INDUSTRYWIDE STUDIES REPORT OF WALK-THROUGH SURVEY OF

JOHNSON & JOHNSON PRODUCTS
Sherman, Texas

PROJECT NUMBER: P:84:12

SURVEY CONDUCTED BY:
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PURPOSE OF SURVEY:	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).
EMPLOYER REPRESENTATIVES CONTACTED:	Dr. John Paul Jones, Director, Health Service Mr. David M. Woody, National Manager of Safety and Health Mr. David Williams, Safety Manager Ms. Joan Armstrong, Senior Safety and Health Administrator
EMPLOYEE REPRESENTATIVES CONTACTED:	Mr. Bill Mayo, President, Local 513, United Textile Workers Union (UTW)
STANDARD INDUSTRIAL CLASSIFICATION OF PLANT:	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies

ABSTRACT

On January 30-31, 1984, a walk-through survey was conducted at the Johnson and Johnson Products plant in Sherman, Texas. The purpose of the walk-through was to evaluate industrial hygiene and personnel records, as well as plant processes, to determine whether this plant was eligible for the cohort mortality study of ethylene oxide (ETO) exposed workers currently being conducted by NIOSH. This plant began production in 1962, and first used ETO in 1966 in the sterilization of medical supplies. This plant meets the eligibility requirements as defined in the protocol, i.e., 1) that the plant must contribute at least 400 person-years to the study, 2) must have adequate personnel records to identify the exposed, 3) and must not have any serious confounding due to other leukemogens.

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 was a part of the pilot study.

The study protocol calls for a mortality and industrial hygiene study of two phases. The first phase of the study will be restricted to employees who were exposed to EtO for at least three months prior to January 1, 1978, while the second phase will include all exposed employees. This walk-through survey assessed the eligibility of this facility to be included in the first phase of the study (see 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 Johnson and Johnson plant in Sherman, Texas makes a large variety of products, primarily various types of gauze products and sponges, but also a number of products with plastic as well. Components of hospital packs have been produced in Sherman, but assembly of these packs has been done in Wichita Falls and other plants since 1974. The assembled packs have been shipped back to Sherman for sterilization.

This plant began production in 1962. Much of the work force at that time transferred from Dallas, where the company had been located since the 1950's. Air conditioning was installed in 1962. Ethylene oxide (ETO) was first used to sterilize in 1966. Steam sterilization has also been used. Since 1974 this plant has also used gamma radiation (Cobalt 60) to sterilize certain products (disposable hospital packs).

Description of the Workforce

The current workforce numbers 743, with about 540 of those hourly. In 1968 the total was 660, in 1973 it was 791, and in 1978 it was 916 . The current work force is 16% black and 1% Indian, the remainder being white. In 1968 there were 5% black and 5% Indian. Race is not noted in personnel files. Turnover in 1983 was only 4.9%, but in past years has varied widely, with perhaps typical levels being higher, in the range of 10-12%. This range does not include turnover due to layoffs; if layoffs were to be included, the turnover percentage would increase to 20-25%. Typically, employees subject to layoffs would have less than 1-2 years of company tenure.

Process Description

Initially, the product to be sterilized is placed on pallets and loaded into the EtO sterilizer by hand truck. Next, the product is preconditioned in the sterilizer for several minutes by increasing the temperature and humidity. The EtO/carbon dioxide (CO_2) mixture is added to the sterilizer and the product is sterilized under negative pressure. At the end of the sterilization cycle, the amount of vacuum being pulled is increased to remove the EtO gas mixture from the sterilizer. The sterilizer then undergoes a steam flush in order to insure that the product's residual EtO level is maximally reduced. Another vacuum is pulled after which the sterilizer pressure is standardized.

The product is unloaded by hand truck from the sterilizer and may be allowed to sit outside the sterilizer for up to two hours. The quality control spore strips are pulled and the product is moved to the impound area. The product is held there for ten (10) days before release to allow time for microbiological testing of the spore strips (which is currently conducted in the Johnson & Johnson Products, Incorporated, North Brunswick facility). The product is then moved to the Sales Distribution Center where it is sold and shipped.

Description of Past Exposures and Controls Used

In 1966, Johnson & Johnson Products (JJP) purchased a large sterilizer which was equipped to use either steam or EtO. In 1967, a second large EtO sterilizer was purchased. A gas mixture of EtO and carbon dioxide (CO_2) was used under positive pressure to sterilize hospital packs. Due to the high percentage of EtO in the gas mixture, and the explosive property of EtO, a give-away roof was installed over the sterilizer area.

