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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Centers for Disease Control
National Institute for
Occupational Safety & Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati OH 45226-1998

April 15, 1994

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Mr. Mark A. Greenwood
Director
Office of Pollution Prevention
and Toxics
Environmental Protection Agency (TS-792)
401 M Street, S.W.
Washington, D.C. 20460

FYI-0594-0915

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Dear Mr. Greenwood:

Enclosed is a prepublication copy of the National Institute for Occupational Safety and Health (NIOSH) Alert entitled, *"Request for Assistance in Controlling Exposures to Nitrous Oxide During Anesthetic Administration"* (NIOSH publication number 94-100, 1994) which is also being sent to OSHA and MSHA.

Nitrous oxide (N_2O) is used as an anesthetic agent in medical, dental, and veterinary operatories. Animal studies have shown adverse reproductive effects in female rats exposed to airborne concentrations of N_2O and can produce adverse health effects in the offspring. Several studies of workers have shown that occupational exposure to N_2O causes adverse effects such as reduced fertility, spontaneous abortions, and neurologic, renal, and liver disease.

The Occupational Safety and Health Administration (OSHA) does not currently have a standard for N_2O. The NIOSH recommended exposure limit (REL) for N_2O is 25 ppm as a time-weighted average during the period of anesthetic administration. This REL is intended to prevent decreases in mental performance, audiovisual ability, and manual dexterity during exposures to N_2O. An REL to prevent adverse reproductive effects cannot be established until more data are available.

This Alert presents control measures for preventing or greatly reducing exposure to N_2O during the administration of anesthetic gas. These control measures should be part of a comprehensive written safety and health plan for workers.

Please contact me at (513) 533-8302 if you need additional information.

Sincerely yours,

Contains No CBI

Richard W. Niemeier, Ph.D.
Director
Division of Standards Development
and Technology Transfer

Enclosure

10/21/94

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PREPUBLICATION COPY

NIOSH

ALERT

APRIL 1994

REQUEST FOR ASSISTANCE IN

Controlling Exposures to Nitrous Oxide During Anesthetic Administration

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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DHHS (NIOSH) Publication No. 94–100

NIOSH ALERT

Request for Assistance in

Controlling Exposures to Nitrous Oxide During Anesthetic Administration

WARNING!

Workers exposed to nitrous oxide (N_2O) may suffer harmful effects.

The National Institute for Occupational Safety and Health (NIOSH) requests assistance in controlling exposures of workers to nitrous oxide (N_2O) during the administration of anesthetic gas in medical, dental, and veterinary operatories. NIOSH concluded in 1977 that exposure to N_2O causes decreases in mental performance, audiovisual ability, and manual dexterity [NIOSH 1977b]. A recent study of workers [Rowland et al. 1992] and several experimental animal studies [Corbett et al. 1973; Vieira 1979; Vieira et al. 1980, 1983] indicate that adverse reproductive effects may also result from chronic exposure to N_2O.

This Alert presents control measures for preventing or greatly reducing exposure to N_2O during the administration of anesthetic gas. These control measures should be part of a comprehensive written safety and health plan for workers. NIOSH requests that safety and health officials, editors of appropriate journals, manufacturers of anesthetic equipment, union representatives, employers, and managers bring the recommendations in this Alert to the attention of all workers who are at risk.

BACKGROUND

N_2O is used as an anesthetic agent* in medical, dental, and veterinary operatories. This gas is also used as a foaming agent for whipped cream, an oxidant for organic compounds, a nitrating agent for alkali metals, and a component of certain rocket fuels [Beard 1982; Suruda and McGlothlin 1990].

In 1977, NIOSH published a technical report entitled *Control of Occupational Exposure to*

*In dental operatories, agents that cause conscious sedation (such as N_2O) are commonly referred to as "analgesic agents."

