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I. SUMMARY

In April, 1986, the National Institute for Occupational Safety and Health (NIOSH) received a request from Project Orbis, Inc., to evaluate exposures of surgeons, nurses, and other staff members to anesthetic gases and ethylene oxide (EtO) during routine surgical and sterilization activities aboard a specially modified DC-8 aircraft teaching eye hospital. Project Orbis, Inc., is a nonprofit organization whose primary purpose is to exchange eye surgical techniques between visiting eye physicians and host physicians in selected countries throughout the world.

On July 8-11, 1986, a NIOSH industrial hygienist conducted an environmental survey aboard the aircraft during the mission in San Jose, Costa Rica. During the evaluation, personal breathing-zone (PBZ) and general area (GA) air samples were collected for measurement of nitrous oxide (N₂O), halothane, and isoflurane during selected eye operations. To determine the extent of EtO exposure, PBZ and GA air samples were collected during sterilization activities when ampoules of liquid EtO (Amprolene* sterilizing gas) were used to sterilize surgical implements.

N₂O exposures of twelve operating room (O.R.) personnel ranged from 42 to 137 parts per million (ppm) during the period of gas administration. These levels, by comparison, exceeded the NIOSH recommended exposure limit (REL) of 25 ppm, which is believed to be achievable using engineering controls and good work practices. Exposures to halothane and isoflurane ranged from 0.28 to 3.4 ppm and from 0.19 to 2.2 ppm, respectively. Concentrations of both halogenated compounds either met or exceeded the NIOSH REL of 0.5 ppm for 7 of the 12 O.R. staff. Exposures to anesthetic gases were not only confined to the O.R. The recovery room nurse, whose primary exposure to anesthetic gases was from exhaled breath of "off-gassing" postoperative patients, was exposed to N₂O at levels up to 79 ppm and to isoflurane at levels up to 0.96 ppm. Results of the GA air samples revealed that the audiovisual (A/V) room contained relatively high levels of N₂O (10 to 59 ppm) and isoflurane (0.16 to 0.33 ppm) during operations where gas anesthesia was used in the O.R., indicating that the A/V technicians are also exposed to waste anesthetic gases. The relatively high levels of N₂O in the O.R. were attributed to leaks in the anesthesia and cryosurgery machines and to the fact that the anesthesia machine was not equipped with a waste scavenging system.

EtO concentrations measured in the breathing zone of nurses while loading and unloading packaged items from the sterilization chamber ranged from 1.6 to 17 ppm and were highest during the phase in the aeration process when individual packets were removed from the large bags for additional aeration. EtO exposures associated with both of these tasks were relatively brief in nature, typically lasting no more than 1 to 2 minutes. EtO was present in the sterilization room at levels up to 12 ppm when the Orbis staff initially boarded the plane prior to activation of the main power following overnight sterilization. The EtO concentrations dropped to less than 0.3 ppm several minutes after the main power (i.e., ventilation) was turned on. EtO was also present at low concentrations (0.5-0.7 ppm) in the cargo hold during a 10 minute period when nurses were obtaining medical supplies, and was attributed to an exhaust fan used to ventilate sterilization/aeration chamber. Based on the fact the aforementioned activities either involved brief exposure durations and/or low exposure levels, the NIOSH short-term (10 minute) REL of 5 ppm was not exceeded. However, given that EtO is a potential human carcinogen, exposures should be minimized as much as possible.

The data collected during this evaluation indicated that the operating and recovery room staff were being exposed to concentrations of nitrous oxide, halothane, and isoflurane in excess of the NIOSH REL's. Although EtO exposures were relatively brief and below the NIOSH short-term REL, further reduction in exposure should be made in light of the fact that EtO is a potential human carcinogen. Recommendations are made in Section VII which will help to achieve good control of exposures through use of engineering controls, good work practices, and preventive maintenance.

KEYWORDS: SIC 8069 (Specialty Hospitals) nitrous oxide, halothane, isoflurane, ethylene oxide, anesthetic gases, aircraft

II. INTRODUCTION

On April 4, 1986, the National Institute for Occupational Safety and Health (NIOSH) received a request from the nurse administrator of Project Orbis, Inc., to evaluate exposures of surgeons, nurses, and other staff members to waste anesthetic gases and ethylene oxide (EtO) during routine surgical and sterilization activities aboard their specially modified DC-8 aircraft teaching eye hospital. In response to the request, an industrial hygienist from NIOSH conducted an environmental survey aboard the aircraft during the last week of a scheduled 3 week mission in San Jose, Costa Rica. During the survey, air samples were collected to assess worker exposure to the anesthetic gases nitrous oxide (N_2O), halothane, and isoflurane, and to EtO during sterilization activities. Preliminary findings and recommendations were provided to the Project Orbis staff at the conclusion of the survey on July 11, 1986.

