

March 15, 2011

SAFE USE OF ETHYLENE OXIDE

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 best practices for the safe operation of ethylene oxide sterilizers.

2. BACKGROUND

a. Ethylene Oxide (EtO) is a flammable, colorless and highly toxic chemical with 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). VHA is targeting for replacement two types of sterilizer systems; sterilizers with separate aeration and sterilization chambers and sterilizers supplied by EtO tanks that utilize external piping to supply the sterilizing agent. EtO exposures have been most frequently attributed to off-gassing during the transfer of sterilized RME from sterilizers to aerators, and leaks from external EtO supply tank systems and associated piping.

b. The use of EtO to sterilize RME is permissible in VHA and must be available when needed; however, the use of EtO needs to be minimized, as much as possible.

c. The Occupational Safety and Health Administration (OSHA) currently regulates the use of, and exposure to, EtO under title 29 Code of Federal Regulations (CFR) 1910.1047.

d. The Environmental Protection Agency (EPA) regulates EtO as a hazardous air pollutant under 40 CFR Part 63 and as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Use of EtO also triggers reporting requirements under the Emergency Planning and Community Right to Know Act.

e. 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.

f. 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 Handbook 7176, Supply, Processing and Distribution (SPD) Operational Requirements, provides additional information concerning procedures to follow when using EtO sterilization.

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3. POLICY: It is VHA policy that each facility Director must ensure that a written policy and procedure for the safe use of EtO sterilizers, which meets all EPA, FDA, NFPA and VA requirements, is established and submitted, no later than September 30, 2011, to the appropriate Veterans Integrated Service Network (VISN) SPD Management Board.

4. ACTION

a. **Director, Office of Construction and Facilities Management (CFM).** The Director, CFM provides:

(1) Construction procedures, specifications, and design guides to ensure that EtO systems are installed in accordance with manufacturer specifications and Federal, state, and local regulations.

(2) Specifications to ensure that all future installations of EtO systems include the addition of EtO abators.

b. **Deputy Under Secretary for Health for Operations and Management (10N).** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Ensuring VHA Occupational Safety and Health (OSH) and Green Environmental Management System (GEMS) programs satisfactorily address EtO exposure and air pollution control requirements in order to protect public health and the environment.

(2) Establishing OSH and GEMS performance standards for VISN Directors and the Director Safety, Health, Environmental and Emergency Management (10NS).

c. **Assistant Deputy Under Secretary for Health for Clinical Operations (10NC).** The Director, Clinical Operations, is responsible for providing oversight of national policy pertaining to the standardization and reprocessing of RME including the use of EtO sterilization.

d. **Chief Consultant, Occupational Health, Safety and Prevention Strategic Healthcare Group (13D).** The Chief Consultant, Occupational Health, Safety and Prevention Strategic Healthcare Group, is responsible for providing policy and guidelines on occupational health issues related to exposure to EtO.

e. **Director, Safety, Health, Environmental and Emergency Management (10NS).** The Director, Safety, Health, Environmental and Emergency Management, is responsible for providing guidance and other technical support to implement VHA OSH and GEMS program requirements related to EtO at the VISN and VA facility-level, in accordance with Federal, state, and local regulations.

f. **VISN Director.** The VISN Director is responsible for providing adequate resources for the implementation of this Directive and ensuring that:

(1) The sterilization work load analysis at each VISN facility is conducted.

(2) The sterilizer replacement plans are reviewed and approved by the VISN SPD Management Board.

(a) The replacement plans must include potential alternatives to EtO.

(b) Where the need for EtO sterilization capabilities are warranted, a phase-out plan is developed at the facility to include replacement with sterilization equipment that sterilize and aerate in the same chamber. This plan must be submitted to the VISN SPD Management Board for approval and completed within 1 year from the approval date.