N_2O in the Dental Operatory. This report presented methods for limiting the concentration of waste N_2O to 50 parts per million (ppm) during administration—a limit based on the technical feasibility of existing controls [NIOSH 1977a]. Since publication of this technical report, data collected by NIOSH have shown occupational exposures as high as 300 ppm in hospital operating rooms [NIOSH 1985] and exposures higher than 1,000 ppm in dental operatories equipped with scavenging systems[†] (properly operating scavenging systems have been shown to reduce N_2O concentrations by more than 70%) [McGlothlin et al. 1988, 1990].

To determine why occupational exposures to N_2O are excessive even when scavenging systems are used, NIOSH has studied work practices[‡] and engineering controls[§] for dental operatories. This work environment was chosen because N_2O is frequently used as the sole anesthetic agent in dental operatories and exposures there tend to be more difficult to control than in general operating theaters. Control is more difficult in dental operatories because only the patient's nose is covered during anesthetic administration and scavenging, but both the nose and mouth can be covered in general operating theaters.

HEALTH EFFECTS

Animal studies have shown adverse reproductive effects in female rats exposed to airborne concentrations of N_2O [Corbett et al.1973; Vieira 1979; Vieira et al. 1980, 1983]. Data from these studies indicate that exposure to N_2O during gestation can produce adverse health effects in the offspring.

Several studies of workers have shown that occupational exposure to N_2O causes adverse effects such as reduced fertility [Rowland et al. 1992], spontaneous abortions, and neurologic, renal, and liver disease [Cohen et al. 1980]. A recent study [Rowland et al. 1992] reported that female dental assistants exposed to unscavenged N_2O for 5 or more hours per week had a significant risk of reduced fertility compared with unexposed female dental assistants. The exposed assistants had a 59% decrease in probability of conception for any given menstrual cycle compared with the unexposed assistants. For dental assistants who used scavenging systems during N_2O administration, the probability of conception was not significantly different from that of the unexposed assistants. Since environmental exposures were not measured during these epidemiologic studies, no dose-effect relationship could be established.

WORKERS EXPOSED

More than 424,000 workers (i.e., dentists, dental assistants, and dental hygienists) practice dentistry in the United States [BLS 1990]. In 1983, the American Dental Association (ADA) reported that 35% of all dentists used N_2O to control pain and anxiety in their patients [ADA 1983]. The ADA *1991 Survey of Dental Practice* indicated that 58% of dentists reported having N_2O anesthetic equipment, and 64% of those practitioners also reported having a scavenging system [ADA 1992]. The percentage of pediatric dentists using N_2O increased from 65% in 1980 to 88% in 1988 [Davis 1988].

[†]Scavenging systems use local exhaust ventilation to collect waste gases from anesthetic breathing systems and remove them from the workplace.

[‡]Work practices are procedures followed by employers and workers to control hazards.

[§]Engineering controls are hazard controls designed into equipment and workplaces.

OCCUPATIONAL EXPOSURE LIMITS

The Occupational Safety and Health Administration (OSHA) does not currently have a standard for N_2O.

The NIOSH recommended exposure limit (REL) for N_2O is 25 ppm as a time-weighted average (TWA) during the period of anesthetic administration [NIOSH 1977b]. This REL is intended to prevent decreases in mental performance, audiovisual ability, and manual dexterity during exposures to N_2O. An REL to prevent adverse reproductive effects cannot be established until more data are available.

The American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV®) for N_2O is 50 ppm as an 8-hour TWA [ACGIH 1993]. The *1991 Documentation of the Threshold Limit Values and Biological Exposure Indices* states that "control to this level should prevent embryofetal toxicity in humans and significant decrements in human psychomotor and cognitive functions or other adverse health effects in exposed personnel" [ACGIH 1991].

CONCLUSIONS

A large population of health care workers is potentially exposed to N_2O, and NIOSH has documented cases in which exposures substantially exceed existing RELs. NIOSH has concluded that exposure to N_2O causes decreases in mental performance, audiovisual ability, and manual dexterity. Data from animal studies demonstrate that exposure to N_2O may cause adverse reproductive effects. Studies of workers exposed to N_2O have reported adverse health effects such as reduced fertility, spontaneous abortion, and neurological, renal, and liver disease. The recommendations in this Alert should therefore be followed to minimize worker exposures.