III. BACKGROUND

Project Orbis, Inc. is a non profit, international, flying teaching eye hospital whose purpose is to exchange eye surgical techniques between visiting eye doctors and host eye doctors on board a specially modified DC-8 aircraft. Approximately 20 staff members, including ophthalmologists, nurses, administrators, and technicians are associated with each mission, which usually lasts 1 to 3 weeks, in host countries throughout the world.

All eye surgery necessitated the administration of anesthetic agents to patients. Three different techniques were used by the anesthesiologists to sedate patients during these eye operations. The most common technique, used about 85-90% of the time, involved the administration of a local anesthetic. The remaining two techniques involved the use of inhalation general anesthesia. During this survey, nitrous oxide (N_2O) was administered in conjunction with either halothane or isoflurane. The first and more commonly used of the two techniques involved initially giving the patient a sedative/muscle relaxant via I.V. injection, followed by gas administration via intratracheal intubation. In the other technique, primarily used on adolescents, the patient was administered a mixture of N_2O and halothane via a conventional (non-scavenging) gas mask followed by intratracheal intubation with N_2O and one of the halogenated compounds.

During selected operations, cryosurgical techniques were employed by the surgeon to selectively destroy (via necrosis) benign or premalignant lesions in the eye. This procedure involved the use of a cryo probe which is maintained at sub zero temperature by using N_2O gas under pressure (the N_2O acts as a refrigerant). The N_2O gas is introduced via pressured gas cylinder into a control unit which automatically controls freeze and defrost functions via a foot switch. The gas upon exiting the probe is vented from the aircraft via a central vacuum system.

Ethylene oxide (EtO) is used to sterilize selected surgical implements used in the O.R. Items to be sterilized are placed in individualized, sealable plastic packets and then placed in a larger plastic bag with a glass ampoule containing approximately 4 milliliters of EtO (marketed as Amprolene* sterilizing gas). After the larger bag is sealed with a twist tie the ampoule is broken and the bag is placed into a 120 liter capacity chamber which is used for both sterilization and aeration (S/A). Local ventilation is provided along the top of the chamber door to control fugitive EtO emissions. Usually a minimum of 3 ampoules are used per load. Because of the adverse health effects associated with exposure to EtO, the Orbis staff routinely load the S/A chamber at the end of daily activities, immediately before deplaning. After overnight sterilization, the chamber is aerated for approximately 15-17 hours (aeration can only be done during the day because no power is provided to the plane overnight). After this initial aeration period the individual packets are removed from the bag, then placed back into chamber for additional (3-4 hours) aeration. Subsequently, the fully aerated packets are removed and placed into storage cabinets.

Because of the closed-system nature of the sterilization/aeration process, EtO exposure was brief in nature and primarily limited to instances when the items were either placed into or removed from the chamber.

IV. METHODS AND MATERIALS

A. Waste Anesthetic Gases

Exposure monitoring for waste anesthetic gases was conducted on July 10 and 11, during three eye operations involving two different methods of anesthesia administration (tube intubation and mask induction). During each of the three operations, four individuals in the operating room (e.g. an anesthesiologist, surgeon, and two nurses) were outfitted with air sampling devices to measure their exposure to nitrous oxide (N_2O), and to halothane and/or isoflurane. Apart from the O.R. staff, air samples for these anesthetic gases were also obtained from the recovery room nurse who was potentially exposed to these gases from off-gassing postoperative patients. To address a concern regarding potential infiltration of waste anesthetic gases into the audio-visual (A/V) room, stationary air samples were collected in this area during the same time period these gases were being used in the O.R.

N_2O concentrations were measured utilizing two different sampling methods. One sampling method consisted of collecting

composite air samples in 22 liter mylar bags. Low flow pumps, calibrated at 0.2 liters per minute (Lpm), were used to fill the bags with air collected from the worker's breathing zone. All gas bag air samples were subsequently analyzed on-site using a portable Miran 103* infrared spectrophotometer. This instrument was also used as a direct-reading survey meter to determine whether there were any N₂O leaks in the anesthetic gas delivery system or in the cryo units. Pre- and post-survey instrument calibration was achieved by injecting known quantities of pure N₂O gas using a closed-loop calibration system thereby allowing a calibration curve to be drawn encompassing the range of time weighted average N₂O exposure levels expected and/or found during the field survey. It was also used to indirectly assess the general ventilation system in the O.R.

The other method used for measuring N₂O levels was the Landauer Nitrox* dosimeter. This is a passive monitor which contains a proprietary sorbent selective for N₂O. The dosimeter was used for a majority of the personal samples because it offered an alternative to the somewhat cumbersome gas bag sampling method, considering the space limitations aboard the plane.

