INDUSTRYWIDE STUDIES REPORT:
A WALK-THROUGH SURVEY

OF

BECTON DICKINSON LABWARE
BECTON, DICKINSON AND COMPANY
Oxnard, California

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DATE OF SURVEY:
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DISCLAIMER

Mention of company names or products does not constitute endorsement by NIOSH.

PURPOSE:	To evaluate the industrial hygiene records, production processes, and personnel records to determine the suitability of including this facility in the mortality/industrial hygiene study of EtO being conducted by NIOSH researchers.
EMPLOYER REPRESENTATIVES:	Becton, Dickinson and Company Tony Piniat, Senior Program Manager, Corporate Safety, Paramus, New Jersey Pat Hall, Employee Relations Manager, Oxnard Phil Jacobelli, Director of Human Resources, Oxnard
STANDARD INDUSTRIAL CLASSIFICATION:	3079 - Miscellaneous Plastics Products

ABSTRACT

On August 27-28, 1984, a walk-through survey was conducted at Becton Dickinson Labware, Oxnard, California. This division of Becton, Dickinson and Company produces a variety of disposable labware, including petri dishes, flasks, pipettes and roller bottles. The company sterilized these products in two chambers with 100% EtO from 1969 until 1980 when they began using gamma radiation from a $Cobalt^{60}$ source. The purpose of this trip was to evaluate the industrial hygiene records, production processes, and personnel records to determine the suitability of including this facility in the mortality/industrial hygiene study of EtO being conducted by NIOSH researchers.

Industrial hygiene data was collected by corporate headquarters in 1978 and 1980. Ethylene oxide levels were non-detectable in 1978 and ranged from 0.6 - 5.0 ppm in 1980. After corporate review, any additional industrial hygiene data will be sent to us. Personnel records are in excellent condition and complete. In addition, the company has records for compliance with Equal Employment Opportunity regulations which give a yearly breakdown, by department, of all personnel from 1971 to date.

This plant meets all eligibility requirements as defined by the protocol of the EtO mortality study and will be included. 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.

EtO has not been used at this facility since 1982, therefore, there are no industrial hygiene surveys by NIOSH researchers planned at this plant as part of the EtO study.

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 was not part of the pilot study.

This walk-through survey was conducted to determine the suitability of including Becton Dickinson Labware in the industrywide mortality and industrial hygiene study of workers potentially exposed to EtO in industrial sterilization processes. The suitability of including this facility was based on data gathered in this walk-through and is discussed in the Conclusion and Recommendation section. In addition, the data gathered during the walk-through survey will be used to develop, to the extent possible, estimates of exposure to EtO by department and/or job category, level and duration of continuous and peak exposures, and calendar year within this plant. These exposure estimates will then be compiled into an exposure matrix which will be used to determine the existence of a dose response relationship with any positive association observed in the mortality study.

The authority and responsibility for conducting and reporting on field studies in industry was given to NIOSH under the Occupational Safety and Health Act of 1970 (set forth by the 91st Congress, S.9123, Public Law 91-596). Section 20(a)7 states that NIOSH shall conduct and publish industrywide studies of the effects of chronic low level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in the aging adult.

Description of Facility

Becton, Dickinson and Company is composed of 6 operating groups which include a total of 25 divisions. Each division operates from one to six plants with a total of 68 plants worldwide. Fifty of these are domestic with other facilities located in Ireland, Spain, France, Brazil, Mexico, and Canada. This facility was originally Falcon, Inc., then Bioquest, then Falcon (again), and finally Becton Dickinson Labware.

Becton Dickinson Labware produces and sterilizes a variety of laboratory equipment, including petri dishes, pipettes, flasks, and roller bottles. The facility, originally located in Inglewood, California, moved to Oxnard in October, 1969. Ethylene oxide was not used at the Inglewood location. The present site includes 430,000 ft^2 of undeveloped land, 60,000 ft^2 of offices, 75,000 ft^2 of warehousing area, and 85,000 ft^2 of manufacturing space. Until February, 1980 the company sterilized all but 4 products with 100% EtO. Thereafter EtO sterilization was phased out and replaced entirely with gamma radiation from a cobalt source by 1982.

