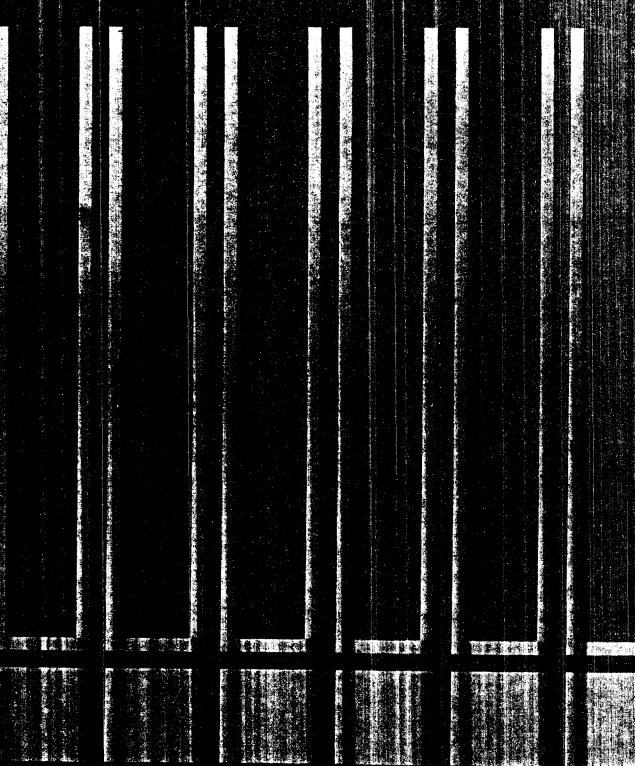
criteria for a recommende occupational exposure to

waste anesthetic gases and vapors



S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ublic Health Service Center for Disease Control ational Institute for Occupational Safety and Health

criteria for a recommended standard....

OCCUPATIONAL EXPOSURE TO WASTE ANESTHETIC GASES AND VAPORS



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE Public Health Service Center for Disease Control National Institute for Occupational Safety and Health March 1977

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 **DHEW (NIOSH) Publication No. 77-140**

PREFACE

The Occupational Safety and Health Act of 1970 emphasizes the need for standards to protect the health and safety of workers exposed to an ever-increasing number of potential hazards at their workplace. The National Institute for Occupational Safety and Health has projected a formal system of research, with priorities determined on the basis of specified indices, to provide relevant data from which valid criteria for effective standards can be derived. Recommended standards for occupational exposure, which are the result of this work, are based on the health effects of exposure. The Secretary of Labor will weigh these recommendations along with other considerations such as feasibility and means of implementation in developing regulatory standards.

It is intended to present successive reports as research and epidemiologic studies are completed and as sampling and analytical methods are developed. Criteria and standards will be reviewed periodically to ensure continuing protection of the worker.

The population being addressed by this waste anesthetic gases criteria document differs from those addressed by previous documents. The majority of workers involved with and exposed to waste anesthetic gases are members of the health care delivery profession. Certain provisions usually included as part of a recommended standard, such as personal protective equipment and clothing, do not appear in this document. This is due to the critical nature of the work involved and to the different circumstances of potential exposure compared to what may be considered the usual type of industrial exposure. The recommendations presented herein should in no way

iii

preclude proper patient care and safety, particularly if patient needs arise that require deviation from the recommended standard.

I am pleased to acknowledge the contributions to this report on waste anesthetic gases and vapors by members of NIOSH staff and the valuable, constructive comments by the Review Consultants on Waste Anesthetic Gases and Vapors, by the ad hoc committees of the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, the American Dental Association, the American Hospital Association, the Society of Oral Surgeons, the American Veterinary Medical American Association, the Association of Operating Room Nurses, and the Association of Operating Room Technicians, and by Robert B. O'Connor, M.D., NIOSH The NIOSH recommendations consultant in occupational medicine. for standards are not necessarily a consensus of all the consultants and professional societies that reviewed this criteria document on waste anesthetic gases. Lists of the NIOSH Review Committee members and of the Review Consultants appear on the following pages.

Jun P. Henkler, H.D.

