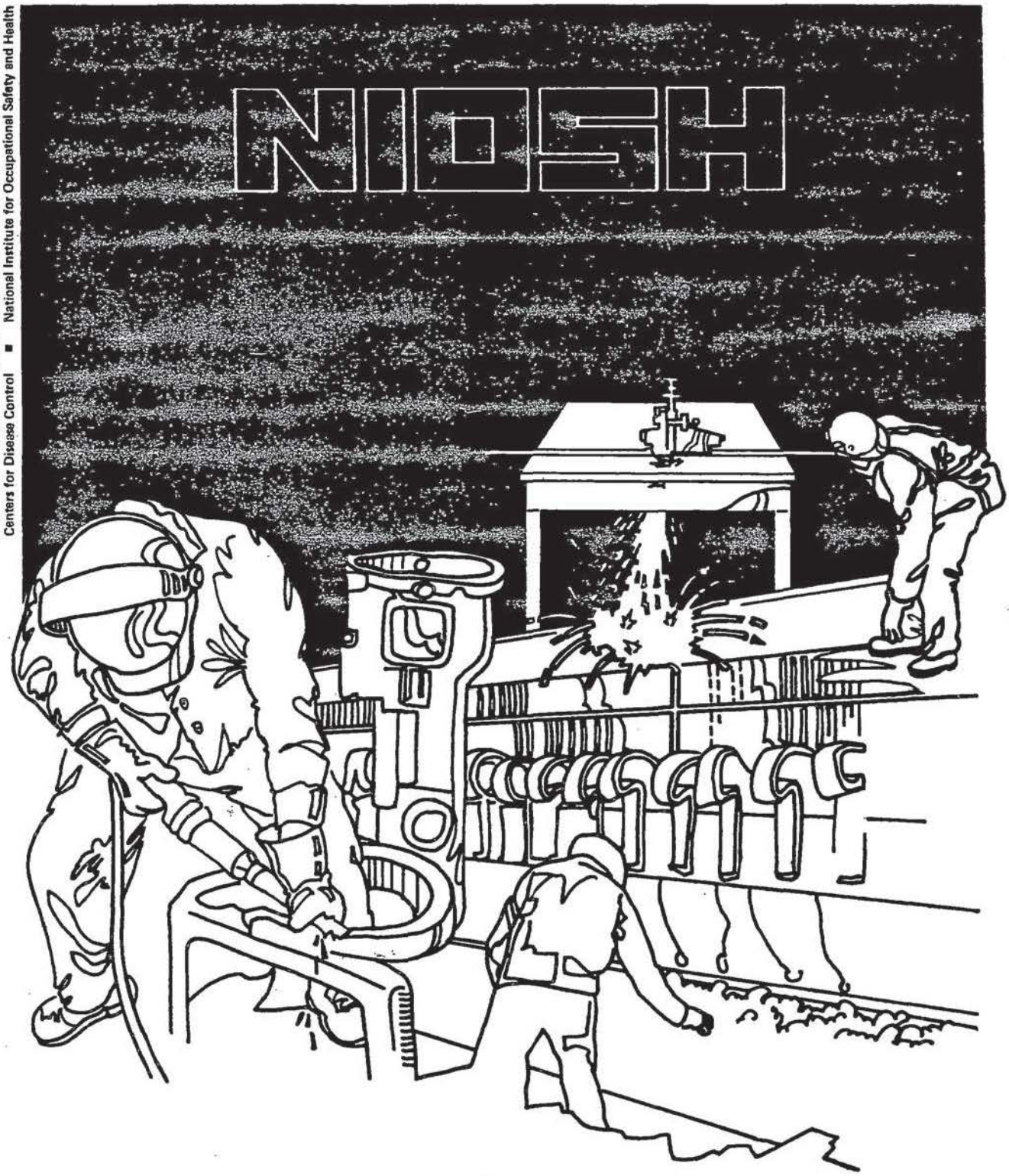
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

HETA 81-350-932
ELLIS HOSPITAL
SCHENECTADY, NEW YORK

HETA 81-350-932
August 1981
Ellis Hospital
Schenectady, New York

NIOSH Investigator:
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I. SUMMARY

In June, 1981, the National Institute for Occupational Safety and Health (NIOSH) conducted an evaluation of potential health hazards associated with the use of ethylene oxide (EtO) in the sterilization of medical equipment and supplies at Ellis Hospital, Schenectady, New York. The only source of ethylene oxide at this facility was the gas sterilizer and its supply cylinders.

