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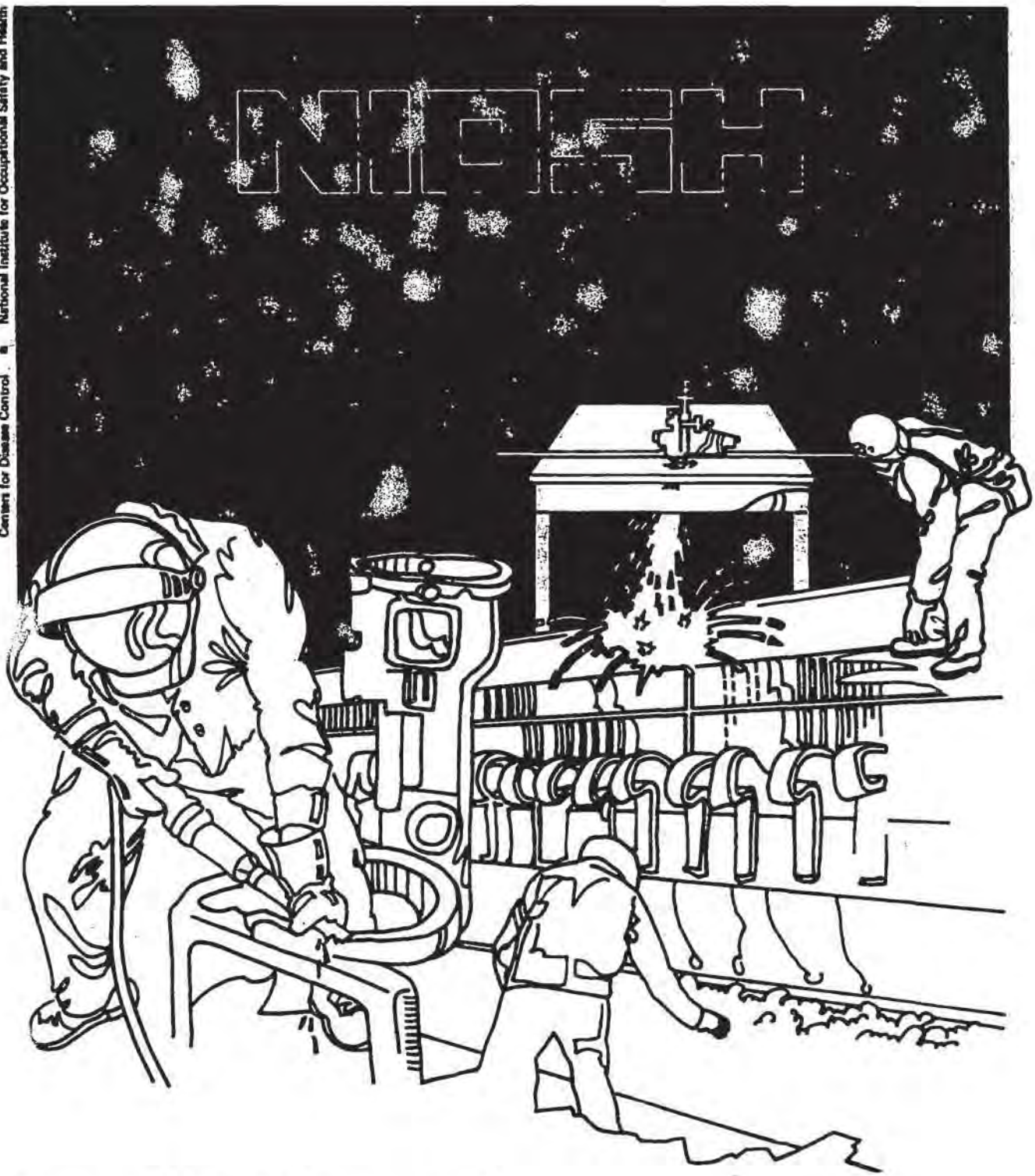

Health Hazard Evaluation Report

HETA 85-292-1811
CLARK COUNTY HOSPITAL
JEFFERSONVILLE, INDIANA

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 or 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.

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

HETA 85-292-1811
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CLARK COUNTY HOSPITAL
JEFFERSONVILLE, INDIANA

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I. SUMMARY

In early April 1985, the National Institute for Occupational Safety and Health received a request from Clark County Hospital, Jeffersonville, Indiana, to evaluate employee exposures while working in the central supply (CS) area. Employees were experiencing multiple symptoms including headaches, dizziness, mucous membrane irritation, and vomiting. Ethylene oxide (EtO), a chemical used to sterilize hospital supplies, was not believed to be the cause, based on previous environmental surveys.

NIOSH investigators visited the hospital on April 10-11, April 19, May 6-7, July 5, and December 11, 1985. During these visits EtO air samples were collected using MIRAN infrared analyzers, a portable gas chromatograph, and charcoal tubes. Air samples were also obtained for organics using charcoal tubes, for aldehydes using Orbo-22® tubes, and for hydrochloric acid (HCl), chlorine (Cl_2), carbon monoxide (CO) and carbon dioxide (CO_2) using gas detector tubes. An evaluation was made of the air exhaust systems as well as the possibility that EtO may leak from floor drains. Questionnaires were administered to 12 employees who worked in the CS area.

Time-weighted average (TWA) personal exposure concentrations for EtO ranged from 0.23 to 0.56 parts per million (ppm) among CS employees. These concentrations are below the OSHA standard of 1 ppm, but above the NIOSH recommended criterion of 0.1 ppm. Short term area concentrations of up to 77 ppm were detected in the cart storage area. The combined effects of lack of a dedicated EtO exhaust and the volume of exhaust air, which overloaded the exhaust system, resulted in a general room return grill being temporarily converted into a supply.

Area air concentrations of < 1.0 ppm for HCl, < 0.2 ppm for Cl_2, < 5.0 ppm for CO and up to 700 ppm for CO_2 were measured using gas detector tubes.

Symptoms reported by the employees included headache, respiratory problems, diarrhea, nose bleeds, fatigue, nausea, nervous problems, and dizziness. Additionally, employees reported smelling a "sweet" odor during some of the leaks. Most of these symptoms and the sweet odor are consistent with exposure to very high levels of EtO.

Based on these results, the investigators have concluded that a health hazard existed to employees from exposure to EtO. The main problem appeared to be the installation of EtO sterilizers without a dedicated exhaust, coupled with an exhaust system incapable of handling the quantity of air necessary when multiple exhausts were running. The symptoms reported and detection of a "sweet" odor by employees during some leaks suggest that previous exposures were much higher than the air concentrations measured during the NIOSH investigation. Recommendations are included in Section VIII to reduce personal exposures to EtO and to reduce the potential for future EtO leaks.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals) ethylene oxide, EtO, sterilization, dedicated exhaust, medical symptoms, headache, respiratory problems, nausea, dizziness, vomiting, nose bleed.

II. INTRODUCTION

On April 4, 1985, NIOSH received a request from the medical director of Clark County Hospital, Jeffersonville, Indiana, for an assessment of employee exposures in the central supply (CS) area where employees had periodically experienced adverse health effects. Reported symptoms included: eye, nose and throat irritation, respiratory symptoms, headache, face flushing or swelling, nose bleeds, and nausea. The requestor believed EtO was not the problem based on findings of previous environmental investigations. NIOSH investigators conducted site visits on April 10-11, May 6-7, May 13, July 5, and December 11, 1985, and February 27, 1987

Preliminary recommendations were presented in a meeting with hospital personnel on April 11, 1985. Subsequently findings, recommendations, and or project status updates were distributed to interested parties via letters on April 19, May 28, and August 20, 1985; January 23, 1986; February 6, April 20, and July 8, 1987.

III. BACKGROUND

Clark County Hospital was built circa 1940. At the time of the NIOSH investigation, the hospital had a capacity of 230 beds. The sterilizer operation had been moved from its original location to the CS area in 1980. At that time an AMSCO EtO sterilizer was installed. In October 1984 a second larger AMSCO EtO sterilizer was installed. The second sterilizer came complete with an exhaust system to remove EtO. The small sterilizer was retrofitted with an Envirogard® exhaust in February of 1985. Employees began complaining of a variety of symptoms shortly after installation of the second sterilizer.

