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Ethylene Oxide Exposures in Hospitals

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Ethylene oxide (EtO) is used in hospitals as a sterilant of heat- and/or moisture-sensitive hospital supplies and surgical instruments. Comprehensive industrial hygiene surveys were conducted at 12 hospitals to characterize EtO exposure levels for workers in the sterilization areas. Hospitals included in the study were selected to represent a wide range of exposure situations as a result of various engineering controls, administrative controls, and work practices. Sampling results indicated that 8-hour time-weighted average (TWA) personal EtO exposure levels ranged from less than the limit of detection (LOD) of the method to 6.7 ppm, and short-term personal EtO exposures ranged from less than the LOD to 103 ppm. Based upon information regarding the degree of engineering controls and work practices employed, the hospitals were placed in one of four categories. The exposure results for each group of hospitals were compared with the criteria on engineering controls and work practices for that category. As expected, good engineering controls in conjunction with good work practices afforded the best reduction in exposure potential; short-term and long-term EtO exposures were not detectable. While both are effective, good engineering controls were found to be far more influential than good work practices alone in reducing EtO exposure levels. When compared to situations with poor work practices and no engineering controls, good work practices alone were found to effect a sizable reduction in exposure. Elliott, L.J.; Ringenburg, V.L.; Morelli-Schroth, P.; Halperin, W.E.; Herrick, R.F.: Ethylene Oxide Exposures in Hospitals. Appl. Ind. Hyg. 3:141–145; 1988.

Introduction

Ethylene oxide (EtO) is routinely used as a gaseous sterilant of steam- and heat-sensitive items in hospitals, in other health care facilities, and by many manufacturers of medical, dental, and health care products. Recently, the Occupational Safety and Health Administration (OSHA) estimated that EtO is used in 7,700 sterilizers in 6,300 hospitals in the United States.[1] The National Institute for Occupational Safety and Health (NIOSH) estimated in 1977 that more than 10,000 EtO sterilizers were used in various health care facilities and that approximately 75,000 workers were potentially exposed to EtO in those facilities.[2]

EtO has been shown to be a carcinogen and a mutagen in animal toxicity studies.[3,4] Health effects in humans that are suspected to be associated with occupational exposure to EtO include increased incidence of leukemia, adverse reproductive effects, and elevated mutagenic activity.[5,6] The potential for these health effects to occur in workers exposed to EtO prompted a change in exposure recommendations and regulations. The NIOSH recommended exposure limit (REL) for EtO consists of recommendations for an 8-hour time-weighted average (TWA) of less than 0.1 ppm and a short-term exposure limit (STEL) not to exceed 5 ppm.[7] OSHA revised its Permissible Exposure Limit (PEL) from 50 ppm of EtO to 1 ppm for an 8-hour TWA and set the action level at 0.5 ppm.[8] The American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Value (TLV) for EtO is 1 ppm as an 8-hour TWA.[9]

As a result of the concern regarding EtO's toxicity, as well as the paucity of exposure data for hospital workers, a study was initiated by NIOSH researchers to evaluate the occupational EtO exposure ranges of hospital workers. In-depth industrial hygiene surveys were conducted at twelve hospitals to characterize EtO exposures under various work practices and engineering controls. This paper analyzes the effectiveness of engineering controls and work practices on reducing EtO exposure in hospital sterilization areas.

Description of Hospitals Surveyed

A search was conducted to locate hospitals within 150 miles of Cincinnati that used EtO as a sterilant. From this area, 125 hospitals were surveyed by telephone to collect information regarding use of EtO. Seven hospitals were chosen to represent a wide range of engineering controls and work practices. Five additional hospitals, outside the Cincinnati regional area, were selected to broaden the range of possible exposure situations and reduce the potential for regional bias. The following information was obtained for each hospital in order to select those which would represent a wide spectrum of exposure scenarios:

- Size of hospital.
- Extent of EtO usage.
- Type and size of sterilization equipment.
- Areas of hospital where EtO sterilization occurs.
- Extent of engineering controls employed.
- Use of personal protection equipment.
- Number of workers involved in EtO sterilization.

