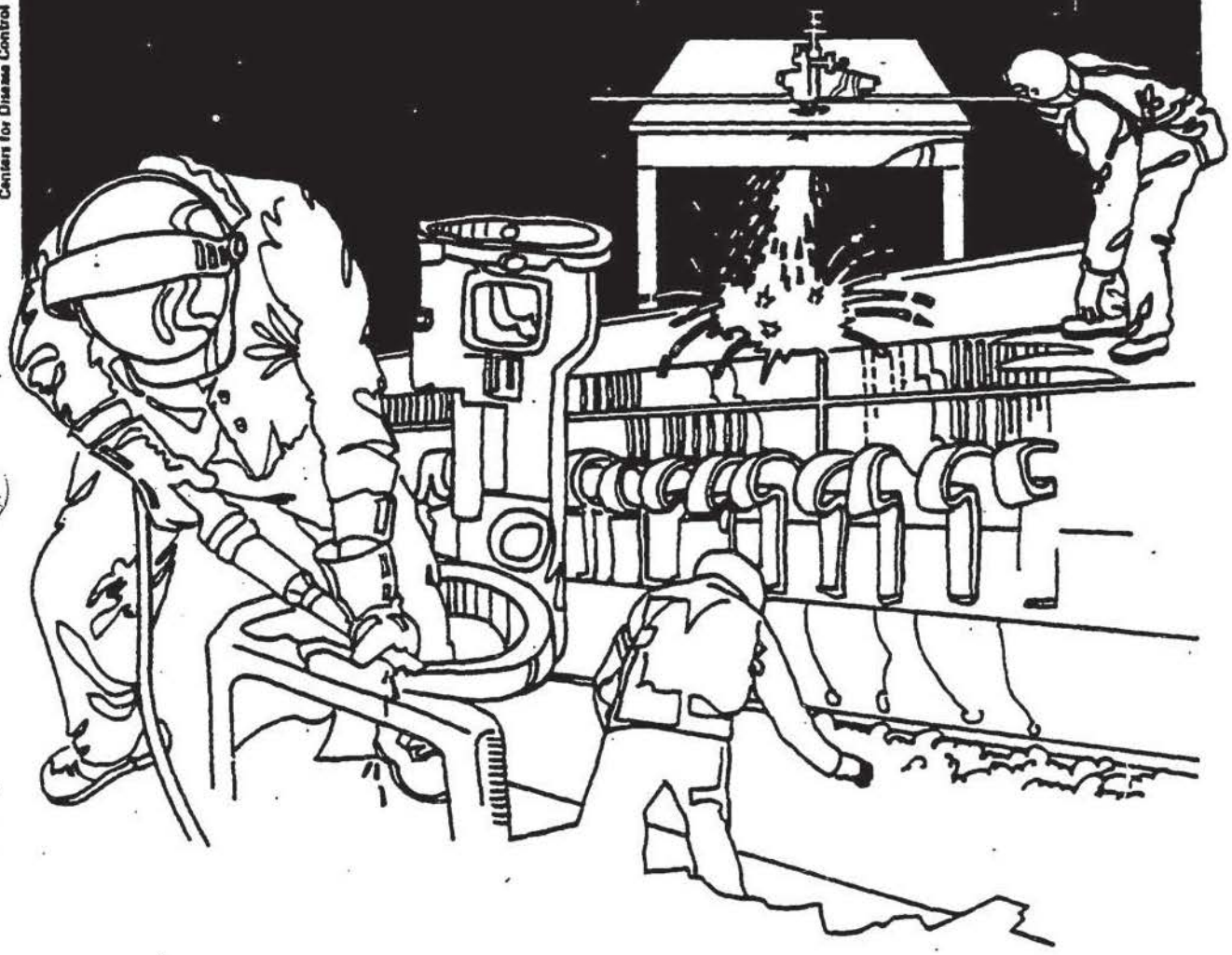
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health

NIOSH



Health Hazard Evaluation Report

HETA 83-335-1618
KENDALL COMPANY
AUGUSTA, GEORGIA

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following 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 Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

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NIOSH INVESTIGATORS
Paul Seligman, M.D.
Rick Gorman, C.I.H.

I. SUMMARY

On July 5, 1983, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate complaints of chronic headaches, skin problems, and equilibrium problems; a concern over an excessive number of miscarriages; and concern over diagnoses of peripheral neuropathy and cataracts as a result of exposure to ethylene oxide (EtO) among employees of the Kendall Company, Augusta, Georgia. The cases of neuropathy and cataracts were published in the medical literature in 1979 and 1982 respectively.[1,2] The Kendall Company uses ethylene oxide to sterilize hospital supplies.