Workers eat in a cafeteria on site, not in production areas. The manufacturing portion of this facility is due to be phased out with layoffs starting in February, 1985.

Description of Workforce

According to plant management, hourly workers at this plant are primarily women and belong to several racial groups. Turnover at the plant is low, particularly among the sterilizer operators which seems to be a desirable position. There has never been a union at this site.

Description of Process

During the period when EtO was used (1969-1982) manufactured goods entered the sterilizing area from the assembly area. Biological indicators (BIs, spore strips) were placed on the pallets in the production area to test completeness of the sterilization. After passing through a short hallway, these products entered a pre-conditioning room, which was kept at an elevated relative humidity (RH) and temperature for 12 hours. They then passed into a loading/unloading room for subsequent transfer to either of two sterilizers. This room had one ceiling mounted, general dilution exhaust fan. Each sterilizer was housed in a separate room, slightly larger

than the sterilizer, behind a roll door. The capacities of these chambers were 1,232 ft^3 and 1,013 ft^3. The roll door in front of the sterilizer was usually closed during sterilization. Each sterilizer room had two wall mounted, general dilution exhaust fans. One was located close to the floor on the side, the other at the rear of the sterilizer room.
These chambers operated for a total cycle time of 10 to 12 hours. The chamber was charged with 100% EtO for 4 and 1/2 hours. The chamber temperature was increased to 130° F, there was a minimum RH of 45%, and an increased % of CO_2. Sterilization was performed on 3 shifts for a total of 5 loads per day. Each cycle finished with 2 chamber evacuations and back purging by a positive displacement water pump. The sterilizer was back filled once with CO_2 and once with filtered air. A water sealed vacuum pump then purged the EtO through the rear of the sterilizer into a recessed open drain.

Upon completion of the sterilization cycle, the roll door was lifted, the sterilizer door cracked open and 5 minutes allowed to elapse before unloading. The roll door remained open until the sterilizer was reloaded. This entire unloading and loading operation by the sterilizer operator took 25 minutes per sterilizer. The sterilizer operators were primarily in the sterilizer control room (typically 50% of their workday). There was one maintenance employee who daily inspected the area exhaust fans as part of a preventive maintenance program.

After removal from the sterilizer, goods were placed in the hallway which connects the sterilizing area with the quarantine warehouse and which is adjacent to the sterilizer control room. Goods from second and third shifts remained in this hallway until first shift when they were moved to the quarantine warehouse staging area. There was no separate aeration room. BIs were pulled by quarantine inspectors in this staging area and taken back to the Biological QC Laboratory for analysis. Pallets were then auto taped (plastic wrapped) and placed in the quarantine warehouse for a minimum of 10-14 days. Seventy five percent of the goods in this warehouse were sterilized with EtO. The door to the adjoining work-in-process warehouse was kept open on 1st shift.

There is a small room in between the two sterilizer rooms which housed the EtO cylinders. This room contained 8 cylinders, 4 per sterilizer, each weighing 550 pounds. These were equipped with threaded connections and the cylinders changed by the sterilizer operator. Peak usage was 2000 pounds per week for both sterilizers. Yearly figures are not available.

Description of Past Exposures

The operation was essentially unchanged from 1969 to 1980, when EtO sterilization substantially decreased. There were no engineering, departmental location, ventilation, process, product, work practice, or employee education changes during this time period. During 6 months of 1979, the sterilizer was operated for 7 days a week, and 6 days a week for 2 months of 1980. After the first unit was disconnected in February, 1980,

the second unit continued to sterilize 2 to 3 loads per week until January 1981. From January 1981 until July 30, 1982 approximately one load per month was sterilized based on Quality Control records for the biological indicators. From February, 1980, until July 30, 1982, the gamma operator ran the remaining sterilizer. At the time of this survey, one sterilizer had been removed while the other unit was disconnected but is still in place. This unit was removed in January 1985. Gamma radiation from the cobalt source is well controlled. Personal monitoring has documented no appreciable exposure.

The sterilizer control room did not have any separate ventilation system. It was equipped with an internal air conditioning system, but since this did not involve any introduction of outdoor supply air, exposures would be expected to be similar to the general sterilizing room levels. There is no recollection of EtO being smelled and there is no record of any spills, leaks, or accidents.

