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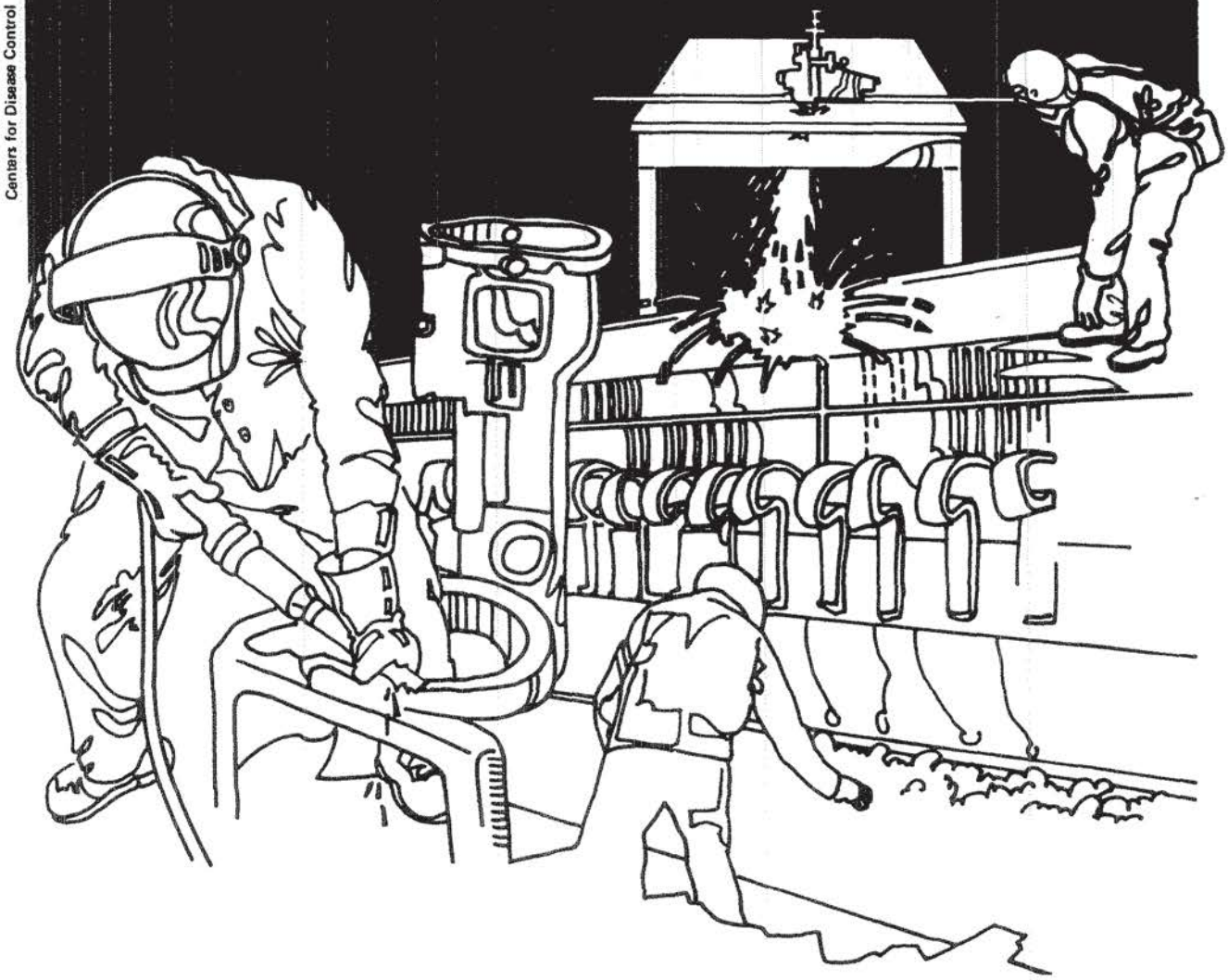

Health Hazard Evaluation Report

HETA 83-217-1425
MEDICAL COLLEGE OF PENNSYLVANIA
PHILADELPHIA, 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 83-217-1425
February 1984
MEDICAL COLLEGE OF PENNSYLVANIA
PHILADELPHIA, PENNSYLVANIA

NIOSH INVESTIGATORS:
Frank A. Lewis, I.H.
Gib Parrish, M.D.