During the period of 1968 to 1978, the quality assurance (QA) technicians physically handled the EtO/CO_2 cylinders. Five (5) cylinders per lot were checked to determine the quality of the gas mixture. This was accomplished by attaching a balloon (heavy punching bag type) to an EtO/CO_2 cylinder, slowly opening the cylinder valve, filling the ballon with the gas mixture, closing the cylinder valve, and crimping the ballon in order to contain the EtO mixture. The balloon was then transferred to an infrared (IR) gas analyzer [a gas chromatograph (GC) was later used] for analysis of the gas mixture. Since the EtO/CO_2 in the cylinders was in a liquid state, and thus under high pressure, it was difficult for the technicians (who were not wearing goggles or gloves) to fill the balloon without being sprayed with the liquid EtO/CO_2 mixture.

In addition, the QA technician ran a pressure check on all of the cylinders (10-12 per shipment) after they were temperature conditioned in the EtO Cylinder Storage room. The pressure check procedure involved attaching a 2-inch long (approximate measure) pressure gauge with a threaded fitting to the cylinder, opening the cylinder valve, determining the cylinder pressure, closing the cylinder valve, and disconnecting the pressure gauge, which remained under pressure. During the disconnecting part of the procedure, the remaining pressure resulted in a small quantity of liquid EtO being sprayed on the QA technician's hands. [No gloves or goggles were worn during the EtO cylinder pressure check (verbal information)]. Levels of EtO monitored while conducting the QA checks were found up to 145 ppm (49 minutes) for 1-hour Time-Weighted Average (TWA) measurements.

In 1969, a larger EtO/steam sterilizer was purchased. In 1970, a leak, due to an improper seal, occurred around an EtO sterilizer door. The leak plus a spark resulted in an explosion in which the sterilizer door was blown open and three (3) employees were burned. The level of EtO around the sterilizer door prior to the explosion was estimated to be at least 30,000 ppm since the explosive range of EtO in air is 3-100%.

In 1971, a Lower Explosive Limit (LEL) monitor/alarm system was installed in the sterilizer area. In addition, duct shrouding ventilation was installed

around all of the EtO sterilizer doors. The amount of EtO mixture used in 1971 reached a peak of 427,000 pounds (lbs).

In 1974, the warehouse was moved (within the plant) and sterilized product was transferred to the new impound area for storage. Due to the new storage location, EtO off-gassing from the sterilized product could no longer diffuse into the manufacturing area. Both EtO and steam sterilized product were held in the impound area for 10 days until biological testing was completed. After biological testing was completed, the product was transferred to the Sales Distribution Center where it remained for 1 day to 1 month prior to being shipped.

During 1974, the number of pounds of EtO used dropped dramatically from 376,000 lbs (in 1973) to 135,000 lbs. This reduction was due to a change in packaging and the installation of Cobalt (Co) 60 sterilization process. Also, in 1974, sterilizer operator work schedules were changed from three 8-hour (hr) shifts per day to two 12-hr shifts. The employees working 12-hr shifts were put on a rotating schedule of 3 to 4 day work weeks. In addition, the pressure under which the product was EtO sterilized was changed from positive to negative, in 1974.

In 1976 and 1978 respectively, the first and third sterilizers purchased were converted from EtO/steam to steam only. From 1978 to the present time, therefore, only one chamber remained that could be used for EtO sterilization. Also, in 1978, the EtO cylinders purchased were under vendor certification, thus eliminating the need for JJP QA employees to handle and sample the EtO cylinders.

In 1979, Johnson and Johnson instituted an internal corporate-wide workplace exposure guideline for EtO of 10 ppm as an 8-hr TWA and a Short-Term Exposure Limit (STEL) of 75 ppm. In 1980, these exposure guidelines were revised; the 8-hr TWA was lowered to 1 ppm and the STEL lowered to 10 ppm.

Prior to 1981, there was no respiratory protection used during the EtO sterilization operation. In late 1981, respirator and qualitative respirator fit testing programs were instituted. MSA full-face cannister respirators specific for EtO were worn when unloading the EtO sterilizer or changing the EtO cylinders. The cannisters were changed after 12 hours of use. A log was maintained to determine and document the amount of time respirators were used.

In 1983, a Perkin Elmer GC with flame ionization detector (FID), recorder, and alarm system (set at greater than 10 ppm) was installed. Around the end of 1983, the MSA cannister respirators were replaced with the newer full-face MSA EtO cannister respirators with end-of-service-life window indicators.

