STUDY PROTOCOL:

CONTROL OF ANESTHETIC GASES IN DENTAL OPERATORIES

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I. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) is the primary Federal agency engaged in occupational safety and health research. Located in the Department of Health and Human Services (formerly DHEW), it was established by the Occupational Safety and Health Act of 1970. This legislation mandated NIOSH to conduct a number of research and education programs separate from the standard setting and enforcement functions carried out by the Occupational Safety and Health Administration (OSHA) in the Department of Labor. An important area of NIOSH research deals with methods for controlling occupational exposure to potential chemical and physical hazards. The Engineering Control Technology Branch (ECTB) of the Division of Physical Sciences and Engineering has been given the lead within NIOSH to study the engineering aspects of health hazard prevention and control.

Since 1976, ECTB has conducted a number of assessments of health hazard control technology on the basis of industry, common industrial process, or specific control techniques. Examples of these completed studies include the foundry industry; various chemical manufacturing or processing operations; spray painting; and the resurrection of exhaust air. The objective of each of these studies has been to document and evaluate effective control techniques for potential health hazards in the industry or process of interest, and to create a more general awareness of the need for or availability of an effective system of hazard control measures.

These studies involve a number of steps or phases. Initially, a series of walk-through surveys is conducted to select plants or processes with effective and potentially transferable control concepts or techniques. Next, in-depth surveys are conducted to determine both the control parameters and the effectiveness of these controls. The reports from these in-depth surveys are then used as a basis for preparing technical reports and journal articles on effective hazard control measures. Ultimately, the information from these research activities builds the data base of publicly available information on hazard control techniques for use by health professionals who are responsible for preventing occupational illness and injury.

II. THE DENTAL INDUSTRY

2.1. Background

For more than 100 years nitrous oxide has been mixed with oxygen and used in dentistry as a general anesthetic agent, an analgesic, and as a sedative. With the development of more effective local anesthetics to manage pain, nitrous oxide is used today primarily for psychosedation. Its use reduces fear and anxiety in the conscious patient. It is estimated that 85 to 90 percent of the patients receiving nitrous oxide and oxygen are well sedated with 40 percent nitrous oxide and 60 percent oxygen (1).

Nitrous oxide was first discovered in 1772 by Joseph Priestly, who combined iron disulfide and water with nitric acid. Its pain relieving properties were documented in 1795 by Sir Humphrey Davy. In 1842 Dr. Horace Wells, a Connecticut dentist, administered N_2O to himself while extracting a tooth. As the first anesthetic introduced into clinical practice this agent quickly became popular. In 1868 Edmund Andrews combined oxygen with nitrous oxide (2). In 1977 T.W. Jones and W. Greenfield estimate that approximately 35 percent of the dentists in the United States have nitrous oxide anesthetic systems at their facility (3). It is estimated that more than 100,000 dental personnel are involved in administering nitrous oxide to about 4.5 million patients annually in the United States (4).

2.2. Federal, Professional, and Trade Association Activities.

In 1977, NIOSH published a technical report on the "Control of Occupational Exposure to N_2O in the Dental Operatory", DHEW (NIOSH) Pub. No. 77-171. This report discussed health effects of increased risk for spontaneous miscarriage rate of wives of male dentists and an increase in liver disease in dentists themselves. The health effects risk was associated with low grade chronic exposure to anesthetics used in the dental operatory. To decrease exposure to anesthetic gases, especially N_2O, the NIOSH technical report listed several control measures including: 1) the use of a scavenging mask (at the time this document was published only the Brown mask, Summit Services, Inc. was market available); 2). Venting the scavenged air outside the building; 3) minimizing speech by the patient during dental procedures; 4) regular preventive maintenance procedures for anesthetic equipment; 5) frequent leak testing of anesthetic equipment by in-house personnel; 6) use of an air sweep fan when necessary to dilute the concentration of anesthetic inhaled by personnel; and 6) monitoring of N_2O in the breathing zone of the dentist. These recommendations were designed for easy use by the dentist; compatible with safe practices in dental inhalation analgesia and anesthesia, and effective in reducing gas concentrations inhaled by personnel (5).

In 1985, the Acting Assistant Secretary of Labor responded to the ANA to develop guidelines for anesthetic waste gases and vapors. In January 1986, the assignment for developing these guidelines was given to the Occupational Safety and Health Administration's (OSHA) Health Response Team located in Salt Lake City, Utah.

In addition, the American Dental Association (ADA) has recognized that exposure to anesthetics, including N_2O, may impose health hazards to dental personnel. In response the ADA along with the American Society of Anesthesiologists recommended control measures whenever inhalation of anesthetic agents are administered. The control measures were: 1) to maintain the lowest reasonably achievable concentrations through leak testing; 2) use of scavenging equipment; 3) air monitoring; and 4) record keeping in all locations where inhalation anesthetics are employed.

III. HEALTH EFFECTS

3.1. Physical Properties.

Nitrous oxide is an odorless, stabile, noncombustible, colorless, tasteless gas that is 1.5 times heavier than air. The oxygen atom accounts for the oxidizing capacity of nitrous oxide and is a thermodynamically unstable endothermic compound. Nitrous oxide is manufactured commercially by thermally decomposing ammonium nitrate and purification of its by-products (6).

3.2. Systemic Effects.

Nitrous oxide does not combine with hemoglobin, but is carried in the blood in a physical solution (7). It is eliminated from the body unchanged, by way of the lungs; a slight amount may be excreted through the pores of the skin (8). Nitrous oxide is a weak anesthetic with rapid onset and rapid emergence (9), and will disappear from the body in 17-35 minutes after anesthesia is discontinued (8). Eighty per cent nitrous oxide depresses myocardial contractility and increases vascular smooth muscle response to norepinephrine (10). It decreases cardiac output, stroke volume, mean atrial pressure, stroke work, and minute volume (11). Similar effects are seen in blood pressure, pulse rate, and respiration (12). In 1979, Vean and King stated that nitrous oxide acted solely on the cerebral cortex, thus causing a mild depression and that nitrous oxide was not allergenic (13). Amess and coworkers point out that nitrous oxide may interfere with the function of vitamin B_{12} (14). More recently, the toxic effects have been traced to the ability of nitrous oxide to inactivate the enzyme methionine synthetase, by oxidizing the enzyme's vitamin B_{12} cofactor. Methionine synthetase allows for the synthesis of methionine, and folinic acid, which is needed for deoxyribonucleic acid (DNA) synthesis (15). Researchers believe that the enzyme inactivation may explain the epidemiologic, clinical, and animal evidence that nitrous oxide can injure various tissues of the body, including the brain, blood-forming elements, lung, kidney, and the developing fetus. Supporting documentation by Sweeney et al, (1985), provided direct evidence that occupational exposure to nitrous oxide may cause depression of vitamin B_{12} activity resulting in measurable changes in bone marrow secondary to impaired synthesis of DNA (16).

3.3. Epidemiological Studies - Human Reproductive Effects.

This agent, along with others including the halogenated anesthetic compounds, have been identified in epidemiological studies as a suspected health hazard to those exposed. The first published report of adverse reproductive effects of work in operating theaters was by Dr. A. I. Vaisman, in 1967 (17). Dr. Vaisman noted that 18 of 31 female anesthesiologists who had been pregnant had experienced at least one miscarriage. Studies in Sweden, the

United Kingdom, and the United States generally showed adverse reproductive effects in females working in operating rooms (18,19,20). In a case-control epidemiological study of dentists, liver disease and spontaneous abortion were significantly higher among dentists (spouses of dentists for spontaneous abortion) exposed to inhalation anesthetics more than 3 hours per week, compared with controls which used no inhalation anesthetics in their practice (21). The most comprehensive epidemiological study of health dysfunction associated with work in the operating room was conducted by NIOSH where data were obtained from 40,044 respondents. Females working in the operating room demonstrated an increased incidence of spontaneous abortion and carcinoma. Birth defects in their offspring were elevated, as were the offspring of non-occupationally exposed wives of exposed male anesthetists. Liver disease was also increased in both males and females. In addition, spontaneous miscarriage and birth defects are confirmed in a survey of female anesthetists in the United Kingdom (21). The findings of several epidemiologic surveys were recently summarized by James T. Purdham of the Occupational and Environmental Health Unit, University of Toronto, Toronto Ontario (Tables 1 & 2) (22). The consistent finding from these studies shows that women exposed to waste anesthetic gases have a higher than expected incidence of spontaneous abortions. Congenital abnormalities in the offspring of exposed women were less strongly associated but were slightly higher than normal (23).

3.4. Animal Studies - Reproductive Effects.

Supporting evidence of the toxic effect of anesthetic agents is shown in laboratory studies. The evidence includes teratogenic effects in various species upon exposure to a wide group of inhalation agents at anesthetic concentrations (21), decreased survival rate in various species, ultrastructural changes in the central nervous system of rat fetuses following a single maternal exposure, decreased ability to solve maze problems in rats, and evidence of testicular damage after a minimum of 2 days exposure to 20 percent N_2O (31).

Several animal studies have focused on anesthetic gases, principally N_2O and halothane, to cause miscarriage or congenital abnormalities (Table 3). When the animals were exposed to high levels of these anesthetics spontaneous abortion (animal fetal resorption) and congenital abnormalities were observed. In one study by Viera and co-workers, spontaneous abortion was observed in rats at 1000 ppm or more (29). Concentrations of 1000 ppm have been commonly found in operating rooms and dental operatories not equipped with scavenging systems.

3.5. Carcinogenicity.

Excess cancer was found in a small group of Michigan nurse anesthetists by Corbett in 1973 (24). However, in another study which evaluated Corbett's work found that the high cancer rate was only for one year and when all the data were considered, there was no significant difference between the nurse anesthetists and the control group (25). Tests for mutagenicity (a test for screening carcinogenic agents - those which are mutagenic also tend to be carcinogenic) in bacterial systems have been shown to be negative in most test systems except for the anesthetic fluroxene (26).

Table 1

SPONTANEOUS ABORTIONS IN FEMALES EXPOSED TO ANAESTHETIC GASES

Authors	Year	Occupation of Exposed Group	Occupation of Controls	Exposed Group: No. of Pregnancies	Exposed Group: % ending in abortion	Control Group: No. of Pregnancies	Control Group: % ending in abortion	Significance
Vaisman	1967	Anaesthesiologist	--------	31	58	----	----	----
Askrog & Harvald	1970	Nurse	--------	229	17	(85)	(12)	N.S.
Cohen et al	1971	O.R. Nurse	General Nurse	36	28	34	9	<0.05
		Anaesthetist	Other Physicians	37	38	58	10	<0.01
Knill-Jones et al	1972	Anaesthetist	Other Physicians	737	18	2150	15	<0.05
Rosenburg & Kirves	1973	Nurse O.R.	Nurse Casualty/I.C.	257	20	150	11	<0.05
Cohen et al	1974	Nurse Anaesthetist	Nurse (Non O.R.)	1826	17	1948	15	N.S.
		Nurse/Technician	Nurse (Non-O.R.)	2781	20	1948	15	<0.001
		Anaesthetist	Pediatricians	468	17	308	9	<0.01
Knill-Jones et al	1975	Anaesthetist	Other Physicians	523	16	7296	11	<0.01
Pharoah	1977	Anaesthetist	Other Physicians	670	14	8374	13	N.S.
Rosenburg et al	1978	Anaesthetist	Pediatricians & Pediatrician wives	86	9	266	13	N.S.
Tomlin	1979	Anaesthetist	--------	58	29	(102)	(10)	<0.05
Cohen et al	1980	Dental Assistant using Anaesthetics	Dental Assistant not using Anaesthetics	400	19	3184	8	<0.01
Lauwerys et al	1981	Anaesthetist Nurse O.R.	Other Physicians Other Nurses	259	8	1519	6	N.S.
Axelsson, Rylander	1982	Operating Room and Others	Medical Ward	185	12	470	9	N.S.

* Adapted from James T. Purdham, Ph.D., Anesthetic Gases and Vapours. Occupational and Environmental Health Unit, University of Toronto, Toronto, Ontario. 1986.

