# INDUSTRYWIDE STUDIES REPORT
# OF WALK-THROUGH SURVEY

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SNYDER LABORATORIES
Dover, Ohio

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DATE OF SURVEY:
January 16-17, 1984

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Industrial Hygiene Section
Industrywide Studies Branch
Division of Surveillance, Hazard Evaluations and Field Studies
National Institute for Occupational Safety and Health
Centers for Disease Control
Cincinnati, Ohio

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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 |

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Abstract

On January 16 and 17, 1984, a site visit to Snyder Laboratories, Dover, Ohio, was conducted to gather data and determine the feasibility of including this facility in a mortality/industrial hygiene study of ethylene oxide (EtO) being conducted by researchers from NIOSH.

During the site visit, industrial hygiene records and personnel records were evaluated and a walk-through survey of the plant was conducted in order to observe all production processes related to EtO sterilization.

Area and/or personal industrial hygiene monitoring for EtO has been conducted by Snyder since 1979 (experimental area sampling was conducted in 1978). An industrial hygiene evaluation of this monitoring data indicated that it would be possible to construct an exposure classification scheme for this facility.

Results of the epidemiologic evaluation of records indicated that this portion of the facility meets all of the eligibility requirements as defined by the epidemiologic portion of the protocol, and could therefore 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.

## 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] Inorder to develop and refine methods to be used for data collection and exposure classification of this selected cohort, a pilot study of six industrial sterilization facilities was initiated. The information gathered during the pilot study was incorporated into the final study protocol. This facility is part of the pilot study.

This walk-through survey was conducted to determine the suitability of including Snyder Laboratories 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 Plant

Snyder Laboratories was established in 1977 after the original company, Snyder Manufacturing Company, was purchased and renamed by Zimmer (a subsidiary of Bristol-Myers). Snyder Manufacturing Company produced industrial clothing, laminants, plastic fabricators, polyvinyl chloride, and polypropylene. In 1961, Snyder entered the medical business and began using EtO as a sterilant. In 1977, when Snyder Labs was created, all non-medical production lines were shut down; however, sterilization of medical products continued. Over the past 20 years the number of products to be sterilized has increased and now includes closed wound suction devices, hemavac products, dermatome blades, dermacarriers, thoracic drainage systems, Raney clips, Gigli saws, and Z drapes.

Prior to 1977, Snyder consisted of 2 buildings (85-96 years old) which were connected by a doorway covered with vinyl strips. Building 1 contained the sterilizers, laminating process, and storage of sterilized product. Building 2 housed the manufacturing, warehouse, and radio frequency sealing areas. A third building was constructed in 1977 and housed only manufacturing processes.

For the period of August 1976-1980, some EtO sterilized product was stored in Building 2. This was due to the rapid growth rate of Snyder which resulted in a need for extra storage space.

In 1982, a new building was erected for the EtO sterilization process. The sterilizers were moved during the summer of 1982 and the building opened in February, 1983. The new building contained the EtO sterilizers and EtO post cycle quarantine storage and shipping areas.

Description of the Workforce

In 1961, Snyder employed 35 workers on 1 shift (7:00 a.m. to 3:30 p.m.) in the medical products area; 3 to 4 of these employees worked directly with EtO. The workforce grew to 100-200 during the 1960's. Currently, Snyder employs 200 workers, 118 hourly and 82 salaried. Approximately 17 current employees are potentially exposed to EtO in the following areas: sterilizer, quality control, maintenance, and finished goods.

Employees work two shifts, 7 a.m. to 3:30 p.m. and 3:30 p.m. to midnight. Snyder has a very stable workforce with the average employee's age being between 40-42. Sixty-five percent of the workforce is female and 98% is Caucasian. The Union representing the Snyder employees is the United Steel Workers (USW) Union, Local 6211.

Description of Process

Initially, the product to be sterilized is placed on pallets and loaded into one of eight preconditioning chambers. The product (depending on its physical make-up) is preconditioned from 8 to 24 hours by increasing the temperature and humidity, which in effect reduces the time required to sterilize each load. Each preconditioning chamber has two doors, one for loading and one for unloading; the latter empties into the sterilizing room.

