IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

COMMUNITY MEDCENTER HOSPITAL
MARION, OHIO

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PLANT SURVEYED:	Community MedCenter Hospital 1050 Delaware Avenue Marion, Ohio 43302
SIC CODE:	8062 (General Medical and Surgical Hospitals)
SURVEY DATE:	October 29 - November 2, 1984
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ABSTRACT

Controls for ethylene oxide (EtO) emitted from the gas sterilization of medical items were evaluated at Marion MedCenter Community Hospital, Marion, Ohio. EtO may have serious health effects, including carcinogenicity, and OSHA has established an 8-hour permissible exposurse limit of 1 ppm. 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 mean of 0.24 ppm with a combination of local exhaust ventilation, sterilzer cycle modifications, and work practices. Short-term exposures while transferring the load to the aerator had a mean value of 2 ppm. The average concentration-time product of 34 ppm-min is less than the 50 ppm-min recommended by NIOSH, however, at the 95% upper confidence level it is 70 ppm-min which is a cause for concern. EtO emissions from the EtO sterilizer drain during the purge caused elevated levels of EtO in the recess room and the slot hood above the door of the sterilizer was not ventilated at the time of the survey. It was recommended that better drain controls and/or improving the exhaust ventilation of the recess room should lower the chance of incidental exposure of the sterilzer operator during the purge cycle.

DISCLAIMER

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

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INTRODUCTION

BACKGROUND FOR CONTROL TECHNOLOGY STUDIES

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

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

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

BACKGROUND FOR THIS STUDY

The present Control Technology Assessment of Ethylene Oxide Sterilization in Hospitals is the result of the research recommendations of the 1983 Feasibility Study of Engineering Controls in Hospitals. During the feasibility study, preliminary surveys were conducted at eight hospitals to assess the potential need for further research in the control of anesthetic gases, antineoplastic drug exposures, and ethylene oxide (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]

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

To identify hospitals which meet the design criteria of the study, ECTB has worked closely with the American Hospital Association and the Ohio Hospital Association, who have publicized and promoted the study to their member hospitals. Community MedCenter Hospital expressed an interest in participating in the study and supplied information about the Supply, Processing, and Distribution (SPD) Department to NIOSH. Based on this information, it was determined that the hospital might fulfill the requirements of the category specifying: a sterilizer using a 12:88 EtO and Freon 12 mixture, no extra evacuation phases at the end of the sterilizer cycle, and no local exhaust ventilation above the sterilizer door. The hospital may add cycle modifications and local exhaust ventilation at two key locations, potentially making this a candidate for a before/after study.

A preliminary survey was conducted in the SPD Department on July 26, 1984. This report documents the information gathered during the in-depth evaluation of the department, October 29 - November 2, 1984

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.[2]

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.[3]

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.[4]

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.[4]

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

PRIMARY EXPOSURE SOURCES

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

Uncontrolled Drain

During the evacuation phase of the sterilization cycle, most of the EtO in the sterilization chamber is removed through the vacuum pump and drain. For sterilizers which evacuate to an uncontrolled drain, much of the EtO used in sterilization may be released into the recess room and/or perhaps to the workroom atmosphere.

Opening of the Sterilizer Door

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

Transferring the Sterilized Load

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

SECONDARY EXPOSURE SOURCES

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

Aeration

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

EtO Gas Cylinders

Ethylene oxide gas is supplied to many sterilizers from pressurized gas cylinders. When replacing empty EtO cylinders, the worker may be exposed to EtO vapors from residual liquid or gaseous EtO in the supply lines. Depending on the location and ventilation around the cylinders, the release of this trapped EtO may contribute to background EtO concentration for the sterilizer operator and other workers.

If the contents of an EtO cylinder were accidently discharged, a large quanity of EtO would be released. This could result in higher concentrations in the vicinity ot the cylinders and in the surrounding work area than 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 Department. 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 in SPD.

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 12 cubic feet. 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. However, when a second sterilizer load is run on

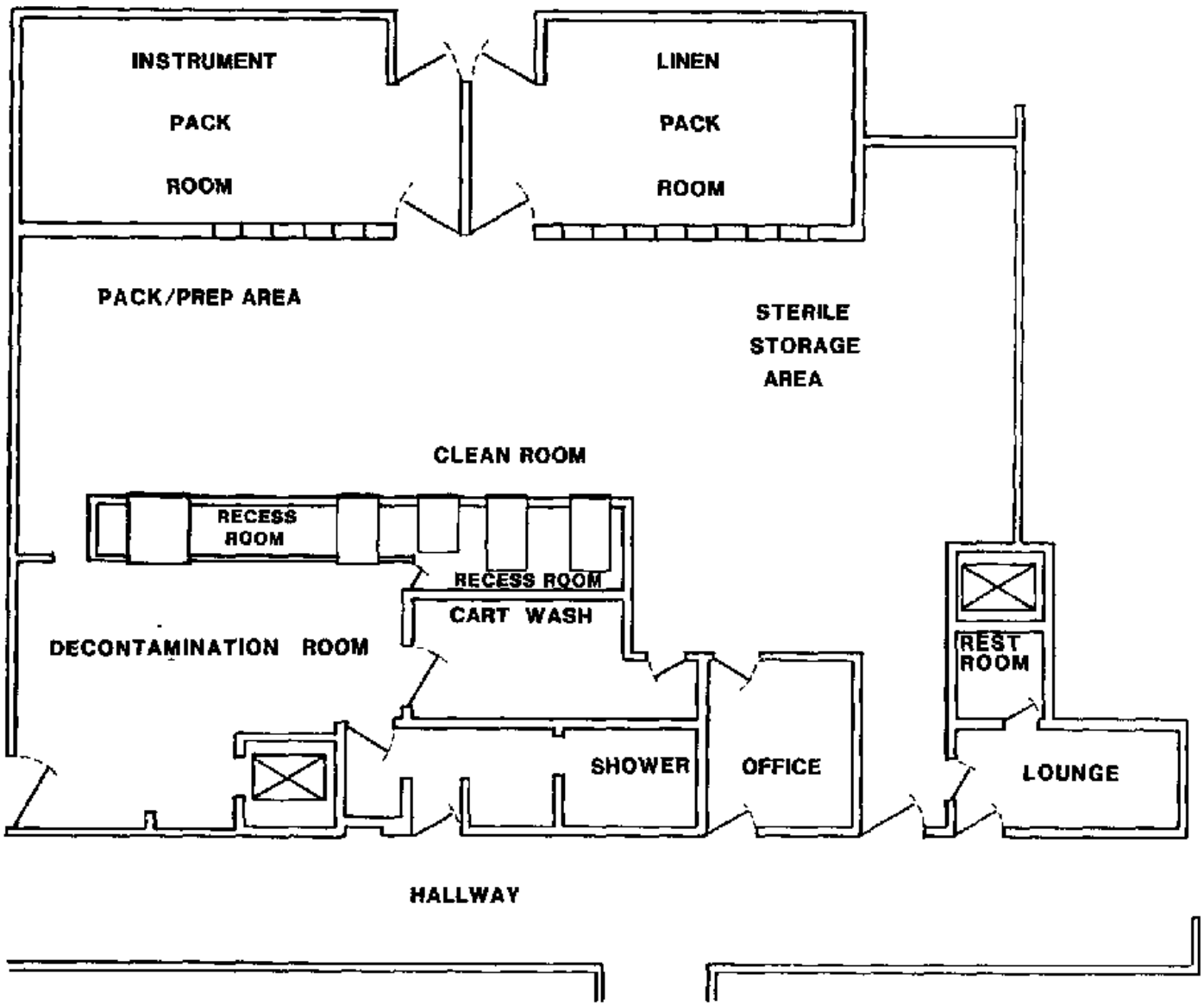

Figure 1. Layout of the sterilization areas of the Supply, Processing, and Distribution Department

the evening shift, the items from the second load must be placed in the aerator manually. Items are rearranged on the cart to accommodate the second load.