The CS area included sterilization (clean room), decontamination, material handling (linen folding), sterile and miscellaneous storage, change rooms, and a supervisor's office (figure 1). The CS staff included 10 people on the day shift and 4 on the second shift. Two of these individuals ran the sterilizer operations and a third worked in the decontamination room. The other members spent most of their time in material handling where they wrapped supplies to be sterilized, worked in the stock room, etc. Sterilizer operators assisted with the other duties as time permitted.

The sterilization area included both sterilizers and an aeration cabinet; all of which were exhausted into a general ventilation system (figures 1,2). The hospital was using a mixture of 12% EtO and 88% dichlorodifluoromethane (freon-12®).

The larger EtO sterilizer (AMSCO model 2047) preconditioned the load to 130°F at a pressure of 26.8 pounds per square inch (PSIG) prior to sterilization. The sterilization period was 1.75 hours at 8 to 8.5 PSIG, after which, there were a number of vacuum purges with continuous air flushing for 16 hours.

The smaller sterilizer (AMSCO model 2025) had a precondition period at 130°F for about 20 minutes. The sterilization cycle lasted 1.75 hours at 10 PSIG, followed by vacuum purges. Next the sterilized items were moved to an aerator where they remained for 12 hours. Prior to the NIOSH visit, surveys and/or inspections had been conducted by AMSCO and Indiana State OSHA. Several small leaks were found but no major problems detected. This had lead the requestor to report that EtO was not the cause of the health effects employees were reporting.

IV. EVALUATION DESIGN AND METHODS

This evaluation began with the anticipation that EtO may not have been responsible for the reported health effects. This necessitated evaluating other potential causative agents. The investigators suspected that a foreign chemical might be migrating to the CS area because the EtO/FREON-12® mixture was reported to be the only chemical used in the area. A literature review revealed other potential chemicals (Table 1) which are known to cause some of the reported symptoms.

During the initial survey on April 10-11, 1985, air monitoring was conducted for EtO using charcoal tubes, for organics using charcoal tubes, for aldehydes using Orbo-22® tubes (n-benzylethanolamine on Supelpak® 20F-20/40), and for Cl_2, HCl, and CO using direct reading gas detector tubes; because these chemicals are known to cause at least some of the reported symptoms. CO_2 air concentrations were also evaluated to assess the adequacy of outside air incorporated into the ventilation system. EtO was still considered a likely causative agent because most of the symptoms reported by employees have been associated with EtO exposure.

The second round of visits occurred in May and June 1985. During these visits air samples were collected for EtO using MIRAN infrared analyzers, a portable gas chromatograph, and charcoal tubes connected to battery-operated pumps. Additionally, the engineering control system was evaluated using smoke tubes, a velometer, and a smoke generating system which was activated inside the sterilizer.

Non-directed questionnaires were administered to 12 of the 14 employees who worked in the CS area. Each employee was asked their age, how long they had worked as CS technicians, if they were experiencing any health effects they believed were caused by their work environment, and if they were experiencing health effects - what the symptoms were.

The fifth visit, conducted on December 11, 1985 consisted of evaluating the possibility that EtO was leaking from floor drains, in the cart storage or steam clean/cart wash rooms. The drain in the cart storage area was isolated by placing a small plexiglass box over it. Air was sampled from the box using a MIRAN infrared analyzer Model 1-A, attached via flexible tubing to the drain. A MIRAN infrared analyzer Model 80 was used to measure EtO at various locations including the floor drain in the spray wash area.

Additional information on sampling and analytical techniques is listed in Table 2.

V. EVALUATION CRITERIA

A. Environmental 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 Recommended Exposure Limits (RELs), 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.[1-3] 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 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.

B. Ethylene Oxide

Ethylene oxide is a colorless gas at room temperature and pressure. It has a characteristic ether-like odor with a widely variable odor threshold in humans; the mean odor threshold is about 700 ppm (1260 mg/m^3). It is completely miscible with water, alcohol, acetone and most organic solvents. It is highly reactive and potentially explosive in the presence of alkali metal hydroxides. In order to reduce explosion hazards, it is often in mixtures, such as 12% EtO and 88% halocarbons.[4]

Acute toxic effects of EtO in humans and animals include skin, respiratory, and eye irritation; skin sensitization; nausea vomiting, and diarrhea; and nervous effects. Chronic effects include anemia, respiratory irritation, and chromosomal aberrations.

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

The findings were corroborated by a study conducted in 1982 by NIOSH.[6] In this study male Fischer 344 rats were exposed to EtO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm (80 rats per exposure group). Increases in the incidence of mononuclear leukemia, peritoneal mesothelioma, and cerebral gliomas were observed among the EtO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of EtO.[7-9] Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that produced EtO.[7] In addition to EtO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloroethyl) ether. Among 89 exposed workers, a statistically significant (p less than .01) excess of leukemia (2 observed versus 0.14 expected) and stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to EtO; however, ethylene oxide and ethylene dichloride were the prime suspects.

In a study in anthor Swedish facility that used EtO to sterilize hospital supplies, Hogstedt reported three cases of leukemia.[8] The 8-hour TWA exposure for EtO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this cohort. One of the cases was exposed to benzene, a known leukemogen, and it was speculated that the combined exposure of EtO and methyl formate might produce a unique risk.

Morgan, et al, conducted a retrospective cohort mortality study of workers involved in the production of EtO at a Texaco Facility.[9] A total of 850 workers were included in the study, of which 767 were potentially exposed to EtO. No EtO was detected in most samples taken in the production area, and all measurements in this area were below 10 ppm. No cases of leukemia were observed in this study; however, the authors estimated that the lowest relative risk that they had a high probability of detecting (80% power) was 10.5.

EtO is also a potent alkylating agent, a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa, and known to cause chromosomal aberrations in a number of animal studies and epidemiologic investigation .[4,6,10-19]

C. Applicable Standards and Recommended Levels

In 1977, NIOSH recommended a ceiling level of 75 ppm for EtO as determined during a 15 minute sampling period.[4] This level, however, was set prior to the recognition of the carcinogenic potential of EtO. Based on recent findings, NIOSH now recommends that EtO exposures not exceed 5 ppm for a maximum of 10 minutes per day and that exposures be controlled to less than 0.1 ppm determined as an 8-hour TWA (NIOSH Policy Statement, July 20, 1983).

The ACGIH recommended a TLV of 10 ppm for an 8-hour TWA based on data available prior to 1982. However, in 1982, the ACGIH issued a notice of intended change in which it was proposed that the TWA concentration be lowered to 1 ppm.[20] This recommendation was reviewed and adopted in 1984. ACGIH has also designated EtO as an A2 carcinogen.[21] 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 of more animal species by appropriate methods.

Prior to June 22, 1984, the OSHA Permissible Exposure Limit (PEL) for EtO was 50 ppm as a TWA concentration for an 8-hour workshift.[22] OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.[23] In addition, an "action level" of 0.5 ppm as an 8-hour TWA was established (by OSHA) as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. The Environmental Protection Agency (EPA) supported the OSHA PEL of 1 ppm in the Federal Register (June 22, 1984).[24]

VI. RESULTS

A. April, May and July Surveys (1985)

During the April 1985 survey all direct-reading samples measured relatively low concentrations. EtO concentrations collected with a MIRAN infrared analyzer ranged from less than 0.01 ppm to 5.0 ppm. The higher concentrations were leak measurements. As employees spent no more than 2-3 hours in the sterilizer room, their TWA exposures were probably less. Analytical problems prevented any quantitation of the long-term personal or area samples.

Area bulk air samples collected on charcoal tubes for organic compound screening and quantitation contained Freon-12®, ethanol, trace amounts of toluene, and a chemical thought to be methyl isobutyl ketone. No aldehydes were detected on two area bulk air samples. Detector tube air samples collected for HCl, Cl_2, CO, and CO_2 measured air concentrations of <1.0 ppm, a trace- <0.2 ppm, <5.0 ppm, and 500 to 700 ppm, respectively. Concentrations for CO_2 were in the range indicating adequate outdoor air was being incorporated into the CS area.

