US DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CINCINNATI, OHIO 45226

HEALTH HAZARD EVALUATION DETERMINATION
REPORT #78-42-498

SWEDISH HOSPITAL
SEATTLE, WASHINGTON

MAY, 1978

I. TOXICITY DETERMINATION

It has been determined that employees who work in the anesthesia equipment room are not exposed to potentially toxic concentrations of ethylene oxide (ETO), a sterilant gas. This is based on sample results that showed ETO time-weighted average (TWA) concentrations of 10-15 ppm and short-term ETO concentrations of 38 and 57 ppm. These concentrations were less than the evaluation criteria of 50 ppm for an eight hour TWA exposure and 75 ppm ceiling concentration for a 15 minute exposure. There was no indication of post-shift irritation of the eyes, nose, throat, or skin of the employees questioned. One employee did, however, indicate that her sense of taste has diminished during her five years in this job.

Recommendations to reduce the amount of ETO that escapes into the room and for medical surveillance of the exposed employees are included in this report.

II. DISTRIBUTION AND AVAILABILITY

Copies of this Determination Report are currently available upon request from NIOSH, Division of Technical Services, Information and Dissemination Section, 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 the NIOSH Publications Office at the Cincinnati address.

Copies of this report have been sent to:

(1) Swedish Hospital
(2) Washington Industrial Safety and Health Agency, Olympia, WA
(3) Occupational Safety and Health Administration, Region X, Seattle, WA
(4) NIOSH Region X, Seattle, WA

For the purpose of informing the 4 employees who work in the anesthesia equipment room all day, and the 15-20 employees who spend a portion of the day in this room, the employer will prominently post the Determination Report near their work area for a period of thirty (30) calendar days.

III. INTRODUCTION

Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 USC 669(a)(6), authorizes the Secretary of Health, Education and Welfare, following receipt of 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 National Institute for Occupational Safety and Health received such a request from the administration of Swedish Hospital, Seattle, WA to determine if the ethylene oxide (ETO) used as a sterilization gas in the anesthesia equipment room is potentially toxic as used or found.

IV. HEALTH HAZARD EVALUATION

A. Description of Process

Swedish Hospital is a general hospital. This request involves only the anesthesia equipment room.

Anesthesia equipment is washed, dried and sterilized before reuse. These functions are conducted in the anesthesia equipment room which is also a storeroom and schedule room. The cleaned equipment is placed in open plastic bags which are placed in the dryer. When dry, the bags are transferred to the sterilizer. The sterilization cycle is approximately 2 hrs. and 15 mins. The cycle consists of drawing and maintaining a vacuum, heating, introduction of the sterilization gas and purging of the gas. The bags are removed and placed on a cart. The items are later removed from the bags and placed individually in an aerator for a period of 12 hours after which time they are ready for use. The sterilization gas consists of a mixture of 12% ethylene oxide and 88% Freon 12 (Dichlorodifluoromethane).

The sterilization unit is installed in a small closet with the front of the unit fit into the wall. There is a louvered door on the side of the closet. There is a 5 inch exhaust ventilation duct in the ceiling of the closet which terminates outside the building.

The exhaust air from the aerator is piped through a four inch duct into the closet.

There are four workers in this room for an entire shift. Since the anesthesia equipment room is also the schedule room, there are an additional 15 to 20 employees who spend a small portion of their shift there. All of these employees are exposed at one time or another to ethylene oxide.

B. Study Progress and Design

1. General

The initial survey was conducted on February 16, 1978 and the environmental sampling was conducted on March 6 and 7, 1978. There was no personal protective equipment (e.g. gloves) worn by the employees when loading and unloading the sterilizer and aerator during the study.

2. Environmental Sampling

The sampling was designed to determine the time weighted average exposure to the employee with the highest potential exposure, that being the person who loads and unloads the sterilizer. Short-term (15 min) exposures were determined during the purge-unload-load portion of the sterilization cycle. General area samples were collected to determine the approximate exposure levels to other personnel working in the room.

