PB86225281

INDUSTRYWIDE STUDIES REPORT:
A WALK-THROUGH SURVEY

OF

KENDALL COMPANY
AUGUSTA FACILITY
P.O. Box 430
Augusta, Georgia 30913

DATE OF SURVEY:
February 1-2, 1984

SURVEY CONDUCTED BY:
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National Institute for Occupational Safety and Health
Centers for Disease Control
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A walk through survey was conducted at Kendall Company (SIC-3842), Augusta, Georgia in February, 1984. The purpose of the survey was to determine the feasibility of including the facility in a NIOSH industry wide mortality and industrial hygiene study of ethylene-oxide (75218). The company produced medical supplies such as gauze pads, sponges, cotton balls, and trays that were sterilized with ethylene-oxide. Fill and dip and chamber sterilization processes were utilized. The facility had approximately 620 employees, of which about 70 percent were female. A review of the personnel records showed that the facility could contribute 19,300 person/years to the NIOSH study. Company air monitoring data showed that all employees were potentially exposed to ethylene-oxide between 1968 and 1983. Starting in 1983, pre employment physical examinations were given. The authors conclude that the facility should be included in the NIOSH study. Recommendations include continuing the industrial hygiene monitoring program for ethylene-oxide, conducting investigations of the ventilation systems, and keeping bond openings in fill and dip operations free from obstruction by boxes and bags.

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PURPOSE:	To evaluate the industrial hygiene records, production processes, and personnel records to determine the suitability of including this facility in the NIOSH Industrywide Studies Branch mortality/industrial hygiene study of ethylene oxide (ETO).
EMPLOYERS REPRESENTATIVES CONTACTED:	Howard Morin, Plant Manager (404) 793-3030 Jeffry Dow, Attorney (617) 423-2000 Alexander Vongries, Medical Director (201) 878-7791 Dan Leonard, Training/Safety Supervisor (404) 793-3030
EMPLOYEE REPRESENTATIVE CONTACTED:	None
STANDARD INDUSTRIAL CLASSIFICATION OF PLANT:	3842 – Orthopedic, Prosthetic, and Surgical Appliances and Supplies

ABSTRACT

On February 1-2, 1984, a walk-through survey was conducted at Kendall Company (a subsidiary of Colgate-Palmolive) at their facility in Augusta, Georgia. The purpose of the survey was to evaluate industrial hygiene and personnel records, production processes, and current or historical use of ethylene oxide (ETO). This survey was conducted as part of an industrywide study of mortality associated with occupational exposure to ethylene oxide. Ethylene oxide has been used at this plant since its opening in 1968. Industrial hygiene data exists since 1977. Evaluation of the history of this facility indicated that all employees were potentially exposed to ETO since 1968. This plant meets all eligibility requirements for the study, and should be included.

INTRODUCTION

Ethylene oxide (ETO) is one of the 25 chemicals of highest production volume in the United States.[1] The major portion of ETO produced is used in the production of ethylene glycol (antifreeze) and as a chemical intermediate for polyester films, fibers, and bottles. A small fraction of ETO, less than 0.24%, has been used by the health care and medical supply industries over the past 35-40 years to sterilize heat-sensitive medical supplies.[1]

ETO, a colorless gas at standard temperature and pressure or a liquid at higher pressures, is miscible with water, ethanol, ether, and most common organic solvents. In addition, it is highly explosive when in concentrations of 3 to 100% (ETO) in air.[2] The biological warning properties are essentially useless since the (ether-like) odor threshold among individuals ranges from 300 to 1,500 parts per million (ppm) and adverse health effects may be elicited at levels much less than this.[3]

Due to the toxicity and possible carcinogenicity of ETO (see section on Toxicity), NIOSH researchers initiated an investigation in 1982 to assess the feasibility of conducting a cohort mortality study and industrial hygiene evaluation of workers exposed to ETO. Based on the data gathered during the feasibility study, it was concluded that the cohort of workers in the health care and medical supply industry, specifically those workers exposed to ETO in industrial sterilization processes, was the most adequate group to support a cohort mortality study.[4] This decision was supported by the findings of a 1977 survey conducted by National Institute for Occupational Safety and Health (NIOSH) researchers which showed that it is in this industry most of the employee exposures occur.[5,6] This survey estimated that approximately 75,000 health care workers were employed in ETO sterilization operations, with an additional 25,000 employees which may have incidental exposure resulting from inadequate engineering controls.[5,6] In order to develop and refine methods to be used for data collection and exposure classification of this selected cohort, a pilot study of six industrial sterilization facilities was initiated. The information gathered during the pilot study was incorporated into the final study protocol. This facility is part of the pilot study.

This walk-through survey was conducted to determine the suitability of including Kendall Company in the industrywide mortality and industrial hygiene study of workers potentially exposed to ETO in industrial sterilization processes. The suitability of including this facility was based on data gathered in this walk-through and is discussed in the Conclusion and Recommendation section. In addition, the data gathered during the walk-through survey will be used to develop, to the extent possible, estimates of exposure to ETO by department and/or job category, level and duration of continuous and peak exposures, and calendar year within this plant. These exposure estimates will then be compiled into an exposure matrix which will be used to determine the existence of a dose response relationship with any positive association observed in the mortality study.

The authority and responsibility for conducting and reporting on field studies in industry was given to NIOSH under the Occupational Safety and Health Act of 1970 (set forth by the 91st Congress, S.9123, Public Law 91-596). Section 20(a)7 states that NIOSH shall conduct and publish industrywide studies of the effects of chronic low level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in the aging adult.

DESCRIPTION OF FACILITY

The Augusta facility of Kendall Company opened in 1968. It produces a variety of medical supplies (gauze pads, sponges, preps, cotton balls, trays), almost all of which have been sterilized with ETO since the plant opened. There is a small amount of steam sterilization. Gas sterilization has been conducted with a mixture of carbon dioxide (CO_2) and ETO which has been produced on site. This facility originally had two 250 cubic foot sterilizers. However, between the years of 1971 and 1983, the two original EtO sterilizers were replaced and four other EtO sterilizers of various sizes and numbers were installed. A small EtO sterilizer was also purchased and installed in the Quality Assurance Laboratory.

In addition to gas sterilization, this facility has used liquid ETO-isopropyl alcohol solutions to sterilize alcohol preps (Webcol) and wet dressings since 1968. Also, an ETO-water solution was used to sterilize catheters and urological products since 1978. In 1982, the use of this ETO solution to sterilize alcohol preps and wet dressings was discontinued.

In the early 1980's, ETO use was several thousand pounds per year which was more than twice the yearly amount used in the early 1970's. The overwhelming majority of ETO was used in gas sterilization.

DESCRIPTION OF THE WORKFORCE

The Augusta facility employed approximately 620 employees in early 1984; about 140 of these were salaried. These employees were about 70% female, 30% male. They were about 40% black. Turnover is estimated at about 2% per month. There are three shifts.

