Ethylene oxide sterilization:
Regulatory roundup

by Susan Flynn BESc, CSPDT

Government regulations, evidence-based and professional organization guidelines and standards, and accreditation body requirements all contribute to the establishment of best practices for the CSSD. When it comes to developing or updating policies and procedures for ethylene oxide sterilization, there is a wealth of guidance and regulations available to reference.

Ethylene oxide (EO or ETO) is one of the low-temperature sterilants used to sterilize heat-and/or moisture-sensitive medical devices that cannot be steam sterilized. Ethylene oxide is valued for its efficacy, its ability to penetrate complex medical devices, and for its long history of device compatibility. Like all chemicals used in low-temperature sterilization processes, ethylene oxide is toxic – after all, its function is to kill microorganisms. It is therefore important that facilities and operators stay current on best practices related to the use of EO to ensure the safety of personnel operating ethylene oxide sterilizers.

This self-study article provides an overview of the regulations and recommended practices guiding the safe use of EO sterilization in the CSSD. Evaluate your facility’s compliance with these requirements and recommendations by answering the self-assessment questions included with each section.

### Occupational Safety and Health Administration (OSHA)

A part of the United States Department of Labor, OSHA’s mission is to provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education and assistance. As OSHA is a regulatory agency, compliance with its regulations is mandatory and OSHA holds employers responsible for providing a safe workplace. Users of ethylene oxide, including those in healthcare, must follow the requirements of OSHA’s occupational exposure standard for EO (29 CFR 1910.1047). Commonly referenced sections of the standard include those on exposure limits, employee exposure monitoring, emergency planning, and employee training.

OSHA has established two Permissible Exposure Limits (PELs) for EO: a 1 part per million (ppm) 8-hour time-weighted average and a 5 ppm excursion limit for any 15 minute period. The employer must conduct initial monitoring to determine representative employee exposure for both time periods in their workplace and demonstrate compliance to the established exposure limits. The 15-minute sampling period should be during the portion of the work shift when the representative employee’s EO exposure will be the highest. The values measured during initial monitoring determine the frequency of ongoing periodic monitoring. If initial employee monitoring results are below OSHA’s EO Action Level of 0.5ppm over an 8-hour time-weighted average, then periodic monitoring is not required for those employees whose exposures are represented by the initial monitoring. Monitoring should be resumed whenever there is a change, such as a modification of the exhaust ventilation system or installation of a new EO sterilizer, that may result in new or additional exposures to EO.

<table>
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<tr>
<th>Permissible Exposure Limits for Ethylene Oxide (OSHA 29 CFR 1910.1047(c))</th>
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<td><strong>8-hour time-weighted average (TWA)</strong></td>
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<td><strong>Excursion Limit</strong> (average exposure over a sampling period of 15 minutes)</td>
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Hospitals can conduct personal monitoring by having employees wear a clip-on, passive EO monitor in their breathing zone for a specified period of time. The monitor is then sent to a lab for analysis. This personal monitoring is not accomplished by EO area monitors which, OSHA clarifies, are used to detect leaks or spills.

A written plan for emergency situations is a required element of the standard. While OSHA doesn’t specify the use of an area monitor, it does require employers to have a method to alert employees to emergency situations. A wall-mounted EO monitoring system is an effective, practical method of satisfying this requirement.
The OSHA EO standard also requires employee training on ethylene oxide. Training should be provided when an employee is first assigned to the area and then annually.

OSHA Compliance Self-Assessment

1. Is representative initial employee exposure to ethylene oxide data, for both 8 hour and 15 min excursion, documented?
2. Does the department have a method to alert employees to an emergency situation (e.g., an EO area monitor with visual and audible alarms)?
3. Does the department have a written plan for emergency situations?

Environmental Protection Agency (EPA)

The EPA is a federal regulatory agency whose mission is to protect human health and the environment. Ethylene oxide is regulated as a pesticide by the EPA. All EPA registered pesticides must have an EPA registration number. Whether you’re using an EPA registered product at home or work, the label will include a strong statement instructing users to follow the directions provided on the product label.

