

**INDUSTRYWIDE STUDIES REPORT OF AN  
IN-DEPTH INDUSTRIAL HYGIENE SURVEY**

**MICRO-BIOTROL  
Griffith Laboratories  
1437 W. 37th Street  
Chicago, Illinois 60609**

**SURVEY CONDUCTED BY:  
Leo Blade, IHS  
Larry J. Elliott, IHS  
John Morawetz, IHS  
Virginia Ringenburg, IHS  
James Woodfin, DPSE**

**DATE OF SURVEY:  
September 13-14, 1984  
January 22-24, 1985**

**REPORT WRITTEN BY:  
Larry J. Elliott  
Alice Greife  
John S. Morawetz  
Virginia Ringenburg  
Leslie Stayner**

**DATE OF REPORT:  
July, 1986**

**REPORT NUMBER: 67.28**

**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**

**DISCLAIMER**

**Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH).**

**PURPOSE:**

To assess the extent of EtO exposure of workers during the sterilization of spices and medical supplies in conjunction with the NIOSH Industrywide Studies Branch mortality/industrial hygiene study of ethylene oxide (EtO).

**EMPLOYER REPRESENTATIVES  
CONTACTED:**

Robert Ufferman, Griffith  
Laboratories, Corporate Personnel  
Manager

Darryl Erickson, Griffith Labs,  
Chicago, Plant Manager

**EMPLOYEE REPRESENTATIVES  
CONTACTED:**

None

**STANDARD INDUSTRIAL  
CLASSIFICATION OF PLANT:**

2099 - Food Preparations, Not Elsewhere  
Classified

## ABSTRACT

On September 13-14, 1984, and January 22-24, 1985, in-depth industrial hygiene surveys were conducted at the Micro-Biotrol Company, a division of Griffith Laboratories USA, Incorporated in Chicago, Illinois. These surveys were conducted to assess the extent of ethylene oxide (EtO) exposure for workers during the use of EtO as a microbial reductant. These surveys were a part of an industrywide study of mortality associated with an occupational exposure to EtO.

Griffith Lab's EtO Treatment Department was founded in the early 1930's, to treat Griffith products (primarily spices and spice blends). Treatment with 100% EtO was conducted on an intermittent basis with 1 to 4 vessels from the early 1930s through the 1940s. In the early 1940s, the operation expanded considerably and EtO treatment was conducted on a full-time basis. Griffith stated using propylene oxide in 1959 and a mixture of 12% EtO to 88% freon in the late 1960s. Griffith's EtO treatment department also offered its services to other companies on a contract basis. Contract EtO treatment is Micro-Biotrol's chief service today.

The Griffith Labs, Chicago facility, houses the Micro-Biotrol, Incorporated Chicago treatment operation, Griffith Design and Equipment Company (since 1975), and Griffith Labs processing (spice grinding, blending, and hydrolized vegetable protein). Micro-Biotrol's president's office and

Griffith Labs corporate headquarters, and the Griffith spice blending and packaging processes were moved to Alsip, Illinois, a suburb of Chicago, in 1975. Micro-Biotrol's Chicago treatment operations were planning to move to Willowbrook, Illinois in mid-1985.

Results of the two in-depth industrial hygiene surveys demonstrated that an OSHA PEL (1.0 ppm), the NIOSH recommended standard (less than 0.1 ppm), and the ACGIH TLV (1.0 ppm) for 8-hour TWA EtO exposure levels would have been exceeded in various jobs. Average EtO exposure levels ranged from <0.11 ppm to 4.03 ppm for the September survey. The average EtO exposure levels for the January survey ranged from <0.11 ppm to 12.13 ppm with vessel operators experiencing the highest exposures. Short-term exposure monitoring also depicted the potential for extremely high peak exposures (6.9 ppm to 444.8 ppm). Season variation in exposure potential was also demonstrated by these surveys.

TABLE OF CONTENTS

	<u>Page</u>
Abstract.....	iv
Introduction.....	1
Description of the Facility.....	2
Description of Process.....	4
Description of Past Exposures.....	5
Description of Medical, Industrial Hygiene and Safety Programs.....	7
Description of Record Systems.....	8
Definition of Exposure.....	10
Description of the Workforce.....	10
Toxicity.....	10
Description of Sampling and Analytical Methods.....	12
Applicable Standards and Recommended Levels.....	13
Discussion of Sampling Results.....	14
Conclusions and Recommendations.....	16
References.....	17
Table 1 - Summary of Personnel Record Sampling.....	20
Table 2 - History of Plant Changes.....	21
Table 3 - Summary of Micro-Biotrol EtO Exposure Data.....	23
Table 4 - Personal TWA EtO Exposure Sample Results.....	26
Table 5 - Personal Short-Term EtO Exposure Levels.....	28
Table 6 - Short-Term General Area EtO Concentration Levels.....	29
Table 7 - General Area EtO Concentration Levels.....	30
Table 8 - Summary Statistics - Personal 8-Hour TWA Exposures.....	31
Table 9 - Summary Statistics - Short-Term Personal Exposures.....	33
Table 10 - Summary Statistics - Short-Term General Area Concentrations...	33
Table 11 - Summary Statistics - General Area Concentrations.....	34
Figure 1 - Wilks Miran Area EtO Monitoring (1-22-85).....	35
Figure 2 - Wilks Miran Area EtO Monitoring (1-23-85).....	36
Figure 3 - Comparison of Survey Date Results.....	37
Figure 4 - NIOSH and OSHA Side-By-Side Sample Comparison.....	38

## INTRODUCTION

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

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

Due to the toxicity and possible carcinogenicity of EtO (see section on Toxicity), NIOSH researchers initiated an investigation in 1982 to assess the feasibility of conducting a cohort mortality study and industrial hygiene evaluation of workers exposed to EtO. Based on the data gathered during the feasibility study, it was concluded that the cohort of workers in the health care and medical supply industry, specifically those workers exposed to EtO in industrial sterilization processes, was the most adequate group to support a cohort mortality study.<sup>4</sup> This decision was supported by the findings of a 1977 survey conducted by National Institute for Occupational Safety and Health (NIOSH) researchers which showed that it is in this industry that most of the employee exposures to EtO occur.<sup>5,6</sup> This survey estimated that approximately 75,000 health care workers were employed in EtO sterilization operations, with an additional 25,000 employees which may have incidental exposure resulting from inadequate engineering controls.<sup>5,6</sup>

On August 13-14, 1984, a walk-through survey of the Micro-Biotrol-Chicago plant was conducted to determine the suitability of including this company in the industrywide mortality and industrial hygiene study of workers potentially exposed to EtO in industrial sterilization processes. It was determined from the information gained during the walk-through survey that Micro-Biotrol should be included in the NIOSH mortality/industrial hygiene study of ethylene oxide exposure. Micro-Biotrol was also selected as a facility suitable for extensive industrial hygiene surveys to assess and document EtO exposure levels. This was the only facility NIOSH researchers were aware of which had not instituted extensive engineering controls to reduce EtO concentration levels. Two in-depth industrial hygiene sampling surveys were conducted; one during warm weather (September) and one during cold weather (January) to assess the extent of EtO exposure to workers within the facility. The data gathered during the walk-through and the in-depth surveys 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 characterization

which will be used along with the mortality data from the epidemiologic study to examine the dose-response relationship.

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

Griffith Labs EtO Treatment Department was established in Chicago, Illinois, as part of Griffith Laboratories, in the early 1930s, to treat Griffith products (primarily spices and spice blends). Micro-Biotrol became a separate sales division under Griffith Labs in 1970. In 1979, Micro-Biotrol became a separate operating division, and in 1984 it became a separate corporation. Also during 1984, Micro-Biotrol began moving its gas treatment facilities out of the Chicago plant. Griffith Labs Chicago, is a large complex of many buildings (see Figure 1); the Micro-Biotrol Chicago plant is primarily located in six of them (B-1 and B-2 first floor, vessels and pre-tempering; C, pretreatment storage; D and G front half, post treatment storage and G second floor, offices and lunchroom). Building B-1 contains Griffith Labs Nu-Spice (a registered trade mark) process on the second floor. Building D, which is shared with Griffith Labs, is used for post treatment storage and shipping. Building E currently houses Griffith Lab's hydrolysate process (basement and first floor) and maintenance (second floor). Prior to 1971, Buildings E and G (second floor) housed the Griffith Design and Equipment Company (GD&E) production area. Hydrolysate moved into the first floor of Building E about 1964. At about the same time, Building D was built and Building I was purchased. Building C was not used from 1966, when the spice extraction process was closed, until the early 1980's. At that time, Building C was remodeled for use as Micro-Biotrol's receiving warehouse. Building H was built in the 1970's to be used as the hydrolysate spray drying area. The hydrolysate spray drying area was originally located next to Building E from the 1960's, until it was moved into Building H. The east half of Building F was remodeled in the mid 1960's to house the home offices, company cafeteria and some laboratories. In the early 1970's, the production offices in the north end of Building F-1 were no longer used. In the early 1970's, Buildings A and J were leased to a commercial cleaning company. The first floor of Building F is the warehouse area for Griffith Labs. The upper floors house mustard grinding and the offices for GD&E, which is a subsidiary of Griffith Labs, USA which produces food processing equipment. GD&E moved into the building in 1975. Building F-1 is a warehouse on the first floor. Building H contains the hydrolysate process on the second floor. Building I was used as a receiving warehouse between 1971 and 1975 for both Micro-Biotrol and Griffith Labs, and housed GD&E production areas after 1975. Griffith's corporate and Micro-Biotrol's Division and Sales offices and Griffith Company headquarters were also located in this complex until 1975 when Griffith headquarters were relocated to a new facility in Alsip, Illinois, a suburb of Chicago. In 1975,

DIAGRAM I  
 GRIFFITH LABORATORIES, INCORPORATED  
 CHICAGO, ILLINOIS



BUILDING

B-1 - 1st Floor  
 2nd Floor

B-2

C

D

E - 1st Floor  
 2nd Floor

F - 1st Floor  
 2nd Floor

F-1

G - 1st Floor  
 2nd Floor

H

I

I

ACTIVITY

Sterilizers, Pre Tempering  
 Patty Pro

Sterilizers

Micro-Biotrol Pretreatment Storage, Vacuum Pumps

Micro-Biotrol Shipping/Warehouse (Post Treatment)

Hydrolsate  
 Maintenance

Warehouse, Spice Grinding  
 Griffith Design and Equipment Company (GD&E) Office

Warehouse

Micro-Biotrol Storage (Post Treatment)  
 Micro-Biotrol Offices and Cafeteria

Hydrolsate

GD&E Production, Prior to 1971 After 1975

Micro-Biotrol and Griffith Receiving Warehouse,  
 Prior to 1971

Griffith Lab's spice blending and packaging operation were also moved to Alsip. In October 1984, Micro-Biotrol's processing operations and offices began a move to Willowbrook, Illinois. The move was completed in July, 1985.