The product is then loaded into the sterilizing chamber by hand truck. After the sterilizer is loaded, the humidity is increased, the temperature is slightly elevated, and the freon/EtO mixture (88 parts freon to 12 parts EtO) is added to the sterilizer. The product is then sterilized under positive pressure; sterilizing time is dependent upon the absorption rate and capacity of the product. After the sterilization cycle, a vacuum is pulled to remove the gas mixture from the sterilizer. The sterilizers at Snyder have a door at each end of the sterilizer; one for loading and the other for unloading product. The product is unloaded from the sterilizer and placed into one of four aeration chambers. The product remains in the aeration chamber for approximately 24 hours at an elevated temperature and air flow [4000 cubic feet per minute (cfm)]. However, the product is not removed from the aeration chamber until the quality control check is completed. After aeration, the sterilized product is transferred to the quarantine warehouse for a minimum of one week prior to shipment.

Description of Past Exposures and Controls Used

Snyder's use of EtO as a sterilant began in 1961 with the installation of a 126 cubic foot ($ft^3$) EtO sterilizer. Two cycles were run per week using a gas mixture of 88 parts of freon to 12 parts of EtO. A fan was used to ventilate the sterilizer room.

In 1970, a double door 360 $ft^3$ EtO sterilizer was purchased and placed in a room adjacent to the 126 $ft^3$ sterilizer, which was enclosed with brick walls. The double door arrangement permitted the sterilizer operator to load and unload product at opposite ends of the sterilizer. The number of cycles was increased to about 4 per week. After each cycle, the sterilized product was unloaded into the hallway outside of the sterilizing room and transferred to the aeration or quarantine room where it was held for 14 days.

The sterilizer room was ventilated with a large window fan which produced a negative pressure in the room. The sterilizer itself was vented to the roof and to the sewer line.

Another potential exposure source was the 100 to 250 lb EtO cylinders. After a cylinder was shut off, the threaded couplings were disconnected, and whatever EtO was left in the line diffused into the room. This potential exposure source was eliminated in the early to mid 1970's by replacing the threaded valves with quick disconnect valves. In 1975, a third EtO sterilizer, also 360 $ft^3$, was purchased.

In 1976, preconditioning chambers were installed as well as a 24-hour post sterilization room. Due to the rapid growth rate of the company, some sterilized product was stored in Building 2. This occurred from 1976 to 1980.

During 1977, the amount of Eto used was approximately 16,000 pounds (lbs.); currently the amount of EtO used has increased to about 30,000 lbs. In 1978, experimental industrial hygiene sampling was started for EtO and large exhaust hoods were installed over the ends of the double door sterilizers. After each cycle was completed, the sterilizer doors were opened slightly and the units were vented (to the roof) for one hour. Industrial hygiene sampling was conducted again in 1979 and each succeeding year thereafter. In addition, the 126 $ft^3$ sterilizer was shut down and a large portable ventilation system (shroud) was installed. The shroud was placed at the loading door of each sterilizer in order to pull any residual EtO away from the sterilizer operator who was unloading product at the opposite end of the sterilizer. The ventilation system was then moved from one sterilizer to another. The system's exhaust was vented to the roof. The building's fresh air intake was located approximately 200 feet from the sterilizer exhaust vents.

Additional 360 $ft^3$ EtO sterilizers were purchased in 1980 and 1983, bringing the total to four. During the summer of 1982, the sterilizers were moved to a new building which was constructed solely for Snyder's EtO sterilizing process. The new building contained 8 double-doored preconditioning chambers; the unloading doors of these chambers opened into the sterilizing room which contained 4 pit mounted, computer operated sterilizers.

In 1983, an HNU$^R$, multipoint direct-reading instrument, was installed and a complete reading cycle of the sterilizer related areas was obtained every 16 minutes. Four aeration chambers with an airflow rate of 4000 cfm were also installed.

Other substances that were used at Snyder include: isopropyl alcohol (used to wipe/clean tables), methyl ethyl ketone (MEK) which was used in very small amounts (about 1 pint/week), polyvinyl chloride (PVC, used in the laminating process), and vinyl plastisol adhesive (used to attach the PVC to nylon). A study conducted by the Occupational Safety and Health Administration (OSHA) indicated that there were no problems with the PVC laminating process.

Snyder has no records of accidents or leaks, however, it was stated that it was not unusual for sterilizer operators to smell EtO. If a malfunction was noticed, the sterilizer was shut down and the cycle started over. In the past, sterilizer gaskets were replaced when a drop in sterilizer pressure was observed. However, in 1979, the company that manufactured the sterilizers began checking the sterilizer doors every 3 months.