1. Summary

On March 30, 1983, the National Union of Hospital and Health Care Employees requested a health hazard evaluation at the respiratory therapy section (RTS) of the Hospital of Medical College of Pennsylvania (MCP) to evaluate the possibility of an abnormal number of spontaneous abortions, ectopic pregnancies, and menstrual irregularities in this department. Concern centered around an exposure to ethylene oxide (EtO) which is used in a gas sterilizer located in the respiratory therapy section.

On April 4, 1983, a NIOSH industrial hygienist conducted a preliminary walk-through of the RTS. Previous air sampling data for EtO (conducted by Honeywell and ECRI, Inc.) work procedures and precautions were reviewed. The NIOSH industrial hygienist returned on June 13, 1983 to evaluate the EtO exposures of three respiratory therapists/technicians via personal air monitoring. The results of these air samples showed no EtO detected in the breathing zone of these workers (limit of detection = 0.26 ppm).

To assess the health complaints, a NIOSH medical officer conducted a site visit at MCP on May 23-25, 1983. The NIOSH investigator interviewed all 14 female employees present during the three days of the visit and one employee, not present, by phone. Reproductive histories showed that one of the 15 women had experienced three spontaneous abortions during the time that she worked at the RTS. However, it was not possible to determine whether these were associated with exposure at work. None of the other women experienced any adverse reproductive outcome that might be associated with work in the RTS.

Based on these results, NIOSH could not attribute any spontaneous abortions, ectopic pregnancies or menstrual irregularities to ethylene oxide exposure at the RTS of MCP. Recent engineering controls instituted in the RTS have improved the ventilation in the area and should reduce EtO exposures. Several additional engineering improvements are included in the recommendation section of this report.

KEYWORDS: SIC (8062) Hospital workers, respiratory therapists, EtO, reproductive health effects, miscarriages, spontaneous abortions.

II. Introduction

On March 30, 1983, the National Union of Hospital and Health Care Employees requested a NIOSH health hazard evaluation to evaluate the possibility of an abnormal number of spontaneous abortions, ectopic pregnancies, and menstrual irregularities among employees of the respiratory therapy section (RTS) of the Hospital of the Medical College of Pennsylvania (MCP). Concern centered around an exposure to ethylene oxide (ETO), which is used in a gas sterilizer located in the respiratory therapy section.

III. Background

The MCP Hospital is situated in northwest Philadelphia and is a teaching hospital of the MCP. The RTS of the hospital is on the third floor and occupies approximately five rooms. These include a room for pulmonary function testing and blood gas analysis, a room for EtO sterilization of equipment, an equipment storage room, an office for the supervisor, a small area for eating and lounging for the RTS and an office area utilized by the head of respiratory therapy and other pulmonary physicians, as well as their office support personnel. The RTS provides the usual respiratory care services to the hospital, including ventilator support, pulmonary toilet, blood gas analysis, pulmonary function testing, and several other miscellaneous functions.

The RTS currently employs 35 individuals. Of these, 32 work directly with the RT equipment and/or perform RT functions mentioned above.

The sterilization process involves the complete destruction of all bacteria and other infectious organisms on plastic respirator parts, resuscitation bags and cascades through the use of a sterilant gas - ethylene oxide (EtO). The "contaminated" parts are dismantled, scrubbed/washed in hot soapy water and rinsed in clean water. The dried parts are then placed in sterilizer bags, sealed and taped with a bio-indicator (turns from green to red to indicate sterilized) and then loaded into a metal bin. The bin is placed in the sterilizer for two (2) hours at 137^{o}F and is then purged for 15 minutes. The sterilized bagged parts are then placed in an aerator for eight (8) hours to dissipate any EtO on/in the bag and parts.

The ethylene oxide sterilizer takes approximately two to three hours to process a load; and an aerator, which must be used to aerate the sterilized equipment, takes eight hours. Therefore, only three loads of equipment can be sterilized per 24-hour period. Until March 11, 1983, the sterilizer room was separated from the RT lounge area by a plexiglas partition approximately 5.5 feet high which did not extend to the ceiling. On March 11, a wall was built to replace the plexiglas partition. The wall extends from floor to ceiling, and a sliding wood door was placed over the exit to the sterilizer room. In addition, the EtO sterilizer was not vented to the outside until this spring. Due to the physical proximity of the sterilizer to the lounge area, employees became concerned about possible EtO exposure.