Table 2

MALFORMATIONS OF OFFSPRING OF EXPOSED FEMALES

Authors	Year	Occupation of Exposed Group	Occupation of Controls	Exposed Group No. of infants born	Exposed Group % malformed	Control Group No. of infants born	Control Group % malformed	Significance
Askrog & Harvold	1970	Nurse	--------	185	0.5	(75)	(0)	N.S.
Knill-Jones et al	1972	Anaesthetist	Other Physicians	893	3.0	1835	3.2	N.S.
Rosenburg & Kirves	1973	Nurse O.R.	Nurse Casualty/I.C.	207	0	133	0	N.S.
Corbett et al	1974	Nurse	--------	434	8.8	(261)	3.8	<0.05
Cohen et al	1974	Nurse	Nurse (Non O.R.)	1480	9.6	1629	7.6	<0.05
		Nurse/Technician	Nurse (Non O.R.)	2210	7.7	1629	7.6	N.S.
		Anaesthetist	Pediatricians	384	5.9	276	3.0	N.S.
Knill-Jones et al	1975	Anaesthetist	Other Physicians	438	1.6	6442	1.1	N.S.
Pharoah et al	1977	Anaesthetist	Other Physicians	578	2.8	7317	1.8	N.S.
Tomlin	1979	Anaesthetist	--------	277	9.4	92	4.3	N.S
Cohen et al	1980	Dental Assistant using Anaesthetics	Dental Assistant not using Anaesthetics	316	5.2	2882	3.6	N.S

* Adapted from James T. Purdham, Ph.D., Anesthetic Gases and Vapours. Occupational and Environmental Health Unit, University of Toronto, Toronto, Ontario. 1986.

3.6. Liver and Kidney Effects.

In a national study sponsored by the American Society of Anesthetists it found that liver disease occurred more frequently among males and females exposed to anesthetic agents. However, kidney disease was less strongly associated with anesthetic exposure (23). Studies supporting these conclusions were also found in England (27). Because the workers were exposed to a mixture of anesthetic agents including halothane and methoxyflurane, it is not known what impact nitrous oxide has on liver and kidney dysfunction. In animal experiments N_2O alone was shown to be without effect (22).

3.7. Central Nervous System Effects.

Human studies testing cognitive and motor skills show that exposure to trace concentrations of anesthetic gas mixtures, N_2O/halothane or N_2O/enflurane, and N_2O by itself resulted in decreased ability to perform complex tasks (28,29). These studies suggest that exposed dentists may be working at less than peak efficiency. However, attempts to duplicate human performance decrements in other laboratory studies have not corroborated these earlier studies (30). While habitual use of nitrous oxide has been linked to damage of the peripheral nervous system, it appears that further research needs to be performed to resolve the safe level of occupational exposure which does not impair performance.

Table 3

ANIMAL TOXICITY DATA

Author	Species	Agent/Concentration	Abortion	Defects
Fink et al, 1967	rat	N_2O/500,000 ppm	yes	yes
Shepard & Fink, 1958	rat	N_2O/700,000 ppm	---	yes
Dussard et al, 1974	hamster	N_2O/6000,000 ppm	yes	---
Corbett et al. 1973	rat	N_2O/100 ppm	no	---
		N_2O/1,000 ppm	yes	---
		N_2O/15,000 ppm	yes	---
Coate et al. 1979	rat	N_2O/50 ppm		
Viera 1979	rat	N_2O/5,000 ppm	yes	yes
Viera et al. 1980	rat	N_2O/250 ppm	no	no
		N_2O/500 ppm	no	no
		N_2O/1,000 ppm	yes	yes
Mazze et al. 1982	mice	N_2O/5,000-500,000 ppm	no	no
Viera et al. 1983	rat	N_2O/250-5,000 ppm intermittently	no	no

* Adapted from James T. Purdham, Ph.D., Anesthetic Gases and Vapors. Occupational and Environmental Health Unit, University of Toronto, Toronto, Ontario. 1986.

3.8. Conclusions.

While there are methodological concerns with many of the epidemiological studies, a number of studies support the conclusion that anesthetic agents adversely affect reproductive outcome, especially spontaneous abortion. Unfortunately, these studies lacked quantitative exposure data to show cause and effect. In addition, support for anesthetic agents, in particular N_2O, to cause liver, kidney, and central nervous system effects at low anesthetic concentrations is less strong. Therefore, more research which combines anesthetic exposures with health outcome, and laboratory studies to support or refute health effects at low concentrations is warranted.

While it is not totally clear what level of N_2O exposure would cause adverse health effects, it would appear that a prudent course of action is to control and reduce exposure to this agent. The NIOSH recommended exposure limit of 25 ppm N_2O per dental procedure will be used as a target for the controls that are evaluated.

IV. ENVIRONMENTAL EVALUATIONS

4.1. Concentrations of N_2O in dental operatories.

Several studies have reported on halothane and N_2O levels. Nitrous oxide air levels were found in dental operatories from 500 ppm to over 6,700 ppm (33). Swenson presented a method to reduce N_2O from 1955 ppm to 175 ppm by employing a circle absorber, a non-rebreathing valve, a non-permeable throat pack, and other control measures. Allen and Scaramella used a modified Mapleson D (Bain) breathing system to scavenge excess N_2O from the dental operatory (34). In one NIOSH study, N_2O levels were reduced from uncontrolled values of 900 $\pm$ 130 ppm to 14 $\pm$ 1.5 ppm by employing a series of conservative control measures including: a scavenging system, venting the patient suction machine to a safe disposal site outside the building, minimizing speech by the patient during dental procedures, regular preventive maintenance procedures for anesthetic equipment, frequent leak testing of anesthetic equipment, use of an air sweep fan when necessary to dilute waste N_2O inhaled by dental personnel, and safe work practices during inhalation analgesia and anesthesia by the dentist (HETA 79-43, HETA 80-102)(35,36). In a companion study, 47 anesthetic gas control procedures were evaluated in an oral surgical suite; two other operatories served as controls. The results show that the dentist's mean inhaled concentration of N_2O was 31 $\pm$ 4.8 ppm (5). Based on these studies, the NIOSH report suggests that following the control procedures mentioned above, N_2O concentrations may be contained at 25 ppm during routine dental anesthesia/analgesia.

4.2. NIOSH Hazard Evaluation and Technical Assistance Studies (HETA'S).

To date, NIOSH has performed over 22 Hazard Evaluations and Technical Assistance studies to evaluate nitrous oxide exposure during dental procedures. In the majority of these studies, nitrous oxide concentrations in dental suites were significantly above the recommended limit of 25 ppm. In two of these studies, N_2O scavenging systems were installed after the initial survey, and a follow-up survey was conducted. While there was a reduction in the observed N_2O levels, the scavenging units did not consistently reduce the N_2O to the recommended concentration. Table 4 summarizes the N_2O evaluations from the NIOSH HETA's.

As shown in the N_2O general area and personal sample results of Table 4, a wide range of concentrations can by found in dental suites. Personal sample results tended to be higher than general area results, and dentist exposures tended to be higher than dental assistant exposures. The different N_2O concentration profile is because N_2O is administered through a nasal mask positioned over the patients' nose, and the dentist

Table 4

NIOSH HETA EVALUATION RESULTS
FOR NITROUS OXIDE IN DENTAL OPERATORIES

HETA #		N_2O Concentration in parts per million Range General Area	Personal	Controls Used.	
78-9		10 - 170	150 - >1400	No	*
78-62		Trace	38 - 171	Yes	*
78-129-544		10 - > 160	40 - 430	Yes	
79-5-564		75 - 3000	90 - 3500	No	
79-43		170 - >1000	180 - >1000	No	**
79-59		54 - 500	258 - 2650	No	
79-107-633		10 - 60	10 - 300	Yes	
80-16		100 - 210	25 - 300	No	
80-102-764		3 - 36	16 - > 250	Yes	**
80-113-813		25	400 - 500	Yes	
80-249-833		200	250 - >1000	No	
81-200-999		150 - >1000	200 - 700	No	
81-342-1005		4 - > 250	175 - > 250	No	
82-070-1148		500 - 650	650 - >1000	No	
84-111-1471		40 - > 250	30 - >1000	Yes	
84-126-155	A	20 - 350		No	
	B	7 - 182	130 - 1300	Yes	
84-204-1600		100 - 750	670 - 2270	No	
84-412-1612	A	70 - 315	2400	No	
	B	30 - 270	830	Yes	
85-408-1666		100	150 - >1000	No	
86-157-1678		50 - 800	700 - >1000	Yes	
86-179-1699		0 - 500	200 - 1000	Yes	
86-328-1773			0 - 50	Yes	

Notes: * : Initial HHE conducted (no scavenging system) and followed up after scavenging system was installed.

** : Initial HHE conducted (no scavenging system) and followed up after scavenging system was installed.

A/B : The same Dentists operated clinics A & B; however, the B clinic had scavenging equipment whereas the A clinic did not.

typically works six to twelve inches above the patient's nose, while the dental assistant will work twelve to eighteen inches above and off to the side of the patient's nose. Excess N_2O will escape from the edges of the nasal mask or from the mouth of the patient during respiration, or while the patient is talking. When a scavenging system was used, N_2O levels decreased, but did not consistently achieve the safe levels recommended by NIOSH. Specific limitations of the scavenging systems evaluated by NIOSH were not mentioned in the HETA reports, however, a few mentioned that the flow of the scavenging unit was not enough to overcome N_2O supply (typically 4 - 7 liters per minute at 40 percent N_2O, 60 percent O_2).

4.3. Sources and distribution of N_2O in the Dental Suite.

Past studies have shown that sources of N_2O in dental suites include leakage from the anesthesia machine, nasal mask, and the patient's mouth (Figure 1) (5). In addition, N_2O may also enter the dental suites from other operatories, from windows, doors, air conditioning inlets, false ceiling spaces, and from the dental aspirators when the machine is not vented to a dedicated exhaust system.

The primary source of environmental N_2O, from unscavenged anesthesia delivery systems, is the flow from the anesthesia machine escaping into the room via the relief valve and around the perimeter of the nasal mask; second is N_2O from the patient's mouth; and third is the high to low pressure N_2O connectors which transport the gas from gas cylinders to the scavenging unit for patient use (5). With regard to the primary source of N_2O exposure, scavenging machines may eliminate much of the residual gas not used by the patient. However, the patient's mouth may be a very significant source of exposure as a result of patient breathing, conversation, yawning, and laughter. In addition, N_2O connectors may also be a source of leakage, especially if the high-pressure hose connectors are loose fitting, because of missing gaskets or seals. Defective bags, breathing hoses, loosely assembled or deformed slip joints and threaded connections may also contribute to excess exposure (5).

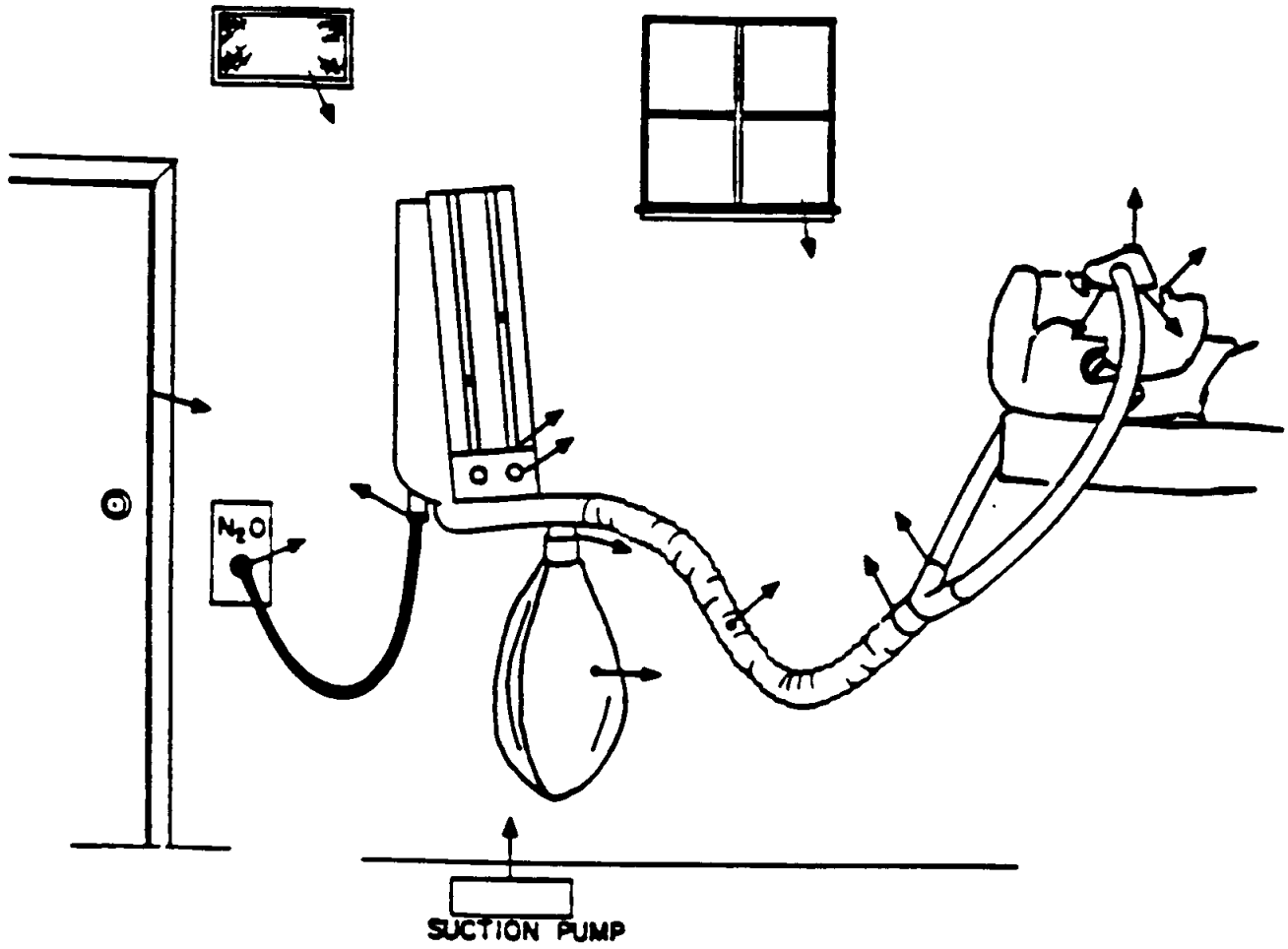


Figure 1

SOURCES OF N_2O IN OCCUPATIONAL EXPOSURE

Arrows indicate leak sources frequently found in the the operatory.

