Operating Room Pollution: Governmental Perspectives and Guidelines

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THE National Institute for Occupational Safety and Health (NIOSH) was created by the Occupational Safety and Health Act of 1970 and charged with the major responsibility for conducting research for new occupational safety and health standards. One specific duty is the development of criteria for recommended standards which describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience. NIOSH conducts and funds research necessary to identify health hazards and to develop criteria for recommended standards. These recommendations are transmitted to the Department of Labor, Occupational Safety and Health Administration (OSHA), which has the responsibility for development, promulgation, and enforcement of standards. NIOSH is organizationally located within the Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare.

Recommendations made to OSHA are transmitted in the form of a NIOSH criteria document. These documents, which are published by NIOSH, are prepared from a critical evaluation of published or publically available medical, biological, engineering, and chemical information. The evidence is carefully reviewed to determine what hazardous effects are relevant in developing criteria for the proposed standards. A criteria document receives a thorough review by professional personnel of NIOSH and other federal agencies, by professional occupational health consultants experienced with the subject of the document, and by professional societies whose membership includes personnel experienced in occupational health or who are familiar with the matters presented in the document. Following a final and thorough review by senior NIOSH personnel and approval by the Institute director, the criteria document is transmitted to the Department of Labor.

Epidemiologic studies conducted among operating room personnel in Russia, Denmark, the United Kingdom, and the United States have suggested that women working in operating rooms had an increased risk of spontaneous abortion and that their children had an increased risk of congenital abnormalities. Two studies reported an increased incidence of cancer among exposed female workers. Adverse effects on the liver and kidneys were also reported in some of the surveys to be more frequent among exposed personnel than among control groups.

The adverse health effects reported in humans have been produced in animals exposed to anesthetic gases but at concentrations much greater than the usual occupational exposure levels. The potential of some common anesthetic agents to produce terata and cause abortions has been established in animal studies when high concentrations of the agents were used. Two studies reported developmental defects in brain, liver, and

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kidney tissues of unborn rats exposed to halothane at 10 to 12 ppm during gestation. Two volatile liquid anesthetic agents, chloroform and trichloroethylene, demonstrated a carcinogenic potential after oral and gastric administration to rats and mice. When administered by inhalation, neither of these agents showed carcinogenic activity for these species.

An extensive study was conducted in the US as a joint effort between NIOSH and the Ad Hoc Committee on the Effect of Trace Anesthetics of the American Society of Anesthesiologists. This program included a contemporary epidemiologic survey of operating room personnel, dentists, and oral surgeons; a future survey to be conducted after the implementation of control procedures to determine the effect of reducing exposure to waste anesthetic gases; an assessment of the health effects of trace anesthetic gases on behavioral performance of operating room personnel; experimental animal inhalation studies with N_2O and halothane to evaluate potential reproductive, teratogenic, and mutagenic effects; the development and evaluation of methods for eliminating waste anesthetic gases in operating rooms and dental offices; and the development of an air monitoring program to determine the effectiveness of control procedures. Following extensive information gathering and the completion of several research studies, development of a criteria document on waste anesthetics was begun.

NIOSH estimates that 214,000 workers in the United States, including anesthesiologists, nurse-anesthetists, operating room nurses and technicians, oral surgeons, dentists and their assistants, and veterinarians and their assistants, are potentially exposed to waste anesthetic gases. The recommended standard developed by NIOSH applies to all personnel, regardless of employment status, who are exposed to inhalation anesthetics and also includes researchers, students, and volunteers. Waste anesthetic gases are defined in the document as inhalation anesthetic gases and vapors that are released into work areas associated with, and adjacent to, the administration of a gas or volatile liquid for anesthetic purposes. The usual occupational exposure to volatile liquid anesthetics, such as halothane, has been reported to be from 1 to 10 ppm and for N_2O to be from 400 to 3,000 ppm.

