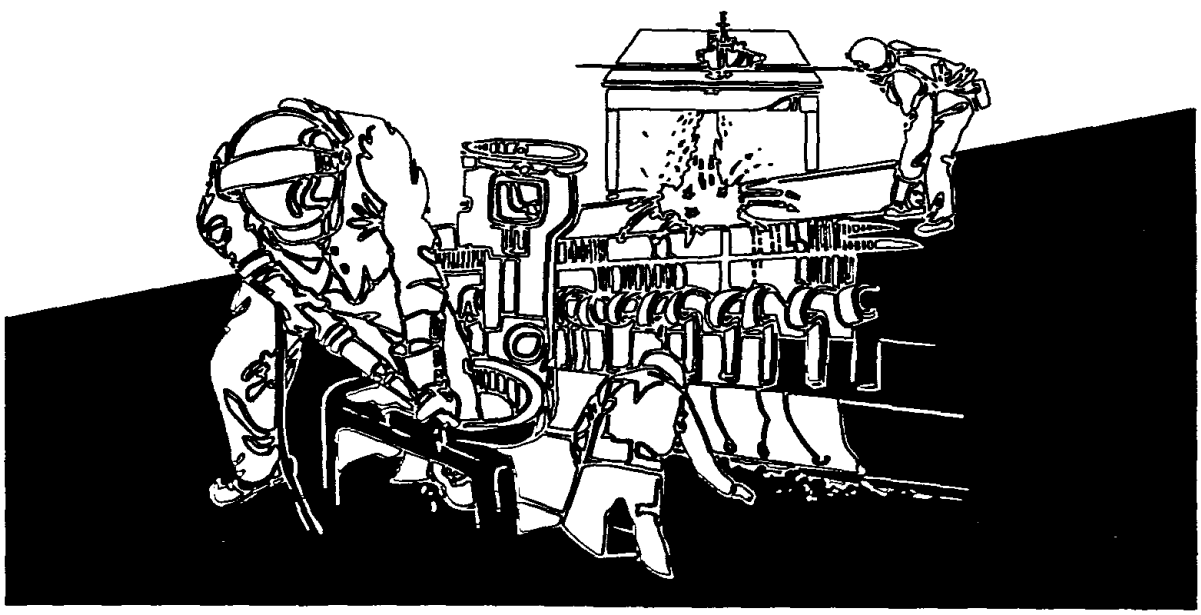
HEALTH HAZARD EVALUATION REPORT

HETA 91-293-2203
VALLEY HOSPITAL
PALMER, ALASKA



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

CDC
CENTERS FOR DISEASE CONTROL

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer and authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to federal, state, and local agencies; labor; industry; and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

HETA 91-293-2203
APRIL 1992
VALLEY HOSPITAL
PALMER, ALASKA

NIOSH INVESTIGATORS:
Ruth A. Shults, R.N., M.P.H.
Teresa A. Seitz, M.P.H., C.I.H.

SUMMARY

On July 6, 1991, the National Institute for Occupational Safety and Health (NIOSH) received a request for a Health Hazard Evaluation from the International Brotherhood of Electrical Workers (IBEW) to evaluate a possible kidney cancer cluster among employees of Valley Hospital in Palmer, Alaska. The request stated that the employees with cancer were working during an alleged ethylene oxide (EtO) release at Valley Hospital on September 16, 1983, during which the hospital was evacuated. The request also referenced a hospital memorandum dated June 19,1991 that discussed an ethylene oxide leak from the gas sterilizer that occurred on June 18, 1991.

During August 8-12, 1991, and September 4-5, 1991, NIOSH investigators conducted site visits to Valley Hospital to review information regarding the September 1983 incident, to assess current work practices involving the use of the EtO sterilizer, and to conduct environmental monitoring for EtO. A questionnaire survey was conducted among individuals who were employed at the hospital during September 1983 to determine the prevalence of all types of cancer, and cause of death was verified for deceased former employees.

Four deaths were identified within the 1983 employee cohort of 154 people; two of the deaths were due to renal cell carcinoma. Four occurrences of cancer were identified in the 104 surviving cohort members who were contacted; none of the cancers occurred at sites that have been associated with EtO exposure.

Since the installation of the gas sterilizer in 1983, a number of ventilation and procedural changes were made over the years in an effort to reduce worker exposures to EtO. These changes included the addition of an alarm system to detect EtO leaks in the adjacent clean room, the provision of local exhaust ventilation above the gas cylinder, and the establishment of negative air pressure in the sterilizer room with respect to the clean room where Sterile Processing Department (SPD) technicians work. In addition, a few months before the NIOSH evaluation, the sterilizer was modified to incorporate an aeration cycle within the main unit, eliminating the need to transfer the load to a separate aeration unit.

To assess current EtO exposures, environmental monitoring was conducted at Valley Hospital on September 4 and 5, 1991, during two sterilization/aeration cycles. EtO was not detected in the five personal breathing zone air samples obtained on the SPD technicians. In addition, only two of 15 area air samples contained detectable levels of EtO; both of these samples were collected at the sterilizer gas cylinder valves, indicating some leakage in this area. The EtO concentrations on these two area samples were less than 0.02 parts per million (ppm). Area air samples collected 5-6 feet from the cylinder did not contain EtO, indicating that the exhaust ventilation above the gas cylinder was effective in removing these emissions.

NIOSH investigators concluded that the two deaths due to kidney cancer, one each in 1990 and 1991, in the cohort of 154 workers appear to be an excess over the expected annual kidney cancer mortality rate in the U.S. population of 3.6/100,000. While a cluster of two kidney cancer deaths in this small work force has raised concern as to a possible common cause, the statistical methods used to evaluate potential cause-and-effect relationships between exposures and disease are not accurate when applied to such a small population. Although EtO was not detected in any of the personal breathing zone air samples obtained during this evaluation, recommendations are made in the report to prevent future EtO exposures in the event of equipment malfunction or leaks. Recommendations also are made to improve the EtO monitoring program at this facility, as deficiencies were noted in environmental monitoring, reporting, training, and preventive maintenance.

KEYWORDS: SIC 8062 (general medical and surgical hospital), gas sterilization, ethylene oxide, EtO, central supply, health care workers, cancer cluster, renal cell carcinoma, mortality.

INTRODUCTION

On July 6, 1991, the National Institute for Occupational Safety and Health (NIOSH) received a request from the International Brotherhood of Electrical Workers (IBEW) to evaluate a possible kidney cancer cluster among employees of Valley Hospital in Palmer, Alaska. The employees with cancer were working during an alleged ethylene oxide (EtO) release at Valley Hospital on September 16, 1983, during which the hospital was evacuated. The request also referenced a hospital memorandum dated June 19, 1991, that discussed an EtO leak from the gas sterilizer that occurred on June 18, 1991.

During August 8-12, 1991, and September 4-5, 1991, NIOSH investigators conducted site visits to Valley Hospital to review information regarding the September 1983 incident, to assess current work practices involving the use of the EtO sterilizer, and to conduct environmental monitoring for EtO. A questionnaire survey was conducted among individuals who were employed at the hospital during September 1983 to determine the prevalence of all types of cancer, and cause of death was verified for deceased former employees. The environmental monitoring results were reported in an interim letter to the hospital and union representative dated November 25, 1991.

The NIOSH evaluation did not attempt to determine if EtO was the cause of the symptoms reported by employees on September 16, 1983. Rather, the NIOSH epidemiologic investigation was conducted assuming that EtO exposure may have occurred on that day.

