INDUSTRYWIDE STUDIES REPORT:
A WALK-THROUGH SURVEY

OF

AMERICAN STERILIZER COMPANY
2424 West 23rd Street
Erie, Pennsylvania 16512

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DISCLAIMER

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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:	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies

ABSTRACT

On May 29-30, 1984, a walk-through survey was conducted at American Sterilizer Company (AMSCO), Erie, Pennsylvania. AMSCO has produced hospital sterilizers which sterilize with ethylene oxide (ETO) gas, ETO gas and steam and steam only since the early 1950s. This report will only discuss the production of sterilizers which utilized ETO. In the early 1960s, an industrial line of sterilizers was introduced, a few of which used only ETO. Between 1956 and 1960 AMSCO also conducted contract sterilization services.

ETO (12/88) was used at this facility from the early 1950s to 1982, to test the sterilizers for gross air leaks and proper gauge function. ETO was also used to remove paint, however, this was not a standard manufacturing practice. Testing of the sterilizers involved several set-up and charging cycles. Beginning in 1979, compressed air and Freon 12 were used to test sterilizers, greatly reducing the amount of ETO used. In 1982, all use of ETO was discontinued.

There is a paucity of industrial hygiene data, since the company does not have a formal industrial hygiene program. Industrial hygiene services have been supplied, however, by the insurance carrier since the early 1970s. Personal sampling for ETO exposures was not conducted however. AMSCO did conduct limited general area sampling in 1981. This data, which was collected with an infra-red direct reading instrument, facilitated modifications to the water drainage system in the test block area. In 1982, after improvements in test block facilities and sterilizer design, EtO measurements were again collected with an infra-red direct reading instrument. These measurements, which were simulated breathing zone samples, were collected for a minimum of 40 minutes/cycle, 4 cycles/8hours. From this data the calculated 8 hour Time Weighted Averages were less than 1 ppm.

ETO has not been used at this facility since 1982, therefore, there are no future industrial hygiene surveys planned at this plant as part of this ETO study.

AMSCO has 18 regional offices, staffed by service representatives, located throughout the country. It has been determined that the extent of exposure of these service representatives to ETO, although low, warrants their inclusion in the study. The number of person-years these individuals will contribute, however, can not as yet be determined.

This plant meets most of the eligibility requirements as defined by the protocol. These requirements are: 1) the plant must contribute at least 400 person years (In plant employees would contribute an estimated 1800 person-years, surpassing this minimum requirement.), 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.

The principal problem with this plant, with respect to the inclusion criteria, is that personnel records are incomplete for certain years.

However, the use of supplementary data, such as internal payroll records, internal lists of exposed, and 941 forms filed with the Social Security Administration (SSA), would probably allow reconstruction of the cohort. The inclusion of this plant in the study is therefore recommended.

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]

This walk-through survey was conducted to determine the suitability of including American Sterilizer 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

American Sterilizer Company (AMSCO) was founded in 1894, and first produced sterilizers for hospitals in 1956. This report will only describe the production of the ETO gas or ETO gas and steam sterilizers. The ETO sterilizers ranged in size from 6 to 30 ft^3. In the early 1960s, AMSCO introduced an industrial sterilizer, which had a much larger capacity (30-1000 ft^3) than the hospital sterilizers. A few of these sterilizers used only ETO. AMSCO used an industrial sterilizer to sterilize various customer products from 1956-1960. This contract sterilization was conducted in a walled off corner of the foundry. The sterilized goods were allowed to off-gas outside this area, which was contiguous to the grinding area of the foundry. The foundry fabricates many of the necessary sterilizer parts. The facility also has a cafeteria; however, some employees eat at their job site.

The interior of the assembly and test facility has not changed greatly over the last several years. Various departments have relocated within the plant, but there has been minimal addition or deletion of internal walls except in the welding area. The production, assembly, and test areas share a common area within the plant. All welding is now done in newly constructed welding bays, with each bay having a local exhaust system. This facility discontinued the use of all ETO in 1982. The estimated amount of ETO used from 1956 to 1979 was about 37,000 pounds or an average of 1600 pounds per year. The estimated use for 1980 to 1982 was about 450 pounds per year.