Treatment with 100% EtO was conducted on an intermittent basis with 1-4 vessels (Number 7, 360 ft<sup>3</sup>; number 1 (375 ft<sup>3</sup>) Number 2, 58 ft<sup>3</sup>; Number ?, about 60 ft<sup>3</sup>) from the early 1930s through the 1940s. In the 1950s, the treatment equipment was transferred from the original location on the fourth floor of Building A to the first floor of Building B-2. They were located in Building B-1 and B-2 at the time of these surveys. In the early 1940s, EtO treatment had become a full-time operation, which by 1951, had necessitated the acquisition of two additional vessels (Number X, about 150 ft<sup>3</sup>; Number 8, 259 ft<sup>3</sup>). Vessels 4, 5, 6, (each 279 ft<sup>3</sup>), were added between 1951 and 1961 in Building B-2. Vessel number 1 was removed in 1962. Vessel number X and number ? were removed prior to 1962. In 1970, a new vessel number 1 (660 ft<sup>3</sup>, Bld. B-2) was added. Vessel number 3 (660 ft<sup>3</sup>, Bld. B-1) was installed in 1972, and vessel number 9 (660 ft<sup>3</sup>, Bld. B-1) was added in 1976. Vessel number 2 was removed in 1982, leaving the Micro-Biotrol Chicago plant (which became part of a separate corporation wholly owned by Griffith Laboratories USA in 1984) with 8 vessels. The company's estimated use of EtO for 1983 was 110,364 pounds. Approximately 90% of the merchandise received is treated with 100% EtO or a 12/88 mixture of EtO and freon; the remaining 10% is treated with 100% propylene oxide.

#### DESCRIPTION OF PROCESS

Micro-Biotrol Chicago plant is a contract treatment facility which treats approximately 90% of the merchandise received with EtO (100% or 12/88). Propylene oxide (100%) is used on the remaining 10%. Once the merchandise is received by Micro-Biotrol, it is palletized. Most of the merchandise is placed in a pretempering room, which is at atmospheric pressure and elevated to a predetermined temperature and relative humidity for twelve (12) to twenty-four (24) hours. The preconditioned merchandise is then placed directly into the vessel without being repackaged. Other merchandise, which is not preconditioned, is also placed directly into the vessel without being repackaged, and the vessel is closed. At the time of these surveys, a 3-6 hour gas dwell cycle was run on about 80% of the product. The remaining 20% of the product has a gas dwell time of for 6-12 hours. The type of gas used (100% EtO, 12/88 EtO/freon, or propylene oxide) and the total cycle time are dependent on the type of product and packaging being treated.

At the end of the gas exposure, one or more vacuums are drawn on the chamber before the chamber is allowed to return to atmospheric pressure. The seal on the chamber is broken, and the door is opened a few inches. The employees are instructed to leave the area for five minutes before unloading the vessel. The treated product is taken directly to shipping/warehouse (Bld. D and/or G), where the product off-gases or aerates for 24 hours to 3 days before it is shipped back to the manufacturer. The shipping/warehouse area is located in one contiguous area on the same floor. There are no separate quarantine or aeration areas.

Griffith Laboratories, USA, which is also located in this same building complex, grinds spices (primarily mustard) in Building F, and produces hydrolyzed protein in Buildings E and H. GD&E Company, a subsidiary of Griffith Labs, USA, moved into its current location in Building F in 1975. The GD&E production area has been located in Building I since 1975 and in Buildings E and G prior to 1971.

In 1977, Griffith Laboratories Patty Pro (a registered trademark) department, which produced a protein filler for food products, was disbanded. This department was located upstairs in Building B-1.

#### DESCRIPTION OF PAST EXPOSURES

The interior of this facility been has changed many times since the original construction of the building around the turn of the century. The company has introduced few modifications to the facility, such as changes in work practices which would reduce employee exposure to EtO. No confounding exposures to known leukemogens were identified during these surveys.

#### Facility

##### General

The entire production area has general dilution ventilation. The general flow of air, in the western end of the complex where Micro-Biotrol is located, is through the shipping doors in Building D toward the back or South of the complex (Building C). The air tends to be pulled up to and through the second floor of Buildings B-1 and B-2 due to this general dilution ventilation system. This air, which may have contained large amounts of EtO, may have been able to infiltrate all of the upper floors of this complex. Several areas of the complex are on separate heating, ventilation, and air conditioning (HVAC) systems; however, reentrainment of EtO, which had been exhausted to the outside, may represent a significant contribution to EtO levels within this facility.

There has been many relocation of departments within the complex. Most of these changes are discussed in the Description of Facility section. These changes are also outlined in Table 2. GD&E offices moved into the complex (Building F) in 1975. Prior to the disbanding of the patty pro department (Building B-1, upstairs) in 1977, vinyl strip curtains were installed between the patty pro and maintenance area. The patty-pro area was not utilized at the time of these surveys. The GD&E production was located in the second floor of Building E and G prior to 1971. In 1975, GD&E production moved into Building I.

About 1980, the chamber operators' and Department Heads' desks were removed from the chamber room and placed in an nearby office.

The company reports no major accidents or leaks involving EtO, however, employees did report occasionally smelling EtO when a tank was changed. At the time of this survey, tanks were changed several times per day; in the past however, the tanks were changed less frequently (every 2-3 days).

These reports imply that the ambient levels of EtO may have ranged between 300 and 1500 ppm;<sup>6</sup> the mean odor threshold concentration of EtO is 700 ppm.<sup>6</sup>

#### Treatment Vessels

Each vessel is equipped with a gas recirculation system, and a remote water/vacuum pump and water/gas separator which was installed in 1973. These pumps are located in Building C and are surrounded by vinyl strip curtains. Before 1973, a steam evacuator was used to pull the EtO out of the chamber. The EtO and steam passed through a water/gas separator before the steam entered the drain. The drainage system is completely enclosed from the sterilizer to the sewer thereby prohibiting emission of EtO inside the building from the drain. There are no additional ventilation systems on the vessels.

#### Gassing Stations

The gassing stations, which are located near the treatment vessels, were separated in 1981 from the rest of the area by vinyl strip curtains. A local exhaust ventilation duct, with a slot opening, is located at the floor, toward the rear of the station, and runs the length of the station. This exhaust ventilation system is probably not effective, as EtO does not fall to the ground as had previously been believed and a floor level hood can not practically have a large enough capture velocity to capture gas emitted from a tank valve three to four feet above the floor.<sup>7,8</sup> The vessel operator is responsible for charging the vessels with EtO using a semi-automatic system, which was installed in 1976. Prior to that time, a worker had to open the valve of the gas cylinder, which was placed on a scale, and monitor the volume of gas going into the chamber.

#### Pretempering Room

Vinyl strip curtains were installed in the pretempering room (Building B-1, south end) in 1979. The curtains on the south end of the room serve as the door to Building C.

#### Aeration Area

There are no dedicated areas of the warehouse for aeration or degassing of treated product; therefore, uncontrolled EtO diffusion from the product occurs which adds to the overall ambient EtO levels.

#### Work Practices

Prior to 1962 and up to the date of this survey, much of the pharmaceutical powders were received in polyethylene bag-lined drums. As of the date of the surveys, each of the drum lids and liners were opened prior to treatment. The liners were retied by hand immediately after the products were removed from the chamber, putting the operators in close proximity to the product.

Prior to about 1970, most of the bags of powdered food and pharmaceutical ingredient products were handled on two-wheel handtrucks, which moved the operators face within 1 to 6 inches from the product when transporting it from the chamber to the shipping warehouse. After about 1970, the product

handling moved from the two-wheel handtrucks to palletized bags which then put the operators 4 to 6 feet from the product while transporting it.

In 1983, the company instituted a standard operating procedure (SOP), which required vessel operators to break the seal on a vessel after it had returned to atmospheric pressure (following the last vacuum and air wash), and wait in an adjacent area for 10-15 minutes. Prior to this time, the employee would enter the vessel almost immediately (about 5 minutes) after it had returned to atmospheric pressure.

Maintenance people are assigned to an area on an as-needed basis. All service (sanitation, maintenance, quality assurance) occurs on the day shift.

The use of air purifying respirators (TC#-14G-134) by the sterilizer operators while unloading the vessels was intermittent during the first (September, 1984) in-depth industrial hygiene survey. Both first and second shift sterilizer operators consistently wore air purifying respirators while unloading the vessels during the second (January, 1985) in-depth survey.

#### Gas Usage

Up until about 1960, all products were treated with 100% EtO. In the early 1960's, most of the dry food ingredient products, except whole spices, were switched to treatment with 100% propylene oxide. Because the food ingredient products were mostly ground powders, they had a much higher surface area than medical and laboratory hardware type products and thus they absorbed a higher quantity of EtO. Therefore, the employees were exposed to a higher level of EtO as they moved the product from the chambers to the shipping warehouse. Also, the product offgassing in the warehouse led to a higher level of employee exposure. This was reduced with the switch from EtO to propylene oxide.

In 1970, the EtO treatment of ground spices and seasonings was again approved by the U.S.-FDA (after about a 10 year lapse) and, therefore, treatment of these products switched back from 100% propylene oxide to 100% EtO. This did not affect the use of 100% propylene oxide on other food ingredient products.

Also in the early 1970's, a salmonella outbreak was traced to black pepper, which led to a several fold increase of in the amount of black pepper treated with EtO.

### DESCRIPTION OF MEDICAL, INDUSTRIAL HYGIENE AND SAFETY PROGRAMS

#### Medical

The company gives all employees pre-employment physicals at a near-by clinic. Beginning in 1983, follow-up physicals were given to all employees. The company does not maintain a nurse on staff, however, first-aid kits are available in various areas.

### Industrial Hygiene

Micro-Biotrol does not have an in-house industrial hygiene program. A consulting firm, however, has provided the safety and industrial hygiene services over the past 10 years. In 1980, some sampling for EtO was conducted by the consulting firm with charcoal tubes. In 1983, Micro-Biotrol required EtO monitoring every 3 months with 3M badges and every 2 months with an organic vapor analyzer (OVA). The passive monitoring data, which is summarized in Table 3, reveals that while exposures in all job titles listed were less than the previous Occupational Safety and Health Administration (OSHA) standard of 50 parts per million (ppm) for an 8-hour time-weighted average (8-hour TWA), many of these exposures would exceed the current OSHA 8-hour TWA standard of 1 ppm. In addition, reported values may be low, as there is a trend toward decreased recovery and sampling capacity at high concentrations when using passive monitors.<sup>9,10</sup> The vessel operators are the highest exposed group with 8-hr TWA ranging from 1-24 ppm with an average exposure of 8.5 ppm. The lowest exposed group is the GD&E office workers with an average exposure of 0.3 ppm (8-hr TWA) and a range of <0.5-0.5 ppm.

The company did not have a complete respirator program at the time of these surveys; there was no training or maintenance procedures defined for the use of air-purifying respirators.

### Safety

The company requires the use of hard hats and safety shoes by all employees. Safety glasses are required on an as-needed basis. There is a safety committee composed of management and worker representatives.

