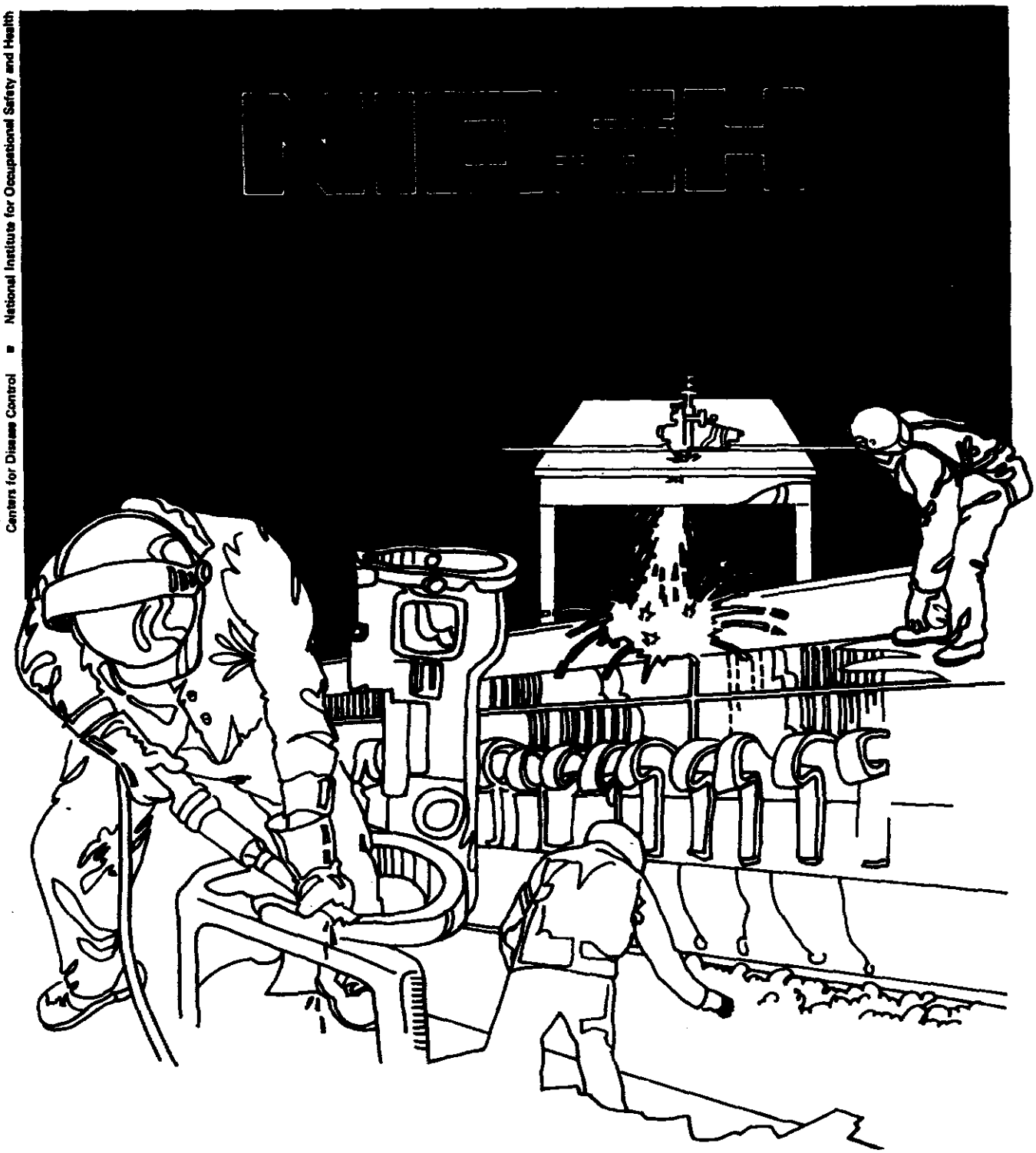
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

HETA 89-006-2002
WASHINGTON HOSPITAL
WASHINGTON, PENNSYLVANIA

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

HETA 89-006-2002
DECEMBER 1989
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I. SUMMARY

In October 1988, the National Institute for Occupational Safety and Health (NIOSH) received a request from the National Union of Hospital and Health Care Employees, AFL-CIO, District 1199P, to evaluate a potential health hazard from exposure to ethylene oxide (EtO) at Washington Hospital, Washington, Pennsylvania. In addition, NIOSH was asked to evaluate a perceived increase in the incidence of cancer among Central Supply Department employees. On February 27-March 1, 1989, an environmental and medical evaluation was conducted at the Washington Hospital Central Supply Department by NIOSH investigators.

