

INDUSTRYWIDE STUDIES REPORT:  
A WALK-THROUGH SURVEY

OF

ETHICON  
Division of Johnson and Johnson  
San Angelo, Texas 76902

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DATE OF SURVEY:  
May 8-9, 1985

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DATE OF REPORT:  
January 8, 1986

REPORT NUMBER: 67.19

Industrial Hygiene Section  
Industrywide Studies Branch  
Division of Surveillance, Hazard Evaluations, and Field Studies  
National Institute for Occupational Safety and Health  
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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)

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**STANDARD INDUSTRIAL  
CLASSIFICATION OF PLANT:**

3841 - Surgical and medical instruments  
and apparatus

## ABSTRACT

On May 8-10, 1985, a site visit to the San Angelo plant of Ethicon (a subsidiary of Johnson and Johnson) was conducted to determine whether this plant was eligible for inclusion in the NIOSH EtO cohort mortality study. During the visit, personnel records and industrial hygiene records were reviewed, and a walk-through survey was conducted. EtO has been used in this facility since 1974. Results of the evaluation of personnel records indicated that, over time, there have been too few exposed employees to warrant the inclusion of this plant in the cohort mortality study.

## INTRODUCTION

Ethylene oxide (EtO) is one of the 25 chemicals of highest production volume in the United States.<sup>1</sup> 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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5,6</sup> 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.<sup>5,6</sup>

This walk-through survey was conducted to determine the suitability of including Ethicon (San Angelo) 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)<sup>7</sup> 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

Ethicon is a division of Johnson and Johnson. The San Angelo Ethicon facility began production of sutures and needles in 1964, and first used EtO in 1974. EtO use continues today. All sterilization takes place in building 3. There are currently 4 sterilizers of approximately 200 cubic feet each in this facility. The first sterilizer began operation in 1974, two more were installed in 1975, while the fourth became operational in 1985. A 12/88 mixture of EtO and freon has been used. Building 3 was occupied by a small number of employees (most of the space was used as a warehouse) until 1979, when a large number of personnel in winding operations were located there.

## DESCRIPTION OF WORKFORCE

There are currently approximately 1160 hourly employees and 375 salaried employees at this plant. Total employment in 1974 was about 1000, and in 1978 it was about 1400. Turnover rates averaged about 20-25% yearly from 1974-1980, when they decreased to 5-10%. Approximately 2/3 of the workforce is female. Among hourly employees, approximately 35% of the workforce is white, 5% is black, and 50% is hispanic, and 10% is oriental.

## DESCRIPTION OF PROCESS

Ethicon, Incorporated, a Johnson & Johnson company, has produced wound closure devices at the San Angelo, Texas, facility since 1964. The current Ethicon product line consists of over 2,000 different suture and needle products. Ethicon receives raw materials, such as steel wire for needles, and processes it as necessary.

After being prepared and wrapped in open vent foil packages in the Foil department, Vicryl and PDS sutures are stored in the dry hold room and then preconditioned in a tenney chamber. The dry hold removes moisture while the tenney chambers keep the product at an increased relative humidity.

The suture package is then sterilized in one of 3 units (Q, R, and S). One side of these packets is allowed to remain open to permit EtO to penetrate the package. Each primary sterilization run utilizes 50 kilogram (kg) of Oxyfume 12 (a mixture of 12% ethylene oxide and 88% dichlorodifluoromethane) which passes through a steam heated volatilizer to ensure complete vaporization. Each charge of gas is automatically weighed and piped from storage cylinders (capacity = 190 kg) into the unit. After charging of the chamber, the cylinder is automatically refilled from a bulk storage tank. These units are identical in terms of their operation, each having a capacity of 213 ft<sup>3</sup>. Internal fans circulate the Oxyfume mixture. At the completion of the cycle, the EtO is purged through a vacuum pump, passes into a common duct for all sterilizers, and is exhausted through an ejector system at a minimum velocity of 130 ft/sec. An average of five air washes are performed to further remove residual EtO from the product.

The sterilized goods are unloaded by the sterilizer operator. Prolene and cotton products remain in the transfer room for a minimum of 6 hours.

