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MEMORIAL HOSPITAL OF SOUTHERN OKLAHOMA
ARDMORE, OKLAHOMA

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I. SUMMARY

In July l987, NIOSH received a request from the Memorial Hospital of Southern Oklahoma, Ardmore, Oklahoma to determine if there was a health hazard from exposure to ethylene oxide (EtO) during its use as a sterilant.

An environmental evaluation was conducted by NIOSH on September 9, and l0, l987 to evaluate EtO exposure among Central Services employees. Employees in this department were informally questioned in order to obtain information on medical problems that may be attributed to EtO exposure. The employees did not report medical complaints and believed they were working in a clean environment.

Nine samples were collected for EtO analyses. Six of these samples were general room samples and three were personal samples. Three of the general room air samples exceeded the American Conference of Governmental Hygienist (ACGIH) threshold limit value (TLV) and the Occupational Safety and Health Administration (OSHA) permissible level of 2.0 mg/M^3. NIOSH recommends the lowest feasible level (LFL less than 0.2 mg/M^3). The three levels were 3.25, 2.63, and 2.40 mg/M^3. Two additional general room air samples were l.60 and 0.03 mg/M^3 while the other general room air sample was below the detection limit of 0.0002 mg/sample. The three breathing zone air samples were below the laboratory limit of detection (0.0002 mg/sample).

The Central Services Department had an alarm system for EtO. The department was equipped with a continuous ET0 monitoring system with a strip chart recorder. The sterilizer and ET0 cylinder rooms were operating under negative pressure which eliminates ET0 contamination of other areas of central services. This department is part of the hospital's new construction and has been designed with adequate general ventilation and controls to eliminate EtO exposure to workers. The high levels of ET0 found in the sterilizer room were due to: 1. An inadequate exhaust ventilation rate during an aborted cycle and 2. the drain pipe from the sterilizer should be more enclosed in the floor drain, and should have an enclosed local exhaust hood built over it that will exhaust the excess EtO during an aborted or regular cycle.

On the basis of the environmental data obtained during this survey, it was determined that a potential for overexposure to ethylene oxide existed for employees who may have to enter the sterilizer room during the sterilization cycle. Recommendations for reducing EtO exposures are included in this report.

KEYWORDS: SIC 8062 hospitals, ethylene oxide, gas sterilization

II. INTRODUCTION

In July l987, the National Institute for Occupational Safety and Health (NIOSH) received a request from management of Memorial Hospital of Southern Oklahoma, Ardmore, Oklahoma to determine if there was a health hazard from exposure to ethylene oxide (EtO). EtO is used in the Central Services Department for sterilization of heat sensitive instruments, equipment and other materials used throughout the hospital.

This request was the result of hospital management's interest in verifying their method of sample collection and analyses. The hospital's liability insurance company told the individual in charge of central services that their method of passive monitoring was not acceptable. The hospital asked for NIOSH assistance in order to develop state of the art techniques in EtO monitoring.

On September 9, and l0, l987 an environmental investigation was conducted to evaluate EtO exposures among central services employees.

III. BACKGROUND

EtO is used at the Memorial 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 first floor of the hospital. The EtO sterilizer is located in central services. The EtO sterilizer is in a specially designed room which is under negative pressure. The only time a worker is in this room is to either fill the EtO sterilizer or empty it. The EtO gas cylinders occupy a separate joining room. This room is also under negative pressure. Both of these rooms were monitored for EtO since workers routinely enter for maintenance and loading and unloading of the EtO sterilizer. Two workers in central services are responsible for operation of the sterilizer. The sterilizer is filled with the instruments and other materials, closed and the sterilization cycle begins. The sterilizer has a 30 minute conditioning phase, after this phase there is a two-hour sterilization cycle, then an 8 hour aeration cycle. After the aeration cycle the sterilizer may be opened and unloaded. If the sterilizer is not unloaded a purge ventilation cycle will repeat every hour or so in order that any residual EtO left on the instruments will be ventilated from the sterilizer. Workers do not enter the EtO sterilization room at any time during the sterilization or aeration cycles. If any problem occurs during the sterilization, or aeration cycle the load is aborted and all the EtO is ventilated out of the sterilizer and out of the hospital by a dedicated ventilation route. This occurred during this evaluation and may account for some of the excessive concentrations found in the sterilizer room.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

On September 9 and l0, l987 an industrial hygiene evaluation was conducted in the Central Services department. Breathing zone and general room air samples were collected on hydrogen bromide treated charcoal tubes and vacuum pumps operated at approximately l50-200 cc/minute. Samples were analyzed using NIOSH method l607. Ventilation measurements were made with a velometer and air movement from positive to negative areas was observed using smoke tubes. Medical evaluation of these workers was not performed during this evaluation. This department has a very

good medical surveillance program and workers were p]eased with the type of medical monitoring that was being done.

V. EVALUATION 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 (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 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.