BACKGROUND

A. September 1983 Evacuation

Valley Hospital is located in Palmer, Alaska, approximately 50 miles north of Anchorage. The hospital had undertaken a major expansion and renovation project in 1983; the new wing which included all in-patient beds, surgery, and emergency room facilities was occupied in August 1983. The hospital employed about 154 individuals. On September 16, there were approximately 70 employees and 19 patients present.

As reported in a December 12, 1983, memorandum from the Alaska State Epidemiologist, hospital employees complained that from the time they occupied the new wing in mid August to the September 16th evacuation, diesel fumes and other noxious odors often could be detected throughout the hospital (Appendix 1).

The memorandum states:

> "...Employees noted associations between detection of the odors and operation of the emergency standby generator. On at least one occasion, employees observed black exhaust smoke from the generator exhaust stack on the roof sucked into the air intake of the hospital ventilation system. Within seconds, people detected the presence of exhaust fumes throughout the hospital."
>
> "Although employees remarked upon the frequent detection of odors and diesel fumes in the hospital between August 15 and September 16, illness had not previously occurred among employees associated with detection of these odors. The odors detected on September 16 were different and unusual compared to ones previously experienced by employees."

During the morning of September 16, 1983, 11 employees reported to the emergency room with prevailing symptoms of nausea, weakness, fatigue, chills, tingling, and watery eyes (Appendix 1). Ten of the 11 associated their symptoms with an unusual odor in the hospital which some described as smelling like ether. The remaining worker did not note any odor prior to becoming ill. All eight employees working in the Medical Records Office and the Business Office were affected.

At around 1:00 p.m. hospital administrators ordered the immediate evacuation of all patients. This was accomplished with the assistance of the local fire department and the emergency medical service, and all gas lines and the ventilation system were turned off. The fire department checked the building for explosive gases using portable sensing devices and found none.

A consulting laboratory was called in to identify the origin of the odor. One suspected source was a new ethylene oxide (EtO) sterilizer that had begun functioning on August 18, 1983. The sterilizer was not in use on September 16, 1983, and had last been used on September 14, 1983.

Two air samples were collected and analyzed for carbon dioxide, oxygen, nitrogen, carbon monoxide, and ethylene oxide (Appendix 1). The laboratory reported the presence of approximately 2900 parts per million (ppm) EtO at the base of the EtO tanks in the gas sterilizer room, and approximately 450 ppm EtO two inches

from the floor in the Business Office. Because EtO was not detected in air samples collected the following day, the hospital was reopened on September 17, 1983. Sampling methods, equipment, and procedures used by laboratory that preformed the environmental sampling were reviewed at that time by NIOSH personnel and were found to be appropriate.

The EtO cylinders were weighed, and records documenting the use of the sterilizer were reviewed to determine how much EtO/Freon® gas should have been used during the 29 day period that the sterilizer had been functional. Assuming that the cylinders contained the correct amount of EtO/Freon® gas when they were delivered, around 34-50 pounds of expended EtO may not have been accounted for. It should be noted, however, that there is a discrepancy in the number of sterilizer cycles which were run during the time period in question, and that at least one investigator believed that one of the cylinders may not have been full when initially received.

B. Subsequent Investigations

Alaska Department of Health and Social Services personnel arrived at Valley Hospital on the afternoon of September 16, 1983, to begin their epidemiologic investigation, which included a brief tour of the hospital and interviews with ill employees. They concluded that there was strong support suggesting that the illness that occurred among the employees on Friday, September 16, 1983, was due to a common source environmental exposure. The odor described by ill employees was consistent with that of EtO, and their symptoms were compatible with those described by others who have been acutely exposed to high concentrations of EtO.

It is unclear from the various reports written at the time of the incident the possible pathway(s) for EtO transport to areas where affected employees were located. Some investigators reported that EtO could have entered the outside air intakes from roof top exhausts, from distribution through the ventilation system directly from the sterilizer room, or from water line cracks in the floor to a crawl space beneath the sterilizer room. The situation is also complicated by the fact that the exhaust fan for the sterilizer area was apparently not in operation on the day of the incident and the electrical connection for the sterilizer's auxiliary exhaust system (Envirogard System) was reportedly not connected properly and was, therefore, not operable.

In a memorandum dated December 12, 1983, the State Epidemiologist stated that there was no proof that the illness was caused by EtO/Freon® gas. He further stated that, assuming that the cause was EtO, it was extremely unlikely that serious acute or long term adverse health effects would occur among the exposed workers.

A regional service specialist from the sterilizer's manufacturer arrived on October 7, 1983, to investigate the role of the EtO sterilizer in the September 16 incident.[1] He performed air monitoring for EtO while running the sterilizer and disabling the exhaust system, and found peak airborne EtO concentrations of 35 ppm. He reported that there were no leaks in the sterilizer unit.

An independent consultant was also contracted by the sterilizer's manufacturer to investigate the incident. His report concluded that there was no reason to believe that the EtO sterilizer had malfunctioned on September 16, 1983.[2] He questioned whether the reported symptoms were due to EtO, stating that because mass spectroscopy was not used to confirm the EtO peak (from the gas chromatography [GC] analysis), the peak could not be positively identified as EtO. Further, he stated that other contaminant sources should have been studied.

C. Current Process Description

EtO sterilization is conducted in the Sterile Processing Department (SPD). One or two SPD technicians are responsible for sterilizer operations on any given day. At the time of the NIOSH survey, the sterilizer was typically operated once per week. In the few months before the NIOSH visit, the sterilizer had been modified to incorporate an aeration cycle within the main unit, eliminating the need to transfer the load to a separate aeration unit at the end of the sterilization/purge cycle. The sterilizer was located in a room that had been designated for this use and was under negative pressure with respect to the adjacent clean room. The decontamination room, where used items were cleaned prior to being sterilized, was under negative pressure with respect to the clean room, so that air flowed from clean to less clean areas throughout the SPD.

The sterilizer was equipped with an auxiliary local exhaust system, called an Envirogard System, which included a dedicated exhaust system, a door vent adapter for exhausting gases released when the door is opened, and a liquid/gas separator for connection to a closed drain system. Local exhaust ventilation had also been added above the gas cylinder to remove any emissions in this area.

EVALUATION CRITERIA

A. Toxicology of Ethylene Oxide

EtO is a colorless gas with a distinctive ether-like odor; it is used in hospitals to sterilize heat-sensitive medical instruments.[3] It is typically supplied to U.S. hospitals in compressed gas cylinders that contain 88% Freon® 12 and 12% EtO.

Although EtO has an odor threshold of about 700 ppm, exposure at 200 ppm may cause irritation of the eyes and upper respiratory system.[3] High concentrations can cause severe skin burns, rashes, headache, nausea and vomiting, shortness of breath, weakness, drowsiness, cyanosis, and pulmonary edema.[3,4,5] Liquid solutions of EtO may cause severe eye irritation or damage,[3,4] and there have been case reports of cataract formation among workers exposed to high levels of EtO.[6]

Ethylene oxide is a known carcinogen in animals. Studies with EtO-exposed rodents have recorded increased frequencies of leukemia, peritoneal mesothelioma, and brain tumors.[7]

Some epidemiological studies of chronic, low-level EtO-exposed workers have reported increases in hematologic and stomach malignancies,[7,8] while at least one other study has reported no increase in cancer among EtO-exposed workers.[9] Several common study limitations may have contributed to this lack of consistent results, including small study populations, EtO-exposed workers having simultaneous exposure to a variety of other chemicals, and difficulty in quantifying past exposures to EtO.