The sterilizers are recessed into a room constructed between the clean room and the decontamination room to enclose the drain and mechanical components of the sterilizers. The recess room has a 9-foot ceiling and two sections measuring 20' x 3' and 14' x 6'. (See Figure 1.) The sterilizers may be accessed for maintenance by entering the recess room through door panels located between the sterilizers from either the decontamination room or the clean room. The door panels are normally locked to restrict access of unauthorized personnel. The backs of the sterilizers and aerator are open to the recess room. Steam and water from the sterilizers are emptied into unsealed 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.

Sterilizer Cycle Features

The cycle is approximately three hours duration, and consists of several phases: initial vacuum and humidification (about 30 minutes), EtO charging of the chamber, dwell period (about 2 hours), and evacuation (about 20 minutes).

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 1 inch by 24 inches. At the time of the survey, no ventilation was provided for this slot other than the recess room exhaust.

General Exhaust Ventilation

In addition to the slot above the sterilizer door, there are twelve 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.

The recess room is exhausted by a dedicated system through two vents in the ceiling. One vent is between the EtO sterilizer and the aerator; the other is near the pass-through washer. 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 #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 #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. The direction of airflow through the vents designated as passive vents depends on the airflow balance between the rooms on each side the vents.

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-pak. The catheterization laboratory prepares items for EtO sterilization except for the sealing of peel-paks 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 10 to 15 minutes have elapsed the operator returns to the sterilizer and fully opens the door. The rack is attached to the cart and the load is pulled from the sterilizer. The operator removes the biological indicators from the load.

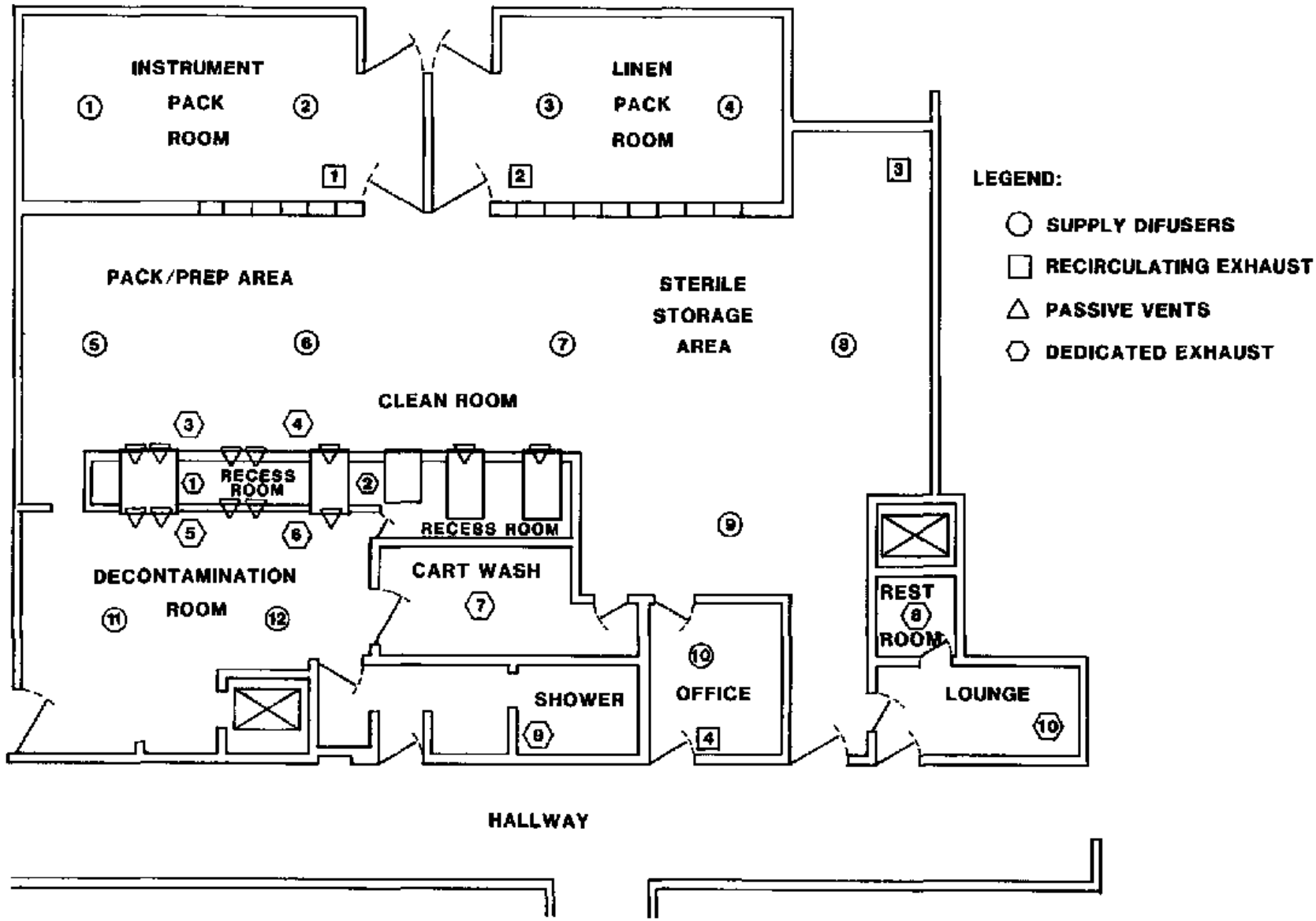

Figure 2. Diagram of the supply and exhaust vents in the sterilization areas.

Next the aerator door is opened and the cart is pushed to the aerator. The rack is disengaged and pushed into the aerator. The cart is then moved away from the aerator and the door is closed. Aeration times are recorded on the door. Finally, the biological indicator is opened and prepared for the laboratory at the wrapping table.

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 checks a cylinder pressure gauge located beneath the lower front panel of the sterilizer. If the pressure is below 30 psi, the operator calls maintenance to replace the cylinder before starting the cycle. The cylinder is replaced about every two months.

METHODOLOGY

Air movement and airborne ethylene oxide concentrations were measured to evaluate the effectiveness of the engineering controls. Table 1 lists some of the major pieces of equipment used.

