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## Learning Objectives

1. Describe the purpose of the Environmental Protection Agency's new National Emission Standards for Hospital Ethylene Oxide (EO) Sterilizers.

2. Describe the requirements of the new standards for hospitals with and without air pollution control devices.

3. Develop a compliance plan for your facility.

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## SELF-STUDY SERIES

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### Regulatory Update:

# EPA emission standard for hospital EO sterilizers

by Susan Flynn, BESC, CSPDT

**A**s a Sterile Processing professional, you have a lot on your plate! In addition to the day-to-day responsibilities of providing reliable service for internal customers, dealing with the daily challenges of Operating Room case schedule changes, equipment maintenance and staff scheduling, you must also stay current with the alphabet soup of federal, state and local associations and agencies that develop recommended practices and regulations relevant to sterile processing. In December 2007, the U.S. Environmental Protection Agency (EPA) issued a final rule regulating emissions from hospital ethylene oxide (EO) sterilizers. This self-study will explore the background and requirements of this new rule. The good news is complying with the final rule shouldn't be difficult, as it basically reflects the current practice of running full loads.

### Background

Over the last 50 years, EO has been established as the "gold standard" of efficacy for low-temperature sterilization. Ethylene oxide offers both penetrability and compatibility with medical device materials, making it an excellent sterilant for heat- and/or moisture-sensitive medical devices that cannot tolerate the preferred method of steam sterilization. Ethylene oxide is used both in hospitals to sterilize reusable medical devices and in industry by medical device manufacturers and contract sterilizers to sterilize single-use medical devices. Outside of healthcare, EO is an important industrial chemical intermediate that is utilized in the manufacturing of surfactants, polyester polymers and antifreeze, an automotive coolant. While a very useful chemical, EO is also considered a hazardous air pollutant (HAP) under the provisions of the 1990 federal Clean Air Act. The Clean Air Act directs the U.S. Envi-

ronmental Protection Agency (EPA) to regulate emissions into the air of listed HAPs.

The EPA categorizes a stationary source that emits or has the potential to emit 10 tons per year (tpy) or more of any HAP or 25 tpy or more of any combination of HAPs as a major source. An area source, such as a hospital, is a stationary source of HAP emissions that is not a major source. Many of the hazardous air pollutants are widely used in a variety of industries. To reach its goal of further reducing pollutant emissions after regulating major sources, the EPA identified area sources responsible for the majority of the HAP emissions. Hospital sterilizers are listed as an area source of EO and the EPA therefore developed a new rule concerning emissions. After releasing a proposed rule for public comment in October 2006, the EPA issued a final rule regulating emissions from hospital EO sterilizers in December 2007.<sup>1</sup>

### So what does the new standard require?

The new EPA standard states that hospitals operating EO sterilizers *without* an air pollution control device must sterilize **full loads** of items having a common aeration time, except under medically necessary circumstances. A logical next question is what does the EPA consider a full load? The regulation defines a full load as "the maximum number of items that does not impede proper air removal, humidification of the load, or sterilant penetration and evacuation of the sterilization unit."<sup>1</sup> Running full loads is considered a generally available control technology (GACT) or management practice. The EPA recognizes that this is already the current practice at most facilities.

In fact, ANSI/AAMI ST41:1999, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*, provides a  
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**SELF-STUDY** from page 42

similarly worded recommended practice in section 6.8.1: "To the extent practical, the operator should attempt to sterilize full loads of items having a common aeration time."<sup>2</sup> For economic and efficiency reasons, the present practice at most facilities is to run a full load, generally at the end of the surgical day.

The standard defines "medically necessary" as "circumstances that a hospital central services staff, a hospital administrator, or a physician concludes, based on generally accepted medical practices, necessitate sterilizing without a full load in order to protect human health."<sup>1</sup> Central services staff include a manager or technician "directly involved or responsible for sterile processing at a hospital."<sup>1</sup> This definition, which maintains decision-making as a central services staff responsibility, helps minimize any workflow disruption that might otherwise be caused by the new standard.