To date, only one published epidemiologic study has reported an increase in kidney cancer mortality among EtO-exposed workers.[10] In a recent, large-scale mortality study of 18,254 EtO-exposed workers in the United States, Steenland et. al. found a statistically significant increase in kidney cancer deaths among EtO-exposed workers whose first exposure to EtO occurred prior to 20 years before their death. While this finding warrants further investigation, the body of literature on animal and human studies of EtO to date has not implicated it as a definite renal carcinogen.

EtO binds to DNA, causing mutations and chromosomal damage. In both animals and humans, EtO produces increased frequencies of chromosomal aberrations and sister chromatic exchanges.[7,11] These genetic changes have been shown to pass from one generation to the next in mice.[12]

Animal experiments with EtO have indicated adverse reproductive effects in both sexes; decreased fertility, increased fetal loss and malformations in rodents have been recorded.[7] There is also limited evidence which suggests that inhalation of EtO can

result in adverse reproductive effects in humans. Hemminki et al. found the spontaneous abortion rate to be significantly higher in EtO-exposed hospital workers in Finland than in unexposed workers.[13] Various limitations in the design and implementation of this study suggest that the results should be interpreted with caution.[4]

B. Occupational Exposure Criteria for Ethylene Oxide

NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure be controlled to less than 0.1 ppm determined as an 8-hour time-weighted average, with a short-term exposure limit not to exceed 5 ppm for a maximum of 10 minutes per day.[5] This recommendation is based on the available risk assessment data, which show that even at an exposure level of 0.1 ppm, the risk of excess mortality is not completely eliminated.[14] Effective as of August 21, 1984, the standard of the Occupational Safety and Health Administration (OSHA) for occupational exposure to ethylene oxide was revised downward from 50 ppm to 1 ppm calculated as a time-weighted average concentration for an 8-hour workshift. This downward revision in the standard was based on the animal and human data showing that exposure to EtO presents a carcinogenic, mutagenic, reproductive, neurologic, and sensitization hazard to workers. Requirements for methods of controlling EtO, personal protective equipment, measurement of employee exposures, training, and medical surveillance of the exposed employees are included in the present federal OSHA standard[15] and the Alaska State OSHA standard.[16]

C. Freon® 12

Exposure to Freons®, including Freon® 12 (dichlorodifluoromethane) may cause eye and skin irritation or sensitization. High concentrations of Freon® can cause central nervous system depression, weakness, dizziness, convulsions, and cardiac arrhythmias.[17] Studies of carcinogenicity have found no significant effect.[18]

D. Kidney Cancer

Kidney cancer comprises 2% of all cancers in the United States; approximately 10,300 Americans die each year from adult kidney cancer. The average age at the time of diagnosis is between 55 and 60 years. Renal cell carcinoma comprises 80% of kidney cancer cases, with a male to female ratio of 2:1.[19] A prolonged period usually exists between the onset of disease and diagnosis of renal cancer, and metastases are present in approximately one-third of patients at the time of diagnosis.[19]

Five year survival rates for renal cancer range from 10% to 50%, depending of the extent of metastasis present at the time of diagnosis.[19]

The etiology of renal cell carcinoma remains obscure. The hereditary condition, Von Hippel-Lindau syndrome, is sometimes associated with renal carcinoma.[19] Epidemiologic studies have implicated cigarette smoking as another possible risk factor.[20,21] Prior to the 1970s, there were few studies of occupational risk factors for kidney cancer; therefore, the accumulated knowledge about occupational kidney cancer to date is in a preliminary stage.[22]

According to Alaska Department of Health and Social Services, 79 Alaskans, 54 males and 25 females, died of kidney cancer during the decade of the 1980s.[23] The Alaska mortality rate was age-adjusted to that of the total 1980 U.S. resident population, resulting in a rate of 3.6 per 100,000 population. This is comparable to the annual age-adjusted kidney cancer mortality rate of 3.7 per 100,000 for the United States as a whole.[24]

E. Cancer Clusters

A cancer cluster is defined as an unusual concentration of cancer cases in time and space.[25] The occurrence of a cancer cluster in a group of workers may be caused by exposure to one or more cancer-causing agents at work, or it may be related to environmental factors, lifestyle or other non-occupational factors, or chance alone. Infrequent diseases such as kidney cancer occasionally "cluster", causing public concern and requiring investigation, but often, a definitive cause-and-effect relationship is not established. This failure to find an association between an exposure and illness can occur for a variety of reasons: the number of cancer cases may be too small to permit adequate epidemiologic analysis for associations between exposure and the development of cancer, records on the population at risk may be inadequate to determine who was exposed and who was not exposed, or no plausible environmental explanation can be found. Clustering can also occur by "chance" alone; that is, two or more cases unrelated to a shared environmental toxin in the workplace may occur by coincidence.

In investigating an apparent cancer cluster, the first question to be answered is whether there actually is an excess of cancer cases above that which one would expect to see in a similar population. If an excess of cancer exists, are the cases

occurring independently or are they somehow related? To address this question one must look at the information such as sex, age, lifestyle habits, non-occupational exposures, and work history among the cases. Lastly, were the cases exposed to a suspected cancer-causing agent at work? If so, what types of cancer are associated with this agent? Has adequate time passed between exposure to the cancer-causing agent and development of cancer to suspect that the two are related? Latency, the time between exposure to a carcinogen and the subsequent detection of cancer, is commonly thought to range from five to 30 years.

In general, in a small group of workers, it is difficult to determine if a particular exposure, such as a chemical or a lifestyle habit, contributes to the cause of a cancer cluster.

METHODS

A. Epidemiologic Investigation

To determine the number of cancer cases within the employee population, NIOSH investigators attempted to contact all individuals who were employed at Valley Hospital in September 1983. Telephone and personal interviews were conducted to determine if the person was working at Valley Hospital on the morning of September 16, 1983, and whether he/she had ever been diagnosed with cancer of any site. Questionnaires were mailed to individuals who could not be reached by telephone.

The union representative and hospital employees reported that three former employees were known to have died; a fourth employee died during the investigation. A review of death certificates verified the cause of death of the four deceased workers. Surviving family members of the kidney cancer cases were interviewed to determine if any known risks factors for kidney cancer existed.

B. Industrial Hygiene Evaluation

The industrial hygiene evaluation included a review of previous air monitoring data for EtO, a review of the engineering controls implemented since installation of the sterilizer in 1983, a qualitative assessment of airflow patterns in the SPD, a review of standard operating procedures, and air monitoring to characterize worker exposures to EtO during routine use of the sterilizer.

To evaluate current exposures to EtO, a total of 20 air samples were collected on September 4 and 5, 1991, including full-shift and short-term personal breathing zone and area air samples. The personal air

samples were collected on the SPD technicians who were present on the days of the survey. The area air samples were collected to identify possible contamination sources such as the EtO cylinders and the sterilizer door, as well as to determine the potential for exposure during specific operations such as opening the sterilizer door and removing the load.

Air sampling and analysis were conducted in accordance with NIOSH Method 1614.[26] Air samples were collected on hydrogen bromide coated charcoal tubes using calibrated air sampling pumps operating at flowrates of 100 or 150 milliliters per minute. The charcoal tubes were desorbed in the laboratory with dimethylformamide and analyzed using gas chromatography with electron capture detection.

