Waste Anesthetic Gases

Information for Management in Anesthetizing Areas and the Postanesthesia Care Unit (PACU)



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American Society of Anesthesiologists Committee on Occupational Health of Operating Room Personnel Arnold Berry, M.D., M.P.H., Chair

Task Force on Trace Anesthetic Gases

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This document has been developed by the ASA Task Force on Trace Anesthetic Gases of the ASA Committee on Occupational Health of Operating Room Personnel, but has not been reviewed or approved as a practice parameter or policy statement by the ASA House of Delegates. Variances from recommendations contained in this document may be acceptable based on the judgment of the responsible anesthesiologist. The recommendations are designed to encourage quality patient care and safety in the workplace, but cannot guarantee a specific outcome. They are subject to revision from time to time as warranted by evolution of technology and practice.

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Introduction

n 1981, the American Society of Anesthesiologists (ASA) published the booklet, "Waste Anesthetics in Operating Room Air: A Suggested Program to Reduce Personnel Exposure," written by the ASA Ad Hoc Committee on Effects of Trace Anesthetic Agents on Health of Operating Room Personnel. It provided details of potential hazards that may be associated with trace concentrations of waste anesthetic gases, information on scavenging and recommendations for work practices from the National Institute for Occupational Safety and Health (NIOSH).

As more information became available, the ASA Committee on Occupational Health of Operating Room Personnel decided that the 1981 booklet required revision. This new booklet contains an analysis of the subject with critical description of important papers to give the reader a working

knowledge of all aspects of the effects of trace levels of waste anesthetic gases in locations where anesthesiologists work, including the postanesthesia care unit (PACU), nonoperating room anesthetizing locations, ambulatory surgical facilities and office-based surgical suites. A section on regulatory agencies' current recommendations is included as well as information on scavenging systems. There is an extensive bibliography. Recommendations are made for scavenging, maintenance of equipment with appropriate documentation, education of personnel working in areas where they may be exposed to trace concentrations of anesthetic gases and work practices.

These recommendations to reduce exposure to waste anesthetic gases must never be paramount to concerns regarding patient safety and should not interfere with quality of care.

Summary

RISKS

Studies have not shown an association between trace levels of waste anesthetic gases found in scavenged anesthetizing locations and adverse health effects to personnel.

RECOMMENDATIONS OF ASA TASK FORCE ON WASTE ANESTHETIC GASES

- Waste anesthetic gases should be scavenged.
- Appropriate work practices should be used to minimize exposure to waste anesthetic gases.
- Personnel working in areas where waste anesthetic gases may be present should be educated regarding current studies on health effects of exposure to waste anesthetic gases, appropriate work practices to minimize exposure, and machine checkout and maintenance procedures.
- There is insufficient evidence to recommend routine monitoring of trace levels of waste anesthetic gases in the O.R. and PACU.
- There is insufficient evidence to recommend routine medical surveillance of personnel exposed to trace concentrations of waste anesthetic gases, although each institution should have a mechanism for employees to report suspected work-related health problems.

Analysis of the Literature

Studies of Possible Adverse Effects of Trace Levels of Waste Anesthetic Gases

he convincing demonstration of the anesthetic properties of diethyl ether by William T.G. Morton and Crawford W. Long in the 1840s was one of the most significant events in the history of medicine. Shortly thereafter, nitrous oxide and chloroform were also introduced as inhaled anesthetics, and these three drugs remained the cornerstone of anesthetic practice for almost 100 years. In 1933, cyclopropane was introduced, followed in 1934 by trichlorethylene and finally by a whole series of fluorinated inhaled anesthetics.

Even in the early days of anesthesia, the dangers of inhaled anesthetics to both patients and operating room personnel were recognized. Patients occasionally suffered serious toxicity, such as hepatic failure, after the use of chloroform, whereas operating room personnel were at risk for fires and explosions with the use of ether and cyclopropane. Moreover, early reports described how operating room personnel exposed to waste anesthetic gases suffered chronically from a multitude of symptoms, including general fatigue, rapid exhaustion and headaches. Many of these reports were anecdotal and, based on the paucity of published discussion from the period, seemed only of moderate concern to the specialty.

This changed in 1967 when Vaisman, from the Soviet Union, published results of a survey of the health of 198 male and 110 female anesthesiologists.² At the time, diethyl ether, nitrous oxide and halothane were the most commonly used inhaled anesthetics in their practices. Again, a high incidence of general symptoms such as headache, fatigue and irritability were reported, but also noted for the first time was an adverse reproductive effect; 18 of 31 pregnancies among anesthesiologists exposed to waste anesthetic gases ended in spontaneous abortion.

In the same year, Fink et al. published results of a study showing that nitrous oxide produced adverse reproductive effects in a mammalian species.³ In particular, rats exposed to high concentrations of nitrous oxide had a significantly increased incidence of skeletal abnormalities. Although the study by Vaisman did not include a control group and was never again included in any serious analysis of epidemiological studies, it together with Fink's study

inspired much research to determine whether trace levels of waste anesthetic gases produce adverse effects.

In Vitro and Nonhuman Studies

Subsequent investigations examined the adverse reproductive effects of inhaled anesthetics in animals and began to assess whether anesthetics were capable of producing other long-term health effects such as liver and kidney damage, cancer and genetic damage. Many studies have now been performed in whole animals or in animal and human tissues and fluids. It is not our intent to describe the extensive literature on this subject but rather to summarize key results.

Mutagenicity

In vitro studies of the mutagenic effect of anesthetics have been performed using cellular and subcellular systems. Mutations are heritable changes in genetic information that are usually deleterious. If they occur in somatic cells that are capable of dividing, all subsequent cells in the line will contain the mutation. If they occur in germ cells, subsequent generations of individuals will contain the mutation. The clinical significance of mutation is several-fold. Somatic mutations may lead to some types of cancer and contribute to other diseases such as atherosclerosis. Indeed, finding that a drug is a mutagen greatly increases the chances that it will also be a carcinogen. Germ cell mutations may lead to congenital anomalies and a multitude of genetically determined diseases.

All modern inhaled and most previously used anesthetics have been tested for mutagenicity in both bacterial and mammalian cell systems. 4.5 The general conclusion from these studies is that currently used inhaled anesthetics, including nitrous oxide, halothane, enflurane, isoflurane, sevoflurane and desflurane, have no mutagenic potential. Furthermore, the results of most tests of damage to DNA have been negative. Only older anesthetics such as trichloroethylene and fluroxene, which contain a double-bonded structure, are mutagens.

Despite these encouraging results, tests of body fluids and blood cells from operating room personnel have given variable results and are difficult to interpret. Results from these studies could be related to other factors in the operating room environment and not necessarily to exposure to trace concentrations of anesthetic gases.

