

Industrywide Studies Report of
An Industrial Hygiene Survey
of
Kettering Medical Center
Kettering, Ohio

Survey Conducted by:
Virginia L. Ringenburg
Paula Morelli-Schroth
Daniel Molina

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Report Written by:
Virginia L. Ringenburg
Paula Morelli-Schroth
Larry J. Elliott

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Industrial Hygiene Section
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Division of Surveillance, Hazard Evaluations and Field Studies
National Institute for Occupational Safety and Health
Centers for Disease Control
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PURPOSE OF SURVEY:

To evaluate the occupational exposure to ethylene oxide (EtO) of hospital workers in the Central Processing and Respiratory Therapy areas of the Kettering Medical Center.

**HOSPITAL REPRESENTATIVES
CONTACTED:**

Jerry Renfro, Administrative Director
Erwin Bishop, Superintendent of Systems,
Plant Engineering Department
Ronald Wiser, Acting Department Manager,
Processing

**EMPLOYEE REPRESENTATIVES
CONTACTED:**

No Union

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ABSTRACT

An indepth industrial hygiene survey was conducted in the Central Processing and Respiratory Therapy areas of the Kettering Medical Center in Kettering, Ohio, on August 14-16, 1985. This survey was conducted to evaluate the occupational exposure of workers to ethylene oxide (EtO). EtO is used to sterilize heat and/or moisture sensitive medical and surgical supplies; and, exposure to EtO may occur during this sterilization process.

Personal breathing zone (BZ) and general area sampling for EtO was conducted by NIOSH researchers during this survey. All personal short-term (5) and Time-Weighted Average (TWA) (4) sampling results were below the limit of detection (LOD) of the respective NIOSH #1607 (0.95 ug/sample) and OSHA #50 (1.7 ug/sample) analytical methods. The area 8-hour TWA sampling results ranged from nondetectable (ND) to 0.81 parts per million (ppm). The 21 area short-term sampling results ranged from ND to 188.4 ppm.

Wilks Miran (infrared) continuous direct-reading results showed measureable peak (area) EtO levels ranging from 0-286 ppm (found when the AMSCO EtO sterilizer #3 door was cracked open following a sterilization cycle).

A 2-minute TWA of 221.9 ppm could result in a TWA concentration of 44.4 ppm for 10 minutes; however, this concentration was measured within the local exhaust ventilation (LEV) envelope of the AMSCO #3 EtO sterilizer. TWAs of 6.8 (12 minutes) and 23.1 (4 minutes) ppm were measured in the Respiratory Therapy area. The 4-minute TWA of 23.1 ppm could result in a TWA of 9.2 ppm for 10 minutes. Both levels (6.8 and 23.1 ppm) were measured on second shift when no one was working in the EtO sterilizing room. All Wilks Miran measurements were area measurements, not personal EtO exposure levels.

Recommendations concerning work practices and installation of engineering controls are offered which could reduce EtO exposure potential in this hospital.

INTRODUCTION

Ethylene oxide (EtO) is a major industrial chemical and is one of the 25 chemicals of highest production volume in the United States.¹ The major portion of EtO is used in the production of ethylene glycol (antifreeze) and as a chemical intermediate for polyester films, fibers, and bottles. A small fraction of EtO, less than 0.24%, has been used by the health care and medical supply industries over the past 35-40 years to sterilize heat-sensitive medical supplies.¹ It is in this industry, however, that most of the employee exposures occur. This was shown in a 1977 survey conducted by researchers from NIOSH in which it was estimated that 75,000 health care workers were employed in EtO sterilization operations.² In addition, another 25,000 employees might be incidentally exposed due to inadequate engineering controls.³

EtO is a colorless gas at standard temperature and pressure or a liquid at higher pressures. EtO is miscible with water, ethanol, ether, and most common organic solvents. In addition, it is highly explosive when in concentrations of 3 to 100% (EtO) in air. The biological warning properties are essentially useless since the (ether-like) odor threshold among individuals ranges from 300 to 1,500 parts per million (ppm) and adverse health effects may be elicited at levels much less than this.^{1,4}

Due to the toxicity of EtO (see Appendix A), a study was initiated in 1984 to evaluate the occupational exposure ranges of hospital workers to EtO.⁵ This study is being conducted under the authority of the Occupational Safety and Health Act of 1970 (set forth by the 91st Congress, S.9123, Public Law 91-596). Specifically, the National Institute for Occupational Safety and Health (NIOSH) was given the authority and responsibility for conducting and reporting on field research studies in industry. Section 20(a)7 states that NIOSH shall conduct and publish industrywide studies of the effects of chronic low level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in the aging adult.

The information collected during this survey, and from the overall study, will be used to aid hospitals in assessing and (if necessary) reducing the EtO exposure potential from EtO sterilization processes.

DESCRIPTION OF FACILITY

The Kettering Medical Center (KMC), built in 1965, is located about 15 miles south of Dayton in Kettering, Ohio. KMC is a full service hospital housing approximately 400 beds of which about 90% are filled. Some of the specific services housed over five floors include: full surgery, orthopedics, cardiology, emergency room care, obstetrics and gynecology, maternity and pediatrics, neurology, pulmonary function, respiratory therapy, and administration.

Ethylene oxide (EtO) sterilization and steam sterilization of medical/surgical supplies is conducted in the Central Processing (CP) area (Figure 1) on the second floor of the hospital. Included in this area are the linen preparation area, clean work room, clean and sterile storage, soiled work room, mechanical access room, dispatch, and office areas (Figure 1).

The clean workroom contains one double door, pass-through, 9 cubic feet (ft³) AMSCO 12% EtO to 88% dichlorodifluoromethane Medallion sterilizer (#5); one single door 30 ft³, 12:88 AMSCO EtO sterilizer (#3); and two 31 ft³ AMSCO EtO aerators.

EtO sterilization is also conducted in the Respiratory Therapy area (Figure 2), which is located on the second floor of the hospital. Respiratory Therapy (RT) contains one 4 ft³ 3M Sterivac, Model 400, 100% EtO sterilizer and one 3M 4 ft³ EtO aerator.

DESCRIPTION OF WORKFORCE

A total of 18 employees work several different shifts over a 24-hour day; five days a week in the CP area. The main shift times are: 7:00 a.m. - 3:00 p.m., 7:30 a.m. - 4:00 p.m., 8:00 a.m. - 4:30 p.m., 9:30 a.m. - 6:00 p.m., 3:00 p.m. - 11:30 p.m., and 11:00 p.m. - 7:30 a.m. The three main sterilizer operators (SPD technicians) rotate weekend EtO sterilizer duties (usually, only one load is EtO sterilized per weekend, i.e., Sunday, after 4:00 p.m.); during the week, one sterilizer operator is assigned to first shift, and two are assigned to second shift, during which two loads are EtO sterilized each weekday. Job titles of the CP personnel are Stores, Processing, and Distribution (SPD) Assistant; SPD Technician; Senior Technician; and Department Manager. The SPD Assistants' and SPD Technicians' tasks include washing instruments and carts, wrapping and packaging items to be sterilized, operating the sterilizers and aerators, changing EtO cylinders, placing sterilized items in the clean and sterile storage area, and loading the appropriate sterilized packs in case carts for transport to surgery.

In the RT area, the 3M EtO sterilizer is usually operated only once a day by a technician on second shift. After the EtO sterilizer is loaded and the cycle start button pushed, the technician leaves the area. Another technician unloads the sterilizer during the first shift, and, only in the case of an emergency, operates the sterilizer during first shift.