A portable, automatic halogen leak detector (TIF5500 MICROPUMP®) was used to detect leaks around the sterilizer door seals as well as by the cylinder valves and distribution lines. This device detects Freon®, which comprises 88% of the sterilizer gas mixture, in concentrations as low as 3 ppm.

RESULTS AND DISCUSSION

A. Death Certificate Review

Death certificate review of the four deceased employees documented the immediate cause of death to be kidney cancer in two individuals; none listed kidney cancer as an underlying or contributing cause of death. One kidney cancer death occurred in 1990 and the other occurred in 1991. Both deaths occurred in females; their ages at the time of diagnosis were 48 and 54 years.

B. Kidney Cancer Risk Factors

Relatively little is known about the causes of kidney cancer, so it is difficult to evaluate the possible role of work history, health history, and lifestyle risk factors in the development of the disease. However, according to information provided by the individuals' family members, one of the Valley Hospital employees who died of kidney cancer had no previous work experience, and the other had worked as a baby sitter and a housekeeper prior to starting at Valley Hospital. One never smoked cigarettes, and the other smoked about one-half pack per day for 25 years, but stopped smoking in 1983.

C. Cancer Incidence

A Valley Hospital payroll register dated September 25, 1983, containing 155 names was used to identify the employee cohort. One individual who started work after September 16, 1983, was excluded, and 4 former employees were known to be dead, thereby leaving 150 participants to be interviewed. One hundred four people were contacted, and all agreed to participate, resulting in a final participation rate of 69%.

Fifty-seven (55%) of the 104 people who were contacted reported being at Valley Hospital on September 16, 1983; three reported diagnoses of cancer. Forty-five (43%) of those contacted reported that they were not at Valley Hospital on the morning of September 16, 1983; none reported ever having been diagnosed with cancer. Two (2%) individuals could not recall if they were present the day of the hospital evacuation; one reported a diagnosis of cancer. There was no apparent source of information to determine how many of the 46 former employees who did not participate in the study have been diagnosed with cancer.

The four occurrences of cancer identified through interviews with the Valley Hospital employee group were all in women: two uterine cancers, one breast cancer, and one rectal cancer. These locations are among the five most common sites for women. One case occurred prior to 1983. No cases of hematopoietic or stomach cancers, the sites thought to be associated with long-term exposure to EtO,[7,8] were reported.

No published information regarding the occurrence of cancer in people acutely exposed to EtO was identified by a computer-assisted literature search.

D. Industrial Hygiene Results

The results of the personal air monitoring for EtO are shown in Table 1. No EtO was detected on any of the short-term air samples collected on the SPD technician when the sterilizer door was opened, or during load removal. EtO also was not detected on any of the full-shift personal air samples. The limit of detection (LOD) for these samples was <0.01 part per million (ppm).

Table 2 lists the results of the area air monitoring for EtO. Two of the air samples showed detectable levels of EtO; both were obtained on the gas cylinder near the valves. A full-shift, time-weighted average (TWA) concentration of 0.014 ppm EtO was obtained in this area on

September 4, 1991, and a trace of EtO was found in this same area on September 5, 1991. These results indicate that there may be some leakage of EtO from the gas cylinder. However, the local exhaust ventilation above the cylinder appears to be effective, as full-shift air samples obtained about five to six feet away from the cylinder did not contain measurable levels of EtO.

Smoke tubes used to visually assess airflow patterns in the SPD confirmed that the sterilizer room was under negative pressure with respect the adjacent clean room. In addition, with all doors to adjacent rooms and the hallway closed, air moved from clean to less clean areas within the department.

CONCLUSIONS

Two deaths due to renal cell carcinoma are known to have occurred in 1990-91 among the 1983 Valley Hospital cohort of 154 employees; this appears to be an excess over the expected kidney cancer mortality rate of 3.6/100,000. However, infrequent diseases such as kidney cancer may occasionally "cluster", without being related to an exposure.[27] While a cluster of two kidney cancer deaths in this small work force has raised concern as to a possible common cause, the statistical methods used to evaluate potential cause-and-effect relationships between exposures and disease are not accurate when applied to such a small population.

The environmental portion of the NIOSH evaluation was performed in an effort to characterize current EtO exposures and to evaluate current work practices and engineering controls. The environmental measurements obtained during two sterilization cycles indicated that SPD workers did not have measurable exposures to EtO. The recent sterilizer modifications and engineering controls incorporated over the years appear to be effective in preventing or minimizing worker exposures to EtO. Because the potential for significant EtO exposure exists in the event of equipment malfunction or leaks, recommendations are made below to prevent future exposures, should use of the sterilizer resume. (Management indicated that the sterilizer is not currently being used). Many of the recommendations made below concern our review of the EtO monitoring program and the standard operating procedures which existed at the time of the NIOSH survey. These recommendations were made in the closing meeting held on September 5, 1991, and in a letter dated November 25, 1991.

RECOMMENDATIONS

1. A formal preventive maintenance program should be established. In addition to the inspections made by the manufacturer, the program should include such procedures as checking for leaks around the door seal, floor drain, and the gas delivery system, as well as an inspection of the local exhaust ventilation systems. For periodic spot checks, a halogen leak tester can be used. These instruments are portable, sensitive, and easy to use. The halogen leak tester detects low concentrations of the Freon® 12 component of the sterilizer gas mixture.

2. Better EtO monitoring records should be kept. A review of the monitoring data collected at Valley Hospital indicated that there were several math errors made in the calculation of full-shift TWA and short-term exposures (STEL) to EtO. In addition, there was missing information on the data sheets, such as the time the passive monitors were worn and the specific job tasks which were performed during the STEL measurements. Other problems identified included the use of STEL monitors for periods exceeding their intended use, and comparatively high levels of EtO on some of the blank badges.

3. Contact the manufacturer of the EtO area monitor to discuss procedures for calibrating this equipment. The product literature indicates that periodic (monthly) calibration should be performed using EtO calibration gas.

4. The doors to the clean room and wash room should be kept closed to maintain the desired pressure differential between the sterilizer room and the hallway.

5. Spare air tanks should be available for use with the self contained breathing apparatus (SCBA). SCBAs are used by maintenance staff when entering the sterilizer room after the EtO alarm has sounded. Employees performing this work should have training in emergency response and in the use, care, and maintenance of the required personal protective equipment (PPE).

6. All employees involved in EtO sterilization operations should receive training on the hazards of EtO, standard operating procedures, the use of PPE, and applicable standards and monitoring procedures.

7. One person should have responsibility for overseeing the EtO program. This person should be knowledgeable about all aspects of the program, including worker training, environmental monitoring, emergency response procedures, standard operating procedures, medical surveillance, and maintenance.

8. A medical surveillance program is required by the Alaska Department of Labor for all employees who are or may be exposed to EtO for at least 30 days per year at a level at or above the action level.[16]

REFERENCES

1. Garrison JD [1983]. Trip report of October 9, 1983 to Robert Dolan and Lee Beers, AMSCO, Seattle Regional Office, regarding October 7, 1983 investigation of EtO sterilizer at Valley Hospital in Palmer, Alaska. (The report is available upon request from NIOSH.)

2. Moore V [1984]. Report of January 12, 1984, to American Sterilizer Company of incident at Valley Hospital, Palmer Alaska, on September 16, 1983. (The report is available upon request from NIOSH.)

3. NIOSH [1988]. Guidelines for protecting the safety and health of health care workers. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 88-119, pp. 5-17 to 5-23.

