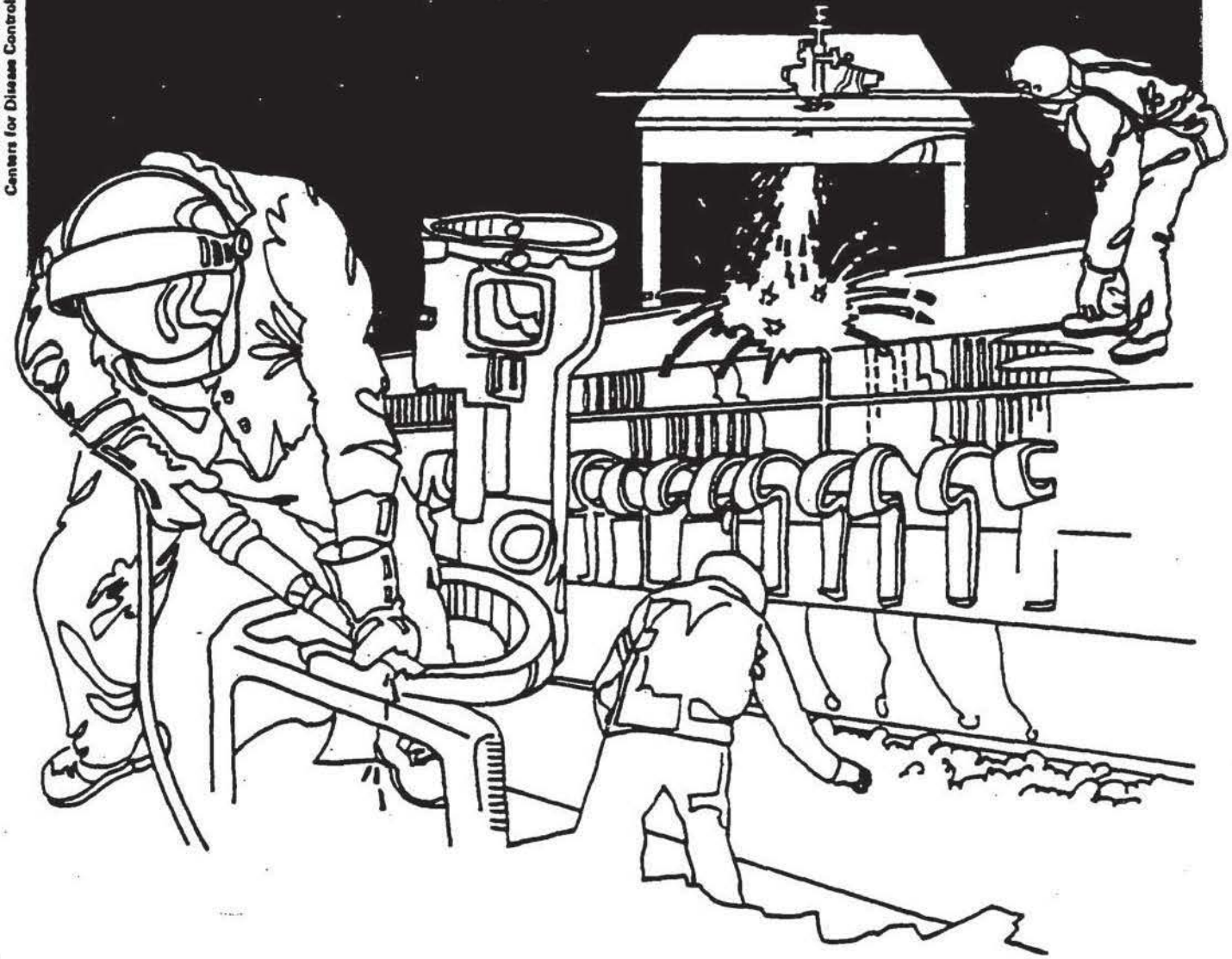
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health

NIOSH



Health Hazard Evaluation Report

HETA 84-174-1490
DENVER GENERAL HOSPITAL
DENVER, COLORADO

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.