John F. Finklea, M.D. Director, National Institute for Occupational Safety and Health

iv

The Division of Criteria Documentation and Standards Development, National Institute for Occupational Safety and Health, had primary responsibility for development of the criteria and recommended standard for waste anesthetic gases and vapors. The division review staff for this document consisted of Howard L. McMartin, M.D., Vernon E. Rose, and Douglas L. Smith, Ph.D., with Loren L. Hatch, D.O., Ph.D., Division of Technical Services, John M. Dement, Division of Surveillance, Hazard Evaluations and Field Studies, John C. Krantz, Ph.D., and Gertrude D. Maengwyn-Davies, Ph.D.

The basic information for consideration by NIOSH staff and consultants was developed by Philip J. Bierbaum and John Μ. Dement, Division of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health. Charles L. Geraci, Jr., Ph.D., had NIOSH program responsibility and served as criteria manager.

v

REVIEW COMMITTEE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Victor E. Archer, M.D. Division of Surveillance, Hazard Evaluations, and Field Studies

John M. Dement Division of Surveillance, Hazard Evaluations, and Field Studies

Loren L. Hatch, D.O., Ph.D. Division of Technical Services

Barry L. Johnson, Ph.D. Division of Biomedical and Behavioral Sciences

Trent R. Lewis, Ph.D. Division of Biomedical and Behavioral Sciences

Charles S. McCammon Division of Physical Sciences and Engineering

REVIEW CONSULTANTS ON WASTE ANESTHETIC GASES AND VAPORS

David L. Bruce, M.D. Department of Anesthesia Northwestern Medical School Chicago, Illinois 60611

Ellis N. Cohen, M.D. Department of Anesthesia Stanford University School of Medicine Stanford, California 94305

Jess Hayden, D.M.D., Ph.D. Department of Pedodontics College of Dentistry University of Iowa Iowa City, Iowa 52242

Vilma R. Hunt, D.D.S. College of Human Development Pennsylvania State University University Park, Pennsylvania 16802

Arthur Neilson Industrial Hygienist Stewart-Todd Associates, Inc. Wayne, Pennsylvania 19087

Miss Jerry G. Peers Executive Director Association of Operating Room Nurses Denver, Colorado 80231

Lloyd B. Tepper, M.D. Corporate Medical Director Air Products and Chemicals, Inc. Allentown, Pennsylvania 18105

CRITERIA DOCUMENT: RECOMMENDATIONS FOR AN OCCUPATIONAL EXPOSURE STANDARD FOR WASTE ANESTHETIC GASES AND VAPORS

Contents

PREFAC	CE	111
NIOSH	REVIEW COMMITTEE	vi
REVIEW	V CONSULTANTS	vii
Ι.	RECOMMENDATIONS FOR A WASTE ANESTHETIC GASES AND VAPORS STANDARD	
	Section 1 - Definitions Section 2 - Environmental (Workplace Air) Section 3 - Control Procedures and Work Practices Section 4 - Medical Section 5 - Labeling and Posting	2 2 3 7 8
	Section 6 - Fire, Explosion, and Sanitation Practices Section 7 - Informing Employees of Hazards from Waste Anesthetic Gases Section 8 - Monitoring Requirements Section 9 - Recordkeeping Requirements	8 9 9 11
11.	INTRODUCTION	12
III.	BIOLOGIC EFFECTS OF EXPOSURE	
	Extent of Exposure Historical Reports Effects on Humans Epidemiologic Studies Animal Toxicity Correlation of Exposure and Effect Summary Tables of Exposure and Effect	15 17 19 29 43 65 76
IV.	ENVIRONMENTAL DATA AND BIOLOGIC EVALUATION OF EXPOSURE	
	Inhalation Anesthesia Techniques and Sources of Waste Anesthetic Gases Environmental Concentrations and Sampling and Analysis Methods Summary of Presently Used Anesthetics and	77 79
	Inhalation Anesthetic Techniques Biologic Evaluation of Exposure	97 98