Source: Control of Occupational Exposure to N_2O in the Dental Operatory. DHEW (NIOSH) Publication No. 77-171, National Institute for Occupational Safety and Health, Cincinnati, OH, 1977.

V. CONTROLS

5.1. Principles of Control.

Occupational exposures can be controlled by the application of a number of well-known principles, including engineering measures, work practices, personal protection, and monitoring. These principles may be applied at or near the hazard source, to the general workplace environment, or at the point of occupational exposure to individuals. Controls applied at the source of the hazard, including engineering measures (material substitution, process/equipment modification, local ventilation) and work practices, are generally the preferred and most effective means of control both in terms of occupational and environmental concerns. In dental operatories, exposure to N_2O may be controlled by:

1). effective scavenging devices that remove excess anesthetic gas,

2). proper maintenance of equipment,

3). regular monitoring of environmental exposure for leaks in the anesthesia equipment delivery systems, and

4). good work practices on the part of the dentist and dental assistant.

Additional controls which may be applied to anesthetic agent control include dilution ventilation, and housekeeping.

In general, a system comprised of the above control measures is required to provide worker protection under normal operating conditions as well as under conditions of procedure upset, failure, and/or maintenance. Procedure and workplace monitoring devices, personal exposure monitoring, and medical monitoring are important mechanisms for providing feedback concerning effectiveness of the controls in use. Ongoing monitoring and maintenance of controls to insure proper use and operating conditions, and the education and commitment of both workers and management to occupational health are also important ingredients of a complete, effective, and durable control system. In dental operatories the principal control for waste anesthetic gases is the use of nasal scavenging systems. The following sections will briefly examine the sources of nitrous oxide exposure with and without the use of scavenging systems.

The following guidelines were developed by the ADA as important and desirable characteristics of scavenging equipment (Appendix A) (37). ADA guidelines state that the equipment must be:

- adaptable to most existing sedation, anesthesia, and exhaust systems,
- constructed so that it does not significantly interfere with normal breathing system and delivery of selected gas concentrations,
- capable of attaining the lowest reasonably achievable level of nitrous oxide within the breathing zone of the dentist (25 ppm),
- effective regardless of the heating and air conditioning system in use, and
- constructed to permit safe and efficient disposal of the gases.

5.2. Nitrous Oxide controls with and without Scavenging Machines.

5.2.1. Anesthesia Equipment without Scavenging Machines.

When N_2O leakage is controlled from the anesthesia equipment, gas concentrations will be highest around the breathing zone of the patient, especially the nosepiece where the anesthetic is administered. The administered gas concentrations escape from the patient and are diluted by mixing with room air. Mixing occurs from the movement of supplied air through ducts or wall mounted air conditioners, and from the movement of the dentist and dental assistant. N_2O concentrations will vary according to the amount of fresh air supplied to the dental room, and the room configuration (i.e., open or closed architecture) (5). Personal exposure to the anesthetic will vary according to the proximal location of the dentist and dental assistant to the breathing zone of the patient. As observed in preliminary surveys, the dentist usually works within 6" to 12" inches above the patient's breathing zone, while the dental assistant works within 12" to 24" of this zone. In a still environment, little dilution of N_2O takes place between the patient and the working level of dental personnel. The concentration of N_2O may increase or decrease in the room dependent upon the general room air ventilation (see section 5.3.). This becomes particularly evident when performing gas analysis with a direct reading instrument (usually a Miran 1-A infrared gas analyzer) over the course of the dental surgery. If the room is not well ventilated, gas concentrations may not return to base-line levels, and background concentrations may increase as other operations using N_2O are performed.

5.2.2. Anesthesia Equipment with Scavenging Machines.

Since the 1977 NIOSH document on controlling waste anesthetic gases in dental operatories recommended the use of scavenging systems, several publications have presented various systems for controlling these gases

(38,39,40). Anesthetic scavenging systems are broken into three components: a scavenging or collection device to hold the waste anesthetic gas in a breathing circuit and ventilator; a disposal system to carry the collected gases from the operating room (i.e., a vacuum system); and a device for ensuring that negative or positive pressures in the system do not adversely affect the patient. The most common scavenging system design includes a scavenging circuit (Mapelson D), and a nasal mask, and a vacuum system. The nasal mask has two concentric masks in which anesthetic gases are supplied through a pair of tubes to the center of the mask. A second set of tubes also attached to the innerspace of the mask provides a means of suction at a flow rate of 45 liters per minute. This configuration allows for scavenging of excess gas supplied to the patient as well as excess gas which may escape around the edges of the mask.

While such scavenging systems have been shown to significantly reduce anesthetic gas exposure, NIOSH field studies have shown that under normal operating conditions such systems do not consistently reduce N_2O to the recommended level of 25 ppm (41-44). A preliminary survey by NIOSH personnel of a dental operatory where a scavenging system was used, exposure sources appeared to come from the patient's mouth (i.e., talking, yawning, etc.), the work practices of the dentist such as turning down the scavenging system exhaust because of the annoying "hissing" sound which comes from the suction, and from leaks in the mask or the scavenging unit itself. At this time there is very little known about the contribution these extraneous sources contribute to the overall exposure.

A study to determine the efficiency of different scavenging devices by means of a standardized experimental model was conducted by Hallonsten in 1982. Eight different masks were tested under well-controlled sedation techniques. Efforts were made to reduce nitrous oxide leakage by employing leak-proof equipment and carefully adjusting the nose mask. All patients were informed about the study. The median dentist breathing zone nitrous oxide concentrations varied from 4 - 385 ppm and the ambient air concentrations ranged from 0 - 55 ppm.(50) These results appear consistent with HETA's for operatories using scavenging systems.

5.2.3. Anesthesia Equipment with Supplemental Exhaust to Scavenging Machines.

Based on a review of the literature several investigators have suggested that a major source of N_2O may be from the patient's mouth (45,46). Exposure to N_2O may increase if the patient talks, yawns, or respires through the mouth instead of the nose while consciously sedated. If the excess N_2O is coming from the patient's mouth it is felt that an exhaust system placed near the source may scavenge the N_2O not captured by the nasal mask.

5.3. Ventilation.

Fresh air dilution by air-conditioning can reduce the concentrations of N_2O in the dental suite. The recirculating type of air-conditioning system is the one most often employed. In a recirculating system, a percentage of air is mixed with fresh air and recirculated back into the room. Depending upon the type of control used for fresh air (i.e., temperature or manual damper for outside air), the volume of air recirculated and diluted, a portion of the dental room air is exhausted outside while the remainder is mixed with fresh air and recirculated back into the room. Therefore, increasing the amount of fresh air decreases the recirculated N_2O. Recirculating systems which are temperature controlled for fresh air mixing, may supply 100 percent fresh air depending upon the temperature outside. In many institutions the most cost/effective temperature setting is 55 degrees. Therefore, 100 percent fresh air will be brought into the building if the outside temperature is 55 degrees.

In addition to recirculating air-conditioning systems there are "one-pass" non-recirculating systems which exhaust all dental air outside the building. Unfortunately, such systems are expensive to operate because of the amount of air-conditioning required for comfortable room temperatures. Wall mounted air-conditioning units are another alternative to bringing fresh air into the work environment. The draw back is the dampers are usually manually controlled for bringing in outside air. In some units the dampers are not easily accessible and therefore not adjusted for the changing seasons. In many buildings where energy efficiency is required, the dampers of these units are locked closed by maintenance personnel so that only room air is recirculated.

VI. OBJECTIVES OF THIS STUDY.

The objective of this study is to provide information which can be used to consistently achieve airborne N_2O exposures of less than 25 ppm time-weighted average (TWA) per dental procedure for dental personnel. Based on this research, dental administrators and consultants who may be responsible for making improvements, writing specifications, and allocating funds will be better able to make the proper decisions if they have more complete information about effective controls in the dental operatory.

Furthermore, this NIOSH control technology evaluation is to document representative values of exposure to N_2O and the corresponding factors affecting the control of these emissions using engineering control strategies. Scavenging systems which are currently on the market will be evaluated and compared to control of N_2O emissions at the NIOSH recommended concentration of 25 ppm time-weighted average during the period of administration. This research is not to compare one scavenging system with another, but to examine the specific control components of each system to reach the NIOSH recommended N_2O TWA. If existing controls do not reach the NIOSH recommended limits for N_2O, then research will be conducted to develop controls that will reach this level. This study will also examine general and local ventilation systems, the relative source contributions of each scavenging and anesthetic delivery system, and the work practices of dental personnel, to address the interactive nature of these systems to effectively reduce airborne emissions during dental surgery.

Dissemination of this research will be in the form of written recommendations to Federal, professional and trade associations regarding effective control of N_2O below the 25 ppm TWA per procedure in the dental operatory. These recommendations may consist of improved scavenging system design, better ventilation controls, and good work practices to reach the NIOSH goal of reduced N_2O airborne emissions.

VII. CONDUCT OF STUDY.

7.1. General.

Several preliminary activities have been conducted in order to focus our energies on the most effective control strategies for reducing N_2O gas in dental operatories. Contacts have been made with health professionals who are familiar with N_2O control systems and information has been solicited regarding the effectiveness of such controls. NIOSH researchers have visited the American Dental Association to collaborate on N_2O control systems and establish ongoing communications with this organization. Preliminary field surveys have also been conducted at a dental operatory to determine the feasibility of real-time N_2O monitoring and videotaping of dental work practices. A preliminary meeting was held regarding the goals of this research including dissemination of findings on scavenging systems, work practices, and ventilation controls. Based on the research conducted to date, a basis for future field studies to assess the effectiveness and utility of N_2O scavenging systems in dental operatories has been established. The Hazard Evaluation and Technical Assistance Branch of NIOSH has consistently found excess exposures to N_2O in dental operatories. There are seven commonly used scavenging systems on the market for removing nitrous oxide from the dental operatory; one has been approved and recommended for use by the American Dental Association, three others are under review for approval. The approval guidelines for anesthesia equipment and scavenging machines are shown in Appendix A. To date, the scavenging systems designed to consistently remove N_2O have not performed to the NIOSH recommended levels of 25 ppm during dental surgery; as demonstrated by several Hazard Evaluation and Technical Assistance studies. A protocol has been devised which will quantify N_2O levels during surgery and provide information about the performance of four market-available scavenging systems. Based on this protocol, scavenging system design and work practices may be improved to reduce N_2O levels in dental operatories.