The EPA periodically reviews the benefits and associated risks with the continued pesticide usage of chemicals, a process known as a Reregistration Eligibility review. In 2008, the EPA completed a Reregistration Eligibility Decision (RED) for Ethylene Oxide. In recognition of the public health benefits associated with the use of EO to sterilize medical devices, the decision permitted the continued use of ethylene oxide as a pesticide provided users adopt new risk mitigation measures indicated on EO labels.

The EPA RED for EO summarizes required labeling changes for three categories of EO pesticide users: hospitals/healthcare facilities; contract sterilization facilities; and beekeepers. There are two specific restrictions for EO usage in hospitals and healthcare facilities:

- “Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.”
- “After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.”

In addition to the specific restrictions for EO usage in hospitals described above, amended EO labels must include language about Personal Protective Equipment (PPE). The EPA recommends handlers wear a long-sleeved shirt and long pants, shoes and socks, and chemical resistant gloves. Respiratory protection is recommended when the ambient ethylene oxide concentration equals or exceeds the 1 ppm 8-hr time-weighted average Permissible Exposure Limit (PEL) stipulated by OSHA.

Under the provisions of the EPA’s Clean Air Act, ethylene oxide is considered a hazardous air pollutant (HAP) and hospitals are classified as area sources. The EPA issued a regulation in 2007 controlling air emissions from hospital sterilizers using ethylene oxide. The regulation requires hospitals to adopt a management practice of sterilizing full loads of items having a common aeration time. An exemption to full loads is allowed under medically necessary circumstances. The date and time of all EO sterilization cycles should be documented and any cycles not containing a full load (for medically necessary reasons) should be noted. The use of an air pollution control device, such as the 3M™ EO Abator, is an alternative compliance method.

Note that while this federal EPA regulation doesn’t require hospitals to purchase air pollution control equipment for ethylene oxide sterilizer exhaust, individual state or local regulations may be more stringent and restrict EO emissions to the atmosphere.

EPA Compliance self-assessment:

1. Unless medically necessary, does your facility run full loads of items to be EO sterilized or run the sterilizer exhaust through an air pollution control device such as an EO abator?
2. Does your facility perform EO sterilization and aeration in one chamber?

Association for the Advancement of Medical Instrumentation (AAMI)

AAMI is dedicated to increasing the understanding, safety, and efficacy of medical instrumentation. AAMI Standards and Recommended Practices represent a national consensus and many have been approved by the American National Standards Institute (ANSI) as American National Standards. Every CSSD doing EO sterilization should have a copy of ANSI/AAMI ST41.2008, Ethylene oxide sterilization in health care facilities: Safety and effectiveness, on hand in the department. AAMI ST41 incorporates guidance from OSHA’s occupational exposure standard for EO, as it relates to the practice of hospital-based EO sterilization, throughout the document.

AAMI ST41 recommends EO sterilization is centralized within a facility and that the sterilizers be located in a separate containment area that is actively ventilated (Section 3). This recommendation is intended to provide the maximum operational safety including control of personnel traffic patterns. Signs, with specific text provided by OSHA and AAMI, indicating the use of EO should be posted outside the containment or “regulated” area. EO sterilizers should be located in a room with a minimum of 10 total air exchanges per hour and the ventilation should be monitored and documented at least annually.

Typical EO sterilization parameters are provided in Section 8 of AAMI ST41. The operator is reminded to use packaging that is FDA cleared for use with EO, to place items loosely (to facilitate movement of moisture and sterilant) within the sterilizer baskets, and to select one of the programmed cycles offered by the sterilizer manufacturer. To ensure residual EO is removed from absorbent items prior to handling and patient use, consult the medical device and packaging material manufacturers for recommended aeration times. The sterilizer should be unloaded only after the load has been aerated for the time recommended for the load item having the longest aeration time.

