IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

WOOSTER COMMUNITY HOSPITAL
WOOSTER, OHIO

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INTRODUCTION

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

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

These studies involve a number of steps or phases. Initially, a series of walk-through surveys is conducted to select plants or processes with effective and potentially transferable control concepts or techniques. Next, in-depth surveys are conducted to determine both the control parameters and the effectiveness of these controls. The reports from these in-depth surveys are then used as a basis for preparing technical reports and journal articles on effective hazard control measures. Ultimately, the information from these research activities builds the data base of publicly available information on hazard control techniques for use by health professionals who are responsible for preventing occupational illness and injury.

BACKGROUND FOR THIS PROJECT

The present Control Technology Assessment of Ethylene Oxide Sterilization in Hospitals is the result of the research recommendations of the 1983 Feasibility Study of Engineering Controls in Hospitals. During the feasibility study, preliminary surveys were conducted at eight hospitals to assess the potential need for further research in the control of anesthetic gases, antineoplastic drug exposures, and ethylene oxide (EtO) sterilization operations. Based on the feasibility study, a need for the evaluation and documentation of effective engineering controls for EtO sterilization was identified.

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

throat. Dermal exposure to aqueous solutions of EtO may cause burns and allergic sensitization. Animal toxicity studies have shown EtO to be a mutagen and a carcinogen. Studies of exposed workers have indicated increased mutagenic activity in human cells, an increase in the incidence of leukemia, and adverse reproductive effects. Many of these effects, both for exposed animals and humans, were observed at concentration levels lower than the former OSHA permissible exposure limit (PEL) of 50 parts EtO per million parts air (ppm), expressed as an 8-hour time-weighted average (TWA). As a result of these studies and the urgings of workers' groups, OSHA began the rulemaking process to issue a new standard in early 1983. On June 15, 1984 OSHA issued a new PEL of 1 ppm (8-hour TWA) for ethylene oxide based on its determination that EtO is a potential human carcinogen.[1] NIOSH recommends exposure be limited to less than 0.1 ppm (8-hour TWA) with a ceiling limit of 5 ppm for a period not to exceed 10 minutes in an 8-hour shift.[2]

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

BACKGROUND FOR THIS SURVEY

Wooster Community 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 two categories: a sterilizer using 100 percent EtO with extra evacuation phases at the end of the sterilizer cycle and local exhaust ventilation above the sterilizer door, and a sterilizer using 100 percent EtO with in-chamber aeration.

A preliminary survey was conducted in the CS Department on August 29, 1984. Findings of this preliminary survey indicated the Central Service Department had instituted engineering control technology for minimizing employee exposure to EtO and had developed a comprehensive program to protect its employees. Local exhaust ventilation had been provided in critical areas. Both of the sterilizers had a continuous fresh air purge phase following completion of the cycle. One of the sterilizers had an in-chamber aeration feature. The sterilizers and aerators were isolated in a small room with dedicated ventilation. Proper work practices for employees were clearly outlined in a procedure and policy manual, and based on observation of the transfer of a load from the sterilizer to the aerator, the operator followed those procedures. The CS Supervisor provided an in-service program every 3 months and taped seminars from the International Association of Central Service Managers on the hazards and safe use of EtO. In addition, the hospital staff were very conscientious about EtO control and had made every effort to follow the guidelines of the

American Hospital Association and the Health Industry Manufacturers Association for the safe and controlled use of EtO in sterilization operations.

An in-depth survey of the Central Service Department of Wooster Community Hospital was conducted on February 4-8, 1985 to evaluate its operations and associated controls for EtO exposure. This report documents the information pertinent to that evaluation.

POTENTIAL HAZARDS, EXPOSURE GUIDELINES, AND EXPOSURE SOURCES

Workers exposed to EtO may experience both acute and long-term health effects. EtO is a central nervous system depressant, and in air can cause acute irritation to the eyes, upper respiratory tract, and skin at concentrations of several hundred to 1,000 ppm. Exposure to high concentrations may also cause headache, dizziness, nausea, and vomiting. Dilute (1 percent) aqueous solutions can cause blistering of human skin after prolonged contact, and allergic sensitization can also occur in some individuals.[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 mononuclear cell 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.[1] The American Conference of Governmental Industrial Hygienists has also adopted 1 ppm as an 8-hour time-weighted average Threshold Limit Value (TLV); however, it has allowed for an excursion limit such that short-term exposures should exceed 3 ppm no more than 30 minutes during a workshift and should never exceed 5 ppm.[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.[2]

PRIMARY EXPOSURE SOURCES

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

Opening of the Sterilizer Door

In some situations, the most significant EtO emission source on a daily

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

Transferring the Sterilized Load

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

SECONDARY EXPOSURE SOURCES

Other exposure sources may not be as readily apparent, but may also provide important contributions to the background levels of EtO in the workroom air. Some of these sources may only intermittently release EtO.

Aeration

Post-sterilization aeration is essential for protection of the patients who will use the items and for controlling occupational exposure to EtO. While in the aerator the sterile items continue to off-gas. If the aerator cabinet is not vented out of the building or to a dedicated exhaust, it can become a major contributor to the background EtO levels.

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.

Evacuation Line

The gaseous contents of the sterilizer chamber are evacuated through a venturi pump and out of the building through a copper line. Any poor fitting or leak in the line could result in an EtO exposure source.

HOSPITAL, EQUIPMENT, AND PROCESS DESCRIPTION

HOSPITAL AND CENTRAL SERVICE DEPARTMENT DESCRIPTION

Wooster Community Hospital is a not-for-profit, acute care facility with 169 beds. Services which the hospital provides include: general surgery, eye surgery, obstetrics, neonatal care, urology, and an ambulatory care unit. The original hospital structure was completed and occupied in 1950. Ethylene oxide gas sterilization operations for the hospital are conducted in the Central Service Department located in the basement of a section of the hospital constructed in 1970.

The CS Department employs nine persons distributed over three shifts. The day shift employs four persons and a supervisor. Typically, one person works in the decontamination room and two others work in the sterilization and packing room (hereafter referred to as the clean room). Another person, the team leader, is assigned to operate the sterilizers and process the loads. This person is very mobile within the department and also picks up and delivers supplies to other departments in the hospital. The department supervisor spends most of her time in an office or moving between the different areas of the department. During the evening shift, three persons are in the department. One person is assigned to decontamination, one person works in the clean room, and the team leader operates the sterilizers. The night shift employs one person to work in both the clean room and the linen pack room.