DESCRIPTION OF PROCESS

Currently, there are two ETO processes at Kendall: fill and dip, and chamber (medical supply) sterilization. In the fill and dip process, urological catheters as well as syringes are manually filled with a solution of 0.45% ETO and distilled water. This process was started in 1978.

The chamber sterilization process is conducted under positive pressure in the production EtO sterilizers. In addition, the Kendall Augusta Central Quality Assurance Lab also has an ETO sterilizer. Initially, the product is preconditioned for several hours at an elevated temperature and humidity. Following the preconditioning phase, the sterilizer is loaded, the humidity is increased, the temperature is elevated, and the ETO/CO_2 mixture is added to the sterilizer. The product is then sterilized for several hours;

sterilizing time varies depending upon the absorption rate and capacity of the product. After the sterilization cycle is completed, the sterilizer is ventilated. By using a patented process (liquid/gas separator), a large majority of the ETO is recaptured and recirculated into a system where it can be reused. Once the recapture cycle is completed, air vacuums are applied to pull the residual ETO out of the product. An air flush is simultaneously activated in which air is forced to the back of the sterilizer where the exhaust duct is located. The product is then removed from the sterilizer and transported (pulled vs pushed) to an aeration chamber where it remains for several hours at an increased temperature and humidity. After the aeration cycle is completed, the sterilized product is warehoused, quality control (Q.C.) checked, and shipped.

DESCRIPTION OF PAST EXPOSURES AND CONTROLS USED

Kendall's use of ETO as a sterilant began in 1968. Initially, ETO was mixed in the plant with isopropyl alcohol in the Chem Mix Room for use in the Webcol area, and with carbon dioxide (CO_2) for use in the sterilizers. The ETO/alcohol mix was placed in a satellite tank near the gauze line where the tank lid was periodically opened to add more liquid ETO/alcohol mix. The mixture was fed from the tank into a trough and each gauze sponge was dipped into the troughed mixture and placed in a foil pouch, which was steam sealed. This ETO/alcohol line expanded from one machine in 1968 to several machines in 1978. There was no local ventilation on the ETO/alcohol line. ETO was also used in the Wet Dressing area where a mixture of 0.4-0.5% ETO and saline or water was manually added to packs of dressing material. The majority of ETO, however, was used in two 250 cubic foot (ft^3), two pallet ETO sterilizers purchased in 1968. At that time, the ETO barrels were stored in the plant and there was no local ventilation or personal protective equipment in use. In addition, a 0.45% EtO and sterile water mix was used to fill Foley catheters and syringes on the urological and fill and dip lines, respectively.

Between 1971 and 1973, additional sterilizers were purchased and the amount of ETO usage increased to several thousand pounds. However, the amount of ETO used decreased in 1974 and 1975. Also, the ETO barrels were no longer stored within the plant after 1975.

In 1976, an additional ETO sterilizer was purchased and the two original sterilizers were removed.

In 1977, the first accidental EtO sterilizer leak occurred. Fatigue cracks and leaks were identified at the openings between the inner and outer shells of one of the production sterilizers. Staybolts were installed and the ETO leaks were eliminated.

In 1977, a respirator program was started. From 1977 to 1980, half-face MSA organic vapor cannister respirators, limited to use in concentrations not exceeding 10 ppm, were worn by the sterilizer operators. In addition, the product was left in the sterilizer for several hours for off-gassing of ETO. A track was also installed on which the loads of product were pushed or pulled; however, sterilizer operators would sometimes have to enter the sterilizer. After the product was removed from the sterilizer, it sat in the sterilizer room for a short period of time.

In 1978, a fourth production ETO sterilizer was added, as well as a small EtO sterilizer for use by the Kendall Augusta Quality Assurance Lab. A few hundred pounds of ETO has been used in the smaller ETO sterilizer in any given year.

The ETO/sterile water mixture was batched (poured by hand into a lided cart) in the Webcol area. It was then wheeled through the plant to the Urological area where the fill and dip process is located. The cart was placed underneath the work bench and the mixture was siphoned through the top of the cart into the vicinity of the workers. Each worker stood at the work bench in front of a waste bin which held the excess ETO/water mixture. When full, the bins were emptied into an open bucket. Grab samples showed that atmospheric ETO levels ranged from 1,000 ppm inside the bin to 20 ppm one foot above the waste bin water level. The bins were not emptied until the water level attained an approximate height of four (4) inches. There was no local ventilation on the fill and dip lines.

A 1978 administrative issuance stated that workers were required to stand 1 foot from the waste bins. A line was also placed on each bin as an indicator that the bin was to be emptied.

In 1979, complaints of eye irritation and dry throat were common. In addition, a second accident occurred. A sterilizer door hinge bolt failed while the sterilizer was under positive pressure and the sterilizer door blew off. The front of the sterilizer and the sterilizer door had to be replaced. Also, the thermoforming room was enclosed with walls during 1979.

In 1980, a third accident occurred -- another door hinge bolt fractured which resulted in the sterilizer door sagging about two to three inches. There was no explosion because the sterilizer was at atmospheric pressure at the time of the fracture. The sterilizer door was subsequently repaired.

Two cases of blisters caused by skin exposure to ETO have occurred. A maintenance worker had blisters on the face and a contractor had blisters on his feet from ETO in his shoes.

During 1981, one of the EtO sterilizers was replaced with a larger sterilizer, and the amount of ETO usage increased. Ventilation hoods were installed above each sterilizer door; an air-flush system was installed in the sterilizers, and directional air fans were installed to blow ambient air towards the ventilation hoods. In addition, the half-face organic vapor cannister respirators were replaced with full-face MSA ETO cannister respirators limited to use in concentrations not exceeding 1000 ppm. Scott Air Pacs [self-contained breathing apparatus (SCBA)] were also purchased for use by maintenance workers and sterilizer cleaners who had to enter the sterilizer vessel for maintenance and cleaning purposes. In September 1981, the full-face MSA cannister respirators were replaced with positive pressure ambient air-supplied hood respirators.

Administrative issuances of policy in 1981 included the following: 1) a sterilizer operator was required to wear an air-line hood if he was within six (6) feet of hot (sterilized) product, 2) fork-lift trucks had to be driven backwards so that the flow of any ETO that had been emitted from the sterilized product would be directed away from the drivers breathing zone, 3) quality assurance (QA) testing of sterilized product before 24 hours of aeration was prohibited (24 hour rule) and, 4) a hazardous material handling policy and procedure check list was instituted. Personal protective clothing such as face shields, polyvinyl gloves, and aprons was used where EtO and alcohol were batched. This solution was piped to the wet packaging machines thus eliminating much of the manual handling of ETO.

Several changes were also made in the sterile hold area in 1981. First, the type of product stored in the sterile hold area was changed from a mixture of steam and ETO sterilized product to ETO chamber sterilized and Webcol (ETO sterilized) products only. Second, the number of ventilation fans was increased in the sterile hold/quarantine areas. Third, the sterile hold area was expanded and rack capacity was increased to improve aeration conditions for the ETO sterilized products.

