IN-DEPTH SURVEY REPORT:

MODIFIED CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

COMMUNITY MEDCENTER HOSPITAL
MARION, OHIO

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HOSPITAL SURVEYED:	Community MedCenter Hospital 1050 Delaware Avenue Marion, Ohio 43302
SIC CODE:	8062 (General Medical and Surgical Hospitals)
SURVEY DATE:	October 7 - 11, 1985
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ABSTRACT

Modified controls for ethylene oxide (EtO) emitted from the gas sterilization of medical items were evaluated at Community MedCenter Hospital, Marion, Ohio. EtO may have serious health effects, including carcinogenicity, and OSHA has established an 8-hour permissible exposure limit of 1 ppm. An initial evaluation was conducted in October, 1984; and a second evaluation was conducted in October, 1985 after the installation of a manufacturer-supplied control system.

Personal exposures and area concentrations were sampled with charcoal tubes, gas bags, and/or an infrared analyzer. The full-shift exposures for the sterilizer operator were controlled to a average of less than 0.05 ppm (compared to a average of 0.24 ppm before the installation of controls) with a combination of local exhaust ventilation at the emission sources, sterilizer cycle modifications, and work practices. Short-term exposures while transferring the load to the aerator had a average value of less than 0.22 ppm--versus 1.98 ppm before controls were added. The results of sampling including monitoring in front of the sterilizer with an infrared analyzer indicated that employee exposures would be less than the 5-ppm ceiling limit which NIOSH has recommended not be achieved for more than 10 minutes in any workday.

EtO was detected in front of the sterilizer during the purge cycle due to an unsealed drain connection and inadequate recess room exhaust. Temporarily sealing the drain controlled EtO emissions during purge. It was recommended that the drain be permanently sealed in accordance with the manufacturer's instructions and that recess room exhaust ventilation be increased to handle the airflow induced by the heat from the enclosed equipment to prevent the escape of EtO from the recess room into the work area.

DISCLAIMER

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

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 (EtO) sterilization operations. Based on the feasibility study, a need for the evaluation and documentation of effective engineering controls for EtO sterilization was identified.

The health effects of ethylene oxide have been under intense study for several years. EtO exposure may cause irritation of the eyes, nose, and throat.

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

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

BACKGROUND FOR THIS SURVEY

The Supply, Processing, and Distribution (SPD) Department of Community MedCenter Hospital was initially surveyed October 29 - November 2, 1984 as a hospital in the category specifying: a sterilizer using a 12:88 EtO and Freon 12 mixture, no extra evacuation phases at the end of the sterilizer cycle, and no local exhaust ventilation above the sterilizer door.[2] Following that survey, this hospital added an Envirogard® EtO emission control system marketed by the sterilizer manufacturer. To determine if the EtO exposures changed as a result of the modifications, a second in-depth evaluation was conducted from October 7 - 11, 1985. This report documents the information gathered during that second survey.

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.[3]

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

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

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

In addition to the OSHA PEL of 1 ppm, the standard mentions an action level of 0.5 ppm, above which semi-annual monitoring is required. The American Conference of Governmental Industrial Hygienists also adopted 1 ppm as an 8-hour time-weighted average Threshold Limit Value (TLV); however, it has allowed for an excursion limit such that short-term exposures should exceed 3 ppm no more than 30 minutes during a workshift and should never exceed 5 ppm.[6] 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.[7]

PRIMARY EXPOSURE SOURCES

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

Uncontrolled Drain

During the evacuation phase of the sterilization cycle, most of the EtO in the sterilization chamber is removed through the vacuum pump and drain. For

sterilizers which evacuate to an uncontrolled drain, much of the EtO used in sterilization may be released into the recess room and/or 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 may 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 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 higher concentrations

in the vicinity of the cylinders and in the surrounding work area than would be possible from any other source.

Pressure Relief Valve

Another possible source of EtO is the sterilizer safety valve. If the sterilizer becomes overpressurized during the cycle, this emergency relief valve releases EtO gas. If not 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 SUPPLY, PROCESSING AND DISTRIBUTION DEPARTMENT DESCRIPTION

Community MedCenter Hospital is a not-for-profit, acute care facility with 153 beds. Services which the hospital provides include: general surgery, orthopedic surgery, neurosurgery, cardiovascular catheterization, and obstetrics. The hospital has been remodeled and new wings added within the last few years. The SPD Department is located on the ground floor in a section of the hospital which was completed in September 1981.

Ethylene oxide gas sterilization operations for the hospital are conducted only in the SPD. This department performs EtO sterilization for surgery, obstetrics, anesthesiology, the catheterization laboratory, x-ray, and emergency. A clinic, associated with the hospital, also sends some equipment to be gas sterilized.

The layout of the SPD 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 sterile supplies and to prepare case carts for surgery. The opposite end of the room serves as a processing area where clean items are received from decontamination and prepared for sterilization. A third area of the room is occupied by a bank of sterilizers (two steam and one EtO), an aerator, and a pass-through washer that are recessed in the wall space between the decontamination room and the clean room.

The SPD Department employs six persons distributed over three shifts. The day shift employs three persons, one of whom is assigned to operate the sterilizers and process loads in the sterilization room (referred to as the clean room). The sterilizer operator and one other worker may spend their time in the following areas: in the instrument room, in the linen room, at work counters in the clean room, and at the wrapping table in front of the sterilizers. The third person working the day shift is assigned to decontamination. During the evening shift, one person is assigned to decontamination, and one person is assigned to work in the clean area which may include duties in the instrument room, in the linen room, at work counters in the clean room, at the wrapping table in front of the sterilizers, and operation of the sterilizers. The night shift employs one person in the clean room whose duties are stocking supplies and operating the steam sterilizers.

EQUIPMENT AND PHYSICAL DESCRIPTION

The EtO gas sterilizer is an American Sterilizer Company (AMSCO), Medallion Cryotherm double-door model, purchased in 1982. Its internal chamber size is 20 inches by 20 inches by 38 inches, and the volume is 8.8 cubic feet or approximately 250 liters. The aerator is manufactured by AMSCO with an approximate volume of 14 cubic feet.

The sterilizers are recessed into a room constructed between the clean room and the decontamination room to enclose the drains and mechanical components of the equipment. The recess room has a 9-foot ceiling and two sections measuring 20 ft x 3 ft and 14 ft x 6 ft. (See Figure 1.) The sterilizers may