Because of NIOSH's somewhat limited experience with the Nitrox* dosimeter in terms of its comparability to the gas bag method, we collected side-by-side air samples with both methods from six individuals, for purposes of comparison.

Air samples for halothane and isoflurane were collected with activated charcoal using low flow sampling pumps calibrated at 0.2 Lpm. These samples were collected in the worker's breathing zone for the same time period as those samples for N₂O. Both analytes were analyzed by gas chromatography using NIOSH Method 1003 with modifications.⁽¹⁾ The limit of detection for the analysis was 0.1 milligram per sample for both analytes.

B. Nitrous Oxide Exposures During Cryosurgery

To address a concern regarding potential N₂O exposures from the cryosurgery units, NIOSH collected air samples from three O.R. personnel who either adjusted or were in the vicinity of the cryo machine while it was being used. Monitoring was conducted during operations where the patient was administered N₂O as well as those operations where only a local anesthetic was given. NO₂ sampling methods similar to those described above were used to evaluate personal exposures and to evaluate the N₂O delivery and exhaust lines of both cryo units for the presence of leaks.

C. Ethylene Oxide Exposures Associated with Sterilization Activities

Exposure monitoring for ethylene oxide (EtO) was conducted on July 8-11, 1986. EtO exposures were evaluated by collecting both personal and general area air samples. Breathing zone air samples were collected from nurses during selected tasks, predominately of short duration, which afforded the greatest potential for exposure to EtO. These tasks included: (1) breaking of ampoules containing liquid EtO and then placing bags containing broken ampoules and surgical implements into the sterilization/aeration (S/A) chamber; (2) unloading of sterilized, partially aerated bags from the chamber and removing of individual packets and then placing them back into chamber for further aeration; and (3) removal of medical supplies from the cargo hold where the exhaust fan for the S/A chamber was located.

Because the Orbis staff typically enter the aircraft before the main power is turned on, there was concern that, following overnight sterilization, there would be EtO inside the aircraft. To address this concern, general area air samples were collected in the sterilizer room (an area where fugitive EtO would most likely be present) both before and after the main power was turned on (which, among other things, activated the local exhaust system for the S/A chamber as well as the general ventilation system).

To determine whether residual EtO was present in a sterilized, aerated plastic Amprolene* bag, a short-term air sample was taken inside a used bag shortly after it was removed from the S/A chamber.

EtO concentrations were measured using sorbent tubes and, in some cases, direct-reading indicator (detector) tubes. The sorbent tubes, containing hydrogen-bromide impregnated charcoal, were attached via Tygon* tubing to personal sampling pumps calibrated at either 0.2 or 1.5 Lpm. The higher flowrate was used in sampling situations where the exposures time was limited (i.e., less than about 10 minutes.) Samples were analyzed by gas chromatography according to NIOSH Method 1614. The limit of detection for the analysis was 2.6 micrograms per sample.

Although not nearly as sensitive as the sorbent tubes, the detector tubes were used primarily because they provided a direct indication of the EtO concentration at the time of sample collection.

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 Exposures Limits (REL's), 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 REL's and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH REL's 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 REL's standards, 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. Anesthetic Gases

Reports by Vaisman⁽²⁾ and Askrog and Harvald⁽³⁾ 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. In 1974, the American Society of Anesthesiologists published the results of a study⁽⁴⁾ 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.

In a study published by NIOSH in 1976,⁽⁵⁾ "nitrous oxide (N₂O) 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. N₂O 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.^(6,7)

Mortality and other epidemiologic studies have raised the question of possible carcinogenicity of anesthetic gases, but sufficient data are presently lacking to list N₂O or halothane as suspected carcinogens.

In an epidemiological study of dentists, Cohen et al.⁽⁸⁾ 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 N₂O alone or a halogenated agent. However, in a review of that study, NIOSH⁽⁵⁾ concluded that "the halogenated anesthetics alone do not explain the positive findings of the survey and N₂O exposure must be an important contributing factor, if not the principal factor". This conclusion is based on a calculation which assumed that as many as 1 in 10 of the dentists using an inhalation anesthetic employ 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⁽⁶⁾ recommended a TWA exposure of 25 ppm during anesthetic administration in hospitals. This recommendation is based primarily on available technology in reducing waste anesthetic gas levels in these environments.