Eight 8-hour and two short-term (during loading and unloading of EtO sterilized articles from the sterilizer) personal breathing zone (PBZ) air samples were collected and analyzed for EtO. The samples did not indicate any airborne exposure to EtO above the limit of quantitation [0.01 part per million (ppm)]. The Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) is 1.0 ppm as an 8-hour time-weighted average (TWA) and 5 ppm as a short-term exposure limit (STEL). NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.1 ppm as an 8-hour TWA, with a STEL not to exceed 5 ppm for a maximum of 10 minutes per day.

Five 8-hour general area air samples were collected at "worst case" locations (above the sterilizer door, adjacent to the gas cylinder valves, at a location where previously sterilized items had been placed, on the shelf across from the sterilizer, and above the EtO liquid-gas separator). All EtO concentrations, with the exceptions of the sample collected 6" above the EtO gas cylinder valve (1.63 ppm) and the sample collected directly above the EtO liquid-gas separator (0.011 ppm), were below the limit of detection (approximately 0.004 ppm). Ten short-term area air samples and direct EtO concentration readings using a Miran 103 were obtained during certain work practices (loading and unloading of the sterilizer) and operational cycles of the sterilizer (aeration, sterilization, and exhaust). All results were less than the limit of quantitation and below the detection limit of the instrument. The direct-reading instrument was also used to check for leaks around the sterilizer door and by the gas cylinder valves. Placing the air sampling probe as close to the valves as possible, EtO air concentrations of approximately 25 ppm were observed, indicating a small leak in the gas cylinder valves.

Interviews with employees and a review of employee health records did not identify evidence of job-related health effects in Central Supply Department employees. Because the identified cancer cases were of several different and relatively common types not known to be associated with EtO, it is unlikely that these cases were related to EtO exposure.

Based on the environmental data and medical evaluation, the NIOSH investigators found no evidence of a health hazard from ethylene oxide exposure in the Central Supply Department. Recommendations for further reducing potential exposures are presented in Section VIII of this report.

KEYWORDS: SIC 8062 (general medical and surgical hospitals), gas sterilization, ethylene oxide, central supply

II. INTRODUCTION

In October 1988, the National Institute for Occupational Safety and Health (NIOSH) received a request from the National Union of Hospital and Health Care Employees, AFL-CIO, District 1199P, to evaluate a potential health hazard from exposure to ethylene oxide (EtO) at Washington Hospital, Washington, Pennsylvania. In addition, NIOSH was asked to evaluate a perceived increase in the incidence of cancer among Central Supply Department employees. On February 27-March 1, 1989, an environmental and medical evaluation was conducted at the Washington Hospital Central Supply Department by two NIOSH industrial hygienists and a NIOSH physician.

III. BACKGROUND

EtO is used in Washington Hospital's Central Supply Department as a sterilant of heat- and/or moisture-sensitive hospital supplies and surgical instruments. The Central Supply Department is located in the basement wing constructed in the mid-1950's. There is a total of approximately 14 Central Supply Department employees on the day and evening shifts.

Both steam and gas (EtO) sterilization is performed. No formaldehyde sterilization processes are performed. There is one EtO sterilizer (Amsco, Model 2027, installed July 1986). This sterilizer is located in an area of the Central Supply Department surrounded by three walls. The sterilizer is recessed into a wall with the body protruding into an adjacent mechanical access area. In the mechanical access area there is a maintenance employee's desk within 6 feet of the EtO sterilizer body. Two EtO gas cylinders are located within the Central Supply Department sterilizer area.

The sterilizer area was ventilated by a dedicated exhaust system. The main exhaust duct was equipped with a swinging vane anemometer alarm. The exhaust air was exhausted directly outdoors to an area removed from air intakes. The sterilizer was equipped with local exhaust ventilation, specifically, a slot hood around the sterilizer door opening, by the liquid-gas separator, and over the pressure release valve.