Contents

V. DEVELOPMENT OF STANDARD

	Basis for Previous Standards Basis for the Recommended Standard Basis for Control Procedures and Work Practices Basis for Environmental Monitoring Basis for Medical Monitoring	102 105 111 113 115
VI.	ENGINEERING CONTROLS AND WORK PRACTICES	116
VII.	RESEARCH NEEDS	125
VIII.	REFERENCES	127
IX.	APPENDIX I - Leak Test Procedures for Anesthetic Equipment	142
X.	APPENDIX II - Sampling Procedures for Collection of Anesthetic Gases	146
XI.	APPENDIX III - Analytical Procedure for Determination of Halothane by Gas Chromatography	151
XII.	APPENDIX IV - Analytical Procedure for Determination of Anesthetic Gases by Infrared Spectrophotometry	160
XIII.	TABLES AND FIGURES	166

I. RECOMMENDATIONS FOR A STANDARD ON WASTE ANESTHETIC GASES AND VAPORS

The National Institute for Occupational Safety and Health (NIOSH) recommends that occupational exposure to waste gases from anesthetic procedures be controlled by adherence to the following sections. The standard applies to all workers, including students and volunteers, regardless of status, who are exposed to inhalation anesthetic agents that escape into locations associated with the administration of, or recovery from, anesthesia. It is designed to protect the health and safety of workers during their working lifetime in locations where exposures to waste anesthetic gases and vapors occur. Compliance with all sections of the standard should minimize potential adverse effects of waste anesthetic gases on the health and safety of workers and their unborn children.

The recommended permissible levels of exposure contained in the following sections, however, cannot be defined as safe levels since information on adverse health effects is not completely definitive and many unknown factors still exist. Therefore, the environmental limits presented should be regarded as the upper boundry of exposure, and every effort should be made to maintain exposures as low as is technically feasible.

The standard is measurable by techniques that are valid and available to industry and government agencies. Sufficient technology exists to permit compliance with the recommended standard in situations where a mixture of agents is used for anesthesia. A special area of concern is the use of nitrous oxide as the sole anesthetic agent, such as in dental procedures, and the health-based recommended exposure level may not be completely achievable at this time. The standard will be subject to review and revised as necessary.

Section 1 - Definitions

(a) Waste inhalation anesthetic gases and vapors are those which are released into work areas (operating room, recovery room, delivery room, or other areas where workers may be subject to job-related exposure) associated with, and adjacent to, the administration of a gas for anesthetic purposes, and include both gaseous and volatile liquid agents. Waste gases and vapors are herein referred to as waste anesthetic gases.

(b) Occupational exposure to waste anesthetic gases includes exposure to any inhalation anesthetic agents that escape into locations associated with, and adjacent to, anesthetic procedures. Such locations shall include, but shall not be limited to, operating rooms, delivery rooms, labor rooms, recovery rooms, and dental operatories.

(c) Scavenging is defined as the collection of waste anesthetic gases from anesthetic breathing systems and subsequent removal of the gases from the workplace.

Section 2 - Environmental (Workplace Air)

(a) Concentration

Work practices and engineering controls shall be implemented so that occupational exposures to waste anesthetic gases are controlled in accordance with the following sections. Such practices and control procedures shall be kept current and updated as necessary to control occupational exposures to waste anesthetic gases to the lowest feasible levels.

(1) Occupational exposure to halogenated anesthetic agents shall be controlled so that no worker is exposed at concentrations greater

than 2 ppm of any halogenated anesthetic agent, based on the weight of the agent collected from a 45-liter air sample by charcoal adsorption over a sampling period not to exceed 1 hour. Agents that shall be controlled, with their respective weights corresponding to 2 ppm, are as follows: chloroform, 9.76 mg/cu m; trichloroethylene, 10.75 mg/cu m; halothane, 16.15 mg/cu m; methoxyflurane, 13.5 mg/cu m; enflurane, 15.1 mg/cu m; fluroxene, 10.31 mg/cu m. When such agents are used in combination with nitrous oxide, levels of the halogenated agent well below 2 ppm are achievable. In most situations, control of nitrous oxide to a timeweighted average (TWA) concentration of 25 ppm during the anesthetic administration period will result in levels of approximately 0.5 ppm of the halogenated agent.

