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I. SUMMARY

In March 1987, NIOSH received a request from University Hospital, University of Colorado Health Sciences Center, Denver, Colorado to determine if there was a health hazard from exposure to ethylene oxide (EtO). In addition, management reported that a stationary, solid state alarm for EtO located in a storage room adjacent to the sterilizer room, had been going off regularly for several months and employees had been complaining of headaches and other (possibly neurological) symptoms.

An environmental evaluation was conducted by two NIOSH industrial hygienists on May 11, 1987 to evaluate EtO exposure among Central Supply Department employees. A medical evaluation was conducted May 20-22, 1987 by a NIOSH physician and included a self-administered questionnaire, a review of exposed employees' medical records, and a neurological examination.

EtO was detected at the limit of quantitation (LOQ) in a time-weighted average, personal breathing zone (PBZ) sample (0.02 mg/m^3) taken from the sterilizer operator. The remaining PBZ samples did not indicate any airborne exposure to EtO above the limit of detection (LOD). EtO was detected in five time-weighted average, general area samples taken in the sterilizer room and the mechanical access room. The concentrations ranged from none detected to 0.2 mg/m^3. EtO was detected at the LOQ in a short term area sample (0.2 mg/m^3) taken in the sterilizer room during the Castle sterilizer 15 minute door crack period. The remaining short term samples did not find any airborne levels of EtO above the LOD. Management and employees related anecdotal information which indicated the solid state alarm may have been going off in response to the use of hair spray and an isopropanol based soap at a nearby sink.

The Central Supply Department employees, the technicians in particular, reported (by questionnaire) an increased prevalence of symptoms consistent with EtO exposure. The Central Supply Department employees had laboratory test results with minor abnormalities which need follow-up. Whether EtO exposure caused the symptoms or laboratory test result abnormalities cannot by determined from our study. EtO was detected in a time-weighted average, PBZ sample taken from the sterilizer operator and in areas where personnel were located. Therefore, the NIOSH investigators concluded a potential for employee exposure to EtO existed during the survey.

On the basis of the data obtained during this survey, it was determined that a potential for exposure to ethylene oxide existed for employees working in the sterilizer room, Central Supply Department, at the University Of Colorado Health Sciences Center. Recommendations to reduce employees' exposures to the lowest feasible level are contained in the full body of this report.

KEYWORDS: SIC 8062 hospitals, ethylene oxide, gas sterilization

II. INTRODUCTION

In March 1987, the National Institute for Occupational Safety and Health (NIOSH) received a request from management of University Hospital, University of Colorado Health Sciences Center, Denver, Colorado to determine if there was a health hazard from exposure to ethylene oxide (EtO). EtO is used in the Central Supply Department for the sterilization of heat and/or moisture sensitive instruments and materials used throughout the hospital. In addition, management reported that a stationary, solid state alarm for EtO located in a storage room adjacent to the sterilizer room, had been going off regularly for several months and employees had been complaining of headaches and other (possibly neurological) symptoms.

On April 16, 1987 an opening conference was held with management representatives during which background information was obtained. Following this meeting, a walk-through survey was conducted in the Central Supply Department.

An industrial hygiene evaluation was conducted by two NIOSH industrial hygienists on May 11, 1987 to evaluate EtO exposure among Central Supply Department employees. A medical evaluation was conducted May 20 - 22, 1987 by a NIOSH physician and included a self-administered questionnaire, a review of exposed employees' medical records, and a neurological examination. Results were discussed in person with the Director, Department of Material Management on August 3, 1987.

III. BACKGROUND

EtO is used at University Hospital as a sterilant of heat and/or moisture sensitive hospital supplies and surgical instruments. All EtO sterilization for the hospital was performed in the Central Supply Department. The Central Supply Department was located in the basement of the University Hospital and comprised of six rooms: one sterilizing room, two storage rooms, two offices, and one break room. The EtO sterilizers and aerator were located in the sterilizing room and one Central Supply technician per shift was responsible for their operation. The other technicians working that shift were responsible for picking up used equipment throughout the hospital, washing used equipment, setting up carts or trays with clean and sterilized equipment, and delivering the cleaned and sterilized equipment to the various floors of the hospital. The Central Supply clerks also helped with these tasks, however they did not operate the sterilizing machines, and therefore rarely entered the sterilizing room. The day shift technicians rotated the responsibility of operating the sterilizing machines, each assigned the task approximately once per week. During the evening shift, however, one technician typically took responsiblity for operating the sterilizing machines. The sterilizer room was equipped with two ethylene oxide sterilizers, a Castle EtO sterilizer and a smaller, table top 3M sterilizer. Accompanying the sterilizers was an aerator which was used for aerating all items immediately following the sterilization and purge cycles of the sterilizers. A stationary, solid state alarm for hydrocarbons was present in a storage room adjacent to the sterilizer room to provide warning to employees in the event of gas leakage. The sterilizer room was not physically isolated within the Central Supply Department.