Late in 1981, the warehouse was walled off so that any ETO emitted from the sterilized product could be better contained.

In June, 1982, a new chemical mixing room was built and put into use in December, 1982. Since that time, tanks of alcohol have been stored in this room, all ETO tanks were moved, and mixing of ETO and CO_2 for use in the chambers was conducted in a shed outside of the plant. Several thousand pounds of ETO were used in 1982 and 1983.

In 1983, the use of ETO was completely eliminated in the wet dressing packs as a result of a production change to retort sterilization (a dry process, the heat for sterilization comes from steam in the outer jacket of the sterilizer). Another production change eliminated the use of ETO in the Webcol/Alcohol Prep area. These products have been sterilized by gamma radiation since 1983 by an outside contractor. In addition, several other major construction changes began in 1983. These included: 1) isolation of both the sterilization and the sterile hold/quarantine areas, 2) installation of separate ventilation systems for both the sterilization and sterile hold/quarantine areas, 3) construction of aeration chambers for all sterilized products and Q.A. samples, 4) installation of a computerized sterilizer program, 5) installation of enclosure ventilation for the urological and fill and dip operations, 6) addition of water drains (which replaced the ETO/water waste bins) to the urological work bench, and 7) installation of lids and line feeds to the carts containing the ETO/water mixture used in the urologic/catheter filling operation. Other 1983 additions included installation of an automatic EtO monitoring system, purchase of a laminar flow hood for the Q.A. sterilizer, and employment of an engineering consultant to evaluate sterilizer hardware and cycles for the purpose of reducing ETO levels. As a result of a computerized sterilizer program, the sterilizer doors cannot be opened until the ETO levels inside the sterilizer have been substantially reduced by the air flush system. In case of an accidental ETO leak, the general room ventilation flow rate can be increased and the flow of ETO into the plant suspended.

During the latter part of 1983 and early 1984, Kendall converted from EtO autosterilization to irradiation sterilization on the major product (Webcol) line.

DESCRIPTION OF INDUSTRIAL HYGIENE, SAFETY, AND MEDICAL PROGRAMS

Industrial Hygiene

An industrial hygiene program was started at Kendall around 1977. During August, 1977, an evaluation of employee exposure to ETO was made by Liberty Mutual Insurance Company. Area sampling was conducted by collecting air in bottles with analysis by gas chromatography (GC). From 1979 to 1982, industrial hygiene monitoring was conducted by a consultant from the Georgia Institute of Technology. In 1979, personal and area 8-hour Time-Weighted Average (TWA) samples were collected with charcoal tubes. In 1981 and 1982, personal 8-hour TWA and short-term sampling was conducted with charcoal tubes, and area sampling was conducted with impingers containing a 0.1 normal solution of sulfuric acid. All samples were analyzed by GC. In 1982, Kendall personnel also conducted ETO sampling with 3M ETO gas diffusion badges. In January, 1983, an ETO survey was conducted by personnel from the Lexington Analytical Laboratory. Instantaneous area monitoring for ETO was conducted with a Century Portable GC; TWA area and personal sampling was conducted with 3M passive diffusion badges and Qazi-Ketchum charcoal tubes. Since then, Kendall personnel have conducted all ETO monitoring with 3M badges. Monitoring occurs twice a year depending upon changes in production and processing.

The various sampling media are analyzed by the Lexington Analytical Laboratory. In addition, continuous area sampling has been conducted with a multi-point Foxboro GC with flame-ionization detector (FID) since late 1983.

Ventilation flow rate checks have not been conducted by Kendall. However, a new ventilation system was installed in the sterilizer area in 1983 which increased the number of air changes per hour.

Safety

From 1977 to 1980, sterilizer operators wore MSA organic vapor cannisters which were adequate for ETO levels of 10 ppm. In 1981, these cannisters were replaced with MSA ETO cannisters which were adequate for ETO levels of 1000 ppm. In September, 1981, positive pressure air-supplied hood respirators replaced the cannister respirators. In addition, SBCAs were purchased in 1981. The SCBA's were worn by employees who entered the ETO sterilizers for cleaning and maintenance purposes. A respirator maintenance, cleaning, replacement, and fit-testing program was to be implemented in 1984.

Safety signs were posted throughout the plant.

Medical
A nurse is in charge of Kendall's Medical Department where records are stored. Pre-employment physicals have been required since 1983.

DESCRIPTION OF PERSONNEL RECORDS AND DEFINITION OF EXPOSED

(1) Description of personnel records

Personnel records have recently been microfiched. Currently all inactive hourly and salaried employees are on microfiche. There are approximately 2400 such records, arranged alphabetically. About 10% of these records pertain to salaried employees. In addition, the personnel records of active hourly employees (approximately 480 in early 1984), with the exception of their work history card, are also on fiche. Work history cards for these hourly employees are not added to the fiche until termination. Active salaried employees (approximately 140) have only hard copy personnel files.

Personnel records for all employees include a work history card which lists a department number and job description, as well as dates, for each job held at the plant. In addition, work history can also be reconstructed from other records in the personnel file, such as the application (listing job held at entry), attendance sheets (listing jobs each year), and termination notice (listing job at termination). The work history card also includes the relevant demographic information such as name, SSN, date-of-birth, and race. Hourly and salaried work histories can be differentiated.

The fiches appear to be complete. A sample of 50 hourly employees was checked, including both active and inactive, who were active in 1980 and identified via 1980 payroll records. All were located in the microfiche.

There are no alternative records identifying employees other than personnel records and payroll records. Payroll records are kept for only 5 years.

(2) Definition of exposed and results of sampling the personnel records

Industrial hygiene records and knowledge of sterilization practices historically indicate the exposure to ETO was essentially plant-wide throughout the history of this facility. Therefore all employees at the plant, past and present, are to be considered exposed.

A random sample of 116 inactive (hourly and salaried) workers was reviewed (about 5%), 25 active hourly workers (about 5%), and 10 active salaried workers (about 7%).

Sampling indicated that about 29% of the approximately 3020 employees who have ever worked at this facility were employed for less than 3 months. Therefore it is anticipated that approximately 2140 workers to qualify the mortality study. Seventy-four of these workers were female.

Nine percent of these individuals were first exposed after 1/1/78, and therefore would not qualify for the first phase of the mortality study. Among those who would qualify for the first phase of the study, based on the sample, the average date-of-birth was 1942, and their average first year of hire was 1972. Assuming that each of these employees would contribute about 10 person-years to the study, on the average, then this facility would be expected to contribute approximately 19,300 person years to the study.