(3) Annual reviews of EtO operations are conducted to determine:

(a) Safe working conditions,

(b) The need for staff training,

(c) The adequacy of EtO exposure monitoring,

(d) The posting of regulated areas,

(e) Communication of monitoring results, and

(f) The performance of emergency drills.

g. **Facility Director.** Each facility Director is responsible for:

(1) Ensuring compliance with OSHA 29 CFR 1910.1047, current VHA policy, and VA Handbook 7176 by developing a written EtO program that addresses:

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

(b) Regulated areas;

(c) Monitoring;

(d) Respiratory protection;

(e) Medical surveillance;

(f) Safe handling of EtO;

(g) Storage of EtO cartridges;

(h) An accidental spill or leak;

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- (i) Emergency first aid procedures;
- (j) Posting, labeling, and recordkeeping;
- (k) Hazard communication;
- (l) EPA requirements found in 40 CFR 63;
- (m) The replacement of sterilizers with separate aeration and sterilization chambers and sterilizers that use plumbed external gas cylinders with a carrier gas; and
- (n) A work load analysis that designates the:
 - 1. Size and use of replacement combined single chamber sterilizers,
 - 2. Use of alternative sterilizing agents,
 - 3. Purchasing of disposable equipment, and/or
 - 4. Contract sterilization services.
- (2) Ensuring the facility sterilization methods have the capacity to sustain RME demand.
- (3) Submitting a plan to the VISN SPD Management Board, no later than September 30, 2011, for the replacement of sterilizers with separate aeration and sterilization chambers and sterilizers that use plumbed external gas cylinders with a carrier gas.
- (4) Ensuring replacement sterilizers are combined single chamber sterilizer and aerator with single use cartridges, and/or the use of approved alternatives, such as contracting the service out or alternative sterilization methods.
- (5) Ensuring systems utilizing external tanks shall be phased out.
- (6) Maintaining a listing of RME that can only be sterilized using EtO. This listing must be developed by the Chief, SPD and reviewed on an annual basis by the Chief of Staff, Nurse Executive, and an Industrial Hygiene (IH) or Safety Representative to ensure there are no other alternative means available to reprocess RME on the listing. In addition, they must:
 - (a) 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.
 - (b) Ensure that Contractors are FDA-approved to provide EtO sterilization services for medical facilities.

(c) Ensure a transportation plan is in place to ensure the sterility of RME when using an off-site contractor.

(d) Ensure documentation regarding the sterilization condition of any devices.

(7) Prohibiting, until a combined single chamber sterilizer is in place, the transfer of all EtO sterilized devices to a separate aerator prior to completion of the sterilization cycle; and ensuring the use of approved alternatives or contracting out the service.

(8) Ensure an EtO sampling strategy is developed and documented to determine employee exposure.

(a) Employee exposure monitoring must be conducted by a qualified, trained IH or Safety Manager initially, periodically, and when sterilizer equipment or work practices change.

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

(c) To minimize exposure, EtO-sterilized items are not to be removed from the unit until the aeration cycle is complete.

(9) Measuring, testing, and ensuring the effectiveness and operation of SPD ventilation systems (air flow rates, room air changes, alarms, and differential pressure) initially, when sterilizer equipment or work practices change, and at least annually.

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

(11) Ensuring annual training of SPD and emergency response employees as identified in the emergency plan.

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

(13) Reporting all emergency events to the VISN Safety Office.

(14) When the OSHA permissible exposure limit for EtO is exceeded, the EtO sterilization program is shut down until controls are implemented to ensure employee exposures are adequately controlled.

(15) Developing a written abatement plan for interim and final process exposure controls and securing its approval by the VISN Director through the VISN IH. The VISN IH reviews, approves, and provides feedback to the facility on the adequacy of the plan. The abatement plan may allow the use of respiratory protection as an interim control to protect employees in OSHA-regulated areas until adequate engineering or work practice controls are fully implemented

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(16) Employee alarm or alert air monitoring systems (e.g., multi-port, direct reading) are installed in work areas where personnel have the potential for exposure to EtO due to emergencies (e.g., leaks, ventilation failure).

(a) These 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 9 CFR 1910.1047(h)(2)).

(17) Submitting alarm events (as they occur) and an abatement plan update to the VISN IH every 3 months until appropriate sampling verifies exposure levels are below the OSHA permissible exposure limit.