Becton Dickinson's corporate office began monitoring EtO with charcoal tubes between 1976 and 1978. There are 2 reports presently available, one for sterilizer operators from 1978 (concentrations were non detectable; less than 0.97 ug/tube) and one from 1980. It is unclear whether the 1980 samples were personal or area measurements. The 1980 samples were taken with Qazi Ketchem tubes. Air volume per sample ranged from 3 to 5 liters. In addition there were two control samples which were non-detectable (less than 5.1 ug). Concentrations ranged from 0.6 to 13 ppm for 10 samples (mean = 4.1 ppm, standard deviation = 3.4, see Table I).

The samples were analyzed by a Becton, Dickinson & Co. laboratory in North Carolina with a Hewlett-Packard Model 5840 gas chromotograph equipped with a flame ionization detector. The samples were desorbed with carbon disulfide and a 3 ul aliquot injected for analysis. This lab is now accredited by the American Industrial Hygiene Association but was not at that time. OSHA did not sample for EtO during the period of its use at this facility.

Additional sampling was conducted by Becton Dickinson during 1977 and 1978 with a Wilks Ethylene Oxide Gas Infrared Analyzer, Model 101. Eight hour time weighted averages (TWA) for the sterilizer operator were computed by Becton-Dickinson based upon the following assumptions:

a) One operator performs all functions.
b) An average of one sterilizer load is processed per shift by the operator.
c) The operator remains in the sterilizer area a large portion of the day.

Average concentrations during each of the operator's tasks ranged from 0 to 145 ppm. Using the above mentioned assumptions, 8 hour TWAs were 10.2, 18.6, and 2.5 ppm. This data is summarized in Table II.

The derivation of a time weighted average from a direct reading instrument is only an approximation. The interpretation of these TWAs must be further

qualified since the technician was not a Safety or Industrial Hygiene professional. Other corporate documentation states that "the EtO operator performs normally assigned duties elsewhere during his shift". This model does assume that for the majority of the shift, the operator has zero exposure, however Attachments II and III do assume a significant period of time in the vicinity of the sterilizer for the purposes of calculating a 8 hour TWA (for example, see Attachmsnt II, A2). If these TWAs are recalculated without assumption (c), the revised values are 8 and 6 ppm (originally 10.2 and 18.6 ppm).

It should be noted that the Wilkes measurements taken on December 12, 1978 were obtained during the same survey that did not detect EtO on charcoal tubes for the sterilizer operator. Although it is difficult to compare methods, an exposure to 19 ppm for 20 minutes during the unloading-loading operation and to 145 ppm for 4 minutes during drum changing (Wilkes data) would result in a TWA of 2 ppm even assuming that there was no other exposure for the remainder of the shift (see Table II, Attachment A).

Description of Medical, Industrial Hygiene and Safety Programs

Medical

There is a medical office which is staffed by a nurse on 1st shift. Additionally, there is a team of eight employees trained in CPR and First Aid on each shift. All supervisors are trained in CPR. Employees are given pre-employment and annual physicals administered by a private doctor, contracted by Becton, Dickinson & Co. No EtO specific examinations were performed during the period of its use.

Industrial Hygiene and Safety

Scott[r] Air Paks were available beginning in 1979 for emergency use. All sterilizer operators were trained by the local fire department in their use but they were never used. These operators wore anti-static shoes.

There was an MDA[r], infrared system which operated 8 to 12 sensors from 1970 to 1980. An alarm and light signal would be triggered if EtO levels approached the OSHA Permissible Exposure Level of 50 ppm. This is reported to have occurred rarely (only once as recollected by personnel presently at plant). No measurements were available from this instrument. A portable leak detector was used by maintenance but this only detected levels at 20% of the lower explosion limit (3%).

There was limited use of a portable Miran infrared analyzer on a cart. This was left in the immediate vicinity of the sterilizer during the entire shift. An attempt was also made to follow the operator during the unloading/loading operation. This instrument did have a strip chart recorder and reports based on these measurements were prepared. No reports have been located at this time.