Section 9 contains guidance unique to EO sterilization including a recommendation that sterilizers be vented either to the outside atmosphere using a dedicated exhaust line or to an emission control system. If EO emissions directly to the atmosphere are permissible, the vent line should be constructed of a material that is impervious to EO and should not end within 25 feet of any building air intake source or near pedestrian traffic. Recommendations about the storage and handling of both EO gas cylinders and unit dose containers of 100% EO are discussed. A list of elements that should be included in a written emergency plan is a nice resource for facilities developing an OSHA compliant emergency plan.

AAMI ST41 includes recommendations on monitoring the EO sterilization process in Section 10, Quality Control. For example, it is recommended that each processed item be labeled with a lot control.
the quarantining of implants until biological indicator results (as described in Section 10.7.2 of AAMI ST41) or a commercially available product that is equivalent in challenge to the routine test pack. The PCD is placed in the area of the chamber considered least favorable to sterilization, generally in the center of the load.

AAMI Compliance Self-Assessment
1. Is the area housing EO sterilizers labeled?
2. Is each EO sterilization cycle monitored with a BI PCD?

Centers for Disease Control and Prevention (CDC)
The CDC is part of the Department of Health and Human Services. CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States. The CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC) publishes many evidence-based guidelines, including the Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. This guideline includes a list of recommendations, a few of which are specific to ethylene oxide sterilization.

The Occupational Health and Exposure category of recommendations states that workers should be informed about the health effects of exposure to infectious agents and chemicals (1.a.) and that a program for monitoring occupational exposure to regulated chemicals should be established (1.d.). The Methods of Sterilization category includes recommendations that low temperature sterilization technologies (e.g., EO) be used to reprocess patient care items that are heat- or moisture-sensitive (14.d.) and that EO sterilized items be completely aerated before use (14.e.).

CDC Compliance Self-Assessment
1. Are EO sterilized items completely aerated before use?

The Joint Commission
An independent, not-for-profit organization, The Joint Commission accredits and certifies more than 19,000 healthcare organizations and programs in the United States. Each year, The Joint Commission updates their manual, Hospital Accreditation Standards (HAS), as a resource for facilities trying to achieve or maintain compliance with The Joint Commission’s requirements. The manual is divided into tabbed chapters, each including standards (i.e., statements that define performance expectations) and more detailed Elements of Performance (EPs) on which hospitals are scored.

So what does the manual have to say about EO sterilization of medical devices? The Environment of Care (EC) chapter discusses the management of risks in the environment. Standard EC.02.02.01 reads: “The hospital manages risks related to hazardous materials and waste.” EP9 under this standard requires hospitals to minimize risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous gases and vapors such as ethylene oxide. Standard EC.02.04.03 reads: “The hospital inspects, tests, and maintains medical equipment.” EP4 under this standard requires hospitals to conduct and document maintenance and performance testing of sterilizers.

On a more general level, ethylene oxide sterilization is one of the tools hospitals can use to satisfy standards in the Infection Control (IC) and National Patient Safety Goal (NPSG) sections of The Joint Commission’s HAS. IC.02.02.01 states, “The hospital implements infection prevention and control activities when doing the following: …EP2 Performing intermediate and high-level disinfection and sterilization of medical equipment, devices and supplies.” NPSG 07.05.01 requires hospitals to implement evidence-based practices for preventing surgical site infections. Effective sterilization of critical items is an essential component of facility efforts to prevent surgical site infections.
The Joint Commission Compliance Self-Assessment

1. Can you describe the methods your facility uses to minimize the risks associated with storing and using ethylene oxide?

2. Does your facility document performance testing and maintenance of its ethylene oxide sterilizers?

Conclusion

This self-study reviewed some of the key regulations and guidelines applicable to the use of ethylene oxide sterilization in hospitals. How did your facility fare in the self-assessment questions? If you identified areas for improvement or further investigation, refer to the source documents referenced at the end of the article to ensure your practices are in compliance with current laws and recommended practices.

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References