To effect an EtO sterilization, the sterilizer was filled with the instruments and other materials to be sterilized, the door was closed, and the sterilizer cycle begun. The sterilizer had a 15-minute conditioning phase, followed by a 2-hour sterilization cycle, then a 12-hour aeration cycle. After the aeration cycle, the sterilizer would be opened and unloaded. If the sterilizer was not unloaded, a purge ventilation cycle would repeat approximately every hour so that any residual EtO left in the sterilized packages would be ventilated from the sterilizer. Maintenance employees were responsible for changing the EtO gas cylinders. They checked the EtO gas cylinder valves for leaks using a hydrocarbon detector at the time the cylinders were changed.

Periodic EtO air monitoring of employees' exposures in the Central Supply Department has been conducted by the hospital using passive dosimeters which meet the precision and accuracy requirements of the Occupational Safety and Health Administration (OSHA) standard. The hospital also used a direct-reading instrument for occasional leak detection testing for EtO.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

On February 28, 1989, NIOSH investigators conducted exposure and environmental air monitoring for EtO. Nine personal breathing zone (PBZ) and fifteen general area air samples were collected as detailed in Tables 1 and 2. The air samples were collected using battery-powered pumps operating at flow rates ranging from approximately 0.1-0.2 liters per minute. The pumps were attached via Tygon tubing to hydrogen bromide-treated charcoal tubes. The tubes were later analyzed by gas chromatography according to NIOSH Method 1607.[1]

Direct EtO concentration readings were obtained using a Miran 103 infrared analyzer during certain work practices (loading and unloading of the sterilizer) and operational cycles of the sterilizer (aeration, sterilization, and exhaust). The direct-reading instrument was also used to check for leaks around the sterilizer door and by the gas cylinder valves.

Smoke tubes were used to qualitatively evaluate the capture effectiveness of the slot exhaust hoods and to assess air movement between rooms and through doors and openings.

B. Medical

The NIOSH medical evaluation addressed three concerns: 1) the perception of excess cancer cases among present and former Central Supply Department employees, 2) the adequacy of the hospital's medical evaluation program, and 3) the current health status of the Central Supply Department employees. Data for this investigation were gathered via private interviews with Central Supply Department employees and review of hospital and employee health records. OSHA Form 200 logs for the calendar years 1985 - 1988 were also reviewed.

V. EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by the workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most

workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects even though their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker, to produce health effects even if the occupational exposures are controlled at the level set by the criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Recommended Exposure Limits (RELs), 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs), and 3) the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs). Often, the NIOSH RELs and ACGIH TLVs are lower than the corresponding OSHA PELs. Both NIOSH RELs and ACGIH TLVs usually are based on more recent information than are the OSHA PELs. The OSHA PELs also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH RELs, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits (STELs) or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

A. Evaluation Criteria for EtO

NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.1 part per million (ppm) determined as an 8-hour time-weighted average (TWA), with a short-term exposure limit not to exceed 5 ppm for a maximum of 10 minutes per day.[2,3] This recommendation is based on the available risk assessment data which show that even at an exposure level of 0.1 ppm, the risk of excess mortality is not completely eliminated.[4] The ACGIH TLV for EtO is 1.0 ppm as an

8-hour TWA and also considers EtO a suspect human carcinogen.[5] Effective August 21, 1984, the OSHA PEL was revised downward from 50 ppm to 1 ppm, calculated as an 8-hour TWA.[6] In March 1988, the OSHA PEL for EtO was revised, adding a short-term exposure limit (STEL) of 5 ppm.[7] Included in the OSHA standard are requirements for methods of controlling EtO, personal protective equipment, measurements of employee exposures, training, and medical surveillance of the exposed employees. The OSHA action level of 0.5 ppm is the level at which employees must initiate monitoring and medical surveillance.