Carcinogenicity

Some currently used and formerly used inhaled anesthetics have undergone carcinogenicity studies in rodents.6-11 These studies are particularly relevant to the effects of long-term exposure to trace levels of waste anesthetic gases because anesthetics were administered many times per week for a large part of the life of the animals, often 18 months or more. Furthermore, the maximum tolerated dose was often tested; that is, the highest dose that did not produce clinical or pathological toxicity in subchronic studies. Both chloroform and trichloroethylene were found to be rodent carcinogens when administered in extremely large dosages by oral gavage, but this route of administration is probably not relevant to inhaled exposure of patients or operating room personnel.12,13

In contrast, when isoflurane, halothane, enflurane, methoxyflurane and nitrous oxide were administered by inhalation and assessed in adequate studies, results for carcinogenicity had been uniformly negative. Although neither sevoflurane nor desflurane have undergone carcinogen bioassays in small rodents, both have been approved for clinical use by the Food and Drug Administration (FDA). Presumably, the general lack of carcinogenicity of current inhaled anesthetics as a group and the specific lack of genotoxicity (damage to DNA thereby causing mutations or cancer) of sevoflurane and desflurane have convinced the FDA that such testing is unnecessary.

Organ Toxicity

In addition to providing information about carcinogenic potential, long-term carcinogenicity studies have afforded investigators the opportunity to assess specific organ toxicity after chronic exposure to inhaled anesthetics. Even at the maximum tolerated dose, no evidence of significant clinical or pathological damage to the kidneys, liver, gonads or other organs was demonstrated for isoflurane, halothane, enflurane and nitrous oxide. Thus, these anesthetics show a remarkable lack of toxicity in long-term animal studies and, presumably, the same would be true for sevoflurane and desflurane.⁶⁻¹¹

Reproductive Effects

Many reports concerning the effects of inhaled anesthetics on reproductive processes of experimen-

tal animals have been published. The complete assessment of any drug involves examining its effect on fertility, mating behavior, embryonic and fetal wastage, congenital anomalies and postnatal survival and behavior. Not all these aspects of reproduction have been assessed for all inhaled anesthetics, but a reasonable picture of their reproductive effects has emerged. Studies have been conducted at trace or subanesthetic concentrations of anesthetics to simulate occupational exposure and at anesthetic concentrations to simulate patient exposure. Most of the significant studies in mammals have recently been discussed in a comprehensive review. 14

In general, nitrous oxide is the only inhaled anesthetic that has been convincingly shown to be directly teratogenic in experimental animals. High concentrations (50 percent to 75 percent) delivered to pregnant rats for 24-hour periods during the period of organogenesis and low concentrations (0.1 percent) delivered to rats throughout pregnancy result in an increased incidence of fetal resorptions and visceral and skeletal abnormalities. ^{15,16} Similar exposure conditions are unlikely to be duplicated in humans.

The currently used potent inhaled volatile anesthetics, halothane, enflurane and isoflurane, are not teratogenic in rodents except when administered at anesthetizing concentrations for many hours on several days during pregnancy. The consensus is that any teratogenic effects observed are caused by the severe and uncorrected physiologic changes associated with the administration of these anesthetics rather than by the anesthetics themselves. These experimental outcomes almost certainly are not relevant to occupational exposure to trace levels of waste anesthetic gases. The two most recently introduced potent inhaled volatile anesthetics, sevoflurane and desflurane, have been tested for teratogenicity in studies sponsored by the manufacturers and are reported to be without reproductive toxicity.5

Human Epidemiological Studies

Since Vaisman's report in 1967, numerous surveys of the health of operating room personnel have been performed. The focus of these surveys has been on adverse reproductive outcomes and cancer, although other health hazards such as hepatic and renal disease have been surveyed occasionally. Early studies appeared to favor the possibility that working in the operating suite was an occupational hazard. Most notable and most influential because of the large number of subjects involved was the 1974 national study supported by ASA on the effects

of trace levels of waste anesthetic gases on the health of operating room personnel. The Some 73,000 members from various professional organizations, including ASA and the American Academy of Pediatrics, were surveyed with about 40,000 responses. Compared with unexposed women, women exposed to waste anesthetic gases were reported to have increased risk of spontaneous abortion, cancer, hepatic disease and renal disease, and their offspring were reported to have an increased risk of congenital abnormalities. Exposed male anesthesiologists were reported to have increased risk of hepatic disease and their offspring to have an increased risk of congenital abnormalities.

During the next decade, many additional studies were completed. Results were less consistent than those of the earlier studies, some supporting and some refuting earlier claims of occupational hazard. In light of the inconsistencies and the different interpretation placed upon results, ASA commissioned a group of epidemiologists and biostatisticians to evaluate the significance of epidemiological studies of possible health hazards associated with exposure to waste anesthetic gases.

The report of the group appeared in 1985 as a special article in Anesthesiology.18 Buring and colleagues reviewed 17 published reports. Studies excluded from their analysis were those involving dentists and dental assistants and those that had no specific endpoints or used noncomparable control groups. Six remaining studies were included in the meta-analysis.^{17,19-23} Results indicated a 30-percent increased risk of spontaneous abortion for women working in the operating room and a similar but less consistent increase in congenital anomalies among offspring of exposed physicians. In addition, an approximately 50-percent increase in liver disease among men and women and a 30 percent increase in kidney disease among women were noted. Finally, an increased risk of cervical cancer, but no other type of cancer, was found.

The investigators noted that all the studies reviewed had weaknesses, including low response rates, inadequate information on nonresponders, anesthetic exposure levels and confounding variables and a lack of verification of outcome events. Additionally, the possibility of responder bias was always present and had been clearly demonstrated in a study by Axelsson and Rylander.²¹ They also noted that the increased risks observed were small and well within the range that might be due to bias or uncontrolled confounding variables. Even if the risks were real, one could not be certain that trace

levels of waste anesthetic gases were responsible rather than many other factors such as radiation and the stress of working in an operating room environment. Stress seems especially likely in light of a recent study from Sweden.²⁴

The investigators believed that the existing data were not sufficient for setting exposure limits. They also believed that additional retrospective studies were unlikely to add significant useful information and that prospective studies were needed to determine if hazards truly exist and are related to waste anesthetic gases.

