Waste Anesthesia Gases and Vapors Exposure Control Policy

Policy #S-001

VA Pittsburgh Healthcare System
Pittsburgh, PA 15240

Service Line(s):
Research and Development (R&D) Department

Signatory Authority:
Dr. Steven Graham, ACOS

Effective Date:
September 15, 2020

Responsible Owner:
Associate Chief of Staff/R&D

Recertification Date:
December 2021

1. PURPOSE AND AUTHORITY

a. Waste inhalation anesthetic gases and vapors are those that are released into rooms used for surgical and other procedures utilizing volatile anesthetics. The waste anesthetic gases and vapors of concern are nitrous oxide and halogenated agents (vapors) such as isoflurane. Employees working in these surgical areas may be subject to environmental exposure associated with the administration of the anesthetic gases. This document outlines the policies and procedures to be utilized by the VA Pittsburgh Healthcare System (VAPHS) Animal Research Program to control and monitor employee exposure to Waste Anesthetic Gases (WAG) and vapors.

b. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research, April 24, 2019.

c. This policy applies to all VAPHS and Veterans Research Foundation of Pittsburgh employees (including without compensation [WOC] appointments) working with animals within the VAPHS Animal Research Facility (ARF) and who may be exposed to waste anesthetic gases and vapors.

2. PROCEDURES

A. Policy

The VAPHS Animal Research Program recognizes that anesthetic gases must be utilized in the conduct of animal research. The VAPHS, Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH) concur that there is insufficient data to establish safe occupational exposure levels for halogenated anesthetic gases. NIOSH, however, has established recommended exposure limits. The VAPHS Animal Research Program has developed exposure control methods to reduce or maintain exposure below these recommended limits.

For surgical procedures that utilize anesthesia, most employees use isoflurane (Forane®). There is no specific work exposure limit established for isoflurane by OSHA. However, based on NIOSH and NIH recommendations, the VAPHS will use the occupational exposure limit (OEL) of 2 ppm over the course of one surgical procedure. To minimize occupational exposure to isoflurane, all research employees must ensure the following:

1. All research employees must wear a monitoring badge for halogenated agents during every procedure that is not performed under a chemical fume hood.
2. Research personnel that utilize isoflurane less than 10 times a year must wear a monitoring badge for halogenated agents during every procedure.
3. For research personnel obtaining DNA samples for PCR using isoflurane, personnel must wear a monitoring badge for the first six procedures. After six procedures of results that are below the OEL of 2 ppm, a monitoring badge for halogenated agents must be worn once every six months (badging months will be April and October).
4. For procedures that are performed under a chemical fume hood (to include surgery table, induction table, and filling vaporizer), a monitoring badge for halogenated agents must be worn the first time the procedure is performed. If the results from the monitoring badge are below the OEL of 2 ppm, then personnel must wear a monitoring badge for halogenated agents once every six months (badging months will be April and October).

*Note: All sampling for halogenated agents is at the discretion of the Industrial Hygienist and/or Biosafety Officer. In addition, after any change in procedure, the investigator and staff must begin the process of wearing a monitoring badge during the initial six procedures with results that are below the OEL of 2 ppm, before being approved to wear a badge every six months.

If an employee is exposed to a concentration above the OEL of 2 ppm, then the employee must contact the Industrial Hygienist or Biosafety Officer who will then review the proper operating procedures for using the equipment and observe the use of the instruments, if necessary. The employee will not be permitted to continue conducting these procedures until after discussions with the Industrial Hygienist or Biosafety Officer. In addition, the employee is required to contact Occupational Health to undergo counseling and an optional exam.

A carrier gas must be used when converting liquid anesthetic agents into a gas or vapor. Most employees use oxygen as the only carrier gas; however, several investigators use a combination of nitrous oxide and oxygen. Like halogenated gases, there is no specific work exposure limit established for nitrous oxide by OSHA. However, the ACGIH states that the exposure limit for nitrous oxide is 50 ppm as a Time Weighted Average (TWA). All research employees must wear a monitoring badge for nitrous oxide for every procedure. At the VAPHS, an action limit will be set at 25 ppm as the concentration during nitrous oxide use. If an employee is exposed

to a concentration above the action limit (25 ppm), but below the exposure limit (50 ppm), the employee will meet with the Industrial Hygienist or Biosafety Officer to discuss ways to ensure the concentration remains under the action limit; work involving nitrous oxide can continue to be performed. If an employee is exposed to a concentration above the exposure limit over the 8-hour TWA (50 ppm), then the employee must contact the Industrial Hygienist or Biosafety Officer who will then also observe the use of the instruments and review the proper operating procedures for using the equipment. The employee will not be permitted to continue conducting these procedures until after meeting with the Industrial Hygienist or the Biosafety Officer. In addition, the employee is required to contact Occupational Health to undergo counseling and an optional exam.