(2) Occupational exposure to nitrous oxide, when used as the sole anesthetic agent, shall be controlled so that no worker is exposed at TWA concentrations greater than 25 ppm during anesthetic administration. Available data indicate that with current control technology, exposure levels of 50 ppm and less for nitrous oxide are attainable in dental offices.

(b) Sampling and Analysis

Procedures for sampling and analysis of air in exposure areas shall be as provided in Appendices II-IV, or by any methods equivalent in sensitivity, accuracy, and precision.

Section 3 - Control Procedures and Work Practices

(a) Control Procedures

As soon as practicable after promulgation of a standard for occupational exposure to waste anesthetic gases, anesthetic delivery systems shall be equipped for scavenging as described below, or by other methods equivalent in effectiveness.

(1) Collection of Waste Anesthetic Gases

Anesthetic gas machines, nonrebreathing systems, and T-tube devices shall be fitted with an effective scavenging device that collects all waste anesthetic gases. Nose masks shall be of the double-suction design, or an equally effective alternative.

(2) Disposal of Waste Anesthetic Gases

Waste anesthetic gases, collected from anesthetic delivery systems, shall be conveyed to disposal sites in such a manner that occupational reexposure does not occur. Disposal methods shall be in compliance with existing local or federal environmental pollution control regulations.

(3) Pressure Balance

A pressure balance between the waste gas-collecting device on anesthetic delivery systems and disposal systems shall be assured so that the gas-collection system does not interfere with proper operation of the anesthetic delivery system.

(b) Work Practices

Work practices shall be utilized to obtain and maintain minimum waste anesthetic gas concentrations and shall include, but shall not be limited to, the following sections.

(1) Prior to the beginning of administration of an anesthetic agent, waste gas disposal systems shall be connected and proper operation determined.

(2) If a face mask is to be used for administration of anesthetics, it shall provide as effective a seal as possible against leakage into the ambient air.

(3) Vaporizers shall be filled in a ventilated area and in a manner to minimize spillage of the liquid agent. When feasible, vaporizers should be filled when the location where the anesthetic will be administered is not in use. The vaporizers shall be turned off when not in use.

(4) Low pressure leak tests, specified in Appendix I, shall be conducted daily for the complete anesthetic machine. All leaks shall be corrected to the extent specified in Appendix I before use of the anesthetic delivery system.

(5) Starting anesthetic gas flow before induction of anesthesia shall be prohibited.

(6) When the breathing circuit is disconnected from the patient after administration of the anesthetic agent has started, anesthetic flowmeters shall be turned off or the Y-piece sealed.

(7) The breathing bag shall be emptied into the scavenging system before it is disconnected from the anesthetic delivery system.

(c) Ventilation

(1) Recovery rooms, labor and delivery rooms, anesthetic gas storage areas, and other related areas in which scavenging techniques are not used shall be provided with air exchange rates in compliance with those specified by the US Department of Health, Education, and Welfare in <u>Minimum Requirements of Construction and Equipment for Hospital and Medical</u> Facilities (HEW Publication No. 74-4000, Rockville, Maryland, 1974).

(2) Recirculating air-conditioning systems may be used if the environmental limits prescribed in Section 2 are not exceeded and the systems comply with ventilation requirements in Section 3(c)(1).

5

· 1

(3) Ventilation systems shall be subject to regular preventive maintenance and cleaning to ensure maximum effectiveness, which shall be verified at least quarterly by airflow measurements.

(d) Anesthetic Equipment Maintenance

(1) Leak tests, as described in Appendix I, shall be made on both high- and low-pressure components so that waste anesthetic gas levels are maintained at a minimum.

(2) Within 180 days after promulgation of a standard for occupational exposure to waste anesthetic gases and at least quarterly thereafter, equipment for administering anesthetic agents shall be tested in accordance with Appendix I to ensure that the low-pressure leak rate is less than 100 ml/minute at 30 cm water pressure, or an equivalent pressure drop, and during the quarter less than 1 liter/minute at 30 cm water pressure. Tests for high-pressure leaks shall be conducted by an appropriate technique presented in Appendix I or equivalent. All new equipment for the administration of anesthetic agents shall meet these requirements. Mechanical ventilators employed for the administration of anesthetic agents shall be tested quarterly for proper functioning.