Three reports from 1977, 1978, 1979 have been located by Oxnard personnel and will be forwarded to us. They include some documentation that sterilizer operators did wear personal sampling pumps.

Description of Records

The personnel department maintains a card system for all current and former employees. These cards contain all of the information needed for the mortality study including: date of birth, sex, race, social security number, and a detailed occupational history. The cards for active workers are organized by department and are in alphabetic order. Active salaried employees' cards are filed separately from the hourly cards. There are about 650 records for active employees and 2448 records for former employees on file.

Personnel files for active employees, and for former workers who terminated employment after 1976 are on file in the personnel office. Additionally, there are personnel files for workers who left the company between 1973 and 1978 which are stored in the basement; it appears that these files are missing records of individuals with names from certain parts of the alphabet. All files for workers that left prior to 1973 are missing. Altogether there are about 650 files for active employees, and 825 files for former employees. The personnel files contain application forms, performance review forms, and job change notices. The application form contains an employee's social security number, date of birth, and an address. The job change notices are filed each time a worker has a change in position or salary, and these forms could be used for constructing detailed work histories; however, it would be far easier to do this with the card system.

Records maintained under the company's affirmative action plan could also be used for identifying potentially exposed workers. These records list workers by department. They also contain information on race and sex. These records are available since 1971.

Identification of Exposed Workers

Based on a review of the processes using EtO and discussions with plant personnel a list of potentially exposed jobs and departments was developed. Employees that worked for at least three months in any of these operations would be eligible for inclusion in the mortality study. Following is a list and description of these departments and jobs:

Department	Job Title	Involving Potential EtO Exposure
1) Quality Control (or Inspector)	Inspector	Worked in sterilization area pulling B.I.s.
2) Quality Control (or Inspector)	Autotaper	Worked in sterilization area sealing bores with a taping machine.
3) Quality Control (or Laboratory)	General Lab Technician	Examined BI's in the lab.

4) Quality Control (or EtO)	EtO Operator	Operated the EtO sterilizers. Unloaded sterile product.
5) Quality Control (or Gamma)	Gamma Sterile Tech	Same as EtO operator. Also operated Gamma sterilization unit.
6) Quality Control (or Quarantine)	Quarantine Warehouseperson	Moved EtO sterilized goods in the quarantine area of the warehouse.
7) Warehouse (or Shipping)	Warehouse person	Worked in the warehouse where EtO sterilized goods were stored and offgassing.
8) Maintenance	Electrician and Mechanics	Serviced the EtO sterilizer.
9) Quality Control	Sterilization Supervisor	Supervises EtO and Gamma Sterilization

* Note the department name in parenthesis is what was found in the personnel records reviewed.

Sampling and Review of Personnel Record System

A sample of approximately 20% of the personnel index cards was selected and reviewed. An attempt was made to determine, based upon these records alone, whether the workers were potentially exposed according to the criteria previously described (see Identification of Exposed Workers section). Information on sex, race, date of birth, year first exposed and duration of exposure was recorded for workers judged to be potentially exposed. A summary of the findings from this review are presented in Table III.

Overall, about 58% of the workers were male, 44% were white, the average year of birth was 1940, the average year first exposed was 1973, and the average duration of exposure was 3.5 years. Eight percent of the individuals were judged to be potentially exposed to EtO. Applying 8% to the total number of records reviewed, it is anticipated that this facility would contribute about 256 workers to the study. Using the average first year of employment of 1973 and assuming follow-up to 1983, it is estimated that this group would contribute 2,560 (10 years x 256 persons) person-years to the study.

Toxicity

Evidence from animal studies suggests that EtO may have carcinogenic properties.[7,8] A group of EtO manufacturers sponsored a study at the Bushy Run Research Center in which male and female Fischer 344 rats were exposed to EtO at airborne concentrations of 10, 33, or 100 parts per million (ppm) for 6 hours per day, 5 days per week for two years.[7] Two

other groups of animals served as controls. Initially, there were 120 animals of each sex, in each exposure group. The researchers observed a statistically significant increase in the incidence of mononuclear cell leukemia among the female rats, and peritoneal mesothelioma among the male rats exposed to EtO. The increase in leukemia incidence was found to increase linearly as a function of EtO exposure. An elevation in mortality from brain cancers (glial type) was also observed in the rats exposed to EtO.