DESCRIPTION OF WORKFORCE

According to company officials, this plant has several hundred current hourly employees, with an average length of service of 17 years, with an average age of 45 years. In addition, there are currently several hundred service employees located in 18 field offices, although these employees were fewer in the past. Service employees repair AMSCO equipment in the field. Service employees are salaried. Hourly employment levels have fluctuated from about 400 in the late 1950s to a peak of 825 in 1974.

Since 1964, the collective bargaining representative for the majority of the plant has been the United Auto Workers, Local 832. There are a very few workers, primarily tool makers, who are represented by the American Sterilizer Independent Union (ASI), Local 1968. Prior to 1964, the ASI represented the majority of the workers.

In 1956, the company was operating on a three shift/day, five day/week schedule. This continued until about 1969, when one shift/day was deleted in the assembly and test departments. Testing of sterilizers was conducted in the first two shifts after 1969. Maintenance and general clean-up was

done on the third shift. Currently, testing is conducted on the first and second shift and maintenance and clean-up on the second shift.

DESCRIPTION OF PROCESS

AMSCO makes hospital sterilizers ranging from 6 to 30 ft^3 and industrial sterilizers ranging from 30 to 1000 ft^3. There is a small foundry located on-site, where many sterilizer parts are fabricated. AMSCO has complete plating, welding, finishing, and painting departments also. Once the various metal components of a sterilizer have been produced, they are sent to an assembly area which is located directly east of the test area or block. In the assembly area, metal parts are assembled and the electronic components are added. The assembled sterilizer is then transported to the test area, where it is checked by the tester for air leaks, proper gauge and electronic component function. Occasionally, an assembler will aid the tester. Following several set-up and charging cycles, the fully assembled and tested sterilizer is sent to packaging and shipping.

Contract sterilization of various materials, such as diapers, was also conducted at this plant between 1956 and 1960. This operation was done near the foundry, and some foundry workers, primarily grinders, may have been potentially exposed to ETO.

DESCRIPTION OF PAST EXPOSURES

There have been many modifications made in the ventilation system, physical location of departments, and work practices which could affect employee exposure to ETO. Most of these changes have occurred in the test block area, where the highest exposures to ETO probably occurred.

Ventilation

Prior to 1974, the exhaust system in the test block area consisted of an overhead canopy which ran the entire length of the block. The opening of the canopy was about 16-20 feet above the floor. While the face or capture velocity of the canopy is not known, it can be assumed that the capture efficiency would be low.

In 1975, this system was removed and a more local exhaust system was installed. This system consisted of a large, overhead duct with several smaller ducts branching from it. These branch ducts could be positioned, with some difficulty, near the safety valves, door and drain of a sterilizer. It is not known if these ducts were flanged.

Flexible tubing which was much easier to position replaced these rigid branch ducts in 1981. This system was augmented in 1982, by the addition of better quality tubing, which was permanently attached to the vent around the sterilizer door and the enclosed drain. The tubing was connected to the test block ventilation system during a test cycle. The capture efficiency of this system was not evaluated during this survey, however, as ETO is no longer used at this facility and the system has been partially dismantled. Time weighted average (TWA) exposures (8-hour) calculated from data collected by the company after these changes were made (with an infra-red

direct reading instrument, in breathing zones simulated under "worse case" conditions (that is, when several sterilizers were exhausted simultaneously) indicated that the personal TWAs were less than 1 ppm (see Table II).

An additional modification to the existing ventilation system was the implementation of a vent permanently mounted above the door of each sterilizer. During the test cycle, this vent would be connected to the test block ventilation system. This vent, which is also manufactured by AMSCO, may be sold as an accessory.

Physical Location of Departments

Various departments have changed location within the plant, however, these changes did not precipitate the construction or rearrangement of walls within the plant. Therefore, relocation of departments did not significantly alter overall ETO levels in the areas contiguous to the test block. The test block area has remained in essentially the same location since the mid 1950s, when sterilizer production began.

AMSCO conducted a contract sterilization service which was located in a room in a corner of the foundry. This service, which employed an industrial size sterilizer, was conducted from 1956-1960. Once the goods had been sterilized, they were removed from the sterilizer and allowed to aerate outside the room. The aeration area was contigous to the grinding area in the foundry.