On August 29-31, 1983, NIOSH conducted an initial visit to gather background information. Current and former employees of Kendall were interviewed, and meetings with physicians at the Medical College of Georgia who treated Kendall employees were held. A walk-through of the plant was conducted and plant monitoring data, sterilizer maintenance records, and individual employee medical records were reviewed. During the walk-through, extensive remodelling efforts were underway in the gas sterilization area. Engineering controls were being installed to reduce both local and plant-wide exposures to ethylene oxide, and to comply with the then proposed reduction of the Occupational Safety and Health Administration (OSHA) EtO standard to 1 ppm over an 8-hour time-weighted average (TWA).

On July 17, 1984, following completion of the engineering controls, NIOSH conducted a second walk-through to plan for a thorough industrial hygiene survey of the plant.

On August 7-8, 1984, peak exposure and longer-term exposure samples for EtO, both personal and area samples, were obtained. The EtO concentration in thirty-three air samples ranged from none detected (N.D.) to 0.83 ppm. All results were below the current OSHA standard of 1.0 ppm, but nineteen (57%) exceeded the NIOSH recommended limit of 0.1 ppm. Peak-exposure sample results, taken during sterilizer down-loading, ranged from 0.3 to 25.0 ppm. These were instantaneous grab samples; so therefore, it is estimated that short-term exposures were most likely below the NIOSH recommended limit of 5 ppm for no more than 10 minutes per work work-shift.

Medical interviews were conducted among 21 current employees. Eye irritation and neurologic symptoms were noted. However, with the permanent removal of EtO from the isopyl alcohol used in making alcohol wipes one month prior to the interviews, the majority of the 21 employees interviewed had noted a diminution or resolution of their symptoms.

A mortality study is currently being carried out by NIOSH researchers among EtO-exposed workers throughout the United States. The Kendall Company is participating in this study.

Based on interviews with current and former employees, and with physicians who treated Kendall employees, a cluster of cases of peripheral neuropathy and cataracts among sterilizer operators occurred at the Kendall Company probably related to intermittent high exposures to EtO from a leaking gas sterilizer in the mid- to late 1970's. EtO exposures are currently within the OSHA standard of 1 ppm over an 8-hour TWA as a result of the installation of extensive engineering controls and removal of EtO from certain product lines. Nineteen (57%) of 33 air samples exceeded the NIOSH recommended standard of 0.1 ppm over an 8-hour TWA. Recommendations are given in Section VIII to further reduce exposures to EtO.

KEYWORDS: SIC 3841 (Medical and Surgical Instruments), ethylene oxide, hospital supply sterilization, neuropathy, cataracts

II. INTRODUCTION

On July 5, 1983, NIOSH received a confidential request from employees of the Kendall Company, Augusta, Georgia to evaluate complaints of chronic headaches, skin problems, equilibrium problems, and a concern over an excessive number of miscarriages. In addition, physicians at the Medical College of Georgia had reported cases of peripheral neuropathy and cataracts related to EtO exposure among Kendall employees.

NIOSH investigators made an initial visit on August 29-31, 1983. A letter summarizing the activities during this visit was forwarded to the requestors and the company on September 26, 1983. A follow-up visit was made on July 17, 1984, to plan for an industrial hygiene survey of the plant. On August 7-8, 1984, an extensive industrial hygiene survey of the plant, involving air sampling throughout the building and short-term peak exposure monitoring in the sterilization area, was conducted. Results from this survey were forwarded by letter to all parties in March 1985.

III. BACKGROUND

The Augusta facility of the Kendall Company was constructed in 1968. At the time of our initial visit, there were 620 employees, 478 hourly, and 142 salaried employees. The company packages and sterilizes medical supplies, including alcohol wipes, gauze pads, surgical dressing supplies, urological kits, and spinal tap trays.

Ethylene oxide is currently used in two areas of the plant. Four large gas sterilizers use a mixture of 12% EtO and 88% CO_2 for sterilizing palletized prepackaged supplies. The fill and dip area uses a mixture of EtO in water to fill urologic catheters. Until July 1983, EtO was used in mixture with isopropyl alcohol (isopropanol) in the production of Webcol (alcohol) wipes. Irradiation sterilization has now replaced EtO as the means for sterilizing this product, thereby eliminating EtO as a potential exposure.

Other than EtO and isopropyl alcohol, other chemicals used at the plant are sodium hydroxide and other alkalis used in the bleaching of industrial rolls of cotton cloth in the production of gauze pads.

In 1977, four cases of ethylene oxide neurotoxicity were reported among employees exposed to a leaking EtO sterilizer in the gas sterilization area.[1] All four sterilizer operators were nondiabetic, nonalcoholic men, aged 27 to 31 years. One worker experienced an acute encephalopathy manifested by headache, vomiting, and lethargy, followed by recurrent major motor seizures. Peripheral sensorimotor polyneuropathy occurred in the remaining three workers, with the diagnoses documented by abnormal nerve conduction velocity (NCV) studies. Two of the three sterilizer operators with the peripheral neuropathy experienced symptoms including headaches, numbness at the tips of fingers and toes, limb weakness, increased fatigability, cramps, trouble with memory and thinking, and difficulty in swallowing liquids.