Vicryl products are taken directly to degassing ovens. These products remain in these units for an average of 18 hours (12 hours minimum). The degassing units exhaust directly to the roof using an exhaust system which is entirely separate from all other ventilation. PDS products are also placed in degassing ovens for 18 hours and then transported immediately to a nitrogen filled glove box in the blanking area for sealing. This product is only a small percentage of all goods. After degassing (in the transfer room or the ovens) sutures are transported by a "loader" through a hallway and passed through loading ports into the sealing room. The loader task rotates weekly among department 07144 employees. Sealers sit at individual work stations and heat seal the open side of the suture packet. Each of these work stations is supplied with HEPA filtered air and is designed to minimize air turbulence.

Approximately 30 work hours are required per run. The requirements of each run have not changed significantly since 1974. This task, as well as blanking, loading, and inspecting is rotated by workers in department 07144. Loading is performed by one worker and takes 6 hours. Sealed goods are passed by the sealer into the dispatch area. The sealed goods are blanked (dye cut) and then transported by the set-up attendant into the overwrap area. Blanking takes 27 work hours per run, typically performed by 7 employees for 4 hours each. A small percentage of all goods is inspected in a room at the rear of the overwrap area. Two inspectors are from department 07156 while an average of two additional workers from department 07144 spend 7.5 hours each, per run, assisting in inspection. All products are then overwrapped (department 07146) with an EtO permeable paper/poly material.

These packets are next packaged into cardboard boxes and placed in the tenney chambers by the sterilizer operator. All goods are resterilized in either the Q, S, or W (232 ft<sup>3</sup>) chamber. Each secondary sterilization run utilizes 57 kg of the Oxyfume mixture during a six hour cycle at 130°F. To purge EtO from the sterilizer, a valve is opened and the chamber is allowed to return to atmospheric pressure with the EtO passing into the same ejector system as the primary sterilization cycle. For one hour and twenty minutes, filtered and conditioned air is allowed to enter the vessel at the same rate as a vacuum pump removes gasses. This prevents the air pressure from dropping below atmospheric.

The sterilizer operator loads and unloads the secondary sterilizer and places the product in the aeration room. After resterilization, all products remain in an aeration room for a minimum of 4 hours. They remain here an average of 7 hours, although this may extend up to 3 days. The QA technicians (unit 87501) are responsible for pulling biologic indicator strips and product samples from the pallets after the secondary sterilization as well as taking gas assays to confirm the purity of the EtO. After aeration, all boxes are wrapped in cellophane and packaged into large cardboard boxes with an additional overwrap of cellophane in the FA-2 area. Vicryl products then are placed in a room at 50°C for an average of 3 days. FA-2 employees remove the product from the aeration room and transport them out of the FA-2 room into a staging area, immediately outside

this department. All goods then are picked up by shipping personnel, shipped to a warehouse located a few miles away, and finally to an Ethicon facility in Cornelia, Georgia.

#### DESCRIPTION OF PAST EXPOSURES

In February 1974, ethylene oxide sterilization began in the southwest corner of Building 3. Before this date, gamma radiation from a Cobalt<sup>60</sup> source was used for all sterilization. As different product lines were developed, a more delicate sterilization process was needed. When EtO sterilization began in this building in February 1974, there were few other workers exposed to ethylene oxide in adjacent departments. Only one unit (S) was operational with one tenney chamber (with increased relative humidity) but no dry hold room.

Goods travelled directly from the transfer room into the clean room with a maximum offgassing period for Prolene, and cotton products of 2 hours. No hallway existed between the transfer room and the sealing room. The sealers collected their goods, placed them in the loading ports, and sealed the packets. No offgassing ovens were used at this point. A separate, sealed heating, ventilation and air conditioning (HVAC) system (Class 100) for the clean side was operated by a 3 ton unit. This was a single pass unit supplied with air from a separate unit from the rest of the building's supply air. The overwrap area was serviced by a 2nd HVAC unit but this was not sealed from the rest of the building's system.

Inspection was performed in the main building and the products then returned to building 3 for reesterilization. A 3,500 cubic feet per minute (cfm) fan exhausted to the roof from ports on the floor on the "dirty" side, two ports on the top of the "clean" side and one in the "pit" to the north side of the S unit. The sterilizer operator changed the Oxyfume cylinders while a maintenance worker changed a filter just upstream of the cylinders (approximately once every three months). At this time, the only personal protective equipment worn during cylinder changing were gloves. Approximately 3 runs could be charged from each cylinder.