Work Practices

There have been many changes in work practices over the years, but the changes that most directly affect the employee exposure to ETO are those related to testing of the sterilizers. The number of cycles conducted to test a sterilizer has varied over the years. Before 1979, testing of a sterilizer consisted of first filling the unit with ETO to test the piping for any leaks. This was followed by three set-up cycles using ETO (12/88) to set the gauges. Air leaks at this point were located using a flame detector. These set-up cycles were followed by four ETO charging cycles. ETO gas was used frequently extensively at this facility not only to test sterilizers. The total estimated amount of ETO used from 1956 to 1979 was about 37,000 pounds. ETO was also used to remove paint, however, this was not a standard manufacturing practice. From 1979 to 1981, compressed air was substituted for ETO during the set-up cycles. Leaks were detected by soap and water. ETO was still used in the four charging cycles that followed however. This decreased the use of ETO to about 450 pounds/year. In mid-1981, the use of ETO in the charging cycles of the industrial sterilizers was discontinued, and by early 1982, ETO was no longer used to charge the hospital sterilizers.

Air Monitoring Data

The company conducted area monitoring for ETO in 1981 and 1982. All monitoring was conducted with a Wilks-Miran 101, a direct reading instrument, in the test block area of the plant.

In 1981, data was collected to ascertain what the peak ETO levels, would be and therefore potential employee exposure, might be from 2 sizes of

sterilizers (8.8 ft^3 and 30 ft^3) and at 8 different sites around the sterilizer (see Table I). Employees were not present during the test. The data represents a peak or instantaneous exposure to ETO. The data revealed that the highest ETO concentration occurred at the sterilizer drain, near the floor. Both sterilizers had peak readings of 750 ppm at this location.

Samples taken on the drain side of either sterilizer, at a height estimated to be in the breathing zone, had values of 35-40 ppm. Other samples were collected in front of the sterilizer [breathing zone (30-40 ppm) and floor (30-35 ppm)] and the opposite side from the drain [breathing zone (20 ppm) and floor (20 ppm)]. In addition, two measurements were taken directly at the door opening (8.8 ft^3 sterilizer 350 ppm, 30 ft^3 sterilizer 650 ppm), and two measurements were taken 1-2 feet in front of the open door (8.8 ft^3 sterilizer 40 ppm, 30 ft^3 sterilizer 125 ppm).

A final measurement was taken at the water trough that runs between the two row of sterilizers being tested. The exact location of this sample site is unknown. This trough receives water from all the sterilizer drains, and is uncovered. A peak reading of 250 ppm was recorded several times during the exhaust phase of the each test cycle. This level would decrease, however, at the completion of each cycle.

These data imply that an employee may have high peak or instantaneous exposure to ETO. The contribution of these exposures to an 8-hour TWA is unknown, due to the brevity of the collection period for each sample.

In 1982, more extensive sampling was conducted to determining a worst case exposure (see Table II). Samples were collected at three locations where testers might be during a sterilizer test. Samples were also collected at two heights (3.3 or 5 feet from the floor) to simulate job dependent breathing zone samples. To simulate a worse case situation, two sterilizers (8.8 ft^3 or 24 ft^3) were exhausted simultaneously, with additional units exhausting periodically throughout the 40 minute sampling period. Time weighted averages (TWA) for an 8 hour shift were based on 4 cycles per shift. All sterilizers were equipped with an AMSCO designed ventilation system around the door. This system, which was mounted permanently on the sterilizer, was sold as an accessory. The data, which is found in Table II, indicate that potential employee exposure to ETO is rather low. These low ETO levels may have been due to the improvements in the existing local exhaust system in the test block and use of a ventilation system permanently mounted on the sterilizer itself.

DESCRIPTION OF MEDICAL, INDUSTRIAL HYGIENE AND SAFETY PROGRAMS

Medical

AMSCO has a medical department which is composed of a full-time nurse on the first and second shift. A physician is available as needed. The medical department is equipped to handle minor emergencies. In addition, several of the employees on both shifts are trained emergency medical technicians.

Pre-employment physicals are given to all employees. There are no follow-up examinations.

In 1982, a physician conducted a medical examination of all employees who were currently or had previously been exposed to ETO. This examination consisted of a chest roentgenogram, blood and urine chemistries, pulmonary function testing, visual acuity and hearing examinations. In addition, work and medical histories were obtained.