The worker with the acute encephalopathy recovered without permanent neurologic sequelae following cessation of EtO exposure. The neuropathies improved and abnormal nerve conduction studies returned to normal over a four-year follow-up period in the three workers with initial NCV abnormalities.[3]

Cataract formation was reported in 1982 in three of the four sterilizer operators who had previously developed EtO-induced polyneuropathy.[2] The age range of the three cases was 29-35 years, and they had no previous medical history suggestive of an increased risk of cataract formation.

IV. METHODS AND MATERIALS

A. Initial Survey (August 29-31, 1983)

Following separate opening conferences with employees on August 28th, and Kendall management and consultants on August 29th, a walk-through of the entire plant facility was conducted to obtain information on the normal operating procedures and to identify jobs with potential EtO exposure.

NIOSH investigators met with groups of employees on two shifts from the areas identified with potential EtO exposure. Individual medical interviews were conducted among 21 current and three former employees. Plant medical records of 32 employees were reviewed. Ten of the 32 medical records were from current or former sterilizer operators. OSHA 200 logs were reviewed from 1976 through 1982. Maintenance records for the gas sterilizing units were examined for the period 1976 through 1983. Past exposures to EtO were evaluated by reviewing environmental monitoring data provided by Kendall. Facility and process changes implemented to reduce EtO exposure from 1977 to 1983 were presented by Kendall management.

B. Follow-up Survey (August 7-8, 1984)

EtO exposures were measured on August 7-8, 1984, using (1) NIOSH Method No. 1607 to evaluate 8-hour, TWA exposures, and (2) a portable gas chromatograph to evaluate short-term exposures. Method 1607 involves the collection of EtO on coconut shell charcoal sorbent tubes and subsequent analysis by gas chromatography utilizing an electron capture detection system. A representative sample of air was drawn through the coconut shell charcoal tubes at a flow rate of 10 to 15 cubic centimeters per minute (cc/min) using battery-operated sampling pumps. Personal breathing zone (PBZ) samples were obtained from six workers on two days in a row by attaching the sorbent tubes to the workers' collars. These were the only workers who performed daily tasks that involved handling EtO-laden merchandise. Other workers' exposures were evaluated by placing EtO samplers in each

representative area of the plant on two consecutive days. For the average sampling rate and sample volume of this survey, the lower limit of detection for this method was 0.05 ppm.

Peak or short-term exposures, during the performance of specific tasks where EtO-laden merchandise was handled, were evaluated by collecting air samples in five-milliliter gas syringes for immediate analysis using a portable gas chromatograph set up in a nearby office area.

The Photovac® gas chromatograph (Photovac, Inc., Thornhill, Ontario, Canada) was equipped with a photoionization detector and a Carbopak BHT column 1/8" x 4'. At ambient temperature (70°F - 74°F), the retention time for ethylene oxide was 1.4 - 1.5 minutes with a carrier gas flow rate of 22 cc/min at 30 psig. Carrier gas was Ultra Zero Air (21% O_2, 79% N_2, Liquid Carbonic Corp., Chicago, Illinois). Standards for calibrating the gas chromatograph were prepared by metering a known amount of Ultra Zero Air into an aluminized Mylar bag (Calibrated Instruments, Inc., Ardsley, New York) and adding microliter quantities of pure ethylene oxide (Linde Specialty Gases, South Planfield, New Jersey) in amounts sufficient to produce a calibration curve in the range of interest. The normal lower limit of detection for this system is below 0.1 ppm, but due to the presence of an interfering peak on the chromatogram, the actual detection limit was 0.3 ppm for this survey. However, since this technique was used to monitor the peak, or highest exposures, this detection limit was satisfactory. The interfering peak was suspected of being isopropyl alcohol (IPA), but this was not confirmed.

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 (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 only 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.

NIOSH recommends that EtO be regarded as a potential human carcinogen.[4] NIOSH recommends that eight-hour time-weighted average exposure to EtO be less than 0.1 ppm and that short-term peak exposure not exceed 5 ppm for more than ten minutes per working day.

The Occupational Safety and Health Administration (OSHA) currently has a permissible exposure limit for occupational exposure to EtO of 1.0 ppm determined as an eight-hour time-weighted average concentration.[5] An "action level" of 0.5 ppm as an 8-hour time-weighted average is the level above which employers must initiate certain compliance activities such as periodic employee exposure monitoring and medical surveillance.[5]

VI. RESULTS

A. Medical

Plant medical records of 32 employees were reviewed. Of these 32 records, ten were for current or former sterilizer operators. The sterilizer operators had received annual or biannual neurological

examinations and electromyograms (EMG's) from July 1977 through June 1983, and an ophthalmological examination in 1980. The plant records were consistent with the three reported cases of peripheral neuropathy.[1] None of the remaining seven sterilizer operators had evidence on record of physical examination or EMG abnormalites.