TOXICITY

Evidence from animal studies suggests that ETO may have carcinogenic properties.[7,8] A group of ETO manufacturers sponsored a study at the Bushy Run Research Center in which male and female Fischer 344 rats were exposed to ETO at airborne concentrations of 10, 33, or 100 parts per million (ppm) for 6 hours per day, 5 days per week for two years.[7] Two other groups of animals served as controls. Initially, there were 120 animals of each sex, in each exposure group. The researchers observed a statistically significant increase in the incidence of mononuclear cell leukemia among the female rats, and peritoneal mesothelioma among the male rats exposed to ETO. The increase in leukemia incidence was found to increase linearly as a function of ETO exposure. An elevation in mortality from brain cancers (glial type) was also observed in the rats exposed to ETO.

NIOSH researchers have recently reported on the results from an animal experiment which corroborated the findings of the Bushy Run Study.[8] Male Fischer 344 rats were exposed to ETO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm. There were 80 rats in each exposure group. Increases in the incidence of mononuclear leukemia, peritoneal mesothelioma, and cerebral gliomas were observed among the ETO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of ETO.[9-11] Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that had previously been included in a hematologic investigation.[9] This facility produced ETO via the chlorohydrin process in which, in addition to ETO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloro-ethyl) ether. Among 89 "full-time" exposed workers, a statistically significant (p less than .01) excess of leukemia mortality was observed (2 observed versus 0.14 expected). In addition, a statistically significant (p less than .01) excess of stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to ETO; however, ethylene oxide and ethylene dichloride were the prime suspects.

Morgan, et al, conducted a retrospective cohort mortality study of workers involved in the production of ETO at a Texaco Facility.[10] A total of 850 workers were included in the study, of which 767 were potentially exposed to ETO. No ETO was detected in most samples taken in the production area, and all measurements in this area were below 10 ppm. No cases of leukemia were observed in this study; however, the authors estimated that the lowest relative risk that they had a high probability of detecting (80% power) was 10.5.

Hogstedt also reported on three cases of leukemia that occurred in a small group of workers at a Swedish company.[11] The company used a mixture of 50% ETO and 50% methyl formate to sterilize hospital equipment. The 8-hour TWA exposure for ETO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this cohort. One of the cases was exposed to benzene, a known leukemogen, and it was speculated that the combined exposure of ETO and methyl formate might produce a special risk.

ETO is also a potent alkylating agent capable of causing irreversible changes or mutations in cellular proteins and DNA in animals.[12,13] ETO is also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.[6]

Chromosomal aberrations related to ETO exposure have been observed in a number of animal studies and epidemiologic investigations.[8,13-20] Yager and Benz observed a dose related increase in sister chromatid exchanges (SCEs) among New Zealand white rabbits that were exposed via inhalation to 50 to 250 ppm of ETO.[14] NIOSH (Lynch, et al) recently reported preliminary findings in which cynomolgus monkeys were exposed to 0, 50, or 100 ppm of ETO for 7 hours per day, 5 days per week.[8] After 24 months of exposure, statistically significant increases were observed in the frequency of chromosomal aberrations (including quadriradial chromosomes) and SCEs in the peripheral lymphocytes of the 50 and 100 ppm exposed groups versus the controls.

Garry, et al, examined the occurrence of SCE in the peripheral lymphocytes of 12 ETO exposed workers and 12 nonexposed controls in a hospital sterilization facility.[15] The exposed group showed statistically significant elevations in the number of SCEs compared to the controls. Particularly high SCE frequencies were observed among 4 workers that had reported either neurologic or respiratory symptoms. The maximum peak exposure level of ETO measured at this facility was 36 ppm.

Cytogenetic abnormalities have also been observed in several studies of workers exposed to ETO. Ehrenberg, in a study of workers at a factory manufacturing and using ETO, observed a high frequency of chromosomal aberrations in 8 workers who were accidentally exposed to high concentrations of ETO. One case of leukemia was also observed among the 37 workers studied.[16]

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to ETO in the sterilization of medical devices in 1978.[17,18] Seventy-five exposed workers at 9 facilities were studied, as well as 37 nonexposed workers who served as controls. Compared to controls, exposed workers were found to have statistically significant increased frequencies of SCEs and chromosomal aberrations.

In response to the findings from the American Hospital Supply study, Johnson and Johnson initiated a cytogenetic study of workers that were also exposed to ETO in the sterilization of medical products.[19,20] Approximately 50 workers not exposed to ETO were compared to 50 exposed workers at three facilities with 8-hour Time-Weighted Average (TWA) exposures to ETO of less than 1 ppm, 1-10 ppm, and 25-200 ppm, respectively. Statistically significant elevations in SCE frequency were observed in the latter two facilities, and these changes have persisted after one year. The frequency of SCEs appeared to increase in a dose response manner. Chromosomal aberrations were also elevated in the high exposure groups; however, these findings were not statistically significant.

APPLICABLE STANDARDS AND RECOMMENDED LEVELS

Prior to June 22, 1984, the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for ETO was 50 ppm as a TWA concentration for an 8-hour workshift.[21] OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.[22] In addition, an "action level" of 0.5 ppm as an 8-hour TWA was established (by OSHA) as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. The Environmental Protection Agency (EPA) supported the OSHA PEL of 1 ppm in the Federal Register (June 22, 1984).[23]

In 1977, NIOSH recommended a ceiling level of 75 ppm as determined during a 15 minute sampling period.[6] This level, however, was set prior to the recognition of the carcinogenic potential of ETO. Based on recent findings, NIOSH recommends that ETO exposures not exceed 5 ppm for a maximum of 10 minutes per day and that exposures be controlled to less than 0.1 ppm determined as an 8-hour TWA (NIOSH Policy Statement, July 20, 1983). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a Threshold Limit Value (TLV) of 10 ppm for an 8-hour TWA based on data available prior to 1982.[24] However, in 1982, the ACGIH issued a notice of intended change in which it was proposed that the TWA concentration be lowered to 1 ppm. This recommendation was reviewed and adopted in 1984. ACGIH has also designated ETO as an A2 carcinogen.[24] 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 carcinogenesis in one or more animal species by appropriate methods.

DISCUSSION OF COMPANY MONITORING DATA

The results of the company ETO sample analyses, specific sampling location, type of sample and sampling media, and statistical analyses of the data (arithmetic and geometric means and standard deviation) are presented in Table I. Table II contains the plant controls implemented to reduce ETO exposure levels.

The data presented in Table I indicate that ETO was present throughout the work environment at this facility.

A variety of sampling media was used during the years that sampling was conducted at Kendall (1977-1984). In 1977, bottle sample kits and a GC were used to conduct area sampling in several departments.

In 1979, charcoal tubes were used as sampling media to conduct personal and area monitoring in several departments. Breakthrough of ETO into the back-up charcoal tube was noted during analysis of personal samples collected on the sterilizer operator, fill and dip operators, gauze pad machine operator, and an area sample collected in the fill and dip area. Therefore, these ETO sample results may be low. In 1981, charcoal tubes and impingers were used to conduct personal and area sampling, respectively. Breakthrough was again detected in ETO samples collected on the sterilizer operator, fill and dip operator, finished goods inspector, and Central Quality Assurance (CQA) laboratory technician. These sample results may also be low.