In 1985, the same year in which Buring et al. published their report, Tannenbaum and Goldberg published their own independent review of the epidemiological literature concerning reproductive outcome after exposure to trace levels of waste anesthetic gases. Their conclusions were essentially the same, and they also recommended that a prospective study be performed with detailed and frequent monitoring of exposure levels and outcome events. They emphasized that data obtained on outcome events should be carefully verified. Several additional reviews, including one by Ebi and Rice, have come to the same conclusions. 26-28

Although most epidemiological studies have investigated operating room personnel, a few have involved dental personnel who work in dental operatories where nitrous oxide is used. Considerable differences may exist between working conditions in these two environments. The American Dental Association has recommended that scavenging of waste anesthetic gases, including nitrous oxide when used for sedation, should be carried out.29 Scavenging of waste anesthetic nitrous oxide may not have always been used in rooms where dentistry is performed, and the rooms themselves are often small. These factors may occasionally result in very high concentrations of nitrous oxide in the atmosphere, even above the 1,000 ppm (parts per million) thought to be associated with megaloblastic anemia.

In one study, three of 20 dentists exposed to concentrations up to 4,600 ppm had abnormal bone marrow, and two of these dentists had abnormal white cells in their peripheral blood.³⁰ Despite these findings, none of the dentists had physical symptoms of hematological disease. In 1992 and 1995, Rowland et al. published two studies that suggested decreased fertility and increased risk of spontaneous abortion among female dental assistants exposed to nitrous oxide when working in unscavenged rooms and exposed to nitrous oxide for more than three hours per week.^{31,32} There were no adverse repro-

ductive effects in female dental assistants who worked in scavenged environments.

Conclusion

The essential conclusion from all the reviews of pertinent epidemiological surveys is that the case for adverse health effects caused by exposure to trace levels of waste anesthetic gases in the operating suite is not proven. In many surveys, small to modest increased risks for some effects have been seen. most notably spontaneous abortion, but biases in data collection or uncontrolled confounding variables are at least as likely to be the cause as the operating room environment. Even if these increases in risk are eventually found to be real, one or more of the many factors present in the operating suite other than trace levels of waste anesthetic gases may be Only prospective studies specifically designed to examine the health effects of exposure to trace concentrations of waste anesthetic gases are likely to provide a more definitive answer.

To date, Spence and his colleagues have conducted and are presently analyzing the only prospective survey to have been performed.^{22,33,34} They surveyed 11,500 female United Kingdom medical school graduates age 40 or less working in hospital practices. They collected data on occupational details, work practices, lifestyle, medical and

obstetric history and some personal details. Interim results indicated that female anesthesiologists had no greater incidence of infertility than other physicians. In addition, the incidence of spontaneous abortion among those surveyed and of congenital abnormalities among their offspring was unrelated to the occupation of the mother, hours of exposure to the operating room environment or the use of scavenging equipment. Also, the incidences of cancer and neuropathy were unrelated to occupation.

There are no data to suggest that waste anesthetic gases are a danger to those women working in a scavenged environment who are contemplating pregnancy or who are already pregnant. Scavenging of waste anesthetic gases should be performed in whatever location an inhaled anesthetic is administered, be it an operating room, an office-based setting or in an area remote from the operating room, e.g. radiology suite, radiation therapy unit.

With scavenging and appropriate work practices, trace levels of waste anesthetic gases are known to be within the exposure limits recommended by the regulatory agencies (see pages 11-15), although the evidence that an unscavenged operating room causes adverse health effects to personnel is unconvincing. PACU personnel are exposed to trace levels of waste anesthetic gases that are lower than those found in operating rooms.

The Role of Regulatory Agencies

The Occupational Safety and Health Act of 1970, Public Law 91-596, was passed by Congress to assure that employers provide safe working conditions for employees. The act created the National Institute for Occupational Safety and Health (NIOSH) as an agency of the Department of Health, Education and Welfare and also the Occupational Safety and Health Administration (OSHA) as an agency of the Department of Labor.35 OSHA, NIOSH and the Food and Drug Administration (FDA) are the three federal agencies concerned with possible hazards associated with exposure to waste anesthetic gases. Other regulatory agencies or recommending bodies that address waste anesthetic gases include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), ASA, the American Dental Association (ADA) and the American Conference of Governmental Industrial Hygienists (ACGIH).

NIOSH Responsibilities:

- to promote research on effects of occupational exposures on the health of workers as a means of identifying occupational hazards;
- to promote means of preventing occupational injuries and illnesses through education of employers and employees;
- to recommend occupational safety standards to regulatory agencies; and
- to assist employers and employees in avoidance and prevention of unsafe working conditions.

OSHA Responsibilities:

- to adopt and mandate job safety and health standards;
- to establish rights and responsibilities for employers and employees for the implementation of safe occupational conditions;
- to require record-keeping on all employees to assess job-related injuries;
- to establish a reporting procedure for any jobrelated injury or illness;
- to evaluate work-related safety practices by entering and inspecting any workplace to determine compliance with mandatory standards; and
- to cite violations of standards in the workplace and apply punitive measures (fines) if necessary.

In December 1971, NIOSH members became involved in the issue of potential hazards associated with chronic exposure to waste anesthetic gases. In June 1972, they met with members of the National Academy of Sciences, National Research Council and the ASA Ad Hoc Committee on Adverse Reactions to Anesthetic Agents to review health surveys that suggested that female operating room workers experienced a high rate of spontaneous miscarriage.^{2,23} In 1974, NIOSH supported an ASA national health survey of operating room personnel comparing these workers to control groups of health care workers who had no history of waste anesthetic gas exposure.¹⁷ It was planned that if the 1974 health survey was positive, scavenging techniques would be recommended and a subsequent health survey would take place in 1978 to compare any adverse health effects after workers would have been exposed to an atmosphere relatively free of waste anesthetic gases. NIOSH withdrew support for the second survey but supported research to 1) assess effects of trace concentrations of anesthetics on behavioral performance of O.R. personnel, 2) to develop methods for eliminating waste anesthetic gases in operating room and dental suites, and 3) to evaluate reproductive and carcinogenic effects in mice following chronic exposure to nitrous oxide and halothane.

As a result of these and other studies, NIOSH cited several major areas of concern regarding the health of workers chronically exposed to waste anesthetic gases, including effects on reproduction, hepatic and renal function, behavioral performance and cancer risk of female personnel. In March 1977, a criteria document stating recommended standards for occupational exposure to waste anesthetic gases was submitted to the Department of Labor and published (DHEW/NIOSH Publication No. 77-140).³⁶ It contained sections on the recommended standards for environmental levels of waste anesthetic gases, data on the biologic effects of exposure, data on the extent of exposure, information on scavenging techniques and a description of methods for monitoring concentrations of waste anesthetic gases. NIOSH's criteria document included the following recommendations.

