (CFM)
Clean room	640	1350 *
Decontamination	725	1210
Linen preparation	1765 *	1765
Preparation and packaging	765	?
Cart holding	190	110
Wet room	0	415 *
Inhalation storage	200	
Office area	275	0
Orthopedic supplies	75	0
Total:*	4635	4850

* includes contribution of "passive vents"

WORK PRACTICE OBSERVATIONS

The exposure times are relatively short (less than 2 minutes) for both operators, considering that the items had to be transferred manually to the aerator. The sterilizer door was fully open less than a minute to pull the load from the chamber.

The biological indicator pack was pulled from the load as the items were transferred from the cart to the aerator. The pack was opened soon after and the pack disposed of in a waste container kept in the aerator. The average total time for pulling the pack and opening it was approximately 1 minute.

CONTROL EVALUATION

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. All short-term charcoal tube results were less than the limit of detection of the analytical method, which corresponds to a concentration of 1.3 ppm. Peak exposures measured in the breathing zone of the operator with a sampling bag/gas chromatograph did not exceed 3 ppm. The peak exposures were not only low, but the durations were short, lasting no more than a few minutes. Concentrations measured in the sterilizer chamber at the conclusion of the pulse purge cycle averaged about 250 ppm.

DRAIN CONTROLS

Worker exposures from the drain are controlled primarily by isolating all of the sterilizer except the front panel in a ventilated recess room. The EtO sterilizer is recessed into a room and the 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 recess room is under negative pressure with respect to the clean room and acts as an exhaust plenum for gases and vapors escaping at the drain and any release of EtO from the sterilizer safety valve. The recess room is locked and only persons authorized by the CS supervisor or maintenance may enter. No EtO was detected by the infrared analyzer at the area location in front of the sterilizer door during the evacuation period, indicating that the ventilation of the recess room was effective.

EtO levels can get relatively high in the recess room during the purge cycles. This room is clearly an area to be avoided during and for some time after the EtO evacuation cycles. The hospital has posted a sign on the door of the recess room stating: "Danger Ethylene Oxide/Authorized Personnel Only/Do Not Enter During Ethylene Oxide Operation Or Servicing". There is no mechanism to alert workers when the sterilizer is in the exhaust phase and the room not must be entered, although a monitor was present which could measure the EtO concentration and signal when it was above 20 ppm.

It can be shown that the ventilation for the recess room met three independent design criteria. First, the ventilation rate was adequate to overcome the thermal air currents produced by heat generating equipment located within the recess room. Second, the volume of air drawn into the room was sufficient to limit the temperature rise to an acceptable level. Third, sufficient dilution ventilation was provided to purge the room of EtO within 30 minutes following a sudden release.

Air Velocity Through Enclosure Openings

Air does not always flow into a room with the same velocity at all openings. In fact, when heated processes are present in the room, air may actually flow out of vents and cracks in the walls near the top of the room if the ventilation system does not exhaust enough air to handle the quantity of air rising to the ceiling due to thermal effects. Hemeon[4] gives an equation to calculate the velocity of this airflow through an orifice at the top of an enclosure. From this, the minimum flow rate to assure that air does not leak out of the room can be calculated. For room temperatures not exceeding 200°F this flow is given by:

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

where:

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

In this situation, the height of the hot air column is taken to be the height of the recess room. The area of the vents was measured during the survey. Estimates of the heat released in the room were obtained from the manufacturers of the equipment and summed to obtain a value for H'.

Using a height of 11 ft, and total vent area of 3.3 ft^2, and estimated heat 10000 Btu/hr for each of the two steam sterilizers (neglecting the heat released by the aerator and gas sterilizer) yields a design flow rate of approximately 690 cfm.

Temperature Rise

Exhaust ventilation may be used to remove excessive heat if a source of cooler air is available (from surrounding areas). The volume of air required for a predetermined temperature rise is given by the following equation adapted from references 4 and 5:

$$Q = 56\ H'/\ T$$

where:

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

Assuming that the recess room temperature should not exceed about 100°F, the acceptable temperature rise would be approximately 30°F. Using the estimates of the heat release from the previous calculation, approximately 625 cfm would be required to limit the temperature rise in the recess room to 30°F.