Environmental measurements were made to determine potential exposures of hospital personnel to ethylene oxide. A total of eight solid sorbent (JCX charcoal) samples, ranging in duration from twelve minutes to two hours, were taken to determine the exposure of the six employees who spend a portion of their work day in this area, as well as the concentration of ethylene oxide at various locations in the work area. Concentrations ranged from below the limit of detection (0.5 parts per million) to 7 parts per million (ppm). The only personal sample was a short-duration (13 minute) measurement taken on the person who opens the sterilizer. This operation, which appeared to involve maximum exposure, yielded a result of 4 ppm for the employee and 7 ppm in the immediate area.

NIOSH has shown in this evaluation that exposures to ethylene oxide are below the OSHA permissible exposure level of 50 ppm. However, since recent evidence indicates that ethylene oxide may be carcinogenic, NIOSH recommends that employers take all reasonable steps to reduce exposures to the extent possible. This level would appear to be below one part per million. Recommendations have been made in Section V of this report to achieve this goal.

KEYWORDS: SIC 8062 (Hospital), Ethylene oxide, Sterilizer

II. INTRODUCTION AND BACKGROUND

On June 4, 1981, NIOSH received a request from the management of Ellis Hospital to determine if there was a health hazard associated with the use of ethylene oxide (EtO) in the sterilizaition of material as done in the hospital's Central Services area. On June 9, an on-site investigation was made. The operation of interest involved moving a wheeled cart of medical material into the sterilizer which is pressurized to approximately 10 pounds per square inch with a mixture of 12% ethylene oxide and 88% Freon piped from cylinders in a nearby storage room. The chamber is heated to 180 to 200°F, and held at those conditions for a minimum of six hours. At the end of the allotted time, the sterilizer chamber is evacuated to the rooftop and a vacuum is created. The vacuum is relieved, the chamber door is opened slightly, and after a few minutes the cart is wheeled approximately 15 feet into an aeration chamber where it is allowed to degas for several hours. The aerator is also vented to the rooftop. Only one person is required intermittently to operate the sterilizer, although from two to six employees are in the area periodically to perform other functions as their duties require.

III. EVALUATION METHODS AND CRITERIA

Environmental measurements were made to determine atmospheric concentrations of EtO during a sterilizer run of approximately two hours duration. These measurements were taken at various points around the sterilizer chamber in both the sterile room and the decontamination room. A sample was also taken in the cylinder storage room. In addition to the full duration measurements, short term samples were taken during the opening of the sterilizer and during transfer of the cart to the aerator, since those operations appeared to involve maximum potential exposure. These samples were obtained using battery powered sampling pumps to draw air through JCX charcoal sorbent tubes. Grab samples were obtained at various points and times throughout the procedure using length-of-stain detector tubes. Ventilation measurements and other observations were made during the procedure.

The effects of overexposure to EtO include eye, skin, and respiratory irritation, vomiting, diarrhea, anemia and altered behavior. In 1977, NIOSH(1) recommended a 15 minute ceiling value of 75 ppm and a time weighted average of 50 ppm to avoid these effects. These values are the current OSHA standards. Additional information since that time suggests the possibliity of carcinogenic effects. On May 22, 1981, NIOSH revised its recommendation and urged employers "as prudent public health policy...to voluntarily assess the conditions under which their workers may be exposed to EtO and take all reasonable steps to reduce exposure to the extent possible." (2)

IV. RESULTS AND DISCUSSION

Tables 1 and 2 of this report show the results of the environmental samples collected on sorbent tubes and by direct measurement, respectively. No EtO was detected in the decontamination room. (The limit of detection was 0.5 ppm.) A two hour sample in the cylinder storage room indicated a concentration of 5 ppm between the two cylinders of EtO. A small leak in the line from the cylinders to the sterilizer was detected in this area by an observation of bubbles formed at a fitting. A direct reading of EtO concentration at 10:10 AM indicated 500 ppm at that time near the leak. There is, however, local exhaust ventilation in this area to remove EtO in the event of such an occurrence, and employees normally do not spend any time in this storage closet.