The ophthalmological examination was also consistent with the four reported cases of cataracts.[2] Of the 12 sterilizer operators examined by an ophthalmologist in 1980, five were noted to have lens changes, four of whom were subsequently reported by Jay et al. as having cataracts. Review of the plant medical records and interviews with employees revealed two additional individuals who worked outside the sterilization area with the diagnosis of cataracts. However, due to the age of these two workers and their low exposures to EtO as compared with sterilizer operators, it appears less likely that their eye changes were the result of EtO exposure.

Interviews with 21 current and three former employees were conducted. Only results from current employees were compiled. Because EtO had been removed from the alcohol wipes the month prior to our initial visit, many of the symptoms included in the table below among the Webcol operators had improved or resolved.

The major work-related complaints are summarized in the following table. Although headaches and eye irritation were the most prominent effects, a proportion of workers interviewed did note neurologic symptoms including fatigue, numbness in the extremities, and dizzy spells. All the symptoms in the table were reported as occurring "often" by an individual worker.

PREVALENCE OF REPORTED SYMPTOMS
AMONG 21 WORKERS

Headache	48%
Eye irritation	33%
Fatigue	24%
Nausea/vomiting	24%
Dizzy spells	19%
Peripheral numbness	14%
Trouble with memory	10%
Paresthesias	10%

Interviews with selected employees identified six miscarriages among four female employees during the period 1977 through 1983. Based on the timing and intervening medical problems, however, five of the six miscarriages appeared not to be related to potential workplace exposures.

B. Environmental

1. Past Exposures

Prior to recent facility and process changes, which have significantly reduced EtO exposures, a large part of the Kendall plant was an open area with numerous point sources of EtO. The most significant sources were the large 4-6 pallet EtO sterilizers where hospital supplies were sterilized using an EtO and CO_2 gas (12% EtO and 88% CO_2), the WEBCOL and Wet Dressing areas where EtO gassed off from the sterilant solutions, and the sterile hold area where EtO was emitted from sterilized packages awaiting shipment. The CQA laboratory (small EtO gas sterilizer) and the "fill and dip" operation which used EtO solutions were also significant point sources of EtO.

Beginning in about 1977, a program was initiated to reduce EtO exposures through facility and process changes. The more significant of these changes are as follows:

1977-1981
- Installation of an air flush system in sterilizers to reduce the amount of released EtO residuals when the doors opened
- Installation of ventilation hoods above each sterilizer door to capture rising gas
- Installation of directional air fans to blow ambient air toward ventilation hoods
- Elimination of post sterilization bag sealing through the use of breathable Tyvek Header Bags
- Initiation of a hazardous material handling policy and check list for periods requiring manual handling of EtO
- Purchase of protection clothing for manual handling of EtO
- Installation of an automatic handling system for EtO eliminate manual handling

1981-1982
- Installation of positive pressure air respirators in the sterilizer area
- Increase in ventilation fans in sterile hold/quarantine
- Discontinuation of any post sterilization repalletization
- Expansion of sterile hold to increase rack capacity in order to foster better aeration

- Implementation of policy that prohibits any Q. A. testing of produce before 24 hours of aeration

- Construction of a separate Class 1, Division 1 building where EtO and alcohol are batched and piped to wet packaging machines

- Replacement of one sterilizer

1983

- Conversion from EtO autosterilization to irradiation sterilization on major produce line - WEBCOL

- Installation of fume hood over catheter filling and syringe filling operation (fill and dip)

- Elimination of EtO as autosterilant in wet dressings through a packaging material change

1984

- Isolation of sterilization area and installation of separate air system

- Construction of degas chambers for all sterilized product and Q. A. samples

- Isolation of sterile hold/quarantine with a separate air system

- Installation of octochrom monitoring system

- Employment of engineering consultant to evaluate sterilizer hardware/cycle for the purpose of reducing EtO

- Computerized sterilizer modernization program

Past EtO exposure data collected by Kendall or their consultants was provided and, in general, serves to characterize exposures between 1979 and 1984. Very little data were made available for the years 1969 through 1979; but, exposures during that period were probably similiar to those in 1979. Most of the personal breathing zone data collected by Kendall were obtained using 3M® passive monitors. Some data were collected using both portable gas chromatographs and charcoal tube methods.