RECOMMENDATIONS

Engineering controls, work practices, and respirators (when necessary) should be used to minimize the exposure of workers to N_2O. Employers should ensure that their workers are adequately protected from N_2O exposure by taking the following steps:

- Monitor airborne concentrations of N_2O.
- Implement appropriate engineering controls, work practices, and maintenance procedures.
- Institute a worker education program that
  - — describes standard operating procedures for all tasks that may expose workers to N_2O, and
  - — informs workers about proper work practices, controls, equipment, and protective gear that should be used when working with N_2O.
- Use the guidelines in the following section to minimize worker exposures to N_2O.

GUIDELINES FOR MINIMIZING WORKER EXPOSURES

Exposure Monitoring

Exposure monitoring should be the first step in developing work practices and worker

education programs, since measurements of N_2O are needed to determine the type and extent of controls that are necessary. Follow the guidelines below to minimize worker exposures:

- Monitor for N_2O when the anesthetic equipment is installed and every 3 months thereafter.

- Include the following types of monitoring:

  — Leak testing of equipment

  — Monitoring of air in the worker's personal breathing zone

  — Environmental (room air) monitoring

- Prepare a written monitoring and maintenance plan for each facility that uses N_2O. This plan should be developed by knowledgeable persons who consider the equipment manufacturers' recommendations, frequency of use, and other circumstances that might affect the equipment.

- Perform air monitoring by gas-bag sampling [NIOSH 1984] or real-time sampling [McGlothlin et al. 1989].

  When real-time sampling is conducted to obtain personal exposure data, attach the sampling train to the lapel of the worker on the side closest to the patient; N_2O concentrations in this location are most representative of those in the worker's breathing zone. Diffusive samplers (referred to as passive dosimeters) are commercially available and may be useful as initial indicators of exposure [Bishop and Hossain 1984].

Engineering Controls and Maintenance Procedures

The following engineering controls and maintenance procedures have been shown to be feasible and effective in reducing exposure to N_2O during anesthetic administration.

Anesthetic delivery. Excessive exposure to N_2O may occur as a result of leaks from the anesthetic delivery system during administration [McGlothlin et al. 1989]. The rubber and plastic components of the anesthetic equipment are potential sources of N_2O leakage because they may be degraded by the N_2O and the oxygen as well as by repeated sterilization.

Figure 1 illustrates sources of possible leaks from anesthetic delivery systems in dental operatories. These sources include leaks from the high-pressure connections—that is, from the gas delivery tanks, the wall connectors, the hoses connected to the anesthetic machine, and the anesthetic machine (especially the on-demand valve). Low-pressure leaks occur from the connections between the anesthetic flowmeter and the scavenging mask. This leakage is due to loose-fitting connections, loosely assembled or deformed slip joints and threaded connections, and defective or worn seals, gaskets, breathing bags, and hoses.

Take the following steps to control N_2O exposure from anesthetic delivery systems:

- Use connection ports with different-diameter hoses for N_2O and O_2 to reduce the possibility of incorrectly connecting the gas delivery and scavenging hoses [Dorsch and Dorsch 1984].