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DENVER GENERAL HOSPITAL
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I. SUMMARY

In February, 1984, the National Institute of Occupational Safety and Health (NIOSH) received a request to evaluate occupational exposures to ethylene oxide in the central supply department at Denver General Hospital, Denver, Colorado. Ethylene Oxide is used for sterilization of many of the items used throughout the hospital.

On May 7, 1984, NIOSH performed an environmental investigation in the central supply department of Denver General Hospital. This evaluation included personal breathing zone and general room air sampling for ethylene oxide. Informal medical interviews were conducted with three technicians and two supervisors.

A total of ten air samples were taken, six on workers and four general area samples in the work area. Only two of the ten air samples had measurable levels of ethylene oxide. A breathing zone concentration of 0.09 mg/M^3 was found on the technician who unloads the sterilizer. A concentration of 0.02 mg/m^3 was found on the general room sample collected on top of the ethylene oxide sterilizer. The other eight samples were less than the laboratory limits of detection of approximately 0.01 mg/m^3. The current OSHA standard is 90 mg/m^3 while NIOSH recommends that ethylene oxide be maintained at the lowest feasible level due to the potential carcinogenicity of ethylene oxide. Good work practices of all the technicians were responsible for the low levels of ethylene oxide in the work environment. The local exhaust ventilation must be maintained in order to insure consistent low level exposure.

The five employees who were interviewed reported no medical problems.

On the basis of the environmental data and personal interviews, NIOSH concluded that no health hazard existed from exposures to ethylene oxide at Denver General Hospital. Recommendations on maintaining this level of compliance are included in this report.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals) ethylene oxide, gas sterilization)

II. INTRODUCTION

In February 1984, the National Institute for Occupational Safety and Health (NIOSH) received a request from management of the central supply department of Denver General Hospital, Denver, Colorado, to evaluate a potential health hazard from exposures to ethylene Oxide (EtO) used for the sterilization of various types of instruments and materials used throughout the hospital.

On May 7 and 8 1984, NIOSH conducted an environmental evaluation. Results of the environmental sampling were discussed with the person in charge of the EtO sterilizer on June 15, 1984.

III. BACKGROUND

Denver General Hospital has only one ethylene oxide sterilizer in the central supply department. This sterilizer is relatively new and in excellent working order. Accompanying the sterilizer is a matching aerator which is used for aerating all items immediately following the sterilization and purge cycles of the sterilizer. Both the sterilizer and the aerator are used daily.

IV. ENVIRONMENTAL DESIGN AND METHODS

Ten air samples were collected for ethylene oxide by drawing air through two charcoal tubes in series held together with flexible tubing. Samples were taken on two consecutive days under a hot sterilization procedure the first day and a cold sterilization procedure the next day. Samples were collected on all employees in central supply working around EtO. General room air samples were also collected in all areas where a possibility of EtO contamination existed. The EtO was analyzed by gas chromatography according to NIOSH Method #1607.

V. EVALUATION CRITERIA

A. Environmental

As a guide to the evaluation of the hazards posed by 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 important to note, however, that not all workers will be protected from adverse health effects if 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 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 evaluation 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.

Two sources of criteria used to assess the workroom concentrations of the chemicals were: (1) the NIOSH criteria for a recommended standard, and (2) the Occupational Safety and Health Administration (OSHA) standards (29 CFR 1910.1000), July 1980. NIOSH recommendations are lower than the corresponding OSHA standards and are usually based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended standards, by contrast, are based solely 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 only 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 or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

	Permissible Exposure Limits 8-Hour Time-Weighted Exposure Basis
Ethylene Oxide	Lowest feasible level NIOSH
	90 mg/m^3 OSHA
	*2 mg/m^3 OSHA

mg/m^3=approximate milligrams of substance per cubic meter of air.
*1984 OSHA Standard which has not gone into effect