Rate of Purging

The rate of decrease of concentration of a contaminant once further generation has ceased is given by Mutchler[6]:

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

where:

C_2 is the concentration at time t_2;
C_1 is the concentration at time t_1;
Q' is the effective ventilation rate;
V is the volume of the enclosed space.

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

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

In this equation, the desired time period for purging must be specified. The initial concentration, C_1, can be estimated by assuming the entire sterilizer contents escape into the recess room. Assuming that a nine cubic foot sterilizer chamber charged with 160 grams EtO suddenly released its contents to the room, the initial recess room concentration would be approximately 2500 ppm. (For this hospital, the volume of the recess room was approximately 1325 ft^3.) To reduce the recess room concentration to 1 ppm in 30 minutes would require 1040 cfm.

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 as possible the air escaping from the sterilizer with an exhaust hood. The pulse-purge phase seemed effective in minimizing the amount of EtO remaining in the sterilizer. Measurements of the chamber concentration immediately after the door was opened, indicated that only about 250 ppm of EtO remained.

The American Conference of Governmental Industrial Hygienists publishes a handbook entitled: Industrial Ventilation - A Manual of Recommended Practice (1). This manual discusses control velocities and capture distances with specific criteria and equations to aid in evaluation and design. 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 sterilizer, ft.

For this particular process, the minimum control velocity (V) should be 50 feet per minute (ft/min). In this case the perimeter of the work area is about 3 feet, and the hood is located 1.5 feet above the sterilizer door. Thus the recommended flowrate would be 315 cfm. Even though the measured flowrate was only 150 cfm, observations of chemical smoke indicated that the canopy hood located above the sterilizer door was capable of capturing contaminants released as far away from the door as 11 inches.

RECOMMENDATIONS AND CONCLUSIONS

Findings of this survey indicate the Central Service 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. The sterilizer modification to include a pulse-purge phase limits the end-of-cycle concentration to about 250 ppm.

Proper work practices for employees are 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 follows those procedures. The CS Department Director provides education and training on proper work practices and the hazards of exposure to EtO.

Although the OSHA standard does not include a short term exposure limit (STEL), the use of the continuous EtO monitor and alarm system can provide a valuable warning for the workers if a severe leak or emergency situation should arise.

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. Periodic personal sampling should be performed for the sterilizer operator over the full shift. Additional monitoring may be required to comply with the OSHA standard. Without this data it is impossible to judge the continuing effectiveness of the control program.

Although a cylinder change operation was not observed during this survey, respiratory, hand, and face protection are recommended for maintenance personnel during cylinder changes or other activities in the recess room.

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

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4. Hemeon, Wesley C. L., 1963. Plant and Process Ventilation, Second Edition: New York, NY: Industrial Press, Inc., pp 186-188.

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APPENDIX

Table A-1 Equipment Used on Field Survey.

Item	Model	Used for
Infrared spectrometer	Miran 1A	continuous area sampling
Hygrothermograph	General Eastern	relative humidity and temperature
Strip chart recorder	Varian	record of EtO conc. and rel. hum.
Hot-wire anemometer	Kurz	air velocity
Velometer Flow Hood	Alnor	volumetric air flow
Gas Chromatograph	Photovac 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
Euclid General Hospital
Euclid, Ohio