7.2. Engineering Control Technology Assessment of Dental Suite.

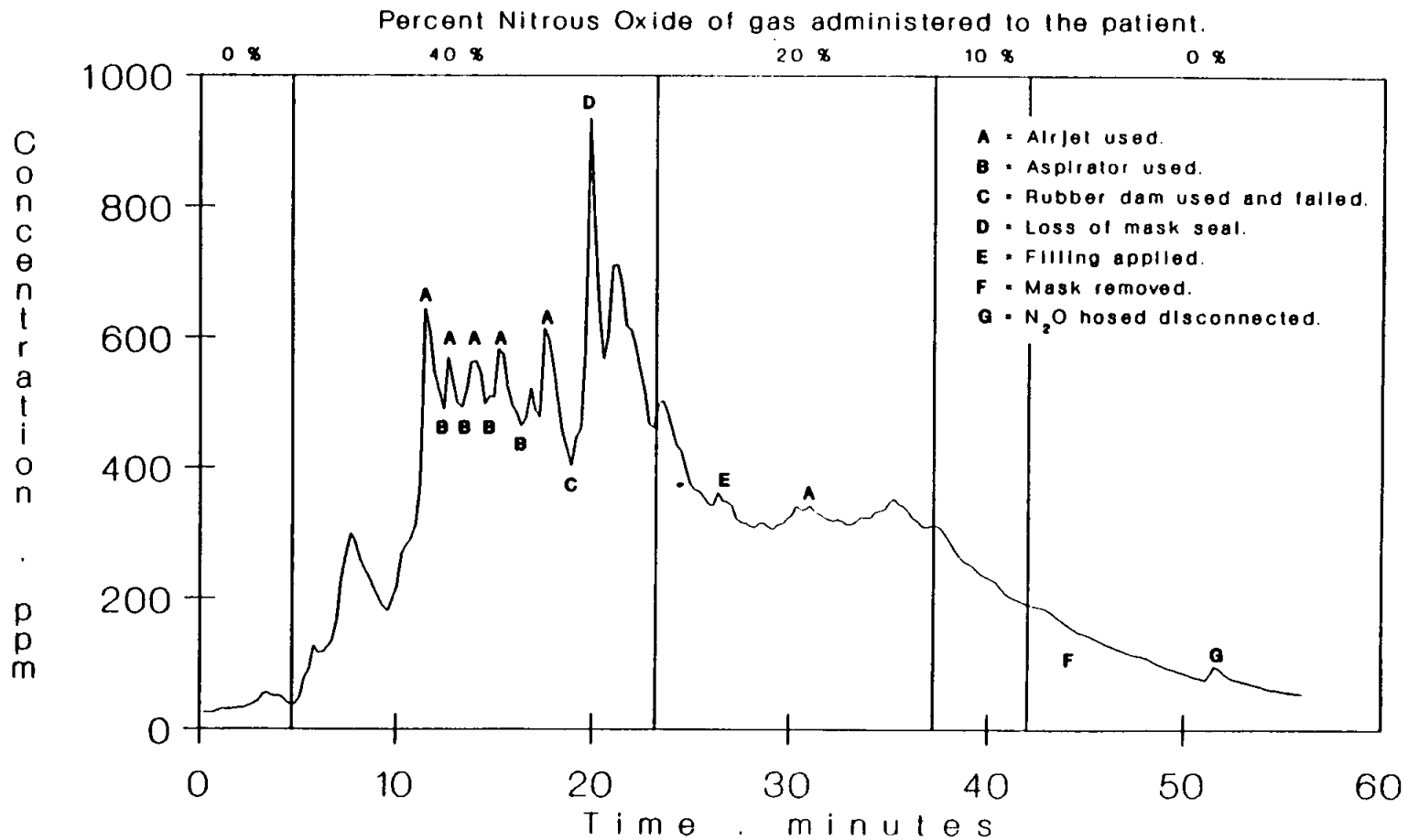
A team of researchers from the Engineering Control Technology Branch visited a dental suite to monitor N_2O during dental surgery. Anesthetic gas data were gathered with a direct-reading instrument (Miran 1-A), work practices were recorded with a videotape recorder and camera ensemble, and general ventilation measurements were taken. Nitrous oxide concentrations within the breathing zones of the dentist and dental assistant ranged from 25 ppm at the beginning of the operation to 950 ppm twenty minutes into the operation. Seven liters per minute (lpm) of gas was supplied to the patient's nasal mask throughout the operation. N_2O was supplied at 2.5 liters per minute while oxygen was supplied at 4.5 liters per minute.

The mixture provided the patientwith 40 percent N_2O and 60 percent oxygen. During the 45 minute operation, the dentist "stepped-down" the N_2O from 40 to 20 to 10 to 0 percent; the general area concentration of N_2O subsequently decreased to 35 ppm 55 minutes after the operation began. Work practices of the dentist and the dental assistant were videotaped and analyzed using traditional job analysis techniques. By combining direct N_2O readings with the videotape analysis, several work elements influenced the concentration of N_2O during the course of surgery. These elements included: use of the scavenging unit, the regulation of N_2O concentration administered by the dentist, the use of a rubber dam, and the dental assistant's use of the saliva aspirator. It also appeared that the patient contributed to the N_2O exposure by talking, coughing, and yawning (Figure 2).

Ventilation measurements were taken in the dental suite which measured 8' x 8' x 10'. The air was supplied at 50 cubic feet per minute through a 6" duct located in the ceiling in the center of the room. Smoke tube measurements indicated the room was under slight positive pressure. Engineering drawings indicated that the air supply should be 160 cubic feet per minute. Discussions with the building engineer about the ventilation system indicated that the duct work is made of fibrous glass and that the fibrous glass tends to "blow out" in places, thus resulting in less air supplied to the dental suite.

Figure 2

Real-Time Nitrous Oxide Concentrations



In summary, this field survey showed that the use of a scavenging system does not guarantee a reduction in safe working levels of N_2O. In the HETA study done of the same facility in 1979 (HETA 79-5) N_2O levels for personal exposure ranged from 90 - 3500 ppm without scavenging systems (47). While the scavenging system reduced N_2O, it does not appear that scavenging alone will decrease anesthetic gases to recommended levels. Work practices including the regulation of N_2O by the dentist during the course of the operation, location of the dentist's breathing zone relative to the patient's, and the use of the saliva aspirator may influence the amount of exposure dental personnel receive while working. In addition, the general ventilation, air supply, exhaust, the amount of fresh make-up air, and room air changes per hour may also influence exposure to dental personnel in the operating room and elsewhere. Poor room ventilation may also influence the time the N_2O stays in the work environment.

7.3. Laboratory modeling for control of N_2O.

Based on the premise that excess N_2O may be generated from the patient's mouth, a laboratory experiment was set up to determine the feasibility of a supplemental scavenging system to capture N_2O from the patient's mouth. A hollow mannequin head with openings at the mouth and base of the neck served as the surrogate patient, smoke was used as a visible indicator for N_2O, and a vacuum cleaner with a flexible hose as the local exhaust. A smoke tube was inserted into a tygon tube and the tygon tube inserted into the base of the mannequin head. The smoke tubes were attached to a diaphragm pump which operated at 26 liters per minute. The pump was manually cycled to simulate patient breathing. The vacuum cleaner and hose attachment was used to simulate a local exhaust. The vacuum cleaner was operated at approximately 50 cubic feet per minute. Three different vacuum cleaner hose attachments were interchanged to determine which best captured smoke from the patient's mouth. The preliminary findings showed that an optimum distance to capture most of the smoke was approximately 2.5 inches above the patient's mouth and 1.5 inches below the chin. While this local exhaust appeared effective in capturing smoke, it appeared impractical and cumbersome for use and may not be readily accepted by practicing dentists. Therefore, a local exhaust system which can be integrated with the existing scavenging systems will be considered in order to achieve a concentration of less than 25 ppm N_2O TWA, assuming this approach is warranted based on the evaluations of existing systems.

VIII. EXPERIMENTAL DESIGN.

8.1. Survey Site and Scavenging system Selection.

Based on the available information from the ADA regarding scavenging devices for control of waste anesthetics in dental operatories and telephone contact with the manufactures listed by the American Dental Association, four scavenging systems will be evaluated (Table 5).

Table 5

SCAVENGING SYSTEMS TO BE EVALUATED
FOR CONTROL OF N_2O

- Blue Mask, Health Care Technology, Inc.
- Brown Mask, Summit Services, Inc.
- Fraser Harlake Nitrous Oxide Scavenging System, Fraser, Sweatman.
- Comfort Cushion Nasal Analgesia Delivery System, Mission White Dental, Inc.

The scavenging systems in Table 5 are market available and in use in many dental practices.

8.1.1. Statistical Assessment and Analysis.

Given the objectives described, it is necessary to formulate an experimental design to account for the variables that exist in dental operations. These variables are divided into two categories: those relating to the process or dental operatory, and those relating to the type of control used.

Process Variables.

These variables (type of dental operation, i.e., tooth extraction versus root canal, age of equipment used, etc.) may be related to the nature of the dental office, and cannot be varied for a particular operation. Such variables will be documented through observation, qualitative description, and professional judgment rather than quantitative measurement. Where practical, these variables will be held constant in the study.

Control Variables.

These variables include the types of engineering and work measures used to reduce or control N_2O exposures and emissions. They may also include key operating parameters (e.g., ventilation rate) of these control measures. These are the principal variables in the study. Study sites will be selected based on the scavenging systems that are being used; and every attempt will be made to pick sites that are physically similar. Since the exposure source in dental operations is in the immediate breathing zone of the dentist and dental assistant, differences in general ventilation may have a minimal effect on N_2O exposure when compared to the control and process variables.

Process Characterization.

In order to make the measured control effectiveness as meaningful as possible, it is important to describe the context of the dental facility or process-related variables that accentuate or limit the N_2O controls in use.

The objective of the process characterization is to identify and describe these variables such that a person who is familiar with dental operations could qualitatively compare the key variables in the case study with those in different situations.

Evaluation Methods

The current plan calls for a minimum of four in-depth field surveys (i.e., one field survey for each scavenging system evaluated). The surveys will include real-time N_2O sampling, videotaping of the dental operation for work practices, and measurement of ventilation rates. Also, observations will be made of control systems, the N_2O used, N_2O gas cylinder usage, and employee training and education of scavenger system use.

Individual survey reports will be sent to the dental clinics surveyed for review and comment. Review comments will be incorporated as appropriate, and copies will be distributed according to procedures outlined in Title 42 of the Code of Federal Regulations (see Appendix B).

Information from the individual surveys will be compiled into a final study report. The final report will be published as a NIOSH Technical Report. This information will also be disseminated to the ADA, scavenging system manufacturers, in peer-reviewed journals, and by presentation at professional meetings.

8.1.2. Site Selection.

Site selection will be on the basis of the control system used and access to monitor such systems under normal operating conditions. The specific controls to be evaluated are the four scavenging systems listed above. Up to four dental operations will be evaluated at each site where a N_2O scavenging system is used. Therefore, not less than 16 dental operations will be evaluated to examine the interaction of process and control variables with regard to N_2O exposure and control.

o Site Selection Criteria.

There are a number of factors involved in the selection of specific sites. We will attempt to select dental suites where N_2O is commonly administered to the patient, and where enough operations are performed on a daily basis so that data collection can be efficiently gathered. Judicious selection of sites will include:

1. The type of scavenging system control being used at the site.
2. The type and quantity of operations performed at the site.

University or hospital settings may be best suited for the NIOSH research team. These establishments tend to have a high volume of patients and may offer more flexibility in conducting research to determine the best N_2O control strategies.

Good work practices and sound management approach are fundamental to the existence of suitable conditions for study.

All site visits will be conducted according to the Regulations for Investigations of Places of Employment, Code of Federal Regulations (CFR), Title 42, Part 85a (see Appendix 6). The project officer will contact each dentist office in advance of their planned visit date and provide details about the project.

8.2. Conduct of In-depth Surveys.

8.2.1. Real-Time Sampling.

During the entire dental operation nitrous oxide will be measured and recorded continuously. The Miran 1-A will be used to measure and record the gas concentration levels. The instrument is designed for field measurement of several gases and vapors, including nitrous oxide. This variable filter, variable path length infrared analyzer with 20.25 meter

cell may be adjusted for the appropriate gas of interest. It has direct reading scales with a response time constant of approximately 15 seconds under continuous operation. The lag time is caused by a combination of factors including: transport of the gas to the analyzing chamber, mixing of gas in the changer, and instrument response. Because of the slight time lag of 15 seconds or less, the peak exposures as well as low exposures will be averaged and will not report the exact nitrous oxide concentrations at the time of exposure. The performance of this instrument for real-time sampling greatly outweighs this minor limitation in exposure averaging. The Miran 1-A sampling port will be located approximately 10" above and behind the patient's breathing zone (the average distance of the dentist and dental assistant's breathing zones) (Figure 3). The following settings will be set for N_2O, with a wavelength of 4.47 micrometers, slit width of 0.50 millimeters, and a pathlength of 6.75 meters. The range of approximately 1 - 1000 parts of nitrous oxide per million parts of contaminated air by volume (ppm), respectively. The Miran 1-A will be calibrated before and after each survey. To avoid a false "zero" during calibration, compressed air will be used for instrument calibration. Nitrous Oxide from the dental clinic will be used as the calibration gas. Gas concentrations registered by the Miran will be recorded by a strip-chart recorder and an analog to digital data-logger (Rustrack Ranger). The strip-chart recordings will be kept for reference should the data-logger malfunction. The data-logger will be programmed to accept and store data from the Miran throughout the procedure. The memory of these recorders will exceed the length of time required to perform all dental operations. Data from the data-loggers will be "dumped" onto a portable Compaq computer for analysis at a later time. A portable videotape recorder and camera ensemble will be engaged during the entire operation. Traditional motion and time measurement techniques will be used to document activities of the dentist, the dental assistant, and as best as possible, the patient during the operation. The internal clock of the camera will be synchronized with the data-logger so that changes in N_2O concentration over the course of the operation can be observed relative to the work activities which causes these changes. The computer which contains the nitrous oxide data will plot a hard copy of these concentrations so that work methods and work practices which caused these changes can be identified.