Table 1 summarizes 8-hour TWA employee exposure data obtained from 1979 through May of 1984. All of this information was obtained through full-shift monitoring using 3M® passive dosimeters except for the 1979 data, which were obtained using charcoal tubes. The highest 8-hour TWA exposures were for those workers handling freshly sterilized product or EtO solutions and ranged from 10 ppm (gauze pad) to 31 ppm (sterilizer operator). From the data available, 8-hour TWA exposures to EtO during the years 1969 to 1982 were approximately as follows for the work area or job identified:

Job/Location	Estimated EtO - 8 Hour TWA (ppm)
Sterilizer Operators	30
WEBCOL Operators	22
"Fill and Dip" Operators	28
CQA Lab Technician	11
Production Areas Adjacent to EtO Sources	10
Peripheral Areas Separated by Walls	5
Front Office Area	5

For the time period 1969-1982 there are very little data available that addresses short-term or peak exposures. Data collected by a consultant in 1977 using bottle sampling kits and analyzed by gas chromatography documented air levels up to 170 ppm between two pallets of sterile stock (about 4" apart) 5 minutes after the pallets were unloaded from the sterilizer. This same technique documented concentrations up to 121 ppm in the breathing zone of the chemical mixer operator who was preparing an EtO solution. Also, a number of the workers interviewed by NIOSH reported that they could detect the odor of EtO during such tasks as removing a biological test strip from a freshly sterilized package and during EtO leaks in the sterilizer area. The odor threshold of EtO has been reported as 500 ppm (50% recognition).[6]

2. Current Exposures

a. 8-Hour TWA Exposures

On August 7 and 8, 1985, 33 air samples were obtained to evaluate the effectiveness of the recently implemented facility and process changes. Twelve of these air samples were breathing zone samples on those workers having the highest potential for EtO exposure. These included two sterilizer operators, a sterilizer maintenance operator, a fill and dip operator, a CQA technician, and a sterile hold operator. Each of these six workers was monitored two days in a row. Worker exposures in other areas of the plant were evaluated by obtaining area air samples in the center of each area such as the office, bleachery, and card room. These results are presented in Table 2.

All of the air samples were below 1.0 ppm (current OSHA standard), ranging from ND to 0.83 ppm. The sterilizer operators wore airline hoods while loading and unloading the sterilizers. The sorbent tubes were placed so they would be under the hood, so the exposures measured are representative of actual exposures on the survey dates. Nineteen (57%) air samples exceeded the NIOSH recommended standard of 0.1 ppm (8-hour TWA).

b. Short-Term (Peak) Exposures

Forty-nine air samples were collected in five-milliliter gas syringes during the performance of specific tasks on five separate sterilizer down-loading operations. All of the samples were collected near the breathing zone of the operator. The operator was wearing an airline hood while removing product from the sterilizers, so, unlike the long-term data, the peak EtO concentrations measured do not represent his actual exposure while in the hood.

The following table summarizes the peak concentrations which are presented in detail in Table 3.

Summary
Peak Concentrations During Sterilizer Down-Loading

Task	Number of Samples	ETO (ppm) Range	ETO (ppm) Average
In front of sterilizer before door opened	5	0.3-0.6	0.4
Opening door*	4	0.5-1.3	1.1
Remove 1st card*	5	0.3-1.0	0.7
Remove 2nd card*	5	1.0-15.8	6.1
Changing Rh sensor*	3	1.0-25.0	9.3
Tagging product**	6	2.6-17.6	7.5
Forklift (in reverse), with product	4	2.0-4.8	3.0
Load into degas chamber (lower level)	5	2.8-10.0	6.0
Load into degas chamber (upper level)	1	2.3	2.3
Front of sterilizer, door open, no product around	2	0.8-1.5	1.6

* Operator was wearing airline hood
** Operator wore airline hood some of the time but not always
The OSHA standard does not specify a short-term exposure criterion. NIOSH recommends that short-term EtO exposure be limited to 5 ppm in any 10-minute period. It is unlikely that this criterion would be exceeded under the conditions evaluated.

VII. DISCUSSION

The recently implemented plan to reduce or eliminate EtO exposure at the Kendall facility in Augusta, Georgia has significantly decreased exposure levels. This is illustrated by the following table, which compares 1977-1982 8-hour TWA exposure data with 1984 data for specific jobs.

EtO Exposure (ppm)

Job	1979-1982	1984	% Reduction
WEBCOL operator	22	0.2	99
Sterilizer operator	31	0.5	98
Fill & dip operator	28	<0.1*	>99
CQA technician	11	<0.1*	>99
Bleachery	4	ND**	100
Card room	4	<0.1*	>99
Office area	5	<0.1*	>99

* <0.1 means that the analysis found evidence of EtO above the lower level of detection but below a level that could confidently be quantitated. It is likely that if EtO was present it was at a concentration less than 0.1 ppm on the average.

** N.D. means not detected or below the limit of detection which for most samples was 0.05 ppm.

Standard control strategies such as substitution, engineering controls (isolation, local ventilation, etc.) and personal protective equipment (airline hoods) were all applied to eliminate and reduce EtO exposures. Kendall is now in a period where they are "fine-tuning" their control programs to further reduce exposures.