In two full-time employees who work in the RT EtO sterilizer room are white males. There has been 0% employee turnover in RT for the past several years. In CP, the workforce consists of 8 males and 10 females; of these, one male and one female are black. There is a CP employee turnover rate of 16.7% per year. There is no union at the Kettering Medical Center.

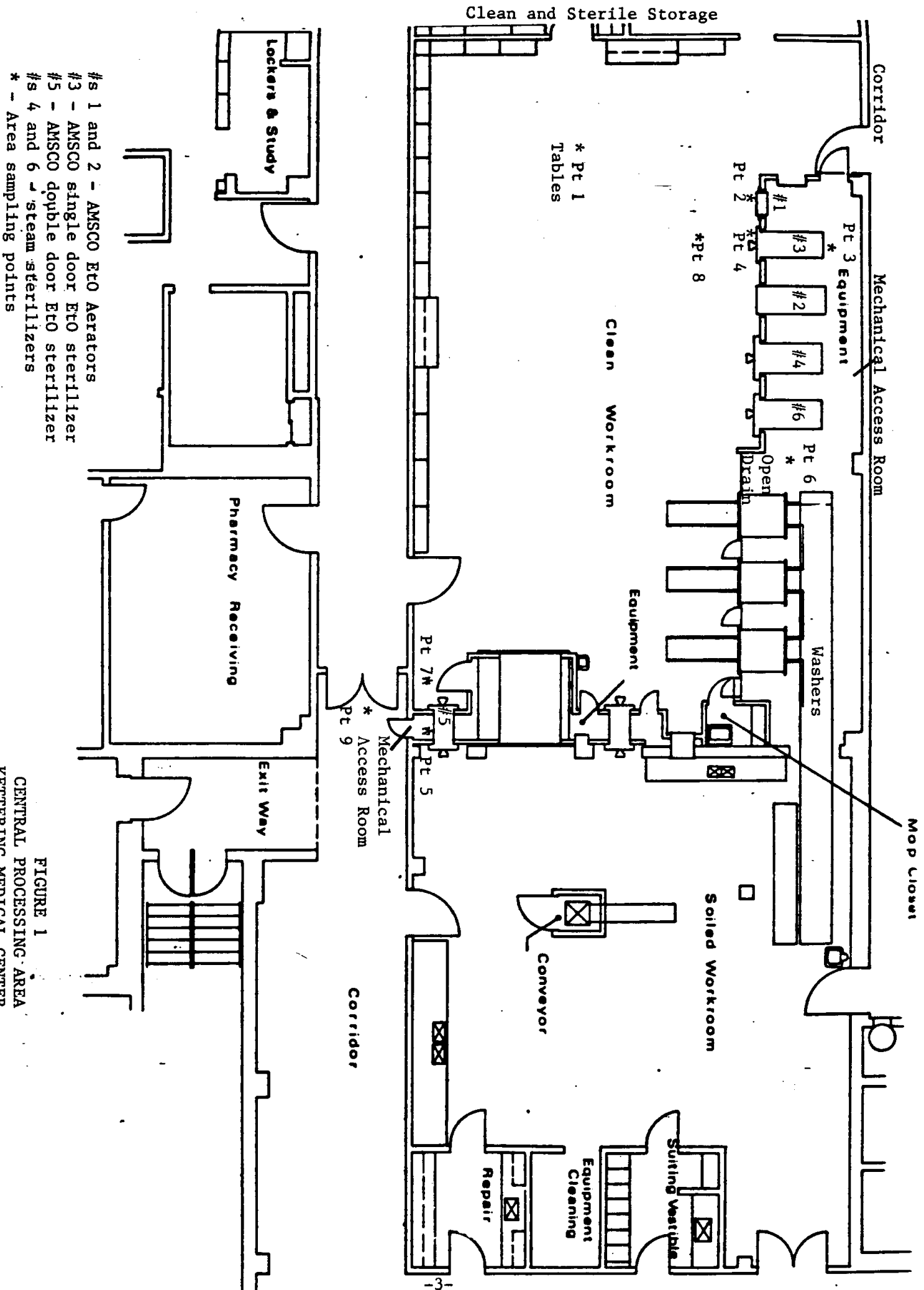
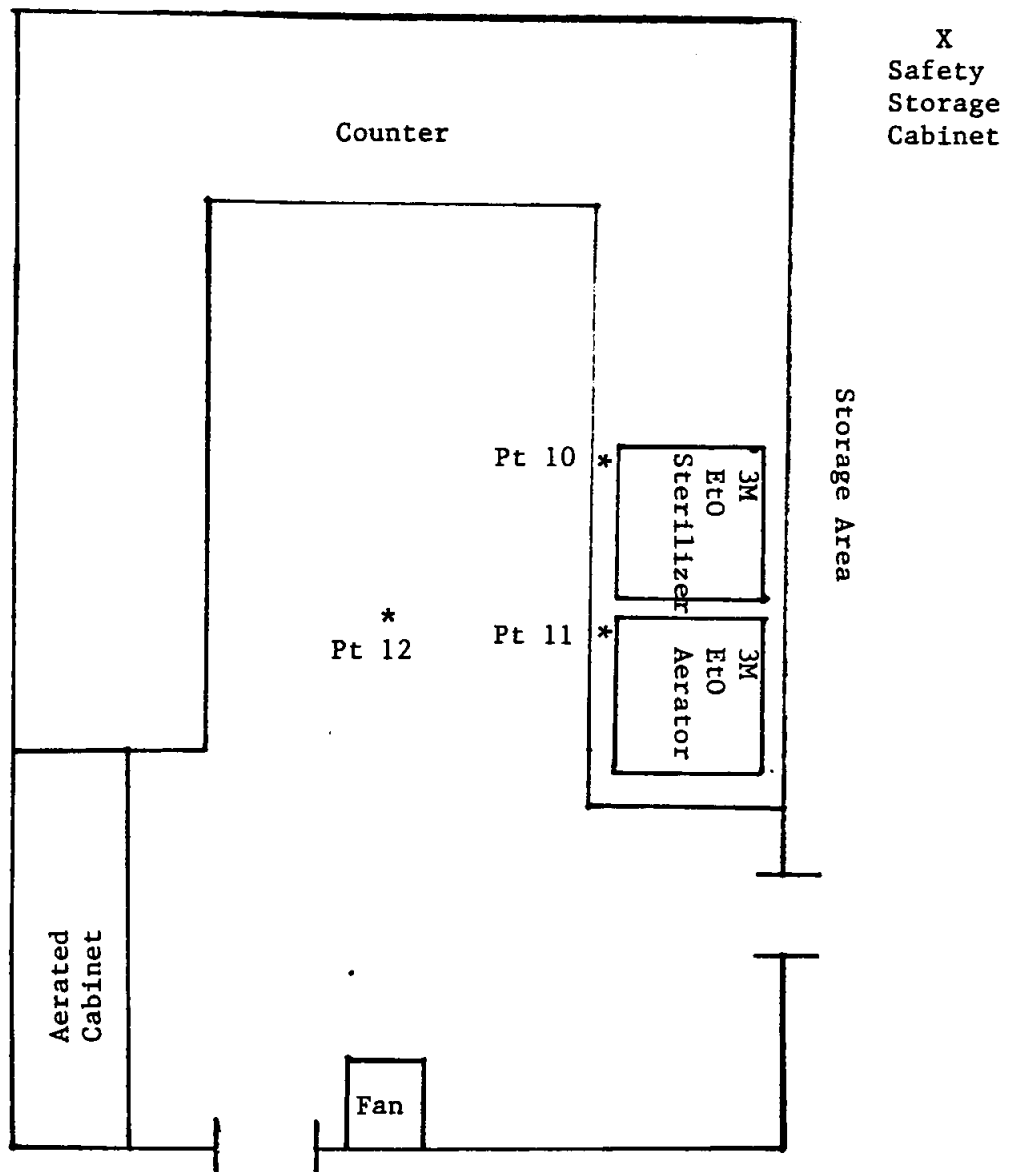


FIGURE 1
CENTRAL PROCESSING AREA
KETTERING MEDICAL CENTER
KETTERING, OHIO
AUGUST 14-16, 1985

FIGURE 2
 RESPIRATORY THERAPY (RT) EtO STERILIZER ROOM
 KETTERING MEDICAL CENTER
 KETTERING, OHIO
 AUGUST 14-16, 1985



* Area Sampling Points

DESCRIPTION OF PROCESS

Prior to being sterilized, various medical/surgical implements which may contain moisture sensitive metal or plastic and/or rubber parts (e.g., catheters, fiber-optic scopes, and dermatome trays) are either wrapped in muslin or a disposable paper wrap, or are packaged according to the manufacturer's instructions in peel packs which consist of see-through, back-to-back, paper and plastic (PVC).