Table 1. Equipment Used on Field Surveys.

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	Kurz 441	air velocity
Velometer Flow Hood	Alnor Balometer	air flow
Gas Chromatograph	Photovac GC 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

MEASUREMENT OF CONTROL PARAMETERS

Sampling was conducted during the day and evening shifts for three consecutive days. The same sets of samples were taken for all shifts.

Charcoal Tube Sampling

To determine personal exposures and average concentrations of EtO at selected locations in the clean room, personal and area samples were collected using coconut shell charcoal tubes according to NIOSH Method 1607. The samples were collected on 400 mg and 200 mg charcoal tubes connected in series, and the sampling train was contained in a plastic holder. MDA pumps, fitted with limiting orifaces, were calibrated at nominal air sampling rates of 10 milliliters per minute (mL/min) for long term (4-hour) samples and 50 mL/min for short-term (15-minute) samples.

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

Gas Bag Sampling

Air samples were collected in Tedlar® (SKC #231) at the sterilizer during the same sample periods as the short-term charcoal tubes. Personal and area bag samples were collected, during certain events, using DuPont pumps. Samples were taken at the area location in front of the sterilizer and on the operator during load transfer from sterilizer to aerator at the same point as the charcoal tubes. The concentration in the sterilizer chamber was also sampled both when the door was first opened at the end of the cycle and approximately 15 minutes later, just before the load was transferred.

These bag samples were analyzed on site using a Photo Vac Portable Gas Chromatograph using a 4" x 1/8" Teflon® Carbopak BHT 40/100 mesh column. The carrier gas was ultra pure air with a nominal flow rate of 15 ml per minute, which gives an EtO retention time of approximately 2 minutes. The attenuation used for these particular analyses were x10 and x100, and the GC was calibrated in both these ranges.

Infrared Analyzer Sampling

Due to the inconstant nature of EtO release during the day, it is desirable to have a continuous record of EtO peak concentations in the breathing zone in front of the sterilizer. To accomplish this purpose an infrared (IR) analyzer was used to monitor the area location in front of the sterilizer. Since the EtO sterilizer is adjacent to steam sterilizers, this location was potentially subject to high humidity levels. Laboratory experiments showed the instrument responded to humidity in the air by indicating a higher concentration of EtO than was present. In the range of 10 to 70 percent relative humidity, a 10 percent increase in the relative humidity produced a 3-ppm increase in the measured EtO concentration. Therefore, the relative humidity of the sampled air was simultaneously measured, and both the EtO concentration and the relative humidity of the air were continuously recorded by a strip chart recorder.

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 the pitot-tube traverse technique.

Within the department, the exhaust airflow through the ceiling vents was measured using an Alnor Balometer® flow hood. The airflow through the slot hood above the sterilizer door was measured using an eight point traverse of air velocity with a hot-wire anemometer. The air supplied by the main recirculating ventilation system was measured at the ceiling diffusers using the Balometer®.

Smoke tubes were used to qualitatively evaluate the supply and exhaust ventilation system. Air flow patterns at selected locations were observed and sketched. Air flow patterns above the sterilizer door were visualized with smoke tubes and recorded on video tape.

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.

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 is provided for processing at each hospital. The test load consists of Peel-Pac® packages containing an 15-inch length of surgical rubber tubing. The number of packages is adjusted to the volume of the sterilizer; for the 8.8-ft^3 volume 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. This increased retention of EtO, provides a challenge to the control system and may aid in evaluating the effectiveness of the controls.

A test load was sterilized each of three mornings. No other loads were processed through the EtO sterilizer during the day shift. Sampling data from this test load provides the basis for comparison with the load processed during the evening shift as well as with other hospitals.

RESULTS

The test load was run during the day shift and the hospital's normal load was processed during the evening shift. Maintenance was performed on the sterilizer by the manufacturers service representative on the third day of sampling. During the evening load on the third day of sampling, the sterilizer did not charge completely, and the cycle had to be manually aborted. This load was sampled the same as the others.

AIR SAMPLING RESULTS

None of the charcoal tube samples was less than the analytical limit of detection. The measured concentrations ranged from approximately 0.1 ppm to 1 ppm for the long-term samples and from 0.5 to 6 ppm for the short-term samples. The concentration-time product for the short-term samples ranged from 10 to 100 ppm-min. The results for all the charcoal tube samples are tabulated in the Appendix. The statistics for each sample group are shown in Table 2.

The most important results in terms of exposure are those for the sterilizer operator. The 10 long-term samples yield an average EtO exposure of 0.24 ppm and a 95-percent upper confidence level is 0.31 ppm. The 12 short-term samples, taken during the unloading of the EtO sterilizer, averaged 1.98 ppm with a 95-percent upper confidence level of 4.1 ppm over a period averaging 17 minutes in duration.

The only other employee sampled was the wrapper, who worked in the sterilizer area wrapping materials in preparation for the sterilizer operation and in the decontamination room cleaning items returned for sterilization. The 12 long-term samples on the wrapper indicate a mean EtO concentration of 0.37 ppm with a 95-percent upper confidence level of 0.73 ppm.

Sterilizer area long-term and short-term samples were taken at a location in front of the EtO sterilizer at a height of about 62 inches. The 12 long-term samples had a mean value of 0.47 ppm with a 95-percent upper confidence level of 0.82 ppm. The 12 short-term EtO samples have a mean of 4.0 ppm with a 95-percent upper confidence level of 7.69 ppm.

The complete set of GC results for the gas bag samples is shown in Table 3. As was previously mentioned, some of these samples are directly comparable to short-term charcoal tube samples.

An example of the IR analyzer peaks resulting from load transfer operations is shown in Figure 3. The shaded area under the curve represent the time period covered by the charcoal tube sample. To make a comparison of the IR results to the charcoal tube and gas bag samples, the IR absorption peaks on the recorder chart needed to be integrated over the same time period as the short term charcoal tube samples were taken. The integration was carried out manually with a Gelman Integrator. The integral loop was traced three times

Table 2. Statistics for charcoal tube data.

SAMPLE LOCATION	STATISTICS (based on ppm EtO)		
Sterilizer Operator long-term samples (mean sample time = 476 min.)	Mean SD VAR 95% UCL* N	= = = = =	0.24 0.035 0.0011 0.31 10
Sterilizer Operator short-term samples (mean sample time = 17 min.)	Mean SD VAR 95% UCL N	= = = = =	1.98 1.03 0.977 4.1 12
Sterilizer long-term samples (mean sample time = 483 min.)	Mean SD VAR 95% UCL N	= = = = =	0.47 0.17 0.027 0.82 12
Sterilizer short-term samples (mean sample time = 483 min.)	Mean SD VAR 95% UCL N	= = = = =	4.0 1.85 3.13 7.7 12
Wrapper long-term samples (mean sample time = 449 min.)	Mean SD VAR 95% UCL N	= = = = =	0.37 0.18 0.031 0.73 12
Bench long-term samples (mean sample time = 481 min.)	Mean SD VAR 95% UCL N	= = = = =	0.28 0.055 0.0027 0.39 12

* Upper confidence limit

Figure 3. Example of IR analyzer peak.