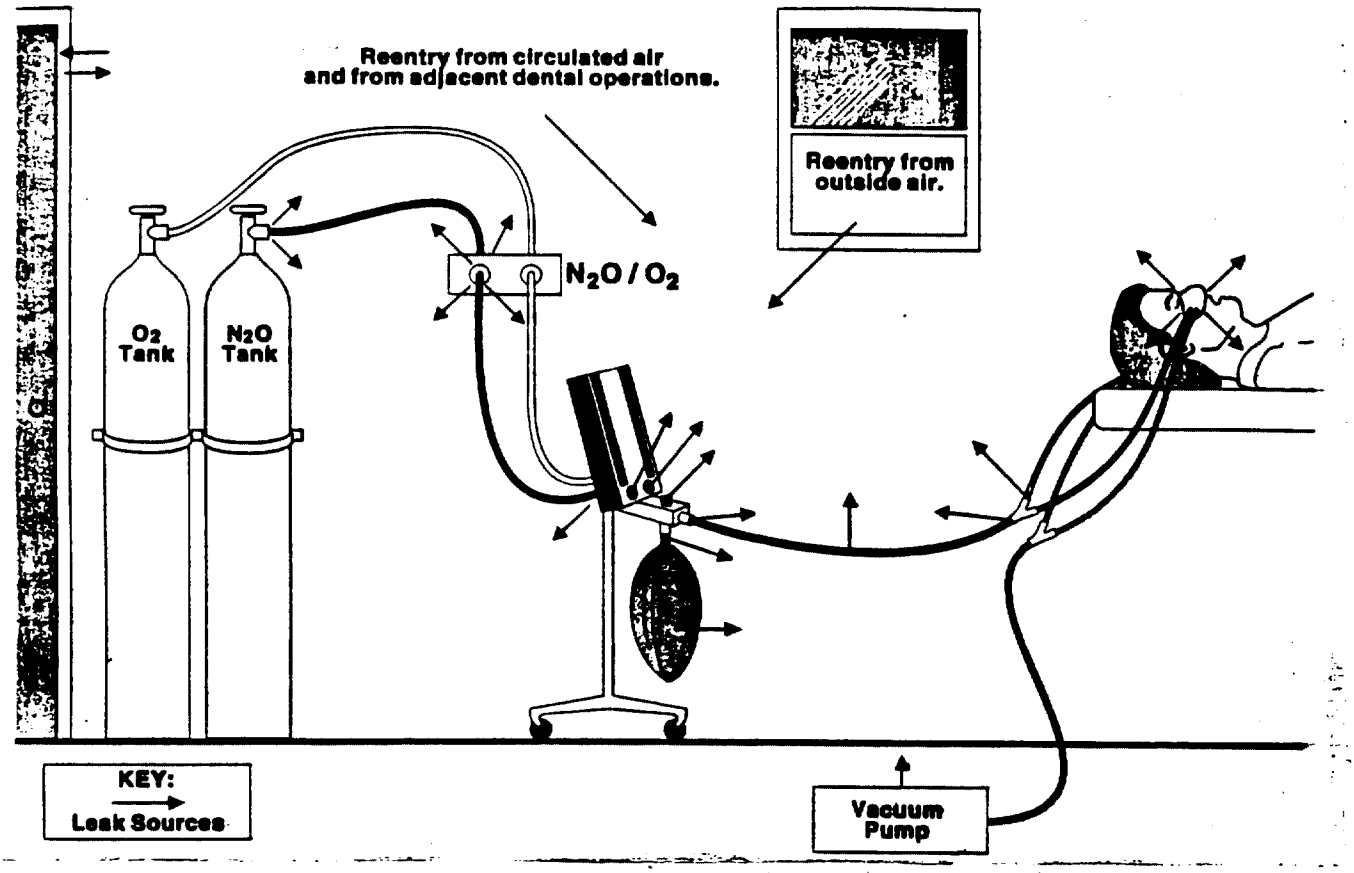


Figure 1. Sources of leaks from anesthetic delivery systems in dental operatories.

- Check all rubber hoses, connections, tubing, and breathing bags daily and replace them when damaged or when recommended by the manufacturer.

- Following visual inspection, perform leak testing of the equipment and connections by using a soap solution to check for bubbles at high-pressure connections. For a more thorough inspection of all connectors, use a portable infrared spectrophotometer (such as a Miran® 1A or 1B) calibrated for N_2O detection [NIOSH 1984].

- Check both high- and low-pressure connections (such as O-rings) regularly, as they may become worn; replace them periodically, according to the manufacturer's recommendations.

- Evaluate the N_2O and oxygen mixing system for leaks when it is first installed and periodically thereafter, according to the manufacturer's recommendations.

- Ensure that gas cylinders are safely handled, used, and stored as specified by the National Research Council [NRC 1981] and as required by OSHA [29 CFR** 1910.101].