4. ATSDR [1990]. Toxicological profile for ethylene oxide. Atlanta, GA: U.S. Dept of Health, Education, and Welfare, Public Health Service, Agency for Toxic Substances and Disease Registry, Publication No. TP-90-16, pp. 11-49.

5. NIOSH [1981]. Current intelligence bulletin 35: ethylene oxide (EtO). Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 81-130.

6. Jay W, Swift T, Hull D [1982]. Possible relationship of ethylene oxide exposure to cataract formation. Am J Ophthamol 93:727-32.

7. Landrigan P, Meinhardt T, Gordon J, Lipscomb J, Burg J, Mazzuckelli L, et al. [1984]. Ethylene oxide: an overview of toxicologic and epidemiologic research. Am J Ind Med 6:103-115.

8. Hogstedt C, Aringer L, Gustavsson A [1986]. Epidemiologic support for ethylene oxide as a cancer-causing agent. JAMA 255(12):1575-1578.

9. Morgan RW, Claxton KW, Divine BJ, Kaplan SD, Harris VD [1981]. Mortality among ethylene oxide workers. J Occup Med 23:767-769.

10. Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S [1991]. Mortality among workers exposed to ethylene oxide. N Eng J Med 324(20):1402-1407.

11. Richmond G, Abraham RH, Nemenzo JH, Hine CH [1985]. An evaluation of the possible effects on health following exposure to ethylene oxide. Arch of Envir Health 40(1):20-25.

12. Generoso WM, Cain KT, Hughes LA, Sega GA, Braden PW, Gosslee DG, Shelby MD [1986]. Ethylene oxide dose and dose-rate effects in the mouse dominant-lethal test. Environ Mutatgenesis 8:1-7.

13. Hemminki K, Mutanen P, Saloniemi I, Niemi ML, Vainio H [1982]. Spontaneous abortions in hospital staff engaged in sterilising instruments with chemical agents. Br Med Jour 285:1461-3.

14. Millar JD [1983]. Statement of the National Institute for Occupational Safety and Health. Occupational Safety and Health Proposed Rule. Occupational exposure to ethylene oxide. July 20, 1983.

15. Occupational Safety and Health Administration [1984]. Occupational exposure to ethylene oxide: Final Rule. 29 CFR 1910.

16. AK Dept of Labor [1987]. Occupational safety and health standards: ethylene oxide. Juneau, AK: Alaska Dept of Labor, Division of Labor Standards and Safety, pp. 10-14.

17. ACGIH [1986]. Documentation of the threshold limit values and biological exposure indices. 5th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists.

18. Proctor NH, Hughes JP, Fischman ML [1988]. Chemical Hazards of the Workplace. 2nd ed. Philadelphia, PA: J.B. Lippincott Co., p. 188.

19. Holleb AI, Fink DJ, Murphy GP [1991]. American Cancer Society textbook of clinical oncology. Atlanta, GA: The American Cancer Society, Inc., pp. 271-274.

20. Bennington JL, Laubscher FA [1968]. Epidemiologic studies on carcinoma of the kidney. 1: association of renal adenocarcinoma with smoking. Cancer 21:1069-1071.

21. Wynder EL, Mabuchi K, Whitmore WF [1974]. Epidemiology of adenocarcinoma of the kidney. J Natl Cancer Inst 53:1619-

22. Schulte P, Ringen K, Hemstreet G, Ward E [1987]. Occupational cancer of the urinary tract. In Brandt-Rauf P, ed. Occupational Medicine: State of the Art Reviews: Occupational Cancer and Carcinogenesis. Philadelphia, PA: Hanley and Belfus, Inc., pp. 85-107.

23. Middaugh JP, Miller J, Dunaway CE, Jenkerson SA, Kelly Tom, Ingle D, et al. [1991]. Causes of death in Alaska 1950, 1980-1989. An analysis of the causes of death, years of potential life lost, and life expectancy. Anchorage, AK, Section of Epidemiology, Division of Public Health, Department of Health & Social Services.

24. NCHS [1991]. Vital statistics of the United States, 1988. Hyattsville, MD: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Health Statistics.

25. NJ Dept of Health [1991]. Occupational cancer and the investigation of reported cancer clusters at work. Trenton, NJ: NJ Dept of Health, Division of Occupational and Environmental Health, Occupational Health Service.

26. NIOSH [1984]. Ethylene oxide: method no. 1614. In: Eller RM, ed. NIOSH manual of analytical methods, 3rd rev. ed. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) publication No. 84-100.

27. CDC [1990]. Guidelines for investigating clusters of health events. MMWR 39 (RR-11).

AUTHORSHIP AND ACKNOWLEDGEMENTS

Report Prepared by:

Ruth A. Shults, R.N., M.P.H.
Health Officer
Medical Section

Teresa A. Seitz, M.P.H., C.I.H.
Industrial Hygienist
Industrial Hygiene Section

Originating Office:

Hazard Evaluations and Technical Assistance Branch
Division of Surveillance, Hazard Evaluations and Field Studies

DISTRIBUTION AND AVAILABILITY OF REPORT

 Single copies of this report will be available for a period of 90 days after the date of this report from the NIOSH Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226. To expedite your request, include a self-addressed mailing label along with your written request. After this time, copies may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

Information regarding the NTIS stock number may be obtained from the NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. Valley Hospital
2. Business Representative, IBEW Local Union 1547
3. Alaska Department of Labor
4. OSHA, Region X

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

TABLE 1

EtO PERSONAL AIR SAMPLING DATA

VALLEY HOSPITAL
PALMER, ALASKA
SEPTEMBER 4-5, 1991
HETA 91-293

JOB DESCRIPTION	DATE	SAMPLING TIME (min)	SAMPLE VOLUME (L)	EtO CONCENTRATION (ppm)[1]
SPD TECHNICIAN	9-4-91	358	35.8	ND[2](<0.01)
SPD TECHNICIAN	9-4-91	412	41.2	ND (<0.01)
SPD TECHNICIAN	9-5-91	450	45.0	ND (<0.01)
SPD TECHNICIAN - while opening sterilizer door prior to removing load	9-5-91	11	1.7	ND (<0.17)
SPD TECHNICIAN - during load removal, following aeration cycle	9-5-91	11	1.7	ND (<0.13)
NIOSH RECOMMENDED EXPOSURE LIMIT				<0.1 (8-hr) 5 (10-min)
OSHA PERMISSIBLE EXPOSURE LIMIT				1 (8-hr) 5 (15-min)

[1] Ethylene oxide (EtO) concentrations are reported in parts per million (ppm) as a time-weighted average over the sampling period.
[2] ND = none detected. The limit of detection (LOD) was 0.5 microgram (ug) of EtO per sample. The limit of quantitation (LOQ) was 1.5 ug/sample.