Industrial Hygiene and Safety

The industrial hygiene program which is conducted by the insurance carrier, was started in the early 1970s. In 1981, in-house sampling for ETO was conducted by the Research and Development department with a Wilks-Miran 101 and represents area exposures (see Table I). In 1982, simulated employer breathing zone samples were collected with the Wilks-Miran 101 (see Table II). A discussion of the data collected in 1981 and 1982 may be found in the Description of Past Exposure section-Air Monitoring Data. Neither the company nor the insurance carrier has ever collected personal samples for ETO. The company requires the use of various safety devices such as safety glasses. Safety showers and emergency eye wash stations are located around the plant.

DEFINITION OF EXPOSED GROUP AND DESCRIPTION OF RECORDS

Exposed employees were primarily the testers who tested the new sterilizers, as well as the assemblers who worked in this same area (see Table III). Testers who work on sterilizers (which may be either steam or gas) currently work in department 3019, the testing department. The assemblers who work nearby, work in department 3072 (final assembly, small sterilizers) or 3073 (final assembly, large sterilizers). Previous to 1975, all departments had a "600" number instead of a "3000" number. Furthermore, prior to 1965, testers and assemblers worked in one department, number 659. In 1965, testers were placed into test department 619, while assemblers remained in the assembly department 659. In 1968, assemblers were split into two current assembly departments, large and small final assembly, with numbers 672 and 673 respectively. At that time, departments 671 (general assembly) and 670 (table assembly) were also created, whereas before these departments had been included in 659. If an assembler is found in 659, he must have worked with a job title of final assembly to have been exposed, whereas table assemblers and general assemblers would not be included.

The question of whether the service representatives should be included as exposed is a difficult one. It would appear that these employees spend less than 5% of their time repairing gas sterilizers. On the other hand, they may be repairing leaky sterilizers and have high peak exposures. Two service employees in the Cincinnati area have been interviewed to try to resolve this question. Based on what has been determined to date, field service representatives will be included in the exposed group, albeit classified as having minimal exposure.

Grinders in the foundry, who worked in department 640 during the years 1956-1960, may have been exposed as a result of offgassing of contract sterilized goods, and are to be included in any exposed group.

Given that the main body of the plant has had very few walls to stop the flow of gas, there may have been some minimal exposure to other workers nearby where sterilizers were tested, for example in the shipping and warehouse areas. However, because of the relatively low amounts of gas used and the prevailing direction of air circulating in the building, these individuals should not be listed in the exposed group.

Records are divided into current hourly employees (who have computerized records dating back to 1980), employees terminated recently but not yet archived (n=50), employees who are retired but still alive (n=200), and hourly employees who are in the archives (n=500). Hourly records are kept separate from salaried employees, in most of these filing systems. When they are not salaried, employees are clearly identifiable. For the purpose of the mortality study, only hourly employees will be considered as potentially exposed with the exception of salaried field service personnel. These persons will all be considered to have been exposed to ETO.

It would appear that there are some records missing for terminated hourly employees who should be among the archived records, particularly for employees terminated between approximately 1975-78. There are three lines of evidence for this: 1) in most plants there are more terminated hourly employees than current ones, yet here the converse is true, 2) in the archived files no boxes were found for hourly terminated employees for the year 1965 and for the years 1975 to the present, 3) hourly employment peake in 1974, after which it dropped by some 100 employees by 1976, therefore th records should show a significant number of terminated employees in the lat 1970's, but this is not the case. The company is searching for more files in the archived file area, which has been moved recently and lacks any central organizing index to cover the hundreds of boxes of files stored there. They are creating an indexing system and re-searching the old warehouse area. There may be ways to re-construct the presence of exposed individuals even if some records are missing, because this plant has relatively low turnover. The company keeps payroll records, by department, on a monthly basis, back to 1977. These records would enable identificatio of any workers who worked in the exposed areas and any who left after 1976. Furthermore, the company has already done a relatively intensive search for exposed individuals in the past, in conjunction with the medical testing which was conducted in 1982. At that time, a list of 49 men was compiled, 44 hourly workers and 5 salaried, who had at one time worked as testers (13 for at least 6 months, or who were currently working as testers (36). The average duration of employment as a tester for these individuals was 9 year