NIOSH researchers have recently reported on the results from an animal experiment which corroborated the findings of the Bushy Run Study.[8] Male Fischer 344 rats were exposed to EtO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm. There were 80 rats in each exposure group. Increases in the incidence of mononuclear leukemia, peritoneal mesothelioma, and cerebral gliomas were observed among the EtO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of EtO.[9-11] Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that had previously been included in a hematologic investigation.[9] This facility produced EtO via the chlorohydrin process in which, in addition to EtO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloro-ethyl) ether. Among 89 "full-time" exposed workers, a statistically significant (p less than .01) excess of leukemia mortality was observed (2 observed versus 0.14 expected). In addition, a statistically significant (p less than .01) excess of stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to EtO; however, ethylene oxide and ethylene dichloride were the prime suspects.

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

Hogstedt also reported on three cases of leukemia that occurred in a small group of workers at a Swedish company.[11] The company used a mixture of 50% EtO and 50% methyl formate to sterilize hospital equipment. The 8-hour TWA exposure for EtO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this cohort. One of the cases was exposed to benzene, a known leukemogen, and it was speculated that the combined exposure of EtO and methyl formate might produce a special risk.

EtO is also a potent alkylating agent capable of causing irreversible changes or mutations in cellular proteins and DNA in animals.[12,13] EtO is

also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.[6]

Chromosomal aberrations related to EtO exposure have been observed in a number of animal studies and epidemiologic investigations.[8,13-20] Yager and Benz observed a dose related increase in sister chromatid exchanges (SCEs) among New Zealand white rabbits that were exposed via inhalation to 50 to 250 ppm of EtO.[14] NIOSH (Lynch, et al) recently reported preliminary findings in which cynomolgus monkeys were exposed to 0, 50, or 100 ppm of EtO for 7 hours per day, 5 days per week.[8] After 24 months of exposure, statistically significant increases were observed in the frequency of chromosomal aberrations (including quadriradial chromosomes) and SCEs in the peripheral lymphocytes of the 50 and 100 ppm exposed groups versus the controls.

Garry, et al, examined the occurrence of SCE in the peripheral lymphocytes of 12 EtO exposed workers and 12 nonexposed controls in a hospital sterilization facility.[15] The exposed group showed statistically significant elevations in the number of SCEs compared to the controls. Particularly high SCE frequencies were observed among 4 workers that had reported either neurologic or respiratory symptoms. The maximum peak exposure level of EtO measured at this facility was 36 ppm.

Cytogenetic abnormalities have also been observed in several studies of workers exposed to EtO. Ehrenberg, in a study of workers at a factory manufacturing and using EtO, observed a high frequency of chromosomal aberrations in 8 workers who were accidentally exposed to high concentrations of EtO. One case of leukemia was also observed among the 37 workers studied.[16]

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to EtO in the sterilization of medical devices in 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.

Conclusions

Personnel records are in excellent condition and will be adequate to determine who was exposed based on job titles. Limited industrial hygiene data is available, but further information will be necessary for a complete analysis of past exposures.

Based on the findings of this report, this plant meets all 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.

EtO has not been used at this facility since 1982, therefore, there are no industrial hygiene surveys by NIOSH researchers planned at this plant as part of the EtO study.

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TABLE I
INDUSTRIAL HYGIENE DATA
BECTON DICKINSON LABWARE
OXNARD, CALIFORNIA
AUGUST 1980

Results of the Measurements of EtO Adsorbed on Activated Charcoal Tubes [1]
Analyzed by Department of Analytical Chemistry, Becton Dickinson and Company
Research Triangle Park, North Carolina