1977 NIOSH Recommendations

Scavenging and Exposure to Trace Concentrations of Waste Anesthetic Gases

- No worker shall experience an occupational exposure to halogenated anesthetic agents at concentrations >2 ppm when used alone or >0.5 ppm when used in combination with nitrous oxide over a sampling period not to exceed one hour.
- Occupational exposure to nitrous oxide when used as the sole anesthetic agent shall not exceed a time weighted average concentration of 25 ppm during anesthetic administration.
- Anesthetic gas machines, non-rebreathing systems and T-tube devices shall have an effective scavenging device that collects all waste anesthetic gases (later, NIOSH supported use of the published FDA apparatus checkout recommendations of 1992 after the original 1986 recommendations were revised).^{37,38}
- Waste anesthetic gases shall be disposed of in a manner such that occupational re-exposure does not occur.

Work Practices. Work practices shall be in place to maintain minimum waste anesthetic gas concentrations including the following:

- Waste anesthetic gas disposal systems are in place prior to starting an anesthetic.
- A face mask shall provide as effective a seal as possible against leakage during anesthetic administration.
- Vaporizers shall be filled in a ventilated area and turned to OFF position when not in use.
- Leak tests shall be performed on both high- and low-pressure components so that waste anesthetic gas levels are maintained at a minimum. Low-pressure leaks occurring in the patient circuit or its components shall be <100 ml per minute at 30 cm H₂O pressure. High-pressure leaks from the gas supply (cylinder or pipeline) to the flow control valve should be a maximum of 10 ml per minute.
- Anesthetic gas flows shall not be started prior to induction of anesthesia.
- Anesthetic flowmeters (i.e., flow control valves) shall be turned off or the Y-piece sealed when the breathing circuit is disconnected from the patient after administration of the anesthetic agent has started.
- Before the breathing bag (reservoir) is disconnected from the anesthetic delivery system, it shall be emptied into the scavenging system.

Appropriate disposal procedures for spills of any anesthetic agent are necessary. The exact procedures for each facility are the responsibility of that facility. According to the manufacturer's Material Safety and Data Sheet, disposal of enflurane and desflurane should be handled in accordance with the Environmental Protection Agency's (EPA) regulations for hazardous wastes. Classification Code #D022 is used for both agents because a byproduct of the manufacture of these agents includes a trace amount of chloroform. Isoflurane and halothane do not contain trace amounts of chloroform or any other regulated byproducts and are not considered hazardous wastes under EPA regulations.

Medical Surveillance

- Comprehensive medical and occupational histories shall be obtained on each employee prior to employment and maintained in the employee's medical record.
- Prior to employment and yearly thereafter, physical examinations of employees exposed to anesthetic gases are recommended.
- Employees shall be provided with information and training on hazardous chemicals in their work area, including potential undesirable effects of exposure to waste anesthetic gases; this information shall be provided at the time of initial employment and whenever a new hazard is introduced into the work area (Toxic and Hazardous Substances Hazard Communication Standard (29 CFR Part 1910.1200).³⁹
- Any abnormal outcome of pregnancies of employees or of the spouses of employees exposed to waste anesthetic gases shall be documented as part of the employee's medical records, and these records shall be maintained for the period of employment plus 20 years.

Upon employment and at least yearly thereafter, each worker shall be informed of possible health effects of exposure to waste anesthetic gases.

Monitoring of Trace Concentrations of Waste Anesthetic Gases

- Air monitoring shall be performed in all locations with the potential of worker exposure to waste anesthetic gases.
- Results of air sampling methods, locations, dates and concentrations measured and results of leak tests shall be maintained for at least 20 years.

With transmittal of the above proposed standards

to the Department of Labor, NIOSH participation ended and OSHA became involved to adopt and enact job health standards, investigate violations of standards in the workplace and enforce standards by citing violations. OSHA is required to publish all rulings in the Federal Register along with the date the new ruling becomes effective. In order for the NIOSH criteria document to become a federal standard, the proposal would have to be published in the Federal Register and subjected to public hearing after which OSHA would finalize the text of the standard to be adopted. Once a standard is promulgated, the Secretary of Labor has the authority to inspect all workplaces in order to determine whether employers are in compliance with the requirements of specific OSHA standards. Employers may be cited for violations of the Occupational Safety and Health Act if it is demonstrated that:

- employees are exposed to a hazard
- the hazard is a recognized one
- the hazard is likely to cause death or serious physical harm

OSHA developed technical instructions to deal with waste anesthetic gases, but no standards have ever been published in the *Federal Register*.⁴⁰⁻⁴²

In 1988, NIOSH published "Guidelines for Health Care Workers" (publication number 88-119), which offers additional guidance and recommendations to improve the management of waste anesthetic gases.⁴³ OSHA has issued guidelines to cover leak test procedures, medical surveillance, sampling and disposal methods, training and exposure to waste anesthetic gases in its Fact Sheet No. 91-38.⁴⁴

OSHA has recently rewritten its advisory document on "Anesthetic Gases: Workplace Exposure." This document is to be published on the Internet, thus allowing information to be updated as necessary with input from ASA.

Essentially the document states the following:

Current OSHA Recommendations

be exposed to a concentration of waste anesthetic gases >2 ppm of any halogenated anesthetic agent based on personal and area sampling methods provided in OSHA Instruction CPL 2-2.20B. When such agents are used in combination with nitrous oxide, levels of 0.5 ppm are

achievable. Nitrous oxide, when used as the sole anesthetic agent, should be controlled so that no worker is exposed at eight-hour time-weighted average concentrations >25 ppm during anesthetic administration.

Waste Anesthetic Gas Management: A welldesigned scavenging system should consist of a collecting device for vapors from breathing systems at the site of overflow, a ventilation system to carry waste anesthetic gases from the operating room and a method for limiting both positive and negative pressure variations in the breathing circuit. Anesthetic equipment should be serviced by qualified service representatives at quarterly intervals to maintain minimum leakage. Each facility shall provide training for workers to help them recognize work practices that decrease risks of unnecessary exposure to trace levels of waste anesthetic gases. practices should reduce gas leakage by avoiding turning on nitrous oxide or the vaporizer until the circuit is connected to the patient, turning off nitrous oxide and the vaporizer when not in use and maintaining the oxygen flow until the scavenging system is flushed.

Sampling procedures for evaluating waste anesthetic gas concentrations in air should be conducted for nitrous oxide and halogenated compounds on a quarterly basis in each anesthetizing location. Monitoring should include leak testing of equipment, sampling air in the workers' personal breathing zone and room air monitoring using gas-bag sampling or real-time sampling. Ventilation and air conditioning systems used in the physical plant should be inspected and tested at regular intervals to ensure that complete room air exchanges occur at a rate of 15 times-per-hour or more. (According to guidelines of the American Institute of Architects. newly constructed medical facilities are required to have systems capable of 15 to 21 air exchanges per hour, of which three must be with fresh outside air.)45 The central vacuum system should be inspected and tested on a quarterly basis.