8.2.2. Personal and Area Sampling.

Personal breathing zone samples will be taken in the breathing zone of the dentist and dental assistant, while general area samples will be taken at the room air exhaust vent and outside the room (Figure 3). The bag samples will be analyzed using a Miran 1-A as described above.

Personal sampling will answer the question of how the employee's time-weighted average (TWA) exposure to N_2O compares with the NIOSH recommended standard of 25 ppm. The following factors may affect the employee's exposure:

Amount of N_2O available for release at the source.

Events which take place during the sampling period.

Activities of workers being sampled.

Time spent in various areas of high or low N_2O concentration.

Work Practices.

Activities of the patient (i.e., talkative, anxious, hyperactive, yawning, etc.).

The amount of N_2O available for release at the source will be determined from the scavenging system gas release. The events which take place during each sampling period and the activities of the workers being sampled will be documented. Personal and general area air exposures to N_2O will be collected in 80 liter bags and analyzed by infrared analysis. Vacuum sampling pumps, modified for bag filling, will be utilized to draw air through a section of tygon tubing (1/4" diameter) and into a Tedlar^{tm} bag. The sampling pumps will be calibrated at a flow rate of 1 liter per minute (l/min) for personal breathing zone samples and for general area samples. The sampling rate may be increased to more than 1 l/min if the dental procedure is less than 30 minutes. The sampling pumps will be turned on when the nitrous oxide scavenging system is turn on at the beginning of the operation and turned off when the scavenging system is turned off at the end of the operation.

NIOSH sampling equipment will be wiped down with a sterilizing agent (sodium hypochloride) following each survey to decrease infectious disease transmission risk to NIOSH personnel and other dental survey participants.

8.2.3. Observation of Work Practices.

The activities of the patient may significantly contribute to the personal exposure of N_2O, especially if the patient talks excessively while the gas is being administered. Therefore, an ergonomic evaluation of dentists and dental assistant work procedures will be conducted to discern potential anesthetic gas exposure during surgery. Dentists and and dental assistants will be videotaped during surgery. Work analysis will be conducted by running the videotapes at normal speed and "freeze frame" to discern elements which may increase or decrease anesthetic gas exposure to the surgical team. Modified motion and time measurement techniques will be used to catalog the work elements. Analysis of the videotapes will be conducted at the NIOSH laboratories. Work elements which may increase the N_2O concentration, will be isolated for detailed inspection. Where possible, recommendations will be provided to modify these work elements in order to decrease exposures.

Following the ergonomic evaluation, the real-time nitrous oxide data will be synchronized with the videotapes to confirm observation of exposure sources, and to quantify N_2O levels during the surgical operation.

When appropriate, biodemographic data such as demographic, work history, and personal techniques toward N_2O control, will be gathered from the dentists and dental assistants to complement work place observations. A schematic which integrates the testing procedure described above is shown in Figure 4.

8.2.4. Evaluation of Ventilation Systems.

The Kurz Model No. 480, TSI Model No. 1630, and Alnor (Balometer) air velocity meters will be used to measure air velocities to determine flow rates in and out of dental operatories. Room air exchange rates will also be evaluated by determining dental operatory size with the amount of fresh air coming into the room. Smoke tubes will be used to assist in observation of general air flow patterns. Where possible, building blueprints will be secured for locating air duct locations and comparing flow rates with building design specifications. Nitrous oxide usage will be determined by finding out how many N_2O cylinders are used per month and the number of patients administered this anesthetic during the month. The amount of N_2O per patient anesthetized and the total number of patients treated at the operatory.

8.2.5. Leak Testing Scavenging Equipment.

Previous studies have shown that anesthetic equipment can have a number of leak sources. Detection of leakage in the high-pressure components of the N_2O system will be accomplished by observation of a pressure gauge for the central N_2O supply. Other high-pressure connections will be leak tested with soap solution being applied around these points and observation of any bubble formation (Figure 5)(5).

Leak testing of low-pressure components of the anesthesia scavenging machine will be determined by over filling the breathing bag with O_2, and palpating the surface to reveal any significant leakage. Breathing holes and other low-pressure components will be leak tested as a unit. Preparations for this test will include removing the bag from the anesthetic machine and adapting a blood pressure gauge to the bag outlet. The breathing connections of the nasal mask will be connected and closed, and the system supplied with O_2 to a pressure of 30mm Hg (Figure 6).

Checking the effectiveness of the anesthetic gas capture capacity of the scavenging nasal mask will be done by inserting a vacuum flow meter in the exhaust ports of the scavenging mask. It has been calculated that adequate scavenging of gas from the nasal area of the patient is 45 l/min when 4 - 7 l/min each of N_2O and O_2 are supplied (5). Schematics of a typical scavenging mask and how it works is shown in Appendix C.

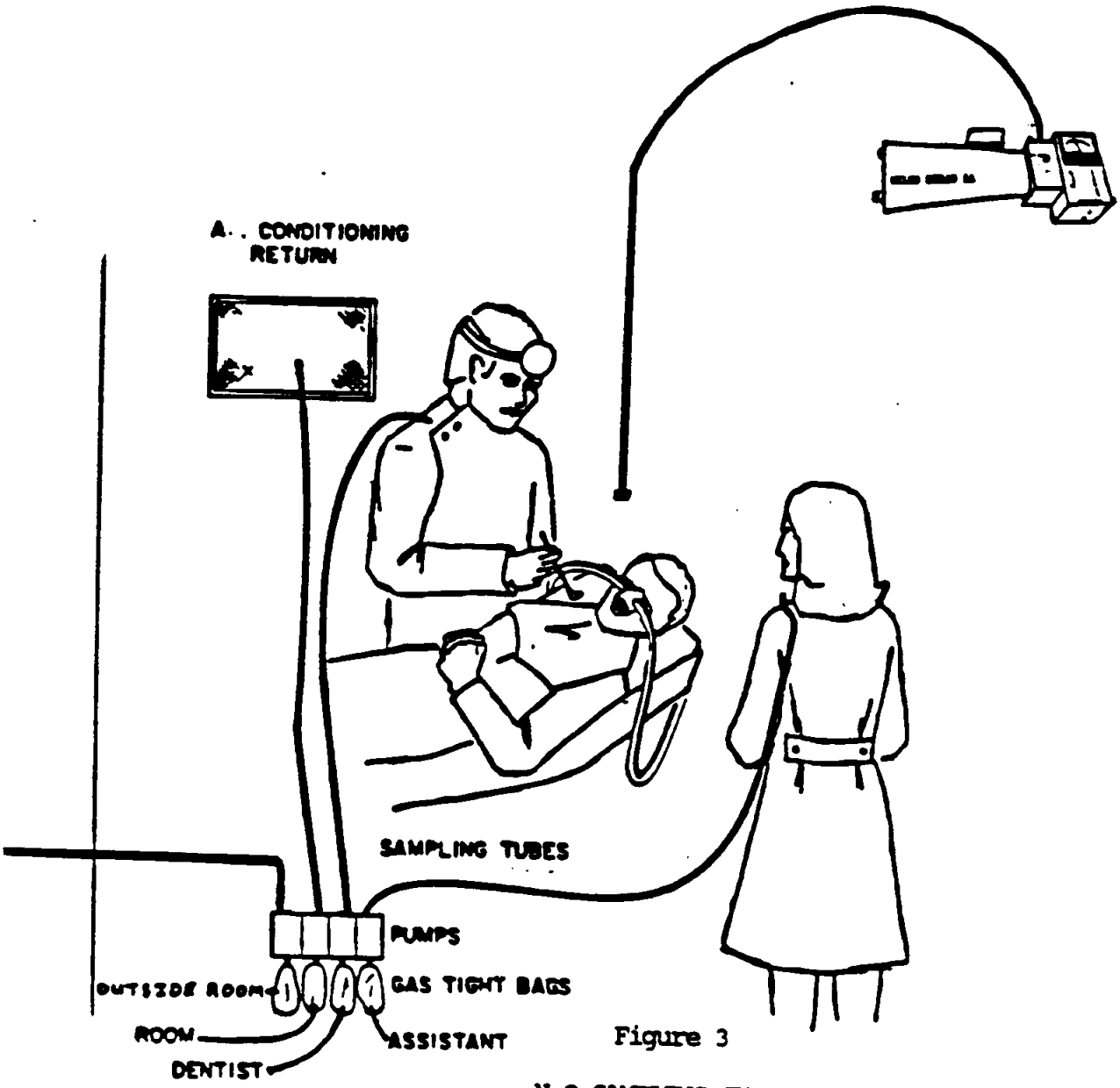


Figure 3

N_2O SAMPLING SYSTEM

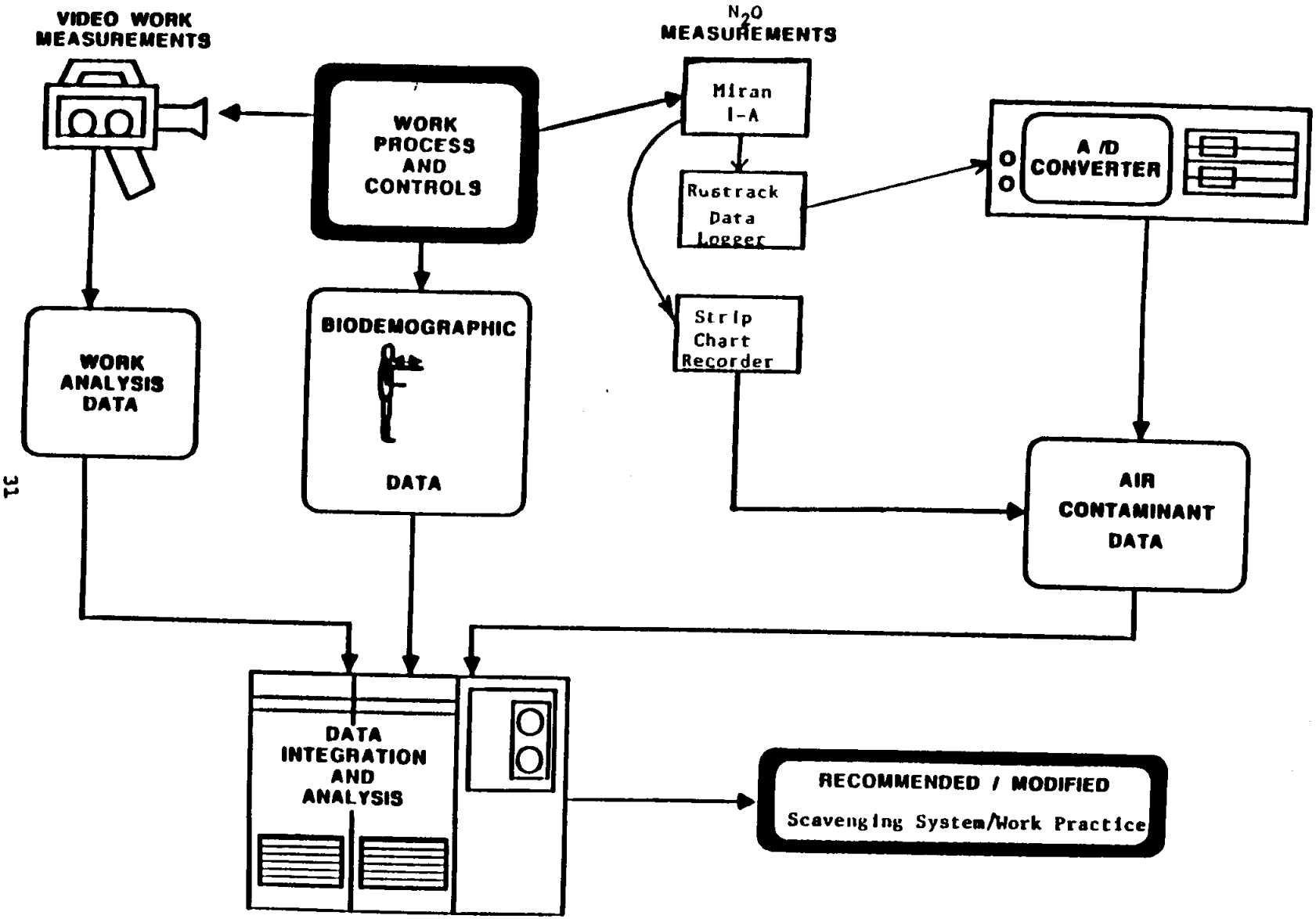
Sampling tubes are arranged for the continuous aspiration of samples in strategic locations, with temporary storage of samples in Mylar gas-tight bags. One tube is aspirated through a Miran 1-A for continuous real-time sampling.