In 1984, a projection was made that JJP might end all EtO sterilization at this facility in 1985. At the time of this report, however, EtO was still being used at this facility, and is expected to be used in the future for sterilization.

In 1985, the Perkin Elmer GC with FID was replaced with an HNU gas chromatograph (GC) with photoionization detector (PID).

Description of Industrial Hygiene, Safety, and Medical Programs

Industrial Hygiene

An industrial hygiene (I.H.) program was started in 1977. Most industrial hygiene monitoring and ventilation measurements (1978) have been conducted by a Safety and Health Administrator. An environmental survey was also conducted by Scott Environmental in 1981.

Personal short-term and area monitoring were conducted in 1977, 1978, and 1980. In 1980, the collection time of personal short-term samples was 36 to 152 minutes. From 1980 through 1983, area and/or personal 8-hour TWA samples were collected; and in 1984, short-term and TWA personal samples were collected. Monitoring was conducted almost exclusively with Qazi-Ketchum (QK) charcoal tubes containing 700 milligrams (mg) of charcoal in the front section and 390 mg in the back section. The charcoal tubes were analyzed at the Corporate Johnson & Johnson Products, Incorporated Research Analytical Laboratory in North Brunswick, New Jersey.

Safety

JJP has seven functioning safety committees; one is designated for those working with EtO. Safety meetings and inspections by area personnel are held monthly. All workers attend annual job specific refresher training courses, and sterilizer supervisors conduct weekly safety checks of the sterilizers. In addition, a written handling procedure and safety training program is provided for the sterilizer operators, sterilizer area supervisors, and maintenance personnel. MSA cannister respirators with end-of-service-life window indicators are worn by all sterilizer operators during potential peak exposure periods, i.e., changing EtO cylinders and loading and unloading the sterilizers.

Medical

JJP has a medical department consisting of two part-time physicians and one full-time nurse on first shift. In addition, JJP has a first aid squad on all shifts (24 hours per day), five days per week. During weekend work hours, supervisors trained in first aid handle any health problems; emergencies are referred to a nearby hospital.

Annual physical examinations and blood work-up are required for all sterilizer operators.

Description of Personnel Records and Definition of Exposed

(a) Description of personnel records

The personnel records are arranged by year of termination, and alphabetically within year of termination. Hourly and salaried employees are stored separately. All personnel records include a work history card which lists changes in department and job title over time. Departments are

assigned a 3-digit number. These numbers have changed only slightly over time. The first digit in the department number, in effect, defines the department, while the second two digits describe the job. In addition to work history cards the personnel files contain demographic information including Social Security Number (SSN), date of birth, and sex.

There are no obvious gaps in the personnel files, which go back in time to the plant opening. A check of 10 men identified by the company as having been exposed to ETO were subsequently located in the personnel files; the work histories of these men did indeed identify them as exposed.

This plant is unionized by the United Texile Workers. Senority lists of craft and production workers exist on a monthly basis for the years 1973, 1975, 1980-85.

Other records include medical records, as well as quarterly earnings reports back to about 1970.

There are approximately 1700 records for terminated hourly employees, and 540 records for current hourly employees.

There are approximately 1160 records for terminated salaried employees, and about 200 records for current salaried employees. The Sherman plant has always had a relatively high number of salaried employees in relation to hourly employees. For example, in 1975 there were about 340 salaried employees at Sherman, and 520 hourly employees. In addition, for the years 1966-1974, salaried employees at the Johnson and Johnson plant in Wichita Falls were included in the records for salaried employees at the Sherman plant. Any terminations among Wichita Falls salaried employees during those years will now be found in the Sherman files. During the period 1967-74 there were approximately 30-50 salaried employees at the Wichita Falls plant, while there were about 350-400 salaried employees at the Sherman plant. No attempt was made to separate out the Wichita Falls terminated salaried employees from the Sherman salaried employees in the files for terminated employees from 1967-74, hence the estimate of the total number of terminated salaried employees is slightly too high.