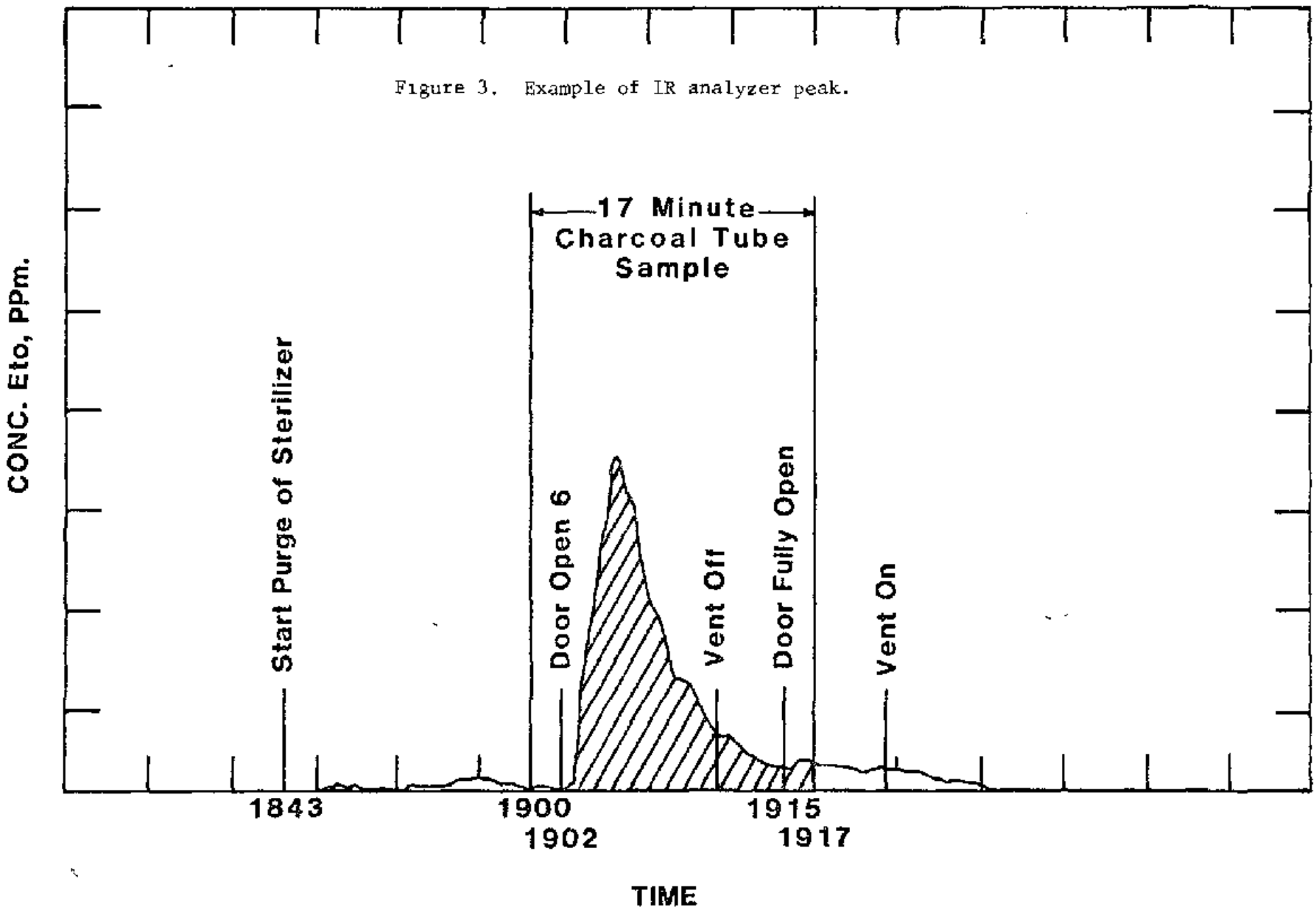

Table 3. Ethylene Oxide Analyses by Photo Vac GC, ppm.

ACTIVITY AND LOCATION	10/30/84 Test	10/30/84 Norm	10/31/84 Test	10/31/84 Norm	11/1/84 Test	11/1/84 Norm	AVG.
LOAD TRANSFER							
Sterilizer Operator-Transfer	2.4	2 0	2.9	2.5	3.9	0 9	2.4
Above Sterilizer Door-Transfer	4.8	4.8	6.2	5 5	7.0	2.8	5.2
Sterilizer Interior-Door Cracked	1300	2300	--	1700	2000	1500	1800
Sterilizer Interior-After 15 Min.	250	73	120	140	700	23	220
Sterilizer Interior-Load Removed	--	--	10	--	--	--	10
AERATOR							
Sterilizer Operator-Arranging Aerator Load	--	--	--	0 5	--	--	0.5
Inside Aerator-Midcycle	--	--	--	0.7	--	1.4	1.0
PURGE CYCLE							
Recess Room-During drawdown	--	--	35*	--	107	--	71
Recess Room-After purge Time 1	--	--	7.2	--	69	--	38
Recess Room- " " " 2	--	--	1.6	--	2.6	--	2.1
Recess Room- " " " 3	--	--	0.8	--	4.3	--	2.6
OTHER							
Above Sterilizer Door-Mid Cycle	0.3	0.7	0.2	--	0.2	--	0.4
Office Across From SPD	--	--	0.2	--	--	--	0.2

* This value is from sample @ 18:47. Other data for 10/31 test load is from samples taken 11:34 to 12:04.

and the readings averaged. The results of these analyses are compared with the charcoal tube and gas bag samples in Table 4.

Table 4. Sterilizer short term samples comparing charcoal tubes, MIRAN IR, and Photo Vac GC.

DATE	TIME	CHARCOAL TUBE*	MIRAN IR	PHOTO VAC GC
10/30	1114	4.5 ppm	5.3 ppm	4.8 ppm
10/30	1713	3.6 "	5.0 "	4.8 "
10/31	1123	5.2 "	5.8 "	6.2 "
10/31	1900	6.1 "	5.8 "	5.5 "
11/1	1027	4.1 "	3.0 "	7.0 "
11/1	1840	0.5 "	3.3 "	2.8 "

* Values are the average of two side-by-side samples.

Statistics (all data in Table 3): N=18; Mean = 4.63, Std. Deviation = 1.55

VENTILATION MEASUREMENTS

The ventilation system in the Supply, Processing and Distribution Department (SPD) is provided by one main supply duct which carries a total of over 10,000 cfm (design value) to SPD and other areas of the hospital. The exhaust air is handled by four separate systems. The main exhaust duct returns air to the supply blower. The flow in this duct is about 8600 CFM (design value). Additionally, three dedicated exhaust systems remove air from the sterilizer areas. 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 is shut off for a 12 minute period (75% on and 25% off). Thus, the recirculating system may be off when the purge or the load transfer takes place. The dedicated exhaust systems do not shutdown during this period so that a measured exhaust flow of 1060 cfm is always in effect.

