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ST. VINCENT HOSPITAL
INDIANAPOLIS, INDIANA

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I. SUMMARY

In May 1992, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation (HHE) from St. Vincent Hospital located in Indianapolis, Indiana, to evaluate potential occupational exposures to ethylene oxide (EtO). The request was initiated by hospital management's concern for workers' potential exposures to EtO in the central processing department (CPD) of the hospital. On June 18-19, 1992, a site visit of the hospital was made by NIOSH investigators to conduct environmental sampling for EtO in the CPD.

To evaluate workers' exposures to EtO, personal breathing-zone (PBZ) air samples were collected on instrument technicians that included one full-shift and five short-term exposure measurements. Fifteen minute short-term exposure air samples were collected during the process of transferring sterilized products from sterilizer units to aerator units. Seven full-shift general-area (GA) air samples for EtO were collected for the purpose of assessing EtO concentrations within the CPD area.

The full-shift PBZ measurement for EtO revealed an 8-hour time-weighted average (TWA) concentration of 0.02 parts per million (ppm), below the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit of 1 ppm and the NIOSH Recommended Exposure Limit (REL) of 0.10 ppm. Full-shift GA air samples collected in the CPD revealed EtO concentrations that ranged from 0.008 ppm to 3 ppm, with some samples exceeding the OSHA and NIOSH exposure criteria for an 8-hour TWA. One of the five short-term exposure measurements revealed a 15-minute TWA concentration of 0.12 ppm, below the OSHA short-term exposure limit (STEL) of 5 ppm for a 15-minute period, and the NIOSH STEL of 5 ppm for a 10 minute period. The other four short-term exposure measurements were none-detected.

Environmental monitoring results revealed elevated levels of EtO gas in the general work environment of the CPD of this hospital. This gives reason to believe that the exhaust ventilation serving the CPD may not be effective in controlling EtO gas at its emission sources. NIOSH investigators concluded that a potential health hazard exists from exposure to EtO if workers were to occupy areas adjacent to the sterilization process frequently and/or for prolonged periods of time. Recommendations are made in Section IX of this report to improve exhaust ventilation and to implement preventive measures in an effort to better control EtO emissions.

KEYWORDS: SIC 8062, (general medical hospital) ethylene oxide, EtO, gas sterilization, central processing.

II. INTRODUCTION

In May 1992, NIOSH received a request for a HHE from St. Vincent Hospital located in Indianapolis, Indiana, to evaluate potential occupational exposures to EtO. The request was prompted by management's concern for workers' potential exposures to EtO in the CPD of the hospital. On June 18-19, 1992, a site visit to the hospital was made by NIOSH investigators to conduct environmental sampling for EtO in the CPD area.

III. BACKGROUND

The CPD is comprised of a sterilizer room, a mechanical access room, a storage room, and a cart-room. The CPD is equipped with two EtO automatic, general purpose sterilizer units: an Amsco Model 2015 Eagle Series sterilizer (sterilizer #11) and an Amsco Model 2045 Medallion Series sterilizer (sterilizer #7). Each sterilizer unit is supplied by one of six gas cylinders (size H, 140 pounds) containing EtO gas stored side-by-side in the mechanical access room. The CPD is also equipped with four separate aerator units used to aerate sterilized hospital products. The sterilizer units and aerator units are mounted in the wall between the sterilizer room and the mechanical room. The sterilizer and aerator unit's front panel (comprised of the door and controls) is in the sterilizer room, and the bulk of each unit is in the mechanical access room. Both sterilizer units use a sterilizing gas mixture containing 12% EtO and 88% freon for sterilizing surgical items and dialysis items. The entire sterilizing process takes approximately 12-14 hours. This includes sterilizing products for 3-3½ hours in a sterilizer unit, and manually transferring the products to an aerator to aerate for 8 to 10 hours.

The sterilizer units and aerators are served by a dedicated local exhaust ventilation system which releases EtO directly to the outdoors. Each sterilizer unit is provided with local exhaust ventilation above the unit door, designed to reduce workers' exposures to EtO when the door is opened. To control possible EtO leaks from the six gas cylinders, the exhaust ventilation system also serves an exhaust hood (1 foot X 5 feet) located approximately one foot above the gas cylinders. A large sheet of canvas material, which drapes around the exhaust hood opening and extends to the floor, is used to enclose the gas cylinders.

The CPD is equipped with an Interscan EtO monitoring system (model 1200 series) comprised of four voltametric sensors used for continuous monitoring of EtO concentrations in the vicinity of the sterilizer units and mechanical access room. Each sensor is equipped with an electrochemical gas detector operated by diffusion. The location of each sensor is presented in Figure 1.

