Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 7713
Transmittal Sheet
April 6, 2017

SAFE USE OF ETHYLENE OXIDE

1. REASON FOR ISSUE: Establish policy for the use and management of ethylene oxide sterilizers at Department of Veterans Affairs (VA) facilities.

2. SUMMARY OF MAJOR CHANGES: This Veterans Health Administration (VHA) directive updates references and responsibilities.

3. RELATED ISSUES: VHA Directive 7701, VHA Directive 7702 and VHA Directive 7703.

4. RESPONSIBLE OFFICES: The Deputy Under Secretary for Health for Operations and Management (10N) and the National Program Office for Sterile Processing (NPOSP, 10NC6) are responsible for the content of this directive. Questions may be referred to the Office of Occupational Safety, Health and Green Environmental Management System (GEMS) Programs at 202-632-7889 or NPOSP at 513-247-2843.

5. RESCISSION: VHA Directive 2011-015, dated March 15, 2011, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Acting Under Secretary for Health

DISTRIBUTION: Emailed to the VHA Publication Distribution List on April 11, 2017.

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1. PURPOSE

This Veterans Health Administration (VHA) directive provides VHA policy for the use and management of ethylene oxide sterilizers to ensure compliance with regulatory requirements and to require practices for the safe operation of ethylene oxide sterilizers. **AUTHORITY:** Title 38 United States Code 7301 and Title 38 Code of Federal Regulations 17.1, 17.63, 17.74, 17.81, 17.82, 51.200, 52.200, and 59.130.

2. BACKGROUND

a. Ethylene oxide (EtO) is a flammable, colorless and highly toxic chemical, exposure to which may cause acute and chronic health effects. It is an established carcinogen and mutagen in animal toxicology models and a suspect carcinogen in humans. EtO is used to sterilize Reusable Medical Equipment (RME). EtO exposures have been most frequently attributed to off-gassing during the transfer of sterilized RME from sterilizers to aerators, and releases from piping and associated systems of external EtO cylinders. As a result, VHA is replacing two types of sterilizer systems: those with separate aeration and sterilization chambers, and those that utilize piping to supply EtO sterilizing agent via external cylinders.

b. The use of EtO to sterilize RME is permissible in VHA, and must be available when needed. EtO sterilization is carefully evaluated to minimize use as much as possible, with the ultimate goal of eliminating EtO entirely within the VHA.

c. Occupational use and exposure to EtO is regulated by the Occupational Safety and Health Administration (OSHA) under 29 CFR 1910.1047, Ethylene Oxide.

d. The Environmental Protection Agency (EPA) regulates EtO under two separate regulations. It is considered a hazardous air pollutant under 40 CFR Part 61, National Emission Standards For Hazardous Air Pollutants, and 40 CFR Part 63, National Emission Standards For Hazardous Air Pollutants for Source Categories. EtO is also considered a pesticide under title 7 U.S.C. 136 et seq., Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

e. The Emergency Planning and Community Right to Know Act (EPCRA) and the Clean Air Act outline the reporting requirements on the use and storage of EtO

f. The Food and Drug Administration (FDA) reviews the efficacy of EtO in the sterilization of a wide variety of medical devices and approves EtO sterilizers for medical use. FDA considers EtO a critical sterilant for the health care industry, particularly for sterilizing and reprocessing medical equipment that is moisture-, temperature-, or radiation-sensitive.

g. National Fire Protection Association (NFPA) Standard 560, “Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation” requires proper installation of EtO sterilizers and ventilation systems. ***NOTE:*** *VHA Directive 1116, Sterile*

Processing Services, provides additional information concerning procedures to follow when using EtO sterilization.

3. POLICY

It is VHA policy to institute protective measures for VHA employees, patients, and visitors from EtO exposure through engineering, administrative, and personal protective equipment (PPE) controls and by incorporation by reference to EPA, OSHA, FDA and NFPA standards. VA medical facilities will strive to eliminate the use of EtO by switching to a suitable substitute, when feasible.

4. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring that all VHA facilities develop and implement procedures to comply with Federal, State, and local safety, and environmental protection statutes and regulations related to EtO.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Establishing Occupational Safety and Health (OSH) program performance standards for the Assistant Deputy Under Secretary for Health for Administrative Operations.

(2) Overseeing the development and implementation of the VHA OSH programs and policies.