In the CP area, the wrapping/packaging is conducted at several tables in the clean workroom (Figure 1). The wrapped/packaged items are then placed on cart shelving or in a wire basket prior to being loaded into AMSCO EtO sterilizer #3 or #5, respectively. After the sterilizer is loaded, the sterilizer door is closed and the operator starts the sterilization cycle in the automatic operating mode. First, the product is preconditioned for 30 minutes by increasing the temperature (128 - 133°F) and humidity of the chamber. Second, the 12:88 EtO gas mixture is introduced into and remains in the chamber for a period of 2-3/4 hours at a pressure of 8-10 pounds per square inch (psi) and a temperature of 128 to 133°F. Following the EtO sterilization phase, a vacuum of 12 to 13 psi is applied to remove the EtO gas from the sterilizer. The sterilizer then undergoes an air flush to reduce the product's residual EtO level. Next, the vacuum and air flush portions of the cycle are repeated; the two evacuation and air flush phases of the cycle take a total of 30 minutes. After the final air flush, the sterilizer operator cracks the chamber door open about 3 to 6 inches and leaves the immediate vicinity of the sterilizer for 5-6 minutes.

The sterilized items are then transferred by cart (pulling vs pushing) from (either of) the AMSCO sterilizer(s) to one of the AMSCO EtO aerators, which run continuously, 24 hours per day. Depending on the manufacturer's recommendations, aeration time (at 120°F) may range from 1 hour for metal instruments to 24 hours for implant items such as heart valves; the aeration time for most items, however, is 12 hours. AMSCO EtO sterilizer #5 is used only for terminal sterilization (contaminated items are sterilized unwrapped) or on an emergency basis. AMSCO EtO sterilizer #3 is used to sterilize two loads each week day and one load on Sunday.

In the RT area, the equipment to be EtO sterilized is wrapped/packaged in the same manner as in the CP area, placed in a wire basket and loaded directly into the 4 ft³ 3M SteriVac, Model 400, EtO sterilizer. Next, the small end of a 100% EtO cartridge is lubricated with a small amount of High Vac grease and the cartridge is inserted into the cartridge section of the sterilizer. After closing the sterilizer door, the sterilizer operator (laboratory technician) selects the appropriate cycle (warm or cold) and begins the automatic cycle by pressing the start button. First, the product is preconditioned for approximately 15 minutes by increasing the humidity and the temperature to 140°F for a warm cycle or to 99°F for a cold cycle. Second, the 3M EtO gas cartridge (positioned within the chamber) is automatically punctured and the EtO diffuses into the chamber where it remains for 1.5 hours for the warm cycle or 3.5 hours for the cold cycle at a pressure of about 13 psi. Third, a vacuum (3.5 psi) is applied and the chamber is continuously purged for 15 minutes to remove the EtO gas from the

sterilizer. The EtO gas is exhausted through a dedicated exhaust system which leads to the roof of the hospital. Following the 15-minute purge, sterilized items normally remain in the sterilizer, under aeration, until they are removed during the 1st shift of the following morning. Occasionally, however, an emergency arises and a load must be EtO sterilized during the day, after which it is transferred to the 3M aerator; the 3M aerator exhausts directly into the RT room. Following aeration, the basket of sterilized items is manually removed from the sterilizer (or aerator). The sterilized items are either used immediately or placed on open shelving in the RT supply storage area. Usually, only one load is sterilized per day during the second shift, when fewer employees are present.

DESCRIPTION OF EtO VENTILATION SYSTEMS

Each of the AMSCO EtO sterilizers, located in the clean workroom, had a local exhaust ventilation (LEV) system. The LEV consisted of a slot hood which ran the width of and 12 and 20 inches above the AMSCO EtO sterilizer doors (#s 3 and 5, respectively). The capture velocity at each of these LEVs was greater than 50 feet per minute (fpm). Both of the AMSCO sterilizers' and aerators' exhausts were part of a dedicated exhaust system which was vented directly to the roof. The roof exhaust vent was located to the east side of the building and about 200 feet from the building's air intake. The building's air intake was located on the west side of the building; and, because the prevailing winds are from the west, reintrainment would be difficult. In addition, LEV hoods were located over the EtO cylinders (2), the EtO sterilizer pressure release valves, and the sterilizer floor drains. These LEV systems were also part of the dedicated exhaust system.

The 3M EtO sterilizer, located in the RT area, had a slot LEV which ran the width of (32.5 in) and directly over the sterilizer door. The 3M LEV was exhausted directly to the east side of the roof. The 3M EtO aerator did not have a LEV; the aerator's exhaust was vented directly to the RT room.

DESCRIPTION OF PAST EXPOSURES

Air monitoring for EtO was first conducted at Kettering Medical Center in the CP area on June 11-13, 1979. Instantaneous personal samples were collected at distances of 1 to 25 feet from the sterilizer door; sample results ranged from 20 to 26 parts per million (ppm) at 1 ft and 22 to 23 ppm at 25 ft from the sterilizer door (Table 1). The sampling and analytical methods were not reported.

All other EtO air monitoring was conducted by the 3M Company using the 3M Diffusional Monitor (or badge). 3M first conducted EtO monitoring on June 1, 1982. Two samples were collected, one personal and one area; the results were 0.54 ppm for an 8-hour Time-Weighted Average (TWA) and nondetectable (ND) for a 14-hour TWA, respectively. The most recent air monitoring was conducted by 3M on June 19, 1985. The 8-hour TWA results ranged from 0.21 (area) to 0.32 (personal) ppm (Table 1).

TABLE 1
PAST ETO MONITORING DATA
KETTERING MEDICAL CENTER
KETTERING, OHIO
1979 - 1985

SAMPLING DATE	JOB TITLE OR SAMPLE LOCATION	SAMPLING TIME	ETO CONCENTRATION (PPM)	COMMENTS
6/11/79 ¹	CP-Sterilizer Operator	11:55 a.m.	17.0	10 ft from EtO sterilizer door
		11:55 a.m.	18.0	15 ft from EtO sterilizer door
		12 noon	23.0	16 ft from EtO sterilizer door
		12:02 p.m.	22.0	25 ft from EtO sterilizer door
6/12/79 ¹	CP-Sterilizer Operator	1:47 p.m.	20.0	1 ft from EtO sterilizer door
		1:47 p.m.	27.0	15 ft from EtO sterilizer door
		1:52 p.m.	23.0	25 ft from EtO sterilizer door
6/13/79 ¹	CP-Sterilizer Operator	2:50 p.m.	26.0	1 ft from EtO sterilizer door
		2:52 p.m.	26.0	15 ft from EtO sterilizer door
		2:48 p.m.	5.0	Not listed
6/1/82 ² 2nd shift	CP-Sterilizer Operator	475 min.	0.54	Changed EtO cylinder
		4 ft. from sterilizer door	850 min.	N.D. ³
6/2/83 2nd shift	Sterilizer Operator	450 min.	0.29	
6/3/82 2nd shift	Sterilizer Operator	420 min.	N.D.	
6/4/82 2nd shift	Sterilizer Operator	480 min.	N.D.	