The Castle sterilizer and Castle aerator were recessed into a wall of the sterilizer room, with the bodies protruding into an adjacent mechanical access room. The mechanical access room was kept locked and contained two cylinders of EtO and Freon-12 in a mixture of 12 to 88 percent by weight. The cylinders were used to supply the Castle sterilizer. Entry into this locked room was restricted to gas cylinder replacement and other required maintenance activities. The Castle sterilizer drainage duct emptied into an open sewer drain located within the mechanical access room. The 3M sterilizer used a small cartridge of EtO gas which was manually seated inside the sterilizer chamber prior to use. After the sterilizer cycle started, the cartridge was automatically punctured. The mechanical access room and sterilizer room were ventilated by a dedicated exhaust system which had a measured exhaust of 1250 cubic feet per minute and approximately 16 air changes per hour.(1) The main exhaust duct was equipped with a swinging vane anemometer alarm. The exhaust air was exhausted directly outdoors to an area removed from air intakes. Both the Castle and

3M sterilizers were equipped with local exhaust ventilation, e.g., slot hoods around the sterilizer door openings.

Each sterilization cycle lasted approximately four hours and included an aeration period. Following the sterilization cycle the instruments were transferred to the aerator for a 12 hour aeration cycle. Work practice requirements included a provision that all employees leave the sterilizer room for a 15-minute period during which the sterilizer door was opened prior to transfer of instruments to the aerator. This 15-minute door crack period was to allow EtO remaining in the sterilizer to dissipate before transferring the load to the aerator. For sterilization and during the load transfer, items were inserted and removed using a wheeled cart. The Castle sterilizer door opened completely during the 15-minute door crack period and the 3M sterilizer door opened approximately two inches. The distance the doors opened was preset by the manufacturer.

Management had been evaluating many alternatives to improve conditions in the sterilizer room including: installing a higher capacity fan, lowering grilles between the mechanical access room and the sterilizer room, insulating pipes in the mechanical access room, removing the gas cylinders from the mechanical access room, installing red lights outside the sterilizer room to warn employees not to enter during the 15 minute door crack period, and installing local exhaust ventilation hoods over the gas cylinders. Periodic monitoring of employees in Central Supply for EtO exposure has been conducted by the hospital using passive dosimeters which met the precision and accuracy requirements of the OSHA standard. The hospital also used a direct reading instrument for occasional leak detection testing for EtO. Written documents had been prepared for leaving the sterilizer room during the 15 minute door crack period, steps to take in response to the hydrocarbon alarm, steps to follow when changing the gas cylinders, and procedures and guidelines for EtO sterilization.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

On May 11, 1987 an industrial hygiene survey was conducted by two NIOSH industrial hygienists in the Central Supply Department. Personal exposures and average concentrations of EtO at selected locations in the sterilizer room were determined by sampling with hydrogen bromide treated charcoal tubes using NIOSH Method 1607.(2) Long-term personal breathing zone (PBZ) samples were used to estimate 8-hour time-weighted average (TWA) exposures for the sterilizer operator and Central Supply technicians. Area samples were taken to indicate the exposure the worker would receive if the full shift was spent at the workstation monitored.

Short-term samples for the sterilizer operator and two sterilizer room area locations were collected using hydrogen bromide treated charcoal tubes and analyzed according to NIOSH Method 1607.(2) The charcoal tube samples were collected for approximately 15 minutes at the start of the 15 minute door crack period and ending when the load transfer was complete. Direct-reading colorimetric detector tubes were used to sample for EtO in the sterilizer room during the load transfer period.

Smoke tubes were used to determine capture effectiveness of the slot exhaust hoods and to assess air movement between rooms and through doors and openings.

B. Medical

All available employees working the day, and evening shifts in Central Supply were asked to complete a self-administered questionnaire. The questionnaire (see Appendix A) was designed to gather information regarding employee demographics, medical history, job history, and symptoms related to ethylene oxide (EtO) exposure. The questionnaire, a modification of the "Swedish 16" neurotoxic questionnaire, has been used in other studies on solvent effects.(3,4) Each of the 33 symptom questions was scored on a 3-point scale: "not at all" (score = 0), "a little" (score = 1), "moderately" (score = 2), and "quite a lot" (score = 3). The symptoms were combined, based on previous factor analyses and biologic plausibility, into eight symptom clusters.(4) The symptom clusters were constitutional, cognitive, gastrointestinal (GI), emotional, skin, respiratory, peripheral nervous system (PNS), and irritative. Each cluster contained four symptom questions and scores could range from 0 to 12, reflecting the frequency and intensity of the cluster's

symptoms. An individual was considered to be suffering from a particular symptom cluster if a score of 7 or greater was generated. In addition to the symptom cluster prevalences, mean symptom cluster scores were calculated for each department.