## Description of Industrial Hygiene, Safety and Medical Programs

### Industrial Hygiene

Snyder employs a metallurgical engineer as a part-time industrial hygienist. Experimental EtO monitoring began in 1978 and routine monitoring continues today.

Personal and/or area Time-Weighted Average EtO monitoring has been conducted with charcoal tubes and/or 3M badges; these sampling media were sent to accredited laboratories for EtO chemical analysis. Continuous monitoring was conducted with a Wilks Miran$^{R}$ in 2 locations in the old building. In October, 1983, an HNU$^{R}$ multipoint sequential EtO analyzer was set up to continuously monitor 10 locations in the new building. These locations included the four corners of the sterilizer room, the air conditioning duct, control room, hall, preconditioning area, and quarantine area. Sixteen minutes is required for a complete monitoring cycle. Ventilation measurements and checks on fan motors have been conducted on a regular basis in the old as well as the new sterilizer locations.

### Safety

Personal protective equipment used at Snyder has included shoe and head coverings; and in 1977, a full-face air supplied respirator was installed in the sterilizer room. In 1981, a Survivair self-contained breathing apparatus (full-face) was placed outside of the sterilizer room; and in 1983, Scott Air Pacs were made available. All respirators were available for emergency use only; no respirators have ever been used at Snyder. A maintenance and cleaning program was instituted, and employees were trained in the proper use of these air supplied respirators.

Management and union employees have formed a joint safety committee and routinely inspect the plant and procedures; only five accidents have been recorded in the last 10 years. Snyder also has a safety training program for supervisors and employees.

### Medical

In 1982, an employee health surveillance program was started by the parent companies, Bristol-Myers and Zimmer. Employees were required to complete a personal history form which was considered the baseline for the surveillance program. A battery of tests were also run on the employees potentially exposed to EtO.

Preemployment physical examinations including blood tests and chest x-ray are required. Snyder also has a microbiology laboratory which is used to monitor the environment and bioburden levels of workers (e.g., the bacteria level found on workers' hands).

Description of the Personnel Record Keeping System and Definition of Exposed Group

It is possible to identify the sex, birthdate, year of entry, year of termination, and department for all employees from personnel records. Exposure status (exposed vs. nonexposed) can be ascertained by identifying the department and dates employed. A detailed work history can be constructed for virtually all employees with the exception of those who worked less than a 3 month probationary period, using the initial job title and department as listed on the application and bid sheets which indicate job changes. Such short-term employees would be excluded in any case from the mortality study, which requires a minimum of 3 months exposure.

It is estimated that there are approximately 585 records total for terminated hourly employees. The records are arranged alphabetically.

These records appear complete; there were no obvious gaps. Ten workers were identified by the company who had terminated prior to 1977. All 10 were found in the files. In the sampling, workers were encountered who were current in the early 1960's, when EtO was first used. In the early 1960's, Snyder (then known as Snyder Manufacturing) had only about 35 employees. It has steadily grown; at present there are approximately 200 employees. A full check on the completeness of the files is to be conducted for all plants in the study, as outlined in the protocol, via the use of payroll records. There are also seniority lists which date back to 1967. The lists include the entire hourly work force, and can be used to check cohort completeness for the years 1967 to the present.

There are 111 records for active hourly employees. Using random sampling, 100 terminated and 50 active hourly employees were sampled.

The files of all 82 active salaried personnel were reviewed as well as 15 inactive salaried personnel. However, it is believed that the records of the 15 inactive salaried employees represent only those salaried who have terminated since Snyder Labs was constituted in 1977. It is not known whether records exist for those salaried employees who terminated before 1977. Few salaried personnel are exposed to EtO, and their exposures are presumed to be slight in relation to hourly personnel. Given these considerations, unless the company is able to locate inactive salaried records, salaried employees as a whole should be excluded from the cohort.

In the history of Snyder, most exposure to EtO occurred at the older New Philadelphia site, in Building 1, which housed the chambers and a lamination process which was discontinued in 1978. Product was usually sterilized, aerated, and stored in Building 1. There was no separate aeration room within Building 1 until 1977, therefore, any off-gassing of EtO would affect all employees in Building 1. Even after that date, product stored in Building 1 would be expected to off-gas in that area. Exposed departments included sterilization, lamination, and warehouse/shipping. Quality control and maintenance department personnel were exposed intermittently.