- 1) Monitoring conducted by Air Test Labs, Inc., sampling and analysis methods unknown
- 2) Monitoring Conducted by the 3M Company using 3M (diffusional) Ethylene Oxide Monitors #3550.
- 3) N.D. - Nondetectable

TABLE 1 (CONT.)
 PAST ETO MONITORING DATA
 KETTERING MEDICAL CENTER
 KETTERING, OHIO
 1979 - 1985

SAMPLING DATE	JOB TITLE OR SAMPLE LOCATION	SAMPLING TIME	ETO CONCENTRATION (PPM)	COMMENTS
9/7/82	Sterilizer Operator	495 min.	7.21	Monitor left in sterilizer (for 1/2 hour) after load removed.
9/8/82	Sterilizer Operator	360 min.	0.46	
9/9/82	Sterilizer Operator	495 min.	0.31	
9/10/82	Sterilizer Operator	465 min.	2.32	
11/22/82	Sterilizer Operator	450 min.	0.75	
11/23/82	Sterilizer Operator	495 min.	0.30	
11/24/82	Sterilizer Operator	480 min.	0.89	
11/26/82	Sterilizer Operator	495 min.	0.36	
5/31/83	Sterilizer Operator	435 min.	0.49	
6/1/83	Sterilizer Operator	480 min.	1.85	Monitor left on front of sterilizer door
6/2/83	Sterilizer Operator	495 min.	0.16	

Monitoring Conducted by the 3M Company using 3M (diffusional) Ethylene Oxide Monitors #3550.

TABLE 1 (CONT.)
 PAST ETO MONITORING DATA
 KETTERING MEDICAL CENTER
 KETTERING, OHIO
 1979 - 1985

SAMPLING DATE	JOB TITLE OR SAMPLE LOCATION	SAMPLING TIME	ETO CONCENTRATION (PPM)	COMMENTS
6/3/83	Sterilizer Operator	480 min.	0.12	
	Front of Sterilizer	480 min.	0.21	
10/25/83	Sterilizer Operator	465 min.	<0.08	
10/26/83	Sterilizer Operator	480 min.	0.33	
10/27/83	Sterilizer Operator	480 min.	0.19	
10/28/83	Sterilizer Operator	480 min.	0.52	
1/16/84	Sterilizer Operator	420 min.	0.35	
1/17/84	Sterilizer Operator	420 min.	<0.09	
1/18/84	Sterilizer Operator	420 min.	<0.09	
1/19/84	Sterilizer Operator	465 min.	<0.08	
1/20/84	Sterilizer Operator	420 min.	<0.09	
9/11/84	Sterilizer Operator	435 min.	0.24	
9/12/84	Sterilizer Operator	435 min.	0.60	

Monitoring Conducted by the 3M Company using 3M (diffusional) Ethylene Oxide Monitors #3550.

TABLE 1 (CONT.)
PAST ETO MONITORING DATA
KETTERING MEDICAL CENTER
KETTERING, OHIO
1979 - 1985

SAMPLING DATE	JOB TITLE OR SAMPLE LOCATION	SAMPLING TIME	ETO CONCENTRATION (PPM)	COMMENTS
9/13/84	Sterilizer Operator	480 min.	0.73	
9/17/84	Sterilizer Operator	480 min.	0.73	
9/18/84	Sterilizer Operator	435 min.	0.36	
12/10/84	Area	435 min.	0.60	
12/11/84	Sterilizer Operator	1065 min.	0.11	
12/12/84	Area	435 min.	0.34	
12/14/84	Area	435 min.	0.57	
12/18/84	Sterilizer Operator	455 min.	0.45	
3/7/85	Area	435 min.	0.70	2 loads sterilized during monitoring
3/8/85	Sterilizer Operator	480 min.	0.73	2 loads sterilized during monitoring
3/11/85	Area	435 min.	0.44	1 load sterilized during monitoring
3/12/85	Sterilizer Operator	480 min.	0.82	2 loads sterilized during monitoring
3/13/85	Area	435 min.	0.60	2 loads sterilized during monitoring

Monitoring Conducted by the 3M Company using 3M (diffusional) Ethylene Oxide Monitors #3550.

TABLE 1 (CONT.)
 PAST ETO MONITORING DATA
 KETTERING MEDICAL CENTER
 KETTERING, OHIO
 1979 - 1985

SAMPLING DATE	JOB TITLE OR SAMPLE LOCATION	SAMPLING TIME	ETO CONCENTRATION (PPM)	COMMENTS
4/18/85	Sterilizer Operator/RT Lab Tech.	425 min.	<0.03	
4/19/85	Sterilizer Operator/RT Lab Tech.	480 min.	<0.02	
4/23/85	Sterilizer Operator/RT Lab Tech.	465 min.	0.03	
4/24/85	Sterilizer Operator/RT Lab Tech.	390 min.	0.08	
6/3/85	Sterilizer Operator	350 min.	0.26	
6/4/85	Sterilizer Operator	420 min.	0.32	
6/5/85	Sterilizer Operator	405 min.	0.22	
6/10/85	Sterilizer Operator	490 min.	0.21	

Monitoring Conducted by the 3M Company using 3M (diffusional) Ethylene Oxide Monitors #3550.
 RT - respiratory therapy

DESCRIPTION OF INDUSTRIAL HYGIENE,
SAFETY, AND MEDICAL PROGRAMS

Industrial Hygiene

Kettering Medical Center has an industrial hygiene program associated specifically with the use of the EtO gas sterilizers. The first air monitoring for EtO was conducted in the CP area during June, 1979, by Air Test Labs, Incorporated.

Since June, 1982, EtO monitoring has been conducted with 3M badges approximately three times a year in CP and once a year in RT.

The CP shift supervisor ensures that the employees wear the 3M badges. Following the monitoring period, the 3M badges are forwarded to the 3M company for chemical analysis. AMSCO conducts the mechanical checks on AMSCO equipment (e.g., door seals) on a semiannual basis.

Safety

This hospital has a safety program for employees in the EtO sterilization areas. The program includes employee orientation and emergency training for spills, fire, explosions, and cardiopulmonary resuscitation (CPR). In addition, a Hospital Safety Committee exists which handles safety issues other than EtO sterilization.

The EtO cylinders are located in the Mechanical Access (MA) room which is partially isolated from the clean workroom. A sign is posted on the wall next to the MA room door which states that no employees are to enter the MA room during the EtO sterilizer exhaust phase or for 1-1/2 hours following the exhaust phase.

The only personal protective equipment provided to the CP sterilizer operator is cotton gloves. The cotton gloves are worn during transfer of sterilized items from the sterilizer to the aerator.

Medical

A complete preemployment physical and visit with the hospital physician are required for all hospital employees. Annual physicals are also required and include a blood work-up involving complete blood count (CBC), serum glucose and electrolyte levels (SMAC and PPBS); urinalysis; tetanus immunization; and TB skin test (PPD). A chest X-ray is required only every four years unless the PPD is positive. At the time this report was written, electrocardiograms (EKGs) have been added to the physical exams, depending on the employee's age. There is no medical program specifically developed for those employees potentially exposed to accidental EtO gas leakage.