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 total balance of all supply and exhaust vents is shown in Table 5. 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.

Table 5. Overall balance of ventilation system

SUPPLY VENT (S)		CFM	EXHAUST VENT (X) & RETURN VENT (R)		CFM
S-1	Inst. Pack Room	125	R-1	Inst. Pack Room	370
S-2	" " "	145	R-2	Linen Pack Room	250
S-3	Linen Pack Room	100	R-3	Clean Room	140
S-4	" " "	95	X-3	" "	125
S-5	Clean Room	260	X-4	" "	530
S-6	" "	225	X-5	Decontam. Room	140
S-7	" "	235	X-6	" "	150
S-8	" "	365	X-7	Cart Wash Room	0
S-9	" "	270	X-1&2	Recess Room	300*
S-10	Office	120	X-10	Lounge	75
S-11	Decontam. Room	180	X-8	Rest Room	80
S-12	" "	140	X-9	Shower Room	50
			R-4	Office	50
Totals		2260 CFM			2260 CFM

* Traverse of 10" x 17" duct in hallway (see Appendix, Table A-2)

The use of smoke tubes showed generally, 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.

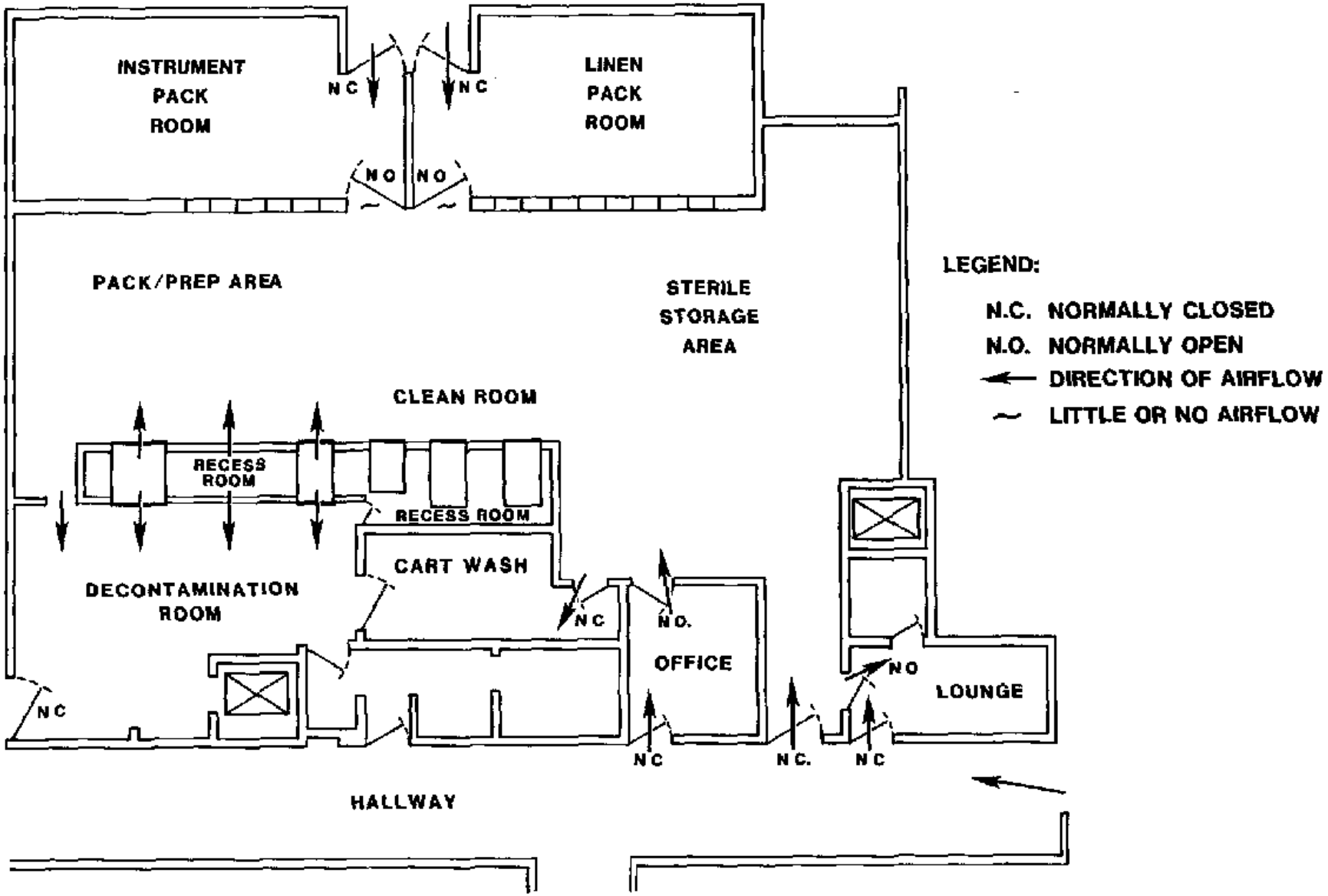

Figure 4. Direction of airflow through doorways, and passive vents.

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. Although these controls were adequate to limit exposures to less than the OSHA PEL, some deficiencies were noticed.

DRAIN CONTROLS

Drain Ventilation

Worker exposures from the drain are controlled primarily by isolating all of the sterilizer except the front panel in a ventilated recess room. However, the ventilation of the recess room was insufficient to contain all the EtO emitted during the chamber evacuation. Samples collected at the area location in front of the sterilizer door during the evacuation period averaged 4 ppm. (See Table 2.)

There are three criteria which may be used to establish the ventilation requirements for the recess room. First, the ventilation rate should be adequate to overcome the thermal air currents produced by heat generated within the recess room. Second, the volume of air drawn into the room should be sufficient to limit the temperature rise to an acceptable level. Third, sufficient dilution ventilation should be provided to purge the room of EtO within an appropriate period of time following a sudden release.

Air Velocity Through Enclosure Openings

Air does not always flow into a room with the same velocity at all openings. In fact, when heated processes are present in the room, air may actually flow out of vents and cracks in the walls near the top of the room if the ventilation system does not exhaust enough air to handle the quantity of air rising to the ceiling due to thermal effects. Hemeon[7] 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 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 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 Mat A	13,800	"
AMSCO	Vac Mat S	13,800	"
Total heat load in the Recess Room		32,700	BTU/Hr.

The open area of the 12 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.

The measured exhaust flow rate for the recess room was 300 cfm. The observed flow of air out of the recess room through the vents in the wall above the equipment supports the assertion that this ventilation rate is inadequate to overcome thermal effects.

Temperature Rise

Exhaust ventilation will remove excessive heat if the incoming air is cooler. The volume of air required to limit the temperature rise in the hotter room is given by the following equation adapted from Hemeon[7] and Mutchler[8]:

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

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

Using the estimates of the heat release from the previous calculation, approximately 900 cfm would be required to limit the temperature rise in the recess room to 30°F. In this case, the temperatures measured in the recess room near the EtO sterilizer were only a few degrees higher than those in the clean room. Air temperatures were not taken around the other equipment which produced most of the heat accounted for the the above calculation.