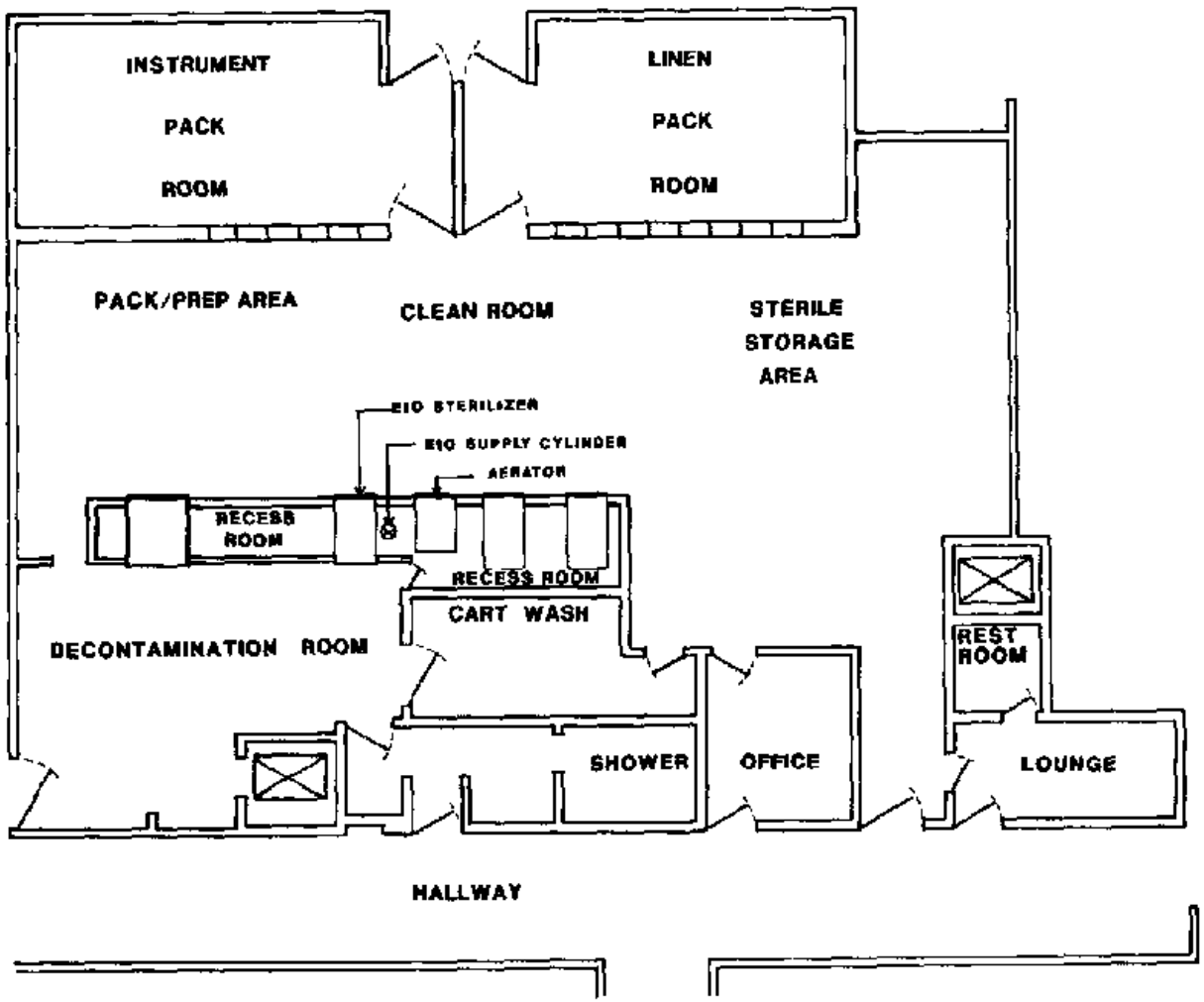

Figure 1. Layout of the sterilization areas of the Supply, Processing, and Distribution Department.

be accessed for maintenance by entering the recess room from either the decontamination room or the clean room through door panels located between the sterilizers. The door panels are normally locked to restrict access of unauthorized personnel. There are no cabinets around the sterilizers in the recess room. Steam and water from the sterilizers are emptied into floor drains located beneath each unit.

The EtO sterilizer is supplied with a gas mixture of EtO (12 percent by weight) and Freon-12 from a cylinder. The cylinder is located in the recess room between the sterilizer and the aerator. An option of the Envirogard® system which this hospital selected provided a spring-loaded valve at the end of the EtO supply line which connects to the supply cylinder. This valve can be used to release excess EtO/Freon trapped in the supply line either before replacing a supply cylinder or changing an supply-line filter. The vent line for this valve is emptied into the ventilated enclosure around the drain line air gap. In its normally closed position, EtO/Freon flows from the supply cylinder to the sterilizer.

Sterilizer Cycle Features

The cycle was approximately 3 hours in duration, and consisted of several phases: initial vacuum and humidification (about 30 minutes), EtO charging of the chamber, dwell period (about 2 hours), and evacuation (about 40 minutes). The evacuation consists of two deep vacuum cycles followed by at least one 20-minute air flush period. The 20-minute air flush, which repeats if the door of the sterilizer is not opened when the buzzer sounds at the end of an air flush period, is another feature of the Envirogard® modification.

Local Exhaust Ventilation

A slot hood is built into the front panel of the sterilizer a few inches above the door to allow air escaping from the open sterilizer door to flow into the recess room. This slot is approximately 3/4 of an inch by 24 inches. The Envirogard® system provides ventilation for this slot and for the enclosure around the required air gap in the sterilizer discharge line to the floor drain.

General Exhaust Ventilation

The ventilation system in the Supply, Processing and Distribution Department (SPD) consists of one main supply duct, which carries conditioned air from air handler No. 2 to SPD and other areas of the hospital, and four separate exhaust systems. One exhaust duct returns air to air handler No. 2. Three dedicated exhaust systems remove air from the sterilizer areas and exhaust it directly outside the building. These additional exhaust systems remove a total design flow of approximately 1800 cfm. The recirculating ventilation system is also computer controlled for energy conservation. Every 48 minutes the air handler suppling SPD (and the return air) is shut off for a 12-minute period.

In addition to the slot above the sterilizer door, there are twelve transfer vents in the recess room wall less than 1 ft above the top of the sterilizer

control panels. These vents are intended to allow the recess room exhaust to remove some of the EtO-laden air from the gas sterilizer as well as the hot, moist air from the steam sterilizers and pass-through washer. Seven vents are on the clean room side--one of these is above the EtO sterilizer; the other five vents are open to the decontamination room. These vents measure approximately 6 in by 18 in, with about half this area open to air flow through the grilles.

The recess room is exhausted by a dedicated system through a vent in the ceiling at one end of the recess room near the pass-through washer. A previously existing vent between the EtO sterilizer and the aerator was closed off when the Envirogard® system, with its own fan, was added to this ventilation system. The aerator is vented to the same dedicated exhaust system that exhausts the recess room.

Heating/cooling air is supplied to the department by a recirculating system with both central conditioning and terminal reheat/cooling units. Each terminal unit at the head of a distribution branch has its own fan. Air handler No. 2 ventilates the SPD department in addition to other areas of the hospital. The entire hospital system is monitored by a computer system and cycled on and off to conserve energy. Air handler No. 2 runs for 36 minutes and is off for 12 minutes each cycle.

In addition to the recess room exhaust, there are two other dedicated exhaust systems which remove air from the department. One of these provides exhaust through vents in the ceiling close to the EtO sterilizer and the pass-through washer in both the clean room and the decontamination room. This same system exhausts the cart wash room. The other system exhausts the lounge, the rest room, and the shower.

The locations of all the vents are shown in Figure 2. Those designated as recirculating exhaust vents remove air from the room and return it to the air handler to be recirculated.

PROCESS DESCRIPTION

The SPD Department sterilizes medical supplies, surgical instruments, and other equipment. Heat- or moisture-sensitive items must be sterilized with EtO gas. These items arrive in decontamination via a "dirty" elevator (from surgery) or may be delivered to the door by the using department. The items are washed, dried, and are passed through the window to the clean room. The items may then be wrapped in linen or heat-sealed in a peel-pack. The catheterization laboratory prepares items for EtO sterilization except for the sealing of peel-packs and delivers these items to SPD.

The sterilizer operator prepares the load for sterilization by arranging the items on a cart rack, placing a biological indicator in the load, and completing the necessary record forms. Demand for certain EtO sterilized items sometimes requires that a second load be run during the evening shift. All these activities take place on the clean-room side.

The sterilizer was purchased with doors on both ends so that items coming to decontamination from an isolation case could be initially gas sterilized from the decontamination side of the double-door sterilizer and then reprocessed. On a routine basis, the EtO sterilizer is not opened on the decontamination side.

Transferring the load

At the end of the evacuation phase of the sterilization cycle a buzzer sounds alerting the operator that the cycle is complete and the door may be opened. The operator opens the door a few inches and leaves the area.

After approximately 15 minutes have elapsed, the operator returns to the sterilizer area, fully opens the sterilizer door, and, wearing gloves, pulls the load from the sterilizer and moves it to the aerator. Once the cart is docked to the aerator, the rack is disengaged and pushed into the aerator. The cart is then moved away from the aerator, the gloves are removed and placed in the aerator, and the door is closed and the time is recorded on the door. At some point in this process, the operator has removed the biological indicators from the load. Finally, the BI pack is opened and prepared for the laboratory at the wrapping table.

All items are aerated at 120°F for a minimum 12 hours. Implants and other specialty items are aerated as specified by the manufacturer. Normally, the aerator is cart loaded directly from the sterilizer. However, two racks can not be placed in the aerator at one time. Therefore, when a second load is run, items must be rearranged to accommodate it.

Replacing the EtO Supply Cylinder

If a supply cylinder empties during a cycle, the cycle is interrupted. The operator must then manually initiate the chamber evacuation phase and call maintenance to replace the cylinder. To avoid an aborted cycle, the sterilizer operator routinely monitors cylinder usage and calls maintenance to replace the cylinder before it is completely empty. The cylinder is replaced about every two months. A supply cylinder containing 135 lb of (EtO/Freon-12) gas should last for 35 to 40 loads in this size sterilizer.

