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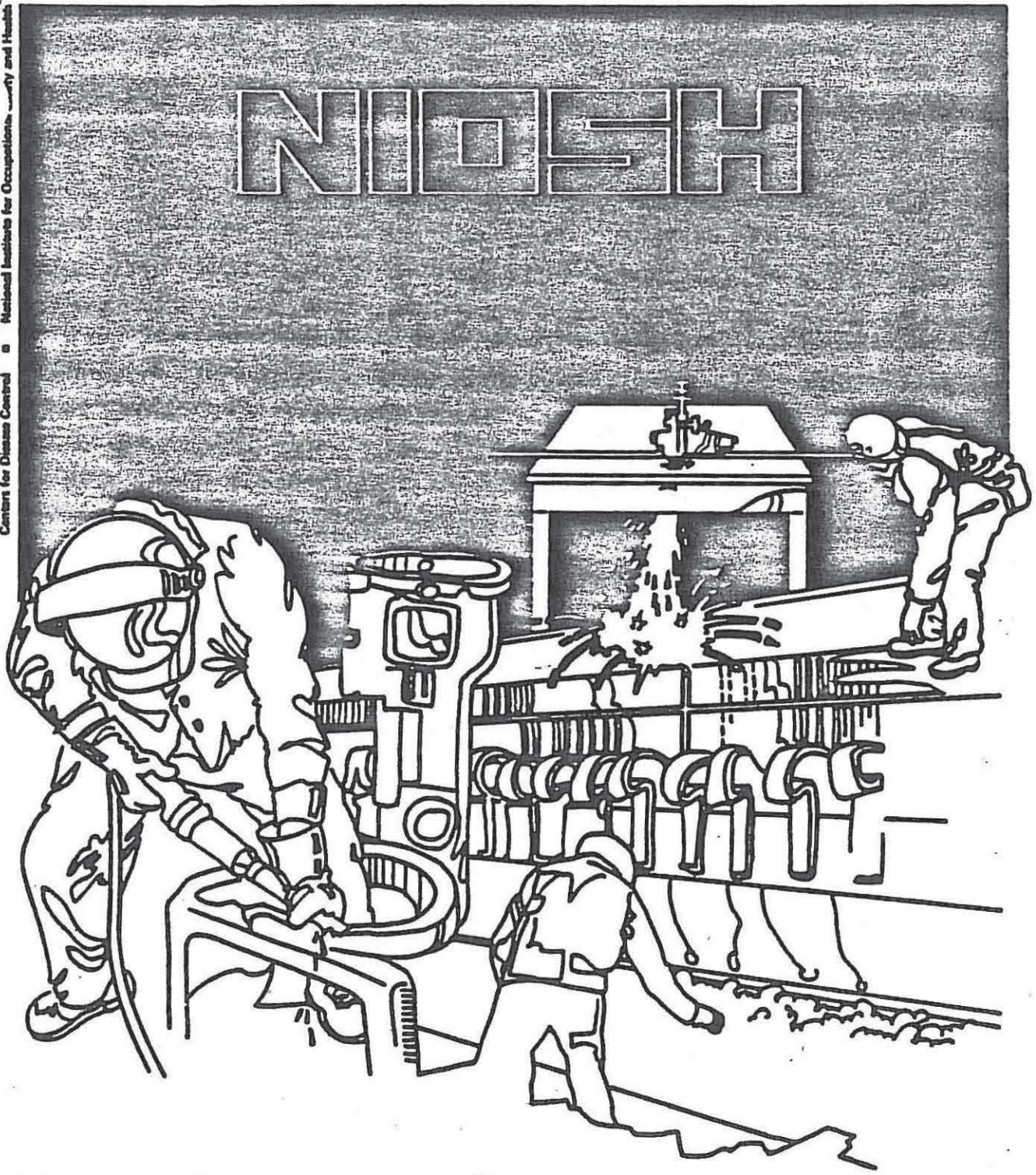

Health Hazard Evaluation Report

HETA 84-046-1584
HENNEPIN COUNTY MEDICAL CENTER
MINNEAPOLIS, MINNESOTA

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.

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I. SUMMARY

On February 2, 1984, the National Institute for Occupational Safety and Health (NIOSH) was requested to evaluate health problems among personnel who had worked in the operating and instrument room area, and in the ear, nose and throat and surgery clinics at the Hennepin County Medical Center, Minneapolis, Minnesota.

In February 1984, NIOSH investigators conducted an initial visit to the facility. In April 1984, a medical survey was conducted during which confidential questionnaires were administered. In July 1984, an environmental survey was conducted during which personal and area air samples for ethylene oxide and waste anesthetic gases were collected in the operating and instrument room areas.

Results of interviews conducted during the initial survey indicated that complaints reported by workers in the ear, nose, and throat clinic and the surgery clinic appeared to be mainly attributed to poor air quality. The results of confidential interviews conducted with 59 of the 70 employees in the operating room areas revealed: 31 (44%) complained of frequent headaches, 28 (40%) of nose or eye irritation, 25 (36%) of light headedness, 21 (30%) unusual tiredness. Seven (78%) of nine nurses in the recovery room complained of frequent headaches. Symptomatology was generally attributed either to poor ventilation or exposure to substances used in these areas. Nurses in the operating room and technicians in the instrument room reported an incidence of reproductive problems, but the investigators determined it was not above the expected background levels for the U.S. population.