TABLE 2
EtO AREA AIR SAMPLING DATA

VALLEY HOSPITAL
PALMER, ALASKA
SEPTEMBER 4-5, 1991
HETA 91-293

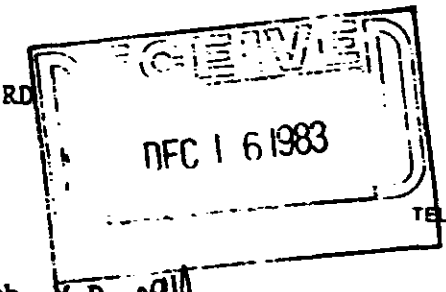
LOCATION/OPERATION	SAMPLING TIME (min)	SAMPLE VOLUME (L)	EtO CONCENTRATION (ppm)[1]
9/4/91			
Wash/prep room near sink	425	42.5	ND[2]
Clean side, on work bench	425	42.5	ND
EtO Rm., in front of aerator	427	42.7	ND
Steam sterilizer room, between sterilizers	424	42.4	ND
EtO Rm., at gas cylinder	422	63.3	0.014
EtO Rm., on sterilizer door	410	61.5	ND
EtO Rm., on door during evacuation cycle	10	1.5	ND
9/5/91			
EtO Rm., on sterilizer door	447	44.7	ND
EtO Rm, approx 4" from sterilizer door while door was cracked, prior to load removal	37	5.6	ND
Clean side, on work bench	451	45.1	ND
Steam sterilizer room, between sterilizers	450	45.0	ND
Wash/prep room, on sink	440	44.0	ND
EtO Rm., at gas cylinder	450	45.0	(trace)[3]
EtO Rm., on door during load removal	16	2.4	ND
EtO Rm., on sterilizer door at beginning of exhaust cycle	11	1.7	ND

[1] Ethylene oxide (EtO) concentrations are reported in parts per million (ppm)/ as time-weighted averages over the sampling periods.
[2] ND = none detected. The limit of detection (LOD) was 0.5 microgram (ug) of EtO per sample. The limit of quantitation (LOQ) was 1.5 ug/sample.
[3] "trace" refers to a concentration between the LOD and LOQ.

APPENDIX 1

MEMORANDUM State of Alaska

TO: FOR THE RECORD



DATE: December 12, 1983

FILE NO:

TELEPHONE NO:

FROM: John Middaugh, M.D.
State Epidemiologist

SUBJECT: Illness at Valley Hospital, Palmer - September 16, 1983

INTRODUCTION

On Friday, September 16, Mr. George Lamour, Air Pollution Office, Municipality of Anchorage, called the Epidemiology Office to report that Valley Hospital, Palmer had closed due to the presence of toxic fumes. He reported that Alaska State Troopers and members of the Anchorage Fire Department were being flown to the facility, all employees and patients were being evacuated from the hospital, and several employees were ill. Dr. Senta, Valley Hospital physician, called the Epidemiology Office soon after Mr. Lamour to report that approximately 8 - 10 employees had been seen at the Valley Hospital Emergency Room with nausea, weakness, faintness and had complained of smelling unusual odors prior to the onset of symptoms. A decision had been made to evacuate the hospital.

Patients from the Intensive Care Unit were transferred by ambulance to Humana or Providence Hospitals. Less seriously ill patients were transferred to the Pioneer Home in Anchorage or to the Palmer Armory located down the street from the hospital. Dr. Senta informed me that the Palmer Hospital employed approximately 70 individuals and had 19 patients in the hospital at the time of the evacuation. Medical staff obtained blood and urine specimens from ill employees. An epidemiologic investigation was initiated.

BACKGROUND

At the time of the evacuation, Valley Hospital was in the midst of a major construction project to expand the hospital by building a new addition and renovating the old building. The new wing was occupied on approximately August 15. All in-patient beds, surgery, and emergency room facilities were located in the new wing. In addition, the medical records office, the business and finance office, and major hospital entry were located in the new wing. The old hospital building containing the out-patient clinic and the supply room located in the basement were still used by patients and staff. Because of ongoing construction activities, medical records was located temporarily in what will become an ultrasound room. The business office was located temporarily in what will become a quiet room for families of patients. A new ethylene oxide gas sterilizer purchased from the American Sterilizer Company, Erie, Pennsylvania (AMSCO) was installed in the new wing. Construction activities were actively in progress at the time of the evacuation of the hospital.

INVESTIGATION

Dr. Kosatsky and Dr. Middaugh arrived by automobile at the hospital approximately 6:00 p.m. Friday, September 16. Officials from the Fire Department had already left the hospital after reporting that no explosive gases could be detected by their portable sensing devices. Mr. Steve Ede, Chemical and Geological Laboratories of Alaska, had obtained gas samples and left the premises.

The hospital had been evacuated at approximately 1:00 p.m., Friday afternoon, and all gas lines and the ventilation system were turned off. Doors were closed to the medical records room, the business office, the operating suites, sterile equipment preparation room, and gas sterilizer rooms. Although hospital staff and Fire Department representatives had intermittently entered the facility after the evacuation, they did not detect any unusual gas odors.

Initial investigation consisted of a brief tour of the hospital site, a visit to the Borough Armory where employees who developed illness were interviewed, and telephone interviews with remaining ill employees who were at home. Late in the evening, Mr. Ede, reported results from his analysis of two gas samples he obtained at the hospital at 5:10 p.m., Friday afternoon, September 16. He reported high levels of ethylene oxide at 1) the base of the tanks of ethylene oxide in the gas sterilizer room, and 2) two inches above the floor in the medical records room where several employees had developed symptoms of illness. (Attachment 1)

Based upon results of the laboratory analyses, the hospital reopened Saturday, September 17 after shutting down the gas sterilizer unit and tanks. Two engineers from the Alaska Department of Environmental Conservation reviewed the heating and ventilation system of the hospital on Saturday, September 17 (Attachment 2). On September 20, Dr. Middaugh returned to the Valley Hospital to interview employees who became ill on Friday, September 17 and to obtain detailed information on the ventilation and heating system in the hospital. Information was shared with representatives of the State Occupational Safety and Health Administration (OSHA) and the AMSCO Company who were also investigating illness at Valley Hospital.

RESULTS

Of the approximately 70 employees and 19 patients present at Valley Hospital on Friday, September 16, 12 individuals who complained of illness were identified by hospital nurses and physicians. All ill employees associated their illness with the detection of strange odors Friday, September 16. All of the affected employees were well upon arriving at work Friday, September 16. Between 9:00 a.m. and 11:00 a.m., 10 employees detected an unusual odor in their work place which they described as sweet, musky, light, like ether, or like burned-broccoli. Within 30 minutes to 2 hours, symptoms developed characterized by nausea (83%), weakness (83%), fatigue(50%), headache (92%), chills (50%) tingling (50%), and watery eyes (42%). Additional symptoms included fatigue, paleness, chills, confusion, feeling of floating, excitement or euphoria, sweating, nasal irritation and feeling flushed (Attachment 3).

Most ill employees were seen in the emergency room and then removed from their hospital workplace. Acute symptoms resolved within a 4 - 12 hour period of time. The onset of illness occurred at almost identical times among the affected individuals. Two males and 10 females were affected; their ages ranged from 15 to 52 years.

Of the eight individuals located in the medical records room and the admitting and business office room, all developed symptoms. In addition, illness affected one individual working in the basement of the old hospital, one person involved in hospital maintenance who was circulating through the hospital including areas of the hospital adjacent to the medical records and admitting office area, one individual working in the laboratory, and one individual whose office was in the old building but who became ill after entering the medical records area.

No patients or hospital employees who were located in the old hospital building, or in the patient wing, or in the emergency room developed similar illness. None of the construction workers became ill.

Late in the evening Friday, September 16, Mr. Ede, Chemical and Geological Laboratories of Alaska, Inc. reported the results of the two air samples he obtained at Valley Hospital at 5:10 that day. He found ethylene oxide at a concentration of 0.2902 moles percent (4400 ppm) at the floor of the sterilizer room and 0.0451 moles percent (684 ppm) at the floor of the business office. These levels are substantially above the current federal OSHA standard of 50 ppm. In view of these laboratory results, the negative results reported by the Fire Department officials for the presence of explosive gas, and the absence of other sources of potentially toxic gas, investigation focused on the ventilation system of the hospital and on the gas sterilizing apparatus.