The exposure to EtO was dependent on proximity to the gas sterilizing room. The Central Supply technicians had the greatest potential exposure, followed by the store keeper who changed the EtO tanks approximately once per week, and the Central Supply clerks, who worked in the central supply department, but not in the sterilizing room. Symptom cluster prevalences and mean symptom cluster scores were generated for the two job titles in the Central Supply Department (technicians and clerks). A 50% sample of the 35 employees working in the Dietary Department with presumably no exposure to EtO, were randomly chosen to represent the non-exposed (control) population.

Statistical analyses were performed using SAS/PC, and EPIINFO.(5,6) The mean symptom cluster scores were analyzed using parametric (Student's t-test) and non-parametric (Wilcoxon) statistical procedures. Since both types of statistical analysis identified the same symptom clusters, we reported only the parametric results. Statistical significance was defined as p less than 0.05.

The medical records of the exposed employees were reviewed. The records included histories and physicals performed by employee health physicians, and laboratory work performed by the hospital after January l987. The laboratory tests included a complete blood count (CBC), measurement of various biochemical constituents of serum (SMA-6, SMA-12), chest radiograph (CXR), and electrocardiogram (EKG).

Neurologic exams were performed by a NIOSH physician. The exam included mental status evaluation, and testing of cranial nerves, muscle strength, sensory system, cerebellar function, and reflexes.

V. EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are based on more recent information than are the OSHA standards. The OSHA standards also may

be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended exposure limits (RELs), by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures. The recommended exposure levels for EtO are as follows:

	Environmental Exposure Limits 8-Hour Time-Weighted Average (TWA)
Ethylene Oxide	LFL (NIOSH) 2 mg/m^3 (OSHA) 2 mg/m^3,A2 (ACGIH)

mg/m^3 = milligrams of substance per cubic meter of air
LFL = Lowest Feasible Level (see below for further explanation)
A2 = Industrial substance suspected of having carcinogenic potential for man

A. Environmental

In l984 the Occupational Safety and Health Administration (OSHA) established a new Permissible Exposure Limit (PEL) for EtO of 2 mg/m^3 as an 8-hour TWA.(7) In addition, an "action level" of 1 mg/m^3 as as 8-hour TWA was established by OSHA as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. Also in l984, NIOSH recommended that EtO exposures not exceed 10 mg/m^3 for a maximum of 10 minutes per day and that exposures be controlled to less than 0.2 mg/m^3 determined as an 8-hour TWA.(8) NIOSH considers EtO to be a potential human carcinogen and no safe level of exposure has been demonstrated, although decreasing the exposure is likely to reduce the probability of developing cancer. The American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Threshold Limit Value (TLV) of 2 mg/m^3 for an 8-hour TWA. The ACGIH also designated EtO as an A2 carcinogen.(9) 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.

B. Medical

Acute Effects

Inhalation of high concentrations to EtO for short exposure periods can produce a general anesthetic effect in addition to coughing, vomiting, and irritation of the eyes and respiratory passages. Early symptoms are irritation of the eyes, nose, and throat and a peculiar taste. Effects, which may be delayed, are headache, nausea, vomiting, dyspnea, cyanosis, pulmonary edema, drowsiness, weakness, incoordination, and abnormalities of EKGs and urinary excretion of bile pigments.(10) Several dermatologic conditions can result from contact with liquid EtO. These include skin blistering, pigment color change, and frostbite.(10)

Chronic Effects

EtO binds to DNA and has been shown to cause point mutations.(11) In both animals and humans, EtO exposure produces increased frequencies of sister chromatid exchanges and chromosomal aberrations.(12,13) EtO is a reproductive toxin in animals, and one study suggests such an effect in humans.(12,14) EtO is an animal carcinogen, and in humans, two epidemiological studies have associated an increase of hematologic, alimentary, and urogenital malignancies with EtO exposure.(12,15-16) EtO has also been shown to cause polyneuropathies and cataracts.(17-19)

VI. RESULTS

A. Environmental

Ten full shift air samples, four personal breathing zone (PBZ) and six general area, were collected on May 11, 1987 for EtO. The results are provided in Table 1. The results of samples collected near the breathing zone of three Central Supply technicians were found to be below the laboratory limit of detection of 0.3 micrograms per sample. The PBZ sample collected from the sterilizer operator was found to be above the laboratory limit of detection but below the limit of quantitation of 0.6 micrograms per sample (0.02 mg/m^3 for the air volume sampled). The results of time-weighted average, general area samples collected in the mechanical access room and sterilizer room ranged from nondetectable (ND) to 0.2 mg/m^3.