B. Toxicological Effects of EtO

Inhalation of high concentrations of EtO for short exposure periods can produce a general anesthetic effect in addition to coughing, vomiting, and irritation of the eyes and respiratory passages. Early symptoms are irritation of the eyes, nose, and throat and a peculiar taste. Other health effects which may be delayed, are headache, nausea, vomiting, dyspnea (shortness of breath), cyanosis (blue pigmentation of the skin, due to inadequate oxygen supply to tissues), pulmonary edema (fluid in the lungs), drowsiness, weakness, incoordination, abnormalities of electrocardiograms arrhythmas, and urinary excretion of bile pigments (bilirubin).[8] Several dermatologic conditions can result from contact with liquid EtO. These include skin blistering, pigment color change, and frostbite.[8]

In both animals and humans, EtO exposure produces increased frequencies of sister chromatid exchanges and chromosomal aberrations.[9,10] EtO is a reproductive toxin in animals[9,10], and one study suggests such an effect in humans.[11] EtO is an animal carcinogen[9], and in humans, two epidemiological studies have associated an increase of hematologic, alimentary, and urogenital malignancies with EtO exposure.[12,13] EtO has also been shown to cause polyneuropathies and cataracts.[14,15,16]

The NIOSH REL is based on the conclusion that EtO is mutagenic and carcinogenic in animals and is also capable of causing adverse reproductive effects.[17]

VI. RESULTS

A. Environmental

The results of the PBZ samples are presented in Table 1. Eight 8-hour and two short term (during loading and unloading of EtO sterilized articles from the sterilizer) PBZ air samples were collected and analyzed for EtO. The samples did not indicate any airborne exposure to EtO above the limit of quantitation (0.01 ppm).

The results of the area air samples are presented in Table 2. Five 8-hour general area air samples were collected at "worst case" locations (above the sterilizer door, adjacent to the gas cylinder valves, at a location where previously sterilized items had been placed, on the shelf across from the sterilizer, and above the EtO liquid-gas separator). All EtO concentrations, with the exceptionsof the sample collected 6" above the EtO gas valve (1.63 ppm) and the sample collected directly above the EtO liquid-gas separator (0.011 ppm), were below the limit of detection (approximately 0.004 ppm). Ten short-term area air samples and direct EtO concentration readings using a Miran 103 were obtained during certain work practices (loading and unloading of the sterilizer) and operational cycles of the sterilizer (aeration, sterilization, and exhaust). All results were less than the limit of quantitation or below the detection limit of the instrument. The direct reading instrument was also used to check for leaks around the sterilizer door and by the gas tank valves. With the air sampling probe placed as close to the valves as possible, EtO air concentrations of approximately 25 ppm were observed.

Records provided by Washington Hospital indicated air monitoring for EtO concentrations as performed using a Wilks Miran 1A infrared spectrometer in August 1982, May-June 1983, and December 1984-January 1985. Results reported by the hospital ranged from none detected to 3.5 ppm EtO for 8-hour TWAs. Instantaneous peaks as high as 190 ppm were recorded. Activities being performed at the times these peaks occurred were not noted. In August 1986, PBZ 8-hour air samples were collected using 3M Diffusional Monitors. All results were less than 0.025 ppm.

B. Medical

Eight suspected cancer cases were reported among current and former employees of the Central Supply Department. Diagnoses were verified from records or personal interview for all of these eight cases. Of the five deceased individuals, two were victims of lung cancer (one squamous cell and one oatcell), with adenocarcinoma of the lung, cervical cancer, and polycythemia rubra vera (a disorder in which red blood cells are over-produced) accounting for the remaining deaths. Three individuals had been treated for adenocarcinoma of the breast and were all alive. There were no cases of leukemia, lymphoma or primary central nervous system malignancies, cancers that have been associated with EtO exposure. Duration of employment prior to diagnosis ranged from 1 1/2 to 10 years.

Medical records of Central Supply Department employees maintained by the hospital's Employee Health Clinic were reviewed. The hospital's policy requires an annual physical exam and includes a

basic hematology profile and liver function tests for employees working with EtO sterilizers. Those records reviewed documented adherence to this policy, which meets the OSHA medical surveillance requirement for workers exposed to EtO at levels greater than the current "action level".