Personal and area samples collected in the instrument room revealed no exposures to ethylene oxide (EtO) above the limit of detection during the operation of the gas sterilizer. EtO was detected in the adjacent mechanical access room (a non-personnel area) at peak concentrations of up to 12.9 parts per million parts of air (ppm), which quickly dissipated. NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure be reduced to the lowest feasible level. The results of personal samples collected during three surgical procedures showed time-weighted average (TWA) concentrations of 138 ppm, 177 ppm, and 66 ppm nitrous oxide (N_2O) for the anesthesiologists. These results exceeded the NIOSH recommended standard of 25 ppm N_2O as a TWA for the period of administration. Personal samples collected for halogenated anesthetic gases during the same procedures revealed TWA concentrations of 3.2 ppm and 0.69 ppm halothane, and 0.44 ppm enflurane, two of which exceeded the NIOSH recommended standard for halogenated anesthetic agents used in combination with N_2O of 0.5 ppm as a TWA for the period of administration. There is currently no Occupational Safety and Health Administration standard for anesthetic agents.

Based on the information obtained during this survey, it has been determined that a hazard from exposure to waste anesthetic gases and vapors did exist at the time of this survey. Recommendations for alleviating this and other potential hazards are included in the body of this report.

Key Words: SIC 8062, hospitals, anesthetic gases, ethylene oxide, air quality

II. INTRODUCTION

On February 2, 1984, NIOSH received a request from the Hennepin County Medical Center for a health hazard evaluation. The request was a result of a previous request NIOSH had received from a former employee of the Medical Center. The former employee was concerned with health problems among personnel who had worked in the hospital's operating and instrument room area, and the ear, nose and throat and surgery clinics.

On February 16, 1984, NIOSH investigators conducted an initial survey at the facility. An opening conference was held with representatives of the hospital administration and the employees during which background information was obtained related to the basis for the request. Following this meeting, a walk-through survey was conducted in the areas of concern. On April 11, 1984, a medical survey was conducted during which confidential questionnaires were administered to the employees by a NIOSH Medical Officer. On July 9, 1984, an environmental survey was conducted during which personal and area air samples were collected in the instrument and operating rooms. Interim letters containing the results of these samples were sent to the hospital administration on August 2, 1984 and October 22, 1984, along with recommendations for reducing employee exposures.

III. BACKGROUND

The Hennepin County Medical Center is a relatively new hospital, completed in 1976. The ear, nose and throat clinic is located on the fourth level, the surgery clinic is located on the third level, and the operating room suites are located on the second level of the hospital. Ten operating rooms surround an inner corridor which serves as a central storage for sterilized equipment and other necessary supplies. The rooms are surrounded by a large outer corridor for patient and staff transit. The staff lounge, special procedure rooms, laboratories, Department of Anesthesiology offices, blood bank, pre-operative holding, and post-operative recovery areas are arranged on the outer perimeter of this corridor. At the time of the survey, there were approximately 80 nurses assigned to the operating rooms, 20 nurses assigned to the recovery room, 20 employees in anesthesiology, and 160 physicians who periodically use the operating rooms.

Prior to operative procedures, patients are brought by staff to the holding area on a gurney. When the operating staff is ready to begin, the patient is taken to the operating room, and transferred to the operating table. At this point, anesthetic gas is administered, either by injection, mask, intubation, or a combination of these methods, depending on the specific circumstances of the operation. The duration of surgery may range from less than 15 minutes to several hours. Following surgery, the anesthetic gas administration is stopped and the patient is administered oxygen and air to breath. When the patient has awakened sufficiently to breath on his own, the mask or tubing is removed. The patient is then transferred by staff from the operating table to a gurney and wheeled to the recovery area across the corridor.

The patient remains in the recovery room under constant monitoring by nursing staff, until stabilization occurs.

Anesthetic machines are kept in each of the operating suites, connected directly to ports located on the wall of the operating rooms, which provide for both gas supply and machine exhaust. The general air supply to the rooms is located above the operating room table, with the exhaust vents located on the lower part of each of the room's four walls, designed to provide laminar air flow. Surgical procedures generally involve, as a minimum, the surgeon(s), the anesthesiologist, and the scrub nurse(s), all who work in close proximity to the patient. Additionally, a circulation nurse(s) is present within the operating room to perform other necessary support activities.

The instrument room, also located in the operating room area, is used for sterilization of equipment used in the surgical procedures. Although the majority of the instruments and supplies used in the operating room are subjected to steam sterilization, certain heat sensitive items require ethylene oxide sterilization. This involves the use of a specially designed gas sterilizer utilizing ethylene oxide and Freon-12 in a mixture of 12 to 88 percent by weight. The gas sterilizer used in this facility has a single door for loading and unloading of the unit. The machine is recessed into the wall of the instrument room, with the body of the sterilizer protruding into an adjacent mechanical access room. The mechanical access room also contains two cylinders of ethylene oxide which are used to supply the sterilizer in a dual loading system. Entry into this room is restricted to gas cylinder replacement and other required maintenace activities for the gas or steam sterilizers. The gas sterilizer is equipped with local exhaust ventilation, and an alarm is present in the sterilizer room area to provide warning to the employees in the event of gas leakage.