A summary of the results of the short-term sampling is presented in Table 2. Three air samples, one PBZ and two general area, were collected for a 16 minute period during which the 3M sterilizer was vented and the load transferred to the aerator (samples 11 - 13 in Table 2). The results of these three short-term samples for EtO were found to be below the laboratory limit of detection of 0.3 micrograms per sample. Work practices included a 15 minute door crack period before unloading the sterilizer. The operator then moved away from the area where the peak EtO concentrations were likely to be present. Based on the airflow pattern observed with smoke tubes, the slot hood controlled emissions from the door, i.e. the distance which the door automatically opened was within the slot hood's capture distance.

Three air samples, one PBZ and two general area, were collected for a 25 minute period during which the Castle sterilizer was vented and the load transferred to the aerator (samples 14 -16 in Table 2). Work practices included a 15 minute door crack period before unloading the sterilizer. The sterilizer operator then moved away from the area where the peak EtO concentrations were likely to be present. Based on the airflow pattern observed with smoke tubes the slot hood did not control emissions from the door, i.e. the distance which the door automatically opened was not within the slot hood's capture distance. EtO was detected at the limit of quantitation in a short term area sample taken in the sterilizer room during the Castle sterilizer 15 minute door crack period. The concentration was calculated to be 0.2 mg/m^3 for the limit of quantitation of 0.6 micrograms per sample and the air volume sampled. The results of the remaining two short-term samples for EtO were found to be below the limit of detection of 0.3 micrograms per sample. No detectable levels of EtO were found with direct-reading colormetric detector tubes.

The reported air changes per hour for the sterilizer room exceeded the minimum of ten air changes per hour recommended by the U.S. Public Health Service; however, visual observation of airflow movement with smoke tubes demonstrated that air was flowing out of the mechanical access room and sterilizer room into adjacent work areas.(19) The airflow movement was most pronounced near the ceiling. Therefore, the ventilation rate was not adequate to overcome the thermal air currents produced by heat generating

equipment located within the mechanical access room and make the mechanical access room a negative pressure zone relative to the sterilizer room. Temperature measurements were not taken in the mechanical access room, however, the two NIOSH researchers felt the volume of air drawn into the room was not sufficient to limit the temperature rise to an acceptable level.

Management and employees related several incidents of the hydrocarbon alarm going off in response to the use of hair spray at a nearby sink and in response to the use of an isopropanol based soap. Management requires all Central Supply employees to evacuate the department and evacuation procedures be followed every time the alarm sounds, regardless of the hydrocarbon source producing the alarm.

B. Medical

Of the twenty-two current employees in the Central Supply Department, twenty (91%) completed questionnaires. Of these twenty, thirteen were technicians, and seven were stock clerks. The two administrative personnel were not asked to complete the questionnaire and thus the response rate was effectively 100%. The task of changing the EtO tanks was assigned to one store keeper who also completed the questionnaire. This group of twenty-one employees, the twenty Central Supply employees and the store keeper, represented the exposed population.

Seventeen of thirty-five Dietary employees were randomly asked to complete the interview. These seventeen represented the nonexposed employees.

Table 3 presents the demographic information for the two groups. No statistically significant differences were found for age, sex, race, smoking status, and length of employment between employees of the Central Supply and Dietary Departments.

The symptom cluster prevalence by department is displayed in Table 4. The exposed department (Central Supply) employees reported an increased prevalence of all symptom complexes with the constitutional and irritative symptoms being statistically significant.

The mean symptom cluster score by department is shown in Table 5. The Central Supply Department employees reported an increased mean score of all symtpom complexes, compared to the Dietary Department, with the constitutional, skin, respiratory, peripheral nervous system, and irritative symptoms being statistically significant.

Stratifying the Central Supply employees by job title, the technicians reported increased constitutional, skin, respiratory, peripheral nervous system, and irritative symptoms. The clerks, on the other hand, reported only increased irritative symptoms (Table 6 and 7).

Medical records of fifteen Central Supply technicians were reviewed. Two technicians who left the institution since February 1987, had completed the medical screening initiated by the employee health physicians, and were not available for the questionnaire. Of these fifteen, the complete blood counts (CBCs) revealed three mild anemias (low red blood cell count), and one mild leukopenia (low white blood cell count). The serum chemistries revealed two mild liver function test (LFT) abnormalities. The chest radiographs (CXRs) revealed two abnormalities of a chronic nature. Two electrocardiograms (EKGs) revealed non-specific minor abnormalities.

Three of the seven Central Supply clerks were evaluated in the employee health clinic. Their CBCs and CXRs were normal. One mild elevation of the LFT was noted, and two EKGs had non-specific minor abnormalities.