IV. ENVIRONMENTAL EVALUATION AND METHODS

Environmental monitoring was conducted in the CPD during the entire second shift (from 2:00 p.m. to 11:00 p.m.) on June 18, 1992, and during the morning of June 19, 1992. During the monitoring, two sterilization cycles and one aeration cycle were completed. To evaluate workers' exposures to EtO, one full-shift PBZ and five 15-minute short-term PBZ samples were collected on three instrument technicians. On the first day of monitoring, the PBZ sample was collected on a worker for the duration of the second shift. On both days of monitoring, the short-term exposure samples were collected on workers during transfer of sterilized products from the sterilizer units to the aerator units. Seven full-shift GA air samples for EtO were collected within the CPD and in surrounding areas. GA air samples were collected at (1) each of the four EtO sensors (as shown in Figure 1); (2) the hallway located west of the CPD area; (3) the work station adjacent to sterilizer units #7 and #11; and (4) at the entrance from the linen-cart room. All PBZ and GA air samples for EtO were collected on solid sorbent tubes (100 milligram hydrogen bromide coated petroleum charcoal), using battery-powered sampling pumps calibrated at a flowrate of 100 cubic centimeters (cc) per minute. Samples were analyzed according to NIOSH Method 1614, using a gas chromatograph equipped with an electron capture detector.

To identify leaks around the door seal and drain of each sterilizing unit, a portable TIF® 5500 halogen leak detector was used. The floor drain serving both sterilizer units was inspected to determine whether it was designed as suggested by the Association for the Advancement of Medical Instrumentation (AAMI).[1] Ventilation smoke tubes were used to visually assess airflow patterns within the CPD.

V. EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by work place exposures, NIOSH field staff employ environmental evaluation criteria for the 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 from eight to ten hours a day, forty hours a week, for a working lifetime without experiencing adverse health effects. However, 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 substance may act in combination with other work place exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled to the level set by the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, thus potentially increasing 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 work place are: 1) NIOSH Criteria Documents and Recommended Exposure Limits (RELs), 2) the

American Conference of Governmental Industrial Hygienists' (ACGIH) threshold Limit Values (TLVs), and 3) the US Department of Labor (OSHA) Permissible Exposure Limits (PELs).[2-4] In evaluating the exposure levels and the recommendations for reducing those levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA PEL.

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

A. Ethylene Oxide (EtO)

Ethylene oxide is a highly exothermic 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 or open flames. 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.[(2)]

The primary mode of exposure to EtO is through inhalation (breathing). Because the odor of EtO cannot be generally detected below approximately 700 ppm, workers can be exposed to high concentrations of this compound without knowing it.[(3)] EtO is an irritant of the eyes, respiratory tract, and skin. Early symptoms of EtO exposure include irritation of the eyes, nose, and throat and a peculiar taste. The delayed effects of exposure include headache, nausea, vomiting, pulmonary edema, bronchitis, drowsiness, weakness, and electrocardiograph abnormalities[(4)]. There have also been reports of cases of neurotoxicity induced by EtO exposure[(5-7)].

Dermal (skin) contact with solutions of EtO 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[(8)]. The severity of skin burns from solutions of EtO appears to be influenced by both the duration of contact with the skin and the strength of the solutions, with solution around 50% appearing to be the most hazardous.[(2)] Both the undiluted liquid and solutions of EtO may cause severe eye irritation or damage,[(9)] and there have been case reports of cataracts among workers exposed to high levels of EtO.[(10)]

EtO has been shown to be carcinogenic to animals. Inhalation of EtO has induced excess leukemia in female rats and peritoneal mesothelioma and leukemia in male rats. An increase in the number of gliomas, a rare malignant tumor of the central nervous system, was also observed.[(11,12)] There is also some limited evidence which suggests that workers exposed to EtO may experience an increased risk of leukemia as compared to unexposed workers.[(13,14)]

EtO 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.[11] These genetic changes have been shown to be heritable (passed from one generation to the next) in experiments with mice.[18] Several studies have demonstrated that genetic changes can also occur among humans exposed to EtO. Workers exposed to EtO have been found to have significantly increased numbers of chromosomal aberrations and sister chromatid exchanges as compared to workers unexposed to EtO.[19,20]

Animal experiments with EtO 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),[21] and an increase in the number of malformed fetuses per litter was observed among female mice administered EtO intravenously during gestation.[22] Male monkeys exposed to EtO have been shown to have reductions in sperm count and sperm mobility.[11] There is also some human evidence which suggests that women exposed to EtO during their pregnancies may experience increased rates of spontaneous abortions, although this information is not conclusive.[23]

NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.10 part per million (ppm) determined as an 8-hour time-weighted average with a short-term exposure limit not to exceed 5 ppm for a maximum of 10 minutes per day.[24] This recommendation is based on the available risk assessment data which show that even at an exposure level of 0.10 ppm, the risk of excess mortality is not completely eliminated.[24] In June 1984, the Occupational Safety and Health Administration (OSHA) standard for occupational exposure to EtO was revised downward from 50 ppm to 1 ppm calculated as a time-weighted average concentration for an 8-hour workshift, with a short-term exposure limit not to exceed 5 ppm for a maximum of 15 minutes per day. This downward revision in the standard was based on the animal and human data showing that exposure to EtO presents a carcinogenic, mutagenic, reproductive, neurologic, and sensitization hazard to workers. OSHA also adopted an action level of 0.50 ppm based on an 8-hour TWA. Included in the present OSHA standard are requirements for methods of controlling EtO, personal protective equipment, measurement of employee exposures, training, and medical surveillance of the exposed employees.[26]

VI. RESULTS

The full-shift PBZ sample for EtO obtained from the instrument technician revealed a concentration of 0.02 parts per million (ppm) calculated as an 8-hour TWA, well below the OSHA PEL of 1 ppm as an 8-hour TWA and the NIOSH REL to maintain exposures below 0.10 ppm. One of the five short-term PBZ samples revealed a concentration of 0.12 ppm, below the OSHA 15-minute short-term exposure limit (STEL) of 5 ppm and the NIOSH 10 minute ceiling limit of 5 ppm. All other short-term samples did not contain EtO above the limit of

detection (LOD) of 0.70 micrograms (µg) per sample; this equates to a minimum detectable concentration (MDC) of 0.008 ppm, assuming a maximum sample volume of 47 liters.

The EtO GA air sampling results are presented in Figure 2. GA air sampling results for EtO ranged from non-detected to 3 ppm, calculated as 8-hour TWAs. The highest EtO concentrations were measured in the sterilizer room and the mechanical room. GA air samples collected in these areas ranged from 0.14 ppm to 3 ppm, all of which exceeded the NIOSH exposure criteria of less than 0.10 ppm.

A visual inspection of the exhaust ventilation system detected a small opening (approximately 1/4 of an inch in diameter) in the duct work leading from the floor drain. As recommended by AAMI, the design of the drain serving the sterilizing unit was appropriate in that an air gap was maintained between the discharge and the drain to avoid siphoning and to control EtO emissions. In accordance with OSHA regulations 29 CFR 1910.1047 (Ethylene Oxide) and 29 CFR 1910.1200 (Hazard Communication), signs and labels are posted in the CPD which inform workers of exposure hazards, potential adverse health effects, and methods for protecting themselves from exposure to EtO. The use of ventilation smoke tubes showed that the mechanical access room was under negative pressure in relation to the hallway (i.e., air was flowing from the hallway into the mechanical access room). However, trace amounts of EtO were measured in the hallway just outside the door of the mechanical access room. The halogen leak detector was used to determine whether EtO leaks were present around the doors of both sterilizer units; no leaks were detected.

The hospital's written procedures of "general work practices" were in accordance with AAMI recommendations.[1] In addition, workers were observed following these work practices.

VII. DISCUSSION

The full-shift PBZ air sample taken on an instrument technician revealed minimal exposure to EtO. During the time of the NIOSH evaluation, it was observed that CPD workers seldom occupied the sterilizer room and did not occupy the mechanical room. According to hospital management, this is typical of a normal work day. However, the workers' risk of being overexposed to EtO increases if they occupy these rooms more often or for prolonged periods of time. Maintenance workers who spend 15 minutes or longer in the mechanical access room are especially at risk of being overexposed to EtO (short-term or long-term), where a measured full-shift TWA concentration exceeded the NIOSH exposure criteria as much as 30 times. Although GA measurements are not representative of workers' personal exposures to EtO, there is reason to believe that personal exposures could exceed the NIOSH and OSHA exposure criteria because the area measurements, especially in the mechanical access room, were high.

Measurements for EtO taken at sterilizer #7 (sensor A) and sterilizer #11 (sensor B) revealed an 8-hour TWA concentration of 0.20 ppm and 1.14 ppm,

respectively. Since the halogen leak detector found no leaks around each sterilizer and aerator door, it is believed that much of the EtO detected on the air samples at these locations was collected when the sterilizer unit doors were slightly opened for 15 minutes immediately following the sterilization process. The process of opening the sterilizer unit doors is standard procedure to allow EtO gas to dissipate into the exhaust vents. It is suspected that the efficacy of the local exhaust ventilation provided above the sterilizer unit doors is not adequate in controlling EtO emissions.