One employee working on the second shift is responsible for operation of the gas sterilizer, although at least one additional employee is also present in the general work area. The sterilizer takes approximately two hours to complete its cycles, following which the instruments are transferred to an adjacent aerator for a 12 hour aeration cycle. Work practice requirements include a provision that all employees leave the room for the 15-minute period during which the machine is vented prior to transfer of the instruments to the aerator. Periodic monitoring of employees in this area for ethylene oxide exposure is conducted by the hospital utilizing passive dosimeters. The hospital also uses a direct reading instrument for occasional leak detection and general area monitoring for ethylene oxide.

IV. MATERIALS AND METHODS

A. Medical

During the initial survey of February 16, 1984, anecdotal interviews were conducted with supervisory nursing personnel in the emergency room, the fourth level ear, nose and throat clinic, the third level surgery clinic, and the second level operating room area. Subsequently, a

medical survey was conducted on April 11, 1984, during which confidential questionnaires were administered to employees working in the instrument room, operating room, and recovery room areas. Information was solicited regarding the employee's work history and the presence of any general or work-related health problems. Also included were specific questions regarding the presence of symptomatology which might be associated with exposures to ethylene oxide and anesthetic gases.

B. Environmental

Based on the interviews conducted and responses to the questionnaires collected during the medical survey, it was determined that environmental sampling would be concentrated in two locations within the hospital - the instrument and operating room areas.

1. Instrument Room

On July 9, 1984, an environmental survey was conducted in the instrument room during which personal and area air samples were obtained for ethylene oxide. A series of consecutive two-hour samples were collected in the breathing zone of the sterilizer operator and a second employee in the area using battery-powered sampling pumps operating at 50 cubic centimeters of air per minute (cc/m). The pumps were connected via tubing to sampling trains consisting of a 400 milligram (mg) and a 200 mg charcoal tube connected in series. Area air samples were collected in a similar manner at various locations throughout the instrument room and in the mechanical access room. The samples were later analyzed in accordance with NIOSH analytical method S-286 modified, utilizing a gas chromatograph equipped with an electron capture detector.[1] A complete listing of information pertinent to sample collection is provided in Table 1.

In addition to the sorbent tube samples, a Foxboro® Miran 80 Computing Gas Analyzer was also utilized in the survey of the instrument room. This device was programmed to provide an integrated readout of ethylene oxide concentration in parts per million (ppm) every 2.45 minutes. The areas and activities monitored included; the mechanical access room during gas cylinder changing, the sterile preparation area of the instrument room during loading and operation, the mechanical access room during the purging cycle of the sterilizer, the instrument room during the 15 minute door venting procedure and the subsequent instrument transfer to the aerator. In addition, leak checks were performed around the door seals of the sterilizer and aerator during the operating cycles.

2. Operating Rooms

On July 10, 1984, an environmental survey was conducted in two of the operating rooms in order to assess exposures to nitrous oxide and the various halothanes used in the surgical procedures. Portable sampling pumps operating at approximately 650 cc/m were used to fill sample collection bags for subsequent analysis. Area samples were collected near exhaust vents on the right and left sides of the operating suites. Due to the need for unencumbered movement among the doctors and nurses

present, the anesthesiologist was the only individual available for the collection of personal samples. Following sample collection, air from the sample bags was analyzed for nitrous oxide using a Foxboro® Miran 103 Specific Vapor Analyzer in accordance with NIOSH analytical method 6600.[2] Information pertinent to sample collection is provided in Tables 2 through 4.

To assess exposures to the halothanes used in the anesthetic mixtures, personal and area air samples were collected in the locations described above using battery-powered sampling pumps operating at 50 cc/m. The pumps were connected via Tygon® tubing to a charcoal tube collection media. Samples were later analyzed in accordance with NIOSH analytical method S-286, utilizing a gas chromatograph equipped with an electron capture detector.[1] A complete listing of information pertinent to sample collection is provided in Table 5.

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 becomes 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 that 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 standards 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 required by the Occupational Safety and Health Act of 1970 (29 USC 651, et seq.) to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a susbstance 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.

A. Ethylene Oxide (EtO)

The acute toxic effects of EtO in humans and animals include acute skin, respiratory, and eye irritation; skin sensitization; nausea, vomiting, and diarrhea; and nervous system effects. Nonmalignant chronic effects in humans include anemia and respiratory irritation, with susceptibility to secondary respiratory infection. Further, occupational exposure to EtO may increase the frequency of mutations in human populations as noted in a 1977 NIOSH Criteria Document.[3] More recently, cases of peripheral neuropathy among exposed workers have been reported.[4]

A recent study demonstrates that EtO induces cancer in experimental animals.[5] A dose-related increase in mononuclear cell leukemia was established in that study; exposures as low as 10 ppm increased the proportion of female rats with the leukemia. Also, experiments indicate that EtO exposure to either male or female animals results in adverse effects on reproduction.[6,7]

In humans, epidemiologic investigations of cancer mortality among Swedish workers exposed to EtO suggest an increased risk of leukemia and other cancers.[8,9] Recent information also suggests that EtO is associated with chromosomal abnormalities in peripheral lymphocytes of exposed workers.[10]

Based on this information, NIOSH recommended in a 1981 Current Intelligence Bulletin that EtO be regarded in the workplace as a potential occupational carcinogen, and that exposure be reduced to the extent possible.[11] An 8-hour TWA below 0.1 parts per million (ppm), and a ceiling limit not to exceed 5 ppm during any 10 minute period in a working day is recommended.[12] The current OSHA standard for EtO is 1 ppm as an 8-hour TWA, wth an action level of 0.5 ppm which triggers employee exposure monitoring and medical surveillance provisions.[13]