Neurologic exam were performed on twelve of the thirteen currently employed technicians, one of the seven Central Supply clerks, and the one exposed store keeper. All exams were within normal limits.

VII. DISCUSSION AND CONCLUSIONS

A. Environmental

EtO was detected at the limit of quantitation (0.02 mg/m^3 for the air volume sampled) in a time-weighted average, personal breathing zone (PBZ) sample taken from the sterilizer operator and at the limit of quantitation (0.2 mg/m^3 for the air volume sampled) from a short term area sample taken in the sterilizer room taken during the Castle sterilizer 15 minute door crack period. The remaining PBZ samples did not indicate any airborne exposure to EtO above the limit of detection. EtO was detected in five time-weighted average, general area samples (concentrations ranged from none detectecd to 0.2 mg/m^3) taken in the sterilizer room and the mechanical access room. EtO was detected in a time-weighted average, PBZ sample taken from the sterilizer operator and in areas where personnel were located. Therefore, the NIOSH industrial hygienists concluded a potential for employee exposure to EtO existed during the survey.

B. Medical

Both the symptom cluster prevalences and the mean symptom cluster scores revealed an increased prevalence of all symtpom complexes among the Central Supply Department personnel.

The technicians have the majority of symptoms in the Central Supply Department, and also have the most potential exposure to EtO. This finding suggests that EtO might be the cause of these employees symptoms.

The questionnaire portion of this study has several limitations. The questionnaire relies on self-reporting of subjective symptoms as a means to determine symptom cluster prevalences and mean symptom cluster scores. In addition, individuals in the same department listen to the problems of co-workers and therefore may be more likely to report symptoms (recall bias).

The abnormalities found on the laboratory screening tests were minor, and their causes non-specific. However, given that EtO exposure causes hematologic malignancies in animals, and human epidemiologic studies link EtO with hematologic malignancies, these abnormal complete blood counts (CBCs) need follow-up. (11,14-15) In addition, EtO has been shown to cause liver damage, which is usually reflected in elevation of the liver function tests (LFTs).(10) Therefore, employees exposed to EtO with abnormal LFTs need follow-up as well. Reports of EtO exposed workers having proteinuria (protein in the urine), and urogenital malignancies (cancers of the urinary tract) suggests the need to incorporate a urinalysis into the surveillance protocol.(17,21) Although the screening procedures will not prevent adverse events from EtO exposure, they may uncover hematologic malignancies early in their course permitting early, aggressive therapy. If EtO induced liver damage is discovered by screening tests, prompt removal from the exposure may limit the extent of liver damage.

The changing of EtO tanks or cylinders is performed by one store keeper. Despite careful detachment procedures employed by this worker, exposure to EtO concentrations exceeding the odor threshold seems to occur occasionally. Therefore, personal protective equipment (respirator and gloves) need to be used. While interviewing and examining the Central Supply employees, the NIOSH physician noted that, in general, the Central Supply employees were misinformed or uninformed about the health hazards posed by EtO exposure, and were unclear about the proper sterilizing procedure.

The Central Supply Department employees, the technicians in particular, had an increased prevalence of symptoms consistent with EtO exposure. The Central Supply Department employees had laboratory test results with minor abnormalities, namely the serum liver function tests and blood counts. The laboratory tests

need to be repeated and the test results evaluated by a physician. Whether EtO exposure caused the symptoms or laboratory test abnormalities cannot by determined from our study.

VIII. RECOMMENDATIONS

A. Environmental

1. University Hospital should continue in its efforts to reduce ethylene oxide exposure to the lowest level possible, continue periodic exposure monitoring, and continue leak detection to ensure the effectiveness of engineering controls.

2. The source of ethylene oxide exposure in the mechanical access room (presumably the drain area) should be identified. Although employees would not normally be present in this area during sterilizer and aerator operation, it would still be advisable to control the EtO emissions at this generation point in order to prevent migration of the gas into the sterilizer room.

3. There is always the possibility of incidental release of EtO in the mechanical access room, so the ventilation should be improved to not allow any airflow out of the room. Thermal effects equations can give an estimate of the flowrate needed.(22) The temperature in the mechanical access room should be maintained between 70 and 100 degrees Fahrenheit.

4. Rather than relying on a "well-ventilated room" as a primary control, it is recommended that effective controls be installed at the major sources of EtO release. The distance the Castle sterilizer door opened during the 15 minute door crack period should be reduced. The door should not open beyond the slot hood's capture distance. Other controls include a ventilated enclosure for the drain air gap, additional cycle phases to reduce the concentration in the sterilizer before the door is opened, and work practices which minimize contact with the sterilizer load.