In November, 1974, a leak developed in the door seal of the S unit. Adequate pressure was maintained by adding makeup gas and the run continued. A large amount of EtO was consumed and a high concentration of EtO is suspected to have spread throughout Building 3. Since this occurred on a Saturday, the potential number of exposed workers was minimized, however, residual EtO probably remained in the building for an extended period of time. Personal interviews conducted by Ethicon reported that leaks have generally been from door gaskets, seals, piping systems, and pumps. This has apparently been true for the entire time these sterilizers have been in use.

In 1975, the Vicryl product line began to be produced at this location. Two more units, and a dry hold room were added. The R unit performed only primary sterilizations while the Q unit performed secondary sterilizations. Additional intake vents were added to the original 3,500 cfm exhaust fan. These were located in the front and back of these additional units (on the

bottom and top, respectively) as well as in the "pit" areas in between the three units. After secondary sterilizations in the S unit, goods were removed from the loading side and passed through a hallway to the aeration area. Four degassing ovens were added to remove excess moisture from two product lines (Vicryl and PDS).

In 1975, the sealing room was enlarged and moved to the corner of the building. It was equipped with a Class 100 HVAC system. A hallway with loading ports to the sealing stations was added. An additional tenney chamber, an enclosed dispatch room (for the passage of goods after sealing), as well as more walls were added in this year.

Up until at least 1976, approximately one sixth of the floor space was occupied by raw materials.

Based upon the sampling results of 1977 (see Industrial Hygiene section), the air flush cycle for the secondary run was extended and there was an increase in the vacuum capacity on the primary runs.

In 1979, the handwinding department moved into this building, next to the FA-2 area. An additional 12,000 cfm exhaust unit was installed that serviced the top areas of the dirty side of the sterilizers. It also drew air from vents in the overwrap area, the men's changing room (for entry into the clean room), and the aeration area. A 8,000 gallon bulk storage tank for Oxyfume 12 was installed. This automated the filling of the charging cylinders after every run. A maintenance worker still has to periodically change a filter, now located downstream of the cylinders, approximately once per month. Between 1979 and 1981, the time prolene and cotton products remained in the offgassing area after primary sterilization runs was extended from 2 to 6 hours. This was instituted primarily to reduce employee exposure.

Up until at least 1980, finished goods were stored in this building. Flow racks retained most products for a period of days before shipment. Bin storage was reserved for specialty items. These goods might remain in this building for months before being shipped. In November, 1980, MSA air purifying cannister respirators and gloves began being used by the sterilizer operator during unloading of the sterilizer and cylinder changing. Until this time, no personal protection equipment was used. These respirators were also used by maintenance personnel during filter changing, leak testing, and opening gas lines.

In 1981, the inspection of sterilized products was moved into building 3 in the sterilization area. Until this year, EtO was exhausted directly to the roof. In the last quarter of 1981, the EtO ejector system was installed. Located at the north end of Building 3, this system mixes exhausted gases with large amounts of outside air and ejects this mixture at a velocity of at least 130 ft/sec.

In 1982, separate primary and secondary aeration rooms, and two more degassing ovens were added. The primary aeration room was equipped with a 2,000 cfm exhaust fan. In June, 1982, the cannister respirators were

replaced with 3M Air Supplied Respirators. Requirements outlined in the OSHA regulation 29 CFR 1910.134 are followed, including a written program, annual medical surveillance, employee training, and respirator maintenance. All Fire Brigade and Hazardous Spill Committee members are trained in the use of the Scott Self Contained Breathing Apparatus (SCBA).

In 1983, five degassing ovens and a dry hold area were added while the aeration room was renovated. A 6,500 cfm exhaust fan was installed that serviced the sides of each of the three sterilizers. The sealing room was enlarged and moved to the south wall. The sealing room was supplied with air from a 10 ton HVAC system. The 2,000 cfm fan for the aeration room was upgraded to 6,500 cfm unit. The task of loading was separated from sealing at this time.

In 1984, three 2,500 cfm exhaust units were installed to service the clean side of the Q, R, and S units. These are automatically triggered 10 minutes before the end of the sterilization cycle. An additional 2,500 cfm fan was installed in the sealing room. It is triggered by the Hnu system (described in the Industrial Hygiene section) when a concentration of 1 ppm is detected and remains on until the concentration drops below 1 ppm.

In March, 1985, a new unit (W) with a capacity of 232 ft<sup>3</sup> was operational. It is dedicated to secondary sterilization. It is serviced by a 6,500 cfm exhaust fan on either side. The 12,000 cfm unit services the front, "dirty" side, while the 6,500 cfm unit in the aeration room draws air from vents on the "clean" side.