Scavenging systems. Control of N_2O at the scavenging mask is the next priority

**Code of Federal Regulations.* See CFR in references.

after control of N_2O leakage from the anesthetic equipment. Leakage from the scavenging mask can be one of the most significant sources of N_2O exposure because the breathing zone of a dentist or dental assistant is within inches of the mask [McGlothlin et al. 1989]. NIOSH research has reported breathing-zone concentrations of N_2O above 1,000 ppm [McGlothlin et al. 1988].

Take the following steps to control N_2O exposure from anesthetic scavenging systems:

- Supply scavenging masks in a variety of sizes so that the mask always fits comfortably and securely over the patient's nose or face.

- Use an automatic interlock system to assure that the N_2O cannot be turned on unless the scavenging system is also activated. N_2O should never be used without a properly operating scavenging system.

- Make sure that the scavenging system exhaust rates (flow rates) are approximately 45 liters per minute (L/min) to minimize leakage of N_2O. Flow rates of less than 40 L/min may result in significant leakage around the mask [NIOSH 1977a]. Monitor the flow rate with a flowmeter that is

  — validated to measure air flow within 5% of actual air flow,

  — permanently connected to the scavenging system vacuum line, and

  — positioned so that it is always visible to the operator.

  Maintain the flowmeter by cleaning and recalibrating it according to the manufacturer's recommendations.

- Use scavenging vacuum pumps that are powerful enough to maintain a scavenging flow rate of at least 45 L/min at each nasal mask regardless of the number of scavenging units in use at one time.

- Vent N_2O from all scavenging vacuum pumps to the outside of the building away from fresh air intakes, windows, or walkways. Scavenging system exhaust should not be vented into a recirculating ventilation system.

Room Ventilation. Take the following steps to assure that the ventilation system effectively removes waste N_2O:

- If concentrations of N_2O are above 25 ppm in work areas, increase the air flow into the room or increase the percentage of outside air to allow for more air mixing and further dilution of the anesthetic gas. Maintain a balanced air supply and exhaust system so that N_2O does not contaminate adjacent areas.

- If concentrations of N_2O are still above 25 ppm, use supplementary local ventilation[††] in conjunction with a scavenging system to reduce N_2O exposure in the operatory [Mickelsen et al. 1993]. The effectiveness of this ventilation depends on its location with respect to the patient and the airflow rates. Do not work between the patient and the exhaust duct, where contaminated air would be drawn through the worker's breathing zone.

[††] Local ventilation is the use of a hood or duct to capture N_2O at the source.

- Dilute N_2O and remove contaminated air from the work area by placing fresh-air vents in the ceiling; direct the supply of fresh air toward the floor and the operating area. Place exhaust-air vents at or near the floor.

Work Practices

Use the following work practices to control N_2O exposures:

- Inspect the anesthestic delivery systems and all connections before starting anesthetic gas administration. Make sure that breathing bags, hoses, and clamps are in place before turning on the anesthetic machine.

- Connect the scavenging mask properly to the gas delivery hose and the vacuum system.

- Do not turn on the machine delivering N_2O until

  — the vacuum system scavenging unit is operating at the recommended flow rate of 45 L/min, and

  — the scavenging mask is secured over the patient's nose or face.

- Fasten the mask according to the manufacturer's instructions to prevent leaks around the mask during gas delivery.

- Do not fill the breathing bag to capacity with N_2O; an overinflated bag can cause excessive leakage from the scavenging mask. The breathing bag should collapse and expand as the patient breaths. This bag activity shows that the proper amounts of N_2O and air are being delivered to the patient.

- Flush the system of N_2O after surgery by administering oxygen to the patient through the anesthetic equipment for at least 5 minutes before disconnecting the gas delivery system.

- Encourage patients to minimize talking and mouth-breathing during dental surgery. When mouth-breathing is apparent, avoid the patient's breathing zone to the extent possible.

Respiratory Protection

Workers should wear respiratory protection when N_2O concentrations are not consistently below 25 ppm; however, practical considerations may prevent them from wearing such protection. Therefore, it is ***essential*** that employers use the engineering controls and work practices described in this Alert to reduce N_2O concentrations below 25 ppm.