5. Since elevated EtO concentrations occur in the mechanical access room, a warning system should be present to alert employees not to enter the room for a specified period of time after the sterilizer evacuation phase is complete. The length of time required may be estimated from rate-of-purging equations.(23)

6. To protect the store clerk changing the EtO supply cylinders, supply line purge systems and/or local exhaust ventilation above the cylinders should be installed. Face shields and gloves should be worn by the employee who changes the cylinder for protection in case of an accident. The gas line connections should be checked for leakage after each cylinder change using a soap solution or halide (refrigerant) leak detector.

7. Respirators should be available to handle emergency situations and may be necessary for routine cylinder changes if engineering controls are inadequate. For situations where the employee encounters an unknown concentration of EtO or in an emergency situation, NIOSH recommends a compressed air, open circuit self-contained breathing apparatus with full facepiece.

8. Personal protective clothing, including butyl or nitryl gloves and faceshields, should be provided to employees required to change EtO cylinders and/or cartridges due to the potential for skin and eye irritation.

9. Further sampling of employees for EtO should be conducted after ventilation improvements have been made to evaluate their effect.

10. Employees operating sterilizer equipment should receive instruction in all parameters of sterilization and aeration procedures. Such training should strictly adhere to equipment manufacturers' installation, operating, routine care, and preventive maintenance instructions.

11. Employees should receive instruction and training on the hazards and toxicity of EtO, including signs and symptoms of acute exposure, and on reporting these to designated health personnel. Employees should be informed of appropriate precautions to take to limit exposure, including safe work practices. In addition, the training should include instruction in respirator operation, decontamination procedures, emergency procedures.

12. Regular scheduled safety meetings should aim to retrain employees working with EtO and remind them of its potential adverse health effects, and the reason for complying with safety procedures.

13. EtO sterilized supplies and instruments should not be released to other hospital departments unless they have been completely aerated. B.Medical

1. The abnormal complete blood counts (CBCs) and liver function tests (LFTs) should be repeated. If any abnormalities remain, an appropriate evaluation should be initiated on an individual basis.

2. As outlined by OSHA, preplacement medical examinations and annual medical screening of all current employees in the Central Supply Department. This screen should include a history and physical examination by a licensed physician with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems, as well as the eyes and skin. Laboratory screening should include a CBC (white cell count with differential, red cell count, hematocrit, and hemoglobin).

3. Medical examinations and consultations should be made available to each employee, as outlined in the OSHA standard (29 CFR 1910.1047), if the employee desires medical advice concerning the effects of current or past exposure to EtO on the employee's ability to produce a healthy child.

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XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH, Publications Office, at the Cincinnati address.

Copies of this report have been sent to:

1. University of Colorado Health Sciences Center
2. U.S. Department of Labor/OSHA - Region VIII.
3. NIOSH Regional Offices/Divisions
4. Colorado Department of Health

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

TABLE 1

TWA CONCENTRATION OF ETHYLENE OXIDE

University of Colorado Health Sciences Center
March 11, 1987

Sample #	Sample Type/Location	Sampling Time	TWA Concentration (mg/m^3)
1	Area/Mechanical Access Room on top of Castle sterilizer	3:18 - 8:50	0.2
2	Area/Mechanical Access Room above floor drain	3:19 - 8:50	< LOD
3	PBZ/Central Supply Technician	3:11 - 9:04	< LOD
4	PBZ/Central Supply Technician	3:05 - 9:04	< LOD
5	PBZ/Sterilizer Operator	2:49 - 8:50	< LOQ
6	Area/Mechanical Access Room above Castle Aerator	3:18 - 8:50	0.1
7	PBZ/Central Supply Technician	3:04 - 9:04	< LOD
8	Area/Sterilizer Room on top of 3M Sterilizer	3:24 - 8:56	0.08
9	Area/Sterilizer Room to side of aerator	3:23 - 8:56	0.04
10	Area/Sterilizer Room ceiling near aerator	3:22 - 8:56	0.04

NIOSH Recommended Standard: Ethylene Oxide - Lowest Feasible Level

Key:
TWA - Time weighted average (calculated for the sampling time indicated)
mg/m^3 - milligrams of substance per cubic meter of air
< LOD - Less than the limit of detection of 0.3 micrograms per sample
< LOQ - Less than the limit of quantitation of 0.6 micrograms per sample

TABLE 2

STEL CONCENTRATION OF ETHYLENE OXIDE

University of Colorado Health Sciences Center
March 11, 1987

Sample #	Sample Type/Location	Sampling Time	STEL Concentration (mg/m^3)
11	Area/Sterilizer Room near aerator	7:44 - 8:01	< LOD
12	PBZ/Sterilizer Operator	7:43 - 8:01	< LOD
13	Area/Sterilizer Room on top of 3M Sterilizer	7:44 - 8:01	< LOD
14	PBZ/Sterilizer Operator	8:25 - 8:50	< LOD
15	Area/Sterilizer Room over Castle Sterilizer	8:25 - 8:57	< LOD
16	Area/Sterilizer Room near aerator	8:25 - 8:52	< LOQ