SAMPLE NO.	DESCRIPTION	DAY	SHIFT	FLOW mL/m	TIME min.	VOL. L	ANAL CODE	EtO ug	EtO ppm	EtO ppm-min
#154	Operator (L-T)	09/25	day	(10)	471	4.629	B	[1.40	[0.168	[79.1
#163	Operator (L-T)	09/25	day	(17)	471	8.061	B	[1.40	[0.096	[45.4
#179	Operator (L-T)	09/25	eve	(8)	463	3.858	B	[1.40	[0.201	[93.2
#189	Operator (L-T)	09/25	eve	(24)	463	11.193	B	[1.40	[0.069	[32.1
#218	Operator (L-T)	09/26	day	(10)	487	4.758	B	[1.40	[0.163	[79.5
#214	Operator (L-T)	09/26	day	(17)	487	8.285	B	[1.40	[0.094	[45.7
#235	Operator (L-T)	09/26	eve	(8)	475	3.935	B	[1.40	[0.197	[93.8
#200	Operator (L-T)	09/26	eve	(24)	475	11.417	B	[1.40	[0.068	[32.3
#242	Operator (L-T)	09/27	day	(10)	489	4.752	B	[1.40	[0.164	[80.0
#237	Operator (L-T)	09/27	day	(17)	489	8.274	B	[1.40	[0.094	[45.9
#252	Operator (L-T)	09/27	eve	(8)	467	3.815	B	[1.40	[0.204	[95.1
#259	Operator (L-T)	09/27	eve	(24)	467	11.069	B	[1.40	[0.070	[32.8
#181	Operator (S-T)	09/25	day	(43)	6	0.258	B	[1.40	[3.012	[18.1
#188	Operator (S-T)	09/25	day	(45)	6	0.267	B	[1.40	[2.910	[17.5
#211	Operator (S-T)	09/25	eve	(41)	14	0.577	B	[1.40	[1.347	[18.9
#217	Operator (S-T)	09/25	eve	(43)	14	0.598	B	[1.40	[1.299	[18.2
#206	Operator (S-T)	09/26	day	(36)	15	0.540	B	[1.40	[1.439	[21.6
#230	Operator (S-T)	09/26	day	(37)	15	0.560	B	[1.40	[1.388	[20.8
#236	Operator (S-T)	09/26	eve	(52)	16	0.832	B	[1.40	[0.934	[14.9
#238	Operator (S-T)	09/26	eve	(54)	16	0.862	B	[1.40	[0.901	[14.4
#250	Operator (S-T)	09/27	day	(38)	15	0.574	B	[1.40	[1.354	[20.3
#251	Operator (S-T)	09/27	day	(40)	15	0.595	B	[1.40	[1.306	[19.6
#239	Operator (S-T)	09/27	eve	(38)	15	0.568	B	[1.40	[1.368	[20.5
#225	Operator (S-T)	09/27	eve	(39)	15	0.588	B	[1.40	[1.321	[19.8

[= None detected, reported number corresponds to limit of detection;
(= Reported number is below limit of quantitation.
ANALYSIS CODE=A: 6 Dec 84/LOD=0.4ug.
ANALYSIS CODE=B: 6 Dec 84/LOD=1.4ug.
ANALYSIS CODE=C: 1st analysis (A), scaled by 0.85

Table A-2 (continued).

Results of Charcoal Tube Air Samples for Ethylene Oxide
Euclid General Hospital
Euclid, Ohio

SAMPLE NO.	DESCRIPTION	DAY	SHIFT	FLOW mL/m	TIME min.	VOL. L	ANAL CODE	EtO ug	EtO ppm	EtO ppm-min
#175	Wrapper	09/25	day	(19)	465	8.889	B	[1.40	[0.087	[40.6
#180	Wrapper	09/25	day	(17)	465	8.094	B	[1.40	[0.096	[44.6
#196	Wrapper	09/25	eve	(9)	462	4.275	B	[1.40	[0.182	[84.0
#192	Wrapper	09/25	eve	(21)	462	9.483	B	[1.40	[0.082	[37.9
#197	Wrapper	09/26	day	(19)	483	9.140	B	[1.40	[0.085	[41.1
#229	Wrapper	09/26	day	(17)	483	8.322	B	[1.40	[0.093	[45.1
#219	Wrapper	09/26	eve	(9)	469	4.066	B	[1.40	[0.191	[89.6
#246	Wrapper	09/26	eve	(19)	469	9.020	B	[1.40	[0.086	[40.4
#232	Wrapper	09/27	day	(19)	499	9.393	B	[1.40	[0.083	[41.3
#226	Wrapper	09/27	day	(17)	499	8.553	B	[1.40	[0.091	[45.3
#258	Wrapper	09/27	eve	(9)	461	4.153	B	[1.40	[0.187	[86.3
#254	Wrapper	09/27	eve	(20)	461	9.212	B	[1.40	[0.084	[38.9
#172	Sterilizer (L-T)	09/25	day	(9)	490	4.473	B	[1.40	[0.174	[85.1
#164	Sterilizer (L-T)	09/25	day	(20)	490	9.977	B	[1.40	[0.078	[38.2
#195	Sterilizer (L-T)	09/25	eve	(19)	459	8.617	B	[1.40	[0.090	[41.4
#209	Sterilizer (L-T)	09/25	eve	(20)	459	9.057	B	[1.40	[0.086	[39.4
#203	Sterilizer (L-T)	09/26	day	(9)	495	4.445	B	[1.40	[0.175	[86.5
#199	Sterilizer (L-T)	09/26	day	(20)	495	9.913	B	[1.40	[0.078	[38.8
#216	Sterilizer (L-T)	09/26	eve	(20)	464	9.503	C	(1.90	(0.111	(51.5
#212	Sterilizer (L-T)	09/26	eve	(22)	464	9.988	B	[1.40	[0.078	[36.1
#223	Sterilizer (L-T)	09/27	day	(9)	502	4.582	B	[1.40	[0.170	[85.1
#193	Sterilizer (L-T)	09/27	day	(20)	502	10.219	B	[1.40	[0.076	[38.2
#224	Sterilizer (L-T)	09/27	eve	(21)	462	9.822	B	[1.40	[0.079	[36.5
#257	Sterilizer (L-T)	09/27	eve	(22)	462	10.324	B	[1.40	[0.075	[34.8