Rate of Purging

The rate of decrease of concentration of a contaminant once further generation has ceased is given by Mutchler[8]:

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

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

Q', the effective ventilation rate, is equal to the actual ventilation rate, Q, divided by a design distribution constant, K, a value between 3 and 10 to correct for incomplete mixing. The lower the value of K, the better the

mixing. Since sterilizer recess rooms are small and typically unoccupied, K will be assumed to be 3. The above equation can be solved for Q:

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

In this equation, the desired time period for purging must be specified. The initial concentration, C_I, can be estimated by assuming the entire sterilizer contents escape into the recess room. The volume of this recess room was approximately 1300 ft^3. Assuming that the 8.8-ft^3 sterilizer chamber charged with 160 grams of EtO suddenly released its contents to the room, the resulting recess room concentration would be approximately 1300 ppm. To reduce the recess room concentration to 1 ppm in 30 minutes would require 900 cfm.

Two sets of data (10/31 and 11/1) allow the calculation of EtO concentration decay curves for the Recess Room. These curves, plotted on semilog paper are shown in Figures 5 and 6. The semilog plots indicate the linearity of the purge rate equation. These data sets can not be combined because each begins with a different concentration. However, one can determine a "half-life" for the curve, which is the time requred to reduce the concentration to 50 percent of the initial value. From the graphs, the average half life is 6 1/2 min, which when inserted into the previous formula for a concentration ratio of 2.0 (1/0.5) gives a value for Q of approximately 400 cfm.

The required recess room ventilation estimated by three different criteria is approximately 900 cfm. This is three times the 300 cfm exhaust flow presently venting the recess room. It should be realized that the assumptions are that the heat and the emitted EtO are uniformly distributed throughout the room and that all heat sources are operating at the same time, neither of which is likely to be true. The method does, however, give some insight into the effect of heat induced ventilation.

Another way to apply this equation is to calculate the heat load that the 300 cfm dedicated exhaust can accommodate. This turns out to be less than 1200 BTU/hr, which is exceeded by all but the EtO sterilizer. These results are confirmed by smoke tube studies, which showed that air moved through the louvers from the recess room into both the decontamination room and the clean room.

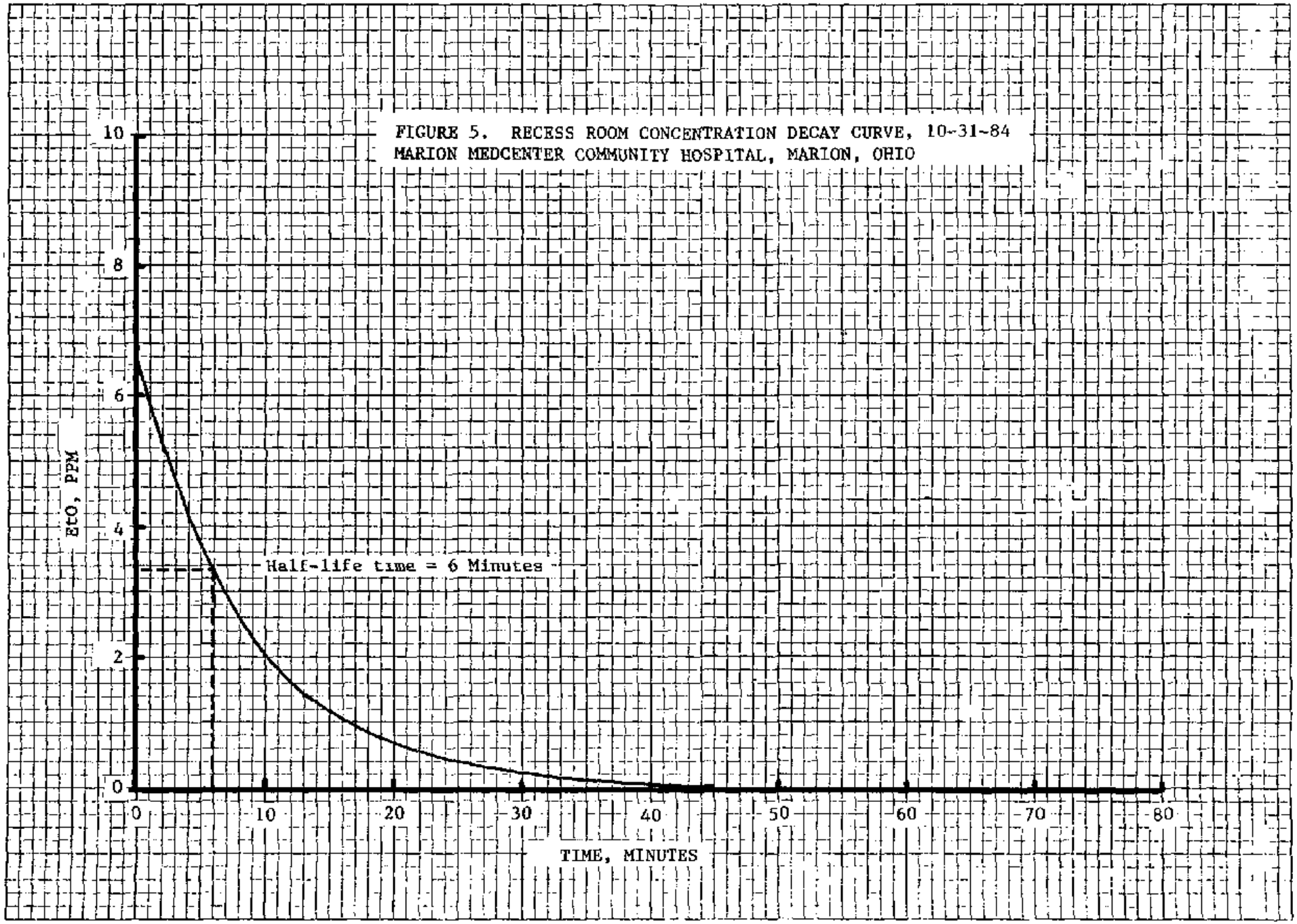
FIGURE 5. RECESS ROOM CONCENTRATION DECAY CURVE, 10-31-84
MARION MEDCENTER COMMUNITY HOSPITAL, MARION, OHIO
EtO, PPM
10
8
6
4
2
0
Half-life time = 6 Minutes
0
10
20
30
40
50
60
70
80
TIME, MINUTES