Medical Surveillance: This should include a preplacement medical examination for all employees subject to occupational exposure to waste anesthetic gases. Employees should be informed of potential adverse effects of exposure to waste anesthetic gases such as spontaneous abortions, congenital abnormalities in

children and adverse effects on the liver and kidneys in compliance with the 1988 OSHA requirement that defines an employee's "right to know." Each institution should provide a mechanism to allow each employee to report a work-related health problem.

OSHA presently has no required exposure limits regulating nitrous oxide and halogenated agents. The levels recommended in the NIOSH criteria document are those that were found in studies to be readily achievable but were never promulgated.

In the past, OSHA inspections of anesthetic departments have resulted in citations when education of personnel with regard to the employee "right to know" clause has not been carried out.⁴⁶

Other Recommendations

American Society of Anesthesiologists (ASA)

See "Guidelines for Nonoperating Room Anesthetizing Locations" approved by the ASA House of Delegates on October 19, 1994.

"In any location in which inhalation anesthetics are administered, there should be an adequate and reliable system for scavenging waste anesthetic gases."

American Dental Association (ADA)29

The ADA recommends scavenging of waste anesthetic gases for all procedures involving anesthetic gases.

American Conference of Governmental Industrial Hygienists (1987)

The American Conference of Governmental Industrial Hygienists proposed in 1987 to adopt a time-weighted average level of 50 ppm for nitrous oxide.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (1997)

The JCAHO has standards pertaining to control of hazardous materials and waste (Table 1):

Table 1

JCAHO Standards

EC.1.5 A management plan addresses control of hazardous material and waste, including monitoring and disposal of gases and vapors and education of personnel on this matter.

Intent of EC.1.5

- a. selecting, handling, storing, using and disposing of hazardous materials and waste from receipt or generation through use or final disposal;
- establishing written criteria, consistent with applicable law and regulation, to identify, evaluate and inventory hazardous materials and waste used or generated;
- c. managing chemical waste, chemotherapeutic waste, radioactive waste and regulated medical or infectious waste, including sharps:
- d. monitoring and disposing of hazardous gases and vapors;
- e. providing adequate and appropriate space and equipment for safe handling and storage of hazardous materials and waste; and
- f. reporting and investigating all hazardous materials or waste spills, exposures and other incidents.

In addition, the hazardous materials and waste management plan establishes:

- g. an orientation and education program for personnel who manage or have contact with hazardous materials and waste that addresses:
 - precautions for selecting, handling, storing, using and disposing of hazardous materials and waste;
 - 2. emergency procedures for hazardous material and waste spills or exposure;
 - 3. health hazards of mishandling hazardous materials; and
 - orientation and education for all appropriate personnel about reporting procedures for hazardous materials and waste incidents, including spills or exposures.
- h. performance standards that address one or more of the following:
 - 1. staff knowledge and skill necessary for their role in managing hazardous materials and waste;
 - 2. the expected level of staff participation in materials and waste management activities;
 - 3. monitoring, inspection and corrective action;

State Regulation

Some states have their own regulations concerning waste anesthetic gases.

Other Countries

British Government Health Services Advisory Committee

In 1996, the British Government Health Services Advisory Committee published its recommendations, Anaesthetic Agents: Controlling Exposure Under the Control of Substances Hazardous to Health Regulations 1994 (COSHH) in which occupational exposure standards (OES) were issued. The OES are for an eight-hour time-weighted average reference period for trace levels of waste anesthetic gases and are shown below.

- 100 ppm for nitrous oxide
- 50 ppm for enflurane and isoflurane
- 10 ppm for halothane

These were chosen because they are well below the levels at which any significant adverse effects occurred in animals and represent levels at which there is no evidence to suggest human health would be affected.

Other European Countries

The Netherlands has a limit of 25 ppm for nitrous oxide. Italy, Sweden, Norway and Denmark set 100 ppm as their upper limit exposure level for nitrous oxide.⁴⁷⁻⁵⁰ The differences illustrate the difficulty in setting standards without adequate data.

Table 1 (Continued)

- 4. routine procedures for emergency and incident reporting that specify when and to whom reports are communicated; or
- 5. inspection, preventive maintenance and testing of applicable equipment.
- emergency procedures describe the specific precautions, procedures and protective equipment used during hazardous material and waste spills or exposures.

The hazardous materials and waste management plan includes how it will be evaluated annually in terms of its objectives, scope, performance and effectiveness.

Examples of Evidence of Performance for EC.1.5

- staff interviews
- management plans for the issue(s) addressed in the standard
- performance standards for the issue(s) addressed in the standard
- emergency procedures for the issue(s) addressed in the standard

Standard

EC.2.4 The hazardous materials and waste management plan is implemented with appropriate documentation.

intent of EC.2.4

The organization implements the hazardous materials and waste management plan and performance standards, including all features described in EC.1.5.

The organization also:

- maintains documentation, including required permits, licenses and adherence to other regulations;
- b. maintains manifests for handling of hazardous materials and waste;
- c. properly labels hazardous materials and waste;
- d. provides adequate, appropriate space and equipment for managing hazardous materials and waste; and
- e. effectively separates hazardous materials and waste storage and processing areas from other areas of the facility.

Examples of Evidence of Performance for EC.2.4

- staff interviews
- building tour (storage, disposal and transport sites)
- review of appropriate permits, licenses and manifests

Scavenging and Monitoring Equipment

here are two major ways in which anesthesia gases can be spilled into the operating room environment. One involves the technique used to administer an anesthetic, and the second is related to the anesthesia machine delivery system and the scavenging system hardware. Problems in either situation can result in significant contamination of the operating room atmosphere (Table 2).

Table 2: Causes of Operating Room Contamination

Anesthetic Techniques

- failure to turn off gas flow control valves at the end of an anesthetic
- · poorly fitting masks
- flushing of the circuit
- filling of anesthesia vaporizers
- uncuffed tracheal tubes (e.g., pediatric)
- pediatric circuits
- sidestream sampling carbon dioxide and anesthetic gas analyzers

Anesthesia Machine Delivery System and Scavenging System

- open/closed system
 - occlusion of hospital disposal system
 - maladjustment of hospital disposal system vacuum
- leaks
 - high-pressure hoses
 - nitrous oxide tank mounting
 - Orings
 - CO₂ absorbent canisters
 - low-pressure circuit

Other Sources

- cryo surgery units
- cardiopulmonary bypass circuit

Issues With Anesthetic Techniques

Issues with waste gas spillage during the administration of an inhalational anesthetic frequently involve technical problems. One of the most common situations is the failure to turn off all of the flow control valves (oxygen, nitrous oxide and air) or vaporizer when the anesthesia circuit is disconnect-

ed from the patient. This commonly occurs at the time of intubation but can also occur at the beginning or end of an anesthetic. In addition, a poorly fitting face mask, especially in a patient with a difficult airway, can easily allow anesthesia gases to flow into the room. Similarly, many practitioners will "flush" the anesthesia circuit at the end of the case in order to hasten the patient's emergence from anesthesia. If the system is flushed into the room rather than into the scavenging system, this also will lead to operating room contamination. Finally, if a patient who is anesthetized with an inhaled agent is allowed to breathe spontaneously while disconnected from the circuit, then anesthetic gases will be exhaled into the room.

