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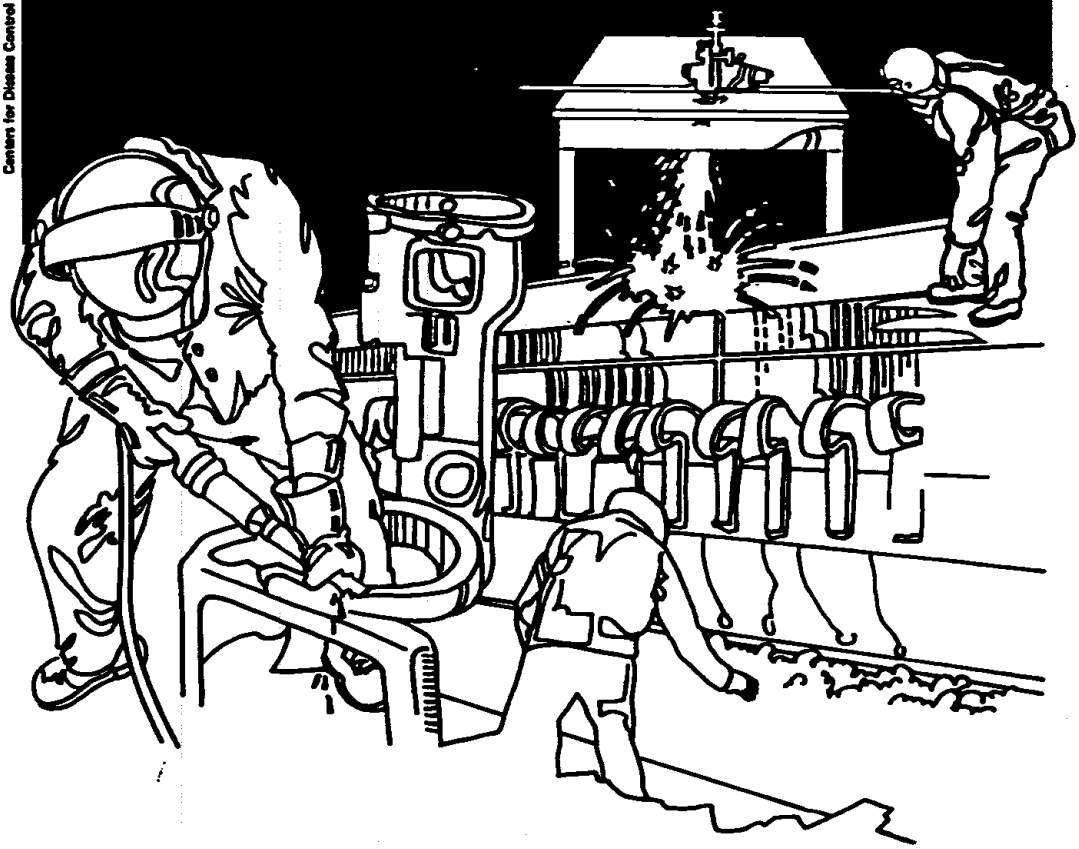

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Report

RDHETA 90-218-2079
FAIRMONT GENERAL HOSPITAL
FAIRMONT, WEST VIRGINIA

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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FAIRMONT GENERAL HOSPITAL
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I. SUMMARY

On March 30, 1990, NIOSH received a request from the management of Fairmont General Hospital, Fairmont, West Virginia to evaluate the potential health hazard to their employees from exposure to ethylene oxide (EtO) during the sterilizing of various instruments and materials.

An environmental survey was conducted by NIOSH investigators on June 13, 1990, to evaluate the EtO exposures among Central Supply employees. Eight samples were collected and submitted for EtO analysis. Of those samples, five were general room (area) samples and three were personal breathing zone samples. Only one sample, collected in the sterilizer room, showed any detectable amounts of EtO. The EtO concentration measured during one complete sterilizing cycle, which included loading the aerator (total 3.4 hours) was 0.32 ppm; with a calculated 8-hour TWA exposure of approximately 0.14 ppm. This calculated 8-hour TWA exposure assumes no additional exposures to EtO during the remaining 4.6 hours of the shift. No EtO was detected on any of the personal breathing zone samples. This was expected since the employee only spends a few minutes in the room loading the sterilizer; and after the cycle, returns for a few minutes to transfer the load into the aerator. A Miran 1A infrared gas analyzer was used to continually monitor for EtO release during the sterilization cycle. The only EtO detected by the Miran was during the exhausting phase. This detection was also verified by the hospital's EtO monitor as the room concentration exceeded the monitor's alarm setting of 2.0 ppm. It appears that the release of EtO comes from the open floor drain and not the sterilizer seals.