[= None detected, reported number corresponds to limit of detection;
(= Reported number is below limit of quantitation.
ANALYSIS CODE=A: 6 Dec 84/LOD=0.4ug.
ANALYSIS CODE=B: 6 Dec 84/LOD=1.4ug.
ANALYSIS CODE=C: 1st analysis (A), scaled by 0.85

Table A-2 (continued).

Results of Charcoal Tube Air Samples for Ethylene Oxide
Euclid General Hospital
Euclid, Ohio

SAMPLE NO.	DESCRIPTION	DAY	SHIFT	FLOW mL/m	TIME min.	VOL. L	ANAL CODE	EtO ug	EtO ppm	EtO ppm-min
#187	Sterilizer (S-T)	09/25	day	(39)	15	0.586	B	[1.40	[1.326	[19.9
#190	Sterilizer (S-T)	09/25	day	(41)	15	0.612	B	[1.40	[1.270	[19.0
#201	Sterilizer (S-T)	09/25	eve	(40)	14	0.563	B	[1.40	[1.380	[19.3
#207	Sterilizer (S-T)	09/25	eve	(42)	14	0.588	B	[1.40	[1.321	[18.5
#215	Sterilizer (S-T)	09/26	day	(36)	15	0.539	B	[1.40	[1.442	[21.6
#198	Sterilizer (S-T)	09/26	day	(38)	15	0.563	B	[1.40	[1.380	[20.7
#205	Sterilizer (S-T)	09/26	eve	(40)	16	0.639	B	[1.40	[1.216	[19.5
#213	Sterilizer (S-T)	09/26	eve	(42)	16	0.667	C	(3.20	(2.663	(42.6
#255	Sterilizer (S-T)	09/27	day	(38)	15	0.574	B	[1.40	[1.354	[20.3
#248	Sterilizer (S-T)	09/27	day	(40)	15	0.600	B	[1.40	[1.295	[19.4
#260	Sterilizer (S-T)	09/27	eve	(38)	15	0.574	B	[1.40	[1.354	[20.3
#233	Sterilizer (S-T)	09/27	eve	(40)	15	0.600	B	[1.40	[1.295	[19.4
#177	Work table	09/25	day	(21)	483	10.240	B	[1.40	[0.076	[36.6
#182	Work table	09/25	day	(19)	483	9.371	B	[1.40	[0.083	[40.0
#174	Work table	09/25	eve	(19)	456	8.654	B	[1.40	[0.090	[40.9
#183	Work table	09/25	eve	(18)	456	8.351	B	[1.40	[0.093	[42.4
#194	Work table	09/26	day	(21)	494	10.395	B	[1.40	[0.075	[36.9
#208	Work table	09/26	day	(19)	494	9.513	B	[1.40	[0.082	[40.3
#241	Work table	09/26	eve	(51)	468	23.829	B	[1.40	[0.033	[15.3
#244	Work table	09/26	eve	(49)	468	22.995	B	[1.40	[0.034	[15.8
#256	Work table	09/27	day	(21)	504	10.375	B	[1.40	[0.075	[37.7
#240	Work table	09/27	day	(19)	504	9.495	B	[1.40	[0.082	[41.2
#253	Work table	09/27	eve	(68)	461	31.369	B	[1.40	[0.025	[11.4
#261	Work table	09/27	eve	(66)	461	30.270	B	[1.40	[0.026	[11.8
#171	Field blank	09/25	day				B	[1.40		
#191	Field blank	09/25	eve				B	[1.40		
#202	Field blank	09/26	day				B	[1.40		
#228	Field blank	09/26	eve				B	[1.40		
#247	Field blank	09/27	day				B	[1.40		
#243	Field blank	09/27	eve				B	[1.40		
#185	Field blank	09/27	eve				B	[1.40		