(b) Definition of exposed and results of sampling the records

Exposure occurred near the sterilizers, and near off-gassing products. The sterilizers in this plant are located in the gauze mill, a large open building (here called building 2). Everyone in this building has been or is potentially exposed to EtO. Levels in building 2 were undoubtably higher before 1974, when volume decreased and when sterilized product began to be stored in a different building. No sampling data is available before the late 1970's. Nevertheless, in the late 1970's and early 1980's, personal sampling has indicated that all employees in building 2 may have been exposed to low levels of EtO. Building 2 has been primarily devoted to gauze products. In addition, many other products (dental floss, J-Pads, trays, and liquid antiseptic) have been made or assembled in building 2. Building 3 (the "fiber mill") has been dedicated to producing fiber products; there is no exposure to ETO in building 3. Building 1 is

dedicated to warehousing and shipping. Employees in building 1 were unexposed until storage of product began there in 1974. Since that time these employees must be considered exposed.

The department numbers to be considered as exposed for hourly employees are 200-299 for the Gauze Mill; 400-499 for Mill IV which was integrated into the Gauze Mill in 1982; 600-619 for Shipping from 1974 onwards; 500-599 for the Sterilizing Department (500-502, 502 is Cobalt sterilization) and other departments in the Gauze Mill (eg., Scott Hi-Loft Underpads (573), J-Pads in the past (550,551), etc.); 701 and 703 for Gauze and Baby Products Maintenance, and 770 for Gauze Manufacturing.

In addition, all salaried individuals in Quality Assurance (QA) (also known as Technical Assurance, Technical Assistance, Technical Services) should be considered potentially exposed. QA has historically tested the ETO and has also analyzed spore strips from off-gassing products. Furthermore, any salaried employees who had previously held hourly jobs in exposed areas would also be exposed. No other salaried personnel were routinely exposed. Undoubtably some other salaried personnel worked occasionally in exposed areas (e.g., engineers), but those individuals cannot be distinguished from salaried personnel records. For our purposes only salaried personnel in QA or with previous hourly experience in exposed areas are considered exposed.

(i) Sampling the hourly records

A 5% sample (approximately) from both active (n=540) and inactive (n=1700) hourly employee files was reviewed. Eighty records were sampled from the terminated employees. Given that the records for terminated hourly employees were stored by year of termination, random samples of equal number for each year were chosen. For active hourlies, a random sample of 25 was chosen. The total number of hourly records considered in this summary, then, is 105.

For a worker to have been exposed, he or she must have worked in building 2 or worked in building 1 after 1974. Furthermore, he or she must have worked in an exposed job at least 3 months, which is a criterion for entry into the epidemiologic study. In the sample of 105 hourly records (terminated and active combined), there were 59 exposed employees (56%) and 28 nonexposed (27%). The balance were exposed, but for less than 3 months. The average date of birth of the exposed population was 1946. The average year of hire for the exposed was 1971. Twenty-eight of the 59 exposed employees were males (50%).

(ii) Sampling the salaried employees

Eighty-three inactive salaried employees (out of 1160), and 17 active salaried employees (out of 200) were sampled. For all salaried, 33% were exposed for at least 3 months. The average date of birth for the exposed was 1947, and the average age of hire was 1971. The percentage of females was 42%.

(iii) Combined hourly and salaried groups

For the whole plant, it is expected that approximately 3600 people have been employed of whom about 1700 have been exposed for more than 3 months (1250 hourly and 450 salaried). About 56% of the hourly employees have been exposed while about 33% of the salaried employees have been exposed. The percentage of females in the exposed is 40%. Overall, the average date of hire for all exposed employees at the plant is 1971. The average date of hire was used as a surrogate for average date of first exposure, although in some cases an individual may have transferred to an exposed job subsequent to being hired. About 10% of the plant employees were hired during or after 1978, and hence would be excluded from the first phase of the mortality study which includes only first exposed prior to 1978. Using 1971 as a date of first exposure, assuming approximately 12 years of follow-up per person, and subtracting the 10% of the employees who would not qualify for the first phase of the study, it is estimated that approximately 18,000 person years of experience would be contributed by these employees to the first phase of the cohort mortality 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, type of sample, and range of EtO concentration are presented in Table I. Table II contains the plant controls implemented to reduce EtO exposure levels.

Abbreviations Key for Table I

1. A = Area Sample
2. P = Personal Sample
3. TWA_8 = 8-hour Time Weighted Average
4. ST = Short-term sample (usually 15-20 minutes)
5. ND = Non-detectable

One-half of the LOD (0.08 ppm) was used as the N.D. value when calculating arithmetic means.