## DESCRIPTION OF RECORD SYSTEMS

### Current Employees

Personnel records for current Corporate (Griffith Labs and Micro-Biotrol Headquarter) and Alsip employees (Griffith Labs and Micro-Biotrol) are filed at the Alsip facility. The Chicago facility maintains personnel files for both Chicago Griffith and Micro-Biotrol's current employees. These files contain application forms, preemployment physical examination reports, and wage, salary, and transfer records. Demographic information (i.e., date of birth and sex) needed for the study could be obtained from the application forms. The wage, salary, and transfer records are filed each time there is a change in position or salary, and could therefore be used for creating detailed occupational histories.

Rate Change Cards are maintained on file for all current Griffith and Micro-Biotrol employees at the Alsip facility. These cards contain most of the information required for the study including: date of birth, social security number, detailed work histories, and current address. These cards also indicate at which facility an individual is currently working. Since all of this information is located on one piece of paper, these cards would provide a far more convenient source of information for the study than the personnel files described above.

At the time of this survey, there were a total of 454 active employees working in the various Griffith operations in the Chicago area. Following is a breakdown of the approximate number of active employees for each of the Chicago divisions: Griffith Corporate - 183 employees, Griffith Chicago plant - 54 employees, Alsip plant - 172 employees, Griffith Labs Incorporated - 17 employees, Griffith Design and Equipment - 11 employees, Micro-Biotrol Corporate - 7 employees, and Micro-Biotrol Chicago plant - 10 employees.

#### Former Employees

Rate cards and personnel files for former employees are interfiled together and stored at a warehouse. These records are identical to the ones described above for active employees and are also separated by the Griffith divisions. Unfortunately, it seems that these files do not contain records for workers terminated prior to the mid-1960s.

There are a total of approximately 1700 personnel records for former employees from the various Griffith operations in the Chicago area.

The file drawer for Micro-Biotrol Chicago, contains only five individual files. The small number of records in this file is due to the fact that Micro-Biotrol became a separate operating division from Griffith in 1979, and only a small number of workers have begun employment with Micro-Biotrol-Chicago plant since then. For Griffith Labs Chicago, there were five file drawers containing 1350 personnel files for all former employees. For the Alsip Plant, there were 2 file drawers containing approximately 295 personnel files for all former employees. Personnel files for Griffith Corporate and Griffith Labs Incorporated were filed together in one drawer containing approximately 51 records of all former employees. For Griffith Design and Engineering, there was one drawer containing approximately 38 personnel files for all former employees.

#### Other Record Systems

The personnel office maintains an index card system which contains a card for every employee that has been employed by Griffith Labs since about 1960. These cards contain the following information: name, social security number, first and last date employed, birthdate, department number, and address. These records do not contain detailed work histories. There are a total of about 4700 of these cards on file.

The payroll department has quarterly earnings reports prepared for IRS back to 1964. They also have a few payroll records from earlier time periods, although these are spotty at best.

In summary, personnel records exist which can be used to identify current workers, and workers terminated since the mid-1960s who have been potentially exposed to EtO. These records contain adequate demographic and occupational history information for the purposes of the mortality study.

## DEFINITION OF EXPOSURE

Employees from Micro-Biotrol Chicago plant, Griffith Chicago plant, and Griffith Design and Equipment had a potential for EtO exposure and will be included in the study. Prior to the construction of the Alsip facility in 1975, all of these workers were located at the Chicago facility, were potentially exposed to EtO, and will be included in the study.

## DESCRIPTION OF THE WORKFORCE

A randomly selected sample of the personnel files of current and former employees was reviewed during the walk-through survey. Information on year of birth, sex, the year of first exposure, and the year exposure ceased was recorded for workers considered to be potentially exposed to EtO. In order to be considered potentially exposed in this review, a worker must have been employed for at least 3 months in an area or job which has potential EtO exposure (see Definition of Exposure Section). Records from the Micro-Biotrol Chicago plant, Griffith Labs Chicago, and Alsip operations (this operation was previously located in the Chicago facility) were included in the review.

In Table 1, the results from this review are presented. All of the workers identified as being potentially exposed to EtO were males. Overall, this group is fairly young with an average year of birth ranging from 1920 to 1949. The duration of exposure at this facility seems to be relatively long, with an average that ranges between about 4 to 9 years. Overall, it is estimated, based upon this sample, that there are 63 current workers and 227 former workers at this facility who would contribute approximately 3748 person-years to the study. This estimate is probably conservative, since the definition of who is exposed and would be included in the study has expanded since the time of this record review. In particular, most of the Griffith-Chicago operations were not considered to have potential for exposure to EtO, however, since this review, environmental monitoring data has been obtained which suggest that additional Griffith operations in the Chicago plant are and have been potentially exposed to EtO. These estimates are also low because they do not include workers from other Griffith operations in the Chicago facility, who may have been exposed.

## TOXICITY

Evidence from animal studies suggests that EtO may have carcinogenic properties.<sup>11,12</sup> A group of EtO manufacturers sponsored a study at the Bushy Run Research Center in which male and female Fischer 344 rats were exposed to EtO at airborne concentrations of 10, 33, or 100 parts per million (ppm) for 6 hours per day, 5 days per week for two years.<sup>11</sup> Two other groups of animals served as controls. Initially, there were 120 animals of each sex, in each exposure group. The researchers observed a statistically significant increase in the incidence of mononuclear cell leukemia among the female rats, and peritoneal mesothelioma among the male rats exposed to EtO. The increase in leukemia incidence was found to increase linearly as a function of EtO exposure. An elevation in mortality from brain cancers (glial type) was also observed in the rats exposed to EtO.

NIOSH researchers have recently reported on the results from an animal experiment which corroborated the findings of the Bushy Run Study.<sup>12</sup> Male Fischer 344 rats were exposed to EtO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm. There were 80 rats in each exposure group. Increases in the incidence of mononuclear leukemia, peritoneal mesothelioma, and cerebral gliomas were observed among the EtO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of EtO.<sup>13-15</sup> Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that had previously been included in a hematologic investigation.<sup>13</sup> This facility produced EtO via the chlorohydrin process in which, in addition to EtO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloro-ethyl) ether. Among 89 full-time exposed workers, a statistically significant (p less than .01) excess of leukemia mortality was observed (2 observed versus 0.14 expected). In addition, a statistically significant (p less than .01) excess of stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to EtO; however, ethylene oxide and ethylene dichloride were the prime suspects.

Morgan, et al, conducted a retrospective cohort mortality study of workers involved in the production of EtO at a Texaco Facility.<sup>14</sup> A total of 850 workers were included in the study, of which 767 were potentially exposed to EtO. No EtO was detected in most samples taken in the production area, and all measurements in this area were below 10 ppm. No cases of leukemia were observed in this study; however, the authors estimated that the lowest relative risk that they had a high probability of detecting (80% power) was 10.5.

Hogstedt also reported on three cases of leukemia that occurred in a small group of workers at a Swedish company.<sup>15</sup> The company used a mixture of 50% EtO and 50% methyl formate to sterilize hospital equipment. The 8-hour TWA exposure for EtO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this cohort. One of the cases was exposed to benzene, a known leukemogen, and it was speculated that the combined exposure of EtO and methyl formate might produce a special risk.

EtO is also a potent alkylating agent capable of causing irreversible changes or mutations in cellular proteins and DNA in animals.<sup>16,17</sup> EtO is also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.<sup>6</sup>

Chromosomal aberrations related to EtO exposure have been observed in a number of animal studies and epidemiologic investigations.<sup>12,17-24</sup> Yager and Benz observed a dose related increase in sister chromatid exchanges (SCEs) among New Zealand white rabbits that were exposed via inhalation to 50 to 250 ppm of EtO.<sup>18</sup> NIOSH (Lynch, et al) recently reported preliminary findings in which cynomolgus monkeys were exposed to 0, 50, or 100 ppm of EtO for 7 hours per day, 5 days per week.<sup>12</sup> After 24 months of

exposure, statistically significant increases were observed in the frequency of chromosomal aberrations (including quadriradial chromosomes) and SCEs in the peripheral lymphocytes of the 50 and 100 ppm exposed groups versus the controls.

Garry, et al, examined the occurrence of SCE in the peripheral lymphocytes of 12 EtO exposed workers and 12 nonexposed controls in a hospital sterilization facility.<sup>19</sup> The exposed group showed statistically significant elevations in the number of SCEs compared to the controls. Particularly high SCE frequencies were observed among 4 workers that had reported either neurologic or respiratory symptoms. The maximum peak exposure level of EtO measured at this facility was 36 ppm.

Cytogenetic abnormalities have also been observed in several studies of workers exposed to EtO. Ehrenberg, in a study of workers at a factory manufacturing and using EtO, observed a high frequency of chromosomal aberrations in 8 workers who were accidentally exposed to high concentrations of EtO. One case of leukemia was also observed among the 37 workers studied.<sup>20</sup>

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to EtO in the sterilization of medical devices in 1978.<sup>21,22</sup> Seventy-five exposed workers at 9 facilities were studied, as well as 37 nonexposed workers who served as controls. Compared to controls, exposed workers were found to have statistically significant increased frequencies of SCEs and chromosomal aberrations.

In response to the findings from the American Hospital Supply study, Johnson and Johnson initiated a cytogenetic study of workers that were also exposed to EtO in the sterilization of medical products.<sup>23,24</sup> Approximately 50 workers not exposed to EtO were compared to 50 exposed workers at three facilities with 8-hour Time-Weighted Average (TWA) exposures to EtO of less than 1 ppm, 1-10 ppm, and 25-200 ppm, respectively. Statistically significant elevations in SCE frequency were observed in the latter two facilities, and these changes have persisted after one year. The frequency of SCEs appeared to increase in a dose response manner. Chromosomal aberrations were also elevated in the high exposure groups; however, these findings were not statistically significant.

#### DESCRIPTION OF SAMPLING AND ANALYTICAL METHODS

Breathing zone (BZ) and area air samples for EtO were collected during these surveys using SKC Model 224-02 Universal Sampling pumps. These pumps were used in conjunction with variable orifices calibrated at a sampling rate of approximately 20 cubic centimeters (cc) per minute. The collection media consisted of coconut shell charcoal in two tubes, 400 milligrams (mg) and 200 mg. The tubes were connected in series and connected to the pump via flexible plastic tubing. For personal sampling, the pumps were placed on an individual with the charcoal tubes positioned in the breathing zone for sample collection. The sampling time on each tube using the SKC pumps varied from 4 minutes to 8 hours.

All samples were analyzed according to NIOSH method number 1607.<sup>25</sup> Specifically, this method involves desorbing the EtO from the charcoal using 3 milliliters (mL) of 1% carbon disulfide/benzene solution for one hour at room temperature. Twenty microliters (uL) of 48% hydrogen bromide (HBr) were added to 1 mL aliquots of each sample. Sodium carbonate was added to each vial and held until carbon dioxide no longer evolved. Each sample was analyzed for the derivative 2-bromoethanol using a Hewlett Packard 5840 gas chromatograph with electron capture detector (GC/ECD). The reported limit of quantitation (LOQ) for this sample analysis was 6.25 micrograms (ug) per sample with a limit of detection (LOD) of 1.9 ug/sample.