DESCRIPTION OF SAMPLING AND ANALYTICAL METHODS

Personal breathing zone and area TWA and short-term samples for EtO were collected during this survey using SKC AIRCHEK I Universal constant-flow sampling pumps. These pumps contained fixed orifices which resulted in sampling flow rates of approximately 20, 50, or 100 cubic centimeters (cc) per minute (min). The collection media for NIOSH Method Number 1607⁶ consisted of two tubes in series; the first contained 400 and the second 200 milligrams (mg) of activated coconut shell charcoal. The charcoal tubes were connected to the sampling pump via flexible plastic tubing. For personal sampling, the pumps were hooked onto an employee's belt and the charcoal tubes were positioned in the breathing zone (BZ). The sampling time per series of charcoal tubes varied from 5 minutes to 7-1/2 hours.

These charcoal tube samples were analyzed according to NIOSH Method Number 1607⁶. Specifically, this method involves desorbing the EtO from the charcoal using 3 milliliters (mL) of a 1% carbon disulfide/benzene solution for one hour at room temperature. Twenty microliters (uL) of 48% hydrogen bromide (HBr) were added to 1 mL aliquots of each sample. Sodium carbonate was added to each vial and held until carbon dioxide no longer evolved. Each sample was analyzed for the derivative 2-bromoethanol using a Hewlett Packard 5840 Gas Chromatograph with an electron capture detector (GC/ECD). The reported limit of quantitation (LOQ) for this sample analysis was 4.74 micrograms (ug) per sample with a limit of detection (LOD) of 0.95 ug/sample.

Concurrent air samples were collected for selected area and personal BZ samples by using the Occupational Safety and Health Administration's (OSHA) Method Number 50 along with the NIOSH Method. The OSHA Method was used in order to evaluate its advantages and disadvantages as compared to NIOSH Method 1607. In addition, side-by-side sampling was conducted to compare NIOSH with NIOSH and NIOSH with OSHA sampling methods. SKC AIRCHEK I Universal constant flow pumps were used to obtain these samples in the same manner as described above except that the two NIOSH or the NIOSH and OSHA sampling media were attached to a dual fixed-flow holder; the flow rate for the OSHA sampling media was set at either 50 or 100 cc/min (approximate values). The collection media for OSHA Method Number 50 consisted of a single tube which contained 100 and 50 mg (front and back sections, respectively) of hydrobromic acid (HBr) treated petroleum base charcoal. Samples were desorbed with 1 mL of dimethylformamide. The derivative 2-bromoethylheptafluorobutyrate was analyzed by GC/ECD. The LOD for this sample analysis was 1.7 ug/sample; the LOQ was 3.4 ug/sample.

EtO exposure levels were determined for the sterilizer operators (CP and RT technicians) on 1st and/or 2nd shifts, August 15-16, 1985. Locations for area sampling in the CP and RT areas were chosen to characterize EtO concentration levels in the various CP and RT areas (Figures 1 and 2).

Area EtO measurements were also obtained using a Wilks Miran Model 80 Infrared Analyzer. This instrument was used to detect leaks in equipment, determine adequacy of aeration periods, identify emission points, and spot check general air concentrations of EtO. The Wilks Miran Model 80 is a

quantitative analysis system which combines a single beam infrared spectrometer with a programmable microcomputer system. The instrument was calibrated with an EtO standard over two overlapping analysis ranges (0-150 ppm and 100-300 ppm). The LOD of the instrument at a wavelength of 3.3 micrometers (um) is 0.2 ppm. Monitoring results were integrated and printed (in ppm) every 24 seconds. These readings were then averaged over the time sampled to arrive at a TWA.

APPLICABLE STANDARDS AND RECOMMENDED LEVELS

Prior to June 22, 1984, the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for EtO was 50 ppm as a TWA concentration for an 8-hour workshift.⁸ OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.⁹ In addition, an "action level" of 0.5 ppm as an 8-hour TWA was established (by OSHA) as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. The Environmental Protection Agency (EPA) supported the OSHA PEL of 1 ppm in the Federal Register (June 22, 1984) and, provided guidance concerning workplace design and work practices which would aid compliance with the OSHA PEL.¹⁰

In 1977, NIOSH recommended a ceiling level of 75 ppm as determined during a 15-minute sampling period.³ This level, however, was set prior to the recognition of the carcinogenic potential of EtO (see Appendix A). Based on recent findings, NIOSH recommends that EtO exposures not exceed 5 ppm for a maximum of 10 minutes per day and that exposures be controlled to less than 0.1 ppm determined as an 8-hour TWA.¹¹

The American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Threshold Limit Value (TLV) of 10 ppm for an 8-hour TWA based on data available prior to 1982.¹² However, in 1982, the ACGIH issued a notice of intended change in which it was proposed that the TWA concentration be lowered to 1 ppm. This recommendation was reviewed and adopted in 1984. ACGIH has also designated EtO as an A2 carcinogen.¹² An A2 carcinogen is defined as an industrial substance suspected of having carcinogenic potential for man. This designation is based on either (1) limited epidemiologic evidence, exclusive of clinical reports of single cases, or (2) demonstration of carcinogenesis in one or more animal species by appropriate methods.

DISCUSSION OF SAMPLING RESULTS AND OBSERVATIONS

The four personal short-term (5-11 min) and five personal TWA (142-447 min) sampling results were below the LOD for both the NIOSH (0.95 ug per sample) and OSHA (1.7 ug per sample) methods. Therefore, the short-term samples were below the NIOSH short-term recommended standard of 5 ppm for a maximum of 10 minutes per day (Table 2); and, the personal TWA sampling results were below the OSHA standard/PEL of 1 ppm for an 8-hour TWA, as well as the NIOSH recommended standard of less than 0.1 ppm for an 8-hour TWA (Table 2).

TABLE 2
PERSONAL ETHYLENE OXIDE (ETO) TWA AND SHORT-TERM SAMPLING RESULTS
KETTERING MEDICAL CENTER
CENTRAL PROCESSING AREA
KETTERING, OHIO
AUGUST 15, 1985

JOB TITLE	SAMPLE NUMBER ¹	SAMPLE VOLUME (LITERS)	SAMPLE TIME (MINUTES)	ANALYTICAL WEIGHT (MICROGRAMS)	CONCENTRATION (PPM)	COMMENTS
SPD ASSISTANT	203	2.56	142	N.D.	<0.10	
SPD TECHNICIAN/ STERILIZER OPERATOR	208	9.10	447	N.D.	<0.03	
	209	22.00	447	N.D.	<0.01	
SPD TECHNICIAN/ STERILIZER OPERATOR	215	1.16	11	N.D.	<0.22	Transfer of load from EtO sterilizer to aerator
	33*	1.10	11	N.D.	<0.86	
SPD TECHNICIAN	216	16.50	342	N.D.	<0.02	
	217	6.08	342	N.D.	<0.04	
SPD TECHNICIAN/ STERILIZER OPERATOR	221	0.49	5	N.D.	<0.53	Transfer of load from EtO sterilizer to aerator
	222	0.49	5	N.D.	<0.54	

¹ - Two sample numbers listed for one sampling location indicate that dual (side-by-side) sampling was conducted.

N.D.-Nondetectable

NIOSH Method LOD: 0.95 ug/sample

LOQ: 4.74 ug/sample

*OSHA tube - OSHA Method LOD: 1.7 ug/sample

LOQ: 3.4 ug/sample

Nine area TWA (47 to 418 minutes) sample results ranged from ND to 0.81 ppm. The 21 area short-term (30 minutes or less) sample results ranged from ND to 3.8 ppm (Table 3).