At the time of the NIOSH survey, the sterilizer gas (EtO) was vented to the roof by an internal exhaust fan during the purge cycle; and a window exhaust fan was used on during the aeration of the parts.

Previous air monitoring (done by Honeywell in 1982/83 and ECRI, Inc. in 1981) was accomplished using direct-reading instruments ("EtO Sniffers"). However, all readings were taken around the sterilizer door gasket for leak testing. These EtO readings showed concentrations of greater than 250 ppm at the gasket. New gaskets were installed after each leak discovery. No personal air monitoring (in the breathing zone) was ever conducted for EtO exposures.

IV. Evaluation Design and Methods

A. Environmental

Three personal air samples were taken to evaluate EtO exposures over the eight-hour workday. The EtO was collected on charcoal tubes at a rate of 200 cc per minute using portable sampling pumps. The analyte was desorbed from the charcoal with carbon disulfide and the sample separated and analyzed using a gas chromatograph with a flame ionization detector (NIOSH Method S-286). The limit of detection was 0.04 milligrams/sample for EtO.

B. Medical

A list of all current employees in the RTS was obtained from the hospital administration. The list included 35 current employees, 32 of whom deal with respiratory therapy equipment or activities. Of these 32, 19 are female. Fourteen of the 19 females were interviewed during the site visit, and one female was interviewed by phone subsequently. One of the current female employees away from work due to illness in her family. The three other females who were not interviewed were not at work during the period of time that the medical officer was present at the respiratory therapy section. The NIOSH medical officer administered the standard NIOSH reproductive questionnaire to the 15 female RTS employees. In addition, the medical officer interviewed the male worker who does most of the EtO sterilization.

V. Evaluation Criteria

A. Environmental Criteria

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 however, important to note 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 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 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.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygiensts' (ACGIH) Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are 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 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 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.

EtO:

The effects of acute exposure to EtO in humans and animals include skin, respiratory and eye irritation; skin sensitization; nausea, diarrhea, and vomiting; and nervous system effects. Nonmalignant chronic effects in humans include anemia and respiratory irritation, with susceptibility to secondary respiratory infection [1,2]. Recently, cases of peripheral neuropathy among workers have been reported [3]. In addition to these acute and chronic effects, an increased leukemia rate in female rats and an increased rate of peritoneal mesotheliomas originating in the testicular mesothelium of male rats have been reported [2]. EtO is also a known mutagen in lower biological species and mammals [2].

Recent experiments in mammals have demonstrated adverse reproductive effects[4]. Among these adverse reproductive effects was a significant reduction in the number of pups born per litter in a group of rats exposed to various levels of EtO for six hours a day for 12 weeks prior to mating.

An additonal potential for transplacental EtO toxicity has been reported [5]. The observed effect was a significant reduction in mean fetal body weight compared to controls and a significant increase in the percentage of malformed fetuses per litter from female rats administered at the high dose level during the second and fourth gestational periods. The malformations were seen principally in the cervical and thoracic regions of the skeleton. Finally a recent retrospective mailed questionnaire study, which included all of the sterilizing staff employees in Finnish hospitals in 1980, showed an increased frequency of spontaneous abortion for the sterilizing staff when workers were exposed during their pregnancy to sterilizing procedures using EtO, as compared to the pregnancies which occurred during non-exposed periods of time [6]. The authors suggested that an increased frequency of spontaneous abortion correlated with EtO exposure. However a Letter to the Editor[7] of the British Medical Journal by NIOSH researchers and a recent review of this article [10] point out several methodological problems with this study and cast some doubt on the conclusions reached.

Spontaneous abortion (miscarriage) is a relatively common pregnancy outcome. Most of these spontaneous abortions occur during the first trimester [8].

Approximately 15-20% of all pregnancies result in a spontaneous abortion [9] for a variety of reasons, including defective uterine environment; chromosomal aberrations; external chemical, viral or radiation exposures; and acute infections. Trauma plays a minor role in the production of abortion. It is also possible that a male factor, perhaps a defective sperm, may account for some spontaneous abortions, although proof is currently lacking [8].

OSHA's standard for occupational exposure to EtO is 50 ppm (90 mg/m^3) as a time-weighted average (TWA) concentration for an eight-hour work shift. Studies of carcinogenicity were not available when this standard was developed.