In a recent study, Cohen et al.⁽¹⁰⁾ reported results on questionnaires sent to 64,000 dentists and dental assistants. Respondents were asked to estimate their occupational exposure to anesthetic gases (e.g., N₂O, halothane etc.) and to complete a health history for the period 1968 to 1978. Over 22,000 dental assistants and 23,000 pregnancies which occurred during the sample period were reported. Among the dentists who responded, 42 percent said they used anesthetic gases regularly in their practices. Approximately one-third of that group were "heavy users", using agents more than 9 hours per week. The study concluded that:

1. Among heavily anesthetic-exposed dentists, an increase in liver disease from 1.9 to 3.2 cases per 100, an increase in kidney disease from 2.4 to 2.9 cases per 100, and an increase from 0.35 to 1.35 cases per 100 in nonspecific neurological disease (numbness tingling, and weakness) were reported relative to the group reporting no exposure to the anesthetic gases.
2. Among heavily exposed female dental assistants, an increase in liver disease from 1.0 to 1.6 cases per 100, and an increase in nonspecific neurological disease from 0.45 to 1.98 cases per 100 were reported relative to the non-exposed group of assistants.
3. The rate of spontaneous miscarriage increase from 6.7 per 100 in the control group to 11.0 per 100 among wives of heavy anesthetic-exposed dentists, and from 7.6 cases per 100 in non-exposed to 17.5 cases per 100 in heavily exposed female dental assistants.
4. Birth defects increased from 3.6 to 5.9 per 100 among children of exposed female assistants; however, no increase in birth defects was reported in children of exposed male dentists.
5. Cancer incidence was unchanged among male dentists, but the rate among exposed female assistants appeared somewhat higher than among those unexposed.

Finally, because dentists work close to the patient's mouth, and tend to use larger volumes of gases to maintain effective anesthetic, they may receive two to three times the dose of anesthetic gases as operating room personnel. Also, a study of individual anesthetic gases used in dental offices revealed that N₂O was the sole agent reported by 81 percent of those dentists using anesthetic gases. Cohen concluded that N₂O, commonly known as "laughing gas", has always been considered to be inert and nontoxic. However, this study indicated that "significant health problems appear to be associated with the use of nitrous oxide."

Although OSHA presently does not have a permissible exposure level for anesthetic gas such as N₂O, NIOSH recommends that exposures be maintained below 25 ppm in hospitals.⁽⁵⁾ This level is believed to be achievable with current engineering control systems and good work practices.

In regards to the halogenated anesthetic gases, NIOSH recommends that the halothane and isoflurane levels be controlled to 0.5 ppm when used in conjunction with N₂O as it was during this evaluation.⁽⁵⁾ In most cases this level can be achieved by controlling nitrous oxide exposure to 25 ppm. In situations where both halothane and isoflurane are used, the exposure should be considered additive since they produce similar health effects.

B. Ethylene Oxide

1. Acute Effects

The primary mode of exposure to ethylene oxide (EtO) is through inhalation. EtO is an irritant of the eyes, respiratory tract, and skin. Early symptoms of EtO exposure include irritation of the eyes, nose, and throat and a peculiar taste. The delayed effects of exposure include headache, nausea, vomiting, pulmonary edema, bronchitis, drowsiness, weakness, and electrocardiograph abnormalities.⁽¹¹⁾ There have also been reports of cases of neurotoxicity induced by ethylene oxide exposure.^(12,13,14)

Dermal contact with solutions of ethylene oxide as low as 1% can cause burns with edema and erythema. Although skin contact with undiluted EtO does not cause burns, it can cause frostbite as a result of rapid evaporation.⁽¹⁵⁾ The severity of skin burns from solutions of ethylene oxide appears to be influenced by both the length of contact with the skin and the strength of the solutions, with solutions around 50% appearing to be the most hazardous.⁽¹⁶⁾ Both the undiluted liquid and solutions of EtO may cause severe eye irritation or damage⁽¹⁷⁾ and there have been case reports of cataracts among workers exposed to high levels of EtO.⁽¹⁸⁾

2. Carcinogenic, Mutagenic, and Reproductive Effects

EtO has been shown to be carcinogenic to animals. Inhalation of EtO has induced excess leukemia in female rats and peritoneal mesothelioma and leukemia in male rats. An increase in the number of gliomas, a rare malignant tumor of the central nervous system, was also observed.^(19,20) There is also epidemiological evidence which suggests that workers with extended and intermittent exposure to low concentrations of ethylene oxide may experience an increased risk of leukemia and stomach cancer, as compared to unexposed workers.⁽²¹⁾

EtO has been shown to cause changes in the genetic material of lower biological species including Salmonella⁽²²⁾ and fruit flies⁽²³⁾ as well as mammals, including rabbits⁽²⁴⁾ and monkeys.⁽²⁵⁾ These genetic changes have been shown to be heritable in experiments with mice.⁽²⁵⁾ Several studies have demonstrated that genetic changes can also occur among humans exposed to EtO. Workers exposed to EtO have been found to have significantly increased numbers of chromosomal aberrations and sister chromatid exchanges as compared to workers unexposed to EtO.^(26,27)