The GA air sample collected at sensor C, which is located at the hood opening within the canvas enclosure, revealed a full-shift TWA concentration that exceeded the OSHA PEL by a factor of three. This may have been the result of EtO leakage from an unsealed gas cylinder supply valve.

The design of the floor drain serving both sterilizer units was as prescribed by AAMI, however, the efficacy of the drain exhaust is questionable. A full-shift area air sample collected near the drain revealed a TWA concentration of 0.72 ppm, exceeding the NIOSH criteria as much as 7 times.

During the evaluation, NIOSH investigators learned that an addition to the hospital is being constructed. Blueprints of this addition show that, after completion, outside air intakes would be located approximately 200 feet from the EtO exhaust grills, thus creating the potential for EtO exhaust re-entrainment. Hospital management personnel discussed plans for re-designing the exhaust ventilation system serving the mechanical access room, to reduce this possibility.

VIII. CONCLUSIONS

On the day of the NIOSH evaluation, environmental monitoring results revealed that a potential health hazard exists in the sterilizer room and the mechanical room of the CPD. EtO gas generated in these rooms was measured at concentrations that ranged from 0.14 ppm to 3 ppm, exceeding the NIOSH exposure criteria of less than 0.10 ppm. This is an indication that the exhaust ventilation provided in these areas is not effective in controlling EtO at emission sources. Efforts should be made to reduce EtO concentrations to the lowest feasible level, because NIOSH considers EtO to be a potential carcinogen.

Although PBZ measurements show that CPD workers were exposed to low concentrations of EtO, these workers are at risk of being overexposed if they occupy the sterilizer room --while sterilizers or aerators are in operation-- more frequently or for prolonged periods of time. In addition, maintenance workers who provide service to equipment in the mechanical room are especially at risk of being overexposed to EtO.

IX. RECOMMENDATIONS

1. It is important that hospital management implement their proposed plans for re-designing the exhaust ventilation system to minimize potential re-entrainment of EtO exhaust. The exhaust system should be designed so that prevailing winds will not carry the exhaust into populated areas or into the open windows, doors, or outside air intakes of buildings. Failure to implement this plan can pose problems in the future.

2. For preventive measures, the exhaust ventilation system should be examined to ensure that it was designed and operates as recommended by ASHRAE.[26] A written maintenance plan should be prepared and implemented that includes regular checks of exhaust ventilation efficacy, of door gaskets, valves, tubing, and piping connections. Provided below are specific recommendations that should be applied:

   A. The exhaust ventilation serving the mechanical access room should be evaluated on a regular basis to assure proper functioning of the system. Exhaust ventilation should be such that the net flow of air has a face velocity of at least 50 to 100 feet per minute (ft./min.).[24] The exhaust ventilation system serving the sterilizer units should be carefully inspected periodically for holes or openings in the duct work where leaks might occur in the discharge duct. Openings that are discovered in the duct work should be sealed.

   B. The door of each sterilizer and aerator unit should be inspected by the manufacturer to determine whether they are adequately sealed to prevent EtO leakage.

   C. According to management, periodic calibration of the EtO monitoring system is conducted approximately every six months. The manufacturer of the EtO sterilizer recommends calibrating each monitor about every 30-45 days. The manufacturer's recommendation should be followed to ensure the monitoring system functions as designed.

   D. To prevent dry trap EtO emissions, periodically pour water into each drain serving the units.

3. After efforts have been made to improve the local exhaust ventilation system, additional PBZ monitoring should be conducted to assess maintenance workers' exposures to EtO while working in the mechanical access room. If the monitoring results show that workers' exposures to EtO exceed the NIOSH exposure criteria, a respiratory protection program is recommended until the workers' exposures are reduced below the exposure criteria. A respiratory protection program should include: (1) an evaluation of each individual worker's ability to perform the work while wearing a respirator, (2) regular training of personnel, (3) periodic environmental monitoring, (4) respirator fit testing, and (5) proper maintenance, inspection, cleaning, and storage. Workers should only use respirators that have been certified by NIOSH and the Mine Safety and Health Administration (MSHA). A preferable method to

reduce maintenance workers' exposures to EtO is to prohibit them from performing tasks in the mechanical room while sterilizers and/or aerators are in operation.

4. The use of canvas material to enclose the EtO gas cylinders at the hood opening may not provide complete control of the emissions. The use of a ventilated cabinet for the gas cylinders should be considered, as this will better control any.