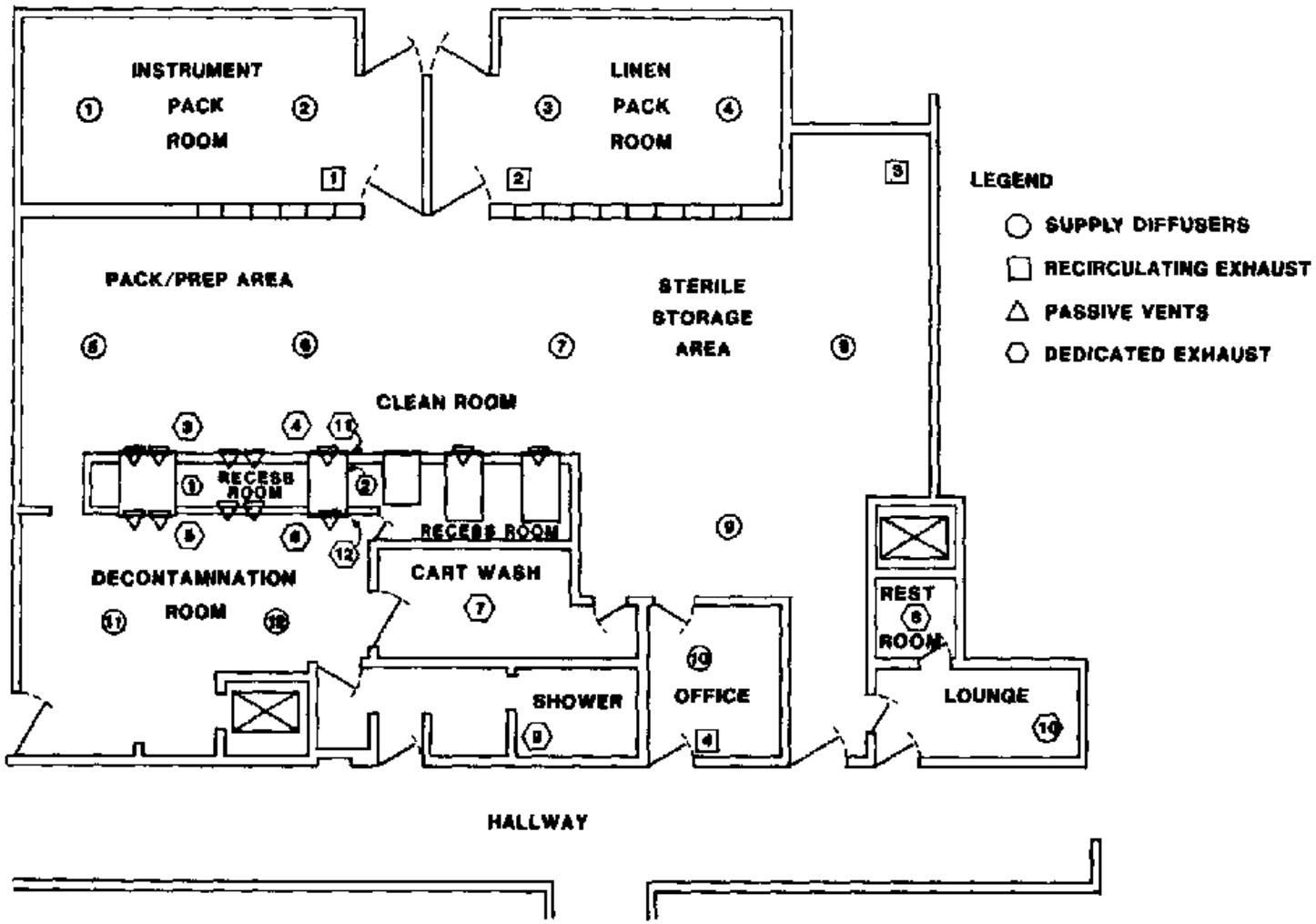

Figure 2. Diagram of the supply and exhaust vents in the sterilization areas.

METHODOLOGY

To evaluate the effectiveness of the engineering control measures, short-term and full-shift concentrations of ethylene oxide were determined and selected ventilation parameters (mainly air velocity and volumetric flow rate) were measured. The major pieces of equipment used in this evaluation are listed in Table A-1 of the Appendix.

PROCESSING A TEST LOAD

In designing this study, it became obvious that conditions in each hospital participating in the study would be so variable that meaningful comparisons between hospitals would be difficult unless some of the variables could be eliminated. Therefore, a test load was provided for processing at each hospital. The test load consists of Peel-Pack packages containing an 15-inch length of latex rubber tubing. The number of packages was adjusted to the amount of EtO in the chamber during sterilization. For an 8.8-ft^3 AMSCO 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. It was hoped that this increased retention of EtO would provide a challenge to the control system.

It was planned to run a test load in the morning of each sampling day. No other loads were to be processed through the EtO sterilizer during the day shift. The hospital's normal load was to be processed during the evening shift, as usual.

MEASUREMENT OF CONTROL PARAMETERS

Charcoal Tube Sampling

To determine personal exposures and average concentrations of EtO at selected locations in the clean room, personal and area samples were collected using coconut shell charcoal tubes according to NIOSH Method 1607[8]. The samples were collected on 400 mg and 200 mg charcoal tubes (SKC No. 226-37) connected in series, and the sampling train was contained in a plastic holder. MDA pumps with limiting orifices rated at 10 milliliters of air per minute (mL/min) and 20 mL/min--one of each value--were used to collect duplicate long-term (8-hour) samples for the sterilizer operator, the area over the sterilizer door, and inside the recess room (4-hour samples); and single 20 mL/min orifices were used to collect long-term samples for an instrument wrapper, an area location in the clean room and in the decontamination room. The same type pumps with of a pair of 100 mL/min orifices to collect duplicate short-term samples (12-30 minutes) for the operator and area location in front of the sterilizer during the load transfer procedure. The day and evening shifts were sampled for 3 days, except for the recess room samples which were collected only during the day shift.

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 ambient air. Long-term area samples were located at a fixed

location approximating the operator's breathing zone in front of the sterilizer, at a work bench near the sampled instrument wrapper, and on a work table along the west wall in the decontamination room. A pair of samples was collected inside the recess room each day for approximately 4 hours bracketing the chamber evacuation at the end of the test load cycle to compare with samples taken on the first survey as part of a sampling methods experiment.

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 open the door at the end of the air flush phase until the load transfer to the aerator was completed, and the operator left the sterilizer area. One sample was collected while the aerator was being rearranged to accommodate a second load.

Gas Bag Sampling

DuPont pumps were used to collect air samples in Tedlar® gas sampling bags (SKC No. 231). A short-term area sample over the sterilizer door was collected during the load transfer procedure at the same location and time as the short-term charcoal tube samples. A sample was collected for the operator while transferring the sterile load to the aerator. One sample was collected while the aerator was being rearranged to accommodate a second load.

To estimate the effectiveness of the air flush phase in reducing the EtO concentration, a sample was collected from inside the sterilizer chamber when the door was cracked open. To estimate the potential concentration of EtO to which the operator might be exposed and the effectiveness of the door-crack period, another sample was collected inside the chamber just before the load was transferred to the aerator. A sample was collected in the recess room near the drain soon after the start of the first vacuum purge to estimate the effectiveness of the drain controls.

These bag samples were analyzed on site with a portable gas chromatograph using a 4" x 1/8" Teflon® Carbopak BHT 40/100 mesh column. The carrier gas was air with a nominal flow rate of 15 mL/min, which gave an EtO retention time of approximately 2 minutes. Two attenuation settings were used, and the GC was calibrated and periodically checked in both these ranges.

Infrared Analyzer Monitoring

Due to the cyclic nature of EtO release during the day, it was desirable to have a continuous record of the estimated EtO concentrations in the breathing zone in front of the sterilizer. The infrared analyzer sampling probe was located over the sterilizer door alongside the charcoal tube area samples. A continuous monitor provided a measure of the background EtO levels as well as indicating higher concentrations which could be associated with certain events.

Peak concentrations may not be accurately measured with an infrared (IR) analyzer. The sensing cell of the instrument has a volume of about 5 liters and the sampling pump a flow rate of 5 L/min. This results in an instrument

response time of approximately 3 - 5 minutes. Thus, short concentration peaks (such as those associated with the load transfer) may be underestimated by the IR analyzer.

Laboratory experiments showed the instrument responded to a known concentration of EtO and humidity by indicating a higher concentration reading than the EtO level which was present. The sensitivity of the response at the 3.3 μm 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 concentrations and EtO humidity levels. This arrangement allowed the response of the infrared analyzer to EtO to be differentiated from relative humidity.

Air Flow Measurements

The airflow in the duct exhausting air from the recess room was measured using a hot-wire anemometer. The duct was traversed at an accessible location above the ceiling in the hallway. The low velocities encountered precluded the use of a pitot-tube and inclined manometer.