Animal experiments with EtO have indicated adverse reproductive effects from EtO exposure. A decrease in the number of pups born per litter was observed among female rats exposed to EtO prior to mating and during gestation⁽²⁸⁾, and an increase in the number of malformed fetuses per litter was observed among female mice administered EtO intravenously during gestation.⁽²⁹⁾ Male monkeys exposed to EtO have been shown to have reductions in sperm count and sperm motility.⁽²⁰⁾ There is also some human evidence which suggests that women exposed to EtO during their pregnancies may experience increased rates of spontaneous abortions, although this information is not conclusive.⁽³⁰⁾

NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.1 ppm as determined by an 8-hour TWA with a short-term exposure limit not to exceed 5 ppm for a maximum of 10 minutes per day. This recommendation is based on the available risk assessment data which show that even at an exposure level of 0.1 ppm, the risk of excess mortality is not completely eliminated.^(31,32) Effective as of August 21, 1984, the standard of the Occupational Safety and Health Administration (OSHA) for occupational exposure to ethylene oxide was revised downward from 50 ppm to 1 ppm calculated as a TWA concentration for an 8-hour work shift. This downward revision in the standard was based on the animal and human data showing that exposure to EtO presents a carcinogenic, mutagenic, reproductive, neurologic, and sensitization hazard to workers. Included in the present OSHA standard are requirements for controlling EtO, personal protective equipment, measurement of employee exposures, training, and medical surveillance of the exposed employees.⁽³³⁾

VI. RESULTS AND DISCUSSION

A. Waste Anesthetic Gases

The sampling results for nitrous oxide (N₂O), halothane, and isoflurane are presented in Table 1. It should be noted that the results for the paired samples utilizing gas bag (GB) and Landauer dosimeter (LD) sampling devices did not correlate very well for 3 of 6 paired sample sets, with the dosimeter measuring N₂O levels approximately 1.5 to 2.5 times higher than the corresponding GB samples. For purposes of this evaluation the higher of the two values will be used in the exposure assessment.

During the three eye operations all twelve operating room (O.R.) personnel who were monitored were exposed to N₂O at levels in excess of the NIOSH REL of 25 ppm. Time-weighted average (TWA) breathing zone concentrations of N₂O ranged from 42 to 137 ppm. (Despite the differences noted in three of the paired samples, the lower GB sample results in all three cases exceeded the NIOSH REL.) Generally, the highest exposure was measured for the anesthesiologists, which was anticipated based on their proximity to the anesthetic gas source. Concomitant exposures to halothane and isoflurane either met or exceeded the NIOSH REL of 0.5 ppm for seven of the twelve O.R. staff. During the operation where both halogenated compounds were used (mask induction followed by intubation) the combined exposure, taken simply by adding the airborne concentration for each compound, was used for comparison to the 0.5 ppm criterion, since these two compounds produce similar health effects.

The method of gas administration appeared to have an effect on the degree of exposure, especially to the anesthesiologist. His exposure was highest during the operation where the patient was induced with a mixture of N₂O and halothane via a conventional (non-scavenging) mask. During the 5 minute induction procedure N₂O concentrations in the breathing zone of the anesthesiologist exceeded 190 ppm (the upper limit of the Miran analyzer) as compared to levels less than 75 ppm during intubation operations.

N₂O gas leaks were detected along the breathing circuit of the anesthesia machine primarily at flextube/metal connections. This was partially responsible for the relatively high anesthetic gas concentrations found in the O.R. An attempt was made by the anesthesiologist to correct the leaks at the time of testing but he was unsuccessful. He indicated that a tight fit could not be obtained with the existing flex tubing because it did not appear to be interchangeable with the manufacturer's original equipment.

Breathing zone air samples obtained from the recovery room nurse while attending to "off-gassing" postoperative patients revealed TWA N₂O exposures at levels of 24 and 79 ppm, and to isoflurane at levels of 0.87 to 0.96 ppm. Concentrations of both of these anesthetic gases either met or exceeded their respective exposure limits. These results show that the recovery room nurse can be exposed to the same anesthetic gases levels as the O.R. staff, when the primary source of exposure was from gases exhaled from postoperative patients who were given general anesthesia.

The A/V room was found to contain relatively high levels of N₂O and isoflurane during each of the operations where gas anesthesia was used. Concentrations ranged from 10 to 59 ppm for N₂O and from 0.16 to 0.33 ppm for isoflurane. No halothane was detected. Because the ventilation in the O.R. was maintained under positive pressure (air out) relative to adjoining areas, the presence of anesthetic gases in this area was not unexpected, especially considering the relatively high levels measured in the O.R.