For the period of August 1976-1980, product was stored in part of Building 2 as well as in Building 1. Thus, during that period, employees in Building 2 may have been exposed to small amounts of EtO which were still off-gassing. Furthermore, Building 1 and Building 2 were not separated by a closed door but by an open doorway which was covered with vinyl strips, which were not air tight. However, the ventilation in Building 1, including a strong exhaust fan for the lamination process, should have directed any EtO in the ambient air of Building 1 out of Building 1 rather than into Building 2. In general, we can consider employees in Building 2 to have been minimally exposed in the years 1976-1980, and nonexposed in other years.

In the summer of 1982, sterilization was moved to a new building in Dover. After that date exposed employees would include all those in the sterilization department as well as all those in the warehouse who were incidentally exposed due to product which was off-gassing.

For the purposes of this report, work histories were used which listed whether an individual had ever worked in an exposed department. An attempt was not made to determine how long that individual worked in that department, although that data is available in the personnel file. In this report, an exposed individual is so identified if he or she worked at the company for 3 months or more, and ever worked in an exposed department, as defined above. By and large, these individuals will have worked 3 months or more in an exposed department.

The following results are based on the sample of 150 hourly employees.

Overall, approximately 27% of the hourly employees who had been employed at least 3 months had been exposed to EtO. About 10% of the hourly employees could not be classified due to incomplete work histories, usually the result of not having completed the probationary period. However, these workers would not qualify for the mortality study.

Among the exposed hourly workers, the average year of birth was 1947 and the average year of entry was 1971. Among the exposed hourlies, about 9% were first employed after 1978.

Among all exposed hourly employees, about 22% were female.

Management was also asked to identify 8 workers known to have been exposed. The personnel files were then checked for these individuals; all were found, and based on their work history, all were identified as having been exposed.

In summary, there were 696 hourly employees (111 active, and 5[illegible]% inactive). Of these about 10% worked for less than 3 months, and would not be eligible for the mortality study. Nine percent were hired after 1978. These would not be eligible for the first phase of the mortality study. This would leave approximately 563 hourly employees eligible for the first phase of the mortality study, of whom 152 (27%) were likely to have been exposed. The average year of hire for all hourly employees was 1971, and for the purposes of estimation here, 1971 can be taken as an average date of first hire for the 152 eligible hourly employees. Furthermore, for the purposes of this

report, 1971 can be taken to be the first year of exposure, although in some cases individuals may not have been hired into an exposed job. Given that follow-up can be expected to go through at least 1982 for the mortality study, on the average each of the 152 hourly employees would contribute approximately 12 person-years of follow-up to the mortality study. Hence, a total of approximately 1800 person-years should be contributed by Snyder Labs to the mortality study.

Only a handful of the exposed workers were sterilizer operators. The majority of the exposed worked in the lamination process and were exposed as a result of being in Building 1.

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 1972.[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 sampling media, and sampling time are presented in Table 1. Table 2 contains the plant controls implemented to reduce EtO exposure levels.

The data in Table 1 indicate that EtO was present in the work environment at this facility, at least in the sterilizer area. Only two types of sampling media were used during the years that sampling was conducted at Snyder (1978-1983). From 1978 through 1983, charcoal tubes (containing activated coconut shell charcoal) were used as sampling media to conduct area and personal sampling in the sterilizer work area. The lowest documented level in 1980 and 1981, 0.4 ppm, is questionable since this level was below the quantitation limit of the analytical method used (OSHA Method #30).[19] The second type of sampling media used, passive dosimeters or 3M Badges, appeared to be fairly reliable media for EtO monitoring. However, some discrepancies were noted. For example, during September, 1983, three 3M badges were hung on the same sterilizer operator. The results of two badges were close, 2.1 and 2.7 ppm; however, the result of the third badge was 13.1 ppm (see Table 1). The same type of discrepancy was noted on other occasions.

Overall, the EtO exposure levels remained fairly constant over time until the latter part of 1983. During the last three months of 1983, the range of exposure levels documented was 0.5 to 4.8 ppm as personal 8-hour TWAs. (See Table 1.) The only employees sampled were sterilizer operators.

