

Ethylene Oxide Policy

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1. Purpose. The purpose of the ethylene oxide policy is to establish procedures/guidelines to protect the health and safety of all employees of the university community who may be occupationally exposed to ethylene oxide gas. In addition, this policy establishes a process of compliance with Occupational Safety and Health Administration (OSHA) standard 29 Code of Federal Regulations (CFR) 1910.1047.

2. Scope. This ethylene oxide policy applies to all university or hospital employees in those work areas where there is potential exposure to ethylene oxide gas. The university areas covered by this program include but are not limited to: central supply and some research laboratories.

3. Policy. It is the policy of the university to ensure that ethylene oxide gas is handled in the safest manner possible and in compliance with all applicable codes and standards. Engineering controls shall be utilized to maximum extent feasible to maintain exposures below permissible limits, followed by other control methods including work practices, administrative controls, and the use of personal protective equipment.

4. Standard. OSHA issued a standard to assure proper protection of all workers exposed to ethylene oxide – a permissible exposure limit (PEL) of 1.0 parts ethylene oxide per million parts of air (ppm) as an 8-hour time weighted average (TWA) and an excursion limit of five parts ethylene oxide per million parts of air (5 ppm) in a 15-minute period.

5. Definitions and Key Terms.

A. **Action-Level:** The exposure level below which respiratory protection and many other requirements of the ethylene oxide policy need not be implemented. The current action level for ethylene oxide is 0.5 ppm TWA.

B. **Ethylene Oxide:** Ethylene oxide is a flammable, colorless gas at temperatures above 51.3° F (1.7° C) that smells like ether at toxic levels. Ethylene oxide is found in the production of solvents, antifreeze, textiles, detergents, adhesives; amounts are present in fumigants, sterilants for spices and cosmetics, as well as during hospital sterilizations of surgical equipment. See substance technical guideline and Material Safety Data Sheet (MSDS) for additional information.

C. **PEL:** Permissible Exposure Level. The maximum permissible airborne exposure limit to ethylene oxide, that no employee can be exposed to, that is published and enforced as a legal standard. The PEL for ethylene oxide is 1.0 ppm.

D. **Excursion Limit:** Short-Term Exposure Level. This is the maximum concentration of ethylene oxide gas to which workers may be exposed continuously over a period of 15 minutes. The STEL for ethylene oxide is currently 5.0 ppm.

E. **Time Weighted Average (TWA):** The actual measured exposure level averaged over an 8-hour time period.

6. Ethylene Oxide Hazard Assessment. Processes or occupational activities that may result in ethylene oxide exposure:

A. Sources of ethylene oxide emissions into the air include uncontrolled emissions or venting with other gases in industrial settings.

B. Additional sources of ethylene oxide air emissions include automobile exhaust and its release from commodity-fumigated materials, as well as its use as a sterilizer of medical equipment.

C. The general population may be exposed to ethylene oxide through breathing contaminated air or from smoking tobacco or being in the proximity to someone who is smoking. Certain occupational groups (e.g., workers in ethylene oxide manufacture or processing plants, sterilization technicians, and workers involved in fumigation) may be exposed in the workplace.

7. Exposure Monitoring Strategy. University employees who conduct activities or have work areas that fit the ethylene oxide Hazard Assessment (see Section 6 above) are monitored periodically to determine exposure concentrations. Representative monitoring will be conducted to determine employee short-term and full-shift exposures to ethylene oxide. Every employee need not be measured if an "elevated" exposure employee can be identified. TWA measurements shall be primarily determined through the use of passive monitoring badges. If the ethylene oxide monitoring indicates a TWA above 1.0 ppm, then the area supervisor will be contacted and recommendations made to reduce employee exposure. In addition, a written exposure control plan is required to be developed and/or on-hand, describing the corrective actions that are being taken to reduce employee exposures. Every effort should be made by the area supervisor and exposed personnel to reduce exposure levels to below 0.5 ppm on a high-priority basis. If there are tasks that involve brief but intense exposure to ethylene oxide, employee exposure must be measured during these events to assure compliance with the excursion limit. Sample collections are for brief periods (15 minutes) but several samples may be needed to identify the peak exposure. Monitoring will be conducted by OEHS in such manner as to be representative of the 8-hour TWA of each employee. Representative 8-hour TWA employee exposures shall be determined based upon one or more samples representing full-shift exposure for each shift for each job classification in each work area; the frequency of such monitoring is required as follows:

A. Initially, wherever there may be exposure by employees above the PEL to establish a baseline exposure level.

B. Whenever there is a change in processes, equipment, personnel, or control measures which may result in new or additional staff exposure to ethylene oxide.