In the personal interviews, no worker reported currently active health problems attributable to their work. All denied current neurologic symptoms. Four employees reported histories of dermatitis that they associated with the EtO sterilizers in place prior to the current unit. None reported a rash at the time of interview, but two reported minor difficulty with "dry skin", mainly on the hands. Many recalled strange tastes or odors prior to the current unit's installation in 1986, but none had such reported occurrences since then.

VII. DISCUSSION AND CONCLUSIONS

Based on the NIOSH EtO air exposure monitoring data and medical evaluation, the NIOSH investigators found no evidence of a present health hazard from exposure to EtO in the Central Supply Department.

Based on a review of the hospital's EtO monitoring data from 1982, 8-hour TWA concentrations of EtO have been reported above the current OSHA PEL but not above the OSHA PEL in effect at the time of the sampling. The most recent data (August 1986) collected by the hospital for 8-hour TWA concentrations of EtO are within both the current OSHA PEL and NIOSH REL.

Overall, the investigation did not identify evidence of job-related health effects in Central Supply Department employees. The hospital's medical surveillance program meets the OSHA requirement for workers exposed to EtO.

The subject of cancers related to occupational exposures is important and deserves discussion. Any case of cancer is, of course, a major event to those affected and their families, friends, and coworkers. When there is a concern that cases of cancer may be related to a worksite, it is important to address this concern in a careful and well-reasoned manner.

Several factors affect our evaluation of a possible cluster of cancer cases. One of these is whether or not there actually is a true excess of cases over and above that which one would expect to see in a similar population. For example, three of the cancer diagnoses were for cancer of the breast. The American Cancer Society estimates that about 1 in 10 women will develop breast cancer at some time in life.[18] Together, breast, lung and colo-rectal cancer accounted for approximately 54% of new cases and 52% of cancer deaths in women for 1989.[17]

Other factors of importance relate to biological plausibility. EtO has been associated with leukemia in humans, and there are also concerns about stomach and central nervous system tumors.[9] To date, EtO has not been associated with breast, lung or colon cancer.

Latency, the time between exposure to a carcinogen and the subsequent development of cancer, is commonly thought to range from five to 15 years. Duration of employment prior to diagnosis varied in this group. Since this group of cases was also small, considering latency is not helpful in this investigation.

In summary, because the identified cancers were of several different and relatively common types not known to be associated with EtO, it is unlikely that these cases were related to EtO exposure but rather reflect the distribution of cancers in the population at large.

It must be emphasized, however, that EtO is a carcinogen and that, regardless of the results of the medical examination, minimizing exposure is essential. Though the cancer cases identified do not indicate a need for heightened concern, it is appropriate to be concerned about and careful with EtO.

VIII. RECOMMENDATIONS

1. Washington Hospital should continue efforts to reduce EtO levels to the lowest feasible levels.

2. The hospital should review their current standard operating procedures (SOPs) and incorporate the following recommendations:

   * After cracking the sterilizer door open, the employee should wait for 15 minutes before unloading.

   * The fan on the sterilizer unit should be kept on throughout the unloading operation so the flow of air is into the sterilizer.

   * Work practices should be incorporated to keep the operator away from the EtO diffusing from the sterilized items. These practices include 1) using a metal rod with a hook at one end and a handle at the other to pull the rack of sterilized items from the sterilizer, and 2) pulling rather than pushing the cart onto which the sterilized items have just been placed.

   * Gloves which may contain residual EtO should be placed in the sterilizer, with the fan operating to prevent EtO from diffusing into the room.

   * The integrity of seals around the EtO sterilizer doors should be checked on a regular basis. Policies and procedures should be written (and enforced) for a scheduled preventive maintenance program of the EtO sterilizer and the local exhaust ventilation system.

3. Personnel working with the EtO sterilizer should be retrained or tested periodically to ensure that they understand and follow proper procedures for routine operation of the sterilizers and for emergency situations.

4. The EtO gas valves should be routinely checked for leaks with an instrument such as an infrared analyzer capable of detecting minor leaks. The hydrocarbon detector used for this purpose at Washington Hospital was not capable of detecting the gas valve leak found during this survey.

5. The EtO sterilization process should be isolated. The mechanical access room should be enclosed and under negative pressure. The gas cylinders should be placed in this room, and local exhaust ventilation should be used near the cylinder valves. The maintenance employee's desk that was near the EtO sterilizer body should be moved to another area.