Results of May 1985 personal and area long-term samples for EtO are presented in Table 3. Full-shift TWA air concentrations collected on CS area technicians ranged from 0.23 to 0.56 ppm. All values are below the OSHA PEL of 1 ppm, but above the NIOSH REL of 0.1 ppm (as an 8-hour TWA). NIOSH recommends that EtO be regarded as a potential occupational carcinogen and, as such, believes there is no documented safe level, but that reducing the exposure to the lowest level feasible will minimize the hazard. The highest concentration (0.97 ppm) was obtained on a NIOSH investigator who was evaluating EtO leaks. Concentrations measured on three other samples worn by NIOSH investigators were 0.12 to 0.26 ppm.

Results of instantaneous samples collected on May 5-6, 1985, to evaluate potential sources of EtO leaks are presented in Table 4. These values show that during the early stages of the exhaust cycle, very high concentrations of EtO were present at breathing zone height in the cart wash area (figure 1). These readings lasted for only a few minutes during the initial stage of the exhaust cycle. At 1718 (5:18 P.M.) EtO breathing zone concentrations were 65 to 77 ppm, but by 1730 the concentration had fallen to 15 ppm and at 1754 the concentration was 1 to 2.4 ppm. Most of the other high readings were measured within a few inches of suspected EtO leaks, such as the gas cylinder couplings.

Results of the employee interviews are presented in Table 5. Ten of 12 employees reported at least two of a variety of symptoms. Symptoms reported by at least two employees included headache, reported 7 times; respiratory problems, reported 5 times; nose bleeds, diarrhea, and face flushing or swelling, each reported 4 times; fatigue, and nervous symptoms, each reported 3 times; and dizziness, nausea or vomiting, each reported 2 times. Most of these symptoms have been associated with exposures to high concentrations of EtO. Other symptoms, reported 1-2 times included: weight loss, muscle ache, sinus problems, eye discharge, elevated blood pressure, blurred vision, and skin irritation.

Several problems were detected in the ventilation system (figure 2). Foremost was the exhaust ventilation system into which the two Envirogard® systems and the aerator are vented--there are two AMSCO sterilizers, 8.8 ft^3 and 30 ft^3 (each equipped with an AMSCO Envirogard® EtO exhaust system), and one AMSCO aerator. The general exhaust ventilation system also has two ceiling vents in the cart wash rooms and two in the decontamination room as well as a few other vents in rooms on this (the basement) and other floors.

At the end of the sterilizer cycle, the Envirogard® systems exhaust a large quantity of EtO. For the small system, over 150 grams of EtO are evacuated from the chamber in the first ten minutes of the purge cycle, enough to yield a concentration of 700 ppm in a room with dimensions of 20 ft by 25 ft by 8 ft-a volume of 4,000 ft^3. The large sterilizer evacuates over three times this amount.

Running the large sterilizer Envirogard® system causes almost no air to be exhausted by the vents in the cart wash rooms. Running the exhaust system for both the large and small sterilizers caused reverse airflow in the exhaust system for the cart wash rooms, and thus some EtO from the aerator vent and the large sterilizer exhaust flowed out of these vents into the cart wash rooms (figure 3). This problem was demonstrated with smoke introduced into the sterilizer evacuation line, during the July 1985 visit. No smoke was observed coming out of the drains during this test.

Air readily flowed from the cart wash rooms through the open doorways into adjacent rooms. Even with no Envirogard® systems running, the ceiling vents in the cart wash rooms did not exhaust much air. Running the small sterilizer Envirogard® system alone did not appreciably affect the cart wash room ventilation.

The airflow into the ceiling exhaust vents in the decontamination room was decreased by running either (or both) of the sterilizer Envirogard® systems, however reversed flow was not observed. For these vents, the smaller sterilizer had a greater effect, in decreasing the air flow into the exhaust.

The connection of the Envirogard® fan to the circular branch duct above the small sterilizer leaked air into the decontamination room when the fan was running. Although the leak was small, the air from the location of the leak was not captured by the exhaust vent over the sterilizer.

The exhaust velocity through the slot above the door of the small sterilizer of the clean room side was approximately 50 cfm with an average slot velocity of 500 ft/min. The velocity for the slot on the decontamination room side was approximately 40 percent higher, although this door is never opened under normal circumstances. If the door is opened more than 1/2 inch, not all of the air flowing up from the crack between the door and the sterilizer is captured by the slot.

At the end of one cycle, the door was opened approximately 2 inches. A peak concentration of greater than 25 ppm was measured (using a MIRAN model 1-A infrared analyzer) before the door was closed to a 1/2-inch opening. A smoke tube showed that much of the hot-air coming from the door opening was by-passing the slot hood and rising to the ceiling. On another cycle for which the door was opened less than 1/2 inch, the concentration above the sterilizer door never exceeded 3 ppm (by IR). If not held in position, the door would swing fully open.

The load transfer operation does not seem to be a source of elevated EtO exposure. Exposures less than 1 ppm for approximately 2 minutes were measured (using gas sampling bags and a portable GC) in the breathing zone of the operator. During one load transfer, the operator had to bend down close to the load in the sterilizer because one cart was not properly adjusted to the height of the sterilizer opening, causing difficulty in pulling the load from the sterilizer. This could potentially increase the exposure although the short-term sample did not show an increase compared to the other load transfer sampled.

The cabinets enclosing the sterilizers were neither adequately ventilated nor sealed, so that any EtO inside the cabinet is carried up and out of the openings in the top of the cabinet by the heat of the sterilizer. On the small sterilizer, the airflow up through the cabinet due to thermal effects was almost double the amount exhausted by the Envirogard® ventilated air gap in the sterilizer drain line. For the small sterilizer, some of this would be captured by the ceiling exhaust vent above the sterilizer, but most would be carried out into the decontamination room. For the large sterilizer, all the air rising to the top of the cabinet would escape into the clean room.

To make this situation worse, in the case of the large sterilizer, high concentrations (600-1000 ppm by GC) were measured inside the bottom of the cabinet at the start of the purge cycle. Outside the cabinet, concentrations peaking at around 5 ppm (by IR) were measured at breathing-zone height in front of the sterilizer and near the ceiling along the side of the sterilizer above the EtO supply cylinders. This sterilizer had a tube connecting the leak cup of the vacuum pump to the drain, and the air inlet slots of the ventilated air gap (referred to as the liquid gas separator) were covered with tape.

Much lower concentrations (2 - 25 ppm by GC) were measured in the bottom of the cabinet enclosing the small EtO sterilizer. This sterilizer did not have a tube connecting the leak cup of the vacuum pump to the drain, and the ventilated air gap inlet slots were open.

It was not clear if the drains were partially responsible for the high concentrations measured in the cart wash rooms using a MIRAN infrared analyzer model 1-B, although if the traps were dry, this would allow EtO in the drain to escape into the room. Elevated concentrations (1-15 ppm by GC) were measured in the bottom of the cabinet enclosing the small steam sterilizer, which was on the same drain line (upstream) as the small EtO sterilizer. However, only slightly elevated concentrations (1-2 ppm by GC) were measured in the bottom of the cabinet enclosing the large steam sterilizer, which is (upstream) on the same drain line as the large EtO sterilizer. These results are somewhat contradictory, especially considering the high concentrations measured with the MIRAN 1-B above the clean-out adjacent to the large steam sterilizer.

The fact that water collects on the floor under and around the sterilizers indicates that there is a drain problem. The cause could be nothing more than the drains being partially clogged, or it may be that the drain vents are not functioning properly.

B. December Survey (1985)

During the previous visits, EtO exposure problems were identified and possible source of EtO emissions were characterized. The suspected sources were the drains in the cart wash room and the ventilation system serving the sterilizers and decontamination areas of the department.

During the December visit, the drain system was evaluated using a capture box and infrared analyzers. A capture box was sealed over a floor drain, which was suspected of having a dry trap, in the cart wash area. The air inside the capture box was continuously monitored for EtO using a MIRAN model 1-A infrared analyzer and for water vapor concentration with a relative humidity instrument. A MIRAN model 103 infrared analyzer was used to detect EtO at various points in the cart wash area outside the capture box.