3. Medical

A short pre and post shift questionnaire was administered to the three day shift employees who work all day in the anesthesia equipment room. The questionnaire involved the employee's perception of a feeling of irritated eyes, nose, throat and skin, and whether they had any dermatitis.

C. Evaluation methods - Environmental

The employees' exposures to ethylene oxide were determined by the collection of samples in the anesthesia equipment room. The ethylene oxide was collected on charcoal tubes, specifically for use with ethylene oxide. Each tube contained 1200 mg. of activated charcoal. The sampling was conducted using two of the tubes in series at a flow rate of 25 to 100 cc per minute. The samples were iced immediately after collection and sent to the laboratory.

The ethylene oxide present in the charcoal samples was determined using gas chromatographic techniques. A direct reading halide meter was used to measure the Freon-12 in order to estimate the ETO concentration so that appropriate sampling rates and times could be used for the ETO sampling.

D. Evaluation Criteria

1. Environmental Criteria - The evaluation criteria for substances in this evaluation are as follows:

The Occupational Health Standards as promulgated by the U. S. Department of Labor, Code of Federal Regulations, revised January 1976, Part 1910, Title 29, Chapter XVII, Subpart Z, Table Z-1, Z-2, and Z-3, the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV) for Chemical Substances and Physical Agents in the Workroom Environment for 1977 and the NIOSH Recommended Levels published in Reference No. 1.

SUBSTANCE	US DEPT OF LABOR STANDARDS (PPM)	ACGIH TLVs TWA* (PPM)	ACGIH TLVs STEL** (PPM)	NIOSH RECOMMENDED LEVELS TWA (PPM)	NIOSH RECOMMENDED LEVELS STEL (PPM)
Ethylene Oxide	50	50	75	50	75
Dichlorodifluoromethane (Freon-12)	1000	1000	1200	-	-

* TWA - Time Weighted Average

** STEL - Short Term Exposure Limit (15 minutes)

2. Toxic Substance Medical Data

The adverse health effects from exposure to the substances listed are:

1. Ethlylene Oxide (1)

The acute toxic effects of ETO in man and animals include acute respiratory and eye irritation, skin sensitization, vomiting, and diarrhea. Known chronic effects consist of respiratory irritation and secondary respiratory infection, anemia, and altered behavior.

The observations of (a) heritable alterations in at least 13 different lower biological species following exposure to ETO, (b) alterations in the structure of the genetic material in somatic cells of the rat, and (c) covalent chemical bonding between ETO and DNA support the conclusion that continuous occupational exposure to significant concentrations of ETO may induce an increase in the frequency of mutations in human populations. At present, however, a substantive basis for quantitative evaluation of the genetic risk to exposed human populations does not exist.

Limited tests by skin application or subcutaneous injections in mice did not reveal carcinogenicity. However, the alkylating and mutagenic properties of ETO are sufficient bases for concern about its potential carcinogenicity. Neither animal nor human data are available on which to assess the potential teratogenicity of ETO.

2. Dichlorodifluoromethane (Freon-12)(2)

Dichlorodifluoromethane is an odorless gas of very low toxicity. Sayers and his associates exposed dogs, monkeys and guinea pigs 7 to 8 hours daily for a total of 12 weeks at a concentration of 20 percent in air. They observed the tremors and salivation that had been noted in the acute experiments at such concentrations but no further signs of poisoning. Outside of a few cases of pneumonia, which occurred in the controls also, their animals survived without injury.

It would seem that this material is one of extraordinarily low toxicity, presenting very little practical hazard.

The threshold limit of dichlorodifluoromethane was established by the American Conference of Governmental Industrial Hygienists, in April 1959, at 1000 ppm (2950 mg/cu m).

This level was approved, not because injury would be expected at higher concentrations, but, apparently because this is as high a level as has been accepted for any organic vapor, and there is certainly no reason why working conditions cannot be controlled well within such levels by practical engineering control.