[= None detected, reported number corresponds to limit of detection;
(= Reported number is below limit of quantitation.
ANALYSIS CODE=A: 6 Dec 84/LOD=0.4ug.
ANALYSIS CODE=B: 6 Dec 84/LOD=1.4ug.
ANALYSIS CODE=C: 1st analysis (A), scaled by 0.85

TABLE A-3

Results of OSHA/NIOSH/3M Comparison Air Samples for Ethylene Oxide
Sterilizer Recess Room
Euclid General Hospital
Euclid, Ohio

SAMPLING PROCEDURE	SAMPLE No.	DATE	PERIOD START	STOP	TIME (min)	RATE (lpm)	VOL. (l)	ETO (ug)	ETO (ppm)
OSHA	C100	09/25	1148	1613	265	0.101	26.8	14.0	0.290
OSHA	C108	09/25	1148	1613	265	0.099	26.2	15.0	0.318
OSHA	C102	09/26	1147	1555	248	0.099	24.6	10.0	0.226
OSHA	C103	09/26	1147	1555	248	0.101	25.0	10.0	0.222
OSHA	C110	09/27	1141	1545	244	0.099	24.2	11.0	0.253
OSHA	C104	09/27	1141	1545	244	0.101	24.6	11.0	0.248
OSHA&	C105	09/25	1148	1613	265	0.101	26.8	4.0	0.083
OSHA&	C106	09/26	1147	1555	248	0.101	25.0	2.0	0.045
OSHA&	C101	09/27	1141	1545	244	0.101	24.6	0.0	0.000
NIOSH	210	09/25	1148	1613	265	0.023	6.1	3.8	0.345
NIOSH	176	09/25	1148	1613	265	0.021	5.6	3.5	0.347
NIOSH	186	09/25	1148	1613	265	0.021	5.5	3.4	0.345
NIOSH	245	09/27	1141	1545	244	0.021	5.0	2.6	0.286
NIOSH	249	09/27	1141	1545	244	0.023	5.3	2.7	0.280
NIOSH	221	09/27	1141	1545	244	0.021	5.0	2.6	0.286
3M Badge	1724	09/25	1148	1613	265	.049	12.9	5.0	0.214
3M Badge	0206	09/25	1148	1612	265	.049	12.9	4.0	0.171
3M Badge	1149	09/25	1148	1613	265	.049	12.9	4.0	0.171
3M Badge	0093	09/26	1150	1550	240	.049	11.7	3.0	0.142
3M Badge	1165	09/26	1150	1550	240	.049	11.7	3.0	0.142
3M Badge	1176	09/26	1150	1550	240	.049	11.7	3.0	0.142
3M Badge	1860	09/27	1139	1542	243	.049	11.9	3.0	0.140
3M Badge	0211	09/27	1141	1542	241	.049	11.8	3.0	0.141
3M Badge	0011	09/27	1143	1542	239	.049	11.7	3.0	0.142
3M Badge	0909	Blank	0000	0000	000			0.0	.049
3M Badge	1093	Blank	0000	0000	000			0.0	.049
3M Badge	1547	Blank	0000	0000	000			0.0	.049

& indicates sampling pump failure