The layout of the CS Department is diagrammed in Figure 1. Of particular interest in this study is the EtO sterilizer isolation room. This room was constructed in 1982 to house the two EtO sterilizers and the two aerators. The room measures 7 ft. by 11 ft. by 8 ft. Doors into this room are closed at all times. Only the sterilizer operator enters the room routinely and then for less than 5 minutes at any one time. Maintenance personnel occasionally go through the room to enter the recess room for service of the steam sterilizers. It is located behind the steam sterilizer recess room and is entered through the clean room.

The clean room has three functional areas. One end of the room is used to store clean supplies and to wrap and package items for sterilization. Another part of the room serves as a processing area where loads are prepared for steam sterilization and where sterile loads cool before storage or distribution. A third area of the room is occupied by two steam sterilizers that are recessed along one wall. The steam sterilizers may be accessed for maintenance through a small recess room located behind the sterilizers. This room is entered through a doorway from the EtO sterilizer room.

Sterile supplies and instruments are stored in two long, narrow rooms lined with shelves. Sterilizer cycle charts and records are stored in a small room off the clean room.

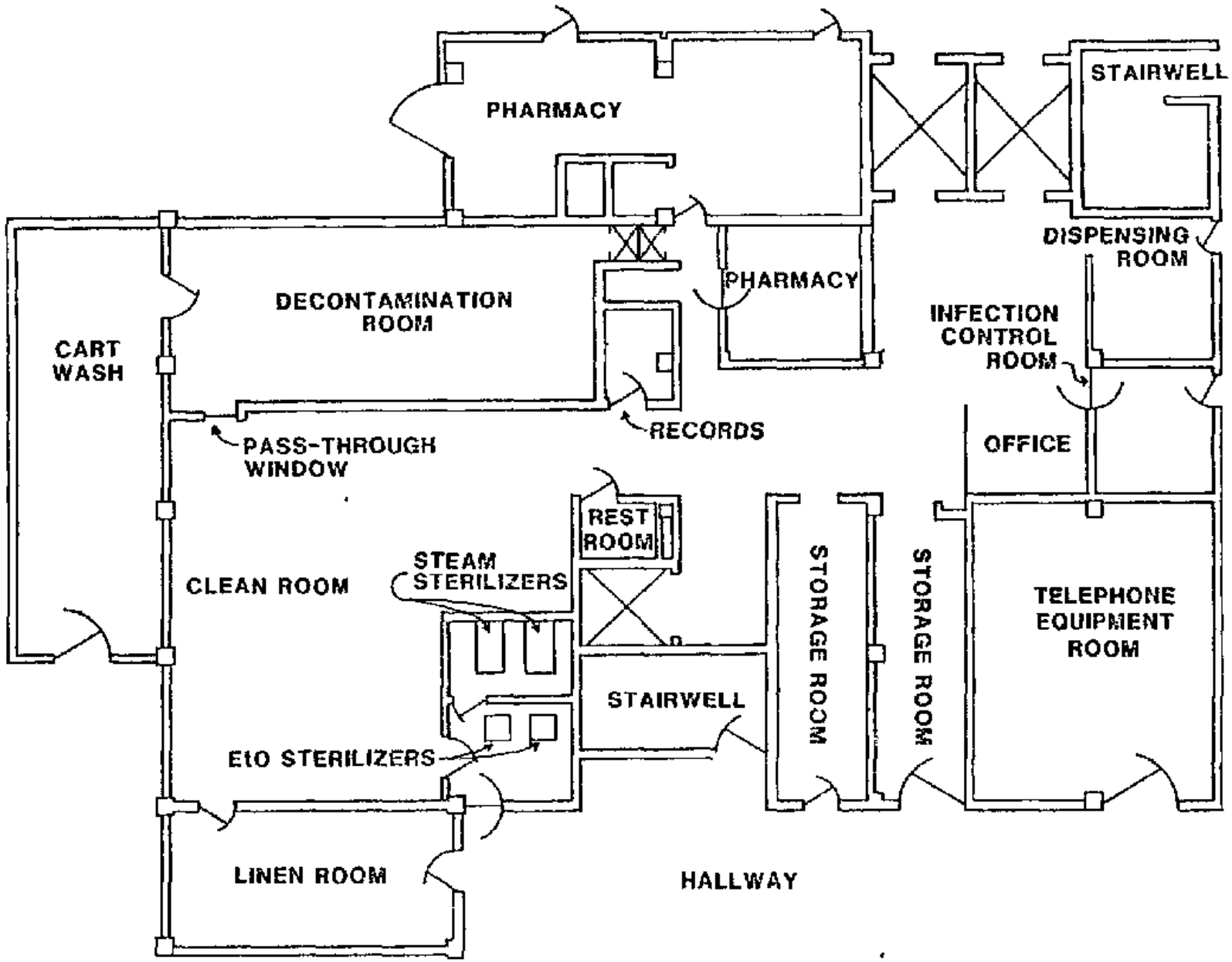

Figure 1. Central Service Department, Wooster Community Hospital.

EQUIPMENT AND PHYSICAL DESCRIPTION

The two EtO gas sterilizers are manufactured by 3M Company. One sterilizer is a Steri-Vac model 400 purchased in 1975 and modified in 1983 to conform to the cycle parameters of the Steri-Vac model 400B. The second sterilizer, a Steri-Vac model 400C purchased in 1983, features in-chamber aeration. Both sterilizers have an internal chamber volume of 4 cu.ft.

The two aerators are manufactured by 3M Company, Steri-Vac models 33 and 33B with internal chamber volumes of 4 cu.ft. Normal aeration time for a load is 8 hours. Special items may require up to 24 hours aeration. Three of the four EtO loads each day are aerated in the two aerators. The evening load processed in the model 400C sterilizer uses the in-chamber aeration feature for loads run on the warm cycle. Each aerator is located beneath an EtO sterilizer.

Sterilizer Cycle Features

Both the Steri-Vac models 400 and 400C have warm(145°F) and cold(99°F) cycle options. A warm cycle runs about 2 hours and 30 minutes, while a cold cycle lasts about 5 hours and 30 minutes. The cycle consists of several phases: initial vacuum, preheat, humidification, EtO gas injection, dwell period, final vacuum, and a 15-minute fresh air purge.

All 3M Company sterilizers operate at negative pressure throughout the cycle. EtO is supplied to the sterilizer by a cartridge of 100 percent EtO inserted into a special slot in the sterilizer chamber. At the appropriate time in the cycle, the cartridge is punctured, filling the chamber with EtO gas. The department uses about 100 to 120 cartridges per month. The cartridges are brought to the department by maintenance personnel in lots of 10. Larger quantities of the cartridges are stored in a building separate from the hospital.