Sample Identity	Measured Peak Area (uV-sec)	Calculated Amount of EtO in Injected Sample (ug) [2]	Total EtO Collected on Charcoal Tube (ug)	Volume of Air Sampled (L)	Calculated Concentration of EtO in Air Sampled	
					(mg/m^3)	(ppm)
A1	2386	6.2	19	3.10	6.1	3.4
A2 [3]	3770	9.2	28	5.04	5.6	3.1
A3	5556	13	39	5.30	7.4	4.1
A4	451	2.1	6.3	5.50	1.1	0.61
B1	3838	9.3	28	3.05	9.2	5.1
B2	3113	7.8	23	3.14	7.3	4.1
B3	3569	8.8	26	5.22	5.0	2.8
B4	1983	5.4	16	5.39	3.0	1.7
C1	1673	4.7	14	2.48	5.6	3.1
C2 [3]	9364	21	63	2.67	24	13

1 Front Sections only; back sections were all below the limit of detection (5.1 ug/ tube).

2 Total amount of EtO injected into the gas chromatograph.

3 Samples A2 and C2 were received unlabelled and were arbitrarily assigned these labels.

TABLE II
WILKES DATA
FALCON PRODUCTS, OXNARD, CALIFORNIA

Operation	Time	EtO	Peak Concentration
November 1977	ATTACHMENT I		
A. Sterilizer #61 Standard Cycle-Petri Dishes			
1. Unload-load	19 min.	14.8 ppm	42 ppm
2. Q.C. Samples	5 min.	17.0 ppm	89 ppm
3. Area Abmient	15 min.	10.5 ppm	

* Wilkes unit is reported to have malfunctioned.

August 1978	ATTACHMENT II		
A. Sterilizer #61 Standard Cycle-1029 Dishes			
1. Unload-load	26 mins.	67.5 ppm	275 ppm
2. Area Ambient	30 mins.	21.5 ppm	
B. Sterilizer #71			
Standard Cycle, 4013s	18 mins.	21.0 ppm	73 ppm
1. Unload-load	90 mins.	14.0 ppm	
C. Drum Change*			
1. Change room ambient	2.5 mins.	0 ppm	
2. Change connections	4.0 mins.	145 ppm	
3. Change room ambient	26 mins.	10 ppm	
D. 8-Hour Time Weighted Average = 10.2 ppm			

* Values obtained from prior recording.

TABLE II (cont)
WILKES DATA
FALCON PRODUCTS, OXNARD, CALIFORNIA

Operation	Time	EtO	Peak Concentration
August 1978		ATTACHMENT III	
A. Sterilizer #61 Standard cycle, 9002 Sputum Kits			
1. Unload-load	26 mins.	57.5 ppm	175 ppm
2. Area Ambient	45 mins.	25.0 ppm	
B. Sterilizer #71 Standard cycle, 2052 tubes			
1. Unload-load	23 mins.	23.4 ppm	50 ppm
2. Area Ambient	5 mins.	15.0 ppm	
C. Drum Change*			
1. Change room ambient	2.5 mins.	0 ppm	
2. Change connections	4.0 mins.	145 ppm	
3. Change room ambient	26 mins.	10 ppm	
D. 8-Hour Time Weighted Average = 18.6 ppm			
December 12, 1978		ATTACHMENT A	
A. Sterilizer #71 Standard cycle, 2095s and 2052s			
1. Unload-load	20 mins.	19.1 ppm	40 ppm
2. Area Ambient	1 min.	1.0 ppm	
B. Drum Change*			
1. Change room ambient	2.5 mins.	0 ppm	
2. Change connections	4.0 mins.	145 ppm	
3. Change room ambient	26.0 mins.	10 ppm	
D. 8-Hour Time Weighted Average = 2.5 ppm			

* Values obtained from prior recording.

TABLE III
SUMMARY OF PERSONNEL RECORDS REVIEW[a,b]

Employment Status	TOTAL # RECORDS (# SAMPLED)	EST % EXP	EST # EXP	% MALE	% WHITE	AVERAGE YR BIRTH	AVERAGE YR 1st EXP	AVERAGE DUR EXP	EST[c] P YRS
ACTIVE	650(143)	13%	85	53%	32%	1941	1975	6.1	680
INACTIVE	2448(480)	7%	171	64%	55%	1940	1972	2.1	1881
OVERALL	3098(623)	8%	256	58%	44%	1940	1973	3.5	2560

a) The following abbreviations are used in this table: EST for estimate, EXP for exposed, YR for year, P YRS for person years.

b) Statistics are based on information from the workers classified as potentially exposed to EtO 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.