B. Toxicology

Ethylene oxide (EtO) is known to be a mutagen in many animal tests. It has been implicated in the development of leukemia and is suspected to be a human carcinogen. There have been reports that exposure to EtO may cause an increase in cataract formation[1]. Based on NIOSH studies and consistent findings of others, evidence supports the conclusion that EtO is a mutagenic, carcinogen, and is capable of causing adverse reproductive effects.[2]

No safe level of exposure to a carcinogen has been demonstrated for

humans. The possibility of developing cancer will be reduced by decreasing exposure. NIOSH has concluded that exposure to EtO should be reduced to the lowest possible level. NIOSH also recommends a ceiling limit of 5 ppm (9mg/m^3) for not more than 10 minutes in any 8 hour work period. An 8 hour exposure limit should be lower than .2 mg/m^3 (NIOSH).

VI. ENVIRONMENTAL RESULTS

On May 7 and 8, 1984, NIOSH conducted an environmental investigation. Six breathing zone and four general room air samples for measurement of EtO were collected. Sampling times were approximately 5 1/2 hours for all samples. This included the entire time that the employees were working with the sterilizer and aerator. Only two of the ten samples exceeded the laboratory limit of detection of 0.01 mg/m^3. These two samples showed 0.09 mg/m^3 on the general room sample taken on top of the aerator and 0.02 taken in the breathing zone of the technician who loads and unloads the sterilizer. Refer to table 1 for concentrations and locations of samples taken during this evaluation.

All three of the employees working with EtO during this survey were interviewed. None of them had work related health problems.

VII. DISCUSSION AND CONCLUSIONS

Based on the environmental results, no health hazard existed during this survey. This ethylene oxide sterilization system was operated carefully and according to written procedures. Adequate local exhaust ventilation was in operation..

VIII. RECOMMENDATIONS

1. Only qualified individuals who have been trained accordingly should be allowed to use the EtO chamber.

2. All new personnel should be briefed on the toxicology of EtO.

3. Ventilation of the ethylene oxide sterilizer, door gaskets and operating procedures should all be reviewed once a month.

IX. REFERENCES

1. Jay, M.D., Walter M.; Thomas R. Swift, M.D.; David S. Hull, M.D.; Possible Relationship of Ethylene Oxide Exposure to Cataract Formation., American Journal of Ophthalmology, 93:727-732, 1982.

2. NIOSH Current Intelligence Bulletin #35, Ethylene Oxide, May, 1981.

X. AUTHORSHIP AND ACKNOWLEDGMENTS

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XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, 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 NIOSH, Publications Office, at the Cincinnati address.

Copies of this report have been sent to:

1. Denver General Hospital.
2. Colorado State Department of Health
3. U.S. Department of Labor/OSHA - Region VIII
4. NIOSH - Region VIII.

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

Table I

Breathing Zone and General Room Air Concentrations
of Ethylene Oxide (EtO)

Denver General Hospital Central Supply
May 7-8, 1984

Sample #	Date	Sample Location	Type of Sample	Sampling Time	mg/m^3 EtO
1	5/7/84	Central Supply	Personnel	8:55-12:25	*
2	5/7/84	Central Supply	Personnel	9:00-12:30	*
3	5/7/84	Central Supply	Personnel	9:07-12:25	*
4	5/7/84	Central Supply	Area	9:10-12:25	*
5	5/7/84	Central Supply	Area	9:20-12:25	0.09
6	5/8/84	Central Supply	Personnel	8:58- 2:50	0.02
7	5/8/84	Central Supply	Personnel	9:00- 2:50	*
8	5/8/84	Central Supply	Personnel	9:10- 2:50	*
9	5/8/84	Central Supply	Personnel	9:12- 2:50	*
10	5/8/84	Central Supply	Personnel	9:15- 2:50	*

Evaluation Criteria *LFL

Laboratory Limit of Detection 0.01 mg/m^3

*Ethylene Oxide is considered a carcinogen and worker exposure should be reduced to the lowest feasible level.