In 1983, the department purchased a continuous fresh air purge feature as a modification for the Steri-Vac model 400. The continuous purge is a standard feature for the Steri-Vac 400C. After the final vacuum of the sterilizer cycle, the chamber is purged with fresh air for 15 minutes. If the sterilizer door is not opened when the buzzer sounds at the end of the 15 minutes, the vacuum pump continues to purge until the operator intervenes.

The Steri-Vac model 400C features in-chamber aeration as an option for the operator. Loads processed on the warm cycle may be left in the chamber after the final vacuum and through the air flush phases. Without operator intervention, the air flush phase continues with the temperature at 140° F for a minimum of 8 hours.

Local Exhaust Ventilation

Both sterilizers have local exhaust hoods over the doors. The Steri-Vac model 400 was retrofitted in 1983 with an exhaust hood, designed and supplied by 3M Company. The hood sits on top of the sterilizer and measures 14 3/16 inches by 30 inches by 4 5/8 inches. The slot over the door measures 1 1/4 inches by 19 inches. The Steri-Vac model 400C has a similar exhaust

hood built into the top panel of the sterilizer as a standard feature. The hood measures 27 1/4 inches by 30 inches by 4 5/8 inches. The slot over the door measures 1 1/4 inches by 19 inches. Both sterilizers have a flow indicator to visually alert the sterilizer operator if the local exhaust fan is not working, however, there is no audible alarm. The sterilizers and the aerators are vented into the same dedicated exhaust system. Local exhaust systems for both sterilizers also are part of the dedicated exhaust.

General Exhaust Ventilation

Heating/cooling ventilation is supplied to the department through a dual-duct, constant air volume system. Some of the supply air is partially recirculated air from another area of the hospital. Air is exhausted from the department through two separate systems and is exhausted to the outdoors. Air from the department is not recirculated. The system through which the sterilizer room is exhausted also exhausts air from decontamination and the pharmacy. The chamber exhaust from the sterilizers is copper piped to the outdoors.

The decontamination room is supplied by three air diffusers. A return exhaust grille is located in the ceiling over the pass-through washer. The decontamination room is under positive pressure with respect to the adjacent cart wash room and slightly positive pressure with respect to the clean room. Doors between the decontamination room and the cart wash room are closed at all times. A pass-through window between the decontamination room and the preparation/packaging area of the clean room is always open.

The clean room has four supply air diffusers. Exhaust is provided by three return exhaust grilles and a louvered vent over the steam sterilizer. The room is under positive pressure relative to the recess room for the steam sterilizers and the surrounding hallways. The clean room is also under positive pressure with respect to the EtO sterilizer room.

General ventilation for the EtO sterilizer room consists of one supply air diffuser and one exhaust grille to a dedicated exhaust system. Additional room exhaust is provided by the local exhaust hoods over the sterilizers' doors. The room is under negative pressure with respect to the clean room and is under positive pressure with respect to the steam sterilizer recess room and with respect to the surrounding hallways.

The recess room for the steam sterilizers is supplied with air through a louvered vent over a steam sterilizer. The room is exhausted by one grille in the duct for the EtO dedicated exhaust system.

PROCESS DESCRIPTION

Heat- or moisture-sensitive items must be sterilized with EtO gas. These items arrive in decontamination in enclosed carts delivered to the door by the using department or via a "dirty trayveyor". The items are washed, dried, and passed into the preparation/packaging area of the clean room through the pass-through window. Very small items are hand cleaned and treated with ultrasonics before passing into the clean room. The items may then be wrapped or heat-sealed in a peel-pak and carried to a table near the EtO sterilizer

room. The sterilizer operator prepares the load for sterilization by arranging the items in baskets, placing a biological indicator in the load, and completing the necessary record forms. The basket is placed in the sterilizer. The production schedule may require two loads run in each of the two EtO sterilizers, one load during day shift and one load during evening shift.

Transferring the Load

For loads which are to be aerated in the aerator, the sequence of events is as follows. At the end of the 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, presses and holds the "open door" switch for about 30 seconds until the door opens, and then pulls the door open about 1 inch so that the door catches on the latch above the door. The operator then leaves the room. At the end of 15 minutes, the operator returns to the sterilizer and opens the door of the aerator located beneath the sterilizer. Next the sterilizer door is swung fully open, and the operator slides the basket out of the sterilizer and into the aerator. The empty EtO cartridge is removed from the sterilizer chamber and put into the aerator. The operator then closes the aerator door and the sterilizer door. Aeration times for the particular load are recorded in a log book in one corner of the room. The operator leaves and closes the door to the sterilizer room.

During load transfer operations for the Steri-Vac 400 sterilizer, the operator also removes two sponges laying on the bottom of the sterilizer chamber. These sponges are placed in the sterilizer to aid the humidification phase per the instructions of the 3M service representative. The sponges are also placed in the aerator with the load.

Preventative Maintenance

The CS Department has a preventive maintenance contract with 3M Company for routine quarterly evaluations. The maintenance protocol specifies the evaluation of the EtO sterilizers and aerators for mechanical function and leak testing. The service person also inspects the sterilizer door gasket and replaces it as needed. Air lines and water lines are checked. Any necessary repairs are made immediately. Only 3M Company service personnel perform maintenance functions for these sterilizers.

Monitoring

The CS monitoring program is performed under contract by Medical Instrumentation Systems, MIS. Monitoring is done every 6 months and consists of area monitoring using a MIRAN IA infrared analyzer. Diffusion badges have been used on one occasion to monitor personal exposure of the sterilizer operator.

METHODOLOGY

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

MEASUREMENT OF CONTROL PARAMETERS

Charcoal Tube Sampling

To determine personal exposures and average concentrations of EtO at selected locations in the clean room, personal and area samples were collected using coconut shell charcoal tubes according to NIOSH Method 1607. The samples were collected on 400 mg and 200 mg charcoal tubes (SKC No. 226-37) connected in series, and the sampling train was contained in a plastic holder. MDA pumps with limiting orifices of approximately 10 milliliters of air per minute (mL/min) and 20 mL/min were used to collect duplicate samples for the sterilizer operator and the area over the sterilizer door for long-term (8-hour) samples, and with limiting orifices of approximately 50 mL/min to collect duplicate samples for the same personal and area locations during the load transfer procedure (short-term, 15-20 minutes). Beginning with load transfers on the evening shift of February 6 and continuing on February 7, short-term samples were collected using MDA pumps with limiting orifices of approximately 100 mL/min. MDA pumps (limiting orifices of approximately 20 mL/min) were used to collect long-term samples for an instrument wrapper and the wrapping area location. Day and evening shifts were sampled for three days.