NIOSH Recommended Standard: Ethylene Oxide - Lowest Feasible Level

Key:
STEL - Short term exposure limit (calculated for the sampling time indicated)
mg/m^3 - milligrams of substance per cubic meter of air
< LOD - Less than the limit of detection of 0.3 micrograms per sample
LOQ - Limit of quantitation, 0.6 micrograms per sample

Table 3

University of Colorado Health Sciences Center
Denver, Colorado

Demographic Characteristics by Departments

	Central Supply N=21 # (%)	Dietary N=17 # (%)	Significance
Sex (female)	17 (81%)	13 (77%)	p = .736[a]
Race			p = .626[a]
White	6 (29%)	5 (29%)	
Black	9 (43%)	8 (47%)	
Hispanic	4 (19%)	1 (6%)	
Asian	2 (10%)	3 (18%)	
Current Smokers	9 (43%)	11 (65%)	p = .180[a]
Age (mean)	43 yrs	38 yrs	p = .252[b]
Length of Employment (mean)	9 yrs	6 yrs	p = .315[b]

[a] P-values were calculated using Fisher's exact test, or Mantel-Haenszel chi-squared tests.

[b] P-values were calculated using a t-test for a parametric distribution.

Table 4

University of Colorado Health Sciences Center
Denver, Colorado

Symptom Cluster Prevalence[1] by Department

	Central Supply N = 21 # (%)	Dietary N = 17 # (%)	Significance[2]
Constitutional *	9 (43%)	0 (0%)	.002
Cognitive	4 (19%)	0 (0%)	.081
GI	1 (5%)	0 (0%)	.553
Emotional	3 (14%)	0 (0%)	.158
Skin	4 (19%)	0 (0%)	.243
Respiratory	4 (19%)	0 (0%)	.081
PNS	4 (19%)	0 (0%)	.081
Irritative *	5 (24%)	0 (0%)	.041

1 As defined by a score of greater than or equal to 7.

2 P-values listed were calculated using Fisher's exact test.

* Statistically significant to p less than .05 comparing each exposed department (Central Supply) to the non-exposed department (Dietary).

Table 5

University of Colorado Health Sciences Center
Denver, Colorado

Mean Symptom Cluster Scores by Department

	Central Supply N = 21	Dietary N = 17	Significance[1]
Constitutional *	5.14	2.18	.001
Cognitive	3.33	1.71	.051
GI	2.62	1.35	.056
Emotional	3.19	1.88	.120
Skin *	3.62	1.82	.026
Respiratory *	4.10	1.35	.002
PNS *	3.19	1.00	.013
Imitative *	3.57	0.65	.005

[1] P-values were calculated using a t-test for a parametric distribution.

* Statistically significant to p less than .05 comparing each exposed department (Central Supply) to the non-exposed department (Dietary).

Table 6

University of Colorado Health Sciences Center
Denver, Colorado

Symptom Cluster Prevalence[1] by Job Title

	Central Supply Technicians N = 13 # (%)	Central Supply Clerks N = 7 # (%)	Dietary N = 17 # (%)
Constitutional	6 (46%)*	1 (14%)	0 (0%)
Cognitive	3 (23%)	1 (14%)	0 (0%)
GI	1 (8%)	0 (0%)	0 (0%)
Emotional	1 (8%)	2 (29%)	0 (0%)
Skin	3 (23%)	1 (14%)	1 (6%)
Respiratory	2 (15%)	2 (29%)	0 (0%)
PNS	4 (31%)*	0 (0%)	0 (0%)
Irritative	2 (15%)	4 (43%)*	0 (0%)

[1] As defined by a score of greater than or equal to 7.

* Statistically significant to p less than .05 (Fisher's Exact Test) comparing exposed technicians (Central Supply) and exposed clerks (Central Supply) to the non-exposed employees (Dietary).

Table 7

University of Colorado Health Sciences Center
Denver, Colorado

Mean Symptom Cluster Scores by Job Title

	Central Supply Technicians N = 13	Central Supply Clerks N = 7	Dietary N = 17
Constitutional	5.69*	4.43	2.18
Cognitive	3.54	3.43	1.71
GI	2.54	2.57	1.35
Emotional	3.00	4.00	1.88
Skin	4.08*	2.86	1.82
Respiratory	4.08*	4.43	1.35
PNS	4.00*	1.57	1.00
Imitative	3.69*	3.86*	0.65

* Statistically significant to p less than .05 comparing exposed technicians (Central Supply) and exposed clerks (Central Supply) to the non-exposed employees (Dietary). P-values were calculated using a t-test for parametric distributions.