In its 1977 review of EtO, NIOSH recommended that occupational exposure be limited to a ceiling concentration of 75 ppm (135 mg/m^3), determined during a 15-minute sampling period. Additionally, NIOSH recommended that the OSHA standard of 50 pm (90 mg/m^3) as a TWA be observed. NIOSH emphasized that its document did not attempt to address the adequacy of the OSHA standard [1].

The values recommended by NIOSH in 1977 were the same as the Threshold Limit Values (TLV's) then recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) for Time Weighted Average (TWA) and Short Term Exposure Level (STEL) concentrations, respectively. In 1979, ACGIH published its intent to change its TLV to 10 ppm (20 mg/cu m^3) as a TWA concentration.

Based on recent findings, NIOSH recommends that EtO be regarded in the workplace as a potential occupational carcinogen. Safe levels of carcinogens have not been demonstrated, but the probability of developing cancer should be reduced by decreasing exposure. The excess cancer risks to workers exposed to EtO at or below the present OSHA standard of 50 ppm as a TWA concentration have not yet been estimated. However NIOSH believes the present standard

needs to be reexamined because its adoption preceded the recognition of the carcinogenic potential of EtO and was established to protect against only acute and nonmalignant chronic effects. As prudent public health policy, NIOSH urges employers, in the interim, 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.

On April 18, 1983, the Occupational Safety and Health Administration proposed a reduction of the OSHA permissible workplace exposure limit for EtO from the current 50 ppm to 100 parts per billion. This was deemed necessary in order to reduce a significant risk of cancer and prevent DNA damage linked to carcinogenic and reproductive effects.

VI. Results

A. Environmental

Three personal EtO air samples (in the breathing zone) were taken over the eight-hour workday for the following job categories in the RTS (4th floor Respiratory Therapy Section/Ethylene Oxide Sterilizer Unit).

1. Chief Therapist/Equipment Aide - worked directly with the sterilizer - one load aerated and one sterilizing.

2. Respiratory Therapist - worked near the unit and handled parts.

3. Respiratory Technician - worked near the unit and handled parts.

The results of the EtO analysis in each of the above job categories showed no EtO detection in the breathing zone over the eight-hour workday. Each sample result was below the limit of detection for EtO (less than 0.04 milligrams/sample.or less than 0.25 ppm)

B. Medical

All 14 available female EtO-exposed employees and one female employee on leave participated in the questionnaire study. Fourteen were black and one was white. The mean age of the group was 30 years (range 22-41). The median duration of employment at MCP was 34 months (range 7-150). The total number of pregnancies in the 15 women was 32. The median number of pregnancies per woman was 2 (range 0-5).

Of the 32 pregnancies, 11 occurred in women while they were working at MCP. Of these 11, one is a current pregnancy; two ended in live births of normal infants; one ended in the birth of a premature (30 week gestation) infant, who required intensive respiratory support; three resulted in spontaneous abortions; and four were terminated. All three spontaneous abortions occurred in the same woman. The premature infant was born to a woman with a systemic disease known to be associated with prematurity.

Among the 32 pregnancies were four first pregnancies which terminated with spontaneous abortion. Of these first pregnancies only one occurred in a woman who was working at MCP prior to or during her pregnancy. Of three second pregnancies resulting in spontaneous abortion, one took place while the mother was working at MCP.

VII. Discussions and Conclusions

The results demonstrate that most of the women in the RTS were of childbearing age and that there was a large number of pregnancies in this group. There appears to be no relationship between employment in the RTS at MCP and spontaneous abortions. With the exception of one woman there were no adverse reproductive outcomes that might be attributed to work at MCP. This one woman, who has had three spontaneous abortions since beginning work at MCP, has had an extensive medical evaluation which has not revealed any basis for her spontaneous abortions. Whether her spontaneous abortions have been due to EtO exposure rather than to endocrine, metabolic or other abnormalities not associated with work, cannot be determined by the findings of this investigation.

The results of this study do not confirm or refute adverse outcomes in reproduction in people exposed to EtO [6]. The exposures in the current study were extremely low and the numbers of people exposed was small. Limitations of the study include the fact that not all women who have ever been employed in the RTS were included in the study and that four women currently working in the RTS were unavailable for the interviews.