When N_2O concentrations are not consistently below 25 ppm, workers should take the following steps to protect themselves:

- Wear air-supplied respirators. Air-purifying respirators (that is, respirators that remove N_2O from the air rather than supply air from a clean source) should not be used because respirator filters do not efficiently remove N_2O.

  As specified by the *NIOSH Respirator Decision Logic* [NIOSH 1987b], the minimum level of protection for an air-supplied respirator is provided by a half-mask respirator operated in the demand or

continuous-flow mode.[#] More protective air-supplied respirators are described in the *NIOSH Respirator Decision Logic*.

- When respirators are used, the employer must establish a comprehensive respiratory protection program as outlined in the *NIOSH Guide to Industrial Respiratory Protection* [NIOSH 1987a] and as required by the OSHA respiratory protection standard [29 CFR 1910.134]. Important elements of this standard are

  — an evaluation of the worker's ability to perform the work while wearing a respirator,

  — regular training of personnel,

  — periodic environmental monitoring,

  — respirator fit testing,

  — maintenance, inspection, cleaning, and storage, and

  — selection of proper NIOSH-approved respirators.

The respiratory protection program should be evaluated regularly by the employer.

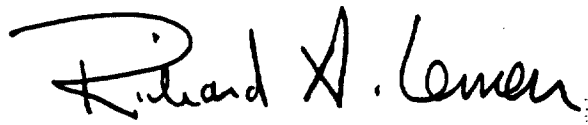
ACKNOWLEDGMENTS

Barbara L. Dames and James D. McGlothlin, Ph.D., were the principal contributors to this Alert. Comments, questions, or requests for additional information should be directed to the following:

Dr. Laurence J. Doemeny
Acting Director, Division of Physical Sciences and Engineering
NIOSH
4676 Columbia Parkway
Cincinnati, OH 45226

Telephone: (513) 841–4321

We greatly appreciate your assistance in protecting the health of U.S. workers.



Richard A. Lemen, Ph.D.
Acting Director, National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

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[#]Note: The assigned protection factor (APF) for this class of respirator is 10. The APF indicates the level of protection provided by a class of respirator [NIOSH 1987b]. An APF of 10 means that the respirator should reduce the air concentration of N_2O for the wearer by a factor of 10 (or to 10% of the concentration without respiratory protection).

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NIOSH *ALERT*

Controlling Exposures to Nitrous Oxide During Anesthetic Administration

WARNING!

Workers exposed to nitrous oxide (N_2O) may suffer harmful effects.

Take the following steps to protect yourself from waste N_2O in the workplace:

1. **Be aware that N_2O may cause the following health effects:**
   - Decreases in mental performance, audiovisual ability, and manual dexterity
   - Adverse reproductive effects
2. **Make sure that the following monitoring procedures are performed when the anesthetic equipment is installed and every 3 months thereafter:**
   - Leak testing of equipment
   - Monitoring of air in the worker's personal breathing zone
   - Environmental (room air) monitoring
3. **Prevent leakage from the anesthetic delivery system through proper maintenance and inspection of equipment. Eliminate or replace the following:**
   - Loose-fitting connections
   - Loosely assembled or deformed slip joints and threaded connections
   - Defective or worn seals, gaskets, breathing bags, and hoses
4. **Control waste N_2O with a well-designed scavenging system that includes the following:**
   - Securely fitting masks
   - Sufficient flow rates for the exhaust system
   - Properly vented vacuum pumps
5. **Make sure that the room ventilation is effectively removing waste N_2O. If concentrations of N_2O are above 25 ppm, take the following steps:**
   - Increase the airflow into the room.
   - Use supplemental local ventilation to capture N_2O at the source.

For additional information, see *NIOSH Alert: Request for Assistance in Controlling Exposures to Nitrous Oxide During Anesthetic Administration* [DHHS (NIOSH) 94-100], or call 1-800-35-NIOSH. Single copies of the Alert are available free from the following:

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