C. Periodic monitoring if the airborne concentration of ethylene oxide is at or above the action level or above the 15-minute excursion limit.

D. If the exposure level is maintained below the action level, as indicated by at least two consecutive measurements taken at least seven days apart, TWA monitoring for those employees whose exposures are represented by such monitoring may be discontinued until there is a change in production, equipment, processes, personnel, or control measures that may result in new or additional exposure to ethylene oxide.

8. Medical Surveillance. The university must implement a medical surveillance program, conducted or supervised by a licensed physician, for an employee under the following circumstances:

A. If the employee is assigned to an area where exposure to ethylene oxide may be at or above the action level for 30 days or more during the year

B. If the employee has been exposed to ethylene oxide in an emergency situation.

9. Monitoring - Reporting Results.

A. The area supervisor shall report the results of all ethylene oxide monitoring to the person(s) monitored within 15 calendar days of the date on which the area supervisor receives the results. Posting of the monitoring results in a location readily and normally accessible to employees is acceptable for this purpose. If the PEL has been exceeded, affected employees must be notified of any corrective action being taken.

B. Time-weighted average measurements may be requested at any time at the discretion of the area supervisor. Where eye or skin contact with liquid ethylene oxide or ethylene oxide solutions may occur, the employer (VCU or VCUHS) shall select and provide at no cost to the employee appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and 1910.133 to protect against such contact with ethylene oxide. This standard applies directly to EtO compressed gas cylinder changes in the central sterile supply area of the main hospital. Where respirators are required, the employer shall select and provide a properly-fitted National Institute for Occupational Safety and Health (NIOSH)-approved respirator at no cost to the employee and shall ensure that the employee wears the protective clothing and equipment provided. Employees utilizing respiratory protection must be included in all elements of the university Respiratory Protection Program.

10. Training Program. All employees with potential exposure to ethylene oxide must receive training to confirm their understanding of ethylene oxide, its hazards, and methods of protection. Employees should be trained at the time of initial assignment and then at least annually thereafter. The training program shall be conducted in a manner in which the employee is able to understand and apply the following information:

A. The properties of ethylene oxide, its forms, uses, synonyms, and common occurrences work areas at VCU and VCUHS.

B. Ethylene oxide exposure limits established by OSHA.

C. Ethylene oxide detection by workers.

D. Health effects of ethylene oxide: a description of the potential health effects of ethylene oxide exposure with signs and symptoms of various ambient concentrations.

E. Routes of exposure, acute/chronic exposure, and carcinogenic effects.

F. Monitoring methods to detect the presence and concentration of ethylene oxide in the work area:

1. Initial monitoring.
2. Periodic monitoring.

G. Overview of applicable OSHA standards:

1. Ethylene oxide standard (29 CFR 1910.1047).
2. Hazard Communication standard (29 CFR 1910.1200).
3. Laboratory Safety Standard (29 CFR 1910.1450).

H. Measures employees must take to protect themselves:

1. Engineering controls.
2. Administrative/work practice controls.
3. Personal protective equipment.

I. Emergency procedures for skin or eye contact

J. Medical surveillance

K. Employee responsibilities regarding signs and symptoms of exposure; appropriate measures to take if you think you have been exposed or have concerns.

11. Signage. The university/hospital shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas. The signage posted for these areas will bear the following legend:

**DANGER
ETHYLENE OXIDE
CANCER HAZARD & REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS
AREA**

The university or health system shall ensure that precautionary labels are affixed to all containers of ethylene oxide that are capable of causing employee exposure at or above the action level and that the labels remain affixed when the containers of ethylene oxide leave the work area.