Concurrent, side-by-side, air samples were obtained for selected area and personal breathing zone samples along with the NIOSH method using the OSHA's Method Number 50.<sup>26</sup> This method was used in order to evaluate its advantages and disadvantages as compared to NIOSH Method 1607. SKC Model 224-02 pumps were used to obtain these samples in the same manner as described above with the exception that a flow rate of 100 cc/minute was used. This particular method uses a HBr-treated petroleum base charcoal in a dual section (100 mg and 50 mg) single tube. Samples are desorbed with 1 mL of dimethylformamide. The derivative 2-bromoethylheptafluorobutyrate is analyzed by GC/ECD. The LOD for this sample analysis was 1.2 ug/sample.

EtO 8-hour TWA exposure levels were determined for various jobs throughout the Micro-Biotrol/Griffith Labs facility where EtO exposure was thought to be evident. Ancillary jobs in which exposure to EtO was intermittent, or thought to be non-existent, were also evaluated to the extent possible. Short-term exposure (4 to 30 minutes) levels were determined for the sterilizer operators during load transfer procedures. Locations for area sampling were chosen to characterize EtO concentration levels in the various areas within the facility. Sampling pumps used during these surveys were checked for significant (greater than  $\pm$  5%) deviation after use, and the samples where a significant deviation was observed were discarded. To assure quality of results, sample blanks and spiked samples were generated, analyzed and reported in accordance with NIOSH Quality Assurance/Quality Control procedures.<sup>25</sup>

Area EtO measurements were obtained using a Wilks Miran Model 80 Infra-Red Analyzer. This instrument was used to detect leaks in equipment, determine adequacy of aeration periods, identify EtO emission points, and spot check general area air concentrations of EtO. The Wilks Miran Model 80 is a quantitative analysis system combining a single beam infrared spectrometer with a programmable microcomputer system. The instrument was calibrated with an EtO standard over two overlapping analysis ranges (0-150 ppm and 100-300 ppm). The limit of detection of the instrument at a wavelength of 3.3 micrometers (um) is 0.2 ppm.

#### APPLICABLE STANDARDS AND RECOMMENDED LEVELS

Prior to June 22, 1984, the OSHA Permissible Exposure Limit (PEL) for EtO was 50 ppm as a TWA concentration for an 8-hour workshift.<sup>27</sup> OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.<sup>28</sup> In addition, an "action level" of 0.5 ppm as an 8-hour TWA was established (by

OSHA) as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. The Environmental Protection Agency (EPA) supported the OSHA PEL of 1 ppm in the Federal Register (June 22, 1984).<sup>29</sup>

In 1977, NIOSH recommended a ceiling level of 75 ppm as determined during a 15-minute sampling period.<sup>6</sup> This level, however, was set prior to the recognition of the carcinogenic potential of EtO. Based on recent findings, NIOSH recommends that EtO exposures not exceed 5 ppm for a maximum of 10 minutes per day and that exposures be controlled to less than 0.1 ppm determined as an 8-hour TWA (NIOSH Policy Statement, July 20, 1983). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a Threshold Limit Value (TLV) of 10 ppm for an 8-hour TWA based on data available prior to 1982.<sup>30</sup> However, in 1982, the ACGIH issued a notice of intended change in which it was proposed that the TWA concentration be lowered to 1 ppm. This recommendation was reviewed and adopted in 1984. ACGIH has also designated EtO as an A2 carcinogen.<sup>30</sup> An A2 carcinogen is defined as an industrial substance suspected of having carcinogenic potential for man. This designation is based on either (1) limited epidemiologic evidence, exclusive of clinical reports of single cases, or (2) demonstration of carcinogenesis in one or more animal species by appropriate methods.

#### DISCUSSION OF SAMPLING RESULTS

Individual 8-hour TWA EtO exposure sample results are listed by survey date and job title in Table 4. These sample results demonstrate the exposure potential for specific jobs throughout the Micro-Biotrol, Griffith Laboratories Chicago facility. These results are considered potential exposure levels due to the varied use of air purifying respirators by the vessel operators. Usage of respiratory protection was irregular (1st shift vs. 2nd shift and September vs. January survey dates) and dependent upon individual operator, shift, and survey date. When it was in usage, respiratory protection only occurred during unloading and transfer of the treated product. General area EtO sampling results in the vessel area indicated that EtO concentrations existed throughout the individual shifts when product treatment occurred. The short-term personal EtO exposure sample results are shown in Table 5 by survey date. These sample results depict the vessel operators' short-term exposure potential during the unloading of a vessel and transporting of the EtO treated product to the warehouse. These short-term results ranged from non-detectable to 444.8 ppm. The variability in short-term results appeared to be related to the number of loads run per day, number of pallets removed, type of treated product, time required to remove the pallets, and the amount of dilution ventilation available (seasonal variation). Table 6 depicts the results of the short-term general area EtO concentration levels by survey date and location. General area EtO concentration levels are listed in Table 7 by survey date and location. These results substantiate the personal sampling results in that EtO is present, over a wide range of concentrations throughout the facility.

Table 8 presents the summary statistics of personal 8-hour TWA exposures by survey date and job title for comparisons between job titles, within a job title, and of seasonal exposure variation. Exposure to EtO was demonstrated in the majority of the jobs sampled. Average EtO exposure levels for the September survey ranged from <0.11 ppm to 4.03 ppm. The vessel operators had the highest 8-hour TWA EtO exposures. The sanitors (sanitation crew) had the second highest exposures which probably reflect the nature of their job; they move throughout the plant and can experience a wide variation in exposure (standard deviation 3.11). The vessel operators also had the highest average EtO exposures during the January survey (12.13 ppm) with the most variation in exposure levels (standard deviation 8.59). Figures 1 and 2 depict the area EtO concentration levels in the vessel room for January 22 and 23 respectively. These graphs represent Miran I.R. monitoring and corresponding charcoal tube results. The peak concentration levels occurred during the unloading of the vessels and represent short-term peak excursions. Other jobs having relatively high average EtO exposure levels included the Q.A. Supervisor (10.33 ppm), Hydrolysate operators (6.84 ppm), Shipping and Receiving (4.81 ppm), Sanitors (5.00 ppm), Mustard Grinding (3.21 ppm), and Maintenance (3.17 ppm). The Q.A. supervisor's exposure (10.33 ppm) was probably the result of exposure to many peak EtO concentrations in the sterilizer area. The summary statistics for the combined survey results are also presented in Table 8. It should be noted that exposure levels appear to be considerably higher in all jobs during the January survey as compared to the September survey (see Figure 3). This is probably due to the lack of dilution ventilation when the doors are kept closed to keep the plant warm, causing seasonal exposure variation in this facility.

Table 9 lists the summary statistics for the personal short-term EtO exposure levels during unloading and transfer of the EtO treated product. The summary statistics for the short-term general area EtO concentration levels are reported in Table 10. Table 11 shows the summary statistics for the general area EtO concentration levels by location. The vessel control room had the highest average EtO area concentration level (9.44 ppm), and the second highest average level (8.66 ppm) was found in the vessel area. The control room was not exhaust ventilated; therefore, this EtO level may be the result of build up of EtO in this area due to the frequency of sterilization loads.

Figure 4 shows the results of the NIOSH and OSHA method side-by-side sampling results during the January, 1985 survey. This graph depicts a very good agreement between the methods at various concentration levels and for various sampling times. These concurrent sampling results also substantiate the finding that EtO exposure potential exists throughout this facility. When these results are compared with the passive monitor data presented in Table 3, the overall accuracy and sensitivity of the passive monitors is suspect.

## CONCLUSIONS AND RECOMMENDATIONS

This plant meets the three eligibility requirements as defined in the protocol and therefore, should be included in the mortality study. These requirements are: 1) the plant must contribute at least 200 person-years to the high exposure group, or 400 person years total, 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.

Some industrial hygiene sampling for EtO has been conducted by the company or a consulting firm. The levels are reported as less than the 8-hr TWA of 50 ppm for all jobs evaluated, however, one job has a TWA as high as 24 ppm..

The results of the NIOSH industrial hygiene sampling clearly indicate ethylene oxide exposure potential existed throughout the facility. The OSHA PEL standard (1.0 ppm), the NIOSH recommended level (<0.1 ppm), and the ACGIH TLV (1.0 ppm) for EtO exposure were exceeded in various jobs during both survey dates. Short-term personal sampling during unloading of the vessels indicated the potential for extremely high peak exposure levels. Although the vessel operators wore air purifying respirators during this procedure, other personnel in the general area were exposed to these peak excursions (e.g., Q.A. Supervisor, 10.33 ppm as an 8-hour TWA). Respirators were not provided nor used in this plant prior to 1984.

Comparison of sampling results from the two in-depth industrial hygiene surveys indicate seasonal variation in EtO exposure as a result of inadequate dilution ventilation and no engineering controls (exhaust ventilation) on the microbial reduction process.

The company should conduct personal exposure monitoring for ethylene oxide in the new plant to assure exposure levels are below the OSHA PEL and action level standards.

The company is encouraged to develop a comprehensive respirator fit-testing, training, and maintenance program if respirators are used in the new plant.

## REFERENCES

1. NIOSH. Current Intelligence Bulletin 35 - Ethylene Oxide (EtO). DHHS (NIOSH) Publication No. 81-130, May 22, 1981.
2. Chemical Economics Handbook, SRI International, Ethylene Oxide, January, 1980.
3. Clayton, G.D.; Clayton, F.E.; eds, Patty's Industrial Hygiene and Toxicology, 3rd Revised ed., Vol. 2A, John Wiley and Sons, New York, 1978.
4. NIOSH. Draft Feasibility Study for a Cohort Mortality Study of Workers Exposed to Ethylene Oxide. Internal report from the Industrywide Studies Branch, June, 1983.
5. National Occupational Hazard Survey, National Institute for Occupational Safety and Health, 1977.
6. Glazer, Z.R., Special occupational hazard review with control recommendations for the use of ethylene oxide as a sterilant in medical facilities. National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 77-200, 1977.
7. Sax, N.I., Dangerous Properties of Industrial Materials, 4th Edition, Van Nostrand Reinhold Company, New York, 1975.
8. Roy, P.A., Engineering Controls of Ethylene Oxide Exposures from Gas Sterilization. The Safe Use of Ethylene Oxide, Proceeding of the Educational Seminar, HIMA Report 80-4, p. 193-208.
9. Rybak, J.A.; Jimenez, P.J.; Frank, R.; McKinney, E.M.; Hunter, J.D.; and S.A. Kraft. Comparison of Passive Dosimeters and Charcoal Tubes with Laboratory and Field Conditions for Several Industrial Solvents. Presented at the 1981 American Industrial Hygiene Conference, Portland, Oregon, May 26, 1981.
10. Kring, E.V., McGibney, P.D., Thornley, G.D., Laboratory Validation of Five Commercially Available Methods for Sampling Ethylene Oxide in Air. Am. Ind. Hyg. Ass. J., 46(10) 620-624, 1985.
11. Snelling, W.M.; Weill, C.S.; and Maronport, R.R., Final report on ethylene oxide two-year inhalation study on rats. Project Report 44-20, Bushy Run Research Center, January 28, 1981. Submitted by Union Carbide Corporation to the U.S. Environmental Protection Agency under section 8(e) of the Toxic Substances Control Act, on behalf of co-sponsors of the study (February, 1981).