Environmental Exposure Limits
8-Hour Time Weighted Average (TWA)

Ethylene Oxide	LFL	(NIOSH) A2
	2 mg/M^3	(OSHA)
	2 mg/M^3	(ACGIH)

mg/M^3 = milligrams of substance per cubic meter of air
LFL = Lowest Feasible Level (See below for further explanation)
A2 = Industrial substance suspected of having carcinogenic potential for man

A. Environmental

In 1984 the Occupational Safety and Health Administration (OSHA) established a new Permissible Exposure Limit (PEL) for EtO of 2 mg/M^3 as an 8-hour TWA.[1] In addition, an "action level" of 1 mg/M^3 as an 8-hour TWA was established by OSHA as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. Also in 1984, NIOSH recommended that EtO exposures not exceed 10 mg/M^3 for a maximum of 10 minutes per day and that exposures be controlled to less than 0.2 mg/M^3 determined as an 8-hour TWA.[2] NIOSH considers EtO to be a potential human carcinogen and no safe level of exposure has been demonstrated, Although decreasing the exposure is likely to reduce the probability of developing cancer. The American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Threshold Limit Value (TLV) of 2 mg/M^3 for an 8-hour TWA. The ACGIH also designated EtO as an A2 carcinogen.[3] An A2 carcinogen is defined as an industrial substance suspected of having carcinogenic potential for man. This designation is based on either (1) limited epidemiologic evidence, exclusive of clinical reports of single cases, or (2) demonstration of carcinogensis in one or more animal apecies by appropriate methods.

B. Medical

Acute Effects

Inhalation of high concentrations to EtO for short exposure periods can produce a general anesthetic effect in addition to coughing, vomiting, and irritaiton of the eyes and respiratory passages. Early symptoms are irritation of the eyes, nose, and throat and a peculiar taste. Effects, which may be delayed, are headache, nausea, vomiting, dyspnea, cyanosis, pulmonary edema, drowsiness, weakness, incoordination, and abnormalities of EKGs and urinary excretion of bile pigments.[4] Serveral dermatologic conditions can result from contact with liquid EtO. These include skin blistering, pigment color change, and frostbite.[4]

Chronic Effects

EtO binds to DNA and has been shown to cause point mutations.[5] In both animals and humans, EtO exposure produces increased frequencies of sister chromatid exchanges and chromosomal aberrations.[6,7] EtO is a reproductive toxin in animals, and one study suggests such an effect in humans, two epidemiological studies have associated an increase of hematologic, alimentary, and urogenital malignancies with EtO exposure.[6,9,10] EtO has also been shown to cause polyneuropathies and cataracts.[11,12,13]

VI. RESULTS

Three breathing zone and six general room air samples were collected and analyzed for ethylene oxide (Et0). All of the breathing zone air samples were below the laboratory limit of detection of 0.0002 mg/sample which represents approximately 0.02 mg/M3. Five of the six general room air samples showed concentrations of 0.03, l.60, 2.63, 2.40, and 3.25 mg/M^3. The other sample was below the laboratory detection limits. The OSHA standard for EtO is 2 mg/M^3 while NIOSH recommends the lowest feasible level.

VII. DISCUSSION AND CONCLUSIONS

Workers were not overexposed to EtO, however, the potential for overexposure exists if a worker goes into the sterilizer room during either an aborted or normal cycle. The floor drains which ventilate the drain pipes from the sterilizer need to be ventilated. An enclosed ventilation system around the floor drain that could be joined with the existing ventilation and exhausted to the outside would help eliminate EtO exposures during normal operation of the sterilizer. This type of ventilation system should also eliminate excessive EtO levels during an aborted cycle. The entire setup for the EtO sterilizer is a good design. Having a separate room for the sterilizer and another separate room for the EtO cylinders with negative pressure in both rooms should eliminate employee exposure without altering anything. Ventilating the floor drain where the EtO sterilizer drains would eliminate the possibility of central service employees and maintenance personnel from receiving exposures during times when it is necessary to enter the sterilizer room during a sterilization cycle.

VIII. RECOMMENDATIONS

1. Memorial Hospital should continue efforts to reduce EtO levels to the lowest feasible levels.

2. Continued monitoring of the EtO levels until good baseline data on low levels in all areas is documented should be a part of the hospital's occupational health program.

3. Ventilating the floor drain in the sterilizer room should reduce levels of EtO to less than detectible.

4. The current good work practices and use of the EtO sterilizer should be continued.

IX. REFERENCES

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XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Information Resources and Dissemination Sectio, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH, Publications Office, at the Cincinnati address.

Copies of this report have been sent to:

1. Memorial Hospital of Southern Oklahoma
2. U.S. Department of Labor/OSHA - Region VIII
3. NIOSH Regional Offices/Divisions
4. Oklahoma Department of Health

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

Table 1
Breathing Zone and General Room Air Concentrations of
Ethylene Oxide (EtO) at
Memorial Hospital of Southern Oklahoma
Ardmore, Oklahoma
September 9, 10, 1987

Sample No.	Date of Collection	Type of Sample	Sample Location	Sampling Time	Mg/M^3 EtO
1	10/9/87	Breathing Zone	All Areas	7:25 - 1:00	*
2	10/9/87	Breathing Zone	All Areas	7:25 - 1:00	*
3	10/9/87	General Room	Top of Sterilizer	7:30 - 1:00	1.60
4	10/9/87	General Room	EtO Cylinder Room	7:30 - 1:00	0.03
5	10/9/87	General Room	Sterilizer Room	7:30 - 1:00	3.25
6	10/10/87	Breathing Zone	All Areas	12:30 - 2:40	*
7	10/10/87	General Room	Cylinder Room	12:30 - 2:50	*
8	10/10/87	General Room	Top of Sterilizer	12:30 - 2:47	2.63
9	10/10/87	General Room	Sterilizer Room	12:30 - 2:45	2.40

Evaluation Criteria 2.0/OSHA
Laboratory Limit of Detection 0.0002 mg/sample A/NIOSH

A = Lowest feasible level (LFL) (NIOSH)