At present, approximately 60% of all products are sterilized with ethylene oxide. This increase in use of EtO has been reflected in a number of parameters. Table I documents the increase in the number of sterilizer runs, as well as the increased purchase of Oxyfume 12. The large increase of Oxyfume purchase in 1979 is due to the initial filling of the bulk storage tank and not actual usage. There was also an increase in the number of overwrap lines from three in 1980 to seven at the present time.

There are presently approximately 25 area mechanics (unit 07812) of which four to five are dedicated to the EtO sterilization area. This is not recorded in the personal records. Of the 15 cleaners (unit 07813), one or two are responsible for the sterilization area. There are 15 electricians (unit 07814), of whom one works in the sterilization area. Unit 87502 includes five PST technicians (product sterility testing) and three chemical technicians. The PST technicians are responsible for cleaning the clean room. Unit 07158 works in the FA-2 area while Unit 07147 normally works in another building and was transferred into the FA-2 area on an infrequent basis. The samples for unit 07147 were taken while they were working in the FA-2 area and as such should not be construed as typical exposures for this unit.

With the exception of cobalt and benzene, there are no other significant exposures at this facility. All Cobalt sterilization operators, Department 87153, wear radiation dosimeter badges during their entire shift. There have been no documented employee overexposures to radiation during this facility's operation. Small quantities of benzene were used in the past by

the QA Chemistry Lab, but not presently. No formaldehyde was used in the manufacturing process, although small quantities were used in the QA Chemistry Lab and in the PST Lab.

In two areas in Building 3, workers used various solvents. Seven to nine employees in Department 07104, Preprocessing, used Toluene, Xylene, 2-Butanone (MEK), and Hexone (MIBK) from the 1970's until late 1980. Department 87450, Duplicating (the print shop), used Cellosolve Acetate and n-Propyl Acetate.

#### DESCRIPTION OF PERSONNEL RECORDS AND DEFINITION OF EXPOSED GROUP

##### (1) Personnel record system

Approximately 2500 hourly employees who terminated between 1964-1978 are ordered alphabetically on microfilm. Similarly, approximately 600 salaried employees who terminated 1964-1978 are ordered alphabetically on microfilm. Approximately 775 wage and salaried employees who terminated between 1979-1984 are ordered alphabetically. Approximately 1160 current hourly employees are ordered alphabetically on hard copy, as are approximately 375 current salaried (exempt and nonexempt) employees.

Each personnel record contains a work history. This work history lists job titles and sometimes department numbers. Department numbers are not consistently listed, but are available (since 1976) on a second form, the payroll action notice (PAN). Job titles have remained fairly consistent since 1974 when EtO was first used at the plant, and it is possible to determine department numbers for each job over time.

Alternative records do exist to ascertain the completeness of the cohort. These include seniority lists and payroll lists.

##### (2) Definition of the exposed

Sterilization began in 1974 in building 3, a large building which included both a warehouse area and EtO sterilization. Departments in building 3 which involved exposure to EtO from 1974-1979 included 144 (sealers), 146 (overwrap), 165 (FA2, packaging), 170 (In-test), and 644 (shipping). In addition, some individuals in department 07191 (suture finish, a salaried department which included EtO operators), and 87501 (quality assurance, a salaried department which sometimes involved work in the EtO area), would have been exposed. In 1979 a large number of personnel moved into building 3 when the handwinding department (116, 123, 127, and 131) was transferred there. In 1981 department 156 moved into building 3. Finally, in 1983 additional departments were moved into building 3 (113, 115, 116, 119, 122). All of the above departments would be considered exposed once they were in building 3.

Despite the relatively numerous departments which involved exposure, in fact subsequent sampling of the personnel records (see below) indicated that very few employees worked in these departments.

Sterilizer operators in department 191 can be identified individually by memory. There have been 13 sterilizer operators over time.

(3) Sampling the personnel records to determine the percentage of workers exposed

Approximately 5% of the personnel records were randomly sampled, for terminated hourly employees (120 who terminated in 1964-78), for terminated wage and salaried employees (50 who terminated 1979-1984), and for current hourly employees (60). Terminated salaried employees (1964-78) were not sampled, nor were current salaried employees, because of these only sterilizer operators (already identified by memory), and quality assurance personnel (of these, only some had been exposed and these were not easily distinguishable), were potentially exposed among salaried personnel. The number of employees who were exposed to EtO prior to 1978, for at least 3 months, were counted to determine whether this plant would qualify for the first phase of the EtO cohort mortality study.