Based on the health data obtained from the ASA survey and other reports in the literature, NIOSH recognized that the adverse effects on reproduction among operating room personnel who are chronically exposed to waste anesthetics were of prime concern in the development of criteria for a recommended standard to control such exposures. Liver disease rates among operating room personnel and decrements in performance following experimental exposure to anesthetics were also factors in the development of the recommended standard. The question of possible carcinogenicity of some anesthetic agents needs to be answered, since some compounds that are similar in structure to some of the halogenated anesthetics have shown carcinogenic potential. However, NIOSH feels that presently available information from animal studies is equivocal and can serve only to generate a degree of concern. Based on the available health data, NIOSH has concluded that a safe level of exposure to waste anesthetic gases cannot be defined and it has therefore been recommended that exposure to the halogenated anesthetics, when used alone, be controlled to the lowest concentrations that can be reliably and reproducibly quantitated using sampling and analysis methods recommended for field use. This concentration is 2 ppm, collected by charcoal adsorption from a 45-litre air sample over a period not to exceed 1 hour, followed by gas chromatographic analysis. When the halogenated anesthetics are used in combination with N_2O, it is recommended that exposures be controlled to the lowest concentrations feasible with available control technology.

The feasibility of controlling exposure to trace anesthetics has been investigated and is presented in the criteria document and in publications of other NIOSH-sponsored studies conducted at the Stanford University Medical Center. The hospital operating room lends itself to a number of control procedures that are both feasible and readily available. Controlling employee exposure to waste anesthetics to the lowest concentrations possible using these control procedures should be the ultimate goal of any control program. Information from hospital operating room studies shows that during periods of administration, time-weighted average (TWA) concentrations of 25 ppm for N_2O and 0.5 ppm for halothane, and other halogenated anesthetics, are attainable. These concentrations were determined by using a more sensitive monitoring technic, namely infrared absorption. Based on the usual mixing ratio of the agents, controlling N_2O

exposures to 25 ppm should keep the concentrations of halogenated agents well below the 2 ppm permissible level of exposure. The method recommended for use in monitoring N_2O levels is infrared absorption analysis in combination with several possible sampling methods.

The cost of equipping an operating room for gas scavenging will depend primarily on the type of control program to be implemented by an institution. The adaptations necessary for most anesthetic delivery systems are relatively simple and inexpensive. The means used to conduct waste gases to the outside range from venting into a nonrecirculating air-conditioning exhaust grille to installation of a special duct system or suction line. The criteria document recommends a scavenging program in combination with good room ventilation. Although some specific recommendations are made, the recommended standard will allow use of any control procedures that are equivalent in effectiveness. One of the responsibilities of OSHA will be to prepare a statement of the economic impact of the recommended standard, and if necessary, to modify the standard.

Besides engineering control procedures, other components of the recommended standard are work practices for operating room personnel, equipment maintenance and leak test procedures and schedules, and requirements for air monitoring, medical monitoring, recordkeeping, and for informing exposed personnel of the hazards. The major recommendations are: quarterly maintenance and high-pressure leak testing of anesthetic equipment combined with daily low-pressure leak tests; making available to all exposed workers information on possible adverse health effects of exposure to waste anesthetic gases, especially possible effects on reproduction; an air monitoring program which requires initial sampling to determine if scavenging is necessary and quarterly sampling thereafter; a medical monitoring program that keeps and updates medical information on exposed workers, especially any abnormal outcome of pregnancy or adverse effects on liver or kidneys; and recordkeeping in agreement with the accepted procedures of existing health programs.

Should OSHA decide to promulgate a standard, following the receipt of the NIOSH criteria document, a complete review of the recommended standard will be initiated. The terms of the proposed standard are published as a Notice of Proposed Rulemaking in the Federal Register. Arguments and evidence regarding the proposed rule may be presented at a scheduled public hearing. Following the public hearing, and any necessary revisions to the standard, OSHA will publish the full, final text of the standard to be adopted and the date that the new ruling will be effective.

The OSHA compliance officer has responsibility for assuring that standards are complied with and enforced. This person is a highly trained individual who has familiarized himself completely with the area he is entering. In a hospital setting, the compliance officer will most likely be an industrial hygienist who will assess and evaluate many situations, not just potential exposures to waste anesthetics. The officer will make a decision on the need for sampling and will also make a determination of any standards that have been violated. Throughout the inspection, the officer is in contact with the employer or principal administration of the site. Penalties for noncompliance are not determined by the inspection officer but by the OSHA area director after receipt of a full report. Penalties for violations that may directly affect worker health are usually monetary, with the actual amount decided upon by the OSHA area director. A more realistic cost of noncompliance, however, may come in the form of loss of manpower or employee efficiency, possible legal action initiated by employees who feel they have been placed in a hazardous situation, and a suffering of character or credibility loss by the institution involved.