VIII. Recommendations

1. Further efforts should be made to improve the ventilation system of the EtO sterilizer and thereby reduce any peak EtO levels that might occur at the time the sterilizer is opened following a cycle.

At the time of the environmental sampling the RTS had just received a local exhaust hood used specifically for EtO gas sterilizers. Although not hooked up at the time it is understood (via phone communication) that it is presently being utilized.

2. Included with this report are the NIOSH and HESIS recommendations to control exposures to EtO.(Reference 1 and 11)

3. Men and women working with the EtO gas sterilizer should be notified of possible reproductive effects of EtO exposure.

IX. References

1. Glazer, Z.R. Special Occupation Hazard Review with Control Recommendations for the Use of EtO as a Sterilant in Medical Facilities. Cincinnati, Ohio; National Institute for Occupational Safety and Health, 1977. (DHHS NIOSH Publication #77 200).

2. National Institute for Occupational Safety and Health. Current Intelligence Bulletin 35 - ETHYLENE OXIDE (EtO). Cincinnati. Ohio. National Institute for Occupational Safety and Health, 1981. (DHHS NIOSH Publication # 81 130).

3. Gross JA, Haas, M.L., Swift TR: Ethylene Oxide Neurotoxicity; Report of Four Cases and Review of the Literature. Neurology 29; 978-983 (1979).

4. Written Communication. Final Report on Ethylene Oxide One-Generation Reproduction Inhalation Study, Project Report 42-7, Carnegie-Mellon Institute of Research, May 1, 1989. Submitted by Union Carbide Corporation to the U.S. Environmental Protection Agency under Section 8(e) of the Toxic Substances Control Act, on Behalf of the Cosponsors of the Study (June, 1979).

5. LaBor JB, Kimmel CA. The Teratorgenicity of Ethylene Oxide Administered Intraveneously to Mice. Toxicol. Appl. Pharmacol. 56:16-22 (1980).

6. Hemminki, R., Mutanen, P, Saloniemi, I, Neimi, ML and Vainio, H. Spontaneous Abortions in Hospital Staff Engaged in Sterilizing Instruments with Chemical Agents. Br Med Jour 285: 1461-1463, Nov. 20, 1982.

7. Gordon, J and Meinhardt TJ. Ethylene Oxide - Spontaneous Abortions (Letter to the Editor). Br Med Jour 286: 1976-1977, June 18, 1983.

8. Niswander KR. Obstetrics: Essentials of Clinical Practice. Little, Brown, and Co.

9. Goldhaber, MK, Staub, SL, Tokuhata, GK. Spontaneous Abortions After the Three Mile Island Nuclear Accident: A Life Table Analysis. American Journal of Public Health 73(7): 752-759, July 1983.

10. Rosenberg, JR. Selected Reviews from the Literature. Journal of Occupational Medicine 26(6): 490, June 1983.

11. Hazard Evaluation System and Information Service. Hazard Alert #3 - Ethylene Oxide (EtO). Berkely, California, HESIS, 1982.

X. Authorship and Acknowledgements

Report prepared by:

Frank A. Lewis, I.H.
Principal Investigator
Region III, NIOSH

Originating office:

Gib Parrish, M.D.
Medical Officer, HETAB
Division of Surveillance,
Hazard Evaluations, and
Field Studies

Report typed by:

Mary Tomassini, Secretary

XI. Distribution and Availability of Report

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, 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 22161. 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. Medical College of Pennsylvania
2. National Union of Hospital and Health Care Employees RWDSU/AFL-CIO
3. NIOSH , Region III
4. 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.

July 1982

STATE OF CALIFORNIA
DEPARTMENT OF HEALTH SERVICES
DEPARTMENT OF INDUSTRIAL RELATIONS CAL/OSHA

HESIS

HAZARD ALERT #3

2151 Berkeley Way
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HAZARD EVALUATION SYSTEM AND INFORMATION SERVICE

Ethylene Oxide (EtO)

Ethylene oxide (EtO) has recently been found to cause cancer in laboratory test animals. It also causes genetic damage in animals and changes in the chromosomes of exposed workers. Because these effects have occurred at levels of exposure below the current legal exposure limit for workers, HESIS and the Division of Occupational Safety and Health have recommended that the legal workplace exposure limit of 50 parts of EtO per each million parts of air (50 ppm) be reduced. The American Conference of Governmental Industrial Hygienists has recommended a voluntary limit of 10 ppm. A number of industries have adopted limits between 1 and 10 ppm.