6. The local exhaust ventilation slot hood above the door of the EtO sterilizer should be repaired. A small gap in the plastic was observed.

7. A monitoring program for airborne EtO should be instituted on a routine basis and when there are system modifications (e.g., changes in the ventilation system, new equipment, or the remodeling of the sterilizer area). This should include 8-hour area and personal air samples, as well as short-term samples collected during certain work practices and sterilizer operational cycles.

8. Current medical surveillance should be maintained.

IX. REFERENCES

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XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are temporarily available upon request from NIOSH, Hazard Evaluations and Technical Assistance Branch, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22162. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. National Union of Hospital and Health Care Employees, APL-CIO, District 1199P
2. Washington Hospital
3. U.S. Department of Labor, OSHA-Region III

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

Table 1

Personal Breathing Zone Air Concentrations of Ethylene Oxide
Washington Hospital
Central Supply Department
Washington, Pennsylvania
HETA 89-006

February 28, 1989

Job Description	Sampling Period	Sampling Volume (L)	Concentration (ppm)
Decontamination	0629-1509	50.8	ND
Orders	0632-1510	51.4	ND
Gas autoclave operator	0635-1508	35.6	ND
Floater	0637-1506	49.0	ND
Linen inspector	0640-1511	51.7	ND
Linen packer	b		
Orders and floater	1306-1939	75.4	trace[a]
Gas autoclave operator	1513-1940	54.3	trace[a]
Transfer of articles from sterilzer	0846-0855	1.3	ND
Loading and starting sterilizer	1611-1615	0.4	ND

Evaluation Criteria:

Occupational Safety and Health Administration (OSHA)	
8-hour time weighted average (TWA)	1.0
Short-term exposure limit	5.0
National Institute for Occupational Safety and Health (NIOSH)	
8-hour TWA	<1.0 Ca
Ceiling (10-minute)	5.0
American Conference of Governmental Industrial Hygienists (ACGIH)	
8-hour TWA	1.0 Ca

a = Value between limit of detection (0.4 microgram/sample) and limit of quantification (1.0 microgram/sample)
b = Due to difficulties with the sampling pump, sample results for this individual are not considered reliable and are therefore not reported.
L = liters
ppm = parts of contaminant per million parts of air sampled
ND = None detected
Ca = NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.1 ppm. ACGIH considers EtO a suspect human carcinogen.

Table 2

Area Air Concentrations of Ethylene Oxide
Washington Hospital
Central Supply Department
Washington, Pennsylvania
HETA 89-006

February 28, 1989

Location	Sampling Period	Sampling Volume (L)	Concentration (ppm)
On shelf where EtO sterilized items are stored	0644-1535	55.9	ND
6" above EtO gas tank valves	0645-1539	51.2	1.63
6" above ETO sterilizer door			
All day sample	0647-1537	53.3	ND
During transfer of items	0846-0902	2.88	ND
During loading of items	1611-1615	0.78	ND
During condition/sterilizing	1632-1853	27.1	ND
During exhaust cycle	1914-1933	4.60	trace[a]
On shelf across from EtO sterilize			
All day sample	0649-1535	52.3	ND
During transfer of items	0846-0903	2.84	ND
During exhaust cycle	1914-1933	2.28	ND
Linen fold and inspect area			
During transfer of items	0846-0904	2.98	ND
Mechanical access area			
During aeration	0652-0735	20.7	ND
During aeration/unload	0736-1523	78.8	0.011
Begining of loading, until exhaust	1524-1856	41.4	ND
During exhaust	1914-1933	4.60	ND

Evaluation Criteria:		
Occupational Safety and Health Administration (OSHA)		
8-hour time weighted average (TWA)	1.0	
Short-term exposure limit	5.0	
National Institute for Occupational Safety and Health (NIOSH)		
8-hour TWA	<1.0	Ca
Ceiling (10-minute)	5.0	
American Conference of Governmental Industrial Hygienists (ACGIH)		
8-hour TWA	1.0	Ca

a = Value between limit of detection (0.4 microgram/sample) and limit of quantification (1.0 microgram/sample)
L = liters
ppm = parts of contaminant per million parts of air sampled
ND = None detected
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