(3) Low-pressure leak tests, as described in Appendix I, shall be performed daily for the complete anesthetic machine. Low-pressure leaks shall be less than 100 ml/minute at 30 cm water pressure, or an equivalent pressure drop. If the leak rate is in excess of the recommendations, the leaks shall be located and repaired before use of the equipment.

(4) After each cleaning, face masks, tubing, breathing bags, and endotracheal tubes shall be inspected for cracks and other leak

sources. Damaged equipment shall not be used.

(5) Whenever room concentrations exceed the environmental limits prescribed in Section 2, leak sources shall be located and repaired prior to the next use of the anesthetic equipment.

Section 4 - Medical

Medical surveillance, as outlined below, shall be made available to all employees subject to occupational exposure to waste anesthetic gases.

(a) Comprehensive preplacement medical and occupational histories shall be obtained and maintained in the employees' medical records, with special attention given to the outcome of pregnancies of the employee or spouse, and to the hepatic, renal, and hematopoietic systems which may be affected by agents used as anesthetic gases. This information should be updated at least yearly and at any other time considered appropriate by the responsible physician.

(b) Preplacement and annual physical examinations of employees exposed to anesthetic gases are recommended and, when performed, the results shall be maintained in the employees' permanent medical records.

(c) Employees shall be advised of the potential undesirable effects of exposure to waste anesthetic gases, such as spontaneous abortions, congenital abnormalities in their children, and effects on the liver and kidneys.

(d) Any abnormal outcome of the pregnancies of employees or of the spouses of employees exposed to anesthetic gases shall be documented as part of the employees' medical records, and the records shall be maintained for the period of employment plus 20 years. This medical information shall

be available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employee or former employee, and of the employer.

Section 5 - Labeling and Posting

(a) Labeling

Containers of gaseous and volatile anesthetic agents shall carry labels as listed in Table I-1.

(b) Posting

Locations adjacent to areas where occupational exposure to anesthetic gases is likely shall be posted with an appropriate sign as listed in Table I-1.

The posting required in this section shall be printed both in English and in the language most predominant among non-English-reading workers, unless they are otherwise trained and informed of the hazardous areas.

Section 6 - Fire, Explosion, and Sanitation Practices

Applicable guidelines and regulations concerning fire, explosion, and sanitation shall be met when instituting scavenging and engineering controls.

TABLE I-1

LABELING/POSTING REQUIREMENTS

Flammable Agents

Nonflammable Agents

(NAME OF AGENT)

CAUTION: HARMFUL IF INHALED CONTINUOUSLY

Keep away from heat, sparks, and open flames. Use with adequate ventilation and/or scavenging equipment. (NAME OF AGENT)

CAUTION: HARMFUL IF INHALED CONTINUOUSLY

Use with adequate ventilation and/or scavenging equipment.

Section 7 - Informing Employees of Hazards from Anesthetic Gases

On assignment, and at least annually thereafter, each worker shall be informed of the possible health effects of exposure to waste anesthetic gases. This information shall emphasize the potential risks to workers of reproductive age and to their unborn children. Each worker shall be instructed as to the availability of such information, which shall be kept on file and accessible to the worker at each place of employment where potential exposure to waste anesthetic gases exists.

Section 8 - Monitoring Requirements

The monitoring program shall be supervised by a knowledgeable individual familiar with sampling and monitoring techniques or by a professional industrial hygienist. The agent to be monitored and the

method chosen will depend on the frequency of the agent's use, availability of sampling and analysis instrumentation, and on whether the facility chooses to initiate its own monitoring program or take advantage of a commercial service.

(a) Sampling shall be conducted in areas that are representative of the concentrations at which workers are exposed during routine procedures incorporating any inhalation anesthetic. The sampling sites shall be chosen by surveying each location to which the standard applies to determine typical waste anesthetic gas distribution patterns, or shall be representative of the breathing zone of the exposed workers.