Within the department, ventilation air flow measurements at each accessible supply or exhaust louver were made with an Alnor Balometer®, a hooded instrument that allows a direct reading of flow into or out of a flush vent. The airflow through the slot hood above the sterilizer door was determined using an eight point traverse of air velocity with a hot-wire anemometer.

Smoke tubes were used to qualitatively evaluate the supply and exhaust ventilation system. Airflow patterns at selected locations were observed and sketched. Airflow patterns above the sterilizer door were visualized with smoke tubes and 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 personal exposure. To evaluate this effect, observations of the operator's work practices during EtO sterilizer activities were made using a video camera/recorder.

RESULTS

A test load was run during the day shift each day and during the evening shift on the first day of sampling since there was no other load to be run. The hospital's normal load was processed during the other two evening shifts.

Some of the workers did not work the same job for a full shift. Often, the wrapper spent much of the shift in the decontamination room.

AIR SAMPLING RESULTS

Charcoal Tubes

Due to the low levels of EtO sampled relative to the capabilities of the laboratory analysis, the charcoal tube results are difficult to analyze. Most of the charcoal tube samples (45 of 62) were less than the analytical limit of detection (LOD). The samples were analyzed in four groups: for one group an LOD of 0.2 μg was reported, for another, 0.4 μg; and for the other two, 0.9 μg. These different LOD's coupled with different sample volumes for the various samples confound the reporting of meaningful values for comparison. In many cases, the actual values may be much less than the result calculated assuming that an amount of EtO equal to the detection limit was sampled.

The results of three samples (Nos. 838, 845, and 869) are so inconsistently and unexplainably high that the values are thought to be erroneous. Other than being reported (denoted with an asterisk) with all the other charcoal tube sample results in Table A-2, these samples are omitted from consideration in this report.

Additionally, two pairs of samples (Nos. 844/846 and 782/738) are inconsistent with each other, and sample No. 844 is inconsistent with both the other samples taken on that day and the other samples taken at that location. These results are questionable but are used as reported.

The most important results in terms of exposure are those for the sterilizer operator. Four long-term samples were above the LOD; yielding an average exposure of 0.045 ppm. The other full-shift exposures are known only to be less than values ranging from 0.015 to 0.66 ppm. The twelve short-term samples were all below 0.43 ppm for sampling periods averaging 21 minutes in duration.

For the wrapper, who worked in the decontamination room cleaning items returned for sterilization as well as in the sterilizer area wrapping materials in preparation for sterilization, the 1st-shift sample on the 1st day indicates a full-shift exposure of 0.22 ppm. One sample was lost before it could be analyzed, the other four were less than values from 0.024 to 0.19 ppm.

The measurable concentrations for the long-term samples in front of the sterilizer averaged 0.054 ppm and the others were less than 0.12 ppm. The detectable short-term samples averaged 0.43 ppm and the others were less than 0.5 ppm.

All the other area samples measured detectable quantities during the 1st day shift and a few samples were detected for other shifts. Of these, the recess room samples showed the most dramatic effect, with a concentration of 2.3 ppm on the first day and an average of 0.24 ppm for the other two days. The decontamination room sample for the day shift on the 2nd day also collected a measurable quantity which along with the 1st day's sample average 0.062 ppm. The general area sample yielded a full-shift average concentration of 0.055 ppm for the 1st day shift. All other area samples are known only to be less than values ranging from 0.022 to 0.11 ppm.

Short-term exposures may best be viewed in terms of the concentration-time product, ppm-minutes. The concentration-time product represents the total "dose" of exposure received during a sampling period. In terms of this product, operator exposures were less than values ranging from 1.8 to 8.3 ppm-min. The detectable door samples averaged 7.8 ppm-min and the others were less than values from 3.5 to 8.3 ppm-min. A pair of samples collected while rearranging the aerator after the load had been in the aerator approximately 4 hours were below detectable limits, indicating that the operator was exposed to less than 1.4 ppm-min or an average concentration of less than 0.7 ppm.

Gas Bag Samples

The results of the gas bag samples repeated for each load are presented in Table A-3. This sampling method indicates that operator exposures during the load transfer were generally less than 2 ppm-minutes, or an average not greater than 1 ppm for duration less than or equal to 2 minutes. The concentration in front of the sterilizer, representing the maximum potential exposure if the operator did not walk away from the sterilizer during the door-crack period, were less than 7 ppm-min for periods of 20 to 30 minutes, yielding an average short-term concentration of less than 0.3 ppm. A sample collected while rearranging the aerator after the load had been in the aerator approximately 4 hours indicated that the operator was exposed to 0.47 ppm-min or an average concentration of 0.3 ppm.

Infrared Analyzer

An example of the IR analyzer peaks resulting from end-of-cycle activities is shown in Figure 3. The peak response during the load transfer operation lasted for 2 to 8 minutes and ranged from 1 to 5 ppm. There was little or no increased response during the door-crack period. During the purge cycle of the first load, the infrared analyzer responded with a broad peak lasting 30 minutes and reaching 3 ppm approximately midway through. After this was observed, the drain was inspected, and an unsealed gap was found where the discharge line enters the floor drain. This was temporarily sealed for the remainder of the survey, and there was no discernable infrared response during the subsequent purge cycles.

Because of the relatively slow response time of the IR analyzer, it may not fully respond to a peak before the peak starts to decrease. However, since it should respond equally slowly to decreasing concentrations as increasing ones, the area under the curve should be truer representation of the exposure dose

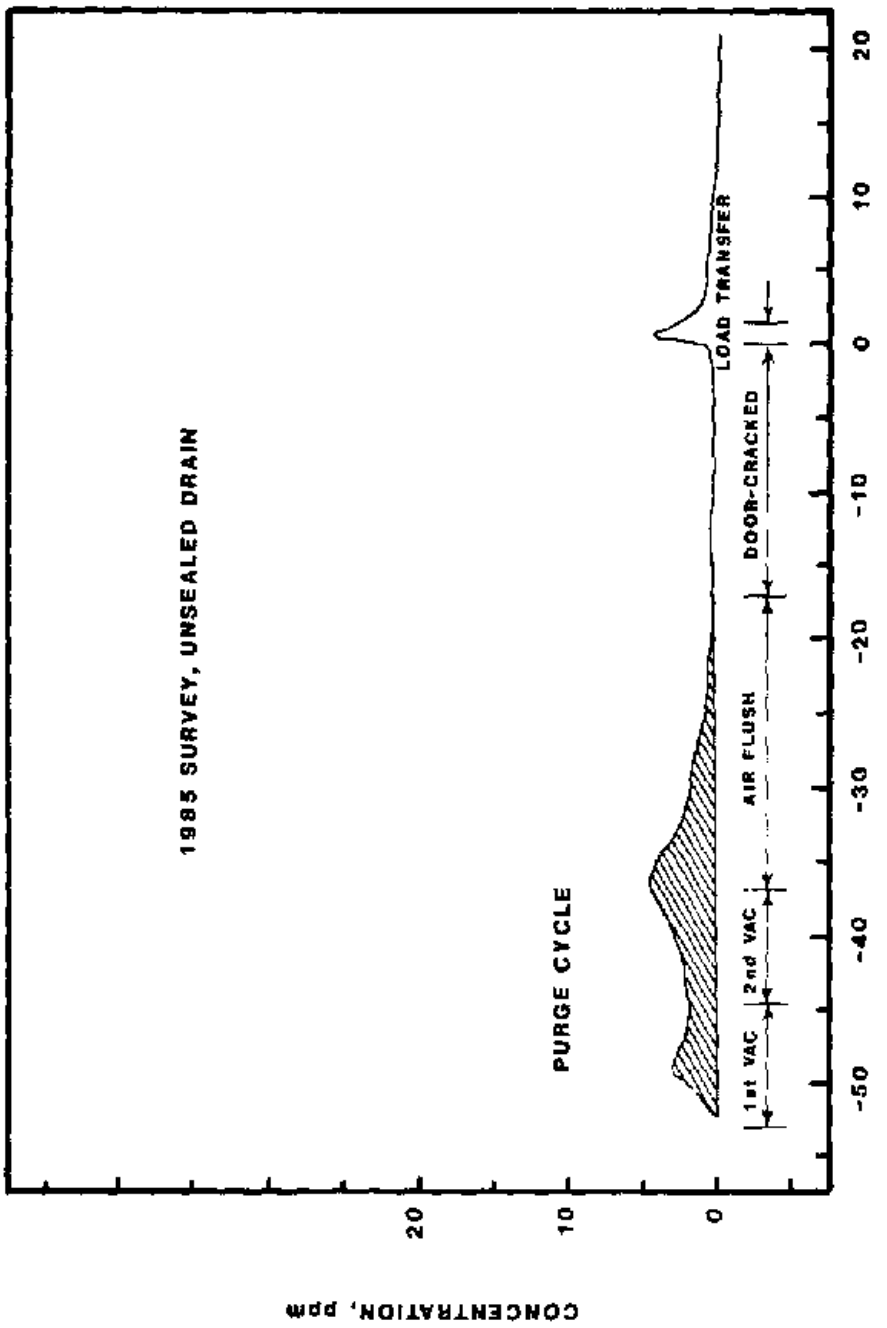

Figure 3. Example of infrared analyzer output.

at the sampling point. Thus, the IR absorption peaks on the recorder chart needed to be integrated. (This was done with a device called a planimeter.) The results of these analyses are compared with the charcoal tube and gas bag samples in Table A-4.