Table I

History of Sampling Methods and Data
Johnson & Johnson Products
Sherman, Texas

Date	Sampling Location/ Job Description	Type of Sample	Range of EtO Concentration (ppm)	No. of Samples	Arith. Mean X (ppm)	Geom. Mean Xg	Geom. Std. Dev. SDg	Comments
1977	Sterilizer Operator	P-ST	0.06-1.0	8	0.3	0.2	2.4	
	Near Sterilizer Door	A-ST	0.03-0.5	5	0.1	0.1	3.0	
	Cylinder Exhaust Hood Behind Sterilizer	A-ST	6.0	1	-	-	-	
	EtO Storage Room	A-ST	40.2	1	-	-	-	
	EtO Cylinder Room	P-ST	144.6	1	-	-	-	
	Lab	A-ST	0.09-58.2	2	29.1	-	-	
	Lab Tech.	P-ST	0.8-83.9	2	42.4	-	-	
1978	Sterilizer Operator	P-ST	0.5	2	0.5	-	-	
	Near Sterilizer Door	A-ST	0.1-0.4	3	0.3	0.2	1.9	
1980	Sterilizer Operator	P-ST	N.D.(1)-2.7	32	0.4	0.2	3.0	Sampling time range: 20 min to 2.5 hrs
	Near Sterilizer Door	A-ST	N.D.(1)-0.9	7	0.3	0.2	2.5	
	Sterilizer Area	A-ST	N.D.(1)-0.1	6	0.1	0.1	1.1	
	Near Gauze Pad Area	A-ST	N.D.(1)-0.3	3	0.2	0.1	2.0	
	Cylinder Change Area	A-ST	N.D.(1)	1	-	-	-	
	Cobalt Area	A-ST	N.D.(1)-0.2	2	0.1	-	-	
	Sterilizer Operator	P-TWA8	0.1-0.3	8	0.2	0.2	1.5	
	Production Supervisor	P-TWA8	0.03-0.1	4	0.01	0.1	2.1	

(1) The Limit of Detection was 0.08 ppm.

Table I (continued)

History of Sampling Methods and Data
Johnson & Johnson Products
Sherman, Texas

Date	Sampling Location/ Job Description	Type of Sample	Range of EtO Concentration (ppm)	No. of Samples	Arith. Mean X (ppm)	Geom. Mean Xg	Geom. Std. Dev. SDg	Comments
1981	Sterilizer Operator	P-TWAg	0.2-0.8	8	0.6	0.6	1.5	
	Safety Technician	P-TWAg	0.3	1	-	-	-	
	Production Supervisor	P-TWAg	0.1-0.4	4	0.3	0.3	1.8	
	Barrier Operator	P-TWAg	0.1	1	-	-	-	
1982	Sterilizer Operators	P-TWAg	0.1-1.0	8	0.4	0.3	2.0	
	Production Supervisors	P-TWAg	0.1-0.3	4	0.2	0.2	1.5	
	Safety Technician	P-TWAg	0.2	1	-	-	-	
	Adaptic Operator	P-TWAg	0.4	1	-	-	-	
1983	Sterilizer Operators	P-STEL	2.5	1	-	-	-	
		P-TWAg*	0.2-0.7	6	0.4	0.3	1.7	
1984	Sterilizer Operators	P-STEL	0.6-6.0	10	2.0	1.5	2.2	13-30 minutes
Jan. only	Sterilizer Operators	P-TWAg*	0.7-2.4	2	1.6	-	-	

* 480 was used as the total number of minutes in all cases when calculating the TWAg in 1983 and 1984. If the actual sampling times of 7.9 to 10.8 hours had been used to calculate the TWAs, the range of EtO concentrations would be 0.12-0.53 ppm; the partial period sample of 3.5 hours would be 0.75 ppm; and the STEL of 13 minutes would be 2.48 ppm for 1983. For January, 1984, if the actual sampling times of 8.1 and 10.9 hours; were used, the TWA concentrations would be 0.74 and 1.77 ppm, respectively.