12. Lynch, D.W.; Lewis, T.R.; Moorman, W.J.; Sabharwal, P.S.; and Burg, J.R., Chronic inhalation toxicity of ethylene oxide and propylene oxide in rats and monkeys -- a preliminary report. Presented at the 21st Annual Society of Toxicology Meeting, Boston, Massachusetts, February 22-26, 1982.
13. Hogstedt, C.; Rohlen, O.; Berndtsson, B.S.; Axelson, O.; and Ehrenberg, L., A cohort study of mortality and cancer incidence in ethylene oxide production workers. *Br. J. Ind. Med.*, 39:276-280, 1979.
14. Morgan, R.W.; Claxton, K.W.; Divine, B.J.; Kaplan, S.D.; and Harris, V.B, Mortality Among Ethylene Oxide Exposed Workers. *J. Occ. Med.*, 23:767-770, 1981.
15. Hogstedt, C.; Malmqvist, N.; and Wadman, B., Leukemia in workers exposed to ethylene oxide. *JAMA*, 241:1132-1133, 1979.
16. Calleman, C.J.; Ehrenberg, L.; Jansson, B.; Osterman-Golkar, S.; Segerback, K.; and Wachtmeister, C.A., Monitoring and risk assessment by means of alkyl groups in hemoglobin in persons occupationally exposed to ethylene oxide. *J. Environ. Pathol. Toxicol.*, 2:427-442, 1978.
17. Ehrenberg, L.; Heische, K.D.; Osterman-Golkar, S; and Wennberg, I., Evaluation of genetic risks of alkylating agents: Tissue doses in the mouse from air contaminants with Ethylene Oxide. *Mutat. Res.*, 24:83-103, 1974.
18. Yager, J.W., and Benz, R.D., Sister chromatid exchanges induced in rabbit lymphocytes by ethylene oxide after inhalation exposure. *Environ. Mutagen.*, 4:121-134, 1982.
19. Garry, V.E.; Hozier, J.; Jacobs, D.; Wade, R.; and Gray, D., Ethylene Oxide: evidence of human chromosomal effects. *Env. Mutag.*, 1:375-382, 1979.
20. Ehrenberg, L., and Hallstrom, T., Haematologic studies on persons occupationally exposed to ethylene oxide. In: International Atomic Energy Agency Report, SM 92/26, pp. 327-334, 1967.
21. Abrahams, R.H., Recent studies with workers exposed to ethylene oxide, in *The Safe Use of Ethylene Oxide*. J.F. Jorkasky, ed. Health Industry Manufacturers Association, Washington, D.C., HIMA Report No. 80-4: 211-220, 1980.
22. Abrahams, R.H., Chromosomal changes in workers exposed to ethylene oxide -- an update. Ethylene Oxide Worker Safety Issues. J.F. Jorkasky, ed., Washington, D.C., HIMA Report No. 82-2:27-38, 1982.

23. Herman, A.A., (Johnson and Johnson Corporate Submittal to OSHA). Pilot research chromosome study of workers at sites where ethylene oxide gas is utilized as a sterilant. Submitted to OSHA, March 30, 1982.
24. Jones, J.P., Chromosomal changes in employees exposed to ethylene oxide. Ethylene Oxide Worker Safety Issues. J.F. Jorkasky, ed., Washington, D.C., HIMA Report No. 82-2, 5-25, 1982.
25. NIOSH Manual of Analytical Methods, 3rd Edition. Ethylene oxide, Method: 1607. P.M. Eller, Editor, DHHS (NIOSH) Publication No. 84-100, 1984.
26. Ethylene Oxide, OSHA Method #50. Organic Methods Evaluation Branch, OSHA Analytical Laboratory. Salt Lake City, Utah, July, 1984.
27. Occupational Safety and Health Administration (OSHA), Safety and Health Standards 29 CFR 1910, General Industry Standards, OSHA 2206, Revised, June, 1981.
28. Federal Register, Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910, Occupational Exposure to Ethylene Oxide. 49(122):25734-25809, June 22, 1984.
29. Federal Register, Ethylene Oxide; Certain Pesticide Products Registered for the Sterilization of Equipment and Supplies in Hospitals and Health Care Facilities. 49(122):25675-25676, June 14, 1984.
30. Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment with Intended Changes for 1983-84, American Conference of Governmental Industrial Hygienists, 1983.

TABLE I  
Summary of Results from the Sampling of Personnel Records<sup>a</sup>

<u>DIVISION</u>	<u>EMPLOYMENT STATUS</u>	<u>TOTAL # RECORDS (#SAMPLED)</u>	<u>EST. %EXP</u>	<u>EST. #EXP</u>	<u>YEAR BIRTH</u>	<u>AVERAGE<sup>b</sup></u>		<u>ESTIMATED PERSON-YRS<sup>c</sup></u>
						<u>YR 1ST EXP</u>	<u>DUR EXP</u>	
Micro-Biotrol (Chicago)	Inactive	5 (5)	40	2	1944	1971	9.0	24
	Active	51 (51)	20	10	1949	1975	7.8	80
Griffith (Chicago)	Inactive	1350 (68)	13	178	1936	1969	3.7	2492
	Active	54 (10)	80	43	1944	1975	6.1	344
Alsip Plant	Inactive	295 (30)	16	47	1933	1969	3.7	658
	Active	172 (17)	6	10	1920	1968	7.0	150
<b>Totals</b>		<b>1927 (181)</b>		<b>290</b>				<b>3748</b>

a The following abbreviations are used in this table; exp for exposed or exposure, dur for duration, yr for year.

b Averages are based on data from the workers classified as being potentially exposed in this review.

c Person years were estimated by multiplying the estimated number of exposed workers times the length of time between 1983 and the average first year of exposure. For example it is estimated that there are 178 former employees that were potentially exposed to EtO at Griffith Labs. The average first year of employment for this group was 1969, and thus the average length of followup would be 14 years (1983-1969) and the estimated number of person-years is 2492 (178 x 14).

TABLE 2  
 History of Plant Changes\*  
 Micro-Biotrol, Incorporated  
 Chicago Plant  
 August 13-14, 1984

<u>YEAR</u>	<u>EVENT</u>
Early 1930s	Griffith Labs established EtO Treatment Department, Building A. Vacuum exhausts on all vessels are conducted before opening.
1930s-1940s	Operated 3 vessels #7, 360 ft <sup>3</sup> ; #2, 58 ft <sup>3</sup> ; #?, about 60 ft <sup>3</sup> .
1950s	Moved EtO operation to Building B-2.
1951	Add 2 more vessels #X 150 ft <sup>3</sup> ; #8, 259 ft <sup>3</sup> .
1951-1961	Add 4 more vessels #4, 5, 6 - 279 ft <sup>3</sup> each; #1, 375 ft <sup>3</sup> .
Pre-1962	Axial blade fans are installed in wall of vessel room to provide dilution ventilation.
1962	Remove vessel #1.
1970	Add new vessel #1, 660 ft <sup>3</sup> ; Micro-Biotrol becomes separate sales division under Griffith Labs
before 1971	GD&E production occupies space in Buildings E and G.
1971-1975	Building I is used as warehouse.
1973	Treatment vessels are equipped with remote water/vacuum pump and water/gas separator.
1975	GD&E production moves back into Building I.
1975	Vinyl strip curtains installed at gassing stations.

\* Changes which may have affected exposure potential to employees in the facility.

TABLE 2 (continued)  
 History of Plant Changes\*  
 Micro-Biotrol, Incorporated  
 Chicago Plant  
 August 13-14, 1984

<u>YEAR</u>	<u>EVENT</u>
1976	GD&E office moves into Building F
1976	Add vessel 33, 660 ft <sup>3</sup> , add vessel #9, 660 ft <sup>3</sup> .
1977	Patt-Pro department is disbanded.
1979	Micro-Biotrol became separate operating Division of Griffith Labs.
1979	Vinyl strip curtains installed at entrance and exit of pretempering room.
1980	Limited industrial hygiene sampling (charcoal tube) for EtO conducted by consulting firm.
1982	Removed vessel 2.
1983	SOP instituted that required vessel operators to open vessel and wait 10-15 minutes in an adjacent area before entering vessel.
1983	Micro-Biotrol established requirement for EtO sampling with 3M Badges every 3 month and Organic Vapor analyzer every 2 months.

\* Changes which may have affected exposure potential to employees in the facility.

TABLE 3  
 Personal EtO Exposure Sample Results  
 Micro-Biotrol, Chicago Plant+  
 Passive Monitors (3M Badges)  
 Ethylene Oxide  
 8 hr TWA

Micro-Biotrol

Corporate Office Date	N@	$\bar{x}$ , ppm	SD	Range, ppm	<LOD*
6-83	3	1.7	1.2	1-3	0
10-83	3	0.3	0.1	< 0.5-0.5 <sup>o</sup>	2
3-84	5	0.25	0	< 0.5	5
9-84	<u>6</u>	<u>0.6</u>	<u>0.3</u>	<u>&lt; 0.5-1</u>	<u>2</u>
	17	2.1	5.9	< 0.5-3	9
<b>Vessel Operators</b>					
6-83	3	9.0	6.6	3-16	0
10-83	3	7.7	4.0	3-10	0
3-84	5	12.8	9.8	5-24	0
9-84	<u>5</u>	<u>9.0</u>	<u>5.8</u>	<u>3-17</u>	<u>0</u>
	16	9.6	2.2	3-24	0
<b>Q A Tech</b>					
6-83	1	3	--	--	0
10-83	1	1	--	--	0
3-84	1	2	--	--	0
9-84	<u>1</u>	<u>2</u>	<u>--</u>	<u>--</u>	<u>0</u>
	4	2	0.8	--	0
<b>Dept. Head</b>					
6-83	1	6	--	--	0
10-83	1	1	--	--	0
3-84	1	6	--	--	0
9-84	<u>1</u>	<u>4</u>	<u>--</u>	<u>--</u>	<u>0</u>
	4	4.3	2.4	--	0
<b>Office Clerk</b>					
6-83	1	1	--	--	0
10-83	1	< 0.5 (7.5 hr)	--	--	1
3-84	1	< 0.5	--	--	1
9-84	<u>1</u>	<u>0.7</u>	<u>--</u>	<u>--</u>	<u>0</u>
	4	0.6	0.4	--	2
<b>Regional Manager</b>					
6-83	1	2.0	--	--	0
10-83	1	< 0.5	--	--	1
3-84	1	0.8	--	--	0
9-84	<u>1</u>	<u>0.7</u>	<u>--</u>	<u>--</u>	<u>0</u>
	4	0.9	0.8	--	1