VENTILATION MEASUREMENTS

An average velocity of 800 ft/min was measured for the slot above the door of the sterilizer on the clean room side. This slot has an area of approximately 0.125 ft^2, giving a volumetric flow rate of 100 cfm. When the Envirogard® fan is turned off, this air flow drops to 30 cfm. This amount is drawn through this system by the fan on the roof. The slot in the decontamination room was not measured and is assumed to have the same values.

The ventilated air gap at the drain (designated by the manufacturer as an LGS) had two openings. One was measured and found to have a flow rate of 23 cfm which dropped to 7 cfm when the Envirogard® fan was turned off. Thus, for the LGS unit, the values are approximately 45 cfm with the fan on and 15 cfm with it off.

The dedicated exhaust system for the recess room (which includes the Envirogard® ventilation) was measured to carry approximately 320 cfm with the Envirogard® running and 165 cfm with it off. Therefore, the ceiling vent in the recess room exhausts approximately 75 cfm when the Envirogard® fan is running, and 90 cfm when the fan is off. Including the LGS ventilation in the recess room total raises the flow rate to 120 cfm with the on and 105 cfm with it off.

The use of smoke tubes showed that air was drawn into the sterilizing area. The clean room seemed to have an excess of supply air, and air flowed into the decontamination room through the open pass-through window. More importantly, air flowed from the recess room into both the decontamination room and the clean room through the vents in the wall above the equipment. The flow out of the recess room was more evident into the decontamination room, perhaps because of the excess supply into the clean room from the recirculating ventilation system. However, there was some flow from the recess room into the clean room during the purge cycle. These observation are illustrated in Figure 4.

The total balance of all supply and exhaust vents is shown in Table A-5. The airflow measurements with the Balometer® and a hot-wire anemometer show that slightly more air is exhausted from the clean room and the adjacent rooms than is supplied. However, the difference of less than 3 percent is small compared to the precision of the measurement methods. Keep in mind that the air changes per hour is not as important to the effectiveness of the ventilation system as is the degree of containment in the recess room and the local ventilation in the area directly in front of the sterilizer and aerator.

WORK PRACTICE OBSERVATIONS

Four different operators unloaded the six loads sterilized during the survey. From a review of the video tape, the following work practices were noted:

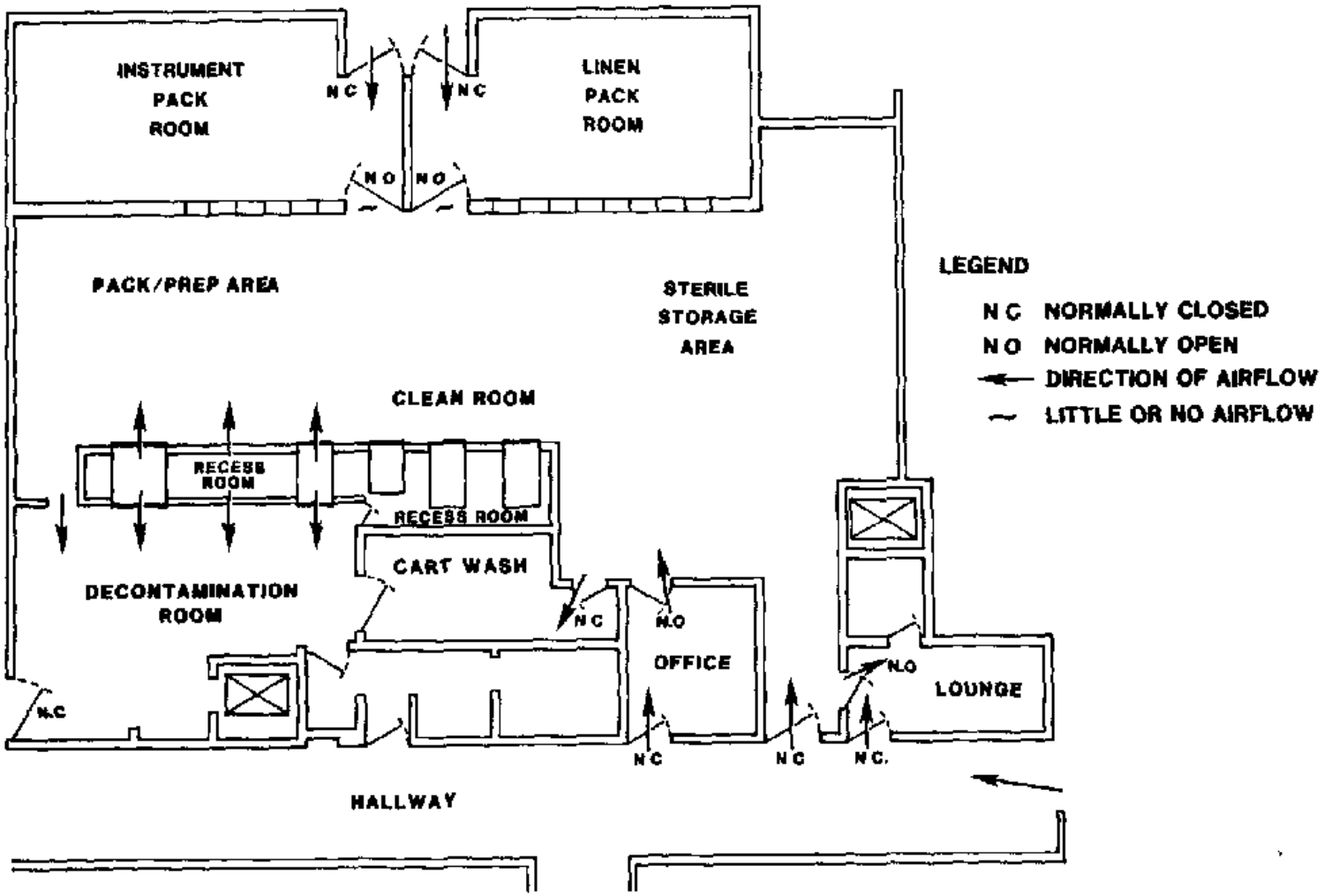

Figure 4. Direction of airflow through doorways, and transfer vents.

when the aerator door was opened with respect to opening the sterilizer door and pulling the load, when the sterilizer door was closed with respect to putting the load in the aerator, how the load was moved from the sterilizer to the aerator, and when the biological indicator pack was removed from the load. In addition, the following times were determined: sterilizer door opened until aerator door closed, sterilizer door opened until sterilizer door closed, and load out of sterilizer until load into aerator. This information is compiled in Table A-6 along with the type of load, whether baskets were used and manually placed in the aerator rather than rolling a rack off the cart into the aerator, and the amount the door was cracked open during the 15-minute waiting period.

Not evident from the tabulated data is that for load Nos. 3, 4 and 5, the sterilizer door was kept open for 14 to 16 seconds before the load was pulled versus 5 to 10 seconds for the other three loads. Also, the load set under the sample while the BI was taken off the rack for 27 seconds during the load No. 1 and for 11 seconds during the load No. 6. For all other loads, the rack was moved to the aerator within 6 or 7 seconds. The practice of removing the BI pack from the load was highly variable, as was the use of gloves.

CONTROL EVALUATION

At this hospital, controls were in place to deal with the three major sources of EtO during each sterilization cycle: the drain during evacuation, the door after opening at the end of the cycle, and the load during transfer to the aerator. Overall, full-shift concentrations averaged less than 0.1 ppm and average short-term concentrations (for approximately 15-minute periods) were less than 0.5 ppm. Table 1 shows that exposures and area concentrations were reduced 75 to 95 percent from the previous survey, and the concentrations inside the chamber when the door was first cracked open and just before the door was fully opened were reduced 65 to 70 percent.