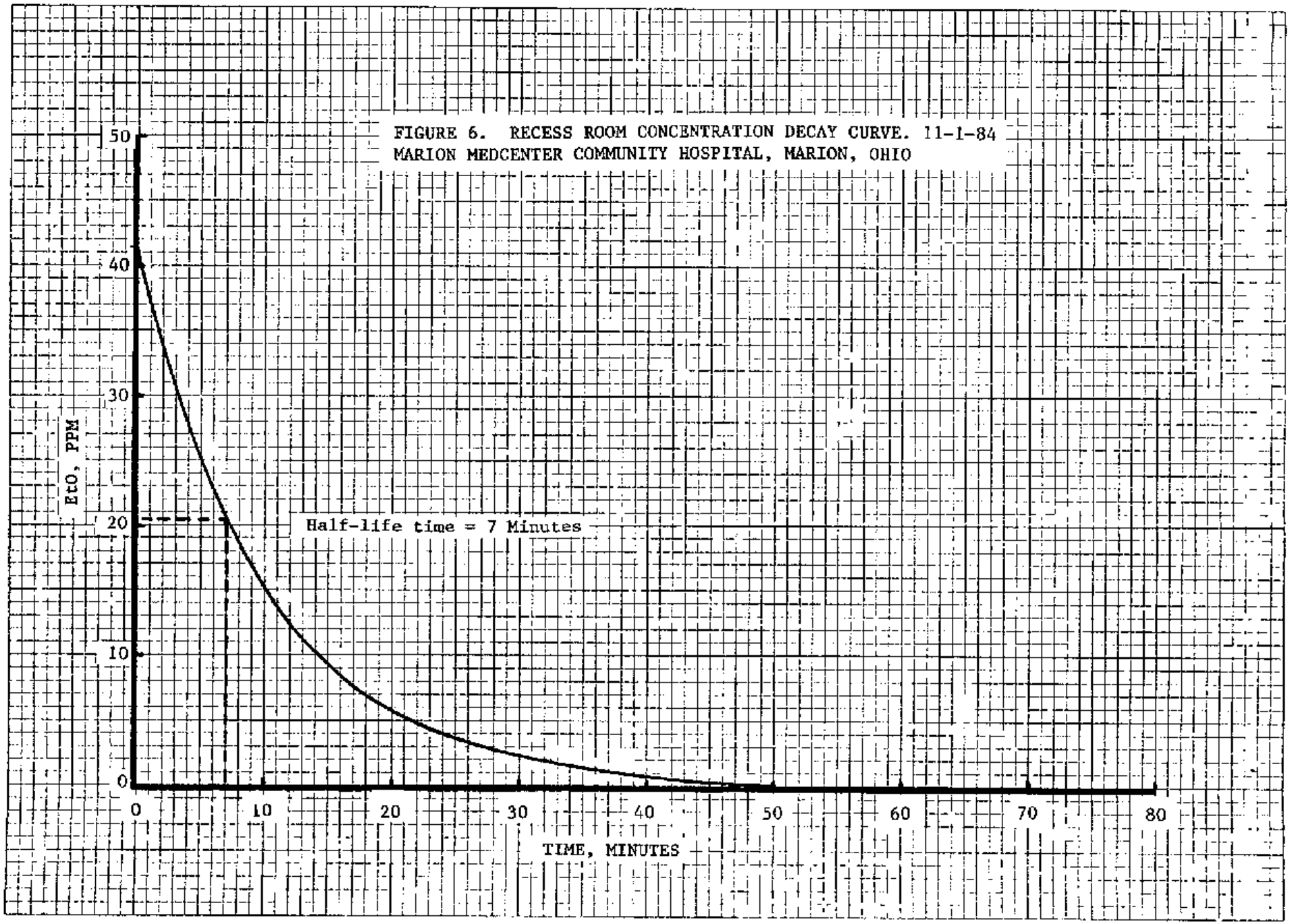
FIGURE 6. RECESS ROOM CONCENTRATION DECAY CURVE. 11-1-84
MARION MEDCENTER COMMUNITY HOSPITAL, MARION, OHIO
50
40
30
20
10
0
EtO, PPM
Half-life time = 7 Minutes
0
10
20
30
40
50
60
70
80
TIME, MINUTES

CONCLUSIONS AND RECOMMENDATIONS

The exposure levels of the workers in the sterilizing operation and in the immediate area are within the OSHA PEL of 1 ppm ethylene oxide. This is true at the 95% confidence level under normal operating conditions, which indicates that the action level (50% PEL) is not routinely exceeded. Therefore, this control system provides adequate protection for the workers based on a 8-hour TWA exposure limit of 1 ppm.

The short term exposure levels representing the period for transferring the sterilizer load to the aerator are higher, averaging 2 ppm, with a 95% confidence level of about 4 ppm, over an average period of 17 minutes. The average concentration-time product of 34 ppm-min is less than the limit of 50 ppm-min recommended by NIOSH; however, the value calculated using the 95-percent upper confidence level, 70 ppm-min, would exceed the recommended limit. OSHA has not adopted a short-term exposure limit.

Moreover, considering that most of this exposure occurred during the time it took to transfer the load (less than a minute), it is highly likely that peak exposures were greater than the 5 ppm ceiling limits recommended by NIOSH and ACGIH.

Installing better drain controls and/or improving the ventilation of the recess room should lower the chance of incidental exposure of the sterilizer workers during the purge cycle. EtO being evacuated from the sterilizer during the purge cycle is emitted from the drain into the recess room. The current 300 cfm exhaust from the recess room is not sufficient to prevent the flow of air through the wall louvers from the recess room into the clean room and the decontamination room.

The planned installation of an Envirogard® control system by the Community MedCenter Hospital should lower the peak values of EtO observed in the work zone of the operator. If properly installed with a sealed drain and an adequately ventilated air gap (referred to as the liquid/gas separator), the purge cycle should no longer emit EtO into the recess room. The ventilated slot above the door should contain most of the EtO escaping from the chamber during the 15-minute door-cracked period (if used) before transferring the load to the aerator. Chamber concentrations prior to transferring the load should be lower due to the extra air flush cycle(s).