TABLE 3 (continued)  
 Personal EtO Exposure Sample Results  
 Micro-Biotrol, Chicago Plant<sup>+</sup>  
 Passive Monitors (3M Badges)  
 Ethylene Oxide  
 8 hr TWA

Micro-Biotrol

<u>Date</u>	<u>N@</u>	<u><math>\bar{X}</math>, ppm</u>	<u>SD</u>	<u>Range, ppm</u>	<u>&lt;LOD*</u>
<b>Warehouse Clerk</b>					
6-83	1	5.0	--	--	0
10-83	1	2.0	--	--	0
3-84	1	3.0	--	--	0
9-84	<u>1</u>	<u>1.0</u>	<u>--</u>	<u>--</u>	<u>0</u>
	4	2.8	1.7	--	0
<b>GDE 9-84</b>					
Office	7	0.4	0.1	< 0.5-0.5	4
Maintenance	3	0.3	0.1	< 0.5-0.5	2
Foreman	1	0.25	--	< 0.5	1
Store Keeper	<u>1</u>	<u>0.25</u>	<u>--</u>	<u>&lt; 0.5</u>	<u>1</u>
	12	0.3	0.1	< 0.5-0.5	8
<b>Griffith Labs 9-84</b>					
<b>Chem Operator/ Packer</b>					
	11	1.3	0.9	< 0.5-3	1
Grinder	2	0.8	0.3	0.6-1	0
Sanitor	4	1.5	0.6	1-2	0
Lift Truck	3	0.8	0.3	0.5-1	0
<b>Supervisors</b>					
Chem Foreman	4	1.0	0.7	< 0.5-2	1
W/H Foreman	1	1	--	--	0
QA Manager	1	0.6	--	--	0
<b>Maint Foreman/ Supervisor</b>					
	3	0.6	0.4	< 0.5-1	1
<b>Plant Manager/ Pro Supv.</b>					
	3	0.6	0.5	< 0.5-1	1
Stores	1	0.25	--	--	1

TABLE 3 (continued)  
 Personal EtO Exposure Sample Results  
 Micro-Biotrol, Chicago Plant<sup>†</sup>  
 Passive Monitors (3M Badges)  
 Ethylene Oxide  
 8 hr TWA

Micro-Biotrol

	<u>N@</u>	<u><math>\bar{X}</math>, ppm</u>	<u>SD</u>	<u>Range, ppm</u>	<u>&lt;LOD*</u>
Maintenance	9	0.7	0.3	< 0.5-1	3
Guard	3	0.6	0.4	< 0.5-1	1
Office	2	0.4	0.2	< 0.5-0.5	1
Secretary	1	0.25	--	< 0.5	1
Clerk	$\frac{1}{46}$	$\frac{0.5}{0.9}$	$\frac{--}{0.70}$	$\frac{--}{< 0.5-3}$	$\frac{0}{10}$

†-Data supplied by company.

@-Number of samples collected.

X-Mean (average concentration level).

SD-Standard deviation.

\*-Number of samples reported less than limit of detection (LOD=0.5).

o-When less than 0.5 (< 0.5) was reported, 1/2 this value (0.25) was used to calculate mean.

TABLE 4  
 Personal TWA EtO Exposure Samples\*  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Job Title</u>	<u>Time (min)</u>	<u>Volume (liters)</u>	<u>EtO/Tube (ug)</u>	<u>ppm</u>	
9/13/84	Engineer Tech.	225	5.2	7.5	0.80	
	Hydrolysate Oper.	188	3.6	5.0	0.76	
	Hydrolysate Oper.	469	9.8	32.1	1.83	
	Hydrolysate Foreman	183	3.9	3.0	0.42	
	Hydrolysate Foreman	473	9.8	10.8	0.61	
	Maintenance	175	3.5	ND**	<0.12	
	Maintenance	193	4.1	3.0	0.41	
	Maintenance	179	3.6	3.0	0.46	
	Nu Spice Foreman	227	4.5	4.0	0.49	
	Q.A. Inspector	199	4.1	ND	<0.10	
	Sanitor	278	5.5	8.0	0.80	
	Sanitor	228	4.7	65.0	7.61	
	Sanitor	223	4.6	10.0	1.21	
	Secretary, Griffith	261	5.2	20.0	2.12	
	Vessel Oper.	369	7.4	19.0	1.42	
	Vessel Oper.	493	9.9	118.0	6.64	
	Supervisor, Micro.	235	4.8	11.0	1.26	
	Warehouseman	200	4.1	4.0	0.54	
	9/14/84	Lab. Super., Griffith	179	3.7	ND	<0.11
		Maint. Store Room Oper.	450	8.9	5.0	0.31
Maintenance		181	3.7	2.0	0.30	
Maintenance		444	9.4	36.0	2.12	
Maintenance		474	10.2	7.0	0.38	
Maintenance		449	8.9	8.5	0.53	
QA Supervisor		485	9.7	7.8	0.44	
Shipping and Receiving		208	4.1	ND	<0.10	
Shipping and Receiving		455	9.2	5.1	0.31	
Warehouseman		387	7.8	13.1	0.93	
1/22/85	Secretary, Griffith	377	3.8	3.1	0.46	
	Guard	455	4.2	13.6	1.80	
	Guard	462	4.6	2.7	0.33	
	Hydrolysate Foreman	207	2.4	19.0	4.47	
	Hydrolysate	213	2.1	28.8	7.66	
	Hydrolysate	165	1.6	12.7	4.38	
	Hydrolysate	470	5.0	37.4	4.19	
	Secretary, Maint. Shop	255	2.3	3.5	0.83	
	Maintenance	457	4.7	15.9	1.87	
	Maintenance	452	5.0	23.8	2.64	
	Maintenance	360	3.5	23.3	3.67	
	QA, Supervisor Micro-Biotrol	250	2.6	47.7	10.33	
	Mustard Grinding	399	4.0	9.6	1.35	
Nu-Spice Oper.	131	1.5	ND	<0.30		

TABLE 4 (continued)  
 Personal TWA EtO Exposure Samples\*  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Job Title</u>	<u>Time (min)</u>	<u>Volume (liters)</u>	<u>EtO/Tube (ug)</u>	<u>ppm</u>
1/22/85	Sanitor	415	4.4	30.5	3.87
	Sanitor	390	3.9	10.1	1.45
	Shipping and Receiving	455	4.5	47.5	5.80
	Vessel Oper.	242	2.6	44.8	9.51
	Vessel Oper.	253	2.7	53.2	11.12
	Vessel Oper.	449	4.8	59.5	6.81
	Sterilizer Oper.	435	4.5	14.1	1.75
1/23/85	Secretary, Griffith	448	4.7	11.0	1.29
	Guard	452	4.2	9.4	1.24
	Guard	462	4.5	6.1	0.75
	Hydrolysate	341	3.5	52.3	8.23
	Secretary, Micro-Biotrol	316	3.1	ND	<0.22
	Mustard Grinding	620	6.0	54.3	5.06
	Sanitor	421	4.6	52.7	6.32
	Shipping and Receiving	464	4.7	25.0	2.95
	Shipping and Receiving	467	5.0	34.0	3.78
1/24/85	Secretary, Griffith	518	4.9	9.2	1.04
	Hydrolysate	438	4.1	71.0	9.73
	Secretary, Maintenance Shop	456	4.3	19.0	2.43
	Maintenance	405	4.8	28.6	3.28
	Maintenance	448	4.4	34.8	4.40
	Secretary, Micro-Biotrol	446	4.4	1.5	0.19
	Nu-Spice Oper.	351	3.6	12.3	1.92
	Nu-Spice Oper.	349	3.7	10.8	1.64
	Sanitor	430	4.5	68.4	8.37
	Shipping and Receiving	455	4.3	52.3	6.72
	Vessel Oper.	541	5.8	149.6	14.28
	Vessel Oper.	461	4.5	236.0	29.29

\*TWA-EtO = Time Weighted Average-Ethylene Oxide exposure for 8 hours assuming unsampled time represented similar exposure.

\*\*ND = None Detected; ppm (parts per million) concentration determined using one half of the detection limit, with result reported as a less than value (<).

TABLE 5  
 Personal Short-Term EtO\* Exposure Levels  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Job Operation</u>	<u>Time (min.)</u>	<u>Volume (liters)</u>	<u>EtO/Tube (ug)</u>	<u>ppm</u>
9/13/84	Vessel Unloading	19	2.1	ND**	<0.2
	Vessel Unloading	37	4.1	51.0	6.9
9/14/84	Vessel Unloading	20	2.2	22.0	5.5
1/22/85	Vessel Unloading	18	0.8	194.0	132.6
		25	1.1	77.7	38.3
		19	0.9	41.5	26.9
		17	0.8	191.0	138.3
1/23/85	Vessel Unloading	11	0.5	391.0	444.9
		17	0.8	84.6	62.3
		17	0.8	192.0	141.4
		4	0.2	105.0	323.1
		14	0.6	39.0	34.3
		12	0.5	81.8	83.9
		8	0.4	39.2	60.3
		15	0.7	36.3	30.3
1/24/85	Vessel Unloading	7	0.3	12.8	21.7
		11	0.5	23.3	25.2
		13	0.6	99.1	90.6
		24	1.1	60.5	30.0

\*Short-Term EtO = Short-Term ethylene oxide exposure levels.

\*\*ND = None Detected; ppm (parts per million) concentration determined using one-half of the detection limit, with result reported as a less than value (<).

TABLE 6  
 Short-Term General Area EtO\* Concentration Levels  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Location</u>	<u>Time (min.)</u>	<u>Volume (liters)</u>	<u>EtO/Tube (ug)</u>	<u>ppm</u>
9/13/84	Vessel Area	37	4.6	86.0	10.28
9/14/84	Maintenance Area	20	2.5	10.0	2.21
	Maintenance Area	20	2.2	ND**	<0.19
	Vessel Area	22	2.8	ND	<0.15
	Vessel Area	19	2.4	39.0	9.08
1/22/85	GD&E Store Room	51	1.0	ND	<0.34
	Vessel Area	15	0.8	66.1	47.91
	Vessel Area	19	1.0	62.6	35.82
	Vessel Area	15	0.8	76.9	55.74
	Vessel Area	16	0.8	47.6	32.35
1/23/85	Vessel Area	15	0.8	9.0	6.49
	Vessel Area	14	0.7	44.1	34.25
	Vessel Area	12	0.6	432.0	389.10
	Vessel Area	15	0.8	75.2	54.19
	Vessel Area	4	0.2	50.0	135.90
	Vessel Area	9	0.5	21.8	26.34
	Vessel Area	15	0.8	166.0	119.60
	Vessel Area	13	0.7	64.4	53.86
1/24/85	Cafeteria	84	4.5	ND	<0.07
	Cafeteria	112	6.0	ND	<0.11
	Micro-Biotrol VP Office	90	4.3	ND	<0.10
	Vessel Area	11	0.6	11.0	10.16
	Vessel Area	25	1.4	81.2	32.99
	Vessel Area	13	0.7	148.0	115.60
	Vessel Area	5	0.3	10.8	21.94

\*Short-Term EtO = Short-Term ethylene oxide exposure levels.