TABLE 1

HISTORICAL EtO MONITORING DATA AT SNYDER LABORATORIES[1]
DOVER, OHIO

| DATE | TYPE OF SAMPLE | SAMPLING MEDIA | PPM OF ETO MONITORED | COMMENTS |
|---|---|---|---|---|
| 6/78 | Unknown | Charcoal tubes[2] | | Sampling was experimental only |
| 7/79 | Area | Charcoal tubes | 73.0<br>7.3<br>0.50<br>0.50 | Sterilizer area |
| 2/80 | Personal $TWA_4$ | Charcoal tubes | 4.9<br>8.2<br>8.5 | Sterilizer operators two 4-hr samples per operator |
| 4/80 | Personal $TWA_4$ | Charcoal tubes | 21.0<br>14.0<br>6.1<br>18.0 | |
| 6/80 | Personal $TWA_4$ | Charcoal tubes | 3.1<br>5.5 | |
| 9/80 | Personal $TWA_4$ | Charcoal tubes | 1.5<br>0.4 | |
| 11/80 | Personal $TWA_4$ | Charcoal tubes | 0.5<br>0.9 | |
| 1/81 | Personal $TWA_4$ | Charcoal tubes | 0.8<br>0.4 | Sterilizer operators two 4-hr samples per operator |

1) All samples were taken in the sterilizer area within 25-30 ft of a sterilizer; personal samples include lunch break, etc.

2) Charcoal tubes were in line with SKC low-flow pumps.

TABLE 1 (CONT.)

HISTORICAL ETO MONITORING DATA AT SNYDER LABORATORIES[1]
DOVER, OHIO

| DATE | TYPE OF SAMPLE | SAMPLING MEDIA | PPM OF ETO MONITORED | COMMENTS |
|---|---|---|---|---|
| 3/81 | Personal $TWA_8$ | Charcoal tubes | 5.1<br>5.4<br>6.4<br>4.7<br>2.2<br>2.3<br>1.7 | One 8-hr sample per operator |
| 4/81 | Personal $TWA_8$ | Charcoal tubes | 2.2 | One 8-hr sample |
| 8/81 | Personal $TWA_4$ | Charcoal tubes | 4.0<br>5.0 | Sterilizer operators two 4-hr samples per operator |
| 11/81 | Personal $TWA_4$ | Charcoal tubes | 2.0<br>3.1 | |
| 3/82 | Personal $TWA_4$ | Charcoal tubes(2) | 0.6<br>0.9<br>2.0<br>3.0 | Sterilizer operators two 4-hr samples per operator |
| 6/82 | Personal $TWA_4$ | Charcoal tubes(2) | 5.4<br>3.5 | |
| 12/82 | Personal $TWA_4$ | Charcoal tubes(2) | 5.0<br>2.1 | |
| 2/83 | Personal Short-term | 3M Badges | 4.5 | Sterilizer operator 75 minute sample |
| | | | 22.7<br>20.0 | Hand unloading chamber, 25 minute sample |

TABLE 1 (CONT.)

HISTORICAL ETO MONITORING DATA AT SNYDER LABORATORIES[1]
DOVER, OHIO

| DATE | TYPE OF SAMPLE | SAMPLING MEDIA | PPM OF ETO MONITORED | COMMENTS |
|---|---|---|---|---|
| 2/83 | Personal $TWA_8$ | 3M Badges | 5.2<br>4.2<br>6.7<br>5.5<br>3.6 | Sterilizer operators |
| | Personal Short-term | 3M Badges | 24.1<br>25.5 | Sterilizer Operators Unloading chamber, 25 minute sample |
| | Area $TWA_8$ | Charcoal tubes | 7.2 | |
| 3/83 | Personal $TWA_8$ | 3M Badges | 4.2<br>3.4 | Sterilizer Operators |
| | | | 7.1 | Experimental 10 min. sample |
| | Personal $TWA_8$ | | 3.1<br>2.2<br>3.0 | Warehouse personnel |
| 5/83 | Personal $TWA_8$ | 3M Badges | $<0.5$<br>$<0.5$<br>$<0.5$ | Warehouse personnel |
| 6/83 | Personal $TWA_8$ | 3M Badges | 0.6<br>1.4<br>1.6<br>1.5<br>1.3 | Sterilizer Operators loading/unloading chamber |
| 8/83 | Personal $TWA_8$ | 3M Badges | 13.3[a]<br>3.4[a]<br>4.9[a]<br>6.7[a]<br>4.8[a] | Sterilizer Operators a) all badges on same worker |

TABLE 1 (CONT.)