HOSPITAL VENTILATION SYSTEM

Employees of the hospital complained that from the time they occupied the new wing of the hospital, August 15-16, 1983, to the time the hospital was evacuated, diesel fumes and other noxious odors often could be detected throughout the hospital. Employees noted associations between detection of these odors and operation of the emergency standby generator. On at least one occasion, employees observed black exhaust smoke from the generator exhaust stack on the roof sucked into the air intake of the hospital ventilation system. Within seconds, people detected the presence of exhaust fumes throughout the hospital.

Although employees remarked upon the frequent detection of odors and diesel fumes in the hospital between August 15 and September 16, illness had not previously occurred among employees associated with detection of these odors. The odors detected on September 16 were different and unusual compared to ones previously experienced by employees.

The air system for the new hospital building was designed to be a return air plenum, operating with two major supply distribution systems. One system supplied primarily the area of the new wing most closely adjacent to the old building and included the medical records room, business and finance room, operating rooms, sterile equipment and gas sterilizer rooms, and the corridors in the adjacent areas. The second major ventilation system supplied the emergency room and the patient section of the new wing. The ventilation was designed to recirculate approximately 50% of return air, exhausting the other 50%. In addition, separate dedicated exhaust systems exhaust air from the building with no air recirculation. The exhaust systems included a dedicated exhaust from the emergency room, operating room and sterilizing area to louvers at the main building exhaust. The main exhaust was located near the air intakes for the building supply systems.

There was no separate air supply to the sterilizer rooms. Air enters the adjacent pack room and moves passively to the rooms in which are located the gas and steam sterilzers, respectively. These rooms are equipped with exhaust ducts only, which enter the main dedicated exhaust system. An exhaust fan forces air from the sterilizer rooms. Exhaust air entering the dedicated main exhaust duct discharges exhaust air around the corner from the air intake to the new building. Air pressure in the new wing is at positive pressure relative to outside air, and to air pressure in the old building. All employees who became ill with the exception of the one person who developed illness in the basement supply room in the old building were located in areas of the hospital which received air supply from the air supply unit most closely adjacent to the main exhaust port.

STERILIZER AREA

Examination of the sterilizer room revealed the presence of two cylinders of ethylene oxide, Freon gas (12%/88% proportion). The ethylene oxide/Freon tanks weigh 185 lbs. each when full. The tanks weighed 150 lbs. and 126 lbs. on September 27. The two tanks were those originally connected to the gas sterilizer when installed in August. Detailed records were available to document use of the sterilizer. (Attachment 4) Between date of installation and September 16, the sterilizer was used a total of 11 times. According to the AMSCO representative, a full run later was observed experimentally to use approximately 4 lbs. of gas per cycle. Assuming that original and recorded weights were accurate, that full canisters were delivered originally to the facility, and that the gas sterilizer was used 11 times at 4 lbs. each, it is possible to account for 320 lbs. of gas - leaving 50 lbs. of gas potentially unaccounted for.

Room Dimensions

Gas Sterilizer room	8x7x8
Steam Sterilizer room	8x7x9
Business Office	9.5x29.5x8
Medical Records	8x16x8
Storage & Supply (old bldg.)	39x15x10
Pipe chase	4x4x20

On September 20, a representative of AMSCO checked the machine operation and installation but found no obvious defects. No source was identified to account for a leak which would explain a loss of 30 - 50 lbs. of ethylene oxide/Freon gas.

Examination of the area in which the sterilizer was located revealed water line holes in the concrete floor in both the room which the gas sterilizer was present as well as the adjacent room in which the steam sterilizer was located. Exploration of the crawlspace underneath the hospital revealed a 4 foot high opening providing a potential avenue for gas to have found its way into the 4 x 4 pipe chase space. The pipe chase walls were penetrated by pipes through unsealed holes. The pipe chase opened up at its other end directly above the desk of the maintenance and supply employee in the basement of the old hospital building. Positive pressure from the hospital interior to the crawlspace and to the pipe chase was readily evident, and brisk air currents could be detected. Air could be felt to flow from the gas sterilizer room to the crawl space and from the crawl space into the 4'x 4'pipe chase space. Since ethylene oxide is 1.5 times more dense than air, it is conceivable that gas could have flowed from the sterilizer room to the crawlspace to the pipe chase space. This would provide a possible explanation for how ethylene oxide/freon gas could appear in the old building.

Air exhausted from the gas sterilizer room flows from the exhaust vent in the ceiling to the main exhaust system which discharges through the louvers outside the building. Under appropriate conditions of wind flow, it is conceivable that gas could be sucked back into the air intake system which supplies the corridor and business and medical records areas. Since the air intake for the emergency room, obstetrical suites, and patient wing of the new hospital is from the more distant location, it is possible to explain the distribution of gas primarily to the area of the hospital where employee illness was observed.

As of December 10, no malfunction of the sterilizer to explain a massive gas leak has been reported by OSHA investigators or by AMSCO company representatives. However, OSHA representatives found that the Enviroguard AMSCO system was not working properly. The wiring was incorrectly installed and the exhaust fan on the gas sterilizer system was not operational.

LABORATORY RESULTS

Mr. Ede, Chemical and Geological Laboratories, Inc., was interviewed at length about the methods he used to perform assays on air samples collected on September 16 - 17. In addition, National Institute of Occupational Safety and Health,(NIOSH), Cincinnati, was consulted and asked to review laboratory methods. NIOSH laboratory personnel with expertise in measuring ethylene oxide also phoned Mr. Ede to review with him his methodology, equipment, and techniques as an additional check on the accuracy of the results reported by the laboratory. Mr. Ede reported that he had analyzed the air samples by gas chromatography. Mr. Ede ran blanks and used a fixed standard as a control from a tank of gas purchased from the same company as the cylinders hooked up to the gas sterilizer at the hospital. NIOSH laboratory personnel reported that the Chemical and Geological Laboratories of Alaska used appropriate methodology, separation columns,

standards, and procedures. To the best of their ability to determine by telephone consultation with Mr. Ede, NIOSH reported that he used approved methods which should be accurate and reproducible. Mr. Ede's methodology for sample collection using a gas collection cylinder and a vacuum canister were also those recommended by the laboratory at the National Institute of Occupational Safety and Health.

No biological tests are specific for documentation of exposure to Freon or to ethylene oxide. Therefore, no tests were recommended to be performed on blood and urine samples.

DISCUSSION

Epidemiologic investigation supports strongly the hypothesis that illness occurring among employees at Valley Hospital in Palmer on Friday, September 16, was due to a common source environmental exposure. Illness, characterized by acute onset and relatively uniform symptoms, occurred among employees working in limited areas in the hospital. Illness was not infectious; no secondary spread of illness occurred among family members of employees affected.

Onset of illness occurred shortly after employees detected an unusual odor which had not previously been noticed in the hospital. The descriptions of the odor were consistent with ethylene oxide. No patients nor hospital employees working in areas of the hospital not supplied by one of the two discrete ventilation units were affected. Potential routes to explain exposures were discovered which could account for observed illness, including one individual who developed symptoms while working in the basement of the old hospital.