The filling of anesthesia vaporizers can lead to operating room contamination. One milliliter of liquid anesthetic agent evaporates to form approximately 200 ml of vapor at room temperature. Anesthesia vaporizers are equipped with two types of filling systems. The "key-indexed" system tends to be associated with much less spillage of anesthetic agent while the "funnel-fill" vaporizers frequently are associated with significant spillage of anesthetic liquid. The funnel-fill option is available with all of the agent-specific vaporizers except desflurane. The desflurane vaporizer's patented filling system virtually assures that no liquid can be spilled during the filling of the vaporizer.

Pediatric anesthesia presents some unique problems with operating room contamination. The trachea of a child is usually intubated with an uncuffed tracheal tube that is designed to permit a gas "leak" at a pressure of approximately 20 cm of water. Certain circuits used in pediatric anesthesia can be difficult to scavenge because they have no inherent scavenging interface. The Jackson-Rees version of the Mapleson D system has been used in pediatric anesthesia for many years and was commonly vented into the room. Special modifications or additional scavenging valves must be added to such systems.

Many anesthesia practitioners use side-stream sampling gas analyzers to monitor end-tidal CO₂ and/or anesthetic agent concentrations. These devices generally aspirate between 50 and 250 ml per minute of gas from the patient circuit. Following analysis, this gas sample must either be directed to the scavenging system or returned to the breathing system.

Anesthesia Machines and Scavenging Systems

All anesthesia machines sold in the United States today are equipped with a scavenging system to dispose of waste anesthetic gases. This scavenging system collects gases that are exhausted via the adjustable pressure limiting (APL), or "pop-off" valve, or from the ventilator pressure relief (PR) (exhaust) valve and directs them to the waste gas disposal system (Figure 1). The standard diameter of the fittings for the scavenging system is 19 mm, but the new international standard is 30 mm. Many newer anesthesia machines have 30mm fittings, and the manufacturers can provide a 30-mm to 19-mm adapter (Figure 1). Normally, all gases that are vented from the anesthesia circuit will be disposed of by the waste gas scavenging system. Only if there are leaks in the anesthesia delivery or gas scavenging systems, or if more gas is delivered to the scavenging system than can be removed, will any anesthetic gases enter the room. The proper functioning of the waste gas scavenging system should be checked as part of the anesthesia machine pre-use checkout procedure.

Waste gas scavenging systems are classified as either closed or open reservoir. In the closed reservoir system, the gases are conducted from the anesthesia circuit APL valve or ventilator pressure relief valve to a scavenging interface or manifold. The interface incorporates a positive pressure relief ("pop off") valve that prevents excessive pressure from building up in the system by venting gas to the room and one or more negative pressure relief valves that prevent excessive negative pressure from being applied to the anesthesia circuit by allowing room air to enter the interface system. The closed reservoir system also has a reservoir bag to compensate for acute changes in gas flow to or from the scavenging interface. From the scavenging manifold or interface, the waste gases are then conducted to the institution's waste gas disposal system (Figures 2a, 2b).

The open reservoir design of scavenging system is valveless and uses a reservoir canister that is open to the atmosphere through several ports whereby positive and negative pressure relief may freely occur. Again, tubing from the anesthesia circuit APL and ventilator PR valves conduct waste gas to the open reservoir system, and connections to the hospital disposal system are also included on the reservoir (Figure 3).

The scavenging system interface or manifold is

subject to several potential problems. If the hose conducting gas from the anesthesia circuit APL or ventilator PR valves becomes kinked or occluded, then the patient may suffer pulmonary barotrauma. If the connection to the hospital's gas disposal system is occluded, then anesthetic gases will be vented to the atmosphere via the positive pressure relief valve. If this valve fails to operate properly, the patient could experience pulmonary barotrauma. Also, the interface or manifold commonly has more intake ports than are normally required. It is important that these extra ports be covered with a tight fitting cap so that anesthetic gases will not escape into the room (Figure 2b).

Once the waste gases leave the manifold or interface, they are conducted to the institution's gas disposal system. This can be accomplished either through an active or a passive mechanism. In an active system, waste gases are actively removed via a vacuum that is applied to the scavenging interface or manifold. There is a flow control valve on the interface that allows the operator to adjust the amount of vacuum that is applied at any given time. If the vacuum is not properly adjusted or becomes disconnected from the scavenging interface, then anesthetic gases will be spilled into the room. The reservoir bag on the scavenging interface also serves as a visual indicator as to whether excess or inadequate amounts of vacuum are being applied to the system. The vacuum for the active system is supplied from the hospital evacuation or suction system. It is best to have a dedicated evacuation system for waste gases that is separate from the institution's main vacuum system. The fittings for this anesthesia waste gas evacuation system are the same diameter-indexed safety system (DISS) and quick-connect fittings as regular vacuum but the high-pressure vacuum hose is now color-coded as light purple instead of the white used for the institution vacuum system.

In the passive type of gas removal system, a hose is run from the scavenging manifold or interface to the operating room ventilation exhaust system. The gases exit from the exhaust system to the outside. If this type of system is used, then the operating room ventilation system must be of the non-recirculating type. The anesthetic gases tend to flow through the exhaust grille because the operating room ventilation system maintains a slight positive pressure in the room. Dangers of this type of system include having the passive hose become compressed or occluded, which results in gases escaping into the room. The disposal hose should

therefore not be placed on the floor and should always be constructed of noncompressible materials. In the passive system, if the gas exit point from the institution should become occluded by debris or ice, then the exhaust gases would not be able to escape to the outside. High winds may also cause a reversal of gas flow in such a system.

Whether the gas removal system is active or passive, it should always be connected to a scavenging interface or manifold. This greatly decreases the likelihood of barotrauma to the patient's lungs and provides a convenient point for interfacing all of the tubing.