Table 1. Comparison of Full-shift Charcoal Tube Results before and after Envirogard® Installation

		Before Envirogard® Oct.30-Nov. 1, 1984		After Envirogard® Oct. 8-10, 1985		
Location (term)-Activity	Type** Sample	No. of Samples	Average ppm	No. of Samples	Average ppm	Percent Reduction
Operator (L-T)	CT	10	0.24	9	<0.05	>79
Sterilizer Door (L-T)	CT	12	0.51	10	<0.06	>88
Other Worker (L-T)	CT	12	0.37	4	<0.09	>76
Work Table (L-T)	CT	12	0.30	4	<0.05	>83
Recess Room - Purge	CT	2	9.2	4	<0.28	>97
Chamber-Door Cracked	GC	6	1750	6	560	68
Chamber-15 min. later	GC	6	210	6	90	57
Operator (S-T)	CT	12	1.9	10	<0.22	>88
Operator-Load Transfer	GC	6	2.4	5	0.56	77
Sterilizer Door (S-T)	CT	12	4.0	9	<0.31	>92
Sterilizer Door (S-T)	GC	6	5.2	5	<0.23	>96

*Values for Oct. 8-10, 1985 do not include data for day shift on Oct. 8 because drain was not properly sealed.
**CT = Charcoal Tube and GC = Gas Bag Samples.

DRAIN CONTROLS

Drain Ventilation

A ventilated enclosure had been installed around the required air gap in the drain discharge line as part of the Envirogard® system. This unit is called a liquid gas separator (LGS) by the sterilizer manufacturer. A comparison of the average recess room concentration measured during the first survey (9.1 ppm) and the average obtained for all loads except the first load of this survey (0.28 ppm) indicates that emissions from the drain were reduced by

approximately 30-fold due to the installation of this device. Over 600 ft/min face velocity was measured at the inlets to the LGS, more than enough to prevent EtO from escaping.

The recess room concentration measured for the one load run during this survey with the discharge-line/floor-drain junction unsealed was approximately eight times higher. This indicates that even with the required air gap enclosed and ventilated, a small leak in the discharge line downstream of the vacuum pump can cause a significant increase in the EtO concentration of the air in the vicinity of the leak.

The appearance in front of the sterilizer of EtO emitted into the recess room indicates that the recess room exhaust ventilation was insufficient to remove all the air rising to the ceiling of the recess room due to the heat generated by the equipment. In fact, since the Envirogard® ventilation system (with its own fan) was connected to the dedicated exhaust system for the recess room, only 105 - 120 cfm was exhausted from the recess room compared to the 300 cfm measured during the 1984 survey. This is far short of the amount necessary to overcome the thermal effects of the hot equipment, as is discussed below.

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 with insufficient ventilation, air may actually flow in through openings in the bottom portion of the room while flowing out of vents and cracks in the walls near the top of the room. Hemeon[9] gives an equation to calculate the velocity of this airflow through an orifice at the top of an enclosure. From this equation, a minimum exhaust flow rate can be calculated which assures that air does not leak out of the room. For room temperatures not exceeding 200°F:

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

where: Q = Minimum required flow rate, cfm;
L = Height of the hot air column, ft,
H'= Sensible heat released to the air, 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 transfer vents above the floor. Estimates of the heat released in the room, obtained from the manufacturer of the equipment are as follows:

AMSCO	EtO Sterilizer	100	Btu/hr.
AMSCO	Aerator	1,500	"
AMSCO	Medallion Washer	3,500	"
AMSCO	Vac-Matic A	13,800	"
AMSCO	Vac-Matic S	13,800	"
Total heat load in the Recess Room:		32,700	Btu/hr.

The open area of the twelve transfer vents was measured to be approximately 0.4 ft^2 each. Using a height of 7 ft, and total vent area of 5 ft^2, and a total heat release rate of 550 Btu/min, the equation yields a design exhaust flow rate of approximately 900 cfm. While this is a theoretical estimate, the result and the observed airflow patterns indicate that more ventilation is needed.

Door Controls

The slot hood above the door controlled EtO emissions during the door-crack period. Smoke-tube visualization showed that all of the air coming from the chamber was captured when the door was opened 2 inches, and most of the air rising from the opening was captured with the door opened 5 inches. The IR analyzer response did not increase during any of the periods the door was open a few inches prior to transferring the load.

Short-term concentration levels above the door during the door-crack period and load transfer are presented in Table 2. Note that the IR analyzer value for the first day shift does not include the peak (due to EtO emitted from the unsealed drain) detected in front of the sterilizer because of inadequate recess room ventilation. Although the results are not well correlated, they all indicate that the potential for exposure standing in front of the sterilizer from the time the door was cracked until the load transfer was completed was less than 10 ppm-min. The NIOSH ceiling limit would allow a total of 50 ppm-min for the workshift. Therefore, the EtO emissions from the door are well controlled. Some of this control is due to the ventilation of the slot hood above the door.

Table 2. Sterilizer Door Short-term Results Determined with Charcoal Tubes, portable GC, and IR Monitor.

Date	Shift	CT ppm-min	GC ppm-min	IR ppm-min
10/8/85	1st	<5.5	5.6	6.54*
	2nd	8.6	4.2	5.50
10/9/85	1st	<3.5	<5.0	2.38
	2nd	<3.7	<5.4	0.74
10/10/85	1st	<3.6	6.3	3.12
	2nd	8.2	<4.3	1.04

* Does not include peak due to EtO from drain escaping recess room.

Controls for Load Transfer

The operators' short-term exposures (ppm-min), which are indicative of the controls during load transfer, are presented in Table 3. The charcoal tube samples were collected from the time the door was opened a few inches at the

end of the cycle until the load was transferred to the aerator. Such small quantities of EtO were collected that all samples were less than detectable limits. The gas-bag samples analyzed with the portable GC were collected just during the load transfer. Thus, they were much lower than the corresponding charcoal tube samples and more indicative of the effectiveness of the controls during load transfer.

Table 3. Operator Short-Term Exposures Determined with Charcoal Tubes and Gas Bas Samples and a Comparison with Portable GC Door Results.

Date	Shift	C-T ppm-min	GC ppm-min	GC Operator / GC Door
10/8/85	1st	<3.8	0.79	0.14
	2nd	<1.9	0.47	0.11
10/9/85	1st	<1.8	0.84	<0.17
	2nd	<3.8	0.20	<0.04
10/10/85	1st	<3.8	0.42	0.07
	2nd	<8.3	1.37	0.32

The reduction of the quantity of EtO remaining when the sterilizer door is opened to pull the load is the primary control during the load transfer. The air bag samples taken inside the chamber when the door was cracked open after the two vacuum purges and one 20-minute air flush yielded concentrations averaging 560 ppm. This type of sterilizer typically has a chamber concentration of 255,000 ppm during sterilization. Theoretical calculations of the amount of EtO removed by a vacuum purge predict a 99-percent reduction in the amount of EtO in the chamber at the end of two purges.[10] The Envirogard® modification added a mandatory 20-minute air flush to complete the purge cycle. Repeating air flushes are optional, although they are initiated automatically if the door is not opened when the buzzer sounds.

This department follows the sterilizer manufacturer recommended practice of opening the door a few inches at the end of the cycle and leaving the room for 15 minutes before unloading the sterilizer. The average concentration inside the chamber at the end of this period before opening the door fully to transfer the load was approximately 90 ppm. Although this value was highly variable, ranging from 38 to 150 ppm, the additional reduction of more than 85 percent indicates that the door-crack period was effective.

During the actual transfer of the load from the sterilizer to the aerator, when the slot hood can not control EtO emissions from the load, work practices can affect exposure. The average operator exposure (ppm-min) for the load transfer (determined from the gas-bag samples) was three times higher for the loads which were pushed to the aerator than for other three loads, even though the sterilizer door was left open longer after the load was removed for the pushed loads.

There was no correlation of exposure with the time required to transfer a load from the sterilizer to the aerator, perhaps because all loads were transferred quickly. The average time that the load was out in the room was 30 seconds, and the average total time for the load transfer (until the last door was closed) was 58 seconds.