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

Short-term samples provided an estimate of the peak concentrations of EtO released when the sterilizer door was opened and the load was transferred to the aerator. Samples were collected both for the sterilizer operator and at the area sampling location in front of the sterilizer from the time the operator walked up to the sterilizer to crack 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 room.

Gas Bag Sampling

DuPont pumps were used to collect air samples in Tedlar® gas sampling

bags (SKC No. 231). A short-term area sample over the sterilizer door was collected for 15 minutes during the load transfer procedure. A 2-3 minute sample was collected for the sterilizer operator while transferring the sterile load to the aerator. To estimate the effectiveness of the air flush phase in reducing the amount of EtO left in the chamber at the end of the cycle, a sample was collected in the sterilizer chamber when the door was cracked open prior to the 15 minute waiting period. Another sample was taken from the sterilizer chamber interior after the 15 minute waiting period, before the load was removed, to estimate the potential concentration of EtO to which the operator might be exposed. These latter two samples were collected for 15 seconds. All gas bag samples were analyzed on-site with a portable gas chromatograph.

Infrared Analyzer Monitoring

Due to the cyclic nature of EtO release during the day, it was desirable to have a continuous record of the estimated EtO concentrations in the breathing zone in front of the sterilizer. A continuous monitor provided a measure of the background EtO levels as well as indicating higher concentrations which could be associated with certain events.

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

The infrared analyzer was physically located outside the sterilizer room and connected by flexible, plastic tubing to sampling probes located in the breathing zone area in front of both sterilizers. The analyzer was connected to the appropriate sampling probe to monitor the sterilizer in use at any given time.

Laboratory experiments showed the instrument responded to a known concentration of EtO and humidity by indicating a higher concentration reading than the EtO level which was present. The sensitivity of the response at the 3.3 um wavelength was approximately 3 ppm EtO for a 10 percent rise in relative humidity. To compensate for this effect, the IR analyzer was connected in series with a hygrothermograph. These instruments were attached to a strip chart recorder to provide a continuous graphic record of changing humidity levels and EtO concentrations. This arrangement allowed differentiation of the response of the infrared analyzer to EtO from relative humidity.

Air Flow Measurements

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

velometer flow hood. Smoke tubes were used to qualitatively assess air movement patterns in the workroom and near local exhaust hoods, and the results were recorded on videotape.

Work Practice Observations

The work practices of the sterilizer operator may have a very important effect on the amount of EtO released into the workplace air and personal exposure. To evaluate this effect, observations of the operators' work practices during their EtO sterilizer activities were made. An activities data sheet was completed for each sterilizer load processed including estimates of the time spent on each activity. Notes were made to aid the association of the sampling results with specific activities, particularly for air bag samples. Each step of the sterilizer activities was videotaped to make additional analyses available.

Processing the Test Load

In designing this study, it became obvious that conditions in each hospital participating in the study would be so variable as to preclude any meaningful comparisons between hospitals unless some of the variables could be eliminated. Therefore, a challenge test load was provided for processing at each hospital. The load consists of packages of rubber surgical tubing, an 8-inch length contained in each "peel-pac". The number of packages is adjusted to the volume of the sterilizer of interest, corresponding to a 30 percent load level. For the 4-ft^3 volume sterilizer, 30 packages were used. The rubber materials of this test load were chosen because EtO is absorbed into rubber during sterilization and off-gases more slowly than some other materials. This increased retention of EtO, provides a challenge to the control system and may aid in evaluating the effectiveness of the controls.

Test loads were sterilized (warm cycles) during the day shift in both the Steri-Vac 400 and 400C for each of the three days of sampling. The department processed two normal loads during the evening shift, one in each sterilizer, for the three days. Sampling data from this test load provides the basis for comparison with similar loads processed in other hospitals.

MEASUREMENT RESULTS

AIR SAMPLING

The results of the analysis of the charcoal tube samples is reported in Table II and summarized in Tables III and IV. The long-term personal samples for the sterilizer operators ranged from 0.01 ppm to 0.04 ppm for a full-shift exposure average of 0.03 ppm. The full-shift exposure average for the instrument wrapper was <0.01 ppm. Averages are over two shifts for three days. All long-term area samples were less than 0.17 ppm.

Five of 24 short-term samples were below the limit of detection (LOD) for the analytical procedure, 0.1 µg per sample. Short-term samples collected during load transfer operations for the sterilizer operator ranged from less than 0.07 ppm to 6.62 ppm for an average exposure of <0.81 ppm. Short-term exposures are best viewed in terms of the concentration-time product, ppm-minutes. An exposure of 5 ppm, even for only 1 minute may seem unacceptably high while one of 0.25 ppm for 20/minutes may seem acceptable, even though both situations involve an exposure to the same quantity of EtO. The concentration-time product compensates for the different exposure time. In terms of this product, operator exposures ranged from <1 to 10 ppm-min with an average of <4 ppm-min.

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 0.5 to 1 ppm lasting about 9 minutes. This peak was seen to begin at the time the load was pulled from the sterilizer. An average 15 minute TWA concentration of 0.4 ppm was calculated from the tracings, refer to Table V.

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

VENTILATION MEASUREMENTS

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

Local exhaust ventilation was measured for each sterilizer. A flowrate of 31 cfm was measured for the hood over the door of the model 400, and a flowrate of 34 cfm was measured for the hood on the model 400C.

WORK PRACTICE OBSERVATIONS

During the survey, the work practices of five sterilizer operators were observed. Among the operators, the specific order in which the tasks associated with the load transfer were performed varied somewhat. All of the operators performed the load transfer in less than 1 minute and were present in the sterilizer room for a total time less than three minutes (including the time spent cracking the door upon completion of the sterilizer cycle).

CONTROL EVALUATION

This hospital has three principal types of controls: isolation, door controls, and controls for the load transfer operation.

Isolation

Isolation of the sterilizers and aerators in a room separates the EtO sources from the workers. The long-term area samples for the sterilizers yielded an average EtO concentration of 0.1 ppm; while the long-term samples for the workroom, wrapping area give an average concentration of 0.01 ppm. In terms of personal exposures, the average instrument wrapper, full-shift exposure was <0.01 ppm, corresponding well with the wrapping area concentration of 0.01 ppm.