Taken in part from: Occupational Exposure to N_2O in the Dental Operatory. DHEW (NIOSH) Publication No. 77-171, National Institute for Occupational Safety and Health, Cincinnati, OH, 1977.

Figure 4

DATA ACQUISITION SYSTEM

for Evaluating N_2O Exposure In Dental Operatories



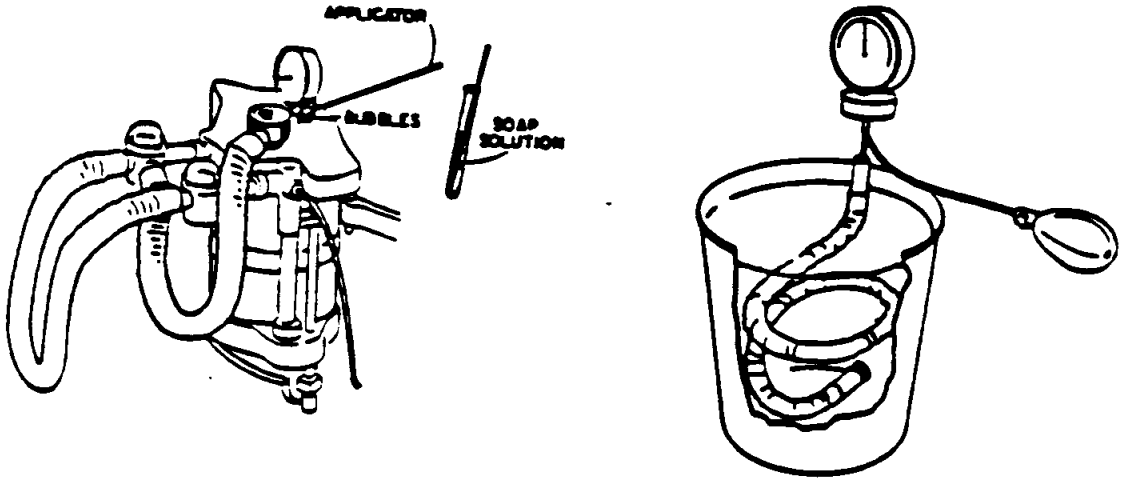


Figure 5

LEAK LOCALIZATION PROCEDURES

When auscultation and palpation fail to reveal leak sites, pressurized components can be tested with soap solution and immersion tests.

Taken in part from: Occupational Exposure to N_2O in the Dental Operatory. DHEW (NIOSH) Publication No. 77-171, National Institute for Occupational Safety and Health, Cincinnati, OH, 1977.

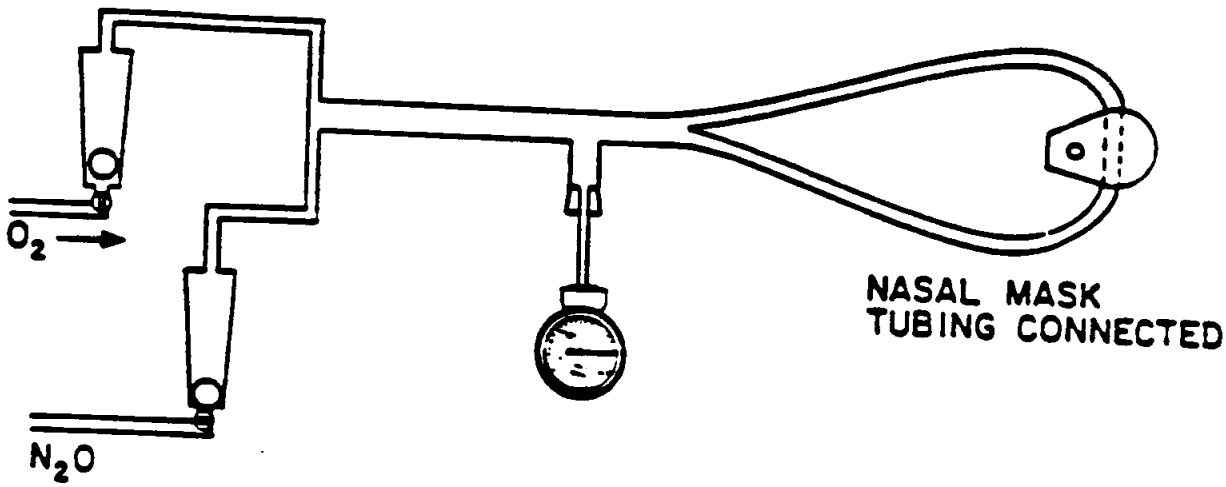


Figure 6

LEAK TESTS FOR LOW PRESSURE N_2O SYSTEM

Bag (not shown) is tested by over-inflating with O_2 and palpating its surface. With bag removed, other components are tested as a unit by establishing that flowrate of O_2 which maintains a static pressure of 30 mm Hg.

Taken in part from: Occupational Exposure to N_2O in the Dental Operatory. DHEW (NIOSH) Publication No. 77-171, National Institute for Occupational Safety and Health, Cincinnati, OH, 1977.

8.3. Data Analysis.

T-tests will be applied to personal sample measurements at each site and between operations to determine the effectiveness of the scavenging system evaluated. The null hypothesis for each site is defined as H_o: mean is less than or equal to 25 ppm TWA and the alternate hypothesis H_a: mean is greater than 25 ppm TWA. T-tests will also be performed on personal sample measurements with and without the supplemental exhaust system in conjunction with the scavenging system being evaluated. Up to six sampling runs will be performed, with a minimum of 4 sampling runs, for each scavenging system (48).

Data on samples collected at dental offices, where several process variables, work site variables, work practice variables and counting variables are present, will be analyzed. Hypotheses concerning the factors contributing to exposure variations among systems will be tested. Variables, both individually and combined, will be tested in models to determine if any variables contribute significantly to the variation in the data. Where possible, analysis of covariance: a technique that combines the features of analysis of variance and regression, will be used. Separate models will be tested for each control situation (i.e., site). It is recognized that because of the limited sample size, statistical significance cannot be demonstrated for all variables encountered in a field study. The Statistical Analysis System (SAS) Procedure, General Linear Model SAS PROC GLM, will be used for this analysis (49). Variables will include, but are not limited to day of sample, type of sample, work activity, work practices, and type of ventilation. In order to be consistent, a checklist will be used at each dental site for completeness of investigation. The checklist will support statistical analysis for patterns and trends among and within dental study sites.

The area sample data will be collected in sets of two: one in the dental office, near the exhaust vent; the other outside the office. Analysis of variance, and analysis of covariance will adjust for the set-to-set differences, and for location-to-location differences. The residual will provide an estimate of the measurement variance. Transformation, such as the natural log transformation, will be applied, if needed to obtain homogeneous variance and normal distribution. Residuals will be plotted to test the appropriateness of each transformation.

The appropriate tests (e.g., F-test, T-test, etc.) will be applied to compare scavenging system means to the background sample means. Multiple comparisons among sample locations will be made. Statistical summaries will then be derived using the data transformed back to the original scale (48).

The statistical analysis will be performed using SAS procedures.

IX. PRODUCTS.

A final report of the survey results will be sent to each dental operatory studied, and will be distributed to various agencies and persons according to procedures outlined in CFR Title 41, 85a Regulations (see Appendix 2). The reports will be on file with the National Technical Information Service (NTIS). These reports should provide valuable information on the effectiveness of the engineering controls for each clinic, and will assist the hospital's engineering and maintenance departments.

Articles for professional journals will be written to summarize the project results. Data will be analyzed and interpreted. The journal articles will provide information which will assist hospital personnel in their control efforts by documenting transferable and innovative control technology and will stimulate research.

The American Dental Association will be kept abreast of all developments related to this project, and sent copies of dental surveys which will go to NTIS. The ADA may choose to organize this information in a booklet and disseminate it to their members, Dental Schools, Schools of Public Health, Universities, and manufacturers. A videotape may also be developed which will serve as a training aid for the practitioners of the dental trade. The videotape will highlight user strategies for controlling N_2O by good work practices, maintenance of scavenging equipment, checking for high to low pressure N_2O leaks, and local and general ventilation. The videotape will also recommend how to evaluate efficiency of the scavenging and how to monitor occupational exposures to N_2O. Researchers in the Engineering Control Technology Branch of NIOSH may assist as consultants if requested by the ADA.

Manufacturers of the scavenging equipment evaluated, will be sent reports describing results and recommendations for improvements, if any, to the scavenging system design and ergonomic function. The goal will be to encourage manufacturers to redesign equipment if necessary to further reduce N_2O exposures. If the result of this research is the design or the modification of an existing scavenging system where more effective control is documented, these design specifications and results will be presented to the manufacturers for integration of such specifications into their system.

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XI. APPENDICES

APPENDIX A

Guidelines for the Acceptance of Nitrous Oxide Sedation Machines and Scavenging Equipment

REVISED GUIDELINES FOR THE ACCEPTANCE PROGRAM FOR

NITROUS OXIDE-OXYGEN SEDATION MACHINES AND DEVICES

Council on Dental Materials, Instruments and Equipment

A company seeking qualification of its product under the classification system is required to comply with the general guidelines for submission of a product, as well as with the specific guidelines for the device:

A. Installation: The manufacturer, in submitting his product for Acceptance, shall agree that the following will be done:

1. The installation of the gas delivery system and the gas storage will be in accordance with the National Fire Protection Association Standards.
2. The complete installation will be supervised by a competent supplier of gases and equipment.
3. The gas cylinders will be stored in locked containers.

The above instructions should be incorporated in the product literature.

B. Fittings:

1. The gas cylinders, hoses and flow measuring devices shall be color-coded in accordance with U.S. Standards: green for oxygen and blue for nitrous oxide.

2. Both pin index safety systems and diameter index safety systems are to be used.

3. The pins shall not be press fitted but shall be attached to the block by a positive means such as welding, screws or machining out of the block to minimize chances of accidental malfunction of the pin index system.

C. Machine

1. A fail-safe device shall be installed to close off nitrous oxide supply and sound an audible alarm if oxygen supply fails. The audible alarm shall be on the analgesia head.

2. The machine must be capable of delivering a flow rate (O_2 + N_2O) of 8 lit/min. On activation of the machine a minimal flow of 2.4 lit/min O_2 will occur. As a result the maximum percentage of nitrous oxide that can be given will be 70%

3. Quick connectors of standard size shall be provided to allow for fitting of resuscitation equipment when gases are supplied centrally.

4. A protective housing shall completely enclose the flow measuring devices and will be fronted by a transparent safety shield.

5. A reservoir bag shall be provided for delivery of nitrous oxide and oxygen.

6. Flow measuring devices should be accurate to ± 5%. The oxygen flow measuring device should be located on the right side of the machine as viewed from the front. The flow measuring devices should provide visual monitor of the gas flow.

7. The reservoir bag shall be mounted high enough to allow unrestricted visual monitoring.

8. An on-demand valve shall be available to allow the automatic admission of room air to the system if gas flows are inadequate for the patient's needs.

9. A nonrebreathing valve shall be an integral part of the normal-mode operating system, with the option of being manually disengaged in the event of an emergency.

D. Instructions:

1. Attached to the machine shall be the caution that the equipment is to be used only under the direct supervision of a physician or dentist.

The Council has established the effective date for classification of products under these guidelines as one year from the date of this announcement. After that date classification of a product will be required before promotion or exhibiting through Association media. Products currently on the List of Classified Dental Materials, Instruments and Equipment as Acceptable or Provisionally Acceptable must show compliance at the time of scheduled renewal of classification.

NOTE: All correspondence and other information sent to the Council should be in triplicate since it is necessary to forward copies to Council Consultants. Please send one original and complete trade package of the device. The device will be returned following review and evaluation of the submission.