This Hazard Alert applies to the use of EtO to sterilize medical supplies*. Hospitals, health facilities, pharmaceutical companies and manufacturers of medical supplies use EtO to sterilize heat-sensitive materials that cannot be steam sterilized. For this purpose, there is no available safer substitute. When used for sterilization, exposure to EtO can occur: 1) while opening the sterilizer door; 2) while transferring materials from the sterilizer to the aerator; 3) while changing cylinder tanks; and 4) at the gas discharge point.

To prevent worker exposure to high concentrations, sterilization facilities should be carefully evaluated for such details as proper design, installation, ventilation, maintenance and operation. The employer has a legal responsibility to develop and institute guidelines for the safe use of EtO, and train employees to understand potential health effects, equipment operation, sources of exposure and control methods. Specific suggestions for limiting exposure begin on page 2 of this Alert.

HOW ETHYLENE OXIDE ENTERS THE BODY

EtO is a gas at room temperature and becomes a liquid below 55°F. It can enter the body by inhalation of the gas or by direct skin contact with the liquid.

HOW TO KNOW YOU ARE EXPOSED

Do not rely on smell to warn of overexposure. Most people cannot smell the sweetish ether-like odor of EtO until it reaches a hazardous concentration. Odor levels can vary depending on the concentration of EtO used and the

*Other exposures may occur when EtO is used as a fumigant.

materials sterilized. In addition, harmful levels may be present without causing any symptoms. The EtO level can be determined only by having qualified personnel monitor the workplace air concentrations on a regular basis.

HOW ETHYLENE OXIDE AFFECTS THE BODY

SHORT-TERM EFFECTS: EYES, NOSE, THROAT, LUNGS, SKIN AND NERVOUS SYSTEM

Exposure to EtO at levels as low as 200 ppm may cause irritation of the eyes, nose and throat.

Brief exposure to levels above 1,000 ppm and longer exposures to lower levels may result in any of the following symptoms: irritation of the lungs, coughing, difficulty in breathing, chest pain, headaches, nausea, vomiting, drowsiness, weakness, or lack of coordination. EtO has a depressant effect on the brain, like alcohol.

In one report, workers with occasional overexposure to EtO developed temporary damage to their nervous system with symptoms that included numbness, beginning in the feet and spreading upward. Recovery occurred when the overexposure ended.

Direct contact of the skin or eyes with liquid EtO can result in severe irritation, burns, or an allergic rash that may not occur until hours after an exposure.

Note: Symptoms should be reported to a supervisor immediately and a physician should be seen.

LONG-TERM EFFECTS: CANCER, REPRODUCTIVE SYSTEM AND GENETIC EFFECTS

EtO causes cancer in laboratory animals. Whether it can cause cancer in humans is difficult to determine and has not been adequately studied.

EtO has damaged the reproductive systems of both male and female test animals. It also caused mutations which were passed on to the animals' offspring. Whether these effects occur in humans is not known. In workers exposed to less than the legal limit, chromosomal (genetic) changes have been found. Whether these changes affect their health is not known.

SOURCES AND CONTROL OF EXPOSURE

Note: EtO use should be limited to those heat-sensitive materials for which there is no substitute sterilant.

STERILIZATION: The door should be sealed until the end of a cycle. Highest exposure occurs when the door is first opened and may reach 1,000 ppm for a brief time. Special ventilation systems should be designed to reduce this exposure. Workers should leave the immediate area as soon as the door is opened until the EtO levels have reached a minimum, as determined by previous monitoring.

AT THE GAS DISCHARGE POINT: Most sterilizers discharge EtO and water into an open sewer line through a floor drain. The high levels of EtO present at the point of discharge can be controlled by special techniques such as a liquid/gas separator and local exhaust ventilation.

TRANSFERRING MATERIALS TO THE AERATOR: Since approximately 5% of the EtO in the sterilizer stays in the sterilized material and its packaging, materials must be placed in a sealed aerator. Exposure may occur with improper transfer of materials, direct handling of sterilized materials, inadequate ventilation of the aerator and incomplete aeration. The transfer of material, from sterilizer to aerator, should be performed without delay. Keep sterilized materials as far away from the breathing zone as possible. Handling of materials before aeration should be avoided and only performed with gloves made especially for use with EtO. Recommended gloves are those made of cotton, which must be aerated after every use, and of polyvinyl alcohol.