The Wilks Miran continuous monitoring results (Table 4) showed peak EtO concentrations of: 286 ppm when the AMSCO EtO #3 sterilizer door was cracked open following the sterilization cycle, 20.4 ppm at the 3M EtO sterilizer door seal (indicating a leak through the door seal during the sterilization cycle), 35.5 ppm in the middle of the RT EtO sterilizer room, and 78.2 ppm at the AMSCO EtO #5 sterilizer drain (in the Mechanical Access Room) during the evacuation phase of the cycle. The sterilizer operator (SPD technician) in the CP area is only in the immediate vicinity of the EtO sterilizer while cracking the sterilizer door. The sterilizer operator in the RT area does not remain in the sterilizer room during the entire shift; however, if an emergency load were run during 1st shift, other employees who enter and work in the room could be exposed. None of the employees enter either of the Mechanical Access areas during the EtO sterilizer evacuation phase of the cycle.

Several observations of work practices were made during this survey which could effect personal exposure to EtO. Personal protective equipment is not worn by the SPD technician in CP when changing the EtO cylinders, or by the RT laboratory technician when seating the EtO cartridge in (or removing it from) the 3M EtO sterilizer or when transferring the sterilized load from the sterilizer to the 3M aerator. Also, the SPD technician did not wait for the required 15 minutes, after cracking the AMSCO (#3) sterilizer door open, before returning to unload the sterilizer. Work practices which did reduce overall EtO exposure potential included conducting most of the EtO sterilization processes on 2nd shift when fewer personnel were present; not entering the immediate vicinity of the AMSCO sterilizers during the EtO sterilization cycle; not entering either of the Mechanical Access Rooms during or for 1-1/2 hours following the evacuation phase of the EtO sterilizer cycle; wearing cotton gloves during load transfer from the AMSCO EtO sterilizer to the AMSCO EtO aerator; and pulling rather than pushing the cart of EtO sterilized product.

Changes in certain engineering controls at Kettering Medical Center would also reduce the potential EtO exposure levels. Both AMSCO EtO sterilizer drainage ducts and the steam sterilizer ducts emptied into an open, unventilated common sewer drain in the CP MA room (behind EtO sterilizer #3). Measureable levels of EtO were found at this common sewer drain (2.8 to 3.3 ppm, Table 3) as well as at the mouth of the air vent pipes (3.4 ppm, Table 4) extending from the main EtO sterilizer drainage duct.

In the RT area, the 3M EtO aerator was being exhausted into the RT EtO sterilizer room; and, the 3M EtO sterilizer had a door seal leak.

TABLE 3
GENERAL AREA ETHYLENE OXIDE (ETO) SAMPLING RESULTS
KETTERING MEDICAL CENTER
CENTRAL PROCESSING AND RESPIRATORY THERAPY AREAS
KETTERING, OHIO
AUGUST 15-16, 1985

DATE	SAMPLING LOCATION	SAMPLE NUMBER ¹	SAMPLE VOLUME (LITERS)	SAMPLE TIME (MINUTES)	ANALYTICAL WEIGHT (MICROGRAMS)	CONCENTRATION (PPM)	COMMENTS ²
8/15/85	CP-Clean Workroom	200	7.72	418	N.D.	<0.07	Background sample at wrapping tables, Pt. 1 ^a
	CP-Clean Workroom	201	3.14	30	N.D.	<0.17	Adjacent to aerator, Pt. 1
		202	3.10	30	N.D.	<0.17	
	CP-MA Area	204	4.92	47	3.0	0.34	Over sterilizer #3 drain, Pt. 2
		30*	4.86	47	10.1	1.15	
	CP-MA Area	206	3.17	211	1.8	0.32	Over sterilizer #3 drain, Pt. 2
		207	8.64	211	N.D.	<0.06	
	CP-MA Area	210	1.51	15	N.D.	<0.35	Over sterilizer #3 drain, Pt. 2
		32*	1.42	15	3.9	1.53	
8/15/85	CP-Clean Workroom	218	1.21	12	59.7	27.4	On sterilizer #3 cracking door and transferring load, Pt. 3
		36*	1.14	12	385	188.4	
	CP-Clean Workroom	219	3.54	194	N.D.	<0.15	On sterilizer #3 during cycle, Pt. 3
		220	3.60	194	N.D.	<0.15	
	CP-Clean Workroom	223	0.62	6	11.4	10.2	On sterilizer #3 cracking door and transferring load, Pt. 3
		224	0.63	6	8.46	7.48	

¹ - Two sample numbers listed for one sampling location indicate that dual (side-by-side) sampling was conducted.

² - Figure 1 contains sampling points 1-9.
Figure 2 contains sampling points 10-12.

CP - Central Processing

MA - Mechanical Access

N.D. - nondetectable

*OSHA tube - OSHA Method LOD: 1.7 ug/sample
LOQ: 3.4 ug/sample

NIOSH Method LOD: 0.95 ug/sample
LOQ: 4.74 ug/sample

TABLE 3 (CONT.)
GENERAL AREA ETHYLENE OXIDE (ETO) SAMPLING RESULTS
KETTERING MEDICAL CENTER
CENTRAL PROCESSING AND RESPIRATORY THERAPY AREAS
KETTERING, OHIO
AUGUST 15-16, 1985

DATE	SAMPLING LOCATION	SAMPLE NUMBER ¹	SAMPLE VOLUME (LITERS)	SAMPLE TIME (MINUTES)	ANALYTICAL WEIGHT (MICROGRAMS)	CONCENTRATION (PPM)	COMMENTS ²
8/15/85	CP-MA Room for Sterilizer #5	225	3.57	187	N.D.	<0.15	Pt. 4
		34*	9.17	187	N.D.	<0.10	
	MA Area	226	1.42	15	7.90	3.09	Over drain while sterilizer #3 evacuating, Pt. 2
		227	1.51	15	8.14	2.98	
	MA Area	228	1.59	16	8.10	2.82	Common sewer drain while sterilizer #3 evacuating, Pt. 5
		230	1.69	16	9.95	3.27	
	CP-aerator #1	229	—	—	N.D.	—	During aeration, Pt. 5
	MA Room for Sterilizer #5	231	1.58	15	142	49.77	At drain while sterilizer #5 evacuating, Pt. 4
		232	1.49	15	139	51.84	
	MA Room for Sterilizer #5	233	1.55	15	N.D.	<0.34	Sterilizer #5 evacuating, Pt. 6
		234	1.57	15	N.D.	<0.34	
8/15/85	Respiratory Therapy	213	7.46	409	7.5	0.56	At 3M sterilizer door seal, Pt. 10
		214	7.56	409	11	0.81	

¹ - Two sample numbers listed for one sampling location indicate that dual (side-by-side) sampling was conducted.

² - Figure 1 contains sampling points 1-9.
Figure 2 contains sampling points 10-12.

CP - Central Processing

MA - Mechanical Access

N.D. - nondetectable

*OSHA tube - OSHA Method LOD: 1.7 ug/sample

LOQ: 3.4 ug/sample

NIOSH Method LOD: 0.95 ug/sample

LOQ: 4.74 ug/sample

TABLE 3 (CONT.)
 GENERAL AREA ETHYLENE OXIDE (ETO) SAMPLING RESULTS
 KETTERING MEDICAL CENTER
 CENTRAL PROCESSING AND RESPIRATORY THERAPY AREAS
 KETTERING, OHIO
 AUGUST 15-16, 1985

DATE	SAMPLING LOCATION	SAMPLE NUMBER ¹	SAMPLE VOLUME (LITERS)	SAMPLE TIME (MINUTES)	ANALYTICAL WEIGHT (MICROGRAMS)	CONCENTRATION (PPM)	COMMENTS ²
8/15/85	Respiratory Therapy	37*	0.98	10	N.D.	<0.96	Transfer of load from 3M sterilizer to 3M aerator, Pt. 10
8/16/85	Respiratory Therapy	241 242	0.18 0.48	10 10	1.2 2.6	3.75 2.99	Transfer of load from 3M sterilizer to 3M aerator, Pt. 10

¹ - Two sample numbers listed for one sampling location indicate that dual (side-by-side) sampling was conducted.