The twelve hospitals selected varied in size (containing from 120 to 750 beds), location of sterilizer, and the size or number

TABLE I. Hospital Summary Information

Hospital	Size of Hospital (# of beds)	Location of EtO Sterilizers*	EtO Sterilizers	
			Number	Size (m^3)
A	450	CS	1	1.27
B	750	CS & RT	3	0.11, 0.34 & 0.85
C	650	RT	2	0.11
D	400	CS & RT	3	0.11, 0.34 & 0.85
E	350	RT & S	3	0.11, 0.85 & 0.85
F	400	CS	2	0.11 & 0.68
G	120	CS	1	0.06
H	240	CS	1	0.68
I	250	CS	2	0.25 & 0.68
J	150	CS & RT	2	0.06 & 0.11
K	150	CS	1	0.68
L	280	CS	1	1.27

*CS—Central Services or Central Supply; RT—Respiratory Therapy; S—Surgery.

of sterilizers utilized (Table I). The number of sterilization loads processed each week ranged from one to twenty for these hospitals. The variety of EtO sterilizers and aerators observed at these 12 hospitals was believed to be representative of the standard types found in hospitals; all known sterilizer manufacturers and a wide variety of sterilizer models were found in these hospitals. The EtO sterilizers and aerators were of two size ranges (Table I): the larger, 0.25 to 1.27 m^3 (9 to 45 ft^3) chambers, and the smaller, 0.06 to 0.11 m^3 (2 to 4 ft^3) units. The larger sterilizers were built-in (i.e., all but the front portion of the sterilizer was isolated in an adjoining mechanical access room) and used a gas mixture of 12 percent EtO/88 percent Freon 12® (dichlorodifluoromethane) which was supplied by gas cylinders. These chambers were loaded by cart and had water-sealed vacuum pumps which require drain systems through which water and EtO were released during the evacuation phase of the sterilization cycle. The smaller (table-top) sterilizers require no drain system, were hand loaded, and used either 100 percent EtO (contained in a small gas cartridge) or a mixture of 84 percent EtO/16 percent inert stabilizers (contained in a small glass ampule). For sterilizers using the 100 percent EtO cartridge, the cartridge was seated inside the chamber; the cartridge was automatically punctured after the sterilization cycle was started. For the process using an EtO ampule, the ampule was manually broken inside a plastic liner bag containing the items to be sterilized, excess air was squeezed from the liner bag, and the bag opening was twisted and closed with a wire tie. Following EtO sterilization (for all types and sizes of sterilizers), the sterilized items were usually transferred to an aeration chamber for 12 to 24 hours for removal of residual EtO. The aerators were approximately the same size as the EtO sterilizers.

One or more of these EtO sterilizers and aerators were found to be typically located in various areas of the hospitals. These areas included Central Supply or Central Services (CS), Respiratory Therapy (RT), and/or Surgery. In some hospitals, the EtO sterilizers and aerators were physically isolated within the CS, RT, or Surgery areas. From the 12 hospitals, 15 different sterilization areas were surveyed.

The existence and extent of engineering controls in these 12 hospitals ranged from very effective controls[10–12] to none. Local exhaust ventilation (LEV) controls included 1) an elaborate and highly effective push-pull system on the sterilizer doors, 2) properly (effective) and improperly (ineffective) installed LEV systems provided by sterilizer manufacturers, and 3) poorly designed and ineffective "homemade" LEV systems. Also, general room air ventilation systems for these hospitals were found to range widely in effectiveness for the control of EtO exposure.

The use of personal protective equipment in the hospitals surveyed was limited to various types of gloves. Primarily cotton gloves, and in some instances surgical gloves, were used to transfer sterilized items from the sterilizer to the aerator or to sterile storage. Respirators were not used in any of the hospitals surveyed or contacted.

The employees who worked in the sterilization areas were usually separated into two job title groups: 1) the sterilizer operators and 2) the folders and packers. The sterilizer operators' duties included loading, operating, and unloading both the EtO and steam sterilizers, transferring the EtO sterilized items from the EtO sterilizer to the EtO aerator, unloading the EtO aerator, and placing the sterilized items in the sterile storage area. At most facilities, the folders and packers rotated duties which included washing instruments and carts, folding linens, and wrapping/packaging the items to be sterilized. At some hospitals, the sterilizer operators and folders' and packers' duties overlapped or were rotated. The number of workers involved in these jobs ranged from two to twenty depending on the size of the hospital and the sterilization workload.