During 1982, personal ETO samples were collected with charcoal tubes and 3M badges or passive diffusion monitors; instantaneous area samples were collected with a Century portable GC.

In 1983, personal and area ETO sampling was conducted throughout the plant using Qazi-Ketchum charcoal tubes and 3M badges; additional area monitoring was conducted with a Century portable GC. During 1984, only personal sampling was conducted and 3M badges were the only sampling media used.

The highest ranges of ETO levels monitored in 1977 were 20 to 121 ppm (area grab samples) in the Webcol area and 9 to 170 ppm (area grab samples) in the sterilizer area. In 1979, three areas (sterilizer, Webcol, and fill and dip) had ETO personal sample results and one area sample result (fill and dip) ranging between 20 to 32 ppm (TWA). In 1981, the highest range of ETO levels was 13.4 to 18.0 ppm which was found on the batcher/retort operator only in the sterilizer area. During 1982, the highest ranges (short-term samples) of ETO were found on the sterilizer operator (18.5 to 46 ppm) and the batcher/retort operator (20.7 to 59.6 ppm). In 1983, the packaging (circle machine) and sterilizer areas had the highest ranges of ETO levels -- 2.1 to 13.5 and 1.1 to 15.7 ppm (TWAs), respectively.

In 1982, side-by-side sampling was conducted in order to compare the 3M badge and QK charcoal tube ETO sampling methods. Although some sample results varied considerably, Kendall reported that 70.6% of the sample result comparisons were favorable. Differences in values were small and ranged from 0.2 to 2.1 ppm.

The engineering and administrative controls instituted in 1981 and 1982 did help in reducing EtO levels throughout the plant. This was noted in the drop of personal 8-hour TWA results from a maximum of 31 ppm for the sterilizer operator in 1979 to 8.5 and 11.6 ppm, respectively, in 1981 and 1982.

After major construction changes, that started during the summer of 1983, were completed in 1984 (see Appendix, Table II, 1983), the EtO levels dropped dramatically. The sterilizer operator's EtO 8-hour TWA in the summer of 1983 was 5.9 ppm; in 1984, it was 0.8 ppm. The sterile hold material handler's EtO 8-hour TWA was 5.2 ppm in the summer of 1983; and 0.6 ppm in 1984.

These results show that isolation of the EtO sterilizers and use of proper ventilation and/or aeration techniques of the sterilizers, sterilized product, sterilizer room, and sterile hold room can reduce an employee's exposure to EtO below 1 ppm.

CONCLUSIONS

Personnel records appeared complete and included sufficient detail to determine dates of employment and work area. Past personal and area EtO monitoring results indicate that all employees at this facility were potentially exposed to EtO between 1968 and 1983.

Kendall has an abundance of industrial hygiene data dating back to 1977. Therefore, it may be possible to construct an exposure classification scheme for job categories.

Based on the findings of this report, this plant meets the three (3) eligibility requirements as defined in the protocol and therefore, should be included in the study. These requirements are 1) the plant must contribute at least 400 person-years to the study, 2) the plant must have adequate personnel records to identify past and present workers exposed to ETO, and 3) the plant must not have any serious confounding exposure to a known leukemogen.

INDUSTRIAL HYGIENE RECOMMENDATIONS

1. Continue the industrial hygiene monitoring program for ETO.

2. Conduct ventilation investigations to insure continued proper operation of the ventilation systems.

3. Keep hood openings (e.g. in fill and dip) free from obstruction by boxes and bags.

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ABBREVIATIONS KEY FOR TABLE I

1. A = Area sample
2. ST = Short-term sample (usually 15-20 minutes)
3. CT = Charcoal tube
4. QK = Qazi Ketchum (charcoal tube)
5. I = Impinger
6. P = Personal sample
7. TWA = 8-hour Time-Weighted Average
8. ASR = Air supplied respirator
9. BZ = Breathing zone
10. GC = Gas chromatograph
11. FID = Flame ionization detector
12. ppm = parts per million
13. Breakthrough = Overload of ETO on charcoal tube causing migration of ETO into the back-up section and possibly out of the charcoal tube
14. 3M = 3M Gas diffusion badge

TABLE I
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1977		Sterile Hold (Clerk)	A-BZ Grab Samples, Bottle Sample Kits & GC	6.0-22.0	3	15.0	13.1	2.0	Sterilized product in area
		Sterile Hold	A-Grab Samples, Bottle Sample Kits & GC	6.0-25.0	11	15.2	13.4	1.8	
		Sterilizer Area	A-Grab Samples, Bottle Sample Kits & GC	9.0-170.0	17	45.2	34.3	2.1	
		Webcol	A-BZ Grab Samples, Bottle Sample Kits & GC	20.0-121.0	6	47.5	36.6	2.1	
		Wet Dressing Packing Machine	A-BZ Grab Samples, Bottle Sample Kit & GC	22.0-24.0	2	23.0	---	---	Using dilute solution of ETO and H_2O
		Heat Sealer	A-BZ Grab Samples, Bottle Sample Kits & GC	1.0-39.0	3	15.3	6.2	6.2	
		Professional Products Area	A-BZ Grab Samples, Bottle Sample Kits & GC	1.0-43.0	2	22.0	---	---	Mixing ETO with H_2O in a tank
		General Manufacturing Area	A-Grab Samples, Bottle Sample Kits and GC	18.0-22.0	2	20.0	---	---	
		General Office Area	A-Grab Samples, Bottle Sample Kits & GC	7.0	2	7.0	---	---	

HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1979	36	Webcol Operator	$P-TWA_8$, CT	20.0-24.0	2	22.0	--	--	
		Batcher/Retort Operator	$P-TWA_8$, CT	16.0	1	16.0	--	--	
	34	Sterilizer Operator	$P-TWA_8$, CT	31.0*	1	31.0	--	--	
	34	Fill & Dip Operator	$P-TWA_8$, CT	25.0*-32.0*	2	28.5	--	--	
	75	Gauze Pad Machine Operator	$P-TWA_8$, CT	10.0*	1	10.0	--	--	
		Production Attendant	$P-TWA_8$, CT	16.0	1	16.0	--	--	
	34	Fill and Dip	$A-TWA_8$, CT	24.5*	1	24.5	--	--	
1981	36	Webcol Operator	$P-TWA_8$, CT	6.4-14.2	3	10.4	9.8	1.5	
		Batcher/Retort Operator	$P-TWA_8$, CT	13.4-18.0	2	15.7	--	--	
	34	Sterilizer Operator	$P-TWA_8$, CT	1.4*-8.5	3	5.7	4.4	2.7	
	34	Fill & Dip Operator	$P-TWA_8$, CT	6.2-14.5*	3	9.7	9.1	1.5	2 samples showed breakthrough
		Finished Goods Inspector	$P-TWA_8$, CT	2.2-9.1*	6	7.8	7.0	1.8	2 QA samples showed breakthrough
	QA/CQA	CQA Lab Tech	$P-TWA_8$, CT	8.1-9.1*	2	8.6	--	--	
	51-56	Sterile Hold Material Handler	$P-TWA_8$, CT	3.5	1	--	--	--	