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APPENDIX, Table A-1

RESULTS OF CHARCOAL TUBE SAMPLES FOR ETHYLENE OXIDE
SURVEY AT COMMUNITY MEDCENTER HOSPITAL
MARION, OHIO

October 30, to November 1, 1984

LOC #	JOB CLASSIFICATION	SAMPLE No	SAMPLE DATE	PERIOD START	PERIOD STOP	TIME min	RATE lpm	VOL l	EtO ug	EtO ppm
GA2	Bench	283	10/30	0725	1459	454	0 019	8 6	3 40	0 220
GA1	Bench	284	10/30	0725	1459	454	0 021	9 5	3 77	0 221
GA2	Bench	311	10/30	1515	2255	460	0 020	9 2	4 73	0 286
GA2	Bench	268	10/30	1515	2255	460	0 021	9 7	3 66	0 210
GA1	Bench	308	10/31	0750	1500	430	0 019	8 2	4 03	0 273
GA1	Bench	304	10/31	0750	1500	430	0 020	8 6	3 58	0 231
GA2	Bench	302	10/31	1302	2257	595	0 016	9 5	5 30	0 310
GA2	Bench	300	10/31	1302	2257	595	0 016	9 5	4 51	0 264
GA1	Bench	320	11/1	0707	1502	475	0 019	9 0	5 00	0 309
GA1	Bench	354	11/1	0707	1502	475	0 020	9 5	5 40	0 326
GA2	Bench	321	11/1	1502	2256	474	0 020	9 5	5 78	0 338
GA2	Bench	353	11/1	1502	2256	474	0 021	10 0	6 98	0 388
BZ1	Operator (LT)	314	10/30	0715	1455	460	0 009	4 1	2 14	0 290
BZ1	Operator (LT)	272	10/30	0715	1455	460	0 020	9 2	4 10	0 248
BZ2	Operator (LT)	313	10/30	1517	2255	458	0 009	4 1	1 82	0 247
BZ2	Operator (LT)	271	10/30	1517	2255	458	0 020	9 2	3 20	0 193
BZ1	Operator (LT)	289	10/31	0756	1503	427	0 009	3 8	1 92	0 281
BZ1	Operator (LT)	278	10/31	0756	1503	427	0 020	8 5	4 21	0 275
BZ2	Operator (LT)	297	10/31	1310	2255	585	0 007	4 1	1 54	0 209
BZ2	Operator (LT)	296	10/31	1310	2255	585	0 016	9 4	3 62	0 214
BZ1	Operator (LT)	336	11/1	0735	1505	450	0 009	4 1	1 62	0 220
BZ1	Operator (LT)	333	11/1	0735	1505	450	0 020	9 0	3 28	0 203
BZ1	Operator (ST)	273	10/30	1114	1132	18	0 041	0 7	2 14	1 697
BZ1	Operator (ST)	265	10/30	1114	1132	18	0 042	0 8	1 93	1 339
BZ2	Operator (ST)	266	10/30	1713	1728	15	0 047	0 7	1 87	1 483
BZ2	Operator (ST)	282	10/30	1713	1728	15	0 048	0 7	1 79	1 419
BZ1	Operator (ST)	291	10/31	1121	1139	18	0 036	0 6	3 20	2 960
BZ1	Operator (ST)	294	10/31	1121	1139	18	0 036	0 6	3 00	2 775
BZ2	Operator (ST)	332	10/31	1900	1917	17	0 040	0 7	2 21	1 673
BZ2	Operator (ST)	315	10/31	1900	1917	17	0 039	0 7	2 03	1 610
BZ1	Operator (ST)	338	11/1	1027	1043	16	0 039	0 6	0 82	0 759
BZ1	Operator (ST)	326	11/1	1027	1043	16	0 040	0 6	0 79	0 731
BZ2	Operator (ST)	364	11/1	1840	1857	17	0 038	0 6	4 21	3 895
BZ2	Operator (ST)	343	11/1	1840	1857	17	0 038	0 6	3 72	3 441
GA1	Sterilizer (LT)	309	10/30	0719	1458	459	0 010	4 6	1 47	0 419
GA1	Sterilizer (LT)	269	10/30	0719	1458	459	0 017	7 8	5 45	0 388
GA2	Sterilizer (LT)	310	10/30	1515	2255	460	0 009	4 1	2 83	0 383
GA2	Sterilizer (LT)	317	10/30	1515	2255	460	0 025	11 5	6 75	0 326
GA1	Sterilizer (LT)	280	10/31	0750	1500	430	0 010	4 3	3 08	0 398
GA1	Sterilizer (LT)	295	10/31	0750	1500	430	0 017	7 3	5 69	0 433
GA1	Sterilizer (LT)	303	10/31	1305	2257	592	0 007	4 1	2 62	0 355
GA2	Sterilizer (LT)	292	10/31	1305	2257	592	0 019	11 2	7 55	0 374
GA1	Sterilizer (LT)	337	11/1	0706	1502	476	0 009	4 3	4 52	0 584
GA1	Sterilizer (LT)	342	11/1	0706	1502	476	0 015	7 1	7 74	0 605
GA2	Sterilizer (LT)	348	11/1	1502	2255	473	0 008	3 8	6 47	0 945
GA2	Sterilizer (LT)	360	11/1	1502	2255	473	0 024	11 4	9 60	0 468
GA1	Sterilizer (ST)	306	10/30	1114	1132	18	0 040	0 7	6 1	4 837
GA1	Sterilizer (ST)	264	10/30	1114	1132	18	0 042	0 8	5 97	4 742
GA2	Sterilizer (ST)	270	10/30	1713	1728	15	0 075	1 1	7 26	3 663
GA2	Sterilizer (ST)	305	10/30	1713	1728	15	0 072	1 1	7 16	3 613
GA1	Sterilizer (ST)	293	10/31	1123	1139	16	0 044	0 7	6 57	5 209
GA1	Sterilizer (ST)	287	10/31	1123	1139	16	0 045	0 7	6 55	5 293
GA2	Sterilizer (ST)	288	10/31	1900	1917	17	0 039	0 7	7 74	6 137
GA2	Sterilizer (ST)	347	10/31	1900	1917	17	0 041	0 7	7 60	6 026
GA1	Sterilizer (ST)	333	11/1	1027	1043	16	0 040	0 6	4 79	4 431
GA1	Sterilizer (ST)	340	11/1	1027	1043	16	0 042	0 7	4 69	3 719
GA2	Sterilizer (ST)	365	11/1	1840	1857	17	0 037	0 6	0 94	0 500
GA2	Sterilizer (ST)	368	11/1	1840	1857	17	0 039	0 7	0 58	0 460
BZ1	Wrapper	312	10/30	0721	1459	458	0 017	7 8	4 50	0 320
BZ1	Wrapper	316	10/30	0721	1459	458	0 019	8 7	5 87	0 375
BZ2	Wrapper	275	10/30	1514	2255	461	0 019	8 8	4 46	0 282
BZ2	Wrapper	286	10/30	1514	2255	461	0 021	9 7	4 18	0 239
BZ1	Wrapper	281	10/31	0757	1500	423	0 017	7 2	4 03	0 311
BZ1	Wrapper	285	10/31	0757	1500	423	0 019	8 0	4 29	0 298
BZ2	Wrapper	299	10/31	1310	2255	585	0 015	8 8	2 66	0 168
BZ2	Wrapper	290	10/31	1310	2255	585	0 017	9 9	2 64	0 159
BZ1	Wrapper	327	11/1	0702	1504	482	0 017	8 2	5 92	0 401
BZ1	Wrapper	330	11/1	0702	1504	482	0 019	9 2	6 48	0 391
BZ2	Wrapper	355	11/1	1509	1947	278	0 019	5 3	7 03	0 736
BZ2	Wrapper	328	11/1	1509	1947	278	0 021	5 8	7 39	0 707

Appendix, Table A-2

Ventilation traverse of 10" x 17" duct from Recess Room, 11-01-84

The duct measures 10" x 17" but is lined with 1.25" of insulation which reduces the duct to 7.5" x 14.5" and a cross sectional area of 0.755 ft^2. A six point traverse was made at points which divided the cross section into six equal areas.

DATA POINT	VENTILATION ON FPM	VENTILATION OFF FPM
1	350	425
2	325	400
3	350	400
4	400	425
5	500	500
6	450	450
Average	396 FPM	433 FPM
Flow	300 CFM	327 CFM

The difference in the values for the ventilation system on and off modes may not be significant. It is logical however that when the ventilation system is Off, the system resistance for the Recess Room dedicated exhaust blower will be less and the flow will be slightly higher.