REVISED GUIDELINES FOR ACCEPTANCE OF NITROUS-OXIDE/OXYGEN SCAVENGING EQUIPMENT

Council on Dental Materials, Instruments and Equipment
American Dental Association

The following guidelines are intended to outline the important characteristics of scavenging equipment used in conjunction with inhalation sedation devices to reduce the occupational exposure to waste nitrous-oxide.

The submission must show that the equipment meets the following product characteristics. In addition, the submission must comply with the Council's "Revised Directions for Submission of Products"

SCAVENGING EQUIPMENT MUST BE:

1. adaptable to most existing dental nitrous-oxide/oxygen administration systems. The manufacturer will state to which systems his device is adaptable.

2. constructed so that it does not significantly interfere with the normal breathing system and delivery of selected gas concentrations. The manufacturer must submit clinical test data showing that the instrument does not interfere with the normal breathing system and the delivery of selected gas concentrations. Areas to be evaluated include: 1) resistance 2) delivered concentrations of gases and 3) pressure changes within the gas flow circuit. Resistance to expiration will be measured at the nasal mask and the first 5 cm. of delivery hose. A diagram illustrating the sites of measurement will be included in the submission.

3. capable of providing N_2O-O_2 levels which comply with or improve upon minimum levels indicated in current NIOSH and OSHA documents.

4. effective regardless of the heating and air conditioning system in use.

5. constructed to permit safe and efficient disposal of the gases: (a) the waste gas must not contaminate air intakes and personnel areas; (b) NFPA standards for disposal of oxidizing agents must be met.

6. effective when more than one device is being used simultaneously. The manufacturer will submit testing data demonstrating such effectiveness. Manufacturer must state the air volume per minute and vacuum level necessary.

7. constructed such that patient rebreathing will be insignificant. In particular during spontaneous respiration there will be no more than a 0.5% increase in carbon dioxide levels. Data will also be presented showing no ingress of room air at inspiration.

8. provided with a means such that the practitioner can easily determine whether the device is operating at levels stated in guideline 3.

Instructions for Use Accompanying the scavenging device must include the following points:

1. The need for equipment maintenance (if there are high pressure or low pressure leaks, scavenging will not be effective). Explanation of methods for maintenance should be given.

2. Commentary regarding technique of nitrous oxide/oxygen agent administration (i.e. N_2O should not be administered until such time as the mask is properly in place. Direct spillage of inhalation anesthetics into the atmosphere is to be avoided).

3. Instructions for proper and safe installation of scavenging equipment and disposal of the waste gases (e.g. waste gases must not contaminate air intakes and personnel areas, NFPA standards for disposal of oxidizing agents met; exhaust system must have sufficient capacity to remove the waste gases).

NOTE: It is not necessary to submit a sample device with the submission unless specifically asked for by the Council. Please prepare all submissions in triplicate.

WTW:la

COUNCIL ON DENTAL MATERIALS AND DEVICES
AMERICAN DENTAL ASSOCIATION

GUIDELINES FOR ACCEPTANCE OF NITROUS-OXIDE/OXYGEN WASTE GAS MONITORING EQUIPMENT

The following guidelines are intended to outline the important and desirable characteristics of gas monitoring equipment used in conjunction with inhalation sedation devices to monitor the occupational exposure to waste nitrous oxide.

The submission must show that the equipment meets the following product characteristics. In addition, the submission must comply with the Council's "Direction for Submission of Products" (May 1973).

MONITORING EQUIPMENT MUST PERMIT THE COLLECTION OF A TIME WEIGHTED AIR SAMPLE, COLLECTED AT A CONSTANT RATE OVER A SPECIFIED PERIOD OF TIME, OBTAINED WITHIN THE BREATHING ZONE OF THE DENTIST DURING ADMINISTRATION OF INHALATION ANESTHETIC AGENTS.

The equipment characteristics must include at least the following capabilities:

1. be simple and easy to operate.

2. permit collection of at least a two-hour time weighted sample.

3. be adjustable to permit more rapid collection of a time weighted sample (around 15 minutes).

4. provide for convenient collection of a sample from the breathing zone of the dentist.

5. the sampler must be properly sealable to maintain sample integrity and avoid leakage of the sample in shipment and storage.

6. be small enough to permit mailing of the collected sample for analysis (except for samplers intended for use at institutions which have in-house analysis capability).

NOTE: It is not necessary to submit a sample device with the submission unless specifically asked for by the Council. Please prepare all submissions in triplicate

RWB:fes

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APPENDIX B

41 CFR 85a

APPENDIX

DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATIONS FOR INVESTIGATIONS OF PLACES OF EMPLOYMENT

(Code of Federal Regulations, Title 42, Part 85a, 41 FR 45003, October 14, 1976; amended at 45 FR 2651, January 14, 1980; amended at 49 FR 4739, February 8, 1984)

Title 42-Public Health

CHAPTER I-PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER G-OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND RELATED ACTIVITIES

Part 85a-OCCUPATIONAL SAFETY AND HEALTH INVESTIGATIONS OF PLACES OF EMPLOYMENT

Sec.

AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and Sec. 508.83 Stat. 803.30 U.S.C. 957. [Authority citation amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

85a.1 Applicability

(a) Except as otherwise provided in paragraph (b) of this section, the provisions of this part apply to investigations of places of employment which are conducted by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970 and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977.
[Section 85a.1(a) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(b) The provisions of this part do not apply to those activities covered by Part 85 of this chapter.

85a.2 Definitions

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the Acts. As used in this part:

(a) "OSH Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.) and "FMSH Act" means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.).
[Sections 85a.2 and 85a.2(a) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(b) "Assistant Regional Director" means any one of the ten Occupational Safety and Health Administration Assistant Regional Directors for Occupational Safety and Health.

(c) "Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary

to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the investigation at any time without prejudice to the subject.

(d) "Investigation" means research projects, experiments, demonstrations, studies, and similar activities of NIOSH which are conducted under section 20 of the OSH Act and section 501 of the FMSH Act.

[Section 85a.2(d) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(e) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

(f) "NIOSH" means the National Institute for Occupational Safety and Health of the Centers for Disease Control, Public Health Service, Department of Health and Human Services.

(g) "NIOSH authorized representative" means a person authorized by NIOSH to conduct investigations of places of employment, including any person that is fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act.

(h) "NIOSH Regional Office" means any one of the ten Department of Health and Human Services Regional Offices, the addresses of which are specified in 5.31 of Title 45, Code of Federal Regulations.

(i) "Places of employment" means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by any employee of an employer.

[Section 85a.2(i) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(j) "MSHA District Office" means any one of the Mine Safety and Health Administration's District Offices.

[Section 85a.2(j) added at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(k) "BOM" means of the Bureau of Mines, Department of the Interior.

[Section 85a.2(k) added at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(l) "Employee" has the same meaning as stated in the OSH Act and for the purpose of this part includes "miner" as defined in the FMSH Act.

[Section 85a.2(l) added at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(m) "Employer" has the same meaning as stated in the OSH Act and for the purposes of this part includes "operator" as defined in the FMSH Act.

[Section 85a.2(m) added at 45 FR 2651, January 14, 1980, effective February 13, 1980]

85a.3 Authority for investigations of places of employment

(a) NIOSH authorized representatives who have been issued official NIOSH credentials are authorized by the Director, NIOSH, under sections 20 and 8 of the OSH Act, sections 501 and 103 of the FMSH Act, and this part: To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements and functional tests of employees within the place of employment as may be directly related to the specific investigation being conducted. Such investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigations, such NIOSH authorized representatives may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, or duplicate employment records, medical records, records required by the Act and regulations, and other related records. In those instances where systems of records subject to review, abstraction or duplication are of a confidential nature, such as medical records, and are abstracted or duplicated, NIOSH will maintain such systems in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the implementing regulation of the Department of Health and Human Services (45 CFR Part 5b).
[Section 85a.3(a) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(b) Areas under investigation which contain information classified by an agency of the United States Government in the interest of national security will be investigated only by NIOSH authorized representatives who have obtained the appropriate security clearance and authorization.

85a.4 Procedures for initiating investigations of places of employment

(a) Except as otherwise provided in paragraph (b) of this section, NIOSH authorized representatives will contact an official representative of the place of employment prior to any site visits and will provide the details of why an investigation of the place of employment is being conducted. Prior to the initiation of a site visit of a place of employment, representatives of the following organizations will be advised of the site visit and the reason for its conduct:

(1) The appropriate State agency designated under section 18(b) of the OSH Act or if no State agency has been designated under the OSH Act and in the case of the FMSH Act, the State agency which, in the judgment of NIOSH, would benefit the most from the investigation's findings.
[Section 85a.4(a)(1) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(2) If there is a local union at the place of employment, the local president, business manager or other appropriate individual.
[Section 85a.4(a)(2) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(3) The appropriate Assistant Regional Director, when investigations are conducted under the OSH Act.
[Section 85a.4(a)(3) amended at 45 FR 2651, January 14, 1980,

effective February 13, 1980]

(4) The appropriate MSHA District Office: the Director, BOM, and the Assistant Director for Mining, BOM, when investigations are conducted under the FMSH Act.

[Section 85a.4(a)(4) added at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(b) Advance notice of site visits will not be given to the place of employment or local union at the place of employment when, in the judgment of the NIOSH authorized representatives, giving such notice would adversely affect the validity and effectiveness of an investigation. Those individuals and organizations specified in 85a.4(a)(1), (a)(3), and (a)(4) will be notified prior to the initiation of such a site visit. After the site visit has been initiated, and, as soon as possible thereafter, the NIOSH authorized representatives will contact those individuals specified in 85a.4(a)(2) concerning the nature and details of the site visit.

[Section 85a.4(b) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(c) In those instances where site visits are not necessary to the conduct of an investigation, the NIOSH authorized representatives will contact an official representative of the place of employment either verbally or through a written communication and provide the details of why an investigation of the place of employment is being conducted. If appropriate, the NIOSH authorized representatives will contact those individuals stipulated in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section about the nature of details of the investigation.

[Section 85a.4(c) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

85a.5 Conduct of investigations of places of employment

(a)(1) Prior to beginning a site visit, NIOSH authorized representatives will present their credentials to the employer, owner, operator or agent in charge at the place of employment, explain the nature, purpose and scope of the investigation and the records specified in 85a.3 which they wish to review, abstract or duplicate.

(2) In those instances where site visits are not necessary to the conduct of an investigation and the initial contact is made verbally, NIOSH authorized representatives will, at the request of the employer, owner, operator or agent in charge at the place of employment, provide a written explanation of the nature, purpose and scope of the investigation and the records specified in 85a.3 which they wish to review, abstract or duplicate.

(b)(1) At the commencement of an investigation, the employer, owner, operator or agent in charge at the place of employment shall precisely identify that information which is trade secret and might be seen or obtained by the NIOSH authorized representatives during the investigation. If the NIOSH authorized representatives have no clear reason to question such identification, such information will not be disclosed by NIOSH in accordance with the provisions of section (15) of the OSH Act. Generally, NIOSH will not question trade secret designations; however, if NIOSH at any time does question such identification, not less than 15 days' notice to the employer, owner, operator or agent will be given of the intention to remove the trade secret designation from

such information. The employer, owner, operator or agent may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, will notify the employer, owner, operator or agent in writing of the decision which will become effective no sooner than 15 days after the date of such notice.
[Section 85a.5(b)(1) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(2) In those instances where the NIOSH authorized representative is a person fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act, the employer, owner, operator or agent in charge at the place of employment may, after advising the NIOSH contractor or consultant in writing, elect to withhold information deemed to be a trade secret from such a NIOSH authorized representative or prohibit entry into the area of the place of employment where such entry will reveal trade secrets. In those instances, where the subject information is needed or access to the area of the place of employment is necessary, in the judgment of NIOSH, to fulfill the goals of the investigation, NIOSH regular employees will then obtain the information or enter the subject area of the place of employment.

(c)(1) NIOSH authorized representatives will be in charge of site visits conducted pursuant to this part.

(2) Where there is a request by the representative of the State agency and/or employees, who were notified pursuant to 85a.4(a)(1) or 85a.4(a)(2) to accompany the NIOSH authorized representatives during the site visit of the place of employment, the NIOSH authorized representatives will allow this request if they determine that this will aid the investigation; or where in the judgment of the NIOSH authorized representatives, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough site visit, they may permit such third party to accompany them during the site visit; provided, however, that access by such person(s) to areas described in 85a.5(c)(4) shall be in accordance with the requirements of such provision and access to areas containing trade secrets shall be with the consent of the employer, owner, operator or agent in charge at the place of employment.