Survey Methods

Each hospital survey was two to three days in duration. Personal exposure sampling of all potentially EtO exposed workers on first, second, and/or third shifts was conducted. NIOSH Methods No. 1607 and/or No. 1614 were used to evaluate personal long-term TWA and short-term exposures in 15 sterilization areas at the 12 hospitals.[13] Method 1607 utilizes two sorbent tubes in series (400 mg and 200 mg, respectively) containing activated coconut shell charcoal. Method 1614 uses a single tube containing two sections (100 mg and 50 mg, respectively) of hydrobromic acid treated petroleum base charcoal. Samples from each method were analyzed for bromated derivatives by gas chromatography with electron capture detection. The limit of detection (LOD) for these methods ranged from 0.01 to 2.3 mg per sample. The LOD varied depending upon the method, sample volume, and/or laboratory conducting the analysis.

In addition, recognized work practices[11,12,14] and the existence, or lack, of effective engineering controls[10–12] which are known to influence EtO exposure potential were identified and noted for each hospital surveyed. The recognized major sources of EtO emission occur during the evacuation phase of the sterilization cycle, during the opening of the sterilizer door at completion of the cycle, and during the transfer of the sterilized load.[11] Engineering controls which have been shown to effectively reduce EtO exposure from these emission sources include LEV at the drain of the sterilizer, LEV above the sterilizer door, and additional vacuum purges to reduce the amount of EtO in the chamber and on the sterilized items.[11,12] Proper work practices which aid in reducing EtO exposure from these emission sources include vacating the sterilization area during the evacuation phase(s), cracking (no more than two inches at the unhinged side) the sterilizer door at the end of the cycle so that the LEV can effectively remove the hot EtO-laden air from the sterilizer while again leaving the sterilizer area for 15–20 minutes, and avoiding close contact with sterilized items which may be emitting EtO during the transfer process.[11,14]

The exposure sampling results for each hospital were compared with the summarized information on work practice and engineering control conditions found in that hospital and also

with the other hospitals surveyed.[15]

To determine if exposure potential was influenced by the existence of engineering controls and/or the utilization of proper work practices, the 12 hospitals were classified according to the degree of engineering controls and work practices employed. Prior to receiving the exposure monitoring results, each hospital was placed into one of four categories according to the following criteria:

Category I: Good engineering controls and good work practices.

Category II: Good engineering controls and poor work practices.

Category III: No engineering controls and good work practices.

Category IV: No engineering controls and poor work practices.

For purposes of this categorization, good engineering controls (as a minimum) consisted of functional LEV above the sterilizer door and at the drain and also adequate general dilution ventilation (> 10 air changes per hour). Improper functioning or the absence of these controls were considered as no engineering controls. Good work practices (as a minimum) consisted of vacating the sterilizer area during the exhaust cycle and door crack period, avoiding close contact with sterilized items, and fully maintaining the sterilizer door seals. The non-performance of these practices or practices which clearly increased exposure potential were considered poor work practices.

Results and Discussion

The arithmetic mean and range of personal 8-hour TWA EtO exposure sampling results for each hospital are shown in Figure 1. These results indicate the variety of full-shift exposures observed across the hospitals. TWA exposure levels ranged from non-detectable (ND) to 6.3 ppm for the sterilizer operators and ND to 6.7 ppm for the folders and packers. The arithmetic mean short-term personal EtO exposure results for each hospital are shown in Figure 2. These results depict a broad range of short-term exposure levels; short-term (2 to 30 minute) exposure levels for the sterilizer operators ranged from ND to 103 ppm. Upon comparing these results with the information in Table I, it appears that exposure potential was not directly influenced by the size of a hospital, location of the sterilizer(s), or the size or number of the sterilizers. For example, hospitals H, I, and L were approximately the same size, with sterilizers in similar locations, and yet mean exposure levels varied greatly across these three hospitals. Similarly, hospitals A and L had the same size sterilizer

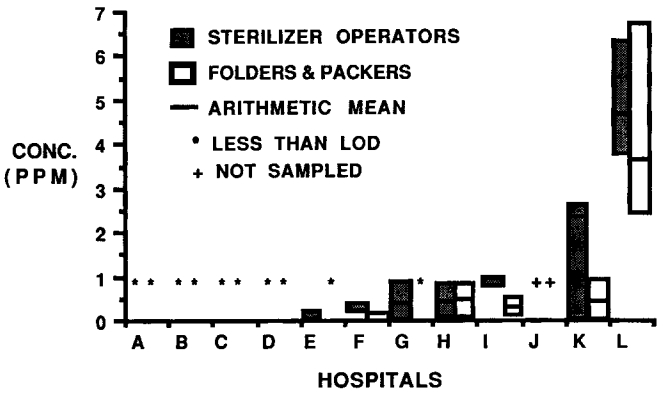

FIGURE 1. Personal 8-hour TWA ethylene oxide exposure by job and hospital (range/mean).