Subsequent to the initial report of Kendall workers with EtO-induced polyneuropathy,[1] five additional cases of peripheral neuropathy related to EtO exposure have been reported.[7,8] None of these reports contained measurements of either chronic or peak exposures to EtO. The observation that workers reported smelling the gas would indicate possible exposures at or above the EtO odor threshold of approximately 500 ppm.[6] The absence of measured exposure levels makes it difficult to determine whether high, intermittent exposures to EtO or lower, more chronic exposures were responsible for the development of neuropathy.

In an unpublished NIOSH study of primates exposed to 50 or 100 ppm of EtO over a two-year period, no abnormalites in electrophysiological tests were noted when compared with a non-exposed control group. No differences between control and EtO-exposed animals in the peripheral nerves were noted on neuropathologic examination.[9] This experimental observation tends to support the conclusion that higher exposure levels are needed in order to develop peripheral neuropathy.

The cases of cataracts reported among Kendall workers were the first reported association between EtO exposure and cataract formation. Products of reaction of EtO with aqueous solutions, in particular, 2-chloroethanol (ethylene chlorohydrin), have been tested on the eyes of rabbits and have been shown to produce cataracts with ocular injections of 10% solutions[10]. Toxic exposures described to cause cataracts in humans following systemic absorption include naphthalene[11] and dinitro-o-cresol.[12] EtO is a known mucous membrane and eye irritant.

In the NIOSH primate study,[9] exposures to 50 or 100 ppm of EtO over a two-year period resulted in a statistically significant dose-related association (p less than 0.02) between exposure to EtO and cataract formation (unpublished data - see Appendix A). A veterinary ophthalmologist, who was not aware of the exposure status of the monkeys, provided the post-exposure examination of the primates. No changes were reported in lid defects, conjunctivitis, corneal lesions, or retinal lesions between exposed and nonexposed primates. This observation supports the findings of cataracts in EtO-exposed workers.

Ethylene oxide is capable of causing damage to chromosomes of plant species, animal species, and man. It is toxic to the reproductive function in both males and females of several animal species producing decreases in litter size, fertility, and sperm counts, and causing a variety of birth defects. EtO is possibly toxic to human reproductive function having been associated with an increased frequency of spontaneous abortions in female members of a hospital sterilizing staff.[13] EtO is a proven animal carcinogen causing dose-related increases in the incidence of leukemia, peritoneal mesothelioma, and cerebral glioma.[14] There is limited evidence for the carcinogenicity of EtO in man.[15]

No safe level of exposure to carcinogens has been demonstrated for man. However, the probability of developing cancer is likely to be reduced through decreasing exposure. OSHA has conducted a quantitative risk assessment[5] based on data from the chronic inhalation bioassay study in Fisher 344 rats undertaken at the Bushy Run Research Center.[14] The assessment found that if 10,000 workers were exposed to EtO for a working lifetime at a dose of 1 ppm, then between 12 and 23 excess cancer deaths would be expected to occur. Even at an exposure to 0.1 ppm, mortality from excess cancer is not completely eliminated.

Because EtO is a potential human carcinogen, workplace exposures should be kept to a minimum in order to reduce the possible risk of cancer and other health effects. Whether EtO exposure leads to excess cancer is currently being addressed by a NIOSH study of hospital supply workers. EtO-handling procedures that caused medical problems in the recent past have now been corrected. Because of the lack of an apparent excess in adverse reproductive outcomes related to employment at Kendall, further investigation of this concern did not seem warranted. Adherence to the medical surveillance guidelines proposed in the OSHA standard,[5] with particular reference to neurologic and ophthalmologic examinations in sterilizer operators, should provide detection of any future adverse health effects related to EtO.

VIII. RECOMMENDATIONS

Substitution

1. Continue to search for alternative sterilization methods for the "Fill and Dip" Operation.

Engineering Controls

1. Closely evaluate the possibility of re-entry of EtO into the plant by placing samples in the supply plenums of the air handling systems.

2. If EtO is re-entering by this route alter the exhaust (usually raising the stack height) and evaluate the possible application of scrubbers or EtO recovery systems, if necessary.

3. Utilize a continuous monitor to study the "Fill and Dip" and CQA operation to determine if EtO is escaping the laboratory hoods. It may be necessary to supply makeup air at the face of the hood.

Respiratory Protection

1. Continue using the airline hoods when loading and unloading the sterilizers or when within 6 feet of the sterilized product.

2. Consider using the same airline hoods fed by a compressed breathing air tank during use of the forklifts. The air tank could be fastened to the forklift.

3. Closely evaluate the airline hoods and the air delivery system for possible EtO sources. More specifically check to insure that:

   a. the fabric of the hood is not absorbing and gassing off EtO.
   b. EtO is not re-entering at the outside air inlet on the side of the building.
   c. EtO is not leaking into the air delivery system on the negative side (upstream) of the pump.