Among current hourly employees, none of the 60 sampled were exposed for 3 months prior to 1978. Among the 120 hourly terminated employees, only 1 was exposed for 3 months prior to 1978. Among the 50 hourly/salaried employees who terminated from 1979-84, one was exposed for 3 months prior to 1978.

Hence, a random sample of personnel records indicated that only 0.4% of the workforce has been exposed (1 of 230). Therefore, only about 18 employees, other than the 13 sterilizers operators, would be expected to have been exposed at this plant. Even if it were assumed that all the sterilizer operators were exposed for more than 3 months prior to 1978, and if if it were further assume that follow-up will be done through 1982 and that the average year of first exposure for both operators and nonoperators was 1976 (halfway between 1974 when EtO was first used and 1978, the cut-off point for entry into the study), then there would be only 186 person-years of exposure at this plant (31 X 6). Hence this plant does not meet the criteria to be included in the study because it has less than 400 person-years for all exposed employees.

## DESCRIPTION OF MEDICAL, INDUSTRIAL HYGIENE AND SAFETY PROGRAMS

### Medical

Ethicon employs three full-time nurses and full-time physicians. Pre-employment physicals are conducted for all employees, as is annual blood pressure and diabetes screening.

### Industrial Hygiene

In late 1977, the first personal sampling of sterilizer operators took place using an acid impinger method.<sup>27</sup> These samples detected 6 and 3 ppm of EtO (4 and 6 hours respectively). Instantaneous samples inside the sterilizer, immediately after opening the door measured 1,330 ppm on a primary run and 1,060 ppm for a secondary run. Concentrations inside the sterilizer 1 minute after unloading measured 350 to 550 ppm. No sampling

took place in 1978. In 1979, Qazi-Ketcham tubes began to be used with pumps calibrated at 25 cc per minute, and have been used to date.

Sampling has always been conducted by QA Chemistry Lab Personnel, the Ethicon Corporate Industrial Hygienist, or the Plant Industrial Hygienist. Peak samples are collected for 15 minute durations while most samples are full shift (more than 7 hours). Analysis of samples was originally conducted by Johnson & Johnson Research Analytical Laboratory in New Brunswick, New Jersey. Since October, 1981, this has been conducted in house by the Plant QA Chemistry Lab. All detectable results are reported. This lab participated for 6 months in NIOSH's Proficiency and Analytical Testing (PAT). It presently participates semi-annually in analyzing spiked samples from the National Loss Control Service Corporation (NATLSCO) as well as utilizing internal QA procedures.

In 1980, the first internal guidelines by Johnson & Johnson were set at 10 ppm for a TWA and 75 ppm for a 15 minute ceiling. J & J's present internal policy is to conduct repeated sampling on anyone exposed to concentrations in excess of an eight hour TWA of 0.1 ppm. Limited sampling was conducted in the intake vents to check for any reentrainment. These studies were negative.

Beginning in August 1982, sampling during unloading and loading of the sterilizer was conducted both inside and outside the sterilizer operator's air supplied respirator. Samples taken outside the respirator were changed every 15 minutes, while those taken inside vary from 30 to 50 minutes. A summary of the extensive sampling conducted from 1979 to date is included in the past exposure section and Table II. Ethicon conducted limited off gassing studies of their products in 1982 (see Table III). These have been both general area samples, both on top of and near the product, and residual samples, the latter to meet FDA requirements.

The first Hnu 501 Environmental Gas Chromatograph area monitor was installed in 1983. The second Hnu area monitor was on line in October, 1984. Each unit takes a minute and a half sample from 10 locations. These units, in conjunction with 5 TI microprocessors, have been expanded from passive to active response systems. Any reading above 1 ppm triggers an audible and visible alarm at the sensor location. This is also recorded on a printed output, with concentrations above 10 ppm noted as "high". The audible alarm can be silenced at the sensor location but it will sound again in 15 minutes if concentrations above 1 ppm persist. The alarm light will remain on as long as the condition exists. Sensors on the clean side of the sterilizers and in the sealing room will trigger their respective exhaust fans. At the present time, the two units control remote alarms at 26 locations, five entryway warning lights, and seven exhaust blowers.