B. Nitrous Oxide Exposures During Use of Cryosurgery Machine(s)

Results of personal monitoring conducted during use of the cryosurgery machine(s) are presented in Table 2. Exposures varied and, as expected, were higher when the cryo unit was used during an operation where N₂O was administered to a patient. Under these conditions an exposure of 120 ppm was measured, which nearly equalled the highest N₂O exposure concentration measured for the anesthesiologist. By comparison, when the cryo machine was used during an operation where no anesthetic gas was given to the patient, N₂O exposure levels did not exceed 16 ppm. Based on these measurements, the cryo machine, even with leaks present (see below), did not produce N₂O exposures in excess of the NIOSH REL of 25 ppm.

Leaks were detected at the high pressure and exhaust lines for each of the cryo units, specifically at the N₂O tank fitting, gas inlet connection, and at the end of the exhaust hose near the wall-mounted evacuation outlet. Furthermore, no suction was evident from the exhaust hose when connected to the evacuation outlet. The exhaust fan for the evacuation system was reportedly disconnected and used to replace a similar but inoperable fan exhaust servicing the restrooms, until the one in the restroom could be repaired.

C. Ethylene Oxide Exposures Associated with Sterilization Activities

Table 3 presents chronologically the air sampling results for EtO. Some problems were encountered with the field blank samples (presence of EtO on all blanks) and, as a result, the concentrations reported for those samples collected on charcoal tubes are to be considered a maximum.

EtO was detected in all three samples collected during loading and unloading of packaged surgical implements from the S/A chamber and in both samples collected during acquisition of medical supplies from the cargo hold. During two separate chamber loading tasks, each lasting no longer than 2 minutes, breathing zone EtO concentrations were measured at 1.6 and 3.5 ppm. Unloading of sterilized, partially aerated bags from the chamber, a task which also lasted about 2 minutes, revealed an EtO concentration of 17 ppm in the nurse's breathing zone. At this point in the aeration process the individual packets were removed from large plastic bags and placed back into the chamber for additional aeration. One of the discarded bags was found to contain 30 ppm EtO as measured with a direct-reading detector tube. EtO was detected at much lower concentrations (less than 0.7 ppm) in the cargo hold during a 10 minute period when nurses were obtaining medical supplies. The source of EtO in this area was an exhaust fan used to ventilate the S/A chamber. Based in the fact that the activities described above either involved brief exposure durations or low exposure levels, the NIOSH short-term 10 minute REL of 5 ppm was not exceeded during these tasks.

Two general area air samples collected on the mornings of July 9 and 11 in the sterizor room immediately after initial boarding of the aircraft but prior to activation of the main power, revealed EtO concentrations of 2 and 12 ppm, respectively. On July 11, concentrations dropped to less than 0.3 ppm several minutes after the general/local ventilation systems were activated. The presence of EtO in the sterilizer room indicated that the sterilization equipment (chamber and/or ducting) is not air tight and, as a result, workers are potentially exposed for a short period of time to fugitive EtO emissions, until shortly after the main power is turned on.

VII. RECOMMENDATIONS

Based on the air sampling results and the observations made during the evaluation, the following recommendations are presented with the goal of minimizing exposure of the Orbis staff to waste anesthetic gases and ethylene oxide.

A. Waste Anesthetic Gases

1. Even though the use of inhalation anesthetic gases is infrequent, it is recommended that a scavenging system be utilized to collect waste anesthetic gases. This would include the use of a scavenging nasal mask in operations where the patient is administered gas via mask induction. Specific information regarding types of waste gas collection methods for the anesthesia machine and scavenging mask are available in reference 6.
2. A preventive maintenance program should be developed and implemented to ensure that the anesthesia machine and cryo machine are free of leaks. These units should be checked for leaks at least monthly. All components of each system can be easily checked for leaks using a soap solution. High pressure leaks (from the tank to the mixing or control unit) can be easily detected by keeping a log of the line pressure when the N₂O tank is turned off at night and of the pressure the next morning. A drop of more than 10% indicates a leak which should be found via the soap solution technique and corrected.
3. The exhaust fan that services the wall evacuation outlet in the O.R. (used to evacuate the exhaust from the cryo unit) should be replaced.
4. Postoperative patients who had received anesthetic gases during their operation should be provided with a scavenging mask during their stay in the recovery room. In situations where the use of masks is not feasible (due to patient illness) a small portable fan should be used to reduce exposures of the attending nurse. The fan should be placed in such a manner that fresh air is directed across the face of the patient, thereby removing localized high concentrations of anesthetic gases exhaled by the patient from the breathing zone of the attending nurse.
5. The anesthesia machine should be serviced at least annually by an authorized factory representative to ensure that the system is working effectively. Records indicated that the last servicing was in the spring of 1983, well beyond the manufacturer's recommended yearly inspection schedule.