(b) For purposes of air monitoring, the inhalation anesthetic agent most frequently used by the institution must be chosen for sampling and analysis. Depending on the circumstances of use, mixed agents versus nonmixed agents, the environmental limits prescribed in Section 2 shall be used as a guideline for determining the effectiveness of the engineering control procedures and work practices required in the standard.

(c) Within 180 days of the promulgation of an occupational waste anesthetic gases standard, all locations with the potential of worker exposure to waste anesthetic gases shall be sampled. Sampling shall be conducted during periods of anesthetic administration and sampling time shall not exceed 1 hour.

Repetitive sampling shall be conducted on a quarterly basis in locations in which mixed inhalation anesthetic agents are used and whenever ventilation, anesthetic equipment, or scavenging techniques are modified.

Section 9 - Recordkeeping Requirements

(a) Records of all collected air samples shall be maintained including date of sample, sampling methods, sample location, analytical method, and measured concentrations. If waste anesthetic gas levels are found above the environmental limit prescribed in Section 2, corrective actions shall be taken and recorded. Results of environmental measurements shall be made available to exposed employees upon request.

(b) Air sampling results and results of leak tests shall be maintained for at least 20 years.

(c) Medical records shall be kept for the duration of employment plus 20 years following an employee's termination of employment or termination of work of a self-employed person.

II. INTRODUCTION

This report presents the criteria and the recommended standard based thereon which were prepared to meet the need for preventing occupational diseases arising from chronic exposure to waste anesthetic gases during the use of gaseous and volatile anesthetic agents in anesthetizing procedures. The criteria document fulfills the responsibility of the Secretary of Health, Education, and Welfare, under Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "...develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels... at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

The National Institute for Occupational Safety and Health (NIOSH), after a review of data and consultation with others, formalized a system for the development of criteria upon which standards can be established to protect the health of workers from exposure to hazardous chemical and physical agents. It should be pointed out that any recommended criteria for a standard should enable management and labor to develop better engineering controls resulting in more healthful work practices and should not be used as a final goal.

These criteria and recommended standard for chronic exposure to waste anesthetic gases are part of a continuing series of criteria developed by NIOSH. The proposed standard applies only to the occupational use of anesthetic agents as applicable under the Occupational Safety and Health Act of 1970. The standard was not designed for the population-at-large,

and any extrapolation beyond occupational exposures is not warranted. The standard is intended to protect against development of systemic effects related to chronic exposure to waste anesthetic gases associated with inhalation anesthesia, and it is considered to be attainable with existing technology.

Current scientific evidence obtained from human and animal studies suggests that chronic exposure to anesthetic gases increases the risk of both spontaneous abortion and congenital abnormalities in offspring among female workers and wives of male workers. Risks of hepatic and renal diseases are also increased among exposed personnel. In addition, psychologic functions may be impaired. A few studies have suggested an increased risk of cancer. Effects on the central nervous system (CNS) due to acute exposures to anesthetic gases have been associated with headaches, fatigue, irritability, etc. However, the exposure levels nausea. attainable with the control procedures and work practices presented in the recommended standard in this document should prevent the effects caused by such acute exposures and significantly reduce the risks associated with long-term exposure.

Although most of the human studies conducted and reported herein deal with hospital operating room personnel, it is the opinion of NIOSH that the health effects of chronic exposure to waste anesthetic gases in other anesthetizing locations could be similar. Therefore, these criteria and the standard were developed for application to all locations where inhalation anesthetics are administered.

More information is needed from the dental and veterinary medical areas to determine the feasible levels to which exposures can be reduced

and the possible presence of adverse health effects related to exposure. A health survey among exposed dentists and their employees should provide some of the information needed to answer these questions.

It is highly recommended that this document be supplemented with the NIOSH technical information publication <u>Development</u> and <u>Evaluation</u> of <u>Methods</u> for the <u>Elimination</u> of <u>Waste</u> <u>Anesthetic</u> <u>Gases</u> and <u>Vapors</u> in <u>Hospitals</u> (GPO Order No. 1733-00061, Superintendent of Documents, US <u>Government</u> Printing Office, Washington, DC 20402).