Considering the test loads separately from the hospital's normal loads, relatively more EtO (ppm-min) was detected in front of the sterilizer for the three loads which were pulled in 10 seconds or less after the sterilizer door was opened than for the other three loads which remained in the sterilizer approximately 15 seconds after opening the door. Due to the poor precision of the monitoring method (IR analyzer) at these levels and the small differences for only a few samples, this result is inconclusive. However, since the time for the load transfer does not seem to matter, standing back from the sterilizer and leaving the load in the chamber for 15 seconds or more after fully opening the sterilizer door may slightly reduce the potential for exposure.

CONCLUSIONS AND RECOMMENDATIONS

The Envirogard® modification greatly improved the control of EtO emissions. Worker exposures were reduced 75 to 90 percent to values within the 0.1 ppm full-shift exposure limit and 5 ppm/10-minute ceiling limit recommended by NIOSH. The concentrations measured in front of the sterilizer were reduced 85 to 95 percent. Although not evaluated by concentration or ventilation measurements, the installation of the spring-loaded valve (for venting either the EtO cylinder connection prior to changing a cylinder or the supply line prior to replacing a filter element) and venting both the outlet of this valve and the outlet of the of the sterilizer overpressure relief valve to the LGS are commendable.

Significantly higher levels of EtO were measured during the first load run during this survey when the sterilizer discharge-line/floor-drain junction was not sealed. It is recommended that this junction be permanently sealed, in accordance with the manufacturer's instructions.

Recess room ventilation has been reduced rather than increased since the first survey. Since there is the potential for large quantities of EtO to be released (via leaks or some other incidental discharge), into this room, the exhaust ventilation for this room should be increased so that air flows into, rather than out of, the room through the transfer vents with all the equipment contained in the room at operating temperature.

Considering the potential for high concentrations in the recess room and in front of the sterilizer due to leaks or incidental discharges, there was no provision for warning people to leave or not to enter these areas when the EtO levels were high. Sensors and alarms should be installed which measure the EtO concentration and signal when it is above preset limits. The warning system should include an audible alarm and lights inside the recess room and on the front panels of the EtO sterilizer in both the clean room and the decontamination room.

Although the differences are small, slightly lower exposures could be obtained by pulling the load to the aerator rather than pushing it and by standing back from the sterilizer after fully opening the sterilizer door and leaving the load in the chamber for 15 seconds or more before pulling the load from the sterilizer. In addition, operator exposures could be lowered still further by modifying the method for placing the biological indicator pack in the load to lessen the close contact with the sterilized items in removing it during the load transfer. One such modification would be to tape the BI pack to a stainless steel rod which would extend to the edge of the rack near the cart handle. This would allow the operator to remove the BI pack with his/her breathing zone at arm's length from the load. The rod could be bent so that the BI could be placed down in the center of the load. One final detail: the BI should be removed after the load is in the aerator--not only will this result in less EtO being emitted into the room, but also if an item falls off the side of the cart, it will drop in the aerator and not on the floor.

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

To insure the continued quality and effectiveness of the engineering controls, personal exposure monitoring should be continued. At a minimum, the sterilizer operator should be monitored for a full shift at least once per year. Additional monitoring would be desirable and may be required by the OSHA standard. This sampling could be conducted by hospital personnel using commercially available diffusion badges.

To protect the maintenance worker changing the EtO supply cylinders, face shields and gloves should be required for protection in case of an accident. Respirators should be available to handle emergency situations and may be desirable for routine cylinder changes. For situations where the worker encounters an unknown (but potentially high) concentration of EtO or in an emergency situation, NIOSH recommends a compressed air open circuit self-contained breathing apparatus (SCBA) with full facepiece.[10]

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Appendix A.

Table A-1. Equipment used on field survey.

SURVEY: Community MedCenter Hospital, Marion, Ohio, October 8-10, 1985.

Item	Model	Used for
Infrared spectrometer	Miran 1A	continuous area sampling
RH and Temp. Monitor	Gen'l Eastern 400 C/D	RH and temperature
Strip chart recorder	Varian	EtO conc. and RH
Hot-wire anemometer	TSI 1650	air velocity
Velometer Flow Hood	Alnor Balometer	air flow
Gas Chromatograph	Photo-Vac 10A10	analysis of bag samples
Personal sampling pump	MDA 808	personal and area TWA smpl
Personal sampling pump	DuPont P-4000	collection of bag samples
Smoke tubes	Draeger	air flow patterns

Table A-2. Charcoal Tube Sample Results.

SURVEY: October 8-10, 1985. Marion Community MedCenter Hospital, Marion, Ohio.

SAMPLE DESCRIPTION	TERM	SAMPLE NO.	DAY	SHIFT	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Operator	Long	742	10/8	1st	470	4.560	(0.5)	(0.061)	(28.6)
Sterilizer Operator	Long	747	10/8	1st	470	7.812	1.0	0.071	33.4
Sterilizer Operator	Long	733	10/8	2nd	392	3.794	<0.2	<0.029	<11.5
Sterilizer Operator	Long	750	10/8	2nd	392	7.588	(0.2)	(0.015)	(5.7)
Sterilizer Operator	Long	776	10/9	1st	457	4.48	<0.4	<0.050	<22.6
Sterilizer Operator	Long	775	10/9	1st	457	7.68	<0.4	<0.029	<13.2
Sterilizer Operator	Long	763	10/9	2nd	455	4.288	<0.4	<0.052	<23.6
Sterilizer Operator	Long	759	10/9	2nd	455	8.576	<0.2	<0.013	<5.9
Sterilizer Operator	Long	838	10/10	1st	448	4.4)	(2.5)	(0.315)	(141.3)
Sterilizer Operator	Long	849	10/10	1st	448	7.53	<0.9	<0.066	<29.7
Sterilizer Operator	Long	844	10/10	2nd	472	4.398	(0.9)	(0.114)	(53.6)
Sterilizer Operator	Long	846	10/10	2nd	472	8.796	<0.9	<0.057	<26.8
Sterilizer Operator	Short	771	10/8	1st	19	1.093	<0.4	<0.203	<3.9
Sterilizer Operator	Short	766	10/8	1st	19	1.137	<0.4	<0.195	<3.7
Sterilizer Operator	Short	736	10/8	2nd	12	0.707	<0.2	<0.157	<1.9
Sterilizer Operator	Short	780	10/8	2nd	12	0.735	<0.4	<0.302	<3.6
Sterilizer Operator	Short	758	10/9	1st	17	1.012	<0.2	<0.110	<1.9
Sterilizer Operator	Short	734	10/9	1st	17	1.052	<0.2	<0.106	<1.8
Sterilizer Operator	Short	789	10/9	2nd	22	1.262	<0.4	<0.176	<3.9
Sterilizer Operator	Short	793	10/9	2nd	22	1.313	<0.4	<0.169	<3.7
Sterilizer Operator	Short	791	10/10	1st	32	1.860	<0.4	<0.119	<3.8
Sterilizer Operator	Short	811	10/10	1st	32	1.934	<0.9	<0.258	<8.3
Sterilizer Operator	Short	861	10/10	2nd	20	1.169	<0.9	<0.427	<8.5
Sterilizer Operator	Short	870	10/10	2nd	20	1.215	<0.9	<0.411	<8.2
Sterilizer Operator	Short	800	10/9	2nd	2	0.148	<0.4	<1.500	<3.0
Sterilizer Operator	Short	751	10/9	2nd	2	0.154	<0.2	<0.721	<1.4
Other Worker	Long	732	10/8	1st	369	3.321	1.3	0.217	80.2
Other Worker	Long	753	10/8	2nd	260	2.528			
Other Worker	Long	744	10/9	1st	457	4.632	<0.2	<0.024	<11.0
Other Worker	Long	756	10/9	2nd	455	4.329	<0.2	<0.026	<11.7
Other Worker	Long	840	10/10	1st	290	2.713	<0.9	<0.184	<53.4
Other Worker	Long	836	10/10	2nd	475	4.546	<0.9	<0.110	<52.2
Recess Room	Long	778	10/8	1st	235	2.255	10.	2.461	578.4
Recess Room	Long	768	10/8	1st	235	5.080	20.	2.185	513.5
Recess Room	Long	755	10/9	1st	246	2.317	1.5	0.359	88.4
Recess Room	Long	781	10/9	1st	246	5.219	3.4	0.362	88.9
Recess Room	Long	850	10/10	1st	267	2.564	<0.9	<0.195	<52.0
Recess Room	Long	847	10/10	1st	267	5.777	(1.9)	(0.183)	(48.7)

Table A-2. Charcoal Tube Sample Results. (Continued)

SURVEY: October 8-10, 1985. Marion Community MedCenter Hospital, Marion, Ohio.