No increased response of the infrared analyzer attached to the capture box, was observed during the purge cycles for either of the gas sterilizers. An infrared analyzer response not associated with any events related to EtO emission was observed and attributed to an unknown contaminant.

The MIRAN 103 did not detect any EtO coming from the ventilation grilles in the cart wash area during the purge cycle of the large sterilizer with the small sterilizer Envirogard® fan off, a procedure which had been previously recommended to the hospital.

VII. DISCUSSION AND CONCLUSIONS

Based on these results, the NIOSH investigators believe that a health hazard existed in the CS area due to employee exposure to ethylene oxide. While the highest breathing zone air concentrations measured during this study were approximately 77 ppm, the severity of reported health effects and the "sweet" odor detected by several employees suggest much higher exposures were present during some of the earlier leaks.

These results emphasize two important factors concerning EtO sterilization operations. First, the importance of short term criteria for EtO exposures. It is possible to have very high exposures to EtO for a short period, but have a relatively low TWA. For example, an exposure of 200 ppm for a 2-minute period (e.g. during the initial stages of an EtO sterilizer exhaust cycle) combined with an exposure of 0.1 ppm for the remaining 7.93 hours of an 8-hour shift would result in an 8-hour TWA of 0.52 ppm. Second, in evaluating this type of problem,

direct reading instruments such as the MIRAN infrared analyzers used by the NIOSH investigators are invaluable. Without such instruments it is very difficult if not impossible to evaluate high eposures that may last only a minute or two.

There have been numerous studies of ethylene oxide exposure by various government and private groups. NIOSH has conducted approximately 32 health hazard evaluations (HHEs), in which EtO exposures were investigated. These include investigations of hospitals as well as other types of facilities. NIOSH has distributed final determinations reports for 16 of these HHEs.[19,25-38] NIOSH has recently completed an industry wide study evaluating ethylene oxide exposure levels of hospital and nursing home employees.[39] NIOSH has also conducted industrywide studies evaluating the toxicity of and control methods for EtO in medical facilities.[4,40]

In the study of hospital and nursing home workers, 8-hour TWA EtO air concentrations collected in 12 facilities (one of which was Clark County), ranged from below the laboratory limit of detection to about 4.75 ppm (figure 4). Nine of the other 11 facilities had mean concentrations 0.5 ppm or less. The exposure levels measured at Clark County are in the range measured in these facilities.

Even though many other studies have reported higher exposure levels of EtO than was measured at Clark County, employee symptoms of the severity experienced by Clark County employees have not often been reported. This, and the fact that several employees reported smelling a "sweet" odor, indicates that much higher EtO concentrations were present during at least some of the leaks. The odor threshold for EtO is reported to range from 290 to 780 ppm.[41] Thus the NIOSH investigators believe it is possible that CS area employees were exposed to several hundred ppm of EtO.

VIII. RECOMMENDATIONS

Recommendations were provided to Clark County Hospital for two distinct purposes, the first set of recommendations were temporary to alleviate ongoing problems and prevent any additional leaks, and enable the hospital to operate safely until renovation could be completed on the existing exhaust system. The temporary recommendations were as follows:

1. The small sterilizer has less impact on the exhaust system so it should be used when only one sterilizer is needed.

2. When the sterilizer exhaust cycle is initiated, employees should leave the area for at least 15 minutes.

3. When employees crack the door on the small sterilizer it should be not more than 1 inch at the widest point.

4. Doors to the various rooms should be kept closed. This should aid the containment of possible emission sources and the elimination of EtO through the exhaust ventilation system.

5. When gas cylinders are changed, a soap solution should be used to check for leaks.

6. The tape should be removed from the openings of the ventilated air gap in the discharge line under each sterilizer. With tape covering the openings the ventilation won't work effectively and it is no longer an air gap as required by plumbing code. The tape does not help reduce EtO emissions.

7. Inspections of the entire system (sterilizers and exhaust system) should be made at least once a week, to check for EtO leaks and/or equipment malfunctions (i.e., defective fan belts).

8. The seal located on the top of the door on the large gas sterilizer is deteriorated and should be replaced.

9. The exhaust pipe on the Envirogard® for the small gas sterilizer needs more caulking.

10. A warning device should be installed on the exhaust system to signal if it is not working properly. One such device is a sail switch.

The second set of recommendations were designed to provide permanent improvements in the working conditions that were observed. Central to these improvements is the intent to reduce the potential for exposure to excessive levels of EtO.

1. A dedicated exhaust system should be installed for the two EtO sterilizers and the aerator. It might be possible to utilize the existing system to some degree. However, it might be more practical to install a new system for the sterilizers and the aerator so that the room exhaust vents of the existing system are retained separately from the sterilizer/aerator exhaust. The most important factor is to separate the sterilizer/aerator exhaust from the general room exhaust through which the NIOSH investigators believe most of the leaks have occurred.

2. An exhaust hood should be built for the EtO tanks at both sterilizers. Additionally, the EtO sterilizer cabinets should be equipped with an exhaust to keep them under a negative pressure. Both these modifications could be incorporated into the new dedicated EtO exhaust system.

3. A venting valve should be installed on all EtO tanks. This will help reduce EtO leaks during changing of the tanks. One such system is available from the sterilizer manufacturer.

4. The output of the compressor relief valve should be connected to one of the openings in the top of the ventilated air gap.

5. Weekly inspections should be made to detect and eliminate any EtO leaks.

6. After all modifications are completed, a follow-up environmental investigation should be conducted to document personal TWA and ceiling EtO exposure levels.

IX. Effectiveness of Recommendations

On February 27, 1987, two NIOSH investigators returned to Clark Coun[illegible] Hospital to determine how many of the recommendations given to h[illegible] representatives had been implemented and assess how effective the recommendations were.

During the previous year (February 1986 - February 1987), employees had not complained of symptoms and passive badge monitoring by hospital personnel indicated exposures were relatively low. EtO sensors had been installed at 6 locations throughout the CS area. Plain opening and slot exhaust hoods had been installed above EtO gas cylinders and sterilizer doors, respectively. Total airflow had been increased for the CS area exhaust system. There appeared to be adequate ventilation for the primary sources of EtO. Additionally, modifications had been made in the physical route of exhaust ducts for the aerator and the large EtO sterilizer (figure 5). As a result of the changes, reversed air flow no longer occurred in the cart wash exhaust ventilation duct, even when both EtO sterilizer exhausts were running.

There are some additional improvements that can be made. For example, plain opening hoods, above the EtO gas cylinders, should be converted into canopy hoods.[42] Addition of at least partial enclosures to the canopy hoods would also be beneficial (figure 6). The tape which was still covering the ventilated air gaps, should be removed. This problem has been previously discussed in this report.

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XII. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Publications Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. 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:

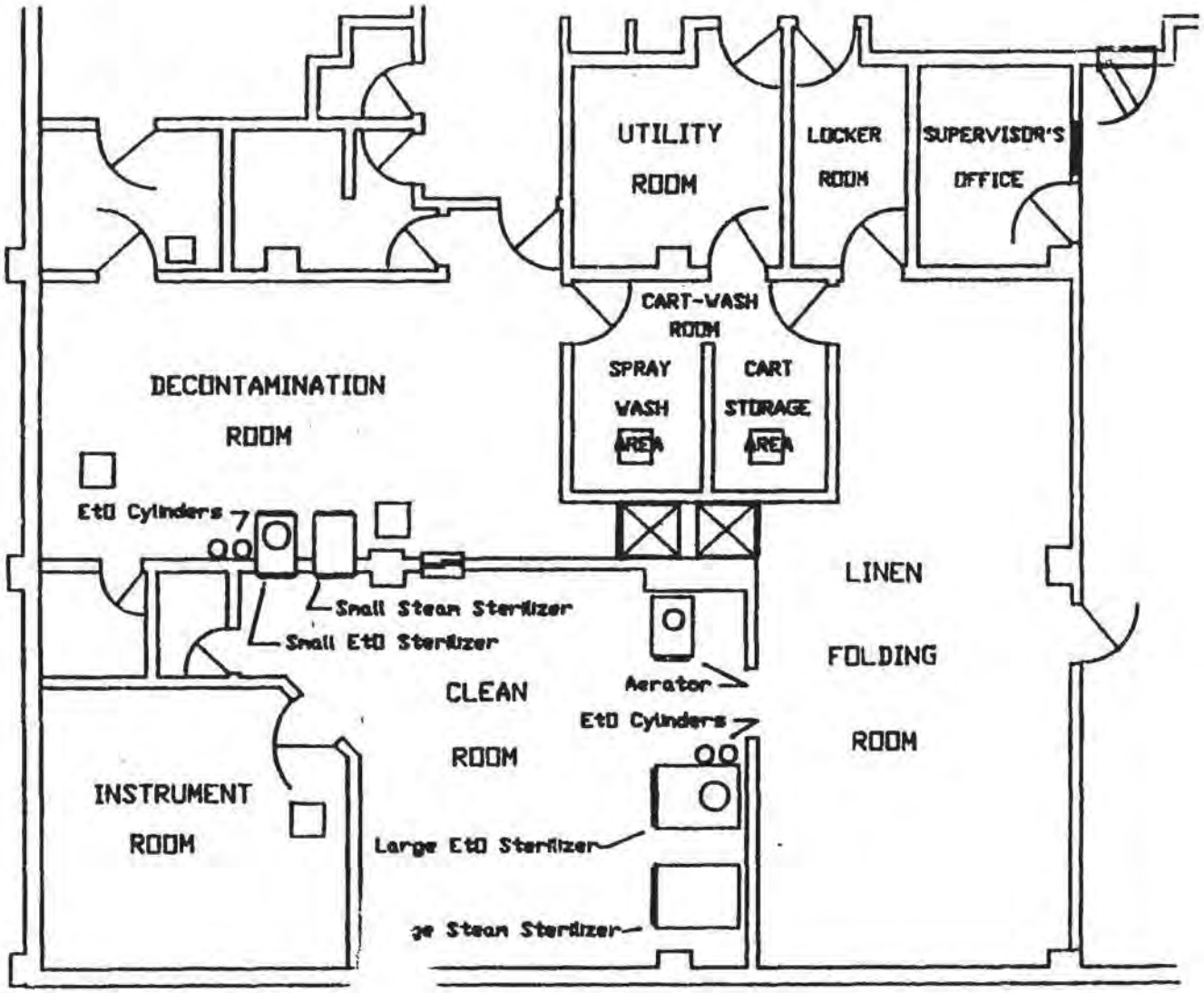
1. Clark County Hospital, Jeffersonville, Indiana
2. OSHA, Region V

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.

Figure 1

Diagram of CS Area
Clark County Hospital
Jeffersonville, Indiana

HETA 85-292



Figure

Diagram of Initial Ventil[illegible]n Configuration
as of May 1[illegible]
Clark County H[illegible]pital
Jeffersonville, Indiana

HETA 85-292

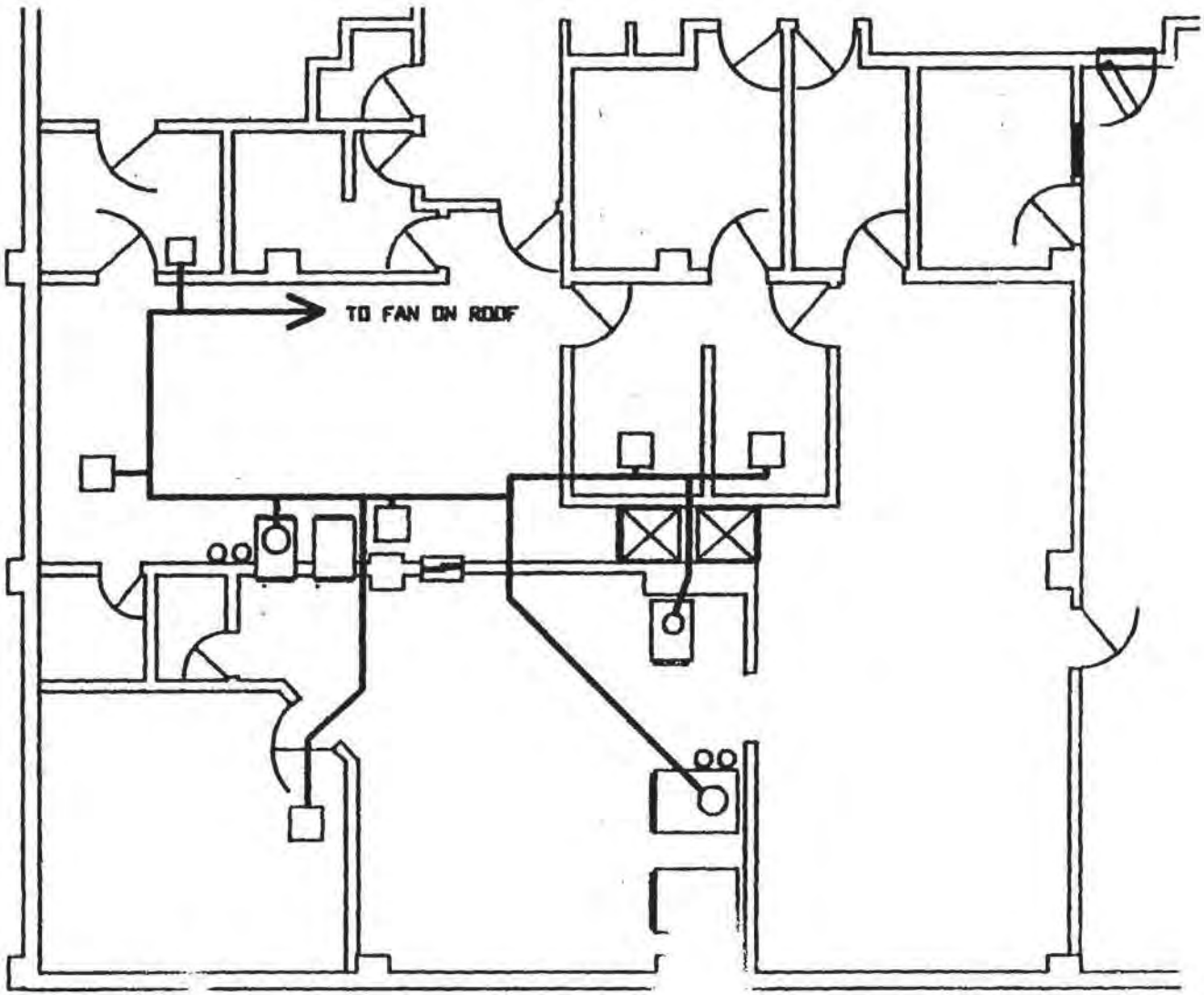
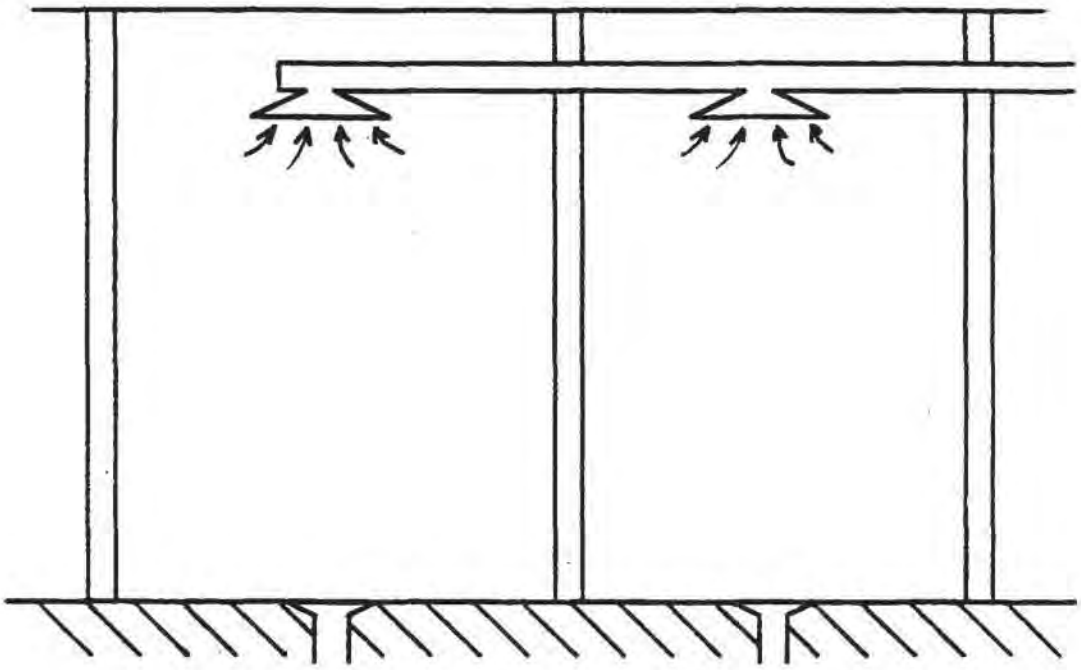