Appendix A

ETHYLENE OXIDE QUESTIONNAIRE

NAME _____ Subject ID _ _ _ _ (1-4)
1 2 3 4

Please respond to each category.

AGE _____years (5-6)

SEX __Male __Female (7)
1 2

RACE __White (1) (8)
__Black (2)
__Hispanic (3)
__American Indian or Alaskan Native (4)
__Asian of Pacific Islander (5)
__Other (6)

When did you begin employment with Central Services, ___/___ (9)
mm/yy

Shift: _Day _Evening _Night (10)

Number of Hours Per Week _Less than 21 hours (1) (11)
_Between 21 and 30 hours (2)
_Between 31 and 41 hours (3)
_Between 41 and 51 hours (4)
_51 hours and over (5)

Below is a list of questions concerning symptoms you may have had.
For each question, put a check mark indicating how much you have been experiencing the IN THE PAST YEAR.

1. Have you TIRED more easily than expected for the amount of activity you do?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (12)

2. Have you felt WEAK for no apparent reason?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (13)

3. Have you had HEADACHES at least once a week?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (14)

4. Have you felt LIGHTHEADED of DIZZY at least once a week?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (15)

5. Have you had TROUBLE REMEMBERING things?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (16)

6. Have you had to MAKE NOTES to remember things?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (17)

7. Have you had difficulty CONCENTRATING?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (18)

8. Have you been CONFUSED or DISORIENTED?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (19)

9. Have you had trouble BUTTONING or UNBOUTTONING your clothes?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (20)

IN THE PAST YEAR

10. Have you noticed a LOSS OF APPETITE?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (21)

11. Have you had DIARRHEA?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (22)

12. Have you had INDIGESTION not caused by something you ate or drank?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (23)

13. Have you had NAUSEA not caused by something you ate or drank?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (24)

14. Have you felt DEPRESSED for no particular reason?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (25)

15. Have you felt IRRITABLE for no particular reason?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (26)

16. Have you been easily EXCITABLE for no particular reason?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (27)

17. Have you had changes or swings in your MOOD more than usual for you?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (28)

18. Have you been PERSPIRING for no particular reason (even when you haven't exerted yourself or it is hot)?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (29)

IN THE PAST YEAR

19. Has your SKIN been excessively DRY?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (30)

20. Have you had a SKIN RASH?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (31)

21. Have you had a SKIN SORES?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (32)

22. Has your SKIN been excessively ITCHY?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (33)

23. Have you had SHORTNESS OF BREATH?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (34)

24. Have you had a chronic COUGH?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (35)

25. Have you had CHEST PAIN?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (36)

26. Have you had CHEST TIGHTNESS?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (37)

27. Have you noticed a change in your SEX DRIVE during the past year?

_Not at all (0) _A little (1) _Moderately (2) _Quite a lot (3) (38)

IN THE PAST YEAR

28. Have you had any LOSS OF MUSCLE STRENGTH in your ARMS or HANDS?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (39)

29. Have you had any LOSS OF MUSCLE STRENGTH in your LEGS or FEET?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (40)

30. Have you had any NUMBNESS or TINGLING in your FINGERS lasting more than a day?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (41)

31. Have you had any NUMBNESS or TINGLING in your TOES lasting more than a day?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (42)

32. Have you had PAINFUL BURNING of your EYES?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (43)

33. Have you had PAINFUL BURNING of your EYES?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (44)

34. Have you had a PAINFUL BURNING of your NOSE or THROAT?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (45)

35. Have you had a PAINFUL ITCHING of your NOSE or THROAT?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (46)

36. Have you felt HIGH from the chemicals you work with?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (47)

IN THE PAST YEAR

37. List the two CHEMICALS you work the most with:

1._____
2._____

38. List the two CHEMICALS which give you the most symptoms:

1._____
2._____

39. Have you had a LOWER TOLERANCE FOR ALCOHOL (takes less to get drunk)?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (48)

40. Are you HAPPY with your job?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (49)

41. Do you think that you are getting SICK from your work?

_Not at all 0 _A little 1 _Moderately 2 _Quite a lot 3 (50)

42. Do you smoke CIGARETTES?

_Not at all 0 _Less than 1 pack per day 1 (51)
_1 to 2 packs per day 2 _More than two packs per day 3

43. Do you have any of the following? (52)

_ Asthma (1) _ Bronchitis (2) _ Emphysema (3)
_ Eczema (4) _ Allergies (5) _ Diabetes (6)
_ Heart Disease (7) _ Psychiatric Illnesses (8)

44. Are you taking any prescription MEDICATION? _Yes(1) _No(2) (53)
If yes, please list: 1._____
2._____
3._____