B. Ethylene Oxide

1. Work practices regarding loading and unloading of the S/A chamber should be modified to minimize exposure to EtO. During loading, the ampoules should be broken only after the bags are placed into the chamber in order to take advantage of the negative pressure provided by the chamber's local exhaust ventilation system. For the same reason, bag contents should be removed from the sterilization bags preferably without removing the items from the chamber. Since used sterilization bags were found to be a source of residual EtO, there is no reason they could not be further aerated with the packaged items and subsequently discarded.
2. To minimize exposures of workers entering the cargo hold during EtO aeration, flexible ducting of sufficient length to extend outside of the cargo hold door should be connected to the exhaust fan servicing the S/A chamber. (This should also be done to the other fan servicing the O.R. wall evacuation outlet once it is replaced.)
3. The general ventilation in the aircraft should be allowed to run at least 5-10 minutes before workers are permitted access into the sterilization room, on mornings following overnight sterilization.

Follow-up environmental sampling for anesthetic gases and EtO should be conducted to assure that the extent of implementation of the above recommendations is adequate to protect the Project Orbis staff members.

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Table 1
Nitrous Oxide, Halothane and Isoflurane Exposures
Project Orbis, Inc.
San Jose, Costa Rica
HETA 86-277
July 10-11, 1986

Date	Sample Description ¹	Operation	Anesthesia Method	Sampling Duration	Sampling Device ²	Sample Volume Liters	Environmental Concentration (ppm) ³			Comments
							Nitrous Oxide	Halothane	Isoflurane	
7-10-86	Anesthesiologist, BZ	Detached Retina	IV. injection/ Endo Tube	0810-1038	GB LD CT	- - 35	68 66 -	- - -	- - 1.2	Patient was administered mixture of N ₂ O, isoflurane, and oxygen via endotracheal tube. Keeler cryo machine, a source of N ₂ O, was used about 10 minutes during operation
7-10-86	Scrub Nurse, BZ	"	"	0810-1041	GB LD CT	- - 33	45 74 -	- - -	0.32	
7-10-86	Circulating Nurse	"	"	0810-1039	LD CT	- 32	76 -	- -	- 0.29	
7-10-86	Visiting Eye Surgeon, BZ	"	"	0810-1035	LD CT	- 34	40 -	- -	- 0.19	
7-10-86	A/V Room, A	"	"	0810-1048	LD CT	- 36	45 -	- -	- 0.18	
7-10-86	Recovery Room Nurse, BZ	-	-	1038-1230	GB LD CT	- - 24	37 79 -	- - -	- - 0.87	Postoperative patient was primary source of exposure to waste anesthetic gases, from exhaled breath
7-11-86	Anesthesiologist, BZ	Detached Retina	Mask Induction/ Endo Tube	0706-0925	GB LD CT	- - 31	121 137 -	- - 3.4	- - 2.2	Patient was induced with mixture of nitrous oxide and halothane then given a mixture of N ₂ O, isoflurane, and oxygen via intubation. Cryo machine was not used.
7-11-86	Scrub Nurse, BZ	"	"	0706-0924	LD CT	- 29	81 -	- 0.29	- 0.40	
7-11-86	Circulating Nurse, BZ	"	"	0706-0934	GB LD CT	- - 33	27 72 -	- - 0.37	- - 0.36	
7-11-86	Visiting Eye Surgeon, BZ	"	"	0707-0921	LD CT	- 31	42 -	- 0.28	- 0.38	
7-11-86	A/V Room, A	"	"	0708-0928	GB CT	- 32	10 -	- trace	- 0.16	

Continued

Table 1 (continued)

Nitrous Oxide, Halothane and Isoflorane Exposures

Project Orbis, Inc.
San Jose, Costa Rica
HETA 86-277

July 10-11, 1986

Date	Sample Description ¹	Operation	Anesthesia Method	Sampling Duration	Sampling Device ²	Sample Volume Liters	Environmental Concentration (ppm) ³			Comments
							Nitrous Oxide	Halothane	Isoflorane	
7-11-86	Recovery Room Nurse, BZ	"	"	0924-1313	GB	-	24	-	-	Postoperative patients were primary source of exposure to anesthetic gases, from exhaled breath
					LD	-	23	-	-	
					CT	51	-	trace	0.96	
7-11-86	Nurse Anesthesiologist, BZ	Cataract	IV. injection/ Endo Tube	0943-1133	LD	-	105	-	-	Patient given N ₂ O, isoflurane and oxygen mixture via intubation Cryo machine was not used.
CT	24	-	-	1.4						
7-11-86	Scrub Nurse, BZ	"	"	0943-1133	LD	-	42	-	-	
CT	23	-	-	0.41						
7-11-86	Circulating Nurse, BZ	"	"	0943-1133	LD	-	68	-	-	
					CT	24	-	-	0.50	
7-11-86	Visiting Surgeon, BZ	"	"	0943-1128	LD	-	53	-	-	
					CT	24	-	-	0.44	
7-11-86	A/V Room, A	"	"	0943-1134	LD	-	59	-	-	
					CT	24	-	-	0.33	
NIOSH Recommended Exposure Limits (during period of administration):							\$25	\$0.5	\$0.5	