The concentration measured inside the sterilizer room was below the OSHA PEL of 1 ppm for an 8-hour TWA exposure, but above the NIOSH recommended criterion of 0.1 ppm. Additionally, concentrations were below both the NIOSH recommended exposure level of 5 ppm for a 10-minute Short Term Exposure Limit (STEL) and 5 ppm for the OSHA STEL ceiling limit.

Based on the sampling results and personal observations, the investigator has concluded that employees were not overexposed to EtO. Even though the room concentration exceeded the NIOSH REL of 0.1 ppm for an 8-hour TWA exposure, no employee was exposed to that concentration. The EtO sterilizer is located in an isolated area of the hospital and personal exposure, if any, is limited to only a few minutes per shift. Specific recommendations for controlling the release of EtO during the evacuation phase are contained in Section VI.

KEYWORDS: SIC 8062 (Hospitals, General Medical and Surgical), Ethylene Oxide, EtO, Sterilization

II. INTRODUCTION

In June 1990, the National Institute for Occupational Safety and Health (NIOSH) received a request from management of the Fairmont General Hospital, Fairmont, West Virginia to evaluate a potential health hazard to Central Supply employees from exposure(s) to ethylene oxide (EtO).

This request was the result of hospital management's interest in verifying their own methods of monitoring and sampling for EtO. Currently, the hospital routinely uses personal passive EtO monitors, has installed a remote EtO sensing monitor, and is semi-annually inspected by a private consultant.

On June 13, 1990, an environmental investigation was conducted to evaluate EtO exposures among central supply employees.

III. BACKGROUND

Ethylene oxide is used at the Fairmont General Hospital as a sterilant for heat sensitive instruments, equipment and other materials that could be destroyed in an autoclave. This hospital has one EtO sterilizer which is located on the basement floor of the old hospital wing and is approximately 50 to 75 yards from the main central supply section. Areas adjacent to the EtO sterilizer room are unoccupied and are used primarily as storage of old X-ray films. Access to the EtO sterilizer room is controlled by a door lock, for which only the charge nurse of Central Supply has a key. Any entry to the EtO room for maintenance or security reasons must be done with prior approval by the charge nurse.

The EtO sterilizer is in a specially designed room which is under negative pressure. Located within this room are a AMSCO Model 2025 EtO sterilizing unit and a AMSCO Model SK1-101 Gas Aerator; both of which are equipped with dedicated Envirogard local exhaust systems. Two EtO supply tanks are also located in the sterilizing room. The hospital was using a mixture of 12% EtO and 88% dichlorodifluoromethane (freon-12). The load to be sterilized is carted to the sterilizer room from central supply. The contents of the cart are then unloaded onto a sterilizer rack and the rack is than rolled into the sterilizer. Once the sterilizer is activated, the load is first preconditioned to 130°F for 0.41 hours. The sterilization period is 1.76 hours, after which follows a 0.67 hour purge. Total cycle time for a run is 2.84 hours. After the cycle is completed, the sterilizer door is cracked for a brief period in order to allow any remaining EtO gas to be captured by the Envirogard system. The contents are then rolled back on the cart and then rolled to and placed in the Aerator. The exposure time for this conversion is typically less than 4 minutes. Once placed in the Aerator, the contents will vacuum purge with a continuous air flush for 8 to 12 hours.

The potential for EtO emissions occurs during the exhausting phase, barring leaks in the EtO charging system or faulty seals on the chamber doors. The typical means for evacuating the chamber is a water ring vacuum pump. Most of the EtO is vented through a stack to the outside; however, a significant amount mixes with the water in the pump seal and is discharged down the drain. At the air break in the plumbing, a portion of the EtO diffuses away from the discharge water and can escape into the work area if it is not carried away by local ventilation.

A second source for EtO emissions is the gas which remains with the sterilized items following exposure. Unless the sterilizer is equipped to serve as an aerator chamber, the load must be removed and transferred for aeration. To do this the door to the sterilizer is opened and the load is manually moved to the aeration chamber.

During this survey, the only time a worker was in the sterilization room was to either fill the EtO sterilizer or empty it; which in any case, only took a few minutes to accomplish. The remainder of the shift was spent at Central Supply or other areas of the hospital. This was typical of the normal operation at this hospital.

IV. EVALUATION AND DESIGN METHODS

Personal breathing zone and general area air samples were collected to determine the potential exposure concentrations of EtO. In addition, a Foxboro MIRAN 1A Ambient Air Analyzer was used for determining sources of EtO release during the sterilizing cycle. Three (3) personal breathing zone and five (5) general area air samples were collected on hydrogen bromide-coated charcoal tubes using vacuum pumps calibrated at a sampling rate of 50 cubic centimeters per minute (cc/min) for time-weighted average (TWA) samples, and 150 cc/min. for 10 minute short-term (ceiling) samples. Samples were analyzed according to NIOSH Analytical Method 1614.[1] These samples were desorbed and reacted with 1 ml dimethylformamide (for 5 minutes), then analyzed by gas chromatography. The analyte, 2-bromoethylheptafluorobutyrate, was detected by electron capture.