(3) Ensuring that staffing and funding are adequate to maintain EtO oversight and management programs.

(4) Ensuring VHA OSH and GEMS programs satisfactorily address EtO exposure and air pollution control requirements in order to protect public health and the environment.

c. **Assistant Deputy Under Secretary for Health for Clinical Operations.** The Assistant Deputy Under Secretary for Health for Clinical Operations is responsible for:

(1) Providing oversight of national policy pertaining to the standardization and reprocessing of RME including the use of EtO sterilization, and

(2) Ensuring that EtO systems are used only in limited situations, when medically necessary and no replacement is available. Facilities are required to use alternatives to EtO when sterilizer facilities are replaced or renovated.

d. **Director, Occupational Safety, Health and Green Environmental Management System Programs.** The Director, Safety, Health and Green Environmental Management System (GEMS) Programs is responsible for providing

guidance and other technical support to implement VHA OSH and GEMS program requirements related to EtO at the Veterans Integrated Service Network (VISN) and facility-level, in accordance with Federal, state, and local regulations.

e. **Chief Consultant, Occupational Health Services, Safety and Prevention Strategic Healthcare Group.** The Chief Consultant, Occupational Health Services, Safety and Prevention Strategic Healthcare Group, is responsible for providing policy and guidelines on occupational health issues related to exposure to EtO.

f. **Director, National Program Office for Sterile Processing.** The Director, National Program Office for Sterile Processing is responsible for developing policy regarding single-use devices (SUD), "Limited use" reusable medical equipment (RME), and standard RME.

(1) The FDA defines a SUD as a "...device that is intended for one use, or on a single patient during a single procedure." SUDs will not be processed by any EtO based sterilizing equipment.

(2) EtO-based sterilization of "Limited Use" RME will follow manufacturers' reprocessing Instructions For Use (IFU) which indicate the amount of uses or cycles the device can safely be used/reprocessed with EtO.

(3) EtO-based sterilization of RME must follow manufacturers' IFU regarding cleaning and reprocessing.

g. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Providing adequate resources for the implementation of this directive.

(2) Establishing a VISN Sterile Processing Service (SPS) Management Board to provide oversight of EtO activities. Responsibilities of the SPS Board include:

(a) Ensuring a sterilization work load analysis is conducted for each VISN facility.

(b) Ensuring Air Pollution Control Devices (abator) on all new EtO sterilizers are installed in accordance with VHA Office of Construction & Facilities Management (CFM) Sterile Processing Service and Logistics Service Design Guide, dated October 1, 2015 or subsequent issue(s), available at: http://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf.

(c) Reviewing and approving sterilizer replacement plans for VISN facilities.

1. Replacement plans must include potential alternatives to EtO.

2. Where a continuing need for EtO sterilization capabilities exists, a phase-out plan is developed to include replacement with sterilization equipment that sterilize and aerate in the same chamber. This plan must be submitted to the VISN SPS Management Board for approval and completed within one year from the approval date.

(d) Conducting annual reviews of EtO operations to determine the facility's compliance with their own written EtO Plan. ***NOTE:*** *See VHA Directive 1116, Sterile Processing Services, for additional responsibilities of the VISN Sterile Processing Service Management Board.*

h. **VA Medical Facility Director.** Each VA medical facility Director is responsible for:

(1) Ensuring that the Associate Director, Patient Care Services develops a written EtO program and ensures compliance with OSHA 29 CFR 1910.1047 and current VHA policy (including VHA Directive 1116). The EtO program will address:

(a) Work practices for the safe use of EtO;

(b) Regulated areas;

(c) Exposure Monitoring;

(d) Respiratory protection;

(e) Medical surveillance;

(f) Safe handling of EtO;

(g) Storage of EtO cartridges;

(h) An accidental spill or leak;

(i) Emergency first aid procedures;

(j) Posting, labeling, and recordkeeping;

(k) Hazard communication; and

(l) EPA requirements found in title 40 CFR 63 Subpart W, National Emission Standards for Hospital Ethylene Oxide Sterilizers.

(m) State and Local environmental regulatory requirements for hazardous air pollutants.

(2) Ensuring the facility sterilization methods have the capacity to sustain RME demand.