\*\*ND = None Detected; ppm (parts per million) concentration determined using one half of the detection limit, with result reported as a less than value (<).

TABLE 7  
 General Area EtO\* Concentration Levels  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Location</u>	<u>Time (min.)</u>	<u>Volume (liters)</u>	<u>EtO/Tube (ug)</u>	<u>ppm</u>
9/13/84	Vessel Control Room	262	5.4	8.5	0.87
	Maintenance Office	270	5.2	2400.0	254.30
	Tempering Area	267	5.4	29.0	2.99
9/14/84	GDE Shop	222	4.4	ND**	<0.10
	Shipping and Receiving	466	5.4	75.0	7.75
	Mustard Grinding	359	4.9	30.0	3.38
1/22/85	Cafeteria	454	7.7	3.0	0.22
	GDE Shop	414	8.2	0.6	0.04
	Vessel Control Room	264	5.1	71.9	7.79
	Vessel Control Room	157	3.0	79.4	14.47
	Micro-Biotrol VP Office	411	9.0	ND	<0.08
	Vessel Area	479	9.7	33.5	1.91
1/23/85	Cafeteria	211	5.2	ND	<0.09
	Cafeteria	327	8.0	ND	<0.04
	GDE Office Area	180	3.4	3.2	0.52
	GDE Office Area	325	6.2	7.8	0.70
	GDE Shop	490	9.8	ND	<0.04
	Hydrolysate Control Room	338	5.7	5.6	0.55
	Maintenance Shop	250	5.0	12.2	1.36
	Vessel Control Room	327	6.5	118.0	10.12
	Vessel Control Room	232	4.6	35.0	4.23
	Micro-Biotrol VP Office	250	5.6	ND	<0.06
	Vessel Area	204	3.4	22.3	3.61
	Vessel Area	320	5.4	127.0	13.11
	1/24/85	GDE Office	169	3.3	2.8
GDE Office		256	5.0	0.9	0.10
GDE Shop		412	9.2	1.6	0.10
Hydrolysate Control Room		247	4.8	6.4	0.75
Hydrolysate Control Room		265	5.1	12.6	1.37
Maintenance Office		137	3.4	3.1	0.51
Maintenance Office		286	7.1	6.0	0.47
Maintenance Shop		288	5.1	24.0	2.62
Maintenance Shop		141	2.5	2.9	0.65
Vessel Control Room		274	5.5	130.0	13.07
Vessel Control Room		192	3.9	48.4	6.94
Vessel Area		277	5.4	127.0	13.12
Vessel Area		199	3.9	80.3	11.54

\*EtO = Ethylene oxide concentration levels.

\*\*ND = None Detected; ppm (parts per million) concentration determined using one-half of the detection limit, with result reported as a less than value (<).

**TABLE 8**  
**Summary Statistics**  
**Personal 8-Hour TWA Exposures**  
**Micro-Biotrol, Chicago, Illinois**  
**September, 1984 and January, 1985**

<u>Date</u>	<u>Job Title</u>	<u>Number of Samples</u>	<u>PPM Exposure Levels</u>			
			<u>Average</u>	<u>Min.</u>	<u>Max.</u>	<u>SD*</u>
September 1984	Engineer Tech.	1	0.80			
	Hydrolysate Oper.	2	1.29	0.76	1.83	
	Hydrolysate Foreman	2	0.52	0.42	0.61	
	Supervisor, Micro.	1	1.26			
	Lab. Super., Griffith	1	<0.11			
	QA Supervisor/Micro.	1	0.44			
	QA Inspector	1	0.10			
	Maint. Store Room Oper.	1	0.31			
	Maintenance	7	0.61	<0.12	2.12	0.62
	Nu Spice Foreman	1	0.49			
	Sanitor	3	3.21	0.80	7.61	3.11
	Secretary, Griffith	1	2.12			
	Shipping and Receiving	2	0.20	<0.10	0.31	
	Vessel Oper.	2	4.03	1.42	6.64	
	Warehouseman	2	0.73	0.54	0.93	
January 1985	Guard	4	1.03	0.33	1.80	0.55
	Hydrolysate	5	6.84	4.19	9.73	2.19
	Hydrolysate Foreman	1	4.47			
	Maintenance	5	3.17	1.87	4.40	0.87
	Mustard Grinding	2	3.21	1.35	5.06	
	Nu-Spice Oper.	3	1.29	0.30	1.92	0.71
	QA Supervisor Micro-Biotrol	1	10.33			
	Sanitor	4	5.00	1.45	8.37	2.60
	Secretary, Griffith	3	0.93	0.46	1.29	0.35
	Secretary, Maintenance	2	1.63	0.83	2.43	
	Secretary, Micro-Biotrol	2	<0.21	0.19	<0.22	
	Shipping and Receiving	4	4.81	2.95	6.72	1.51
	Vessel Operator	6	12.13	1.75	29.29	8.59
Overall for Both Surveys	Engineer Tech.	1	0.80			
	Guard	4	1.03	0.33	1.80	0.55
	Hydrolysate	7	5.25	0.76	9.73	3.13
	Hydrolysate Foreman	3	1.84	0.42	4.47	1.86
	Lab Super., Griffith	1	<0.11			
	Maintenance Store Room Oper.	1	0.31			
	Maintenance	12	1.68	<0.12	4.40	1.46
	Secretary, Maintenance	2	1.63	0.83	2.43	
	Mustard Grinding	2	3.21	1.35	5.06	
	Nu-Spice Oper.	3	1.29	<0.30	1.92	0.71

\* Standard Deviation

TABLE 8 (continued)  
 Summary Statistics  
 Personal 8-Hour TWA Exposures  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Job Title</u>	<u>Number of Samples</u>	<u>PPM Exposure Levels</u>			
			<u>Average</u>	<u>Min.</u>	<u>Max.</u>	<u>SD*</u>
Overall	Nu-Spice Foreman	1	0.49			
for Both	QA Inspector	1	0.10			
Surveys	QA Supervisor	2	5.39	0.44	10.33	
	Sanitor	7	4.23	0.80	8.37	2.97
	Secretary, Griffith	4	1.23	0.46	2.12	0.60
	Secretary, Micro-Biotrol	2	<0.21	0.19	<0.22	
	Shipping and Receiving	6	3.28	<0.10	6.72	2.50
	Supervisor Micro-Biotrol	1	1.26			
	Warehouseman	2	0.73	0.54	0.93	
	Vessel Operator	8	10.10	1.42	29.29	8.33

\* Standard Deviation

TABLE 9  
 Summary Statistics  
 Personal Short-Term EtO Exposure Levels  
 During Unloading and Transfer of Product  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Number of Samples</u>	<u>PPM Exposure Levels</u>			
		<u>Average</u>	<u>Min.</u>	<u>Max.</u>	<u>SD*</u>
9/84	3	4.21	<0.20	6.91	52.66
1/85	16	105.24	21.73	444.86	114.78
Overall	19	89.29	<0.20	444.86	111.59

TABLE 10  
 Summary Statistics  
 Short-Term General Area EtO Concentration Levels  
 Micro-Biotrol, Chicago, Illinois  
 September, 1984 and January, 1985

<u>Date</u>	<u>Job Title</u>	<u>Number of Samples</u>	<u>PPM Exposure Levels</u>			
			<u>Average</u>	<u>Min.</u>	<u>Max.</u>	<u>SD*</u>
9/84	Maintenance	2	1.20	<0.19	2.21	
	Vessel Area	3	6.50	<0.15	10.28	4.52
1/85	GDE Store Room	1	<0.34			
	Cafeteria	2	<0.11			
	Micro-Biotrol VP Office	1	<0.10			
	Vessel Unloading	16	73.27	6.48	389.13	89.73

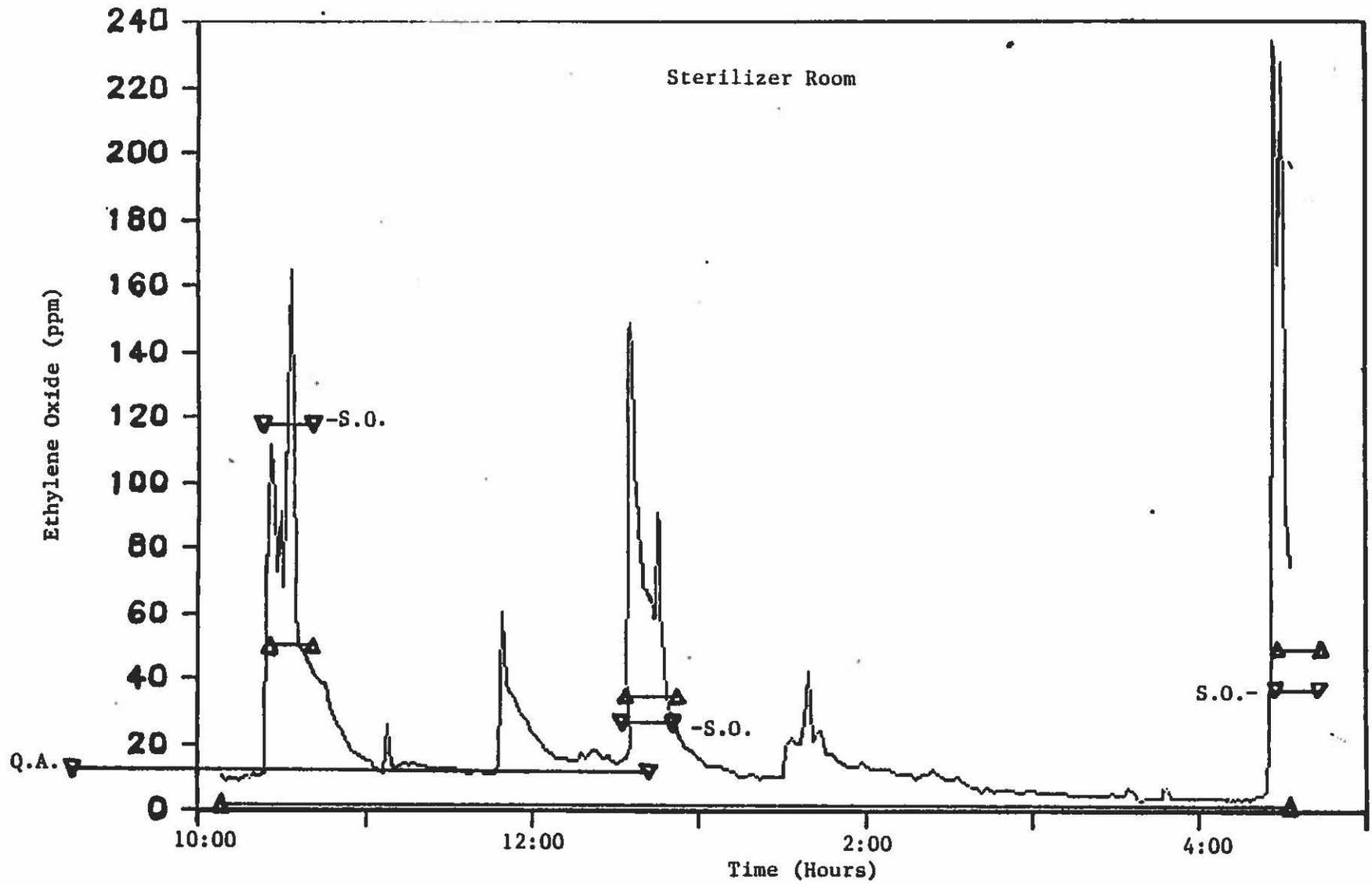
\*Standard Deviation

TABLE 11  
 Summary Statistics  
 General Area EtO Concentration Levels  
 Micro-Biotrol, Chicago, Illinois  
 January, 1985