V. EVALUATION CRITERIA

A. Environmental Criteria

As a guide to the evaluation of the hazard posed by workplace exposures, NIOSH field staff employ environmental evaluations 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 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 source of environmental evaluation criteria for the workplace are: (1) NIOSH Criteria Documents and recommendations, (2) the American Conference of Governmental Industrial Hygienist's (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 permissible exposure limits (PEL's). 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 exposure limits (REL's), 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 or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

B. Toxicological Effects of Exposure to Ethylene Oxide

Ethylene oxide is a major industrial chemical. It is used primarily as an intermediate in the production of other industrial chemicals such as ethylene glycol. Ethylene oxide is used also as a gas sterilant for heat-sensitive items in the health care industry and as a fumigant for such items as spices, books, and furniture.

Ethylene oxide is a highly exothermic reactant and potentially explosive substance. As a result, the handling, storage, and use of EtO presents potentially serious problems. EtO is a gas at room

temperature and a liquid below 55°F. The liquid is relatively stable; however, vapor concentrations greater than 3% are highly flammable, and air mixtures of EtO will explode when exposed to heat of open flames.[2]

Acute Effects

The primary mode of exposure to ethylene oxide is through inhalation (breathing). Ethylene oxide is an irritant to the eyes, respiratory tract, and skin. Early symptoms of EtO exposure include irritation of the eyes, nose, throat and a peculiar taste in the mouth. The delayed effects of exposure include headache, nausea, vomiting, pulmonary edema, bronchitis, drowsiness, weakness, and electrocardiograph abnormalities.[3] There have also been reported cases of neurotoxicity induced by ethylene oxide exposure.[4,5,6]

Dermal (skin) contact with solutions of ethylene oxide as low as 1% can cause burns with edema (swelling) and erythema (redness). Although skin contact with undiluted EtO does not cause burns, it can cause frostbite as a result of rapid evaporation.[7] The severity of skin burns from solutions of ethylene oxide appear to be influenced by both length of contact with the skin and the strength of the solution, with solutions around 50% appearing to be the most hazardous.[2] Both the undiluted liquid and solutions of EtO may cause severe eye irritation or damage and there have been case reports of cataracts among workers exposed to high levels of EtO.[8,9]

Carcinogenic Effects

Ethylene oxide has been shown to be carcinogenic to animals. Two inhalation studies demonstrated carcinogenic responses in F344 rats. Results were similar in both studies and consisted of increased incidence of mononuclear cell leukemia, peritoneal mesotheliomas, and primary brain tumors.[10,11] Inhalation studies using B6C3F_1 mice were interpreted as clear evidence of carcinogenic activity. Dose-related increased incidence of benign or malignant neoplasms of the lung and benign neoplasms of the harderian gland were seen in both male and female B6C3F_1 mice following exposure to EtO vapor at 50 and 100 ppm. In female mice, EtO caused additional malignant neoplasms of the uterus, mammary gland, and the hematopoietic system (lymphoma).[12] There is also some limited evidence which suggest that workers exposed to ethylene oxide may experience an increased risk of leukemia as compared to unexposed workers.[13,14]

Mutagenic Effects

Ethylene oxide has been shown to cause changes in the genetic material of lower biological species including Salmonella[15] and fruit flies[16] as well as mammals, including rabbits[17] and monkeys.[18] These genetic changes have been shown to be heritable (passed from one generation to the next) in experiments with mice.[19] EtO has also been shown to have

a dose-rate effect on genetic material.[20] Several studies have demonstrated that genetic changes can occur among humans exposed to EtO. Workers exposed to EtO have been found to have significantly increased numbers of chromosomal aberrations and sister chromatoid exchanges as compared to workers unexposed to EtO.[21,22]

Reproductive Effects

Animal experiments with ethylene oxide have indicated adverse reproductive effects from EtO exposure. A decrease in the number of pups born per litter was observed among female rats exposed to EtO prior to mating and during gestation (pregnancy)[23], and an increase in the number of malformed fetuses per litter was observed among female mice administered EtO intravenously during gestation.[24] Male monkeys exposed to ethylene oxide have been shown to have reductions in sperm count and sperm mobility.[18] There is also some human evidence which suggest that woman exposed to EtO during their pregnancies may experience increased rates of spontaneous abortions, although this information is not conclusive.[25]

C. Ethylene Oxide Exposure Criteria

NIOSH recommends (1) that workers' exposures be limited to 5 ppm (9 mg/m^3) EtO for no more than 10 minutes per workday, and (2) that the worker's 8-hour time weighted average (TWA) exposure be limited to less than 0.1 ppm (0.18 mg/m^3) EtO. This NIOSH Recommended Exposure Limit (REL) is based on the conclusion that EtO is mutagenic and carcinogenic in animals and is also capable of causing adverse reproductive effects. NIOSH has also concluded that EtO caused chromosomal damage in humans and has the potential for causing cancer and adverse reproductive effects in humans.[26,27]