Workers are immediately evacuated if they are located in an area that exceeds 10 ppm for any one reading. At concentrations between 1 and 10 ppm, employees may be evacuated at the discretion of the supervisor. Written guidelines exist for this circumstance. This may also be initiated if the time weighted average (TWA) exceeds 1 ppm, but this is typically not done at the beginning of the shift. An evacuation may last from a few minutes to

several hours. During 1984 and 1985, summary reports of all evacuations were written. A Miran infrared detector, model 103, is used as a leak detector.

Hair nets are required in all suture manufacturing areas. Annual measurements are taken on exhaust ventilation duct velocity.

## TOXICITY

Evidence from animal studies suggests that EtO may have carcinogenic properties.<sup>7,8</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9-11</sup> 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12,13</sup> EtO is also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.<sup>6</sup>

Chromosomal aberrations related to EtO exposure have been observed in a number of animal studies and epidemiologic investigations.<sup>8,13-20</sup> 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.<sup>14</sup> 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.<sup>8</sup> 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.<sup>15</sup> 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.<sup>16</sup>

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to EtO in the sterilization of medical devices in 1978.<sup>17,18</sup> 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.<sup>19,20</sup> 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.<sup>21</sup> OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.<sup>22</sup> 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).<sup>23</sup>

In 1977, NIOSH recommended a ceiling level of 75 ppm as determined during a 15 minute sampling period.<sup>6</sup> 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.<sup>24</sup> 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.<sup>24</sup> 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.

#### CONCLUSIONS AND RECOMMENDATIONS

While personnel records are adequate to determine who was exposed at this plant, and while good industrial hygiene data is available to estimate exposures, there have been an inadequate number of workers exposed at this plant for more than 3 months prior to 1978 to warrant the inclusion of this plant in the EtO cohort mortality study.

This facility appears to have significantly contained and controlled EtO exposure. Further plans are in progress to further isolate the sterilization process in order to achieve a 0 ppm exposure level.



TABLE II

Ethicon  
San Angelo, Texas  
Ethylene Oxide Personal Sampling Data

Dept. #	Operation	Date	N	ETHYLENE OXIDE			
				Mean (ppm)	Std. Dev.	Range Minimum Maximum	
07812	Area Mech	1985	38	0.152	0.178	0	- 0.75
07812	Area Mech	1984	11	0.729	1.643	0	- 5.89
07812	Area Mech	1983	6	0.298	0.181	0.11	- 0.62
07812	Area Mech	1982	5	1.978	3.537	0.07	- 9.05
07812	Area Mech	1981	10	1.318	0.971	0.19	- 3.4
07812	Area Mech	1980	5	1.288	0.665	0.19	- 2.2
07812	Area Mech	1979	2	15.92	12.28	3.64	- 28.2
07812	Area Mech-0 A	1985	3	1.963	1.251	0.98	- 3.73
07144	Blanker	1985	15	0.064	0.084	0	- 0.35
07144	Blanker/Inspect	1985	1	0.05			
07144	Blanker	1984	2	0.04	0.01	0.03	- 0.05
07144	Blanker	1983	3	0.196	0.124	0.02	- 0.29
07144	Blanker	1982	14	0.839	0.880	0.05	- 3.62
07144	Blanker	1981	6	0.373	0.137	0.2	- 0.6
07144	Blanker	1980	3	0.356	0.189	0.11	- 0.57
87501/2	Chem Tech	1985	2	0.28	0.18	0.1	- 0.46
87501/2	Chem Tech	1984	2	0.065	0.035	0.03	- 0.1
87501/2	Chem Tech	1983	3	0.26	0.082	0.17	- 0.37
87501/2	Chem Tech	1982	6	1.755	3.146	0.03	- 8.77
87501/2	Chem Tech	1981	3	0.533	0.250	0.27	- 0.87
87501/2	Chem Tech	1981	1	239.7			
07831	Cleaner	1985	2	0	0	0	- 0
07831	Cleaner	1982	2	2.515	2.205	0.31	- 4.72
07841	Electrician	1985	1	0			
07841	Electrician	1981	1	1.24			
07850	Engineer	1985	1	0.7			
07850	Engineer	1984	1	0.1			
07115	Epoxy Attacher	1985	17	0.089	0.215	0	- 0.94

A These are full shift samples while the employee was wearing a respirator for a small percentage of the shift.

TABLE II (cont.)