4. Dismantle and launder the airline hoods periodically to minimize EtO buildup on the fabric.

Medical Surveillance

1. Comply with the OSHA recommendations for medical surveillance among employees exposed at or above the action level of 0.5 ppm for at least 30 days per year. This group currently includes the sterilizer operators. Medical surveillance should include medical histories and annual physical examinations with particular attention to the eye and neurologic portions of the examination.

2. Continue medical surveillance for former sterilizer operators who continue to be employed at Kendall.

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X. AUTHORSHIP AND ACKNOWLEDGEMENTS

Report Prepared By:

Paul Seligman, M.D.
Medical Officer
Medical Section

Richard Gorman
Assistant Section Chief
Industrial Hygiene Section

Originating Office:

Hazard Evaluations and Technical Assistance Branch
Division of Surveillance, Hazard Evaluations and Field Studies

Technical Assistance:

Raymond L. Ruhe
Industrial Hygienist
Industrial Hygiene Section

David Egilman, M.D.
Medical Officer
Medical Section

John Morawetz
Industrial Hygienist
Industry-Wide Studies Branch

Virginia Ringenberg
Industrial Hygienist
Industry-Wide Studies Branch

Report Typed By:

Julie Krafft

XI. DISTRIBUTION AND AVAILABILITY OF REPORT

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1. Confidential requestors
2. Kendall Company
3. United Paperworkers International Union
4. NIOSH Region IV
5. OSHA Region IV

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

Table 1

EtO Exposures (ppm)

Kendall Company
HETA 83-335

1977-1984

Location	1979	1982	Jan (83)	Aug (83)	Feb (84)	May (84)
WEBCOL	22	14	5	4	1	0.2
Wet dressing			3			ND
Card room		4	0.7	0.9	0.5	ND
Chem mix	16		3	6	0.4	0.2
Sponge area		12	2	4	1.5	0.1
Orbit seal		14		4	0.4	ND
Maintenance		10.5		3	1.4	0.2
Bleachery		4	1.7	0.5	0.6	<0.1
Kerlix		11	5	2	0.6	ND
Gauze pad	10		2	3	1.4	0.2
Tri-Paque	10		2	3	1.4	0.2
Troy seal		8	3	3	1.3	ND
Urological		9	2	3.5	2	0.2
Fill and dip	28	18	4	3	2.5	ND
CQA lab		11		5	3	0.2
Sterilizer	31	9	5	5	2	0.4
Sterile hold		3	4	2	2	ND
Front office		5	0.3	3	0.4	ND

Note: Data are representative of 8 hour TWA exposures and were obtained using 3M passive dosimeters except for the year 1979 data which was obtained using charcoal tubes. The data are averages of the low and high range for each sample period and are not true averages of all the samples obtained. ND means <0.08 meaning that if EtO was present it was <0.08 ppm.

Table 2

Ethylene Oxide (EtO)

Kendall Company
HETA 83-335

August 7-8, 1984

Location	Date	Sample Type	Sample Time	EtO Concentration (ppm)
Sterilizer Operator #1	8-7-84	Breathing Zone	0621-1430	0.48
	8-8-84	Breathing Zone	0620-1452	0.70
Sterilizer Operator #2	8-7-84	Breathing Zone	0621-1430	0.59
	8-8-84	Breathing Zone	0620-1440	0.50
Sterilizer Maintenance Operator	8-7-84	Breathing Zone	0753-1505	0.38
	8-8-84	Breathing Zone	0733-1454	0.70
Sterilizer Control Room	8-7-84	Area	0715-1525	0.22
	8-8-84	Area	0625-1445	0.30
Sterilizer Area Table Top Adjacent to but outside Control Room	8-7-84	Area	0715-1520	0.83
	8-8-84	Area	0625-1443	0.50
Sterilizer Area at Kendall Monitor #4	8-8-84	Area	0625-1435	0.5

(Continued)

Table 2 (Cont.)

Location	Date	Sample Type	Sample Time	EtO Concentration (ppm)
Sterilizer Area (on fork lift)	8-7-84	Area	0914-1645	0.5
	8-8-84	Area	0625-1435	0.6
Fill and Dip Operator	8-7-84	Breathing Zone	0745-1510	0.13
	8-8-84	Breathing Zone	0740-1513	(0.10)(1)
Urology (center post)	8-7-84	Area	0750-1620	0.13
	8-8-84	Area	0745-1555	(0.10)COA
Laboratory Tech.	8-7-84	Breathing Zone	0830-1615	(0.14)
	8-8-84	Breathing Zone	0805-1608	(0.20)
COA Laboratory, Bench Top	8-7-84	Area	0825-1648	0.13
	8-8-84	Area	0805-1610	0.20
Sterile Hold Operator	8-7-84	Breathing Zone	0810-1457	(0.08)
	8-8-84	Breathing Zone	0715-1500	0.2
Sterile Hold (center post)	8-7-84	Area	0850-note(3)	N.D.(3)
	8-8-84	Area	0642-1542	0.70
Main Production Area (center post)	8-7-84	Area	0838-1650	(.05)
	8-8-84	Area	0630-1540	0.10
Card Room (center post)	8-7-84	Area	0845-1649	N.D.(2)
	8-8-84	Area	0645-1550	(0.10)

Table 2 (Cont.)