B. Anesthetic Gases

Reports by Vaisman and Askrog and Harvald were among the first to identify an increased incidence of spontaneous abortion in women exposed to anesthetic gases and in wives of men exposed to anesthetic gases.[14, 15] In 1974, the American Society of Anesthesiologists (ASA) published the results of a study indicating "that female members of the operating room-exposed group were subject to increased risks of spontaneous abortion, congenital abnormalities in their children, cancer, and hepatic and renal disease." This report also showed an

increased risk of congenital abnormalities in offspring of male operating room personnel. No increase in cancer was found among the exposed males, but an increased incidence of hepatic disease similar to that in the female was found.[16]

In a study published by NIOSH in 1976, "nitrous oxide (N_2O) and halothane in respective concentrations as low as 50 parts per million (ppm) and 1.0 ppm caused measurable decrements in performance on psychological tests taken by healthy male graduate students.[17] Nitrous oxide alone caused similar effects. The functions apparently most sensitive to these low concentrations of anesthetics were visual perception, immediate memory, and a combination of perception, cognition, and motor responses required in a task of divided attention to simultaneous visual and auditory stimuli." Headache, fatigue, irritability, and disturbance of sleep were also reported.[18,19]

Mortality and other epidemiologic studies have raised the question of possible carcinogenicity of anesthetic gases, but sufficient data are presently lacking to list nitrous oxide or halothane as suspected carcinogens.

In a study of dentists, Cohen et al. compared exposed persons who used inhalation anesthetic more than 3 hours per week with a control group who used no inhalation anesthetic. The exposed group reported a rate of liver disease of 5.9 percent, in comparison with a rate of 2.3 percent in the control group. Spontaneous abortions were reported in 16 percent of pregnancies of the wives of exposed dentists, in comparison with 9 percent of the unexposed. This difference was statistically significant. This study did not identify the specific anesthetic being used by the dentists surveyed, that is, whether they used N_2O alone or a halogenated agent.[20] However, in a review of that study, NIOSH concluded that "the halogenated anesthetics alone do not explain the positive findings of the survey and N_2O exposure must be a important contributing factor, if not the principal factor".[21] This conclusion is based on a calculation which assumed that as many as 1 in 10 of the dentists using an inhalation anesthetic employed a halogenated agent. If the actual fraction is less than 1 in 10, the conclusion has added strength.

In a document recommending a standard for occupational exposure to waste anesthetic gas, NIOSH recommended a maximun exposure of 50 ppm on a time-weighted average basis during the anesthetic administration in dental offices.[18] This recommendation is based primarily on available technology in reducing waste anesthetic gas levels in these environments.

When nitrous oxide is used as the sole anesthetic agent in medical procedures, NIOSH recommends that occupational exposure shall be controlled so that no worker is exposed at TWA concentrations greater than 25 ppm during the period of administration. NIOSH recommends that occupational exposure to halogenated anesthetic agents shall be controlled so that no worker shall be exposed at concentrations greater than 2 ppm of any halogenated anesthetic agent during the period of anesthetic administration. When used in combination with nitrous oxide, halogenated anesthetic agents should be controlled to 0.5 ppm, which can

generally be arrived at by controlling nitrous oxide to a TWA concentration of 25 ppm during the period of anesthetic administration.[18]

VI. RESULTS

A. Medical

Anecdotal interviews conducted during the initial survey indicated that complaints reported by the fourth level ear, nose, and throat clinic and the third level surgery clinic appeared to be mainly attributed to general air quality. In both locations air was reported to be "stuffy" or "stagnant" with a lack of fresh air, particularly when compared to the previously occupied facility where windows could be opened. One employee reported upper airway congestion and rhinorhea since moving to the new building, but this problem did not appear to be prevalent among the rest of the workforce in these areas.

Due to the relatively widespread nature of the symptomatology indicated by operating room employees during the initial survey, standardized employee interviews were conducted with all available employees in this area. Of the 70 individuals working in the operating suites at the time of the medical survey, 59 were interviewed by the NIOSH medical officer. Thirty-one (44%) complained of frequent headaches, 28 (40%) of nose or eye irritation, 25 (36%) of light headedness, 21 (30%) unusual tiredness, 13 (19%) of nausea, 12 (17%) of palpitations, as well as 10 (14%) of numbness of tingling. All nine nurses working in the recovery area were interviewed. Seven (78%) complained of frequent headaches, 3 (33%) of nose or eye irritation, 3 (33%) of light headedness, 2 (22%) unusual tiredness, 1 (11%) of nausea and palpitations.

Although the etiology of the reported symptomatology was not clearly evident to the employees, two major areas of concern were expressed. The first involved possible exposures to substances used within the operating room areas (which included the instrument room), particularly EtO. The second dealt with the adequacy of the ventilation system present in the operating room area. Reports of unusual odors (e.g. bus exhaust fumes) and poor air circulation were both reported as frequently occurring problems, especially in the later part of the afternoon.

The interviews revealed no reported reproductive problems amongst nurses in recovery, nor among physicians and nurses in anesthesiology. Nurses in the operating room reported that out of 32 women, 2 had children while on the current job who were born with birth defects. Further, two additional women indicated that they were unable to have children for two and one-half and five years respectively. This inability had not been evaluated by physicians in either case. The 13 men in this area reported no problems with reproduction.