*Breakthrough

TABLE 1 (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

ate	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{X}g$	Geometric Standard Deviation SDg	Comments
981	34	Sterilizer Area	A-TWA8, I	4.0	1	--	--	--	Impinger Solution 0.1N H_2SO_4
	51-56	Sterile Hold	A-TWA8, I	2.0	1	--	--	--	Impinger Solution 0.1N H_2SO_4
	36	Webcol Area Circle Machines	A-TWA8 I	0.6	1	--	--	--	Impinger Solution 0.1N H_2SO_4
	QA/ CQA	CQA Lab	A-TWA8 I	0.8	1	--	--	--	Impinger Solution 0.1N H_2SO_4
982 inter	36	Retort Operator	P-TWA CT	9.6	1	--	--	--	
	34	Steam Sterilizer	P-TWA CT	5.6	1	--	--	--	Sample pulled out of holder for short period of time
	34	Fill & Dip Operator	P-TWA, CT	9.4	1	--	--	--	
	QA/ CQA	CQA Lab Tech.	P-TWA, CT	9.2*	1	--	--	--	
	QA/ CQA	CQA Plastronics Inspector	P-TWA, CT	8.3*	1	--	--	--	
982 ummer	36	Batch Retort Operators	P-TWA QK-CT	3.5-13.8	3	10.0	8.5	2.2	
			P-TWA, 3M	10.5-15.0	3	12.7	12.6	1.2	
			P-STEL, QK-CT	20.7-59.6	3	35.3	31.6	1.7	

Breakthrough

TABLE I (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{X}g$	Geometric Standard Deviation SDg	Comments
1982 Summer	34	Fill & Dip Operator	P-TWA, 3M	18.0	1	--	--	--	
			P-STEL, QK-CT	16.8-23.5	2	20.2	--	--	
	34	Urological Packer & Supervisor	P-TWA, QK-CT	5.8-9.4	4	7.2	7.0	1.2	
	34	Urological Packer & Supervisor	P-TWA, 3M	9.2	1	--	--	--	
	34	ETO Sterilizer operator	P-TWA, CT	9.0	1	--	--	--	
			P-TWA, 3M	9.4-11.6	3	10.8	10.8	1.1	
			P-STEL, CT	18.5-46.0	3	28.8	26.5	1.6	Outside ASR
				1.5-8.3	3	4.6	3.7	2.4	Inside ASR
				2.3-2.5	2	--	--	--	With ASR
		Steam Room Operator	P-TWA, CT	8.2	1	--	--	--	
			P-TWA, 3M	9.4	1	--	--	--	
	QA/ CQA	QA Technician	P-STEL, QK-CT	12.1	1	--	--	--	
		CQA Lab. Tech	P-TWA, QK-CT	9.4	1	--	--	--	
			P-TWA, 3M	11.0	1	--	--	--	
	QA/ CQA	Finished Goods Inspector	P-TWA, 3M	2.6-11.3	5	7.4	6.7	1.7	
			P-TWA, QK-CT	8.6	1	--	--	--	
			P-STEL, 3M	2.9	1	--	--	--	With ASR
			P-STEL, QK-CT	14.0-14.7	2	14.4	--	--	
	QA/ CQA	Chemist	P-TWA, 3M	3.0-7.7	2	5.4	--	--	
			P-STEL, 3M	2.3	1	--	--	--	With ASR
	33	Sponge Machine Operator	P-TWA, QK-CT	8.9-13.8	4	11.3	5.5	1.2	
			P-TWA, 3M	8.3-14.9	4	11.0	10.7	1.3	

TABLE I (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{X}g$	Geometric Standard Deviation SDg	Comments
1982 Summer		Other	P-TWA, QK-CT	9.9-10.5	2	14.1	--	--	
			P-TWA, 3M	7.2-11.6	3	9.9	9.7	1.3	
	75	Orbit Seal	P-TWA, QK-CT	13.6	1	--	--	--	
		Orbit & Hot Seal	P-TWA, 3M	8.3-13.8	2	11.1	--	--	
	51-56	Warehouse Material Handler	P-TWA, QK-CT	12.4	1	--	--	--	
			P-TWA, 3M	3.5	1	--	--	--	
	98	Maintenance	P-TWA, QK-CT	14.4	1	--	--	--	
			P-TWA, 3M	10.5	1	--	--	--	
	83	Office Personnel	P-TWA, 3M	3.8-6.1	3	4.6	4.5	1.3	
	34	Sterilizer Area	A-In, GC	2.0-10.0	2	6.0	--	--	No freshly sterilized product in area
			A-In, GC	30.0-36.0	3	32.0	31.9	1.1	Freshly sterilized product in area
	34	Urological Area	A-In, GC	8.0-9.0	2	8.5	--	--	Fill & dip & packing
	51-56	Warehouse Area	A-In, GC	ND-1.0	2	0.5	--	--	In/near main isle between sterile hold & warehouse
	98	Maintenance	A-In, GC	7.0	1	--	--	--	
		Main Penthouse	A-In, GC	10.0	1	--	--	--	Roof top
		Card Room Penthouse	A-In, GC	1.0	1	--	--	--	Roof top
	34	Main Isle	A-In, GC	3.0	1	--	--	--	Entering plant by Urological room
	33	Sponge Mfg.	A-In, GC	15.0-24.0	3	20.3	19.9	1.3	

TABLE 1 (Continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1983 Winter	34	Fill & Dip	P-TWA, 3M (1)	2.1	1	--	--	--	
			(2)	5.8	1	--	--	--	
	34	Urological Operator	P-TWA, 3M (1)	1.4-2.0	2	1.7	--	--	
	34	Urological Operator	$P\text{-}TWA_8$ (2) 3M	2.7-3.3	2	3.0	--	--	
	36	Chem Mix Room Operator	$P\text{-}TWA_8$ (1)	1.5	1	--	--	--	
			3M (2)	4.7	1	--	--	--	
	75	Circle machine Operator	$P\text{-}TWA_8$ (1)	2.8-5.5	2	4.2	--	--	
			(2)	6.4-8.2	2	7.3			
	36	Wet Packaging	$P\text{-}TWA_8$ 3M	2.8	1	--	--	--	Away from work station 45 minutes
	33	Sponge Mach. Operator	$P\text{-}TWA_8$ (1)	1.1	2	1.1	--	--	
			3M (2)	2.5-3.7	3	3.0	2.9	1.2	
	75	Packaging Operator	$P\text{-}TWA_8$ (1)	2.2-2.6	2	2.4	--	--	
			3M (2)	4.6-5.3	2	5.0	--	--	
	33	Tripaque	$P\text{-}TWA_8$ (1)	1.5-1.7	2	1.6	--	--	
			3M (2)	3.4-4.7	2	4.1	--	--	
	32	Tenter/Card	$P\text{-}TWA_8$ (1)	0.6-0.8	2	0.7	--	--	
			3M (2)	0.8-1.5	2	1.2	--	--	