TABLE: Recommended Exposure Limits

Name of Gas	Occupational Exposure Limit (OEL)	Action Limit	8-hour Time-weighted Average (TWA)
Isoflurane	2 ppm	---	---
Nitrous Oxide	---	25 ppm	50 ppm

B. Procedures to Minimize WAG Exposure

The VAPHS Animal Research Program has developed the following procedures to minimize employee exposure to WAG:

- Equipment Certification & Monitoring Requirements
- Employee Information and Training
- Medical Surveillance
- Labels and Posting
- Record keeping

1. Equipment Certification & Monitoring Requirements

A. Equipment Certification

All anesthesia equipment used in conjunction with the Animal Research Program must be maintained in good working condition. The primary standard for vaporizing recalibration/certification is to be governed by manufacturer's recommendations. Certification consists of the inspection and approval of all mechanics associated with the vaporizer and flow meter.

i. Procedures within the VAPHS:
All vaporizers and flow meters must be shipped out to the manufacturer and calibrated on an annual basis. All anesthesia equipment must be serviced by qualified personnel or by an authorized service center.

ii. Procedures within VA Leased Space Locations:
Facilities from which the VA leases space are expected to adhere to their own local policy regarding certification of anesthesia equipment.

B. Exposure Monitoring

Potential effects of exposure to WAGs are nausea, dizziness, headaches, fatigue, and irritability, as well as sterility, birth defects, miscarriages, and liver and kidney disease. In order to ensure that the concentrations of WAGs are maintained below the NIOSH and ACGIH recommended limits, personal monitoring badges will be utilized. The purpose of the badge is to determine the airborne concentration of WAG and verify that all equipment is safe to use.

The Research and Development Department (R&D) provides personal monitoring badges for employees who perform surgeries for the Animal Research Program. This requirement applies to those employees working on VAPHS property. Monitoring badges are available for both halogenated gases (i.e., isoflurane) and for nitrous oxide. Employees who work in rooms in which WAGs are utilized are required to monitor their exposure during procedures that involve WAG. In addition, for employees that utilize nitrous oxide as a carrier gas, a nitrous oxide badge must be worn during every surgical procedure. The badges, both for halogenated gases and nitrous oxide, are used to monitor a single procedure or time frame not to exceed 8 hours. The badges are in a box outside of the procedure room GA119 in the Animal Research Facility. Within 24 hours after procedure completion, the badges are to be returned to the Animal Research Facility Supervisor (or Acting Supervisor) or designee. The Animal Facility Supervisor (or designee) then sends the monitoring badge to an accredited laboratory for determination of acceptable NIOSH limits. Procedures related to employee notification of monitoring results are described in section B5 Recordkeeping.

2. Employee Information and Training

Each employee, prior to being permitted to work in a WAG area, will receive instructions and training from the Industrial Hygienist or the Biosafety Officer on the following:

- The details of the Hazard Communication Policy developed by the VAPHS and how employees can obtain and use the appropriate hazard information.

- The nature of the hazards and toxicity of WAG, including recognition of the signs and symptoms of over exposure, and the importance of reporting these immediately to Occupational Health personnel.

- The specific nature of the procedure involving WAG that could result in exposure.

- The VAPHS Animal Exposure Preventive Medicine Program (AEPMP) and the importance of medical surveillance.

- Sampling methods and observations that may be used to detect the presence or release of WAG in the work area.

- The measures employees can take to protect themselves from hazards associated with WAG exposure, including specific procedures such as engineering and work practices to reduce exposure levels.

- The location and availability of the written WAG policy.

Once an employee has received the training outlined above, the Industrial Hygienist or Biosafety Officer must provide written verification (in the form of a sign-in sheet) to R&D, which maintains the information per record keeping requirements.

In addition, the VAPHS ARF has developed Standard Operating Procedures (SOPs) which govern the use of anesthetic gases within the ARF. These procedures have been excluded from this policy but may be reviewed in the ARF SOP Manual. The procedures outline the methods to be employed to ensure proper use of the anesthesia and scavenging systems within each operating/procedure room. Each employee must be familiar with and be properly trained in the use of these systems prior to being permitted to work in a surgery area.

3. Medical Surveillance

As part of the AEPMP at VAPHS, the Animal Research Program employees who may potentially be exposed to WAGs will be offered participation in this surveillance program. The details of this program are described in the VAPHS R&D Policy #A-002.

4. Labels and Posting

The section on labels (Section IIIB) of the VAPHS Hazard Communication Program will be implemented to inform employees of the possible health hazards associated with use of each anesthesia unit. The ARF staff will be responsible for labeling the unit in accordance with the requirements of the Hazardous Material Identification System (HMIS), an integral part of the VAPHS Hazard Communication Program.

A Safety Data Sheet (SDS) for each anesthetic gas must be made available to

Animal Research Program employees. Binders containing SDSs are maintained in the ARF. The location of SDS in other facilities (VA leased space) must be visibly displayed in rooms in which anesthetic gases may be utilized. Each SDS communicates detailed hazard/safety information for each anesthetic gas.