<u>Date</u>	<u>Job Title</u>	<u>Number of Samples</u>	<u>PPM Exposure Levels</u>			
			<u>Average</u>	<u>Min.</u>	<u>Max.</u>	<u>SD*</u>
1/85	Cafeteria	3	<0.11	<0.04	0.22	0.07
	GDE Office	4	0.44	0.10	0.70	0.22
	GDE Shop	3	<0.06	<0.04	0.10	0.03
	Hydrolysate Control Room	3	0.89	0.55	1.37	0.35
	Maintenance Office	2	0.49	0.47	0.51	
	Maintenance Shop	3	1.54	0.65	2.62	0.82
	Vessel Control Room	6	9.44	4.23	14.47	3.54
	Micro-Biotrol VP Office	2	<0.07	<0.06	<0.08	
	Vessel Area	5	8.66	1.91	13.12	4.88

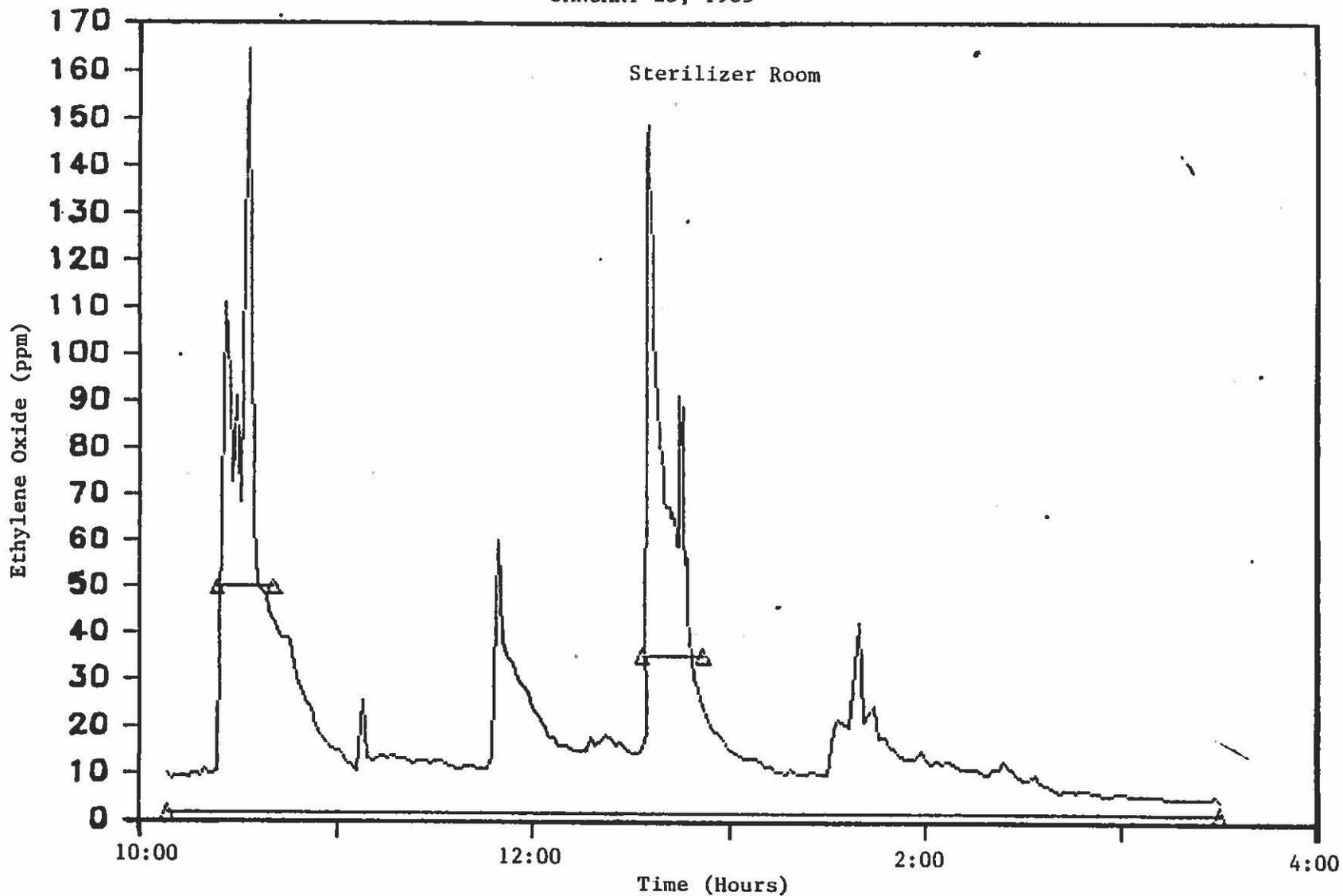
\*Standard Deviation

WILKS MIRAN MODEL 80 I.R.  
 AREA ETHYLENE OXIDE MEASUREMENTS  
 MICROBIOTROL, CHICAGO, ILLINOIS  
 JANUARY 22, 1985



- Miran I.R.    
   Charcoal Tube Area Sample    
   Charcoal Tube Personal Sample  
 Q.A.-Q.A. Supervisor  
 S.O.-Sterilizer Operator (Load Transfer)

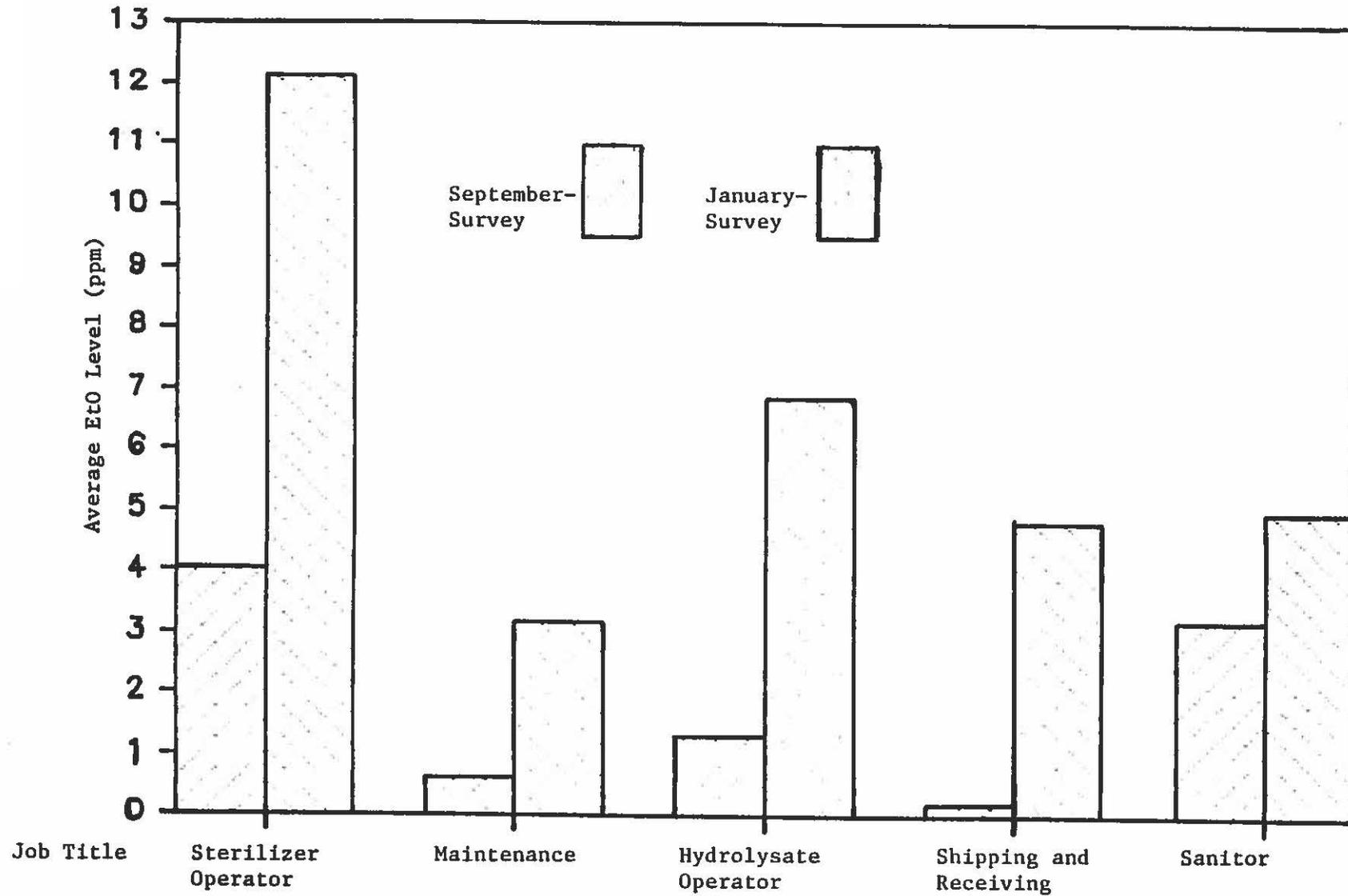
WILKS MIRAN MODEL 00 I.R.  
AREA ETHYLENE OXIDE MEASUREMENTS  
MICROBIOTROL, CHICAGO, ILLINOIS  
JANUARY 23, 1985



 -Miran I.R.

 -Charcoal Tube  
Area Samples

COMPARISON OF SURVEY DATE RESULTS  
ETHYLENE OXIDE LEVELS  
MICROBIOTROL, CHICAGO, ILLINOIS  
SEPTEMBER, 1984 AND JANUARY, 1985



ETHYLENE OXIDE PERSONAL SAMPLE RESULTS  
 NIOSH AND OSHA SIDE-BY-SIDE SAMPLES  
 MICROBIOTROL, CHICAGO, ILLINOIS  
 JANUARY, 1985