Air from the sterilizer room is exhausted outdoors and is not part of a recirculated air system. Therefore, EtO in the room should not contaminate other areas of the hospital. However, the supplied air volume is greater than the exhaust air volume creating a net positive pressure in the sterilizer room. EtO contaminated air could escape the room through cracks and doorways.

Door Controls

Both sterilizers were fitted with a local exhaust ventilation hood over the door supplied by the sterilizer manufacturer. This slot hood provided control of EtO vapors escaping from the chamber when the door was opened a few inches at the end of the cycle. Based on the air flow patterns observed with smoke tubes, the slot hood seems to control emissions from the door to about 3 inches. Measured air flow was 31 cfm for the model 400 and 34 cfm for the model 400C. The manufacturer recommends that air flow be 100 cfm. The hood has a rotometer to visually indicate to the operator that the ventilation is working.

The American Conference of Governmental Industrial Hygientists publishes a handbook entitled: Industrial Ventilation - A Manual of Recommended Practice [7]. This manual discusses control velocities and capture distances with specific criteria and equations to aid in evaluation and design. For the case of a slot hood, the required exhaust volume is given by

$$Q = 2.8\ LVX$$

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

For this particular process, the control velocity should be between 50 and 100 feet per minute (ft/min)--with the upper limit of the range recommended. In this case the volumetric flowrate is known (31 cfm and 34 cfm), so the

maximum capture distance can be estimated by solving this equation for X. For a desired control velocity of 100 ft/min, the maximum capture distance calculated from the equation is about 1 inch. Smoke tubes indicated the hoods perform somewhat beyond the predicted distance.

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. To aid the sterilizer operator in cracking the door to a distance less than the control distance of the hood, the manufacturer has designed a latch on the hood which catches on the door as it is opened and holds the door open about 1 inch during the 15 minute waiting period. This insures that EtO-laden air escaping the chamber is captured by the hood.

Short-term area samples over the sterilizer door collected during the load transfer operation averaged 0.21 ppm for the model 400 and 0.38 ppm for the model 400C. The average short-term exposure during the same period for the sterilizer operator was <0.81 ppm and <4 ppm-min. These exposures are less than the NIOSH recommended guidelines. MIRAN IA tracings show EtO levels peaking while the load is pulled, indicating the slot hood is effective in controlling emissions from the door during the door crack period.

Controls for Load Transfer

The primary controls are reducing the quantity of EtO remaining in the load and keeping the worker's breathing zone away from areas of high concentration of EtO. Keeping the load in the sterilizer with vacuum purges and/or air flushes may reduce the quantity of EtO. Both sterilizers have one final vacuum purge (0.24 Bars) and one 15 minute fresh air flush (at 0.9 Bars) as the standard cycle with additional air flushes to continue unless the operator intervenes. Theoretical calculations of the amount of EtO removed by a vacuum of 0.24 Bars give 75 percent reduction in the amount of EtO in the chamber at the cycle completion. One sterilizer load (Feb. 6: day shift, model 400C) was allowed to continue through one additional air flush. The air bag sample taken inside the chamber when the door was cracked open yielded a concentration of 70 ppm. This value is much less than the average of 600 ppm. As can be seen in Table V, these particular samples were highly variable, however, this result may indicate the potential reduction in EtO concentration with additional air flush phases. The area short-term, over the door samples for this load resulted in an average EtO concentration of 0.31 ppm. Comparable samples on the other two days of the survey showed average concentrations of 0.54 ppm (Feb. 5) and 0.42 ppm (Feb. 7). Again, this is an indication of the reduction in EtO concentrations which may be achieved with additional air flush phases.

During the actual transfer of the load from the sterilizer to the aerator, the slot hood over the door is not large enough to control EtO emissions from the load as it is pulled from the chamber. Work practices, therefore, become very important. In most of the load transfer operations observed, the operator opened the aerator door before opening the sterilizer door to transfer the load. During the transfer of one load, however, the operator opened the sterilizer door first, removed the basket, held the basket close to the body

while opening the aerator door, then inserted the basket in the aerator, and closed both doors. The operator, short-term samples for this load were almost three times greater than the samples for the second load the same operator processed, 0.42 ppm compared to 0.14 ppm. Comparable loads processed by other operators who opened the aerator door first, resulted in exposures of less than 0.24 ppm and 0.11 ppm.

Another work practice which may effect the operator's exposure is the disposition of the spent EtO cartridge. The cartridge may be placed in the basket before the basket is removed from the sterilizer or the basket may be placed in the aerator first, then the cartridge removed and put into the aerator. One operator consistently followed the latter practice and tended to have the higher exposure results compared to the other operators.

In analyzing the exposure results and comparing the videotape recording of the load transfers, some of the higher exposures experienced by the evening shift operators may be partly attributed to the position of the operator during the door cracking procedure and the subsequent interior chamber concentration sample collected by NIOSH personnel. The evening shift operators tended to stand close to the sterilizer while the sample was collected. Day shift operators stayed several feet away from the sterilizer during the same time period. The collection of the interior chamber concentration sample prolonged the time the operator would normally spend in the sterilizer room, and thus may have caused a slight increase in exposure for the operators who stood near the sterilizer.

An interesting comparison of the operator's short-term exposure relative to the sterilizer unloaded is presented in Table IX. Average operator exposures while unloading the model 400C were 42 percent higher (based on ppm-min) than exposures received during unloading the model 400. It is possible that the supply air diffuser located in the corner near the model 400C created circular air currents. Air from the diffuser may flow down the wall and swirl back up in front of the sterilizer carrying EtO-laden air into the operator's breathing zone.

In general all operators completed the load transfer operation very quickly, in less than 1 minute. Short-term exposures ranged from less than 0.05 ppm to 6.62 ppm and from <1 to 10 ppm-min. Except for two short-term samples, these exposures meet the ACGIH short-term exposure guidelines for excursion limits (that short-term exposures should exceed 3 ppm no more than 30 minutes during a workshift and should never exceed 5 ppm). The exposures also meet the NIOSH short-term exposure recommendations that a ceiling limit of 5 ppm not be achieved for more than 10 minutes in a workday.

CONCLUSIONS AND RECOMMENDATIONS

Control of the full-shift personal exposures, as measured with charcoal tubes, is excellent. All values are less than 0.05 ppm. All full-shift area concentrations are less than 0.2 ppm. Likewise, short-term exposures are well controlled. Ninety-two percent of short-term, time-weighted average charcoal tube results were less than 1 ppm. The OSHA permissible exposure limit of 1 ppm, 8-hour TWA was met as well as the "action level" of 0.5 ppm. Both ACGIH and NIOSH recommendations for 8-hour TWA exposures and short-term excursion limits were met.