Hospitals sterilizing medical devices under research and development may use the medically necessary exception to run a less than full load as the EPA understands such devices may have to be sterilized separately from devices used in patient care.

The use of an air pollution control device is an acceptable alternative compliance option to the management practice of running full loads. The EPA defines an air pollution control device as "a catalytic oxidizer, acid-water scrubber, or any other air pollution control equipment that reduces the quantity of ethylene oxide in the effluent gas stream from sterilization and aeration processes."<sup>1</sup> The 3M EO Abator, depicted in Figure 1, is a commonly used air pollution control device for 100% EO sterilizers.

The abator converts EO from the sterilizer exhaust into carbon dioxide and water vapor through a heated catalytic process. Hospitals with air pollution control devices will have to submit an Initial Notification of Compliance Status but do not have to run full loads. Note



**Figure 1:**  
3M EO Abator, an example of an air pollution control device

that while an air pollution control device is an alternative compliance option, the rule does not require hospitals to purchase air pollution control devices.

After EO sterilization, some facilities transfer the load of sterilized

goods to a separate chamber for aeration. While sterilizers must be connected to an air pollution control device under the alternative compliance option, it is not necessary to connect the aerator exhaust to the air pollution control device. Note, however, that connecting aerator exhaust to an air pollution control device may be required by some state or local regulations and the new standard does not change any such existing requirements.

Some jurisdictions across the country already require the use of an air pollution control device to minimize EO emissions to the atmosphere. The new EPA National Standard doesn't change your obligation to comply with any existing regulations. While states are prohibited from setting standards that are *less* stringent than EPA national standards, this final rule does not affect state or local emission standards that are *more* stringent than the requirements of the new national emission standard.

**Does the new standard apply to my facility?**

The emission standards apply to new and existing hospital sterilizers that emit EO. The rule defines a hospital as a facility

that provides patient care 24 hours per day on an inpatient basis.

**What new record keeping must be done?**

Thorough documentation is second nature in the sterile processing department. Hospitals generally already maintain detailed sterilizer records and follow the recommended practice described in ANSI/AAMI ST41:1999, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*, section 7.2.2, of documenting each sterilization cycle.<sup>2</sup> New record keeping required by the EPA standard for EO sterilizers not equipped with an air pollution control device is to record whether a full load was run.

Hospitals may wish to update their paper or electronic sterilizer log system to include a place to document whether a full load was run, and if not, a statement that the less than full load was medically necessary. These "records must be in a form suitable and readily available for expeditious review" and kept for 5 years. The rule specifies that records must be kept onsite for 2 years. Review your current sterilizer record retention policy to be sure it is consistent with the requirements of the new standard. Additionally, hospitals should keep a copy of their Initial Notification of Compliance Status on file.

**How much time do we have to comply?**

Hospitals with existing EO sterilizers must comply by December 29, 2008. Hospitals starting up new sterilizers after December 28, 2007 must comply upon startup. All facilities must submit an Initial Notification of Compliance Status no later than 180 days after their compliance date. The standard doesn't provide a form for the Initial Notification of Com-

**Table 1: Compliance requirements for hospitals with and without air pollution control devices.**

Hospitals with EO sterilizers, but without an air pollution control device	Hospitals with an air pollution control device but not subject to state or local regulation must	Hospitals with an air pollution control device and subject to state or local regulation
<ol style="list-style-type: none"> <li>1. Submit an Initial Notification of Compliance Status describing your installation (name and address of the owner, physical location of the source, description of the EO sterilization facility including the typical number of sterilization cycles/year, etc.) and certifying that you will adhere to the full load management practice.</li> <li>2. Record the date and time of each sterilization cycle.</li> <li>3. Note any sterilization cycles that were not a full load, including a statement from a hospital central services staff member, hospital administrator, or a physician that it was medically necessary.</li> </ol>	<ol style="list-style-type: none"> <li>1. Submit an "Initial Notification of Compliance Status certifying that you are venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device. You must certify that you are operating the control device during all sterilization processes and in accordance with manufacturer's recommended procedures."<sup>1</sup></li> </ol>	<ol style="list-style-type: none"> <li>1. Submit an "Initial Notification of Compliance Status certifying that you are operating the sterilization unit in accordance with your State or local regulation and following control device manufacturer's recommended procedures."<sup>1</sup></li> </ol>