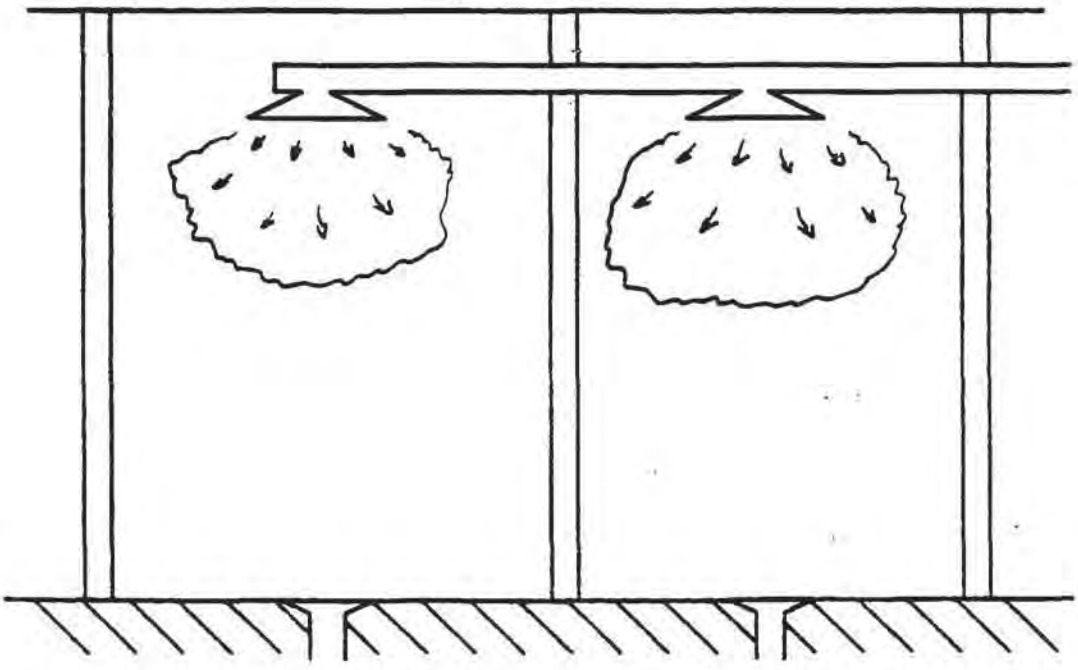
Diagram of Cart Wash Room
Clark County Hospital
Jeffersonville, Indiana

HETA 85-292

INITIAL VENTILATION CONFIGURATION



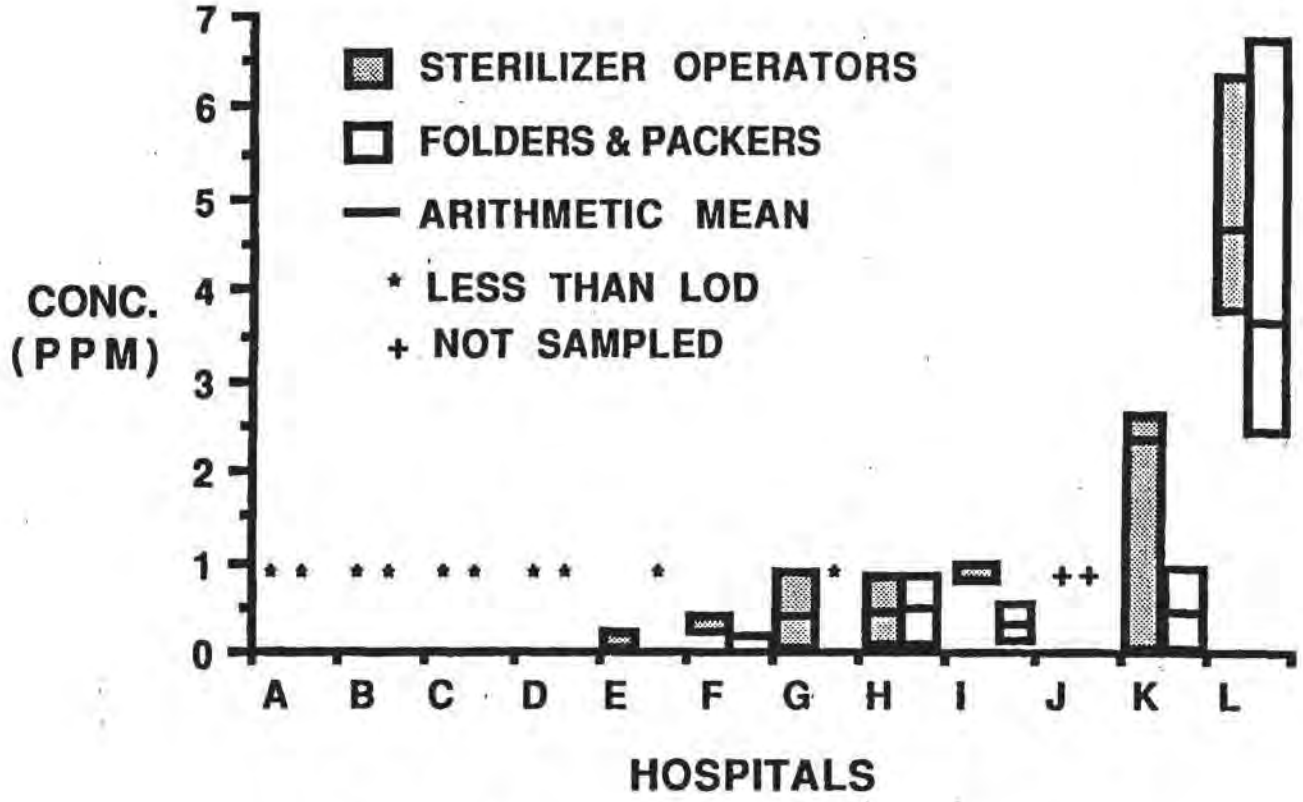
STERILIZER FANS NOT RUNNING



STERILIZER FANS RUNNING

Figure 4

Personal 8-hour TWA Ethylene Oxide Exposure by Job and Hospital



NOTE: These data were collected during a NIOSH Industry Wide Study, see reference no. 37.

Figure 5

Diagram of Corrected Ventilation Conf[illegible]ation
as of February 1987
Clark County Hospital
Jeffersonville, Indiana