Engineering controls worked very well in limiting exposures and maintaining low EtO concentrations in the workroom air. Although all exposures were very low, further reductions could be achieved:

1. by increasing the frequency of use of the in-chamber aeration feature of the model 400C.

2. by increasing the number of air flush phases at the end of the cycle for those loads which are transferred to aerators.

3. by increasing the exhaust flowrate for the slot hoods over the sterilizer doors to meet the manufacturer's recommendation of 100 cfm.

It is important that all sterilizer operators observe the proper sequence of opening the aerator door before the sterilizer door when transferring the load, and operators should keep the basket of sterile products as far away from the breathing zone as possible during the transfer.

Devices should be installed on the ventilation systems exhausting air from the sterilizer room and the local exhaust ventilation hoods for the sterilizers to warn if the systems malfunction. The indicators should be visible and audible to the sterilizer operator in the clean room, and the EtO sterilizer should not be run unless both ventilation systems are fully operational.

EtO evacuated from the sterilizer chamber through an evacuation line to a courtyard could potentially reenter the hospital through windows and air conditioning window units surrounding the perimeter of the courtyard. Consideration should be given to this possibility and action taken to relocate the evacuation line.

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APPENDIX

TABLE I. Equipment Used on Field Survey.

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

SURVEY: February 5-7, 1985. Wooster Community Hospital, Wooster, Ohio.

SAMPLE DESCRPITION	TERM	SAMPLE NO.	DAY	SHIFT	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Operator	Long	442	2/5	1st	486	4.795	0.32	0.037	18.0
Sterilizer Operator	Long	573	2/5	1st	486	9.920	0.71	0.040	19.3
Sterilizer Operator	Long	563	2/5	2nd	462	4.340	0.26	0.033	15.4
Sterilizer Operator	Long	577	2/5	2nd	462	9.701	0.54	0.031	14.3
Sterilizer Operator	Long	472	2/6	1st	496	10.126	0.16	0.009	4.3
Sterilizer Operator	Long	477	2/6	1st	496	4.894	0.13	0.015	7.3
Sterilizer Operator	Long	462	2/6	2nd	475	4.466	0.16	0.020	9.4
Sterilizer Operator	Long	507	2/6	2nd	475	9.983	0.36	0.020	9.5
Sterilizer Operator	Long	506	2/7	1st	482	9.828	0.21	0.012	5.7
Sterilizer Operator	Long	463	2/7	1st	482	4.750	0.15	0.018	8.4
Sterilizer Operator	Long	476	2/7	2nd	499	4.631	0.36	0.043	21.5
Sterilizer Operator	Long	510	2/7	2nd	499	10.351	0.79	0.042	21.1
Sterilizer Operator	Short	560	2/5	1st	19	0.746	0.55	0.409	7.8
Sterilizer Operator	Short	571	2/5	1st	19	0.739	0.55	0.413	7.8
Sterilizer Operator	Short	562	2/5	1st	20	0.792	0.17	0.119	2.4
Sterilizer Operator	Short	570	2/5	1st	20	0.785	0.22	0.156	3.1
Sterilizer Operator	Short	465	2/5	2nd	1	0.041	<0.1	<1.354	<1.4
Sterilizer Operator	Short	513	2/5	2nd	1	0.040	<0.1	<1.388	<1.4
Sterilizer Operator	Short	497	2/5	2nd	1	0.062	0.56	5.013	5.0
Sterilizer Operator	Short	565	2/5	2nd	1	0.062	0.74	6.624	6.6
Sterilizer Operator	Short	466	2/6	1st	5	0.226	<0.1	<0.246	<1.2
Sterilizer Operator	Short	480	2/6	1st	5	0.228	<0.1	<0.243	<1.2
Sterilizer Operator	Short	479	2/6	1st	16	0.624	<0.1	<0.089	<1.4
Sterilizer Operator	Short	491	2/6	1st	16	0.618	0.11	0.099	1.6
Sterilizer Operator	Short	502	2/6	2nd	16	1.059	0.53	0.278	4.4
Sterilizer Operator	Short	516	2/6	2nd	16	1.013	0.62	0.340	5.4
Sterilizer Operator	Short	469	2/6	2nd	18	1.014	0.20	0.109	2.0
Sterilizer Operator	Short	498	2/6	2nd	18	0.970	0.19	0.109	2.0
Sterilizer Operator	Short	464	2/7	1st	18	1.025	0.16	0.087	1.6
Sterilizer Operator	Short	519	2/7	1st	18	1.035	0.15	0.080	1.4
Sterilizer Operator	Short	521	2/7	1st	18	1.072	0.27	0.140	2.5
Sterilizer Operator	Short	526	2/7	1st	18	1.082	0.13	0.067	1.2
Sterilizer Operator	Short	523	2/7	2nd	18	1.176	1.2	0.566	10.2
Sterilizer Operator	Short	535	2/7	2nd	18	1.229	1.0	0.452	8.1
Sterilizer Operator	Short	530	2/7	2nd	19	1.081	0.97	0.498	9.5
Sterilizer Operator	Short	537	2/7	2nd	19	1.130	0.98	0.481	9.1

Table II. CHARCOAL TUBE SAMPLE RESULTS, CONTINUED.

SURVEY: February 5-7, 1985. Wooster Community Hospital, Wooster, Ohio.