(1) = 1st shift
(2) = 2nd shift
(3) = 3rd shift

TABLE I (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1983									
Winter	34	ETO Sterilizer	P-TWA (1)	7.0	1	--	--	--	
		Operator	3M (2)	6.1	1	--	--	--	
	34	Steam Sterilizer	P-TWA (1)	2.9	1	--	--	--	
		Operator	3M (2)	5.0	.1	--	--	--	
	51-56	Sterile Hold	P-TWA (1)	5.2	1	--	--	--	
		Operator	3M (2)	3.0	1	--	--	--	
	QA &	QA Test Lab	P-TWA (1)	2.6	1	--	--	--	
	CQA		3M (2)	3.3	1	--	--	--	
	83	Front Office	P-TWA (1)	0.3	1	--	--	--	
			3M						
		Canteen	A-TWA (1)	0.3	1	--	--	--	
			QK-CT (2)	0.8	1	--	--	--	
	36	Chem Mix Area	A-TWA, QK-CT	1.3-7.3	5	3.7	3.1	2.0	
	36	Wet Dressing Sealer	A-TWA, QK-CT	4.0	1	--	--	--	
	75	Circle Machine	A-TWA, QK-CT	2.1-13.5	8	8.0	6.7	2.0	
	32	Card Room	A-TWA, QK-CT	0.5	1	--	--	--	
	33	Sponge Machine Area	A-TWA, QK-CT	1.1	1	--	--	--	

1) = 1st shift
2) = 2nd shift
3) = 3rd shift

TABLE [illegible] (Continued)

HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1983 Winter	75	Orbit Seal	A-TWA, QK-CT	1.2	1	--	--	--	
	75	Tray Seal Area	A-TWA, QK-CT	0.2	1	--	--	--	
	32/33	Aisle	A-TWA, QK-CT	4.9	1	--	--	--	Between Kerlix & Sponge Areas
	34	Sterilizer area	A-TWA, QK-CT	6.6-1.07	4	8.6	8.4	1.3	
	34	Sterilizer area	A-TWA, 3M	1.1-15.7	5	5.3	3.3	2.8	
	36	Webcol	A-TWA, 3M	5.8	1	--	--	--	
	36/33	Aisle	A-TWA, 3M	2.0	1	--	--	--	
	QA/CQA	Lab	A-TWA, 3M	1.4	1	--	--	--	
		Entrance & Aisles	A-TWA, 3M	0.2-1.9	5	1.0	0.7	2.4	
	33	Tripaque	A-TWA, 3M	1.1	2	1.1	--	--	
	83	Front Office	A-TWA, 3M	0.2	1	--	--	--	
	51-56	Sterile Hold	A-TWA, QK-CT						
			A-TWA, 3M	1.8-3.3	2	2.6	--	--	
	36	Webcol	A-TWA, GC	3.0	1	--	--	--	
	36	Chem Mix Room	A-TWA, GC	2.0	1	--	--	--	
	75	Circle Machine	A-TWA, GC	5.0-12.0	5	8.6	8.3	1.4	
	32/33	Aisle	A-TWA, GC	4.0	1	--	--	--	Between Kerlix & Sponge Areas
	33	Tripaque	A-TWA, GC	3.0	1	--	--	--	

(1) = 1st shift
(2) = 2nd shift
(3) = 3rd shift

TABLE 1 (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
	34	Sterilizer Area	A-TWA, GC	3.0-8.0	3	5.0	4.6	1.7	
	51-56	Sterile Hold	A-TWA, GC	1.0-5.0	3	2.0	0.6	10.4	
1983 Winter	QA/CQA	Lab	A-TWA, GC	0.3-3.0	2	1.7	--	--	
		Canteen	A-TWA, GC	0.3	1	--	--	--	
	83	Front Office	A-TWA, GC	0.5	1	--	--	--	
1983 Summer	34	ETO Sterilizer Operator	P-TWA (1 & 2) 3M	5.1-5.9	2	5.5	--	--	
			P-TWA (3) QK-CT	2.0-8.3	3	5.3	4.6	2.1	
	34	Fill and Dip	P-TWA (1 & 2) 3M	2.6-3.1	2	2.9	--	--	
		All other	P-TWA (1 & 2) 3M	2.3-5.0	11	3.4	3.3	1.2	
	75	Packaging Operators	P-TWA (1 & 2) 3M	2.6-4.6	8	3.4	3.3	1.2	
	QA/CQA	QA & CQA Lab Techs	P-TWA (1 & 2) 3M	1.2-5.1	7	3.7	3.2	1.8	
			P-TWA (3) QK-CT	1.2	1	--	--	--	

(1) = 1st shift
(2) = 2nd shift
(3) = 3rd shift

TABLE I (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1983 Summer	75	Packaging Operators	P-TWA (3) QK-CT	3.6-5.6	3	4.4	4.3	1.3	
	33	Tripaque/Sponge	P-TWA (1 & 2) 3M	2.4-5.1	18	3.6	3.5	1.2	
			P-TWA (3) QK-CT	1.5-5.9	7	3.7	3.3	1.6	
	32	Bleachery/Card	P-TWA (1 & 2) 3M	0.2-1.3	6	0.8	0.7	1.9	
			P-TWA, QK-CT	0.2-0.8	3	0.5	0.4	2.0	
	36	Batcher Operator	P-TWA (1 & 2) 3M	2.2-10.9	2	6.6	--	--	
			P-TWA (3) QK-CT	3.3	1	--	--	--	
	36	Webcol Operator	P-TWA (1 & 2) 3M	2.6-7.2	6	3.8	3.5	1.5	
			P-TWA (3) QK-CT	0.7-4.5	4	2.7	2.2	2.2	
		Other Operators	P-TWA (1 & 2) 3M	2.1-3.4	4	2.8	2.8	1.2	
	51-56	Sterile Hold	P-TWA (1 & 2) 3M	1.1-2.5	2	1.8	--	--	
		Ster. Maintenance	P-TWA (1) 3M	6.1	1	--	--	--	