The personnel files for in-plant personnel (not field representatives) were sampled for all of the records systems described above. Ten individuals were sampled from recent terminations which had not yet been archived, 40 from current hourly, 53 from terminated hourly, and 18 from retirees who were still alive and receiving pensions. One hundred and twenty-one record in total were sampled, out of an estimated total number of hourly records o

1300 (9.3%). Thirty of these individuals worked in exposed job categories for more than 3 months (25%). This would indicate that overall 322 hourly exposed individuals would be expected at this company not counting the field service representatives. The average year of first exposure for the exposed individuals was 1967, and the average year of birth was 1930. These individuals should contribute about 5100 person-years.

Records for field service representatives were not sampled during the visit, therefore, their numbers cannot be determined at this time. It is likely that there will be several hundred such individuals.

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.

CONCLUSIONS AND RECOMMENDATIONS

Personnel records were adequate to determine who was exposed based on job categories. There is a question of some missing personnel records for terminated employees in the late 1970's, but it may be possible to identify the exposed in these years by finding the missing records or by using an

alternative source such as, payroll records, internal lists of exposed, or data submitted to the SSA.

Sparse industrial hygiene data does exist, therefore it may be possible to construct an exposure matrix for this facility. ETO has not been used at this facility since 1982, therefore, there are no future industrial hygiene surveys planned at this plant as part of this ETO study.

Based on the findings of this report, this plant meets most eligibility requirements as defined by the protocol and should be tentatively included in the study pending further investigation of missing personnel records. 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. There is some problem at this plant with missing records (eligibility requirement #2), but use of alternate data sources may make possible the reconstruction of the cohort.

AMSCO has 18 regional offices, staffed by service representatives, located throughout the country. It has been determined that the extent of exposure of these service representative to ETO warrants their inclusion in the study. It cannot be determined as yet, the number of person-years these individuals will contribute.

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TABLE I

PEAK ETO CONCENTRATIONS+
AMERICAN STERILIZER COMPANY - 1981
ERIE, PENNSYLVANIA

STERILIZER	SAMPLING SITE*	1ST PULSE (PPM)	2ND PULSE (PPM)	DOOR OPEN (PPM)
8.8 ft^3	1	35	10	
	2	750	20	
	3	45	10	
	4	30	10	
	5	20	10	
	6	20	10	
	7			350
	8			40
30.0 ft^3	1	40	15	
	2	750	75	
	3	30	10	
	4	35	15	
	5	20	10	
	6	20	10	
	7			650
	8			125

1 = drain, breathing zone
2 = drain, floor
3 = front, breathing zone
4 = front, floor
5 = side, breathing zone
6 = side, floor
7 = directly in front of open door
8 = 1-2 feet in front of open door

+ All samples were collected by the company with a Wilks-Miran 101, a direct reading instrument.

TABLE II

"WORSE CASE" ETO CONCENTRATIONS[+o]
8 HOUR TIME WEIGHTED AVERAGE
AMERICAN STERILIZER COMPANY - 1982
ERIE, PENNSYLVANIA

STERILIZER	SAMPLING SITE *	ELEVATION (feet)	TWA 8 HOUR (ppm)
8.8 ft^3	1	3.3	.9
		5	.9
	2	3.3	.1
		5	.07
	3	3.3	.25
		5	.4
24 ft^3	2	3.3	.7

*1 = 2 feet in front of sterilizer.
2 = Midpoint between 2 sterilizers.
3 = 1 foot behind sterilizer.

+ All samples were collected by the company with a Wilks-Miran 101, a direct reading instrument.
o Worse case = several sterilizers exhausted simultaneously.

TABLE III

DEFINITION OF WORKERS EXPOSED TO ETO
AMERICAN STERILIZER COMPANY
ERIE, PENNSYLVANIA
1985

YEAR	JOB	DEPARTMENT	DEPARTMENT NUMBER
1956-60	Grinder	Foundry	640
1965	Tester	Test	619
	Assembler	Assembly	659
1968	Assembler	Assembly lg.	672
		Assembly sm.	673
	Final Assembler	Assembly	659
Present	Tester	Testing	3019
	Assembler	Final Assembly sm.	3072
	Assembler	Final Assembly lg.	3073