SAMPLE DESCRPITION	TERM	SAMPLE NO.	DAY	SHIFT	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Instrument Wrapper	Long	572	2/5	1st	485	9.793	0.55	0.031	15.1
Instrument Wrapper	Long	449	2/5	2nd	475	10.501	0.17	0.009	4.3
Instrument Wrapper	Long	481	2/6	1st	497	10.019	0.12	0.007	3.3
Instrument Wrapper	Long	484	2/6	2nd	478	10.648	<0.1	<0.005	<2.5
Instrument Wrapper	Long	468	2/7	1st	488	9.780	0.17	0.010	4.7
Instrument Wrapper	Long	509	2/7	2nd	476	10.506	0.10	0.005	2.5
Wrapping Table	Long	568	2/5	1st	489	10.669	0.43	0.022	10.9
Wrapping Table	Long	559	2/5	2nd	485	10.623	0.20	0.010	5.1
Wrapping Table	Long	475	2/6	1st	496	10.718	0.18	0.009	4.6
Wrapping Table	Long	473	2/6	2nd	476	10.317	0.18	0.010	4.6
Wrapping Table	Long	492	2/7	1st	491	10.498	0.15	0.008	3.9
Wrapping Table	Long	534	2/7	2nd	496	11.047	0.12	0.006	3.0
Sterilizer Door 400	Long	448	2/5	1st	481	8.112	1.3	0.089	42.8
Sterilizer Door 400	Long	453	2/5	1st	481	4.605	0.85	0.102	49.3
Sterilizer Door 400	Long	450	2/5	2nd	498	4.354	0.72	0.092	45.7
Sterilizer Door 400	Long	457	2/5	2nd	498	12.245	1.6	0.073	36.1
Sterilizer Door 400	Long	486	2/6	1st	501	4.800	0.62	0.072	35.9
Sterilizer Door 400	Long	495	2/6	1st	501	8.456	1.0	0.066	32.9
Sterilizer Door 400	Long	471	2/6	2nd	476	11.777	1.8	0.085	40.4
Sterilizer Door 400	Long	501	2/6	2nd	476	4.187	0.81	0.107	51.1
Sterilizer Door 400	Long	489	2/7	1st	499	8.503	1.4	0.091	45.6
Sterilizer Door 400	Long	524	2/7	1st	499	4.827	1.0	0.115	57.4
Sterilizer Door 400	Long	527	2/7	2nd	487	11.867	2.3	0.108	52.4
Sterilizer Door 400	Long	538	2/7	2nd	487	4.219	0.93	0.122	59.6
Sterilizer Door 400	Short	567	2/5	1st	17	0.590	0.23	0.216	3.7
Sterilizer Door 400	Short	574	2/5	1st	17	0.713	0.25	0.195	3.3
Sterilizer Door 400	Short	485	2/5	2nd	18	0.748	0.33	0.245	4.4
Sterilizer Door 400	Short	558	2/5	2nd	18	0.619	0.40	0.359	6.5
Sterilizer Door 400	Short	490	2/6	1st	16	0.609	0.17	0.155	2.5
Sterilizer Door 400	Short	504	2/6	1st	16	0.504	0.17	0.187	3.0
Sterilizer Door 400	Short	461	2/6	2nd	18	1.047	0.52	0.276	5.0
Sterilizer Door 400	Short	499	2/6	2nd	18	1.098	0.33	0.167	3.0
Sterilizer Door 400	Short	517	2/7	1st	18	1.143	0.32	0.155	2.8
Sterilizer Door 400	Short	536	2/7	1st	18	1.089	0.29	0.148	2.7
Sterilizer Door 400	Short	531	2/7	2nd	18	1.203	0.41	0.189	3.4
Sterilizer Door 400	Short	544	2/7	2nd	18	1.262	0.44	0.194	3.5

Table II. CHARCOAL TUBE SAMPLE RESULTS, CONTINUED.

SURVEY: February 5-7, 1985. Wooster Community Hospital, Wooster, Ohio.

SAMPLE DESCRPTION	TERM	SAMPLE NO.	DAY	SHIFT	TIME min.	VOL. L.	EtO µg	EtO ppm	EtO ppm-min
Sterilizer Door 400C	Long	451	2/5	1st	479	4.575	1.0	0.121	58.1
Sterilizer Door 400C	Long	575	2/5	1st	479	9.632	2.0	0.115	55.2
Sterilizer Door 400C	Long	564	2/5	2nd	500	9.084	1.5	0.092	45.8
Sterilizer Door 400C	Long	566	2/5	2nd	500	4.615	0.96	0.115	57.7
Sterilizer Door 400C	Long	467	2/6	1st	501	10.044	1.3	0.072	36.0
Sterilizer Door 400C	Long	508	2/6	1st	501	4.771	0.75	0.087	43.7
Sterilizer Door 400C	Long	483	2/6	2nd	476	4.358	1.2	0.153	72.7
Sterilizer Door 400C	Long	488	2/6	2nd	476	8.577	2.2	0.142	67.8
Sterilizer Door 400C	Long	512	2/7	1st	496	10.052	1.5	0.083	41.1
Sterilizer Door 400C	Long	515	2/7	1st	496	4.775	0.83	0.096	47.8
Sterilizer Door 400C	Long	518	2/7	2nd	488	4.414	1.3	0.163	79.8
Sterilizer Door 400C	Long	528	2/7	2nd	488	8.688	2.2	0.141	68.6
Sterilizer Door 400C	Short	433	2/5	1st	19	0.631	0.64	0.563	10.7
Sterilizer Door 400C	Short	569	2/5	1st	19	0.763	0.71	0.516	9.8
Sterilizer Door 400C	Short	482	2/5	2nd	15	0.506	0.34	0.373	5.6
Sterilizer Door 400C	Short	487	2/5	2nd	15	0.612	0.35	0.317	4.8
Sterilizer Door 400C	Short	459	2/6	1st	19	0.576	0.36	0.347	6.6
Sterilizer Door 400C	Short	474	2/6	1st	19	0.696	0.34	0.271	5.2
Sterilizer Door 400C	Short	493	2/6	2nd	16	1.091	0.73	0.371	5.9
Sterilizer Door 400C	Short	503	2/6	2nd	16	1.040	0.67	0.358	5.7
Sterilizer Door 400C	Short	514	2/7	1st	18	1.194	0.88	0.409	7.4
Sterilizer Door 400C	Short	522	2/7	1st	18	1.138	0.87	0.424	7.6
Sterilizer Door 400C	Short	460	2/7	2nd	15	1.034	0.54	0.290	4.3
Sterilizer Door 400C	Short	529	2/7	2nd	15	0.989	0.57	0.320	4.8
Field Blank		445	2/5	1st			<0.1		
Field Blank		576	2/5	1st			0.11		
Field Blank		478	2/5	2nd	42		<0.1		
Field Blank		561	2/5	2nd			<0.1		
Field Blank		578	2/5	2nd			0.16		
Field Blank		458	2/6	1st	26		0.1		
Field Blank		470	2/6	2nd			<0.1		
Field Blank		505	2/6	2nd			<0.1		
Field Blank		511	2/7	1st			<0.1		
Field Blank		533	2/7	1st			0.12		
Field Blank		525	2/7	2nd	110		<0.1		
Field Blank		545	2/7	2nd			<0.1		
Q/A Q1225		494					8.8		
Q/A Q1228		500					11.		
Q/A Q1261		520					14.		
Q/A Q1266		540					5.		