E. Evaluation Results and Discussion

1. Environmental Results

The entire sterilization process was evaluated. As mentioned previously, the sterilizer is housed in a small closet with the front of the unit fitting flush with the wall. There is a louvered door on the side of the closet and a slot for exhaust ventilation just above the sterilizer door. The closet has a minimal amount of exhaust ventilation. The exhaust duct of the aerator, located about four feet away, is piped directly into the closet above the sterilizer. The exhaust rate from the closet was deficient when the aerator was on and also when the sterilizer was purging. Thus, ETO would routinely be expected to leak into the room. This was checked with smoke tubes which showed the air was exiting the louvers in the closet door and the slot over the sterilizer door. During the purging, the closet was under more positive pressure. A halide meter was used to confirm the presence of Freon-12 in front of the sterilizer during the purge cycle. It was also used to confirm that the gases were not leaking out of the sterilizer around the door seals. The sample results show that the ETO levels were higher during 15 minute sample periods when the sterilizer purged, was unloaded and reloaded for the next cycle.

The sample results are shown in Table 1. March 6 was a slow day in that the sterilizer was not used in the morning. The sample results during the morning show that the ETO concentrations were all below detectable amounts. A load was put in the sterilizer in the afternoon. A breathing zone sample of the employee who loaded and unloaded the sterilizer and was in the room during the sterilization cycle had a time weighted average exposure of 13 ppm during the period.

Additional samples were collected on March 7. Fifteen minute breathing zone samples collected during two purge-unload, load operations were 57 and 38 ppm respectively. These are less than the short term exposure limit of 75 ppm for fifteen minute periods. General area samples collected between the sterilizer and the aerator during the same two time periods were 41 and 37 ppm respectively.

A general area sample collected at the schedule desk which is near the sterilizer and where the employee spends a considerable amount of time, was less than 6 ppm. The sample was collected from the start of the sterilization cycle to the start of the purge cycle. The time weighted average for a complete cycle (load, sterilize, purge, unload - samples #5 and 7) was 10 ppm. This is similar to the 13 ppm measured during a complete cycle the previous day. Based on the samples collected during two complete sterilization cycles, the time weighted average exposure would be approximately 10 to 15 ppm which is well below the current criteria of 50 ppm for an eight hour day.

Separate samples were not collected for Freon-12. Freon-12 and ETO are present in the gas mixture at a ratio of 7.3 to 1. Using this ratio, the time weighted average for Freon-12 would be about 75 to 100 ppm when the ETO concentration was 10-15 ppm and about 400 ppm when the ETO concentration was 57 ppm. These concentrations are all less than the Freon-12 evaluation criteria of 1000 ppm.

2. Employee Interview Data

The three full time day shift workers were asked for their own perception of pre and post shift eye, nose, throat and skin irritation, and whether they were experiencing any dermatitis. The response to this question was negative. One employee with about five years of ETO exposure stated that her sense of taste is not very good any more.

F. Conclusions

It has been determined that employees who work in the anesthesia equipment room are not exposed to potentially toxic concentrations of ethylene oxide (ETO), a sterilant gas. This is based on sample results that showed ETO time weighted average (TWA) concentrations of 10-15 ppm and short term ETO concentrations of 38 and 57 ppm. These concentrations were less than the evaluation criteria of 50 ppm for an 8 hour TWA exposure and 75 ppm ceiling concentration for a 15 minute exposure. There was no indication of post shift irritation of the eyes, nose, throat or skin of the workers questioned. One employee did, however, indicate that her sense of taste has diminished during her five years in this job.

G. Recommendations

On the basis of this study the following recommendations are made:

1. The exhaust ventilation rate of the sterilizer closet to the outside of the building should be increased so that a constant negative pressure is maintained in the closet under all conditions. The most severe conditions are when the aerator is in operation, the sterilizer is in the purge portion of the cycle, the sterilizer door is opened, or when these conditions exist simultaneously.

2. The cabinet door (below the sterilizer door) should be modified to permit it to be in the closed position at all times. At present the ETO gas line runs through the opening thus preventing the door from closing.

3. The door of the sterilizer should be cracked open for several minutes after the sterilization cycle has ended, before the contents are unloaded.