HETA 85-292

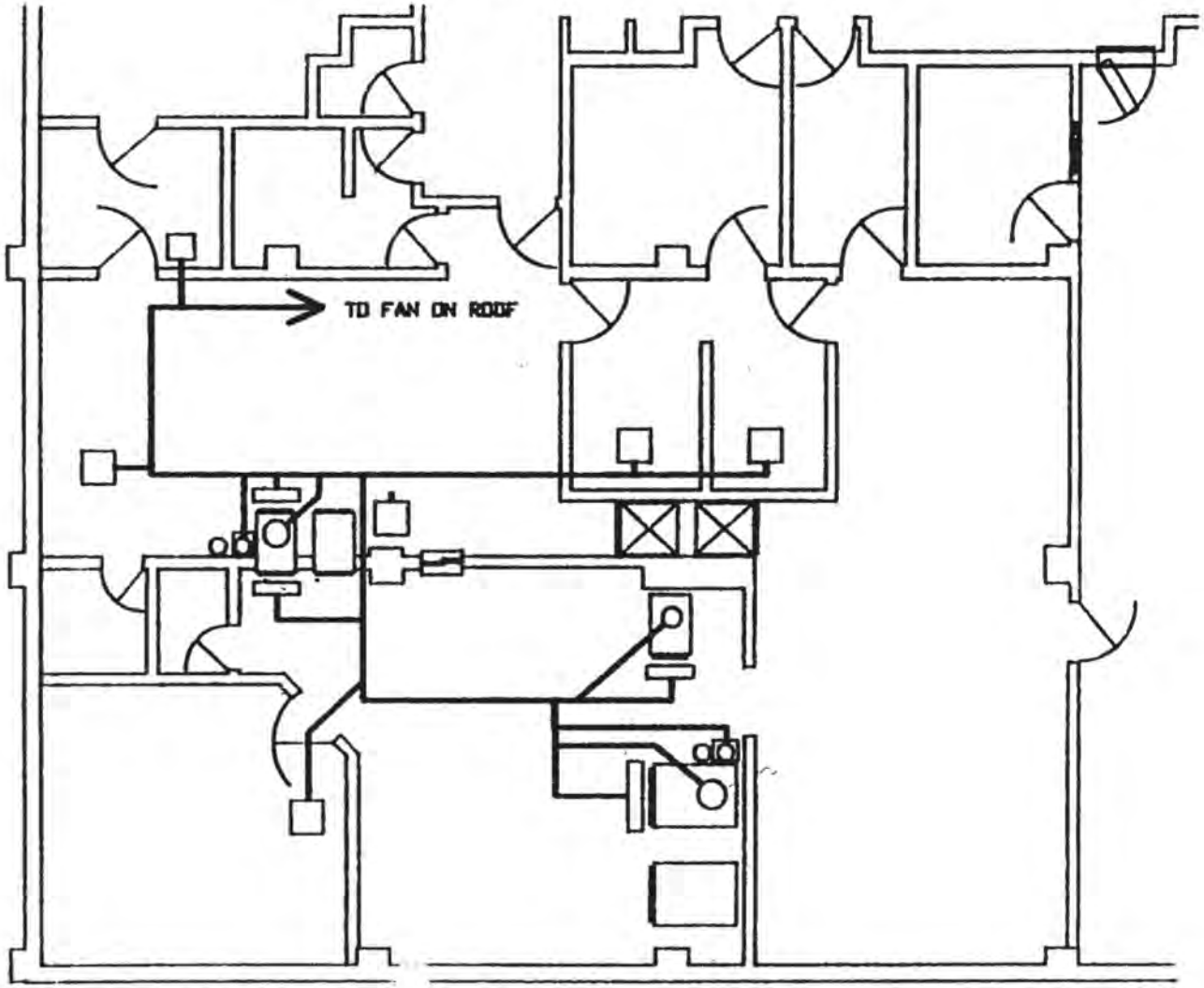
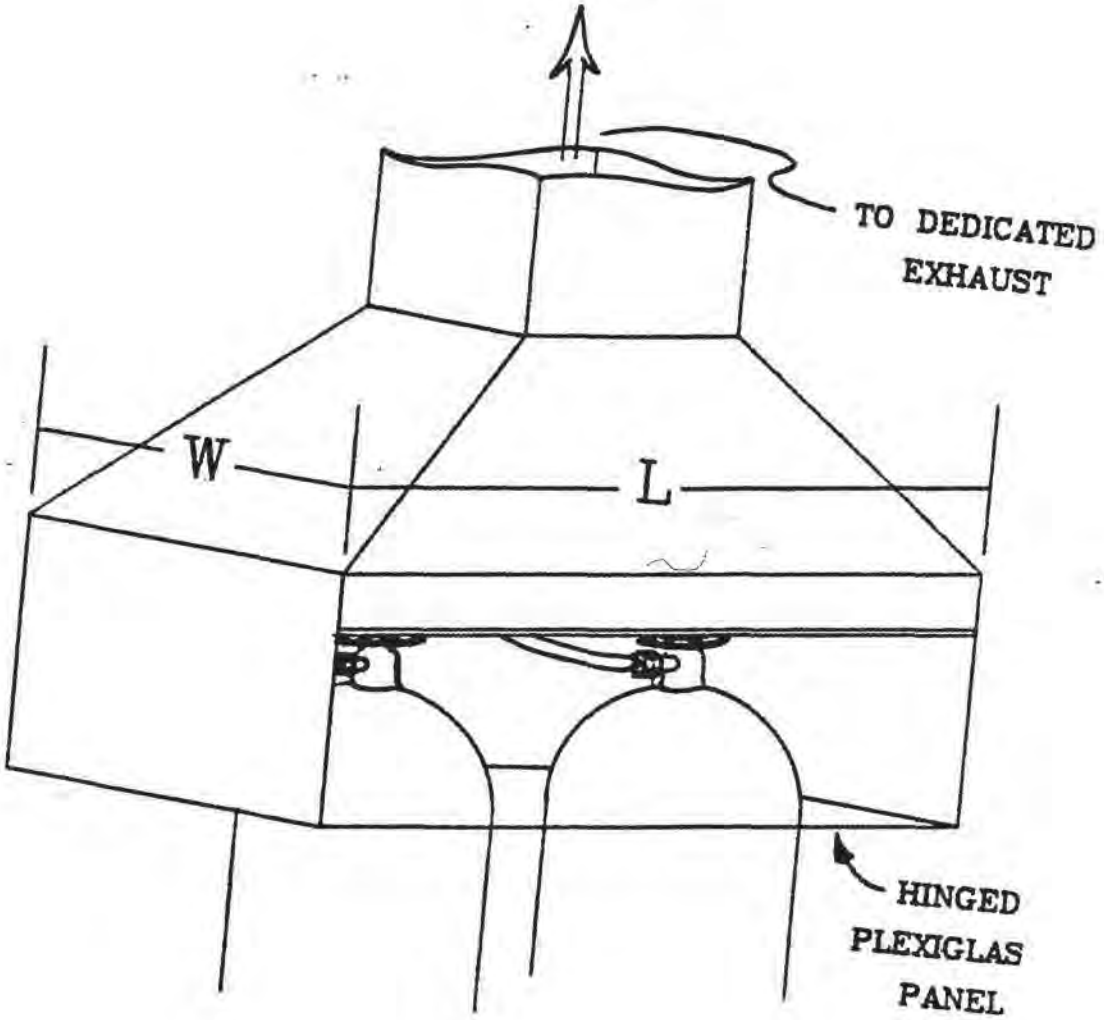


Figure 6

Recommended Cylinder Hood Design
Clark County Hospital
Jeffersonville, Indiana

HETA 85-292



The hinged plexiglas panel can be raised for removing the empty cylinders and sliding in new ones. In the down position, the plexiglas panel prevents the worker's face from being sprayed when the supply lines are being disconnected/reconnected. The exhaust flow rate should be 100 cfm per square-foot of area (LW) of hood opening.

Table 1

Chemicals Which Cause Symptoms
Like Those Reported by CS Area Employees

Clark County Hospital
Jeffersonville, Indiana
HETA 85-292

Chemical Name	Chemical Formula	Health Effects Associated with Exposure
Ethylene glycoldinitrate	$C_2H_4(NO_3)_2$	throbing head; dizziness; nausea, vomiting; abdominal pain; hypotens; flush; palpitations; methemoglobinemia; delirium, depress central nervous system; angina; skin irritation
Epichlorohydrin	C_3H_5OCl	nausea, vomiting; abdominal pain; respiratory distress, cough; cyanosis; irritation of eyes and skin with deep pain; considered carcinogen
Ethylene chlorohydrin	CH_2ClCH_3OH	irritation of mucous membranes; nausea, vomiting; vertigo, incoordination; numbness, vision disturbance; headache; thirst; deliruim; low blood pressure, collapse, shock, comma
Gluteraldehyde*	$OCH(CH_2)_3CHO$	irritation of eyes, nose, throat and skin; skin sensitization; headache
Formaldehyde	HCHO	irritation of eyes, nose and throat, burning eyes; cough; bronchial spasm; pulmonary irritation; dermatitis; nausea, vomiting; loss of consciousness
Chlorine	Cl_2	burning of eyes, nose and throat; lacrimation; rhinorrhea; cough; chocking; nausea, vomiting; substernal pain; headache; dizziness; syncope; pulmonary edema; pneumonia; hypoxia; dermatiti
Hydrochloric acid	HCl	inflammation of nose and throat and laryngeal; cough, burning throat, chocking; burning eyes, skin; dermatitis
Ethylene oxide	EtO	irritation of eyes, nose, and throat peculiar taste; vomiting; diarrhea; dyspnea; cyanosis; pulmonary edema; drowsiness; weakness; incoordination; burns eyes, and skin; frostbite potential carcinogen

Health effects are as listed in NIOSH pocket guide to chemical hazards except for * which were obtained from 1986 ACGIH TLV Documentation.