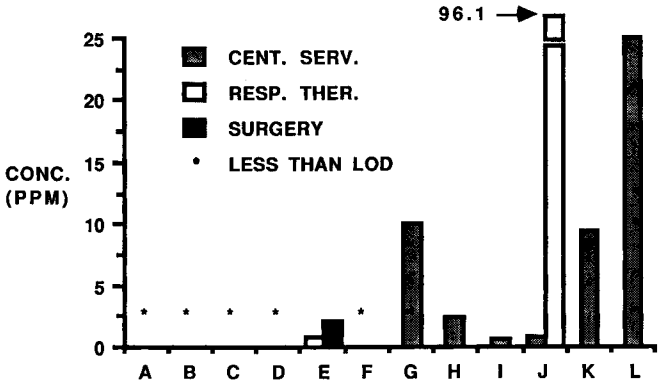

FIGURE 2. Mean personal short-term ethylene oxide exposure by area and hospital.

in the same area of the hospital, yet hospital A, with a larger sterilization workload, had non-detectable exposure levels compared to levels greater than 5 ppm for hospital L.

The effect of proper work practices and effective engineering controls on exposure potential is characterized in Figures 3 and 4. The range of exposure levels, arithmetic means, standard deviation, geometric means, and geometric standard deviation for each category is shown in Figure 3 for 8-hour TWA exposures and in Figure 4 for short-term exposures. While the data set is small, the 12 hospitals are believed to be representative of the broad range of conditions existing at the time of the surveys. Conditions in one hospital fit the criteria for Category I, five sterilization areas from four hospitals are represented in Category II, four hospitals are represented in Category III, and sterilization areas from five hospitals are represented in Category IV.

As expected, effective engineering controls and good work practice resulted in reducing EtO exposure to less than detectable levels while the lack of effective controls coupled with poor work practices resulted in unacceptable levels of EtO exposure. Detectable levels of EtO exposure also were found to exist for the given conditions of Categories II and III. Good engineering controls alone (Category II), however, were more influential than just good work practices (Category III) in lowering EtO exposure potential. An 84 percent difference in full-shift exposure and a 52 percent difference for short-term exposure were attributed to good engineering controls versus good work practices alone. It must be recognized that the short-term exposures shown in Figure 4 are the primary contribution to the full-shift exposures depicted in Figure 3. This is because the sterilizer operators, by nature of the procedure, must perform tasks which increase their potential for exposure. Thus, reducing exposure via LEV at the emission sources during the short time intervals when EtO can escape the sterilizer chamber directly into the breathing zone of the operator is more effective than the associated good work practices.

When comparing the exposure levels for Categories III and IV, it is evident that good work practices also result in an exposure reduction. A 69 percent difference in full-shift exposure (arithmetic means) and a 95 percent difference in short-term exposure were observed when good work practices were employed in the absence of engineering controls as compared with hospitals with poor work practices and no engineering controls. Only a 15 percent difference between these categories is observed for the full-shift exposure (Figure 3) when the geometric means are compared. Thus, the short-term exposure aspect is the most important factor to be considered when analyzing these data. The

