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EARL K. LONG MEMORIAL HOSPITAL
BATON ROUGE, LOUISIANA

NIOSH INVESTIGATOR:
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I. SUMMARY

In March 1987, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Earl K. Long Memorial Hospital in Baton Rouge, Louisiana, to evaluate a potential health hazard from ethylene oxide (EtO) used to sterilize various instruments and materials.

On May 14, 1987, a NIOSH investigator conducted an environmental evaluation of the central supply service area of the hospital. Four (4) personal breathing-zone (PBZ) and five (5) general area (GA) eight-hour time-weighted average (TWA) samples, as well as one (1) each – PBZ and GA – 10-min. ceiling sample, were collected. All EtO concentrations, with the exception of one (1) GA sample (1.3 ppm) were below the analytical limits of quantitation (0.02 ppm); the U.S. Department of Labor, OSHA (1.0 ppm, 8-hr. TWA; 0.5 ppm, action level); NIOSH (<0.1 ppm, 8-hr. TWA; 5.0 ppm, 10-min. ceiling); and American Conference of Governmental Industrial Hygienists, ACGIH (1.0 ppm, 8-hr. TWA) standards and/or recommended levels of exposure. No EtO was detected in either the personal breathing zone or general area "ceiling" sample.

Six (6) employees were interviewed in an attempt to determine whether reported symptoms were job-related. Four (4) employees indicated occasional eye irritation, dry/sore throat, and/or rash on their legs, and three (3) of the four employees felt that their medical symptoms were job-related, and generally improved when away from the workplace.

Based on the environmental data, the NIOSH investigator found no evidence to support a conclusion that a health hazard from ethylene oxide existed for hospital employees in the central supply service room. Recommendations for reducing potential exposures are indicated in Section VIII of this report.

KEYWORDS: SIC 8062 (general medical and surgical), ethylene oxide, central supply.

II. INTRODUCTION

In March 1987, the National Institute for Occupational Safety and Health (NIOSH) received a request from the staff at the Earl K. Long Memorial Hospital in Baton Rouge, Louisiana, to evaluate a potential health hazard from employee exposure(s) to ethylene oxide (EtO) in the central supply service area of the hospital.

On May 24, 1987, NIOSH conducted an environmental evaluation. Results of the survey were briefly discussed with the requestor, by telephone, in July 1987.

III. BACKGROUND

The central supply service department, providing services within Earl K. Long Memorial Hospital since 1968, is responsible for: a) the use of EtO as an agent to sterilize heat-sensitive medical items; b) washing, disinfecting/sterilizing, assembling and wrapping of medical instruments, trays and other reusable items; c) distributing small supplies to other units of the hospital; d) ordering and storing special-order items not maintained by the warehouse; and e) storing sterile products.

A supervisor and three (3) other employees perform duties during the 7 AM - 3 PM shift and one (1) employee works on the 3 PM-11 PM and 11 PM-7 AM shifts.

It should be noted that the "normal" EtO sterilization procedure calls for the sterilized items to remain in the sterilizer for a period of twelve (12) hours once the cycle has been completed and prior to items being removed. On the day monitoring was conducted, items were removed immediately after the cycle was completed.

In reality, the sterilizer is used as an aerator, unless it becomes necessary to sterilize another batch of items, in which case the initial batch is removed from the sterilizer, placed in the actual aeration chamber, and the second batch of items are placed in the sterilizer to proceed through the cycle.

IV. ENVIRONMENTAL DESIGN AND PROCEDURES

Five (5) personal breathing-zone (PBZ) and six (6) general area (GA) air samples were collected on hydrogen bromide-coated charcoal tubes by using vacuum pumps at sampling rates of 100 cubic centimeters per minute (cc/min.) for 8-hr. time-weighted average (TWA) samples, and sampling rates of 200 cc/min. for the 10-min. ceiling samples. Samples were analyzed by gas chromatography according to NIOSH Method 1614 with modifications.

Six (6) employees were interviewed to determine whether any reported symptoms were job-related.

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 Hygienists° (ACGIH) Threshold Limit Values (TLV°s), and 3) the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA), occupational safety and 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 employers are 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.

Exposure Standard - ETHYLENE OXIDE

NIOSH recommends that ethylene oxide be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.1 part per million (ppm) determined as an 8-hr. time-weighted average, with a short-term exposure limit not to exceed 5 ppm for a maximum of 10 minutes per day. This recommendation is based on the available risk assessment data which show that even at an exposure level of 0.1 ppm, the risk of excess mortality is not completely eliminated[23]. Effective as of August 21, 1984, the standard of the Occupational Safety and Health Administration (OSHA) for occupational exposure to ethylene oxide was revised downward from 50 ppm to 1 ppm, calculated as a time-weighted average concentration for an 8-hr. workshift. 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. 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[24].