In June 1984, the Occupational Safety and Health Administration (OSHA) promulgated a new standard for EtO that included a permissible exposure limit (PEL) of 1 ppm (1.8 mg/m^3) measured as an 8-hour time weighted average (TWA). The previous PEL was 50 ppm (90 mg/m^3). During the rulemaking proceedings that led to the establishment of 1 ppm OSHA PEL in June 1984, the issue of whether there was a need for a short-term exposure limit (STEL) for worker protection from EtO was raised. In January 1985, OSHA determined that adoption of a STEL for EtO was not warranted by the available health evidence. Resulting from litigation in 1986 (Public Citizens Health Group vs Tyson, U.S. Court of Appeals, District of Columbia Circuit), the Court decided that the OSHA Act compels OSHA to promulgate a short-term limit. In April 1988, OSHA

amended its existing standard by adopting an excursion limit for EtO—that is, no worker may be exposed to an airborne concentration that exceeds 5 ppm (9 mg/m^3) as averaged over a sampling period of 15 minutes.[26,28] The American Conference of Governmental Industrial Hygienists (ACGIH) has adopted 1 ppm as their TWA - Threshold Limit Value (TLV). Additionally, EtO has been classified by ACGIH as a suspected human carcinogen.[29]

VI. RESULTS AND RECOMMENDATIONS

Eight samples were collected and submitted for EtO analysis. Of those samples, five were general room (area) samples and three were personal breathing zone samples. Area sampling sites included rooms adjacent to, and above the sterilizing room, hallways outside the sterilizing room, as well as inside the sterilizing room. Dual personal samples were collected on the Central Supply employee responsible for the operation of the sterilizer. Only one sample, collected in the sterilizer room, showed a detectable amount of EtO. The EtO concentration measured during the complete sterilizing cycle, which included loading the aerator (total 3.4 hours) was 0.32 ppm; with a calculated 8-hour TWA exposure of approximately 0.14 ppm. This calculated 8-hour TWA exposure assumes no additional exposures to EtO during the remaining 4.6 hours of the shift. No EtO was detected on any of the personal samples. This was expected since the employee only spends a few minutes in the room loading the sterilizer; and after the cycle, returns for a few minutes to transfer the load into the aerator. A Miran 1A infrared gas analyzer was used to continually monitor for EtO release during the sterilization cycle. The only EtO detected by the Miran was during the exhausting phase. This detection was also verified by the hospital's EtO monitor as the room concentration exceeded the monitor's alarm setting of 2.0 ppm. Assuming that the EtO loading found on the sampling tube occurred during the exhausting cycle, then it could be expected that the room concentration would range from 1.5 ppm to 2.5 ppm. This assumption was also verified by the hospital's EtO monitor. It appeared that the release of EtO was from the open floor drain and not the sterilizer seals. Even though the EtO concentrations were below PEL levels, it is recommended that the gas escaping from the open floor drain be controlled. During the evacuation phase, 90% to 99% of the EtO in the chamber is discharged into a drain through the water-sealed vacuum pump. Even if the drain air gap between the sterilizer evacuation line and the sewer drain pipe is enclosed and ventilated, significant quantities of EtO may be emitted if the ventilation flow rate is inadequate or if the plumbing from the vacuum pump to the trap in the sewer drain line is not sealed. A ventilated enclosure should be placed around the air gap between the sterilizer evacuation line and the drain. Consult the sterilizer manufacturer for the proper exhaust ventilation rate. The vacuum pump discharge line should be installed to prevent water spillage. An air gap must be maintained between the discharge and the drain to avoid siphoning. The air gap should be partially enclosed, baffled, and ventilated. The floor drain junction should be sealed, as should all other connections of the sterilizer evacuation line and the drain line (except the opening into the ventilated enclosure).[26]

Reducing the potential for accidental exposures to EtO, especially during supply tank change over needs to be addressed by the hospital management. Guidelines for controlling accidental exposures can be found in NIOSH's Current Intelligence Bulletin 52, Ethylene Oxide Sterilizers in Health Care Facilities, Engineering Controls and Work Practices. It is recommended that the guidelines for exposure sources and specific control methods, particularly for supply cylinders, be followed and adopted at the Fairmont General Hospital.

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VIII. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Surveillance, Hazard Evaluations, and Field Studies, 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 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. Safety Director, Fairmont General Hospital
2. Allegheny Regional Joint Board of Retail, Wholesale, Department Store Union
3. U.S. DOL - OSHA
4. Ed Spirer, HETAB, NIOSH
5. Close-out File (RDHETA 90-218)

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.