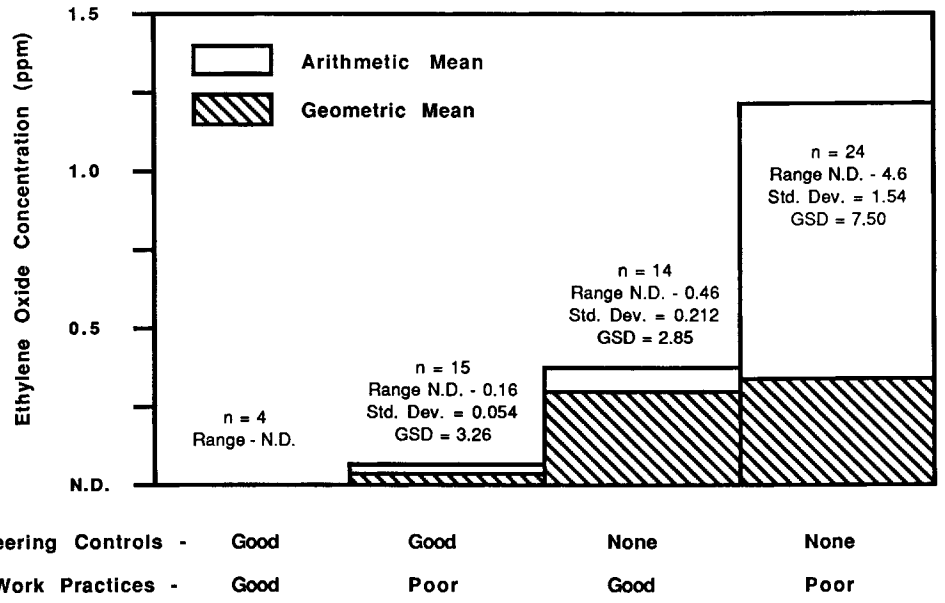

FIGURE 3. Mean 8-hour TWA ethylene oxide exposures associated with degree of engineering controls and work practices.

95 percent difference (92 percent based on geometric means) for the short-term exposure (Figure 4) in this case reflects the sterilizer operator's prudent practice of vacating the area during the exhaust cycle and avoiding close contact with sterilized items.

Conclusions/Recommendations

From industrial hygiene surveys of 15 EtO sterilization areas in 12 hospitals, based on the existence of engineering controls and observations of work practices, it is shown that engineering controls and/or good work practices can effectively reduce EtO exposure. Engineering controls are more effective than just good work practices in reducing exposure potential. Proper work practices, in the absence of good engineering controls, also were shown to effect a considerable reduction in EtO exposure. Effective engineering controls in conjunction with proper work practices afforded the best reduction in EtO exposure for hospital workers.

The obervations from these 12 hospitals are believed to represent the range of engineering controls, process parameters, equipment type, and a wide variety of work practices. It can not be determined from this sample which specific engineering control, work practice, or combination thereof was most influential in reducing exposure to EtO. Comprehensive industrial hygiene surveys designed to control specific variables would be required to make such determinations.

Engineering controls which collectively reduced EtO exposure included LEV above the sterilizer door, LEV at the sterilizer drain, good general area ventilation of the sterilizer room, and additional vacuum purges. Work practices which collectively aided in a reduction of EtO exposure included vacating the sterilizer room area during the exhaust cycle, opening the door 1–2 inches at the end of the cycle and again vacating the area to allow the EtO in air concentration to decrease, and limiting the amount of

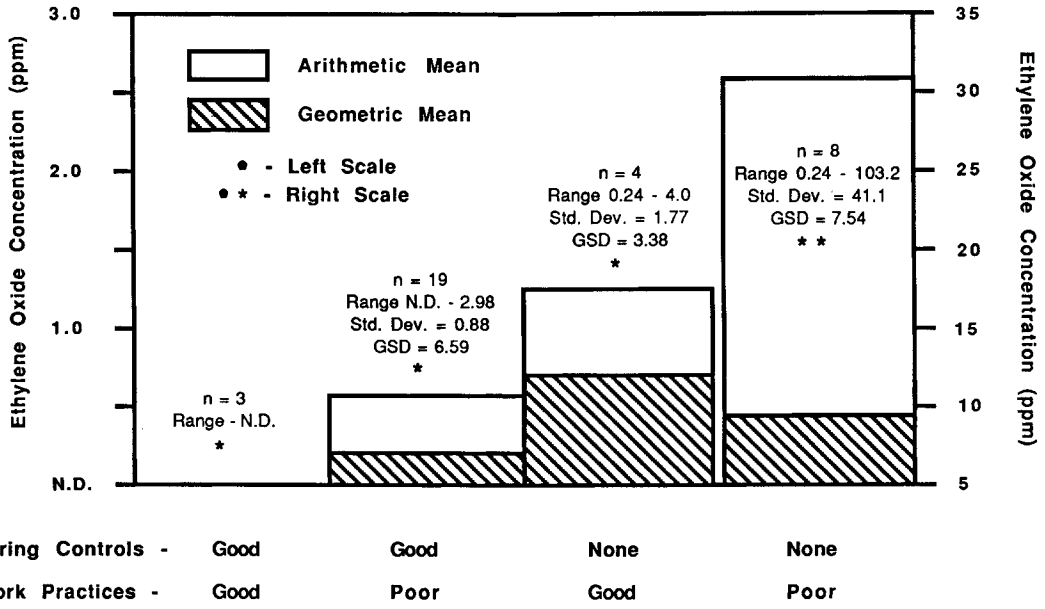

FIGURE 4. Short-term ethylene oxide exposures associated with degree of engineering controls and work practices.

time and close contact when handling the sterilized items.

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