12. Engineering Controls. The policy of VCU is that supervisors of all ethylene oxide-related work activities with potential for exceeding the action level shall implement feasible engineering controls. Examples of engineering controls include ventilation systems, air pollution control devices, laboratory hoods, enclosures, shields, barriers, isolation chambers, automatic emergency shut off valves, and remote-control equipment. The following considerations should be included in the design and installation process for such equipment:

A. To minimize ethylene oxide exposure and control the buildup of gases and vapors in the general work area, it is important that adequate room ventilation be provided. The recommended ventilation rate for areas containing ETO is ten air changes per hour (EPA, 1996).

B. If the facility ventilates containers of contaminated clothing and equipment, the facility shall establish an appropriately labeled storage area for this purpose and locate and arrange this area in a manner that minimizes employee exposure to ethylene oxide. The facility shall allow only persons trained in recognizing the hazards of ethylene oxide to remove containers from the storage area.

13. Work Practices/Administrative Controls. Work practices and administrative procedures are also an important part of an exposure control program. If an employee is asked to perform a task in a certain manner to limit the exposure to ethylene oxide, it is extremely important that the recommended procedures are followed.

14. Personal Protective Equipment (PPE). Certain types of PPE are effective in controlling ethylene oxide exposure. In normal work situations, PPE should be used only as a supplement to engineering controls. Employees must not take ethylene oxide-contaminated materials, clothing, or equipment home.

A. Impermeable Gloves: Latex gloves are among the appropriate glove choices for protection against skin contact with ethylene oxide. Check with OEHS for other material options.

B. Eye and Face Protection: Eye and face protection in the form of goggles will reduce exposure in cases of splash hazards.

C. Respiratory Protection: When employees are required to wear respirators to reduce exposure, employees must be enrolled in VCU's Respiratory Protection Program as required by OSHA. Contact OEHS at 828-1392 to enroll in the Respiratory Protection Program. VCU requires respirator use in the following situations:

1. During emergencies and during entry into areas of unknown ethylene oxide concentration.

2. As an interim control during the period to evaluate, purchase, and install engineering control equipment and/or modify work practices to achieve compliance with the PELs.

3. In work situations where engineering and work practice controls are not yet capable of reducing employee ethylene oxide exposure to or below the PEL.

4. During cleaning, maintenance, repair, and other work where engineering and work practice controls are not feasible.

15. Emergency Situations. Leak sensors are in place in VCUHS areas where ethylene oxide is used. In case of a leak:

A. Personnel should immediately evacuate the effected area when the monitor alarm sounds.

B. Seek medical assistance for exposed personnel.

C. Call the OEHS or VCU Telepage Operator immediately.

D. Never re-enter a contaminated area without fully encapsulating clothing, a self-contained breathing apparatus (SCBA), and back-up personnel until the area has been cleared by OEHS or area supervisor.

16. Housekeeping and Spill Response. Supervisors of facilities where ethylene oxide is utilized shall create and maintain a program to detect leaks and spills. The equipment leak and spill detection program should include:

A. Regular visual inspections of ETO cylinders, manifolds, and fittings for evidence of leaks and spills.

B. Preventative maintenance of equipment, including surveys for leaks at regular intervals.

C. Regular testing of monitoring equipment to assure proper function.

D. Provisions for refrigerated ethylene oxide spill containment, surface decontamination, and waste disposal in work areas where spillage may occur.

E. Prompt cleanup of spills and repair of leaks using persons who wear appropriate protective clothing and equipment and are trained in the proper methods for ethylene oxide cleanup and decontamination.

Sources & Further Reading:

A. OSHA Ethylene Oxide Regulations, 1910.1047:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10070

B. OSHA Fact Sheet, Ethylene Oxide (2002):

http://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf#search=%22OSHA%20Ethylene%20oxide%20Fact%20Sheet%22

C. EPA Environmental Best Practices for Health Care Facilities: Reducing Ethylene Oxide and Glutaraldehyde Usage (2002):

<http://www.epa.gov/region09/waste/p2/projects/hospital/glutareth.pdf>