Environmental Criteria Summary - Ethylene oxide

OSHA, 8-hour, TWA, standard	1.0*ppm
OSHA, action level**	0.5 ppm
NIOSH, 8-hour, TWA, recommendation	<0.1 ppm
NIOSH, recommended 10-minute ceiling	5.0 ppm
ACGIH, 8-hour, TWA, recommendation	1.0 ppm

*ppm - parts of contaminant per million parts of air sampled, at a pressure of 760 millimeters of mercury and 25 degrees Centigrade

**action level - level at which industry must initiate monitoring and medical surveillance

B. Toxicological

Ethylene oxide (EtO) 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 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[1].

Acute Effects

The primary mode of exposure to ethylene oxide is through inhalation (breathing). Ethylene oxide 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[2]. There have also been reports of cases of neurotoxicity induced by ethylene oxide exposure[3-5].

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[6]. The severity of skin burns from solutions of ethylene oxide appears to be influenced by both the length of contact with the skin and the strength of the solutions, with solutions around 50% appearing to be the most hazardous[1]. Both the undiluted liquid and solutions of EtO may cause severe eye irritation or damage[7], and there have been case reports of cataracts among workers exposed to high levels of EtO[8].

Carcinogenic Effects

Ethylene oxide 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[9,10]. There is also some limited evidence which suggests that workers exposed to ethylene oxide may experience an increased risk of leukemia as compared to unexposed workers[11,12].

Mutagenic Effects

Ethylene oxide has been shown to cause changes in the genetic material of lower biological species including Salmonella[13] and fruit flies[14] as well as mammals, including rabbits[15] and monkeys[10]. These genetic changes have been shown to be varitable (passed from one generation to the next) in experiments with mice[16]. 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 aberations and sister chromatid exchanges as compared to workers unexposed to EtO[17,18].

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)[19], and an increase in the number of malformed fetuses per litter was observed among female mice administered EtO intravenously

during gestation[20]. Male monkeys exposed to ethylene oxide have been shown to have reductions in sperm count and sperm motility[10].

VI. RESULTS

Four (4) personal breathing-zone (PBZ) and five (5) general area (GA) eight-hr. time-weighted average (TWA) samples, as well as one (1) each -- PBZ and GA -- 10-min. ceiling sample, were collected. As shown in Table 1, all EtO concentrations, with the exception of one GA sample (1.3 ppm), were below the limit of quantitation of the analytical method (0.02 ppm), and also below the OSHA, NIOSH, and ACGIH standards and/or recommended levels of exposure shown in Section V. No EtO was detected in either the PBZ or GA "ceiling" sample.

Of the six (6) employees interviewed, four (4) indicated occasional eye irritation, dry/sore throat, and/or rash on their legs, and three of the four employees felt that their medical symptoms were job-related, and generally improved when away from the workplace for reasonable periods of time.

VII. DISCUSSION AND CONCLUSIONS

The normal EtO sterilization operating procedure established by the hospital calls for items to remain in the vented sterilizer for twelve (12) hours once the cycle has been completed.
On May 14, 1987, the sterilizer was opened immediately following completion of the cycle to accomodate environmental monitoring activities of the NIOSH investigator. Ethylene oxide samples were, therefore, obtained under "worst case" conditions, and concentrations would most likely be higher than normally encountered.

In conclusion, and based on results of environmental monitoring conducted on May 14, 1987, the NIOSH investigator determined that a health hazard from over-exposure to EtO did not exist for hospital employees in the central supply service room.

VIII. RECOMMENDATIONS

1. Although only one (1) general area sample exceeded the action level (0.5 ppm), consideration should be given to relocating the sterilizer/aerator to a recessed area or separate room for purposes of isolating workers from potential EtO exposures/heat/noise.

2. In accordance with OSHA requirements (General Industry Standards, 29 CFR 190.1047), for all persons working with/exposed to EtO, and/or where the action level (0.5 ppm) has been exceeded:

   a. maintain a medical surveillance program (initial/periodic examinations, etc.)

   b. conduct environmental monitoring to determine employee exposures to EtO.

3. Maintain an updated "standard operating procedures": manual containing EtO sterilation techniques, and continue thorough on-job training programs, including the sterilization procedures with EtO.

4. Minimize EtO dermal contact by using gloves and forceps to remove items from the sterilizer.

5. Ensure that an effective maintenance program is implemented (i.e., inspection/removal of leaking seals and gaskets; inspection of ventilation systems, etc.).

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X. AUTHORSHIP AND ACKNOWLEDGEMENTS

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Copies of this report have been distributed to:

1. Earl K. Long Memorial Hospital, Baton Rouge, Louisiana
2. NIOSH, Atlanta Region
3. OSHA, Region VI

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