Ta

Sampling and Anal Techniques

Clark Count pital
Jeffersonvil ndiana

HETA 85-292

Chemical	Flow	Sampling Device or Media	Analytical Technique
Ethylene oxide TWA samples	20 cc/min	2 Charcoal Tubes in series	Each sample analyzed using NIOSH method no. 1607, analysis conducted using a gas chromatograph equipped with an electron capture detector
Ethylene oxide instaneous/ grab sample		A. MIRAN infrared analyzer models 1-A, 1-B, 80, 103	Direct reading
		B. Portable gas chromatograph	Direct reading
Aldehydes*	100 cc/min	Orbo-22 tubes	Samples desorbed with toluene and screened for 8 aldehydes using a gas chromtograph equipped with a flame ionization detector.
Organics	100 cc/min	Charcoal tubes	Samples desorbed with 1 ml CS_2 and screened initially using a gas chromatograph with a flame ionization detector, then quantitated for specific organics using gas chromatograph/mass spec.
HCl, Cl_2, CO, CO_2	100cc/stroke	Dräeger gas detector tubes and pump	Colorimetric - direct reading

Table 3

Ethylene Oxide Air Concentrations
Personal and Area Long-Term Samples

Clark County Hospital
Jeffersonville, Indiana
HETA 85-292

May 6-7, 1985

Sample Number	Location/Job	Date	Sample Time	Volume (liters)	Air Concentrations (ppm)
101	CS Technician	5/6	1502-2253	9.61	0.25
102	CS Technician	5/6	1502-2259	9.71	0.56
204	CS Technician*	5/7	1341-2111	10.4	0.23
205	CS Technician*	5/7	1340-2110	9.9	0.46
103	NIOSH Investigator	5/6	1515-1921 2018-2146	7.59	0.34
105	NIOSH Investigator	5/6	1453-1920 2017-2308	8.83	0.25
201	NIOSH Investigator	5/7	1235-2005	9.2	0.26
	NIOSH Investigator	5/7	1241-1806	6.96	0.97
203	NIOSH Investigator	5/7	1300-2038	10.16	(0.1)
104	Area Sample- Wrapping Room	5/6	1527-2227	9.28	0.75
220	Area Sample Wrapping Room	5/7	1250-1850	7.52	0.76
221	Area Sample- Sterilization Room	5/7	1255-1855	7.58	(0.1)

Exposure Criteria (ppm): OSHA = 1
NIOSH = 0.1**

() Indicates the amount of EtO on charcoal tube was between the laboratory of detection (1.1 ug/sample) and of quantitation (5.8 ug/sample).
*Sample worn by two employees due to shift change.
**NIOSH recommends that EtO be regarded as a potential occupational carcinogen.

Table 4

EtO Instaneous Air Concentrations
Area Samples Collected with the MIRAN 1-B Infrared Analyzer

Clark County Hospital
Jeffersonville, Indiana
HETA 85-292

May 6-7, 1985

Sample Location	Time of Sample	Date	Air Concentration (ppm)
Drain clean out in sterilizer room	1752	5/6	100
Drain opening for large autoclave	1756	5/6	5.0
Drain opening for small autoclave	1800	5/6	1.0-.
Slot opening on liquid gas separator-Envirogard® of small EtO sterilizer	1802	5/6	0.7-1.1
[illegible]eral area (B.Z. height) in front of [illegible]l EtO sterilizer	1805	5/6	0.5-1.8
[illegible]nches above closed drain cap of clean out	1808	5/6	4.0-30
B.Z. height above closed drain cap of clean out	1810	5/6	0.5-1.0
Drain opening for large autoclave	1813	5/6	0.9-1.3
B.Z. height in sterile storage area	1830	5/6	0.0
Above load transferred to small EtO aerator	1835	5/6	1.0-1.5
2 inches above manhole cover in sterile storage area	1856	5/6	0.6-0.7
Cylinder coupling/large EtO sterilizer	*	5/6	4.6-7.7
Ambient air (B.Z. height/6 inch horizontal distance from above coupling point)	*	5/6	1.4-1.6
Cylinder coupling/small EtO sterilizer	*	5/6	60-82
Ambient air (B.Z. height/6 inch horizontal distance above coupling point)	*	5/6	1.0-1.3
Drain clean out (2 inches above closed cap) in sterilizer room	1701	5/7	1.8-3.0
6 inches above drain in cart wash/steam room	1703	5/7	219.0
6 inches above drain in cart storage room	1705	5/7	169.0
B.Z. height-ambient air in sterilizer room	1708	5/7	0.6-1.6
B.Z. height-ambient air in sterilizer storage area	1711	5/7	0.0

(continued)

Table 4 (Cont.)

Sample Location	Time of Sample	Date	Air Concentration (ppm)
2 inches above drain in janitors room/ decontamination side	1715	5/7	3.0-4.9
B.Z. height ambient air in cart wash area	1718	5/7	65.0-77.0
B.Z. height ambient air in decontam. area	1720	5/7	9.3-11.0
Above hole in duct on Envirogard® unit on small sterilizer	1721	5/7	7.0-8.8
B.Z. height-ambient air by desk in sterilizer storage	1723	5/7	2.4-13.0
B.Z. height-hallway outside decontamination area	1726	5/7	17.0
B.Z. height-hallway outside decontamination area	1728	5/7	12.0-15.0
B.Z. height-cart wash area	1730	5/7	15.0
B.Z. height-ambient air in sterilizer room	1734	5/7	3.5-7.4
B.Z. height-ambient air cart storage near wrapping area	1736	5/7	7.4
B.Z. height-ambient air cart washing room	1738	5/7	6.4-9.9
B.Z. height-ambient air decontam. room	1740	5/7	7.0-7.4
B.Z. height-ambient air hallway outside CS area, door open from decon. room	1742	5/7	6.6-7.3
B.Z. height ambient air outside main door of central supply (top half of door open)	1743	5/7	7.0-7.2
B.Z. height-ambient air in doorway of supervisor's office	1745	5/7	3.6-3.8
B.Z. height-ambient air at desk in sterile storage area	1747	5/7	3.9-4.2
B.Z. height-ambient air of cart storage near wrapping area	1748	5/7	3.2-3.4
B.Z. height-ambient air in sterilizer room	1750	5/7	2.8-3.1
B.Z. height-ambient air in cart wash area	1754	5/7	1.0-2.4

B.Z. = Breathing zone sample. Other samples represent values measured within a few inches of a source.

* = Times for these samples were not recorded

note: at 1734 on 5/7 passageway doors in CS area were closed

Table 5

Summary of Reported Health Effects

Clark County Hospital
Central Supply Area
Jeffersonville, Indiana
HETA 85-292

Employee Code	Nose Bleed	Diarrhea	Face Flushing and/or Swelling	Headache	Dizzy	Respiratory Symptoms	Nausea or Vomiting	Fatigue	Nervous Problem
A				X	X	X			
B	X			X		X			
C*	X	X	X	X		X	X	X	
D*			X			X			
E*		X		X		X			
F*	X	X		X					X
G*					X				
H									
I*		X	X	X			X	X	X
J			X						X
K									
L	X			X				X	
Total number of times reported:	4(33%)	4(33%)	4(33%)	7(58%)	2(17%)	5(42%)	2(17%)	3(25%)	3(25%)

Age range = 27-64
Years working as CS technician = 0.5 to 15

*Other reported symptoms included: weight loss, muscle ache, eye discharge, sinus problem, elevated blood pressure, blurred vision and skin irritation.

Note: None of the employees reported any of these symptoms prior to 1985.