Measurements made in the sterile room near the sterilizer showed a concentration of 2 to 3 ppm over the two hour run. Concentrations of 4 and 7 ppm were measured during the opening of the sterilizer and subsequent transfer of the cart to the aerator, a process which took approximately 12 minutes. Direct measurement near the sterilizer door during the run, and in the general area between the sterilizer and aeriator during transfer, indicated no detectable levels of EtO by this method. (The limit of detection for the direct reading method is approximately 25 ppm.) A direct measurement of 75 ppm was made at the face of the sterilizer as its seal was cracked to effect opening.

Measurement of air flow at the ventilation ducts above the EtO cylinders indicated a face velocity greater than 800 fpm (feet per minute) at both of the 3 inch branches, although air velocity at the control valve was less than 50 fpm.

The environmental measurements made in this evaluation indicate personal exposure to EtO to be below levels which have been shown to cause acute and chronic effects. Since the potential for carcinogenicity is suggested, prudent judgement would dictate, however, the reduction of personal exposures to the lowest possible level.

V. RECOMMENDATIONS

In order to minimize the personal exposures of hospital employees to even small amounts of EtO, logical administrative and procedural steps should be considered. A minimum number of employees should be located in the sterile room during the operation of the sterilizer. Those who are in that area would be best located at points not near the chamber. The employee who opens the sterilizer and transfers the cart to the aeriator should not linger in this area. Fittings in the gas supply line should be leak tested, and every time cylinders are changed or other alterations made the appropriate fittings should be rechecked for leaks. The addition of a flair or flange on both exhaust ducts above the gas cylinder would increase the efficiency of this system.

VI. AUTHORSHIP AND ACKNOWLEDGEMENTS

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VII. DISTRIBUTION AND AVAILABILITY

Copies of this Determination Report are currently available upon request from NIOSH, Division of Technical Services, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from the NIOSH Publications Office at the Cincinnati address.

Copies of this report have been sent to:

1. Ellis Hospital, Schenectady, New York
2. NIOSH, Region II
3. OSHA, Region II

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

VIII. REFERENCES

(1) Special Occupational Hazard Review with Control Recommendations for the Use of Ethylene Oxide as a Sterilizer in Medical Facilities, U. S. Dept. of Health, Education and Welfare, Public Health Service, CDC, NIOSH, Pub. No. 77-200, August, 1977

(2) Current Intellegence Bulletin 35, Ethylene Oxide (EtO), Dept. of Health and Human Services, Public Health Service, CDC, NIOSH, Pub. No. 81-130, May 22, 1981

TABLE I

SOLID SORBENT ETHYLENE OXIDE MEASUREMENTS

Ellis Hospital
Schenectady, New York
HETA 81-350

June 9, 1981

LOCATION	DURATION	CONCENTRATION
Sterile Room, on table 5 ft. in front of sterilizer	9:57 - 11:57	2 ppm
Sterile Room, left side of sterilizer door	9:57 - 11:57	3 ppm
Cylinder Room, between cylinder valves	9:55 - 11:55	5 ppm
Sterile Room, on table near aerator during unloading and transfer to aerator	11:41 - 11:53	7 ppm
Decontamination Room, near seal on left side of sterilizer door	10:00 - 11:55	N.D.*
Decontamination Room, right side of sterilizer door	10:00 - 11:55	N.D.
Sterile Room, breathing zone level near table approx. 7 feet from sterilizer	9:59 - 11:57	2 ppm
Personal breathing zone sample on employee unloading sterilizer and transferring load to aerator	11:39 - 11:52	4 ppm

*None Detected, Limit of Detection 0.5 ppm

TABLE II

DIRECT READING ETHYLENE OXIDE MEASUREMENTS

Ellis Hospital
Schenectady, New York
HETA 81-350

June 9, 1981

LOCATION	TIME	RESULT
Cylinder Room - at connection to right solenoid value	10:10	500 ppm (bubbles seen at connection)
Sterile Room - left side of sterilizer door	10:40	N.D.*
Sterile Room - right side of sterilizer door	10:45	N.D.
Sterile Room - at face of sterilizer immediately upon opening	11:45	75 ppm
Sterile Room - general area between sterilizer and aerator during transfer of cart	11:50	N.D.

*None Detected, Limit of Detection 25 ppm