² - Figure 1 contains sampling points 1-9.
 Figure 2 contains sampling points 10-12.

CP - Central Processing

MA - Mechanical Access

N.D. - nondetectable

*OSHA tube - OSHA Method LOD: 1.7 ug/sample
 LOQ: 3.4 ug/sample

NIOSH Method LOD: 0.95 ug/sample
 LOQ: 4.74 ug/sample

TABLE 4
GENERAL AREA CONTINUOUS ETHYLENE OXIDE (ETO) MONITORING RESULTS
(WILKS MIRAN)
KETTERING MEDICAL CENTER
CENTRAL PROCESSING AND RESPIRATORY THERAPY AREAS
KETTERING, OHIO
AUGUST 15-16, 1985

DATE	SAMPLING ₁ LOCATION	SAMPLING TIME	CONCENTRATION (ppm) RANGE	TWA	COMMENTS
8/15/85	Central Processing	3 minutes	0	0	AMSCO aerator door seal
	Central Processing	11:49am-11:53am	0	0	Removal of aerated items from aerator, Pt. 2
	Central Processing	4:06pm-4:20pm	0	0	Near AMSCO sterilizer #3 while sterilizer operating, Pt. 4
	CP-MA Area	6:45pm-7:01pm	0-0.4	0.2	
	CP-MA Area	7:01pm-7:08pm	0.3-9.1	3.0	By drain while sterilizer #3 evacuating, Pt. 3
	CP-MA Area	7:08pm-7:13pm	1.0-8.7	3.9	Top of open copper vent pipes, behind equipment numbered 2, 4, and 6
	CP-MA Area	7:13pm-7:25pm	0.7-7.9	1.3	By drain, Pt. 3
	Central Processing	7:25pm-7:27pm	166.8-286.0	221.9	By sterilizer when door cracked open, Pt. 4

1 - See Figure 1 for information on sampling point (Pt) locations in the CP area.
See Figure 2 for information on sampling point (Pt) locations in the RT area.
CP - Central Processing
MA Area - Mechanical Access Area

TABLE 4 (CONT)
GENERAL AREA CONTINUOUS ETHYLENE OXIDE (ETO) MONITORING RESULTS
(WILKS MIRAN)
KETTERING MEDICAL CENTER
CENTRAL PROCESSING AND RESPIRATORY THERAPY AREAS
KETTERING, OHIO
AUGUST 15-16, 1985

DATE	SAMPLING ₁ LOCATION	SAMPLING TIME	CONCENTRATION (ppm) RANGE	TWA	COMMENTS
8/15/85	Central Processing	7:27pm-7:30pm	0.5-5.2	1.1	7-1/2' from cracked sterilizer door during load transfer, Pt. 8
	Central Processing	7:30pm-7:32pm	0.9-8.7	3.9	At BZ during load transfer from sterilizer to aerator
	Central Processing	7:32pm-7:37pm	0.7-2.0	1.1	At BZ during load transfer from sterilizer to aerator
	Respiratory Therapy	7:40pm-7:52pm	0-20.4	6.8	At 3M door seal while sterilizer in cycle, Pt. 10
	Respiratory Therapy	7:52pm-7:56pm	12.1-35.5	23.1	In the middle of the room while sterilizer in cycle, Pt. 12
	Respiratory Therapy	7:57pm-8:05pm	0	0	1' above sterilizer while sterilizer in cycle
	Central Processing	8:58pm-11:50pm	0-0.2	0.01	Sterilizer #5 in cycle, Pt. 7
	MA Room for Steril. #5	11:50pm-11:54pm	0-0.6	0.09	Sterilizer #5 in cycle, Pt. 5

¹ - See Figure 1 for information on sampling point (Pt) locations in the CP area.
See Figure 2 for information on sampling point (Pt) locations in the RT area.
CP - Central Processing
MA Area - Mechanical Access Area
BZ - Breathing Zone

TABLE 4 (CONT)
 GENERAL AREA CONTINUOUS ETHYLENE OXIDE (ETO) MONITORING RESULTS
 (WILKS MIRAN)
 KETTERING MEDICAL CENTER
 CENTRAL PROCESSING AND RESPIRATORY THERAPY AREAS
 KETTERING, OHIO
 AUGUST 15-16, 1985

DATE	SAMPLING ₁ LOCATION	SAMPLING TIME	CONCENTRATION (ppm) RANGE	TWA	COMMENTS
8/15/85	MA Room for Steril. #5	11:54pm-11:56pm	44.3-78.2	58.0	At drain while sterilizer #5 evacuating, Pt. 5
	MA Room for Steril. #5	11:56pm-11:57pm	6.2-8.3	7.2	Sterilizer #5 evacuating, Pt. 5
	In hallway outside of MA Room for Steril. #5	11:57pm-11:58pm	0	0	Sterilizer #5 evacuating, Pt. 9
	Central Processing	11:58pm-12:20am	0-0.4	0.27	3 ft from EtO sterilizer (#5) door
8/16/85	Respiratory Therapy	9:10am-9:17am	0	0	Load transfer from EtO sterilizer to aerator
	Respiratory Therapy	9:17am-9:21am	0	0	Around aerator door while sterilized product inside chamber, Pt. 11

1 - See Figure 1 for information on sampling point (Pt) locations in the CP area.
 See Figure 2 for information on sampling point (Pt) locations in the RT area.
 CP - Central Processing
 MA Area - Mechanical Access Area

There was no EtO alarm system in either the CP clean workroom or RT sterilizer room, or for the AMSCO or 3M EtO sterilizer or aerator exhaust systems. However, ventilation alarm systems have been ordered. Also, the AMSCO EtO sterilizer and aerator exhaust ductwork connections were not sealed.

Engineering controls which did reduce the overall EtO exposure potential included LEV hoods over the EtO cylinder valves, the individual AMSCO EtO sterilizer floor drains, and the AMSCO EtO sterilizer pressure release valves. Slot LEV hoods are located over each AMSCO EtO sterilizer door and continue to function for 30 minutes after the sterilization cycle is completed. Both of the AMSCO and the 3M EtO sterilizers and the AMSCO aerators have dedicated exhaust ventilation systems which are vented directly to the roof. These exhaust vents are located on the east side of the building; the building's intake vents are located about 200 ft away, on the west side of the building. The prevailing winds are from the west; the wind direction and distance between the exhaust vents and building intake louvers would make reentrainment (of EtO) difficult.

CONCLUSIONS

The four personal short-term (5 to 11 min) and five personal TWA (142 to 447 min) sample results were below the NIOSH short-term recommended standard of 5 ppm for a maximum of 10 minutes per day and the NIOSH recommended standard of less than 0.1 ppm for an 8-hour TWA, respectively. Nine area TWA (47-418 min) sample results ranged from ND to 0.81 ppm. The 21 area short-term (30 min or less) sample results ranged from ND to 3.8 ppm.