In the instrument room, one of the two men interviewed reported two problem pregnancies, six and eight years after beginning work in this area. One of the three women indicated a reproductive problem also.

All other reports of reproductive problems by personnel could not be associated with the time of current employment in the operating suite area.

B. Environmental

1. Instrument Room

With few exceptions, the results of the sorbent tube samples for EtO were found to be below the limit of detection of 0.541 micrograms/tube. The exceptions included 3 area samples collected approximately 5 feet above the sterilizer drain in the mechanical access room. Concentrations in these samples were 0.89 ppm for a 114 minute period during which charging of the sterilizer with EtO occurred; 2.11 ppm for a 130 minute sample during which vacuum purging of the sterilizer chamber occurred and the sterilization cycle was completed; and 2.23 ppm for a 113 minute sample during which the aerator was being operated.

No ethylene oxide was detected above the limit of detection (approximately 0.1 ppm) by the direct reading instrument in any of the areas examined during the sterilization process, with the exception of the mechanical access room during the sterilizer's purging cycle. During this event, measurements performed one and one-half feet above the drain showed concentrations of ethylene oxide up to 12.9 ppm, dissipating below the limit of detection within a 10 minute period. It should be noted that during normal operations, no personnel would be expected to be present in this area.

2. Operating Rooms

The results of the samples collected and analyzed by the direct reading instrument for nitrous oxide are provided in the attached Tables 2, 3, and 4. Personal samples collected near the breathing zone of the anesthesiologists, revealed TWA concentrations for the duration of the surgical procedures to be 138 ppm and 66 ppm for procedures 1 and 3, respectively. Although the exact TWA concentration could not be determined for procedure 2 due to a pump malfunction, the concentration measured for a significant portion of the procedure was 177 ppm. These results are in excess of the NIOSH recommended standard of 25 ppm for nitrous oxide during the period of administration.

The results of the sorbent tube samples collected for halogenated anesthetic gases are presented in Table 5. Personal samples collected near the breathing zone of the anesthesiologists revealed TWA concentrations below the limit of detection (LOD) in the first procedure, and at concentrations of 3.2 ppm and 0.69 ppm in procedures 2 and 3, respectively. Enflurane, which was used in the list procedure, was detected in the personal sample for the anesthesiologist at a concentration of 0.44 ppm. The two personal samples for halothane exceeded the NIOSH recommended standard of 0.5 ppm for halogenated anesthetic agents when used in combination with nitrous oxide.

The results of area samples for nitrous oxide and halogenated anesthetics are also presented in Tables 2 through 5. The data from

these samples indicates high levels of nitrous oxide in several of the area samples collected near floor exhaust vents in the operating rooms. Although no definite determination can be made from this data regarding personal exposures, it would seemingly indicate a potential for significant exposures for other personnel present in the operating room, particularly to nitrous oxide. Also of interest is the apparent differences in concentrations of nitrous oxide occurring on the opposite sides of operating room 8. Although this could be due to such factors as the position of anesthetic administration in relation to the air supply and exhaust vents, it is also possible that an imbalance in the room's ventilation system may exist.

VII. DISCUSSION AND CONCLUSIONS

Based on the information obtained during the survey, two major factors appear to be associated with the acute symptomatology which was reported; 1) general air quality within the facility, and 2) environmental exposures to substances used within the facility (i.e., waste anesthetic gases and vapors). Since a majority of this symptomatology is of such a nature that it could be attributed to either of these factors, it is difficult to determine a single source of the complaints. This is particularly true for the operating room where the influence of either of the two factors could be present. It is also probable, that a combination of these factors may be responsible for some of the reported problems; ie., inadequate ventilation contributing to a build up of airborne concentrations of substances used in an area. For the purpose of clarity, each of these areas will be discussed separately below.

A. Indooor Air Quality

Much of the acute symptomatology reported by the hospital employees interviewed is consistent with those complaints generally associated with poor indoor air quality. Building-related illness episodes have been reported more frequently in recent years as buildings have been made more air-tight in order to conserve energy and to reduce air conditioning expenses. Modern buildings, such as the medical center, are constructed primarily of steel, glass, and concrete, with large windows that cannot be opened, thus making the building totally dependent on mechanical systems for air conditioning. Contaminants may be present in make-up air or may be introduced from indoor activities, furnishings, building materials, surface coatings, and air handling systems and treatment components. Symptoms often reported are eye, nose, and throat irritation, headache, fatigue, and sinus congestion. Occasionally, upper respiratory irritation and skin rashes are reported. In some cases, the cause of the symptoms has been ascribed to an airborne contaminant, such as formaldehyde, tobacco smoke, or insulation particles, but most commonly a single cause cannot be pinpointed.

Imbalance or malfunction of the air conditioning system is commonly identified, and in the absence of other theories of causation, illnesses

are usually attributed to inadequate ventilation, heating/cooling, or humidification.

In 1981, the National Research Council (National Academy of Sciences) issued a report urging a major national effort be mounted to study the subject of indoor air pollution.[23] Some of the major types of contaminants found in indoor air are summarized in Appendix 1. Indoor air should not contain concentrations of these or any other contaminants known to impair health, or to cause discomfort to a substantial majority of the occupants. Ambient air quality standards/guidelines available from federal, state, or local authorities should be consulted. If the air is thought to contain any other contaminants, reference to OSHA, ACGIH, and NIOSH recommendations should be made; for application to the general population, the concentration of these contaminants should not exceed 1/10 of the limits which are used in industry. A discussion of the appropriate environmental criteria for indoor air quality, along with several examples of common contaminants found in both industrial and non-industrial (indoor air) environments are provided in Appendix 2.