(18) Installing Air Pollution Control Devices on all new EtO sterilizers in accordance with CFM Design Guides. Existing and new EtO sources are required to submit Initial Notification of Compliance Status reports to EPA (see subpar. 5c).

(19) That any existing EtO sterilizers without Air Pollution Control Devices have Air Pollution Devices installed by October 1, 2014, in accordance with CFM Design Guides.

(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 SPD staff, a hospital administrator, or a physician must be provided and documented that the sterilization cycle not containing a full load was medically necessary.

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

(1) Developing a sterilizer replacement plan to include a work load analysis that designates the:

(a) Size and use of replacement combined single chamber sterilizers with aerator,

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

(c) Purchasing of disposable equipment, or

(d) Contracting for sterilization services.

(2) Maintaining a listing of RME that can only be sterilized using EtO.

(a) This listing must be developed by the Chief, SPD and reviewed on an annual basis by the Chief of Staff and Nurse Executive to ensure there are no other alternative means available to reprocess RME on the listing.

(b) In addition, at the time of the review, they must:

1. 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.

2. Ensure that Contractors are FDA-approved to provide EtO sterilization services for medical facilities

3. Ensure a transportation plan is in place to ensure the sterility of RME when using an off-site contractor.

4. Ensure documentation regarding the sterilization condition of any devices.

(3) Prohibiting, until a combined single chamber sterilizer is in place, the transfer of all EtO sterilized devices to a separate aerator prior to completion of the sterilization cycle.

(4) Ensuring the use of approved alternatives or contracting out the service.

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

(6) Ensuring annual training of SPD and emergency response employees, as identified in the facility's emergency plan.

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

(8) Ensuring that when the OSHA-permissible exposure limit for EtO is exceeded, the EtO sterilization program is shut down until controls are implemented to ensure employee exposures are adequately controlled.

(9) Ensuring that employee alarm or alert air monitoring systems (e.g., multi-port, direct reading) are installed in work areas where personnel have the potential for exposure to EtO due to emergencies (e.g., leaks, ventilation failure). These air monitoring systems are not to be used to evaluate routine employee exposure levels for OSHA compliance.

(10) Ensuring the OSHA requirement 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 9 CFR 1910.1047(h)(2)), is met.

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i. **Facility Chief, SPD.** The facility Chief, SPD is responsible for all EtO sterilization activities within the facility, and must:

- (1) Maintain all records of EtO sterilization that occur.
- (2) Report immediately all EtO leaks in accordance with the local emergency procedures.
- (3) Ensure employees receive mandated medical surveillance based on results of exposure monitoring and exposures related to emergency situations.
- (4) Ensure the proper application of engineering controls, work practices, and sterilizer operations to minimize staff exposure to EtO.
- (5) Ensure that SPD operations conform to written standard procedures.
- (6) Report changes in sterilizer equipment or work practices to the facility Safety or IH Department.
- (7) Ensures that appropriate facility staff complete assigned medical examinations, training, and properly wear personal protective equipment.
- (8) Develop and maintain an annually-reviewed list of all RME that can only be processed by EtO.

5. REFERENCES

- a. OSHA EtO Information <http://www.osha.gov/SLTC/ethyleneoxide/>
- b. NIOSH EtO Information <http://www.cdc.gov/niosh/topics/ethyleneoxide/>
- c. NESHAPS Subpart WWWW Ethylene Oxide Brochure
<http://www.epa.gov/ttn/atw/area/sterilizersb.pdf>
- d. EPA Review and Decision: Hospital Sterilizers February 2010
http://www.epa.gov/pesticides/reregistration/ethylene_oxide/ethylene_oxide_fs.html

6. FOLLOW-UP RESPONSIBILITY: The Deputy Under Secretary for Health for Operations and Management (10N) is responsible for the contents of this Directive. Questions may be directed to the Director, Safety, Health, Environmental and Emergency Management (10NS) at (202) 266-4547.

7. RESCISSIONS: None. This VHA Directive expires March 31, 2016.

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