CHANGING THE TANK: Exhaust ventilation systems are available that reduce exposure during changing of containers. Personal protective equipment such as splash-proof goggles, face shield, gloves and self-contained breathing apparatus may be necessary during some procedures as determined by qualified personnel. Commmercial EtO is available in pure (100%) concentration or diluted with an inert gas to reduce flammability. Special precautions must be taken to prevent fire and explosions whenever 100% EtO is used. Consult your local fire code.

NOTE ON RESPIRATORS: Only air-supplied respirators are approved for EtO by the National Institute of Occupational Safety and Health (NIOSH). Chemical cartridge respirators are not approved because of EtO's poor warning properties.

LOCATION AND DESIGN OF FACILITIES: Sterilizers and aerators must be located so that personnel other than those required by the operations are not exposed. Air flow direction should be toward the sterilizer and aerator locations. Centralization and isolation of all sterilization processes are strongly recommended. Only authorized personnel should have access as indicated by posting. Food, beverages and smoking material must not be allowed in work areas.

WORKPLACE SAFETY PROGRAMS FOR ETHYLENE OXIDE

TRAINING AND EDUCATION: Sterilization, operation and maintenance must be supervised and conducted by personnel who understand the potential health hazards of EtO and the techniques by which exposure can be reduced. A complete program of training (as required by Cal/OSHA General Industry Safety Order 3203) covering the sterilization process, operating instructions, potential health hazards, control measures and results of environmental monitoring should be provided to personnel before assignment. A continuing education program of current knowledge should be presented at least once every year. Records of all training programs must be maintained. Attendance is required by the Joint Commission on Accreditation of Hospitals (JCAH).

EQUIPMENT MAINTENANCE: All facilities should have a written program for preventive maintenance, carried out by trained personnel and recorded. As EtO can cause deterioration of gaskets, seals and fittings and result in leaks, careful maintenance of equipment is an essential preventive measure.

ENVIRONMENTAL MONITORING: To assure a safe work environment and establish compliance with legal limits and voluntary guidelines, measurement of EtO concentrations during and after normal use of sterilization equipment is required. Sampling should be conducted at the sterilizer, in workers' breathing zones and in areas where they might be exposed during the work routine. The frequency of routine monitoring will depend on the extent of EtO use, but should be at least every 6 months and whenever the system has been changed or repaired. Monitoring results should be maintained and available to employees.

MEDICAL SURVEILLANCE: A medical program should evaluate both the acute and chronic effects of EtO. A thorough medical history and physical examination, with particular attention to the hematological, neurological and reproductive systems, should be done initially and updated yearly. These medical records and the results of monitoring for exposure levels are required by California law and must be available to the worker.

FIRST AID

CONTACT WITH LIQUID: Immediately remove contaminated clothing and thoroughly wash contaminated skin with soap and water. Flush eyes with large amounts of water. See a physician immediately. Contaminated clothing should be laundered and rubber goods aerated before use. Contaminated leather shoes should be discarded.

INHALATION OF GAS: Move immediately to fresh air. If any symptoms occur; a physician must be seen as soon as possible.

FOR FURTHER INFORMATION, CONTACT THE FOLLOWING:

Your supervisor, health and safety committee or union representative

HESIS (Hazard Evaluation System and Information Service)
Department of Health Services/Department of Industrial Relations
2151 Berkeley Way, Room 504, Berkeley, CA 94704
(415) 540-3014 (call collect)

Cal/OSHA Consultation Service (for employers)
See your local phone book under California, State of, Industrial Relations

Cal/OSHA Division of Occupational Safety and Health (for employees)
See your local phone book under California, State of, Industrial Relations

For detailed recommendations on use of EtO, see Good Hospital Practice: Ethylene Oxide Gas - Ventilation Recommendations and Safe Use from the Association for the Advancement of Medical Instrumentation, Suite 602, 1901 North Fort Meyer Drive, Arlington, Virginia 22209, (703) 525-4890 ($20 per copy plus $2 handling charge).

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