(3) NIOSH authorized representatives are authorized to deny the right of accompaniment under this paragraph to any person whose conduct in their judgment interferes with a fair and orderly site visit. In all instances, a representative of the employer shall be permitted to accompany the NIOSH authorized representatives during the site visit of the place of employment.

(4) With regard to information classified by an agency of the United States Government in the interest of national security, only persons authorized to have access to such information may accompany NIOSH authorized representatives in areas containing such information.

(d)(1) NIOSH authorized representatives are authorized: To collect environmental samples and samples of substances; to measure environmental conditions and employee exposures (including measurement of employee exposure by

the attachment of personal sampling devices to employees with their consent); to take or obtain photographs, motion pictures or videotapes related to the purpose of the investigation; to employ other reasonable investigative techniques, including medical examinations, anthropometric measurements and standardized and experimental functional tests of employees with the informed consent of such employees; to review, abstract, and duplicate such personnel records as are pertinent to mortality, morbidity, injury, safety, and other similar studies; and to question and interview privately any employer, owner, operator, agency, or employee from the place of employment. The employer, owner, operator, or agency shall have the opportunity to review photographs, motion pictures, and videotapes taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.
[Section 85a.5(d)(1) amended at 49 FR 4739, February 8, 1984, effective March 9, 1984]

(2) Prior to the conduct of medical examinations, anthropometric measurements or functional tests of any employees, the NIOSH authorized representatives will obtain approval of the procedures to be utilized from the NIOSH Human Subjects Review Board and no employee examination, measurement or test will be undertaken without the informed consent of such employee.

(e) NIOSH authorized representatives will comply with all safety and health rules and practices at the place of employment and all NIOSH, Occupational Safety and Health Administration, and Mine Safety and Health Administration regulations and policies during a site visit and will provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer, owner, operator or agent in charge at the place of employment.
[Section 85a.5(e) amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

(f) The conduct of site visits will be such as to preclude unreasonable disruption of the operations of the place of employment.

85a.6 Provisions of suitable space for employee interviews and examinations

An employer, owner, operator or agent in charge at the place of employment shall, on request of the NIOSH authorized representatives, provide suitable space at the place of employment, if such space is reasonably available, to NIOSH to conduct private interviews with, and medical examinations, anthropometric measurements and functional tests of employees. NIOSH authorized representatives will consult with the employer, owner, operator or agent as to the time and place of the private interviews, medical examination, anthropometric measurements and functional tests and will schedule same so as to avoid undue disruption of work at the place of employment. NIOSH will conduct the medical interviews, measurements, examinations, and tests specified under this part at its own expense.

85a.7 Imminent dangers

Whenever, during the course of, or as a result of, an investigation

under this part, the NIOSH authorized representatives believe there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer, owner, operator or agent in charge at the place of employment and those employees who appear to be in immediate danger of such allegation and will inform the agencies identified in 85a.4(a)(1), (a)(3), and (a)(4).
[Section 85a.7 amended at 45 FR 2651, January 14, 1980, effective February 13, 1980]

85a.8 Reporting of results of investigations of places of employment

(a)(1) Specific reports of investigations of each place of employment under this part, with identification of the place of employment, will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, with copies to the appropriate officials and Agencies notified pursuant to 85a.4(a). Prior to release of such reports, a preliminary report will be sent by NIOSH to the employer, owner, operator or agent for review for trade secret information and technical inaccuracies that may inadvertently be presented in the report. If requested in writing, the data used to compile the reports will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, except that data will not be released in a form that is individually identifiable.

(2) All specific reports of investigations of each place of employment under this part will be available to the public from the NIOSH Regional Consultant for Occupational Safety and Health in the appropriate NIOSH Regional Office.

(3) In certain instances, specific reports of investigations of each place of employment will not be prepared. In such instances, a closing conference at the place of employment will be conducted by the NIOSH authorized representatives and those individuals participating in the site visit to discuss the findings of the site visit and appropriate recommendations.

(b)(1) Any specific findings of individual employee medical examinations, anthropometric measurements and functional tests will be released by NIOSH authorized representatives to the company physician, private physician, or other person only pursuant to the written authorization of the employee; otherwise, the specific findings and other personal records concerning individuals will be maintained in accordance with 45 CFR, Part 5b and section 3 of the Privacy Act of 1974 (5 U.S.C. 552a). Notice of all NIOSH systems of records as defined in 45 CFR 5b.1(n) as a result of the investigations of places of employment pursuant to this part will be published in the FEDERAL REGISTER under Notices of Systems of Records for the Department of Health and Human Services.

(2) In cases where an employee shows positive significant medical findings, the employee and the physician(s) designated by the employee under 85a.8(b)(1) will be immediately notified by NIOSH.

(3) A summary of the findings of the examinations for each employee will be sent by NIOSH to the individual.

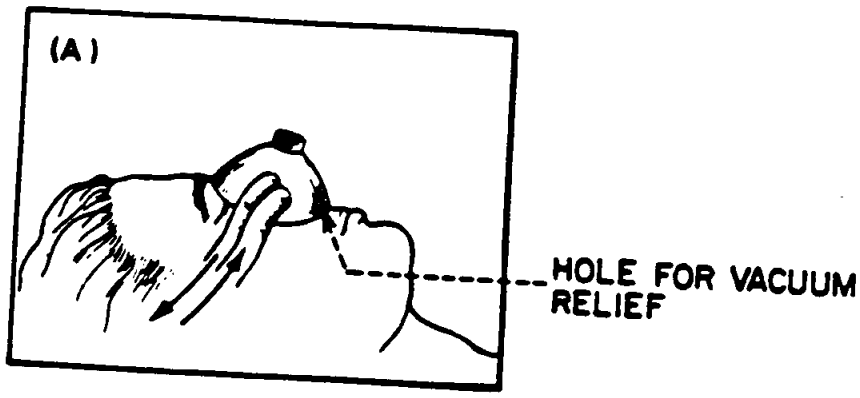
(c) The findings of a total investigation generally will be disseminated as part of NIOSH criteria documents, NIOSH technical

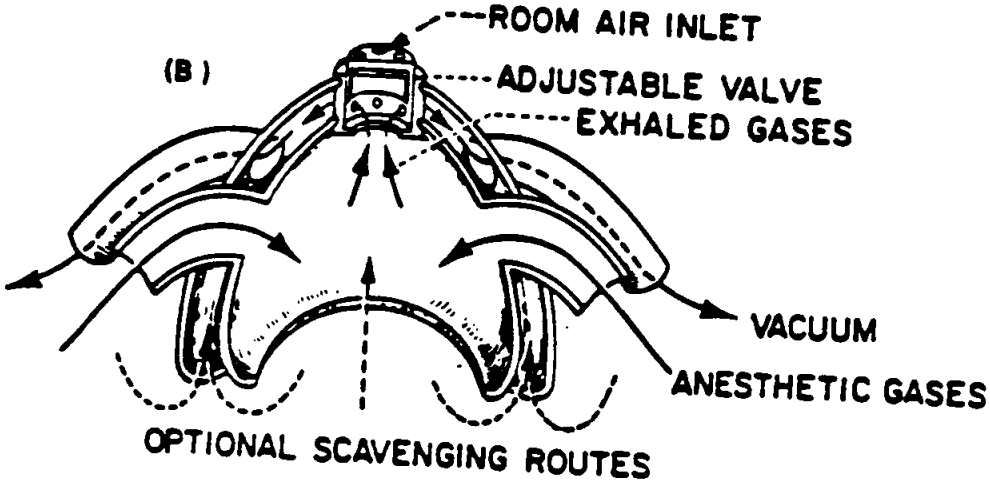
reports, NIOSH information packets, scientific journals, presentations at technical meetings, or in other similar manners. These findings of a total investigation will be presented in a manner which does not identify any specific place of employment; however, it should be noted that the specific reports of investigations of each place of employment under this part are subject to mandatory disclosure, upon request, under the provisions of the Freedom of Information Act (5 U.S.C. 552).

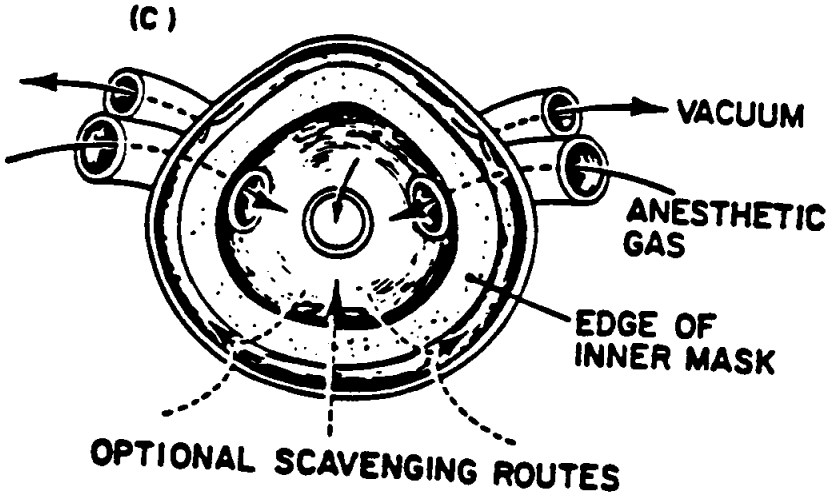
[Title 42, Part 85a added 41 FR 45003, October 14, 1976]

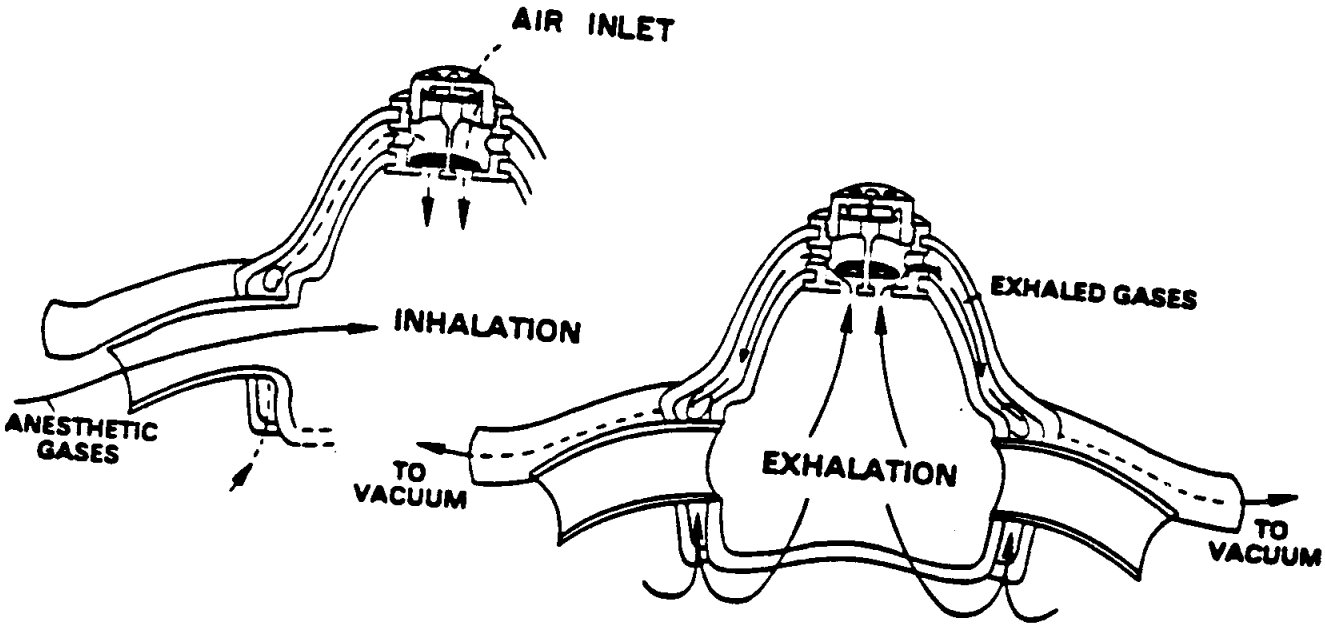
APPENDIX C

Schematics of Nitrous Oxide Scavenging Masks


(A)
HOLE FOR VACUUM RELIEF


(B)
ROOM AIR INLET
ADJUSTABLE VALVE
EXHALED GASES
VACUUM
ANESTHETIC GASES
OPTIONAL SCAVENGING ROUTES


(C)
VACUUM
ANESTHETIC GAS
EDGE OF INNER MASK
OPTIONAL SCAVENGING ROUTES


AIR INLET
INHALATION
ANESTHETIC GASES
TO VACUUM
EXHALED GASES
EXHALATION
TO VACUUM