Kettering Medical Center has instituted the following: engineering controls (such as LEV over the AMSCO and 3M EtO sterilizer doors and the AMSCO pressure release valve and floor drain, and dedicated exhaust ventilation for both of the AMSCO EtO sterilizers and aerators and the 3M EtO sterilizer), administrative controls (such as restricting entry to the MA areas during and for 1-1/2 hours after the exhaust phase of the EtO sterilization cycle), and work practices [such as wearing cotton gloves when unloading the AMSCO sterilizer and pulling versus pushing the cart of (AMSCO) EtO sterilized items] in an effort to reduce employees' exposure to EtO.

EtO exposure potential at Kettering Medical Center could be further reduced by instituting the additional engineering controls, administrative controls, and work practices offered in the Recommendations section of the report.

RECOMMENDATIONS

The following recommendations are offered to reduce the exposure potential to EtO at Kettering Medical Center. All recommendations are based on cited references or good industrial hygiene practices.

1. SPD technicians who change EtO cylinders (CP area) and laboratory technicians who insert EtO cartridges into and remove them from the 3M sterilizer (RT area) should be provided with and required to wear nitril rubber or butyl rubber gloves¹³ and a face shield during these activities.
2. Thick cotton gloves should be worn when unloading the RT 3M EtO sterilizer, especially if the load is removed from the sterilizer before being aerated overnight.
3. Cotton gloves (worn while unloading the EtO chambers), towels, empty 3M EtO cartridges, or other articles which may contain residual EtO should be placed in the EtO aerator to prevent EtO from diffusing into the CP and/or RT environments.^{14,16-18}
4. Excessive breathing of EtO vapors should be avoided by directing the breathing zone (turning the head) away from the sterilized items (CP and RT areas).^{14,15,17}
5. The rule of waiting for 15 minutes to unload the AMSCO EtO sterilizer (after cracking the sterilizer door open) should be enforced. Also, personnel (CP and RT) working with the EtO sterilizers should be retrained or tested periodically to ensure that they understand and follow proper procedures.
6. The integrity of the 3M EtO sterilizer and aerator door seals (in RT) should be checked on a regular basis,¹⁴⁻¹⁶ and repaired if needed, so that there is no EtO leakage. Policies and procedures should be written (and enforced) for a scheduled preventive maintenance program for the EtO sterilization and aeration equipment.
7. The 3M aerator should have a dedicated exhaust to the roof.
8. An audible and visual pressure differential alarm system (e.g, sail switch activated) should be installed to indicate a ventilation system failure. At the time this report was written, a visual alarm had been added to the EtO sterilizer #5, and is being added to the EtO sterilizer #3 exhaust ventilation. Sterilizer ductwork connections should be sealed in case of an electrical and/or ventilation system(s) failure, and to increase the efficiency of the system.
9. The open, common sterilizer sewer drain, located in the CP MA room, should be enclosed and/or ventilated. This would reduce the chance of EtO diffusing from the MA room into the clean workroom during the exhaust phase of the EtO sterilization cycle.

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APPENDIX A
TOXICITY OF ETHYLENE OXIDE

Toxicity

Evidence from animal studies suggests that EtO may have carcinogenic properties.^{19,20} A group of EtO manufacturers sponsored a study at the Bushy Run Research Center in which male and female Fischer 344 rats were exposed to EtO at airborne concentrations of 10, 33, or 100 parts per million (ppm) for 6 hours per day, 5 days per week for two years.¹⁹ Two other groups of animals served as controls. Initially, there were 120 animals of each sex in each exposure group. The researchers observed a statistically significant increase in the incidence of mononuclear cell leukemia among the female rats, and peritoneal mesothelioma among the male rats exposed to EtO. The increase in leukemia incidence was found to increase linearly as a function of EtO exposure. An elevation in mortality from brain cancers (glial type) was also observed in the rats exposed to EtO.

NIOSH researchers have recently reported on the results from an animal experiment which corroborated the findings of the Bushy Run Study.²⁰ Male Fischer 344 rats were exposed to EtO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm. There were 80 rats in each exposure group. Increases in the incidence of mononuclear leukemia, peritoneal mesothelioma, and cerebral gliomas were observed among the EtO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of EtO.²¹⁻²³ Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that had previously been included in a hematologic investigation.²¹ This facility produced EtO via the chlorohydrin process in which, in addition to EtO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloro-ethyl) ether. Among 89 "full-time" exposed workers, a statistically significant (p less than .01) excess of leukemia mortality was observed (2 observed versus 0.14 expected). In addition, a statistically significant (p less than .01) excess of stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to EtO; however, ethylene oxide and ethylene dichloride were the prime suspects.

Morgan, et al, conducted a retrospective cohort mortality study of workers involved in the production of EtO at a Texaco Facility.²² A total of 850 workers were included in the study, of which 767 were potentially exposed to EtO. No EtO was detected in most samples taken in the production area, and all measurements in this area were below 10 ppm. No cases of leukemia were observed in this study; however, the authors estimated that the lowest relative risk that they had a high probability of detecting (80% power) was 10.5.

Hogstedt also reported on three cases of leukemia that occurred in a small group of workers at a Swedish company.²³ The company used a mixture of 50% EtO and 50% methyl formate to sterilize hospital equipment. The 8-hour TWA exposure for EtO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this cohort. One of the cases was exposed to benzene, a known leukemogen, and it

was speculated that the combined exposure of EtO and methyl formate might produce a special risk.

EtO is also a potent alkylating agent capable of causing irreversible changes or mutations in cellular proteins and DNA in animals.^{24,25} EtO is also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.³

Chromosomal aberrations related to EtO exposure have been observed in a number of animal studies and epidemiologic investigations.^{20,25-32} Yager and Benz observed a dose related increase in sister chromatid exchanges (SCEs) among New Zealand white rabbits that were exposed via inhalation to 50 to 250 ppm of EtO.²⁶ NIOSH (Lynch, et al) recently reported preliminary findings in which cynomolgus monkeys were exposed to 0, 50, or 100 ppm of EtO for 7 hours per day, 5 days per week.²⁰ After 24 months of exposure, statistically significant increases were observed in the frequency of chromosomal aberrations (including quadriradial chromosomes) and SCEs in the peripheral lymphocytes of the 50 and 100 ppm exposed groups versus the controls.

Garry, et al, examined the occurrence of SCE in the peripheral lymphocytes of 12 EtO exposed workers and 12 nonexposed controls in a hospital sterilization facility.²⁷ The exposed group showed statistically significant elevations in the number of SCEs compared to the controls. Particularly high SCE frequencies were observed among 4 workers that had reported either neurologic or respiratory symptoms. The maximum peak exposure level of EtO measured at this facility was 36 ppm.

Cytogenetic abnormalities have also been observed in several studies of workers exposed to EtO. Ehrenberg, in a study of workers at a factory manufacturing and using EtO, observed a high frequency of chromosomal aberrations in 8 workers who were accidentally exposed to high concentrations of EtO. One case of leukemia was also observed among the 37 workers studied.²⁸

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to EtO in the sterilization of medical devices in 1972.^{29,30} Seventy-five exposed workers at 9 facilities were studied, as well as 37 nonexposed workers who served as controls. Compared to controls, exposed workers were found to have statistically significant increased frequencies of SCEs and chromosomal aberrations.

In response to the findings from the American Hospital Supply study, Johnson and Johnson initiated a cytogenetic study of workers that were also exposed to EtO in the sterilization of medical products.^{31,32} Approximately 50 workers not exposed to EtO were compared to 50 exposed workers at three facilities with 8-hour Time-Weighted Average (TWA) exposures to EtO of less than 1 ppm, 1-10 ppm, and 25-200 ppm, respectively. Statistically significant elevations in SCE frequency were observed in the latter two facilities, and these changes have persisted after one year. The frequency of SCEs appeared to increase in a dose response manner. Chromosomal aberrations were also elevated in the high exposure groups; however, these findings were not statistically significant.