5. Studies show that high exposures to EtO often arise during the transfer of sterilized products from the sterilizer unit to the aerator unit.[23] Sterilizer units are now provided with the capability to transfer sterilized products directly from the sterilizer unit to the aerator unit without worker assistance. There are also sterilizer units that have a built-in aerator so that no transfer is needed. These new technologies reduce worker risk of exposure to EtO. For future reference, these technologies should be considered.

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Figure 1
Overhead Floor Plan
St. Vincent Hospital
Indianapolis, Indiana
HETA 92-273
June 18-19, 1992

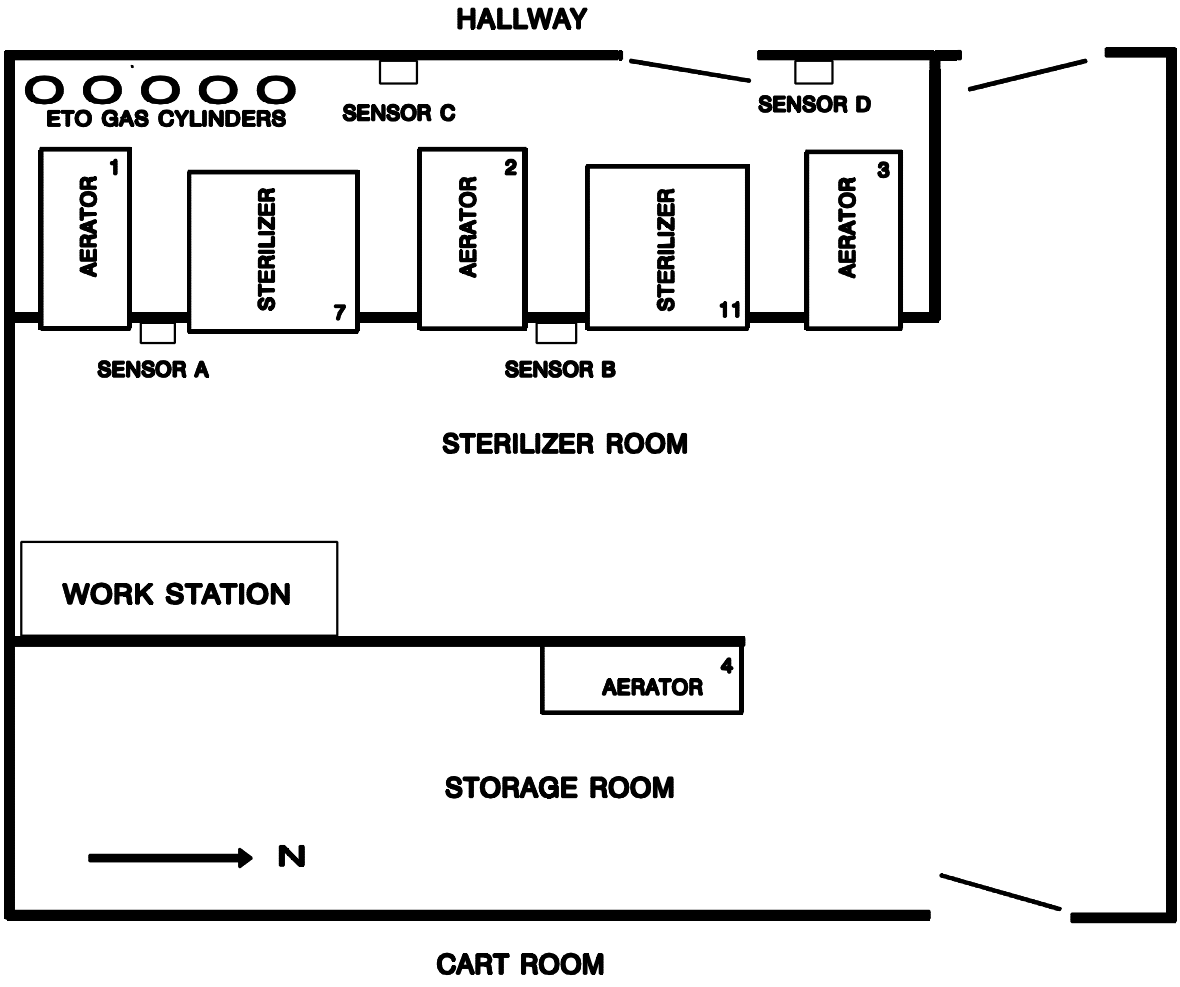

Figure 2
Full-Shift General-Area EtO Concentrations
St. Vincent Hospital
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