(3) Removing and replacing sterilizers that use plumbed external gas cylinders with a carrier gas. Sterilizers utilizing externally plumbed gas cylinders with carrier gas are not permitted in VA Facilities. ***NOTE:*** *Decommissioned EtO sterilizer equipment and external aerators must be removed.*

(4) Ensuring EtO sterilizer unit assemblies that are in use at VA medical facilities are constructed with combined single chamber sterilizer and aerator with single use cartridges and/or the use of FDA approved alternative sterilization methods. The unit assemblies will be installed in accordance with the VHA Office of CFM Design Guide, Sterile Processing Service and Logistics Service, dated October 1, 2015, available at: http://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf. ***NOTE:*** *This linked document is outside VA control and may or may not conform to Section 508 of the Rehabilitation Act of 1973.*

(5) Prohibiting the transfer EtO sterilized devices to a separate aerator prior to the completion of the sterilization cycle. To minimize exposure, EtO-sterilized items are not to be removed from the unit until the aeration cycle is complete.

(6) Ensuring an EtO sampling strategy is developed and documented to determine employee exposure.

(a) Ensuring employee exposure monitoring must be conducted by a trained and qualified Industrial Hygienist (IH) or Safety Manager. Monitoring will be performed initially, periodically, and when sterilizer equipment or work practices change, and must include 8-Hour time-weighted average (TWA) and/or 15-Min Excursion Limit monitoring as appropriate.

(b) All related standard operating procedures must be reviewed and employee work tasks observed and documented during exposure monitoring.

(7) Shutting down EtO sterilization processes when the OSHA permissible exposure limit for EtO is exceeded until the employee exposures are adequately controlled.

(8) Measuring, testing, and ensuring the effectiveness and operation of SPS ventilation systems, to include air flow rates, room air changes, alarms, and differential pressure. This action will be performed according to the following schedule:

(a) Initially upon installation,

(b) When sterilizer equipment or work practices change, and

(c) Quarterly, in accordance with VHA Directive 1116, Sterile Processing Services, and American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAAMI) Standard 41 (2008/Rev 2012), “Ethylene oxide sterilization in health care facilities: Safety and effectiveness".

(9) Developing a written plan for emergency situations involving the release of EtO, in accordance with 29 CFR 1910.38, Emergency Action Plans.

(10) Ensuring annual training of SPS and emergency response employees as identified in the emergency plan. New hire employees will receive emergency response training prior to assignment.

(11) Ensuring emergency drills are conducted at least annually and include all SPS, maintenance, housekeeping and any other staff who may be affected by an EtO release or emergency.

(12) Reporting all emergency events to the VISN Safety Office through the Issue Brief Process.

(13) Installing employee alarm or alert air monitoring systems (e.g., multi-port, direct reading) in work areas where personnel have the potential for exposure to EtO due to emergencies (e.g., releases, ventilation failure).

(a) These area air monitoring systems are not to be used to evaluate routine employee exposure levels for OSHA compliance.

(b) OSHA requires that where there is the possibility of employee exposure to EtO due to an emergency, a means must be developed to alert potentially-affected employees of such occurrences promptly (see 29 CFR 1910.1047(h)(2)).

(14) Verifying existing EtO sterilizers have Air Pollution Control Devices in accordance with the VHA Office of CFM Design Guide, Sterile Processing Service and Logistics Service, available at: http://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf. NOTE: This linked document is outside VA control and may or may not conform to Section 508 of the Rehabilitation Act of 1973.

(a) In the interim, a management program must be implemented to ensure only full loads of items having a common aeration time are sterilized at one time.

(b) When sterilization of full loads having a common aeration time is not possible, a statement by central services SPS staff, a hospital administrator, or a physician must be provided and documented that the sterilization cycle not containing a full load was medically necessary.

(15) Ensuring new renovation and or construction projects within SPS are designed in accordance with ANSI/AAMI Standard 41, and VHA Office of CFM Design Guide, Sterile Processing Service and Logistics Service.

(16) Ensuring all renovation and or construction projects within SPS are forwarded, reviewed and approved by the National Program Office for Sterile Processing (10NC6).

i. **Facility Nurse Executive.** The facility Nurse Executive is responsible for:

(1) Developing a sterilizer replacement plan to include:

(a) Workload analysis,

(b) Use of single use cartridges and FDA approved alternative sterilizing agents,

(c) Purchasing of disposable equipment, and

(d) Contracting for FDA approved sterilization services that comply with local, state, and Federal transportation regulations. ***NOTE:*** *The VHA goal is the reduction and elimination of EtO in VHA facilities.*

(2) Ensuring that a list of RME that can only be sterilized using EtO is developed and reviewed.