TABLE III. Full-Shift TWA Exposures/Area Concentrations.

Worker/Location	Shift	No. Samples	Average Concentration, ppm	Standard Deviation
Operator	Day	6	0.02	0.01
	Evening	6	0.03	0.01
Wrapper	Day	3	0.02	0.01
	Evening	3	<0.01*	0.00
Sterilizer 400	Day	6	0.09	0.02
	Evening	6	0.1	0.02
Sterilizer 400C	Day	6	0.1	0.02
	Evening	6	0.13	0.02
Wrap Table	Day	3	0.01	0.01
	Evening	3	0.01	0.00

*One sample used in computing the average was less than the limit of detection for the analytical method.

TABLE IV. Short-Term Charcoal Tube Results.

Location	Shift	No. Samples	Average Concentration in ppm	Standard Deviation	Average Concentration ppm-min	Standard Deviation
Operator	Day	12	<0.18*	0.12	<4.64	6.56
	Evening	12	<1.43**	2.03	<5.43	3.14
Sterilizer 400	Day	6	0.18	0.03	3.0	0.4
	Evening	6	0.24	0.07	4.3	1.19
Sterilizer 400C	Day	6	0.42	0.10	7.88	1.86
	Evening	6	0.34	0.03	5.18	0.58

*Three samples used in computing the average were less than the limit of detection for the analytical method.
**Two samples used in computing the average were less than the limit of detection for the analytical method.

TABLE V. MIRAN DATA.

Date	Load	Sterilizer	Peak ppm	Duration minutes	Average ppm	Total ppm-min	15 min TWA, ppm
2/5/85	Test	400C	2	23	1	23	1.5
	Test	400	--	--	--	--	---
	Normal	400C*	1	6	0.5	3	0.2
	Normal	400	0.5	6	0.25	1.5	0.1
2/6/85	Test	400C	0.5	10	0.5	5	0.3
	Test	400	0.5	10	0.5	5	0.3
	Normal	400C*	1	6	0.5	3	0.2
	Normal	400*	0.5	6	0.5	3	0.2
2/7/85	Test	400C	0.5	6	0.5	3	0.2
	Test	400	--	--	--	--	---
	Normal	400C*	1.5	20	0.6	12.5	0.8
	Normal	400*	1	12	0.5	6	0.4
		Average	0.8	9.5	0.5	6	0.4

*Loads were sterilized at 100°F, all others were sterilized at 140°F.

TABLE VI. GC Sampling Results.

Activity/ Location	2/5/85 Test 400C	2/5/85 Test 400	2/5/85 Normal 400C*	2/5/85 Normal 400	2/6/85 Test 400C	2/6/85 Test 400	2/6/85 Normal 400C*	2/6/85 Normal 400*	2/7/85 Test 400C	2/7/85 Test 400	2/7/85 Normal 400C*	2/7/85 Normal 400*	Avg.	SD
Operator BZ During Load Transfer	9.6	<0.1	1.5	0.4	0.2	0.5	1.2	0.8	0.3	0.3	0.3	5.2	<1.7	2.7
Over Sterilizer Door	0.7	<0.3	0.2	0.3	0.3	0.2	0.3	0.2	0.4	<0.2	0.2	<1.5	<0.4	0.4
Sterilizer Interior 15min. After Door Open	0.9	<1.0	4.0	8.8	5.3	8.0	46.0	26.0	22.0	4.0	45.0	72.0	<20.3	2.0
Sterilizer Interior Immed. After Cycle Complete	6.4	--	1440	600	70	300	82	1180	520	660	1080	284	566	463

*Loads were sterilized at 100°F, all others were sterilized at 140°F.

TABLE VII. Comparison of Charcoal Tube, GC, and MIRAN IA Data During Load Transfer.

Sample	Date	Shift	Sterilizer	Ethylene Oxide Concentration, PPM Charcoal	GC	MIRAN IA
Operator	2/5/85	1	400C	0.41	9.6	--
		1	400	0.14	<0.1	--
		2	400C*	5.82**	1.5	--
		2	400	<1.37**	0.4	--
	2/6/85	1	400C	<0.24	0.2	--
		1	400	<0.09	0.5	--
		2	400C*	0.31	1.2	--
		2	400*	0.11	0.8	--
	2/7/85	1	400C	0.11	0.3	--
		1	400	0.07	0.3	--
		2	400C*	0.49	0.3	--
		2	400*	0.51	5.2	--
	Average:			<0.81	<1.7	--
	Standard Deviation:			1.55	2.73	--
	Sample Time:			15 min.	2 min.	--
Over the Sterilizer Door	2/5/85	1	400C	0.54	0.7	1.5
		1	400	0.21	<0.3	--
		2	400C*	0.35	0.2	0.2
		2	400	0.30	0.3	0.1
	2/6/85	1	400C	0.31	0.3	0.3
		1	400	0.17	0.2	0.3
		2	400C*	0.36	0.3	0.2
		2	400*	0.22	0.2	0.2
	2/7/85	1	400C	0.42	0.4	0.2
		1	400	0.15	<0.2	--
		2	400C*	0.31	0.2	0.8
		2	400	0.19	<1.5	0.4
	Average:			0.29	<0.4	0.4
	Standard Deviation:			0.11	0.36	0.40
	Sample Time:			15 min.	15 min.	15 min.

All loads sterilized on first shift were test loads.
*Loads were sterilized at 100°F, all others were sterilized at 140°F.
**Sample time was 1 minute.

TABLE VIII. General Ventilation Data.

Area	Supply (CFM)	Exhaust (CFM)
Clean Room	2400	1400*
EtO Sterilizer Room	230	185**
Linen Room	580	440
Decontamination Room	330	425
Infection Control Office	--	--
Dispensing Room	--	100
Pharmacy Solutions Room	540	505
Totals	4080	3045

*Includes passive exhaust vent over steam sterilizer.
**Includes sterilizer exhaust hoods.

TABLE IX. Operator Short-Term Exposures Related to Sterilizer.

Location	Shift	No. Samples	Average Concentration in ppm	Standard Deviation	Average Concentration ppm-min	Standard Deviation
Sterilizer 400	Day	6	<0.10*	0.03	<1.85	0.68
	Evening	6	<0.66**	0.53	<4.18	3.57
Sterilizer 400C	Day	6	<0.26**	0.12	<3.68	2.94
	Evening	6	2.21	2.6	6.67	1.98

*One sample used in computing the average was less than the limit of detection for the analytical method.
**Two samples used in computing the average were less than the limit of detection for the analytical method.