(1) = 1st shift
(2) = 2nd shift
(3) = 3rd shift

TABLE I (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1983 Summer		Other	P-TWA (1 & 2) 3M	2.1-3.5	2	2.8	--	--	
			P-TWA (3) QK-CT	3.8	1	--	--	--	
		Sears Warehouse	P-TWA (1) 3M	1.2-2.5	3	2.0	1.9	1.5	
	83	Secretary	P-TWA (1) 3M	2.7	1	--	--	--	
	QA/CQA	QA/CQA Lab Techs.	P-TWA (1)	0.1- 0.3	4	0.1	0.1	2.8	
			3M (2 & 3)	0.1	3	0.1	--	--	
1984 Summer	34	ETO Ster. Oper.	P-TWA (1)	0.3-0.8	2	0.6	--	--	
			3M (2)	0.1-0.3	2	0.2	--	--	
	34	Fill & Dip Oper.	P-TWA (1,2 & 3) 3M	0.1	4	0.1	0.1	1.0	
		Packer & Other	P-TWA (1)	0.1-0.4	5	0.2	0.1	3.3	
			3M (2)	0.1	3	0.1	--	--	
			(3)	0.1-0.2	5	0.1	0.1	2.1	
	75	Packaging	P-TWA (1,2 & 3) 3M	0.1	9	0.1	--	--	
	33	Tripaque	P-TWA (1,2 & 3) 3M	0.1	6	0.1	--	--	
	33	Sponge Oper.	P-TWA (1)	0.1-0.4	6	0.1	0.1	2.8	
			3M (2)	0.1	6	0.1	0.1	1.0	
			(3)	0.1	6	0.1	0.1	1.0	

(1) = 1st shift
(2) = 2nd shift
(3) = 3rd shift

TABLE 1 (continued)
HISTORY OF ETO SAMPLING METHODS AND DATA AT
KENDALL, AUGUSTA, GEORGIA

Date	Dept. No.	Sampling Location/ Job Description	Type of Sample & Equipment	Range of ETO Concentration (ppm)	No. of Samples	Arith. Mean $\overline{X}$ (ppm)	Geom. Mean $\overline{Xg}$	Geometric Standard Deviation SDg	Comments
1984 Summer		Other	P-TWA (1 & 2) 3M	0.1-0.3	4	0.1	0.1	2.5	
	32	Bleachery/Card Operator	P-TWA (1,2 & 3) 3M	0.1-0.1	7	0.1	0.1	1.5	
	36	Webcol	P-TWA (1,2 & 3) 3M	0.1-0.3	12	0.1	0.1	1.9	
	36	Batcher/Retort Operator	P-TWA (1,2 & 3) 3M	0.1-0.3	3	0.1	0.1	3.4	
		Other	P-TWA (1 & 2) 3M	0.1	2	0.1	--	--	
	51-56	Sterile Hold	P-TWA (1) 3M	0.1-0.6 0.1	3 1	0.3 --	0.2 --	4.0 --	
	51-56	Material Handler	P-TWA 3M	1.3	1	--	--	--	Bethune trailers
	51-56	Storeroom	P-TWA (1,2,3) 3M	0.1-0.2	3	0.1	0.1	2.7	
		Sterilizer Maintenance	P-TWA 3M	0.3	1	--	--	--	

(1) = 1st shift
(2) = 2nd shift
(3) = 3rd shift

TABLE II
CONTROLS IMPLEMENTED TO REDUCE ETO
EXPOSURE LEVELS AT
KENDALL, AUGUSTA, GEORGIA

Date	Engineering Controls	Administrative Controls	Monitoring Systems	Other Changes	Range of ETO Exposure level Measured (ppm)
1968	General room Ventilation	None added	None added	---	None measured
1975	None added	ETO barrels stored outside the plant	None added	--	None measured
1976	Two original sterilizers removed				None measured
1977	Track installed in sterilizing area for easier transport of palleted product	OV respirator program instituted for sterilizer operators Product left in sterilizer 1.5-4 hours for aeration purposes	1st ETO monitoring conducted (All area samples)	--	1.0-170.0
1978	None added	Urological workers required to stand 1 ft. away from ETO/water waste bins "Full" indicator line placed on ETO/water waste bins	None added	--	None measured
1979	Thermoforming room enclosed with walls	None added	Personal and area ETO monitoring conducted	--	10.0-32.0 (breakthrough)
1980	None added	OV half-face respirators replaced with full-face MSA ETO canister respirators (1000 ppm limit)	None added		None measured
1981	Ventilation exhaust hoods installed above each ETO sterilizer door Air-flush system installed in each sterilizer		Personal and area monitoring conducted	--	0.6-18.0

TABLE 11 (continued)
CONTROLS IMPLEMENTED TO REDUCE ETO
EXPOSURE LEVELS AT
KENDALL, AUGUSTA, GEORGIA

Date	Engineering Controls	Administrative Controls	Monitoring Systems	Other Changes	Range of ETO Exposure level Measured (ppm)
1981 (cont.)	Directional air fans installed	SCBAs purchased for use by maintenance & cleaning personnel required to work within sterilizer			
	Class 1, Division 1 building constructed for batching of ETO	Full-face MSA canister respirators replaced with positive pressure ambient air-supplied hood			
	Pipe lines installed for transport of ETO	Sterilizer operators required to wear ASR when within 6 ft. of hot sterilized product			
	Number of ventilation fans increased in sterile hold/ quarantine areas	Workers required to drive fork-lift trucks backwards when transporting ETO sterilized product			
	Sterile hold area expanded & rack capacity increased to improve aeration conditions	Sterilized product required to be aerated 24 hrs. before being QA tested			
		Hazardous material handling policy and procedure check list instituted			
	Sterile hold in the warehouse enclosed with walls	Personal protective clothing purchased for workers manually handling ETO			
		Sterile hold changed to ETO sterilized products only			

...ued)
...s IMPLEMENTED TO REDUCE ETO
EXPOSURE LEVELS AT
KENDALL, AUGUSTA, GEORGIA

ate	Engineering Controls	Administrative Controls	Monitoring Systems	Other Changes	Range of ETO Exposure levels Measured (ppm)
982	New chem mix room constructed; ETO cylinders & mixing of ETO moved to a shed outside of plant	None added	Personal & area ETO monitoring conducted		N.D.-59.6
83	Fume hoods installed over urological & fill & dip operations	Production change eliminated use of ETO in wet dressing packs and Webcol/Alcohol Prep Area	Installation of microprocessors & multiport automatic GC-FID monitoring system.	Employment of an engineering consultant for the purpose of reducing ETO levels.	0.2-15.7
	Major construction changes started:				
	Sterilizer area & sterile hold/ quarantine areas isolated & separate ventilation systems installed				
	Aeration chambers & computerized sterilizer program				
	ETO sterilizers retrofitted (enlarged)				
	Enclosure ventilation installed over urological fill & dip operation				

TABLE II (continued)
CONTROLS IMPLEMENTED TO REDUCE ETO EXPOSURE LEVELS AT KENDALL, AUGUSTA, GEORGIA

Date	Engineering Controls	Administrative Controls	Monitoring Systems	Other Changes	Range of ETO Exposure level Measured (ppm)
	Water drains installed to replace urological ETO/water waste bin				
	Lids & feed lines installed on carts containing ETO/water mixture				
	Installation of a laminer flow hood for QA sterilizer				
	Computerized sterilizer program restricts ETO sterilizer door opening until internal sterilizer ETO levels have been substantially reduced by the air flush system				
1984	Construction changes started during summer of 1983 were completed	None added	Same as 1983	---	0.1-0.8