Ethicon  
San Angelo, Texas  
Ethylene Oxide Personal Sampling Data

Dept. #	Operation	Date	N	ETHYLENE OXIDE			
				Mean (ppm)	Std. Dev.	Range Minimum Maximum	
07195	EtO Clerk	1984	1	0.04			
07195	EtO Clerk	1983	6	0.331	0.433	0.03	- 1.26
07195	EtO Clerk	1982	11	0.903	1.198	0.07	- 3.72
07195	EtO Clerk	1981	2	0.47	0.04	0.43	- 0.51
07191	EtO Coordinator	1985	2	0.33	0.26	0.07	- 0.59
07195	EtO Coordinator	1984	2	0.07	0.04	0.03	- 0.11
07812	EtO Mechanic	1982	2	0.175	0.045	0.13	- 0.22
07191	EtO Operator	1985	128	0.308	0.660	0	- 7.03
07191	EtO Operator	1984	26	0.589	0.403	0	- 1.67
07191	EtO Operator	1983	14	0.675	0.931	0.01	- 3.68
07191	EtO Operator	1982	15	0.994	0.971	0.04	- 4.03
07191	EtO Operator	1981	27	1.449	1.424	0.25	- 7.32
07191	EtO Operator	1980	7	3.788	3.587	0.88	- 12.05
07191	EtO Operator	1979	8	9.14	6.289	0.86	- 19.4
07191	EtO Operator	1977 <sup>B</sup>	2	5.5	0.5	5	- 6
07191	EtO Supervisor	1984	2	0.01	0.01	0	- 0.02
07191	EtO Supervisor	1983	4	0.195	0.075	0.11	- 0.3
07191	EtO Supervisor	1982	9	1.145	1.869	0.07	- 6.33
07191	EtO Supervisor	1981	1	0.04			
07165	FA-2 Operator	1985	19	0.092	0.096	0	- 0.41
07165	FA-2 Operator	1984	5	0.096	0.059	0.05	- 0.21
07165	FA-2 Operator	1983	3	0.263	0.071	0.19	- 0.36
07165	FA-2 Operator	1982	9	0.612	0.616	0.05	- 1.52
07165	FA-2 Operator	1981	2	0.71	0.39	0.32	- 1.1
07158	Hand Packer	1981	3	1.72	1.553	0.29	- 3.88
07158	Hand Packer	1980	5	1.386	0.637	0.67	- 2.38
07158	Hand Packer	1979	1	0.31			
07131	Handwinder	1985	44	0.119	0.240	0	- 1.33
07131	Handwinder	1983	6	0.208	0.360	0.01	- 1.01
07131	Handwinder	1982	7	1.348	1.704	0.17	- 5.32
07191	HW Supervisor	1982	1	0.05			

<sup>B</sup> Samples taken with impingers (Reference #27).

TABLE II (cont.)

Ethicon  
San Angelo, Texas  
Ethylene Oxide Personal Sampling Data

Dept. #	Operation	Date	N	ETHYLENE OXIDE			
				Mean (ppm)	Std. Dev.	Range Minimum Maximum	
07170	IT Matl Hand	1985	8	0.127	0.138	0	- 0.46
07170	IT Matl Hand	1984	4	0.182	0.113	0.07	- 0.34
07170	IT Matl Hand	1983	5	0.174	0.098	0.01	- 0.3
07170	IT Matl Hand	1982	11	1.216	1.997	0.1	- 7.39
07170	IT Matl Hand	1981	2	0.48	0.02	0.46	- 0.5
07144	Inspect	1985	18	0.081	0.135	0	- 0.56
07811	Instr Mechanic	1985	1	0			
07811	Instr Mechanic	1984	1	0.05			
07811	Instr Mechanic	1981	2	0.58	0.22	0.36	- 0.8
07133	Labyrinth	1981	3	0.123	0.046	0.06	- 0.17
07144	Loader	1985	54	0.236	0.183	0.06	- 0.99
07144	Loader	1984	17	0.280	0.145	0.06	- 0.56
07144	Loader	1983	6	0.43	0.222	0.18	- 0.77
07144	Loader/Inspect	1985	8	0.111	0.094	0	- 0.33
07116	Min Assembler	1985	2	0.015	0.015	0	- 0.03
07147	Misc Assembler	1982	6	1.043	1.413	0.08	- 4.11
07147	Misc Assembler	1981	2	0.76	0.66	0.1	- 1.42
07146	Overwrap Opr	1985	24	0.114	0.179	0	- 0.85
07146	Overwrap Opr	1984	3	0.043	0.004	0.04	- 0.05
07146	Overwrap Opr	1983	19	0.178	0.110	0.01	- 0.47
07146	Overwrap Opr	1982	68	0.812	0.853	0	- 4.22
07146	Overwrap Opr	1981	3	0.75	0.400	0.21	- 1.17
07146	Overwrap Opr	1980	4	0.547	0.383	0.12	- 1.11
87502	PST Tech	1985	3	0.186	0.157	0.07	- 0.41
87502	PST Tech	1984	2	0.225	0.125	0.1	- 0.35
87502	PST Tech	1983	7	0.158	0.102	0.09	- 0.4
87502	PST Tech	1982	2	0.465	0.365	0.1	- 0.83

TABLE II (cont.)