HISTORICAL ETO MONITORING DATA AT SNYDER LABORATORIES[1]
DOVER, OHIO

| DATE | TYPE OF SAMPLE | SAMPLING MEDIA | PPM OF ETO MONITORED | COMMENTS |
|---|---|---|---|---|
| 9/83 | Personal $TWA_8$ | 3M Badges | 2.7[b]<br>2.1[b]<br>13.1[b] | Sterilizer Operators<br>b) 3 badges on 1 worker |
| | | | 3.2[c]<br>8.0[c] | c) 2 badges on 1 worker |
| | Personal $TWA_8$ | 3M Badges | 1.5[d]<br>1.5[d]<br>4.8<br>2.0 | d) 2 badges on 1 worker |
| 11/83 | Personal $TWA_8$ | 3M Badges | 0.5<br>3.6<br>2.2<br>1.4 | Sterilizer Operators |
| 12/83 | Personal $TWA_8$ | 3M Badges | 2.5<br>1.6<br>2.5<br>1.6 | Sterilizer Operators |

TABLE 2
CONTROLS IMPLEMENTED TO REDUCE ETO EXPOSURE LEVELS AT
SNYDER LABORATORIES, DOVER, OHIO

| DATE | ENGINEERING CONTROLS | ADMINISTRATIVE CONTROLS | MONITORING SYSTEMS | OTHER CHANGES | RANGE OF ETO EXPOSURE LEVELS MEASURED (ppm) |
|---|---|---|---|---|---|
| 1961 | Room exhaust fan | None added | None added | | None measured |
| 1970 | 126 $ft^3$ sterilizer enclosed with brick walls<br><br>Large window fan installed<br><br>New sterilizer exhaust vented to roof and sewer line | Workers required to transfer sterilized product to aeration or quarantine room where it was held for 14 days | | | None measured |
| 1970-75 | Threaded couplings on Eto cylinders replaced with quick disconnect valves | None added | None added | | None measured |
| 1976 | 24-hour post sterilization room installed | None added | | | None measured |
| 1977 | None added | Workers restricted from sterilizing room during EtO sterilizing cycle | Wilks Miran EtO monitoring/alarm system installed | | None measured |
| 1978 | Large exhaust hoods installed over ends of double door sterilizers | Workers required to crack sterilizer doors and allow chambers to vent for 1 hour | Started experimental EtO sampling | | Experimental only |

TABLE 2 (continued)
CONTROLS IMPLEMENTED TO REDUCE ETO EXPOSURE LEVELS AT
SNYDER LABORATORIES, DOVER, OHIO

| DATE | ENGINEERING CONTROLS | ADMINISTRATIVE CONTROLS | MONITORING SYSTEMS | OTHER CHANGES | RANGE OF ETO EXPOSURE LEVELS MEASURED (ppm) |
|---|---|---|---|---|---|
| 1979 | Large portable ventilation system (shroud) installed | $126ft^3$ sterilizer shut down | | Sterilizer manufacturer started 3 month checks on door gasket | < 1-73.0 |
| 1980 | None added | None added | None added | | < 1-21.0 |
| 1981 | None added | None added | None added | | < 1-6.4 |
| 1982 | Ventilation system installed in sterilizer room | Worker access to sterilizer room limited to moving product<br><br>Workers required to utilize EtO sterilizer control room | | Sterilizers moved to new building<br><br>8 double-doored preconditioning chambers installed<br><br>Sterilizers pit mounted and computer operated | < 1-5.4 |
| 1983 | 4 aeration chambers installed (4000 cfm-airflow) | None added | HNU multi-point EtO monitor installed | | < 1-25.5 |

## Conclusions

Snyder Laboratories has a small amount of industrial hygiene data dating back to 1979 (1978's data was experimental only). Therefore, it would be possible to construct an exposure classification scheme for job catagories 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.

## Recommendations

The following recommendations are based on work practices observed and EtO levels measured (by Snyder) 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. Redesign the method of unloading and loading the sterilizers (e.g., place pallets on wheeled cart and pull/push the load with a long hooked rod) so that the sterilizer operators do not physically have to enter the sterilizer.

3. Periodically conduct ventilation investigations to insure proper operation of the ventilation system.

4. Institute use of air-supplied or NIOSH EtO approved canister respirators until adequate engineering controls and/or work practices have lowered the workers' TWA exposure level to 1 ppm or less. If canister 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.

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