4. The entrance to the area where ETO is used as a sterilant should be posted with signs indicating:

DANGER:
AUTHORIZED PERSONNEL ONLY
ETHYLENE OXIDE AREA
EXTREMELY FLAMMABLE GAS
MAY BE HARMFUL IF INHALED

5. Medical Surveillance

Medical surveillance should be made available to all persons subject to occupational exposure to ETO per NIOSH published literature (1)

a. Preplacement medical examinations should include at least:

1. Comprehensive medical and work histories with special emphasis directed to symptoms related to eyes, blood, lungs, liver, kidneys, nervous system, and skin.

2. A comprehensive physical examination, with particular emphasis given to pulmonary, neurologic, hepatic, renal, and ophthalmologic systems, and the skin.

3. A complete blood count to include at least a white cell count, a differential count, hemoglobin, and hematocrit.

4. In addition to the medical examination, employees should be counseled by the physician to ensure that each employee is aware that ETO has been shown to induce mutations in experimental animals. The relevancy of these findings in animals to male or female employees has not yet been determined. The findings do indicate, however, that employers and employees should do everything possible to minimize exposure to ETO.

b. Periodic examinations should be made available on an annual basis, and more frequently if indicated by professional medical judgment based on such factors as emergencies and the pre-existing health status of the employee. These examinations should include at least:

1. Interim medical and work histories.

2. A physical examination as described above for the preplacement examination.

V REFERENCES

1. NIOSH - Special Occupational Review with Control Recommendation - Use of Ethylene Oxide as a Sterilant in Medical Facilities. DHEW (NIOSH) Pub. #77-200.

2. Patty, Frank - Industrial Hygiene and Toxicology. Vol. II, Intersciences Publishers, N.Y., N.Y.

VI AUTHORSHIP AND ACKNOWLEDGEMENTS

Report prepared by

Arvin Apol
Industrial Hygienist
Region X
Seattle, Washington

Originating Office

Jerome P. Flesch, Chief
Hazard Evaluation and
Technical Assistance Branch
Cincinnati, Ohio

TABLE 1

ETHYLENE OXIDE (ETO) CONCENTRATIONS MEASURED
IN THE ANESTHESIA EQUIPMENT ROOM

	JOB OR LOCATION	SAMPLE NUMBER	DATE	TIME ON	TIME OFF	TOTAL TIME (min)	FLOW RATE cc/min	TOTAL VOLUME LITERS	ETO PPM
BZ	Employee conducted general work in room. Sterilizer not in operation.	1	3-6-78	7:40 a.m.	11:25 a.m.	225	23.4	5.27	<4*
BZ	Employee unloaded aerator, unloaded sterilizer (door was open for 2 hrs) Load sterilizer.	2	3-6-78	8:00 a.m.	8:15 a.m.	15	50.8	0.76	<29
GA	At schedule desk	3	3-6-78	11:35 a.m.	1:30 p.m.	55	50.8	2.79	<8
BZ	General working area. At 3:00 p.m. the sterilizer purged; was unloaded and loaded.	4	3-6-78	12:30 p.m.	3:40 p.m.	190	25.6	4.87	13
BZ	Sterilizer purged, unload and load sterilizer; worked around sterilizer and schedule desk.	5	3-7-78	1:15 p.m.	1:31 p.m.	16	96.8	1.55	57
GA	Between sterilizer and aerator 4 ft. above floor. Sterilizer purged and was loaded.	6	3-7-78	1:15 p.m.	1:31 p.m.	16	50.8	0.81	41
GA	At schedule desk	7	3-7-78	1:31 p.m.	4:05 p.m.	154	26.5	4.08	<6
BZ	Sterilizer purged; unloaded and loaded sterilizer. Employee worked around sterilizer and schedule desk.	8	3-7-78	4:05 p.m.	4:20 p.m.	15	96.8	1.45	38
GA	Same as #6	9	3-7-78	4:05 p.m.	4:20 p.m.	15	50.8	0.76	37

* Detectable limits - 0.04 mg/sample

Note 3-6-78 - light work load - TWA for Entire Shift was 8.1 ppm. During one sterilization cycle it was 13 ppm.
3-7-78 - Average during one sterilization cycle (load, sterilize, purge, unload) was 16-10 ppm. Short term exposure for 16 min of the cycle was 57 ppm.