Ethicon  
San Angelo, Texas  
Ethylene Oxide Personal Sampling Data

Dept. #	Operation	Date	N	ETHYLENE OXIDE				
				Mean (ppm)	Std. Dev.	Range Minimum Maximum		
87501	QA Technician	1985	15	0.080	0.060	0	-	0.23
87501	QA Technician	1984	4	0.122	0.075	0.03	-	0.24
87501	QA Technician	1983	2	0.135	0.015	0.12	-	0.15
87501	QA Technician	1982	9	0.483	0.774	0.09	-	2.66
87502	QA Technician	1981	7	0.777	1.143	0.17	-	3.56
87501	QA Technician	1980	1	1.08				
07198	S/R Operator	1981	1	0.39				
07198	Salv/Redress	1985	43	0.159	0.220	0	-	1.36
07144	Sealer	1985	42	0.232	0.257	0	-	1.34
07144	Sealer/Blanker	1985	5	0.098	0.077	0	-	0.22
07144	Sealer/Inspect	1985	10	0.088	0.017	0.06	-	0.12
07144	Sealer	1984	16	0.225	0.178	0.07	-	0.72
07144	Sealer	1983	15	0.427	0.418	0	-	1.59
07144	Sealer	1982	26	1.098	1.413	0.09	-	6.11
07144	Sealer	1980	38	2.406	2.863	0.25	-	14.01
07146	Setup Attend	1985	3	0.02	0.03	0.00	-	0.06
07146	Setup Attend	1984	1	0.06				
07146	Setup Attend	1983	3	0.413	0.202	0.13	-	0.59
07146	Setup Attend	1982	6	0.721	0.969	0.08	-	2.84
07146	Setup Attend	1981	2	0.255	0.065	0.19	-	0.32

TABLE III

Ethicon  
San Angelo, Texas  
Ethylene Oxide Offgassing Data

DATE	LOCATION	TOTAL SAMPLE TIME	TWA RESULTS	COMMENTS
5/18/82	PROLENE Cart	480 Minutes	0.10 ppm	One day after sterilization
9/15/82	PROLENE Cart	15 Minutes	0.07 ppm	Blanking area-before Overwrap
9/15/82	PROLENE Cart	15 Minutes	0.08 ppm	Blanking area-before Overwrap
9/16/82	PROLENE Cart	15 Minutes	6.82 ppm	Aeration Room
5/14/82	Center of PROLENE Cart	480 Minutes	37.71 ppm	Palletized cart
5/18/82	PROLENE Pallet	477 Minutes	3.62 ppm	
6/21/82	PROLENE Pallet	450 Minutes	60.75 ppm	Inside pallet
9/15/82	PROLENE Tote	15 Minutes	0.74 ppm	Immediately after FA-2 Wrap
9/15/82	PROLENE Tote	15 Minutes	12.98 ppm	Inside plastic cover
9/15/82	PROLENE Tote	15 Minutes	0.19 ppm	In Shipping area
5/13/82	In Tote of PROLENE	475 Minutes	54.44 ppm	Under plastic cover
6/21/82	VICRYL Pallet	450 Minutes	2.06 ppm	Inside pallet
6/28/82	VICRYL Tote	462 Minutes	0.21 ppm	Inside plastic cover
5/18/82	Inside VICRYL Tote	475 Minutes	22.69 ppm	Under plastic cover
5/12/82	On VICRYL Cart	405 Minutes	4.44 ppm	Aeration Room & FA-2
5/18/82	Center of VICRYL Cart	480 Minutes	3.73 ppm	Aeration Room to FA-2 to Hot Room
5/18/82	Shipping bins	475 Minutes	0.46 ppm	
6/21/82	Shipping bins	453 Minutes	1.21 ppm	
6/25/82	Shipping Bins	474 Minutes	0.70 ppm	
3/22/82	Hot Room	480 Minutes	0.38 ppm	Room full

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