Location	Date	Sample Type	Sample Time	EtO Concentration (ppm)
Bleachery (center post)	8-7-84	Area	0842-1649	N.D.
	8-8-84	Area	0650-1548	N.D.
Industrial Engineering Office	8-7-84	Area	0852-1650	(0.05)
	8-8-84	Area	0700-1558	(0.10)
Exposure Standards:	NIOSH			0.1 TWA 5.0 (10 min.)
	OSHA			1.0
	ACGIH			1.0

Note: (1): Values in parenthesis are between limit of detection (LOD) and limit of Quantitation (LOQ) and means there was a definite indication that the substance was present but not in quantity high enough to be confidently reported.

(2): ND means not detected or below the laboratory limit of detection which was 0.42 ug/sample. For the average sampling rate and sample volume this would mean that if EtO was present it was below 0.05 ppm.

(3): Pump stopped after 200 minutes.

Table 3

Peak EtO Concentrations*

Kendall Company
HETA 83-335

August 7-8, 1984

Time of Day	Task	EtO (ppm)
	Run #1 **Down-Loading Sterilizer #3**	
1038	Preparing to open sterilizer door	0.6
1043	Opening door	1.3
1044	Pulling out first pallet	1.0
1045	Reached in to get second pallet	13.3
1046	Positioning second pallet	3.3
1047	Entered sterilizer to change RH sensor	25.0
1049	Tagging product	5.0
1050	First pallet lifted with fork lift	2.0
1054	Load pallet into degas #1 (lower level)	4.0
1056	Lift first pallet, second cart	5.3
	Run #2 **Down-Loading Sterilizer #2**	
1246	Preparing to open sterilizer door	0.3
1247	Pulling out first cart	0.3
1247	Reached in to get second cart	15.8
1248	Tagging product	3.6
1250	Six feet from cart	3.0
1251	Forklift moving in reverse with product	4.8
1252	Forklift moving in reverse with product	2.8
1253	Load 3 of 6 pallets into degas #1 (lower)	10.0
1257	Lead last pallet into degas #1 (lower)	8.0
1258	Front of sterilizer, no product in area	0.8

Table 3 (Cont.)

Time of Day	Task	ETO (ppm)
	Run #3 Down-Loading Sterilizer #1	
0921	Preparing to open sterilizer door	0.5
0922	Opening door	2.0
0923	Pulling out first cart	1.0
0925	Pulling out second cart	2.0
0927	Tagging product, cart #2	17.6
0928	Half way between the two pallet carts	11.6
0930	Forklift in reverse, with product	2.0
0934	Load first pallet, degas #1, lower level	4.5
0937	Front sterilizer #1, door open, no product in area	1.5
	Run #4 Down-Loading Sterilizer #4	
1210	Preparing to open door	0.6
1213	Opening door	0.6
1215	Pulling out first cart	1.0
1215	Pulling out second cart	1.0
1216	Changing RH sensor	2.0
1217	Togging first cart	5.3
1217	Togging second cart	3.5
1218	Loading second pallet into degas #3 (lower)	2.8
1220	Loading last pallet into degas #3 (top)	2.3
1222	Front of sterilizer #4, no product in area	1.0
1223	Inside sterilizer, door opened	0.6
	Run #5 Down-Loading Sterilizer #3	
1212	Preparing to open door	0.3
1213	Opening door	0.5
1214	Pulling out cart #1	0.3
1215	Pulling out cart #2	1.0
1216	Changing Ph sensor	1.0
1217	Togging first pallet	2.6
1219	Between the 2 carts	3.0
1220	Forklift in reverse, with product	2.0
1221	Restacking boxes on pallet (boxes fell off)	3.3

* Sterilizer operator was wearing an air supplied hood when opening, closing or entering sterilizers.

APPENDIX A

OCULAR EXAMINATION OF MONKEYS EXPOSED TO ETHYLENE OXIDE AND PROPYLENE OXIDE

EXPOSURE	# examined	# with incipient cataract
NONE	7	0^{+}
EO_{50}*	7	2^{+}
EO_{100}*	7	4^{+}
PO_{100}**	7	1
PO_{300}**	7	0

*EO_{50} and EO_{100} refer to exposure to 50 ppm and 100 ppm of ethylene oxide over a 2-year period.

**PO_{100} and PO_{300} refer to exposure to 100 ppm and 300 ppm of propylene oxide over a 2-year period.

+ - p less than 0.2 using a 2 x 3 chi-square contingency table for ETO-exposed monkeys as compared with controls.