Other Sources of Contamination

The other major source of operating room contamination comes from leaks in the anesthesia gas delivery and scavenging systems. The high-pressure nitrous oxide hose as well as the nitrous oxide tank on the anesthesia machine can leak significant amounts of gas because the pressure in these systems usually exceeds 50 pounds per square inch gauge (psig). If the nitrous oxide tank does not fit properly into the hanger yoke on the anesthesia machine, then it will leak very large amounts of nitrous oxide into the air because the pressure in the tank is usually in excess of 700 psig. Any part of the anesthesia machine or circuit that does not fit together tightly or develops a hole will also leak anesthetic gases into the room. This can occur in plastic hoses that are deformed or have been penetrated by a sharp object or when O-rings are cracked or missing. Also, if the filler cap on the vaporizer is not properly tightened, this can be the source of a significant leak. Finally, at any connection where two components come together with a rubber fitting, a leak can develop if the rubber is cracked or worn or the pieces are not properly aligned. A typical example of this is the carbon dioxide absorber canisters. Leaks in the low-pressure system of the anesthesia machine (i.e., all parts downstream of the flow control valves) can usually be detected by a careful anesthesia machine leak check. Leaks in the high-pressure part of the system can be detected by performing a high-pressure system leak check or by monitoring of ambient operating room air.

Two other sources of operating room contamination that are not under the direct control of the anesthesiologist include cryosurgery and the cardiopulmonary bypass machine. Many cryosurgery units use nitrous oxide at a rate of up to 90 liters per minute. If this is not scavenged, significant operating room contamination will occur. In addition, potent inhaled volatile anesthetic agents are commonly added to the cardiopulmonary bypass circuit. Therefore, the gas exiting the cardiopulmonary bypass circuit should be scavenged. In the examples in the previous paragraph, a separate scavenging system should be used.

Once any anesthetic gases have spilled into the room, the trace gas concentration is dependent upon the operating room ventilation system. New operating rooms are required to have 15 to 21 air exchanges per hour of which three must be with fresh, outside air.45 It is important that the institution's maintenance department regularly verify that the air exchange in each operating room is adequate. The non-recirculating type of ventilation system brings fresh (outside) air into the operating room with each air exchange. This type of system will decrease the concentration of anesthetic agents in the operating room ambient air more quickly than a recirculating type of ventilation system. The recirculating system partially recirculates the air in the operating room and adds fresh air to the mixture. There are also a certain number of fresh air exchanges each hour. The recirculating system has the advantage of being more economical in terms of heating and air conditioning costs.

Monitoring of Exposure to Trace Gas Concentrations and Measurement of Trace Levels of Waste Anesthetic Gases in the Workplace

Monitoring levels of anesthetic gases in operating room air can aid detection of gas leaks. Some institutions have found that high-pressure leaks occur following servicing of anesthesia machines. The following methods are available for sampling trace levels of waste anesthetic gases in the operating room ambient air:

Grab Sampling. This method is useful for monitoring steady state levels usually caused by a leak from the high-pressure system (i.e., nitrous oxide pipeline, high-pressure system of the machine). Grab sampling involves taking an air sample from the operating room when it is "down," i.e., not being used. Air is sampled into an inert container that is then sealed and sent to a laboratory for analysis. Because gas leakage during the administration of an anesthetic is commonly inter-

mittent, grab sampling when an operating room is inactive may not reliably represent trace levels present in an operating room that is active. Another disadvantage is that the results are delayed.

Time-Weighted Average Sampling. This is the conventional method for evaluating personnel exposure because the results indicate average exposure over time. In this method, a pump is used to continuously collect a sample of operating room air into a bag over a one- to eight-hour period. The contents of the bag are then analyzed. Miniature time-weighted averaging sampling pumps and bags can also be used, but this has generally been for research purposes and is not practical for large numbers of personnel.

Passive dosimeters analogous to radiation badges worn by personnel in radiology departments are available to monitor nitrous oxide exposure. They are designed to be worn in the breathing zone of the operating room worker and to function for periods of greater than one hour up to 168 hours. Dosimeters are uncapped at the beginning of the exposure period and recapped at the end of the exposure period. The wearer keeps a record of the exposure period and, when sampling is complete, the dosimeter is labeled with the worker's name and total exposure time and mailed to an out-

side laboratory. Here the trapped nitrous oxide is released and analyzed, and the results presented in parts per million per hour of exposure. In addition to monitoring personnel exposure, dosimeters also may be used for fixed-area monitoring.

Continuous Sampling. Use of a portable infrared analyzer that continuously samples and analyzes for levels of volatile anesthetic agents is the most convenient method for monitoring the operating room atmosphere. These devices provide a continuous readout of the concentration of anesthetics in the atmosphere and can also be used to "sniff" out leaks in equipment. If left to sample continuously over prolonged periods, a timeweighted average concentration value can be displayed. Portable, battery-powered infrared analyzers for monitoring trace gas levels are capable of detecting concentrations of anesthetics in the ambient air (N₂O, 0-100 ppm; inhaled anesthetics, 0-10 ppm) and include on-board data logging that permits timed logging, single-sample logging and continuous logging of data. Gas is sampled via a wand, filter and flexible tube into the analyzer that can therefore be used for analyzing grab samples, time-weighted averaging and for "sniffing" out leaks in equipment.

Waste Anesthetic Gases

Recommendations

Scavenging to Reduce Exposure Levels

Recommendation: A scavenging system should be used in all anesthetizing locations. It is the responsibility of each institution to organize and document a program of maintenance and checking of all anesthetic equipment including the scavenging system.

Rationale: Reducing exposure to waste anesthetic gases by scavenging is the currently accepted practice, although adverse health effects to personnel have not been shown. A properly working scavenging system will reduce levels of trace gases in any anesthetizing location to levels that meet the exposure limits recommended by the regulatory agencies (25 ppm for nitrous oxide, 2 ppm for halogenated anesthetic agents).

Work Practices

Recommendation: Information should be made available to all concerned personnel regarding appropriate work practices to reduce levels of waste anesthetic gases in the ambient air.

Rationale: Attention to the details of work practices is effective in minimizing exposure to waste anesthetic gases (see NIOSH and OSHA recommendations, pages 12-14).

Monitoring of Trace Levels of Waste Anesthetic Gases

Recommendation: No recommendation is made for routine monitoring of waste gases in the ambient air in anesthetizing locations. There are no data to support that this is necessary.

Rationale: The use of a well-maintained scavenging system reduces the concentrations of waste anesthetic gases in the operating room to levels that meet the NIOSH recommendation. When indicated, e.g., in the event of equipment malfunction, levels of trace gases may be measured as outlined on pages 18-19.