Neither NIOSH nor OSHA has developed ventilation criteria for general offices. Criteria often used by design engineers are the guidelines published by the American Society of Heating, Refrigeration and Air-Conditioning Engineers (ASHRAE). Until recently, the ASHRAE Ventilation Standard 62-73 (1973) was utilized, but recommendations were based on studies performed before the more modern, air-tight buildings became common. Older buildings permitted more air infiltration through leaks in cracks and interstices, around windows and doors, and through floors and walls. Modern buildings are usually much more airtight and permit less air infiltration. Due to the reduced infiltration, ASHRAE questioned whether the 1973 minimum ventilation values assure adequate outdoor air supply in modern, air-tight buildings.

Subsequently, ASHRAE has revised its standard and has published the new standard, ASHRAE 62-1981, "Ventilation for Acceptable Indoor Air Quality". These standards are expressed as outdoor air requirements, usually dependent on occupancy or other special factors. The standard for hospital patient rooms is 35 cubic feet of air per minute (cfm) per bed for smoking areas, and 7 cfm/bed for non-smoking areas, and for medical procedure areas the standard is 35 cfm/person for smoking areas, and 7 cfm/person for non-smoking areas. Both assume an estimated occupancy of 10 persons per 1000 ft^2 of floor area. Higher ventilation rates are recommended for spaces where smoking is permitted bacause tobacco smoke is one of the most difficult contaminants to control at the source. Areas that are nonsmoking areas may be supplied at the lower rate provided that the air is not recirculated from, or otherwise enters from, the smoking areas.[24]

For operating rooms, the ASHRAE standard requires 40 cfm/person, and for recovery rooms, 15 cfm/person. This assumes an estimated occupancy of 20 persons per 1000 ft^2 in both of these areas. In addition, procedures which generate contaminants may require higher general ventilation rates or the use of local exhaust ventilation, depending on the specific substances being used.[24] It should be noted that there are additional guidelines, special requirements, or codes in effect for

hospitals which determine the minimum ventilation rates, filter efficiencies, relative humidity, and design temperature ranges.[25] Such sources should be consulted to insure that all applicable requirements are being met.

B. Environmental Exposures

1. Instrument Room

The results of the environmental survey in the instrument room did not indicate any airborne exposure to EtO above the limits of detection for personnel working in that area. EtO was detected in area samples in the mechanical access room, but under normal working conditions this would not be expected to present a hazard to personnel in the instrument room. Therefore, ethylene oxide did not appear to be a major factor in employee exposures at the time of this survey. With regards to reproductive effects, the small number of personnel in the instrument room area prevent any definitive statement concerning cause and effect of the individual reproductive problems reported in the interviews.

2. Operating Room Area

The results of the environmental survey indicate that concentrations of nitrous oxide in personal samples were above the NIOSH recommended standard during the three surgical procedures monitored. In addition, the concentration of halothane in personal samples also exceeded the NIOSH recommended standard for halogenated anesthetic gases during two of the three procedures. Although personal sample collection was limited to anesthesiologists, the concentrations of nitrous oxide found in area samples indicate that other operating room personnel may also be subject to exposures in excess of the NIOSH recommended standard.

The acute symptomatology reported by employees in this area is certainly consistent with the known effects of these substances. With regards to reproductive effects, here again the small number of exposed individuals prevents a clear statement concerning the causes of the problems reported by personnel in this area. Both the rate of undiagnosed sterility and birth defects fall well within the normal background frequency range experienced in this country, yet these effects have been reported in the medical literature as related to trace anesthetic gas exposure. Although this study has not produced information to substantiate such a relationship in these cases, it would be prudent to implement those controls necessary to reduce exposures to these substances within the recommended levels.

VIII. RECOMMENDATIONS

Based on the information obtained during this evaluation, the following recommendations are made in order to alleviate the reported symptomatology and to prevent the occurrence of future health problems.

A. Indoor Air Quality

The building's heating, ventilation, and air-conditioning system should be evaluated by qualified individuals to determine if minimum air flow and proper air quality are being provided as specified in such documents as ASHRAE Standard 62-1981 and Guidelines for Construction and Equipment of Hospital and Medical Facilities, particularly in those areas noted in the report where frequent complaints associated with inadequate ventilation were reported.[24,25]

B. Ethylene Oxide

The medical center should continue in its efforts to reduce ethylene oxide exposure to the lowest level possible. Adherence to the guidelines contained in the NIOSH Special Occupational Hazard Review with Control Recommendations: Use of Ethylene Oxide as a Sterilant in Medical Facilities, the NIOSH Current Intelligence Bulletin 35: Ethylene Oxide, and the provisions of the OSHA standard for ethylene oxide, should help to ensure that employee exposures are maintained at safe levels.[3,11,13] Particular attention should be given to continued periodic exposure monitoring and leak detection to ensure the effectiveness of existing engineering controls. Additionally, the source of ethylene oxide exposure in the mechanical access room (presumably the drain area) should be identified. Although personnel 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 point of generation in order to prevent migration of the gas into adjacent work areas.