Laboratory results demonstrated very high levels of ethylene oxide in the gas sterilizer room and in the medical room where illness occurred among employees. After telephone review of laboratory methodology, NIOSH confirmed that appropriate sampling methods, equipment, and procedures were utilized by Chemical and Geological Laboratories of Alaska. There are no symptom complexes among ill employees which are diagnostic of exposure to ethylene oxide or to Freon. Nevertheless, symptoms which occurred are compatible with symptoms which have been described among others acutely exposed to high concentrations of these gases. (1, 2)

Serious problems were discovered with the ventilation and exhaust systems of the new hospital. In addition, several problems were discovered in the design, installation and operation of the gas sterilizer. However, none of these findings have explained the etiology of the gas leak, and there is no proof that the illness was caused by ethylene oxide/freon gas.

Prompt action by hospital personnel and administrators to evacuate patients and close the hospital is to be commended. All employees had recovered from their acute symptoms when reinterviewed on September 20, 1983. Based on epidemiologic investigation, and assuming the cause was from acute exposure to ethylene oxide/freon gas, it is unlikely that any serious acute medical problems could be expected from the type of exposure which might have occurred. While it is also theoretically possible that long term adverse effects could occur from exposure to ethylene oxide, the possibility is so extremely remote as to not warrant serious consideration.

REFERENCES:

1. Special Occupational Hazard Review with Control Recommendations Use of Ethylene Oxide as a Sterilant in Medical Facilities, August 1977, DHEW (NIOSH) Publication No. 77-200.

2. Ethylene Oxide (ETO), Current Intelligence Bulletin 35, May 22, 1981, DHHS (NIOSH) Publication No. 81-130.

We wish to thank the following individuals for their assistance and cooperation:

Mr. Eric Buckland, Hospital Administrator; Penny Chmielewski, Head Nurse; Drs. Senta, Sloan and Moser; Axel Johnson; Mr. Vincent Morris and Mr. Jim Ericson, AMSCO; Sandy Witek, OSHA; Mr. Bob Martin and Steve Zrake, DEC; Mr. Steve Ede, Chemical and Geological Laboratories of Alaska; Dr. Jim Melius, NIOSH; Stuart Ashley, Mechanical Engineer, OSHA.

JM/cv

Attachments

ATTACHMENT #1

CHEMICAL & GEOLOGICAL LABORATORIES OF ALASKA, INC.

P.O. BOX 4-1276
Anchorage, Alaska 99509

TELEPHONE (907) 562-2343

ANCHORAGE INDUSTRIAL CENTER
5633 B Street

ANALYTICAL REPORT

From Valley Hospital — Product Air Samples

Address Palmer, Alaska — Date September 16, 1983

Other Pertinent Data

Analyzed by SE — Date 9-16/17-83 — Lab No. 3449

REPORT OF ANALYSIS
AIR SAMPLES
VALLEY HOSPITAL
PALMER, ALASKA

ples taken September 16, 1983

	9/16 FLOOR OF STERLIZER ROOM 1710 Hrs.	9/17 FLOOR OF STERLIZER ROOM 1430 Hrs.	9/16 FLOOR OF BUSINESS OFFICE 1713 Hrs.	9/17 FLOOR OF BUSINESS OFFICE 1433 Hrs.
bon Dioxide, Mole %	0.0521	0.0562	0.1286	0.0678
gen, Mole %	20.5043	20.6038	20.7044	20.7188
rogen, Mole %	79.1535	79.3400	79.1219	79.2134
ylene Oxide, Mole %	0.2902	<0.005	0.0451	<0.005
bon Monoxide, ppm	<5	<5	<5	<5

ATTACHMENT #2

STATE OF ALASKA

DEPT. OF ENVIRONMENTAL CONSERVATION

BILL SHEFFIELD, GOVERNOR

Telephone: (907) 274-2533
Address: 437 "E" Street
Suite 200
Anchorage, Alaska
99501

September 23, 1983

Eric Buckland
Hospital Administrator
Box H, The Valley Hospital
Palmer, Alaska 99645

Dear Mr. Buckland:

The purpose of this letter is to review our preliminary conclusions and recommendations to you with regards to the ethlyene oxide problem of September 16-17, 1983.

Conclusions

1. If the results of the air sampled by Chemical and Geological Laboratories are correct, a leak must have occurred in the gas sterilizer unit located in the sterile room.

2. The mode of transport for the gas to other areas of the hospital may have been via air duct then to the central air circulating system, or through the waterline holes in the concrete floor.

3. The problem apparently abated once the ethylene oxide tank valves were turned off and the contaminated air eventually dissipated.

Recommendations

1. Put in a leak detection system that would give both a visual and audio alert. Follow the manufacturer's instructions.

2. In consultation with a qualified mechanical engineer, install an air evacuation system in the sterile room that would exhaust air directly to the outside of the hospital. This should be tied to the leak detection system with a manual switch outside the room.

3. Contact the manufacturer of the gas sterilizer unit and have them examine the unit before reuse.

If we can be of further assistance, do not hesitate to contact this office.

Sincerely,

Steve Zrake
Regional Oil and Hazardous
Waste Program Manager

SZ/msr
cc: Bob Martin
Joe LeBeau

ATTACHMENT #3

VALLEY HOSPITAL

CASE NO.	AGE/SEX	Occupation / Location	TIME TO WORK / TIME OF ONSET	ODOR	SYMPTOMS: cough	SOB	chills	fever	nausea	vomiting	weakness	dizzy	fatigue	confusion	fainting	headache	numbness	drowsiness	excitement	tingling	diaphoresis	watery eyes	nasal irritation	flushed	BP	DURATION
1	41/M	Material Mgr / basement	____ / 12:15pm	sweet, musky, light					x		x	x	x	x	x	x						x	x	x	180/108	
2	18/F	File clerk / Med. records	7:30am / 10:00am	strong odor			x		x		x		x		x	x							x			
3	52/F	clerk / Med. records	6:45am / 9-10 am	faint odor	x	x			x		x	x	x			x					x	x	x			6 hou
4	29/F	Typist / Med. records	8:00am / 9-9:30am	faint odor			x				x	x				x	x				x	x				8 hou
5	36/F	Clerk / Med. records	8:30am / 11:00am	ether			x		x		x		x			x									140/92	4 hou
6	32/F	____ / lab	11:30am / 4:30pm	burned broccoli			x	x	x		x			x	x	x		x		x						
	31/M	maintainence	8:00am / 12:00pm	ether					x	x	x	x		x		x				x						4 hou
8	20/F		7:30am / 11:30am	burning			x		x		x	x	x		x	x			x	x						
9	34/F	reception / Admit. Off.	7:00am / 11:30pm	ether							x		x			x				x					148/100	
10	44/F	____ / Admit. Off.	7:30am / 10:30am	ether		x			x			x			x					x		x				
11	43/F	____ / Billing Off.	7:30am / 11:00am	fumes			x		x							x				x	x					
12	41/F	Finance / Old Bldg.	____ / 3:30pm	n/a		x			x		x				x	x			x			x				2 days

Palmer Valley Hospital

Gas Sterilizer Utilization Record

DATE	GAS ON	GAS OFF
8/18	10:55	12:40
8/18	1:50	2:05
8/21	3:00	abort
8/22	11:00	1:55
8/24	1:10	4:15
8/25	1:30	4:55
9/04	11:52	1:45
9/06	1:31	4:30
9/07	1:11	4:20
9/11	10:30	1:20
9/14	1:50	4:30