SAMPLE DESCRIPTION	TERM	SAMPLE NO.	DAY	SHIFT	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Door	Long	767	10/8	1st	492	5.003	(0.6)	(0.067)	(32.7)
Sterilizer Door	Long	746	10/8	1st	492	8.744	1.3	0.083	40.6
Sterilizer Door	Long	779	10/8	2nd	473	4.236	(0.6)	(0.079)	(37.2)
Sterilizer Door	Long	773	10/8	2nd	473	10.057	(0.5)	(0.028)	(13.1)
Sterilizer Door	Long	764	10/9	1st	491	4.994	<0.4	<0.044	<21.8
Sterilizer Door	Long	752	10/9	1st	491	8.728	<0.2	<0.013	<6.2
Sterilizer Door	Long	774	10/9	2nd	485	4.290	<0.4	<0.052	<25.1
Sterilizer Door	Long	749	10/9	2nd	485	10.185	(0.2)	(0.011)	(5.3)
Sterilizer Door	Long	837	10/10	1st	485	4.921	<0.9	<0.102	<49.2
Sterilizer Door	Long	859	10/10	1st	485	8.601	<0.9	<0.058	<28.2
Sterilizer Door	Long	854	10/10	2nd	487	4.267	<0.9	<0.117	<57.0
Sterilizer Door	Long	851	10/10	2nd	487	10.132	<0.9	<0.049	<24.0
Sterilizer Door	Short	782	10/8	1st	19	1.112	<0.4	<0.200	<3.8
Sterilizer Door	Short	738	10/8	1st	19	1.150	(0.6)	(0.290)	(5.5)
Sterilizer Door	Short	765	10/8	2nd	17	1.068	(1.0)	(0.520)	(8.8)
Sterilizer Door	Short	745	10/8	2nd	17	1.106	1.0	0.502	8.5
Sterilizer Door	Short	770	10/9	1st	17	1.048	<0.4	<0.212	<3.6
Sterilizer Door	Short	772	10/9	1st	17	1.085	<0.4	<0.205	<3.5
Sterilizer Door	Short	801	10/9	2nd	27	1.549	<0.9	<0.322	<8.7
Sterilizer Door	Short	790	10/9	2nd	27	1.603	<0.4	<0.138	<3.7
Sterilizer Door	Short	802	10/10	1st	32	1.915	<0.9	<0.261	<8.3
Sterilizer Door	Short	794	10/10	1st	32	1.982	<0.4	<0.112	<3.6
Sterilizer Door	Short	848	10/10	2nd	20	1.212	(0.9)	(0.412)	(8.2)
Sterilizer Door	Short	869	10/10	2nd	20	1.255	9.1	4.024	80.5
Work Table	Long	737	10/8	1st	489	5.015	(0.5)	(0.055)	(27.1)
Work Table	Long	760	10/8	2nd	475	4.804	<0.2	<0.023	<11.0
Work Table	Long	754	10/9	1st	491	4.862	<0.2	<0.023	<11.2
Work Table	Long	762	10/9	2nd	486	4.859	<0.4	<0.046	<22.2
Work Table	Long	835	10/10	1st	485	4.652	<0.9	<0.107	<52.1
Work Table	Long	845	10/10	2nd	487	4.842	20.	2.292	1,116
Decontamination Rm.	Long	743	10/8	1st	484	7.106	0.9	0.070	34.0
Decontamination Rm.	Long	757	10/8	2nd	475	5.000	<0.2	<0.022	<10.5
Decontamination Rm.	Long	769	10/9	1st	488	7.257	(0.7)	(0.054)	(26.1)
Decontamination Rm.	Long	740	10/9	2nd	487	5.145	<0.2	<0.022	<10.5
Decontamination Rm.	Long	839	10/10	1st	486	7.210	<0.9	<0.069	<33.7
Decontamination Rm.	Long	834	10/10	2nd	485	5.121	<0.9	<0.098	<47.3

Table A-2. Charcoal Tube Sample Results. (Continued)

SURVEY: October 8-10, 1985. Marion Community MedCenter Hospital, Marion, Ohio.

SAMPLE DESCRIPTION	TERM	SAMPLE NO.	DAY	SHIFT	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Field Blank		741	10/8	1st			<0.2		
Field Blank		748	10/8	2nd			<0.2		
Field Blank		777	10/8	2nd			<0.4		
Field Blank		761	10/9	1st			<0.4		
Field Blank		739	10/9	2nd			<0.2		
Field Blank		735	10/9	2nd			<0.2		
Field Blank		860	10/10	1st			<0.9		
Field Blank		833	10/10	2nd			<0.9		
QA1604*		693					6.7		
QA1606		795					7.3		
QA1613		783					2.1		
QA1614		841					(2.0)		
QA1615		868					<0.9		

* QA = Quality Control Sample

Table A-3. Ethylene Oxide Analyses by Portable GC, ppm.

Location - Activity	Date:	10/8/85		10/9/85		10/10/85		
	Type of Load:	Test	Test	Test	Norm	Test	Norm	AVG.
LOAD TRANSFER								
Sterilizer Operator-Transfer		0.6	0.4	0.9	0.2	0.3	1.0	0.6
Above Sterilizer Door-Transfer		0.3	0.2	<0.3	<0.2	0.2	<0.2	<0.2
Sterilizer Interior-Door Cracked		650	675	290	550	550	623	560
Sterilizer Interior-After 15 Min.		150	88	105	70	65	38	90
Above the Load-During Transfer		--	--	--	7	--	106	57
AERATOR								
Sterilizer Operator-Arranging Aerator Load		--	--	--	0.3	--	--	0.3
Inside Aerator-Midcycle		--	--	--	1.8	--	--	1.8
PURGE CYCLE								
Above Drain-Early in Purge		5000*	94	100	76	5.7	4	56
OTHER								
Above Drain in Cart Wash Room		--	--	--	--	--	<0.2	<0.2
Operator opening BI		--	--	--	--	--	0.2	0.2

*Value not used in computing Average. Load processed with unsealed drain in Recess Room.

Table A-4. Data from Infrared Monitor Tracings.

Date	Shift	Load	Activity	Conc ppm	Duration minutes	Average ppm-min
10/8/85	1st	Test1	Purge	1.44	30.0	43.10
	1st	Test1	Transfer	0.75	8.7	6.54
	2nd	Test2	Transfer	1.45	3.8	5.50
10/9/85	1st	Test3	Transfer	0.88	2.7	2.38
	2nd	Norm1	Transfer	0.46	1.6	0.74
10/10/85	1st	Test4	Transfer	0.64	4.9	3.12
	2nd	Norm2	Transfer	0.42	2.5	1.04

Table A-5. Overall balance of ventilation system, October, 1985.

	Supply Vents	Flowrate cfm		Exhaust (X-) and Return (R-) Vents	Flowrate cfm
S-1	Inst. Pack Room	120	R-1	Inst. Pack Room	410
S-2	" " "	125	R-2	Linen Pack Room	250
S-3	Linen Pack Room	80	R-3	Clean Room	650
S-4	" " "	90	R-4	Office	0
S-5	Clean Room	250	X-1	Recess Room	75
S-6	" "	215	X-2	Drain Enclosure (LGS)	45
S-7	" "	220	X-3	Clean Room	90
S-8	" "	340	X-4	" "	80
S-9	" "	255	X-5	Decontam. Room	100
S-10	Office	100	X-6	" "	100
S-11	Decontam. Room	150	X-7	Cart Wash Room	0
S-12	" "	170	X-8	Rest Room	60
			X-9	Shower Room	75
			X-10	Lounge	30
			X-11	Slot Hood in Clean Rm.	100
			X-12	Slot Hood in Decontam.	100*
Totals:	Supplied: 2115 cfm			Exhausted:	2165 cfm

* Not measured, value for X-11 used as an estimate.

Table A-6. Work Practice Observations.

Load No.	Operator	Times			Ster door			
		Ster Open until Aer Clsd sec	Ster Open until Ster Clsd sec	Load out in room sec	closed before Transfer	Baskets or Rack	Door Opened in.	Cart Pushed or Pulled
1	A	57	34	40	before	rack	2	pushed
2	B	41	49	23	after	rack	2	pulled
3	A	50	23	23	before	rack	2.5	pushed
4	B	44	51	23	after	rack	0.5	pulled
5	C	53	71	19	after	basket	1.5	swung
6	D	69	22	50	before	rack	2	pushed