Medical Surveillance

Recommendation: Routine medical surveillance for effects relating to exposure to waste anesthetic gases is not warranted. An education program is recommended for all personnel working in areas where anesthetic agents are used. The program should include information regarding the status of the current literature with regard to possible adverse health effects and emphasis on attention to work practices and checking and maintenance of all equipment, as outlined in this document. Each institution should provide a mechanism for employees to report any adverse health effects thought to be associated with working in the operating room suite.

Rationale: Current data fail to demonstrate that trace concentrations of waste anesthetic gases are associated with any health hazards to exposed personnel working in scavenged anesthetizing locations where work practices to minimize contamination are carried out.

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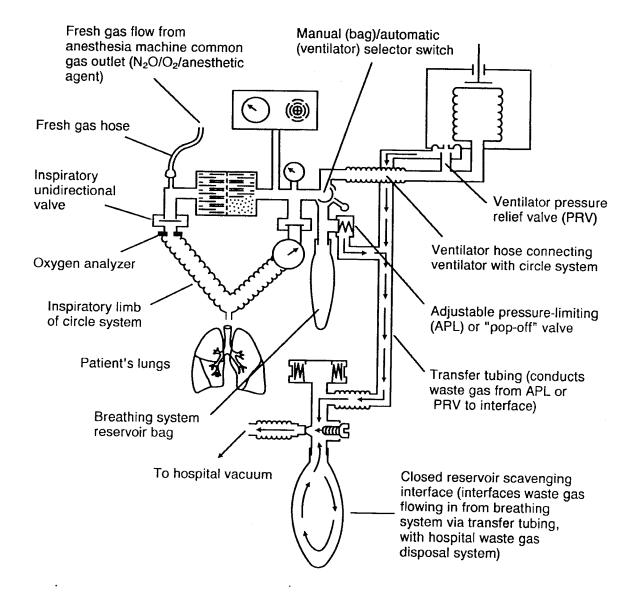
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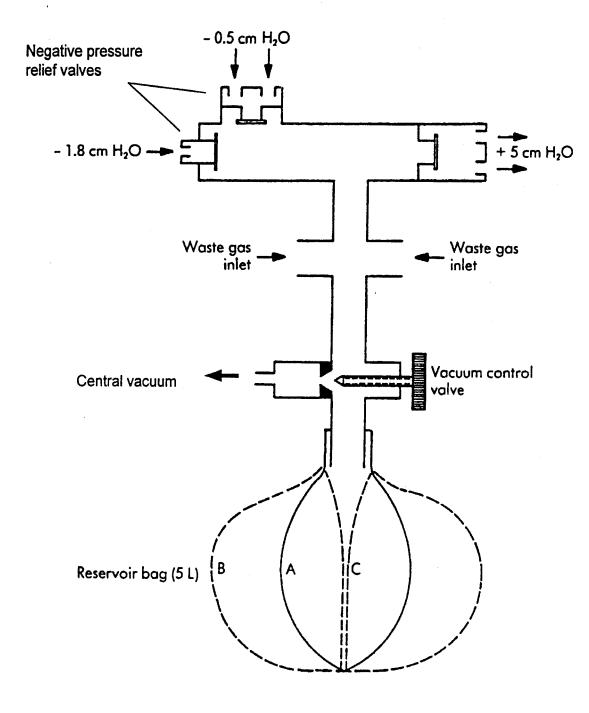
Figures

Figure 1



Circle breathing system connected to a closed-reservoir scavenging interface. (Adapted from North American Dräger, Inc., Telford, PA, with permission.)

Figure 2a



A drawing of the North American Dräger closed reservoir scavenging interface. Position A is the normal distention of the scavenging reservoir bag. In position B, the bag is over-distended, while position C shows the bag collapsed due to the excessive vacuum being applied to the interface. (Adapted from North American Dräger, Inc., Telford, PA, with permission.)

Figure 2b

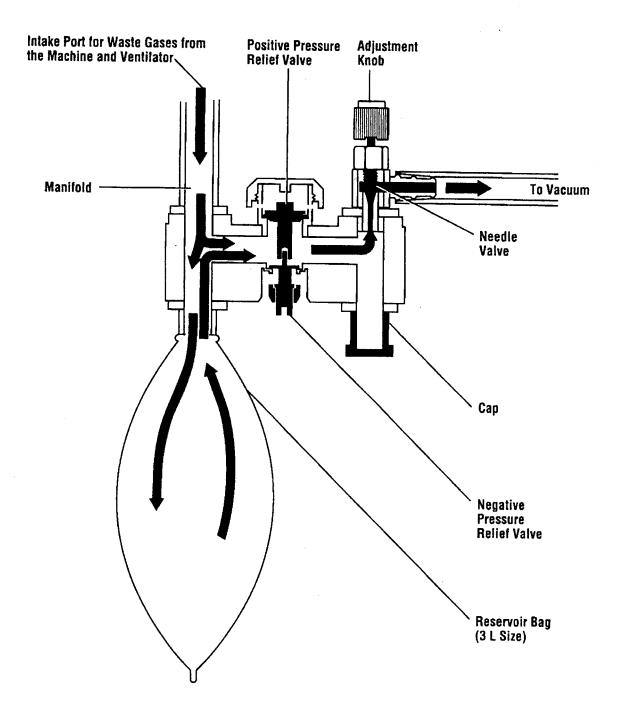


Diagram of the Datex-Ohmeda closed reservoir with active scavenging to the interface. The interface contains both a negative and positive pressure relief valve. (From Datex-Ohmeda, Madison, WI, with permission.)

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Figure 3

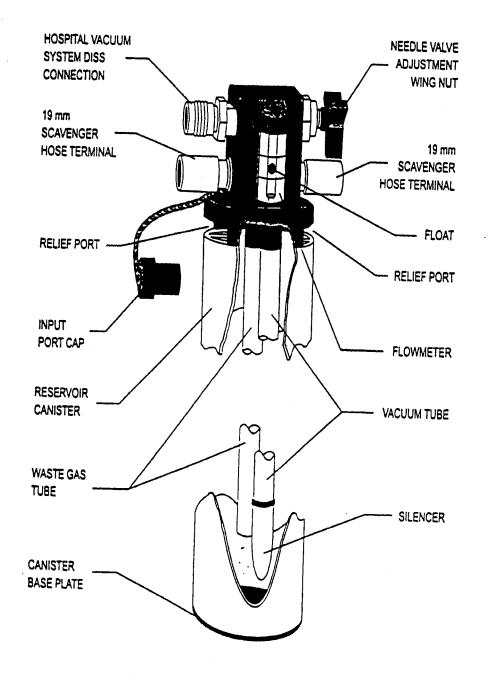


Diagram of an open reservoir scavenging system. (From North American Dräger, Inc., Telford, PA, with permission.)

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