1. BZ = breathing zone air sample; A = stationary air sample

2. Sampling devices: GB - gas bag; LD - Landauer (nitrous oxide) dosimeter; CT = charcoal tube

3. Environmental concentration expressed in parts per million (ppm), as a time-weighted average over the sampling period.

trace = above limit of detection but below limit of quantitation

Table 2

Nitrous Oxide Exposures During Use of Cryo Machine in Operating Room

Project Orbis, Inc,
San Jose, Costa Rica
HETA 86-277

July 10, 1986

Date	Sample Description ¹	Operation	Anesthesia Method	Sampling Duration	Sampling Device ²	N ₂ O Concentration ³ (ppm)	Comments
7-10-86	Biosystem Engineer, BZ	Detached Retina	IV/Endo	0855-0934	LD	120	Cryo machine used about 10 minutes during sampling period. Concomittant exposure to waste anesthetic gases.
7-10-86	Scrub Nurse, BZ	Cornea transplant	local	1537-1643	GB	16	Cryo machine used about 10-15 minutes during sampling period. No N ₂ O administered during operation.
7-10-86	Biosystem Engineer, BZ	"	"	1537-1556	GB	9	Spent part of time outside of O.R.
NIOSH Recommended Exposure Limit:						\$25	

1. BZ = breathing zone air sample

2. Sampling devices: LD - Landauer (nitrous oxide) dosimeter; GB - gas bag

3. Environmental concentration in parts per million (ppm), as a time-weighted average over the sampling period.

Table 3
Ethylene Oxide Concentrations
Project Orbis, Inc.
San Jose, Costa Rica
HETA 86-277

July 8-11, 1986

Date	Sample Description	Sample Type ¹	Sampling Method ²	Sample Time	Sample Volume (liters)	Environmental Concentration (ppm)		Comments
						CT Method	DT Method	
7- 8-86	Head Nurse, Sterilizer Rm	BZ	CT	1543-1545	3.3	1.6	-	Nurse broke 3 Amproleneé ampoules (through bags) then placed bags into sterilization/aeration chamber
7- 9-86	Sterilizer Room	GA	DT	0710-0715	-	-	2	Sample taken immediately after entering aircraft before activation of general ventilation system.
7- 9-86	Sterilizer Room	GA	DT	0838-0843	-	-	ND	Sample taken about 75 minutes after activation of general and local exhaust ventilation systems
7-09-86	Cargo hold	GA	CT	0724-0942	28	0.5	-	Same as above
7-09-86	Nurse, cargo hold	BZ	CT	0806-0816	15	0.7	-	Sample collected while nurse was obtaining medical supplies
7-10-86	Nurse, sterilizer room	BZ	CT	1358-1400	3.4	17	-	Nurse removed 3 Amproleneé bags from chamber, removed contents, then placed individual bags back into chamber for further aeration.
7-10-86	Inside used, sterilized Amproleneé bag	P	DT	1403-1408	-	-	30	Sample taken immediately after contents were removed from chamber
7-10-86	Nurse, Sterilizer Room	BZ	CT	1735-1736	1.1	3.5	-	Nurse broke 5 Amproleneé ampoules (through bags) then placed bags into chamber

(continued)

Table 3 (continued)

Ethylene Oxide Concentrations

Project Orbis, Inc.
San Jose, Costa Rica
HETA 86-277

July 8-11, 1986

Date	Sample Description	Sample Type ¹	Sampling Method ²	Sample Time	Sample Volume (liters)	Environmental Concentration (ppm)		Comments
						CT Method	DT Method	
7-11-86	Sterilizer Room	GA	CT	0634-0640	9	12	-	Sample taken immediately after entering aircraft before activation of general ventilation system.
7-11-86	Sterilizer Room	GA	CT	0647-0703	24	0.3	-	Sample taken about 7 minutes after activation of general and local exhaust ventilation systems
NIOSH Recommended Exposure Limit						0.1 5 (10 min ceiling)	0.1 5 (10 min ceiling)	

1. BZ = breathing zone air sample; GA = general area air sample; P = process air sample

2. CT = charcoal tube (H-Br treated); DT = detector tube.

3. Environmental concentration in parts per million (ppm), as a time-weighted average over the sampling period.

ND = nondetectable; less than 1 ppm for the detector tube or less than 2.6 micrograms per sample for charcoal tube method.