Table II

Controls Implemented to Reduce EtO Exposure Levels
Johnson & Johnson Products
Sherman, Texas

Date	Engineering Controls	Administrative Controls	Monitoring Systems	Range of EtO Levels Measured (ppm)
1966	Give-away roof installed over sterilizer area	None added	None added	
1971	Duct shrouding installed around all EtO sterilizer doors	None added	LEL monitor/alarm system installed	
1973	Warehouse was moved resulting in less EtO diffusing into manufacturing area	None added	None added	
1974	Cobalt 60 sterilization process added resulting in a large decrease in amount of EtO used EtO sterilizer pressure changed from positive to negative during sterilizing cycle	Sterilizer operator shift schedule revised	None added	
1976	One EtO sterilizer converted to a steam sterilizer	None added	None added	
1977	None added	None added	Short-term personal & area monitoring conducted	0.1-144.6
1978	One EtO sterilizer converted to a steam sterilizer. A ventilation check was made in the sterilizer area	EtO cylinders were required to have vendor certification	Short-term EtO monitoring conducted	0.1-0.5

Table II (continued)

Controls Implemented to Reduce EtO Exposure Levels
Johnson & Johnson Products
Sherman, Texas

Date	Engineering Controls	Administrative Controls	Monitoring Systems	Range of EtO Levels Measured (ppm)
1979	None added	Corporate-wide workplace exposure guideline for EtO of 10 ppm as an 8-hr TWA instituted	None added	
1980	None added	EtO exposure guideline lowered to 1 ppm as an 8-hr TWA and 10 ppm STEL added	Short-term and TWA EtO monitoring conducted	N.D.-2.7
1981	None added	Respirator and qualitative fit testing programs instituted	Personal TWA_8 EtO monitoring conducted	0.1-0.8
1982	None added	None added	Personal TWA_8 EtO monitoring conducted	0.1-1.0
1983	Contractor conducted ventilation survey	Respirator program up-dated	Perk & Elmer GC with FID, recorder, and alarm system installed Personal TWA_8 EtO monitoring conducted	0.2-0.7*
1984 (January only)	None added	Projection made to eliminate all EtO sterilization in 1985	Personal STEL and TWA EtO monitoring conducted	0.6-6.0 STEL* 0.7-2.4 TWA

* See Table 1 footnote.

The data in Table I indicate that EtO was present in the work environment at this facility, at least in the sterilizer and EtO cylinder storage areas. The sampling media used during 1977 consisted of two charcoal tubes in series; the front and back-up tubes contained 400 and 200 mg of charcoal, respectively. In 1978, JJP discontinued use of these charcoal tubes and replaced them with Qasi-Ketchum (QK) charcoal tubes. Both types of sampling media were used to conduct area and personal EtO monitoring in the sterilizer work area and EtO cylinder storage room.

In 1983, the 8-hour TWAs were always computed as if the total sampling time were 480 minutes. In fact, the sampling times ranged from 212 to 647 minutes. It is unclear what assumptions were made regarding employees' exposure to EtO to account for the discrepancies between 480 minutes and actual sampling times. Therefore, actual EtO levels may be higher or lower than reported.

Overall, the EtO exposure levels remained fairly constant from 1980 through January, 1984. During January, 1984, the range of exposure levels documented on sterilizer operators was 0.7 to 2.4 ppm (1.8 ppm TWA for the actual sampling time of 10.9 hours) as personal 8-hour TWAs and 0.6 to 6.0 ppm as personal short-term exposure levels. (See Table I.)

Conclusions

Johnson & Johnson Products has industrial hygiene data dating back to 1977. Therefore, it would be possible to develop an exposure classification strategy for job categories in this plant. In addition, based on the findings of this report, this plant meets all of the eligibility requirements as defined by the protocol and should be included in the study. These requirements are: 1) the plant must contribute at least 400 person years, 2) the plant must have adequate personnel records or other records that can be used for identifying past and present workers exposed to EtO, and 3) the plant must not have any serious confounding exposure to a known leukemogen. Regarding this last point, it should be noted that Cobalt 60 sterilization has been conducted since 1974. However, this process is well controlled, and radiation badges show no appreciable exposure to gamma radiation for the small number of plant employees who work with this process.

Recommendations

The following recommendations are based on work practices observed and EtO levels measured by JJP at the time of the walk-through survey. They are offered as an aid to reduce exposure potential to EtO, and are based on cited references or "good industrial hygiene practices".

1. Continue the industrial hygiene monitoring program for EtO.
2. Periodically conduct ventilation investigations to insure proper operation of the ventilation system.
3. Continue using approved respiratory protection until adequate engineering controls and/or work practices have lowered the workers' TWA exposure level to the "action level" of 0.5 ppm or less. When cannister respirators are used, the workers should be quantitatively fit tested.

It should be kept in mind, however, that respirators should not be considered a substitute for adequate engineering controls.

4. Periodically clean all air handling units and filters to insure proper air flow.
5. Compute TWAs using the actual amount of sampling time. The 8-hour TWA may then be estimated, based on whether the working conditions and EtO exposure levels remained the same or changed.

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