C. Waste Anesthetic Gases and Vapors

In light of the fact that the environmental data collected represented only two of the ten operating rooms during three surgical procedures, additional environmental monitoring should be conducted by the Medical Center to determine if these exposures are representative of those normally present in the operating rooms. Such a survey should also encompass areas related to the operating rooms, such as the recovery room where a potential for exposure to the anesthetic agents may also exist. In those areas where exposures exceeding the NIOSH recommended standard are found, control procedures should be implemented in order to reduce exposures to within the recommended levels. Detailed recommendations regarding specific control procedures, work practices, monitoring procedures, and medical surveillance are provided in the NIOSH criteria for a recommended standard....occupational exposure to waste anesthetic gases and vapors.[18] Copies of this document were provided to te Medical Center along with the results of the environmental surveys. Adherence to the recommendations specified in this document should help maintain exposures within acceptable levels and protect the health of the employees in this area.

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IX. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination 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 Services (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from the NIOSH publications office at the Cincinnati, address. Copies of this report have been sent to the following:

A. Hennepin County Medical Center
B. Employee Representatives
C. U. S. Department of Labor, OSHA - Region V
D. NIOSH Regional Offices/Divisions

TABLE 1

RESULTS OF ENVIRONMENTAL SAMPLES COLLECTED FOR ETHYLENE OXIDE
Hennepin County Medical Center
July 9, 1984

Sample Type/ Location	Time Start	Time Stop	Total Time	TWA Concentration of Ethylene Oxide (ppm)
Personal/ Sterilizer Operator	1506	1716	130	< LOD
	1716	1920	124	< LOD
	1920	2117	127	< LOD
Personal/ Nursing Assistant	1511	1714	123	< LOD
	1714	1927	133	< LOD
	1927	2127	120	< LOD
Area/ Table 17' from sterilizer	1533	1718	105	< LOD
	1718	1934	136	< LOD
	1935	2125	110	< LOD
Area/ OR reception	1545	1755	130	< LOD
	1755	1938	103	< LOD
	1938	2129	111	< LOD
Area/ Above left of sterilizer door	1513	1717	124	< LOD
	1717	1924	127	< LOD
	1924	2127	123	< LOD
Area/ 5' above drain (mech. access room)	1526	1720	114	0.89
	1720	1930	130	2.11
	1932	2125	113	2.23

NIOSH Recommended Standard: Ethylene Oxide - Lowest Feasible Level

Key:
TWA - Time weighted average (calculated for the sampling time indicated)
ppm - Parts of contaminant per million parts of air
<LOD - Less than the limit of detection of 0.01 micrograms per sample
OR - Operating room

TABLE 2

RESULTS OF ENVIRONMENTAL SAMPLES COLLECTED FOR NITROUS OXIDE
Hennepin County Medical Center
Procedure 1 - Operating Room No. 8
July 10, 1984

Sample Type/ Location	Time Start	Time Stop	Total Time	TWA Concentration of Nitrous Oxide (ppm)
Personal/	0849	0923	34	80
Anesthesiologist	0923	0952	29	235
	0952	1022	30	135
	1022	1052	30	140
	1052	1110	18	90
			141	138*
Area/	0854	0924	30	> 300
Right Wall Exhaust	0924	0954	30	> 300
	0955	1023	28	270
	1023	1055	30	7
	1055	1110	15	7
			133	> 194*
Area/	0854	0920	26	7
Left Wall Exhaust	0920	0949	29	27
	0950	1020	30	25
	1020	1050	30	32
	1050	1110	20	15
			135	22*

NIOSH Recommended Standard: Nitrous Oxide - 25 ppm during period of administration

Key:
ppm - Parts of contaminant per million parts of air
TWA - Time-weighted average
* - Indicates a cumulative TWA for the duration of the procedure
> - Greater than (readings off scale; exact concentration could not be determined)

TABLE 3

RESULTS OF ENVIRONMENTAL SAMPLES COLLECTED FOR NITROUS OXIDE
Hennepin County Medical Center
Procedure 2 - Operating Room No. 7
July 10, 1984

Sample Type/ Location	Time Start	Time Stop	Total Time	TWA Concentration Nitrous Oxide (ppm)
Personal/	0930	0958	28	177
Anesthesiologist	0959	1040	41	(Sample Invalid)
Area/	0935	1003	28	27
Right Wall Exhaust	1003	1035	32	54
			60	41*
Area/	0929	1000	31	32
Left Wall Exhaust	1000	1034	34	22
			65	27*

TABLE 4

RESULTS OF ENVIRONMENTAL SAMPLES COLLECTED FOR NITROUS OXIDE
Hennepin County Medical Center
Procedure 3 - Operating Room No. 7
July 10, 1984

Sample Type/ Location	Time Start	Time Stop	Total Time	TWA Concentration Nitrous Oxide (ppm)
Personal/ Anesthesiologist	1100	1125	25	66*
Area/ Right Wall Exhaust	1100	1125	25	7*
Area/ Left Wall Exhaust	1100	1126	26	5*

NIOSH Recommended Standard: Nitrous Oxide - 25 ppm during period of administration

KEY:
ppm - Parts of contaminant per million parts of air
TWA - Time-weighted average
* - Indicates a cumulative TWA for the duration of the procedure

TABLE 5

RESULTS OF ENVIRONMENTAL SAMPLES COLLECTED FOR HALOGENATED ANESTHETICS
Hennepin County Medical Center
July 10, 1984