(3) Ensuring the reprocessing instructions from the original manufacturer for each item on the list are reviewed to determine if sterilization by EtO is required, or if alternative means are acceptable.

(4) The EtO-critical RME list must be developed by the Chief, SPS and approved by the Facility Director. It will be reviewed on an annual basis by the Chief of Staff, Nurse Executive, a representative from the Safety Department, and/or Green Environmental Management Systems Managers to ensure there are no other alternative means available to reprocess RME on the listing. The intent of this requirement is to eliminate the use of EtO whenever possible.

(5) Ensure the reprocessing instructions from the original manufacturer for each item on the list is reviewed to determine if sterilization by EtO is required, or if alternative means are acceptable.

j. **Facility Chief, Sterile Processing Services.** The facility Chief, SPS is responsible for all EtO sterilization activities within the facility, and must:

(1) Develop a list of RME that can only be sterilized by EtO. This list must be reviewed on an annual basis by the Chief of Staff, Nurse Executive, a representative from the Safety Department, and/or Green Environmental Management Systems Managers to ensure there are no other alternative means available.

(2) Maintain all records of EtO sterilization that occur.

(3) Report immediately all EtO releases in accordance with the local emergency procedures.

(4) Ensure employees receive mandated medical surveillance based on results of exposure monitoring and exposures related to emergency situations.

(5) Ensure the proper application of engineering controls, work practices, and sterilizer operations to minimize staff exposure to EtO.

(6) Ensure that SPS operations conform to written standard procedures.

(7) Report changes in sterilizer equipment or work practices to the facility Safety or IH Department.

(8) Ensure that appropriate facility staff complete assigned medical examinations, training, and properly wear personal protective equipment.

(9) Consult the sterilant unit-dose container manufacturer to determine how many cartridges may be stored in the sterilizer area.

(10) Ensure suitable flammable liquid storage conforms to National Fire Protection Association (NFPA) 30. EtO flammable storage cabinets will be directly vented to the outside according to VHA SPS design guide.

5. REFERENCES

a. Title 29 CFR 1910.1047, Ethylene Oxide (EtO) Standard, available at: https://www.gpo.gov/fdsys/pkg/CFR-2006-title29-vol6/pdf/CFR-2006-title29-vol6-sec1910-1047.pdf.

b. Title 40 CFR Part 63 - NESHAPS Subpart WWWWW Ethylene Oxide Brochure, available at: http://www.epa.gov/ttn/atw/area/sterilizersb.pdf.

c. VHA Directive 1116(2), Sterile Processing Services (SPS), available at: http://www.va.gov/vhapublications/publications.cfm?pub=1.

d. VHA Office of Construction & Facilities Management Design Guide, Logistics Service and Sterile Processing Service, available at: http://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf.

e. ANSI/AAMI, ST58/Ed. 3: 2013, Chemical sterilization and high-level disinfection in health care facilities; Annex N, Gas and vapor monitoring, available at: https://standards.aami.org/kws/public/projects/project/details?project_id=69. ***NOTE***: *This linked document is outside VA control and may or may not conform to Section 508 of the Rehabilitation Act of 1973.*

f. ANSI/AAMI ST41/Ed.4, Ethylene oxide sterilization in health care facilities: Safety and effectiveness, available at: https://standards.aami.org/kws/public/projects/project/details?project_id=64. ***NOTE***: *This linked document is outside VA control and may or may not conform to Section 508 of the Rehabilitation Act of 1973.*

g. EPA Review and Decision: Hospital Sterilizers February, 2010, available at: http://www.epa.gov/pesticides/reregistration/ethylene_oxide/ethylene_oxide_fs.html. EPA Ethylene Oxide (ETO): Hospitals and Healthcare Facilities Must Use a Single Chamber when Sterilizing Medical Equipment with ETO, available at: http://archive.epa.gov/pesticides/reregistration/web/html/ethylene_oxide_fs.html.

h. OSHA EtO Information Page, available at: http://www.osha.gov/SLTC/ethyleneoxide/. NIOSH EtO Information, available at: http://www.cdc.gov/niosh/topics/ethyleneoxide/.