pliance Status but does detail the required information and provide both e-mail and U.S. mail addresses to which the notification can be sent.<sup>1</sup>

## Summary

The use of EO has not been banned and the EPA recognizes the necessary use of EO to sterilize certain medical devices.<sup>1</sup> The new EPA National Emission Standards for Hospital Ethylene Oxide Sterilizers requires hospitals that do **not** have an air pollution control device to adopt the management practice of running full loads of items having a common aeration time except under medically necessary circumstances. The date and time of all EO sterilization cycles should be documented and any loads not containing a

full load for medically necessary reasons should be noted.

The rule does not require hospitals to purchase an air pollution control device. The use of an air pollution control device is, however, an acceptable alternative to the management practice of running full loads. All hospitals operating EO sterilizers should submit an Initial Notification of Compliance Status providing a description of their EO sterilization system and their intended certification plan (i.e. intention to run full loads or use of an air pollution control device) within 180 days of their compliance date. **HPN**

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*MN. She is routinely involved in troubleshooting and addressing sterilization questions. Flynn's role at 3M includes providing education for customers and sales personnel on improving the performance of the sterilization process and implementing best practices. Flynn is a certified Central Sterile Processing and Distribution Technician. In addition she is a member of several AAMI working group committees that are developing recommended practices.*

## References

1. Federal Register / Vol. 72, No. 248 / Friday, December 28, 2007 / Rules and Regulations. Environmental Protection Agency. 40 CFR Part 63: National Emission Standards for Hospital Ethylene Oxide Sterilizers. A copy of the final rule can be found at: <http://www.epa.gov/fedrgstr/EPA-AIR/2007/December/Day-28/a25233.pdf>
2. Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.* ANSI/AAMI ST41:1999. Arlington, VA: AAMI, 1999. American National Standard.

## CONTINUING EDUCATION TEST • APRIL 2008

### Regulatory Update: EPA emission standard for hospital EO sterilizers

#### Circle the one correct answer

1. Ethylene oxide (EO) is used to sterilize heat- and/or moisture-sensitive medical devices.
  - A. True
  - B. False
2. The Environmental Protection Agency (EPA) regulates emissions of hazardous air pollutants.
  - A. True
  - B. False
3. The EPA has identified hospital EO sterilizers as area sources of EO.
  - A. True
  - B. False
4. To comply with the new EPA Emission Standards for Hospital Ethylene Oxide sterilizers, hospitals operating an EO sterilizer *without* an air pollution control device must run full loads of items having a common aeration time.
  - A. True
  - B. False
5. Under the new EPA Emission Standards for Hospital Ethylene Oxide sterilizers, less than full loads can be run if medically necessary.
  - A. True
  - B. False
6. Hospitals have until June, 2012 to comply with the new standard.
  - A. True
  - B. False
7. The EPA has *not* banned the use of EO as a hospital sterilant.
  - A. True
  - B. False
8. Hospitals using EO sterilizers *without* an air pollution control device must document the date and time of each EO sterilization cycle.
  - A. True
  - B. False
9. Hospitals using EO sterilizers must purchase an air pollution control device to comply with the new EPA Emission Standards for Hospital Ethylene Oxide sterilizers.
  - A. True
  - B. False
10. All facilities using EO sterilizers must submit an Initial Notification of Compliance Status.
  - A. True
  - B. False

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