OR Number/ Procedure	Sample Type/ Location	Sample Time (minutes)	TWA Concentration Enflurane	TWA Concentration Halothane
Or No.8/ 1st	Personal/ Anesthesiologist	128	0.44 ppm	< LOD
OR No. 9/ 1st	Area/ Left Wall Exhaust	127	2.29 ppm	0.47 ppm
OR No. 7/ 2nd	Personal/ Anesthesiologist	75	< LOD	3.2 ppm
OR No.7/ 2nd	Area/ Left Wall Exhaust	76	< LOD	0.57 ppm
OR No. 7/ 3rd	Personal/	32	< LOD	0.69 ppm
OR No. 7/ 3rd	Area/ Left Wall Exhaust	28	< LOD	< LOD

NIOSH Recommended Standard: Halothane and Enfulrane
2 ppm as a TWA for the period of administration when used by themselves.
0.5 ppm when used in combination with nitrous oxide.

Key:
TWA - Time weighted average (calculated for the sampling time indicated)
ppm - parts of contaminant per million parts of air
< LOD - Less than the limit of detection of 0.01 milligrams per sample
OR - Operating Room

Appendix 1

COMMON INDOOR AIR CONTAMINANT SOURCES[23]

Products of combustion
Carbon monoxide and nitrogen dioxide are often considered the most important toxic products of the combustion of fossil fuels and other organic materials. Gas stoves may be a significant source of these pollutants. Carbon monoixde is an asphyxiant, and nitrogen dioxide a pulmonary irritant.

Formaldehyde
Formaldehyde and other aldehydes may be released from foam plastics, carbonless paper, particle board, plywood, and textile fabrics. Formaldehyde is an irritant to the eyes, nose, mouth, and throat. It is also a possible human carcinogen based on its ability to produce nasal cancer in rats.

Sprayed-on insulation materials
Asbestos, fibrous glass, and mineral wool fibers have been used in some buildings in sprayed-on fireproofing insulation for walls, ceilings, and structual steel beams. Fibers and dust particles may be dislodged from the insulation and become airborne. Asbestos fibers can cause pulmonary disease and cancer. Mineral wool and fibrous glass particles are irritants.

Tobacco smoke
Tobacco smoke contains several hundred toxic substances, the more important of which are: carbon monoxide, nitrogen dioxide, hydrogen cyanide, formaldehyde, hydrocarbons, ammonia, benzene, hydrogen sulfide, benzo< a)pyrene, tars, and nocotine. Tobacco smoke can irritate the respiratory system and, in allergic or asthmatic persons, often results in eye and nasal irritation, coughing, wheezing, sneezing, headache, and other related sinus problems. People who wear contact lenses often complain of burning, itching, and tearing eyes when exposed to cigarette smoke. While cigarette smoking is the leading cause of lung cancer in the United States, currently available evidence is not sufficient to conclude that passive or involuntary smoking causes lung cancer in non-smokers. (U.S. Dept of Health and Human Services. The health consequences of smoking: a report of the Surgeon General. Washington, D.C.:1982)

Microorganisms and allergens
Microorganisms have been spread through ventilation systems in buildings where air filters became wet and moldy, where pools of stagnant water accumulated under air conditioning cooling coils, and where decaying organic matter was found near air conditioning intakes. Health effects may be infections, irritation, or allergic symptoms.

Hydrocarbon vapors
Hydrocarbon vapors are released from dispersants and toners used in photocopying machines and telecopiers, from printing processes, and from certain cleaning compounds. Hydrocarbons can be irritants and, at high concentrations, are central nervous system depressants.

APPENDIX 2

ENVIRONMENTAL CRITERIA FOR INDOOR AIR CONTAMINANTS

The primary sources of air contamination criteria generally consulted include: (1) National Institute for Occupational Safety and Health (NIOSH) Criteria Documents and recommendations for occupational exposures, (2) the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV's), (3) the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) federal occupational health standards, and (4) the indoor air quality standards developed by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE). The first three sources provide environmental limits based on airborne concentrations of substances to which workers may be occupationally exposed in the workplace environment for 8 to 10 hours a day, 40 hours per week for a working lifetime without adverse health effects. The ASHRAE standards are general air quality standards for indoor environments, and are applicable for the general population exposed for up to a 24-hour day of continuous exposure without known toxic effects.

Several examples of common contaminants found in both industrial and non-industrial (indoor air) environments are shown below with their relevant environmental exposure criteria:

Contaminant	Concentration/Exposure Period		Source
	8-Hour TWA	Continuous	
Carbon monoxide (ppm)	50	---	OSHA/ACGIH
	35 (200^{C})	---	NIOSH
	---	9	ASHRAE
Formaldehyde (ppm)	3	---	OSHA
	CA	---	NIOSH
	---	0.1	ASHRAE
Total particulates (mg/m^3)	15	---	OSHA
	10	---	ACGIH
	---	0.26 (24-hr^{C})or 0.075 (1-yr mean)	ASHRAE
Asbestos (fibers/cc)	2	---	OSHA
	0.5--2	---	ACGIH
	0.1,CA	---	NIOSH
	---	CA	ASHRAE

KEY:
ppm - parts of contaminant per million parts of air
mg/m^3 - milligrams of contaminant per cubic meter of air
CA - lowest feasible level (suspect or confirmed carcinogen), use best control technology
C - short-term (15-30 min) or ceiling limit

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