The vaporizers and flow meters are sent to be calibrated and certified annually. Vaporizer unit certification labels will be affixed at the time of inspection/verification.

5. Record Keeping

A. Personal Monitoring: The laboratory that analyzes the monitoring badges will provide employee results to designated members of the R&D Office (includes the Biosafety Officer). The designated members of the R&D Office will be responsible for notifying the employee, as well as the study Principal Investigator and Industrial Hygienist or Safety Department designee of results within 5 business days of receipt. A copy of the results will be maintained by R&D. In addition, in the case of a WAG overexposure, the designated member of the R&D Office will be responsible for notifying the affected employee, as well as the study Principal Investigator, Industrial Hygienist (or Safety Department designee), ACOS for Research, Safety Manager, Chair of IBC and IACUC Committees, Occupational Health, and Research Compliance Officer within 5 business days of receipt of the results. The affected employee will be required to undergo counseling with Occupational Health (see VAPHS R&D Policy #A-002 for additional information). Prior to continuing work with WAG, the Industrial Hygienist or Biosafety Officer must also observe the employee working with the anesthetic gas equipment in order to ensure that the individual is properly using the equipment. Information on a WAG overexposure is presented at the next fully convened IBC and IACUC Committee meetings for review.

B. Medical Surveillance: The VAPHS will provide for retention of the results of the medical surveillance program and tests conducted by Occupational Health. All medical examination results will be maintained in the employee's medical file.

C. Employees: R&D will maintain records of all individuals working with and thus potentially exposed to WAGs. This record will contain notations as to dates of training and any subsequent incidents of note.

Copies of the reports of personnel monitoring/air sampling results are maintained by R&D. All records are retained in accordance with VHA's Records Control Schedule (RSC 10-1).

6. ASSIGNMENT OF RESPONSIBILITIES

a. Facilities Management Services will be responsible for preventative maintenance of affected heating, ventilation, and air conditioning (HVAC) systems and scavenging systems.

b. Industrial Hygienist will coordinate all industrial hygiene monitoring, conduct the WAG training sessions, train Research employees on how to use a monitoring badge when working with isoflurane and nitrous oxide, and review the procedures used during surgeries when an overexposure occurs. If the Industrial Hygienist is not available for an extended period, the Biosafety Officer will coordinate monitoring, conduct training, and discuss/review surgical procedures after an overexposure to avoid delays in training or delays in determining a cause for overexposures.

c. Research and Development Department (R&D) will be responsible for ensuring that all employees within the Animal Research Program have undergone WAG training regarding work practices designed to reduce ambient WAGs during the administration of anesthesia. R&D will keep records on the training dates, topics and attendees. In addition, R&D will be responsible for notifying employees of results from the monitoring badges and ensuring that any exposed employee is identified for baseline and annual medical surveillance through Occupational Health. Exposure records are also forwarded to Occupational Health to be placed in medical records.

d. Occupational Health is responsible for providing health assessments for employees enrolled in the Animal Research Program and that utilize WAG. If a Research employee is overexposed, they will provide guidance on health issues that may arise from increased exposure to anesthetic gases and vapors, as well as an offer an optional exam.

e. ARF Supervisor/Staff will assist in training Research employees on how to use a monitoring badge when working with isoflurane and nitrous oxide. ARF Supervisor/Staff are also responsible for preventative maintenance of the anesthesia delivery units (both vaporizer and flow meter).

7. REFERENCES

-The National Institute for Occupational Safety and Health (NIOSH) - Criteria for a Recommended Standard: Occupational Exposure to Waste Anesthetic Gases and Vapors. The Department of Health, Education, and Welfare (DHEW) [NIOSH] Publication No. 77-140

-United States Department of Labor, Occupational Health and Safety Administration, Anesthetic Gases: Guidelines for Workplace Exposures (https://www.osha.gov/dts/osta/anestheticgases/)

-VAPHS Medical Center Memorandum EC-001 Hazard Communication Program

-VAPHS R&D Policy #A-002

-Waste Anesthetic Gas (WAG) Surveillance Program-National Institutes of Health, Office of Research Services, Division of Occupational Health and Safety, November 2016

https://www.ors.od.nih.gov/sr/dohs/Documents/Waste%20Anesthetic%20Gas%20(WAG)%20Surveillance%20Program.pdf

8. REVIEW

This policy is reviewed at recertification, when there are changes to the governing document (for example, national policy or an accreditation body mandate), and any regulatory requirement for more frequent review.

9. RECERTIFICATION

This Policy is scheduled for recertification fifteen (15) months from the Effective Date. In the event of contradiction with national policy, the national policy supersedes and controls.

10. SIGNATORY AUTHORITY

//signed copy on file //

Gretchen Haas, MD
Chair, Research and Development Committee
Date Approved: September 15, 2020

//signed copy on file //

Steven Graham, MD, PhD
Associate Chief of Staff Research and Development Department
Date Approved: September 15, 2020

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

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