



4th Annual

Hospitals for a Healthy Environment Fall Extravaganza

Workshop & Tradeshow

Oct 2, 2009

National Emission Standards for Hospital
Ethylene Oxide Sterilizers

Final Rule published December 28, 2007

Purpose

- **The purpose of the presentation is to provide compliance assistance as well as pollution prevention information regarding 40 CFR Part 63 Subpart WWWW Final Rule (5W)**
- **Summary of the regulations controlling air emissions for hospital sterilizers using ethylene oxide**

Overview

- **What Is an Area Source?**
- **Who Does This Rule Apply To?**
- **Requirements**
- **What are the Impacts?**
- **What Is/Was The Compliance Date?**
- **How do I know if my sterilization facility is existing or new?**
- **The Permitting Requirements?**
- **Records & Reporting That Are Required?**
- **References**
- **State & Local Permitting Contacts**



New EPA Regulations for Hospital Sterilizers

40 CFR Part 63 Subpart WWWW

- EPA has requirements to reduce air pollution on hospital sterilizers that use the chemical ethylene oxide (EO). This chemical poses health risks to anyone who breathes the air that contains it.

<http://www.epa.gov/ttn/atw/area/fr28de07b.pdf>

EPA regulations for Hospital Sterilizers

40 CFR Part 63 Subpart WWWW

- The regulations require hospitals that have sterilizers that use ethylene oxide to do several things to minimize the chemical from getting into the air during its use.

What Is an Area Source?

- "Area" sources are those stationary sources that emit less than 10 tons annually of a single hazardous air pollutant (HAP) or less than 25 tons annually of any combination of HAPs.
- Any stationary source that is not a major source.

(A major source is a stationary source of HAPs that emits, or has the potential to emit in the absence of controls, at least 10 tons per year (TPY) of an individual HAP or 25 TPY of any combination of HAP.)

Who Does This Rule Apply To?

- Hospitals that are area sources of HAP emissions and own or operate an ethylene oxide sterilization facility.
- “Hospitals” are defined as those facilities that provide medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under 24 hr/day nursing care.

Who Does This Rule Apply To?

(cont)

- Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services on an outpatient basis.

Requirements



- Hospitals must have a management practice to sterilize full loads of items having a common aeration time. An exception to full loads is allowed under medically necessary circumstances.
- Medically necessary refers to circumstances that necessitate sterilizing without a full load to protect human health. The medically necessary circumstance can be decided by a hospital central services staff member, a hospital administrator, or a physician, based on generally accepted medical practices.

Requirements (cont.)

- Hospitals which route the chemical ethylene oxide to an add-on air pollution control device are in compliance with the rule requirements.
- *APCD Air pollution control device* means 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.

How The Rule May Impact Hospitals

- Approximately 630 hospitals nationwide that do not currently have add-on APCDs for EO will be expected to implement the management practice.

Sterilization Cycle Records Should Include:

- Date and time of each sterilization cycle.
- Whether the cycle contained a full load or not.
- If not run full load, a statement from hospital staff that it was medically necessary.

What Is/Was The Compliance Date?

- Existing Sources: December 29, 2008.
- New Sources: December 28, 2007 or upon startup if startup occurs after December 28, 2007.



How do I know if my sterilization facility is existing or new?

- You are an existing source if you began construction or reconstruction of the EO sterilization facility before November 6, 2006.
- You are a new source if you began construction or reconstruction of the EO sterilization facility on or after November 6, 2006.



The Permitting Requirements?

- Hospital EO sterilizer area sources are not required to obtain a title V operating permit provided they are not required to obtain an operating permit for another reason.



Required Recordkeeping



- Hospitals must keep a copy of the notification.
- Hospitals must keep copies of Sterilization Cycle Records for each sterilizer not equipped with an add-on air pollution control device.
- Hospitals must maintain records in a form available for quick review.

What Reporting Is Required?

- **Reporting:**

- Initial Notification of Compliance Status (INOCS), due 180 days after your compliance date.
- INOCS informs EPA that the hospital is subject to the Standard and indicates where compliance is based on following the management practice or on use of an add-on APCD that reduces EO emissions to the atmosphere.
- INOCS provides certification of compliance with standards.

What Records Are Required?



- Recordkeeping:
 - Records include copies of INOCS and Sterilization Cycle Records for each sterilizer not equipped with an add-on APCD.
 - Records to be maintained in a form suitable and readily available for expeditious review.
- Maintain records for 5 years
- Maintain records on site for at least 2 years

Notification

All hospitals must send a notification to EPA with some general information by June 25, 2009:

- Name and address of owner or operator of hospital sterilizer
- Address (physical location) of the sterilization facility
- Confirmation of how the hospital is complying with the regulation.
- An example of this notification is found here:
http://www.epa.gov/ttn/atw/area/inocs_example.doc

References

- <http://www.epa.gov/ttn/atw/area/fr28de07b.pdf>
- <http://www.4cleanair.org/contactUsaLevel.asp>
- http://www.epa.gov/ttn/atw/area/inocs_example.doc
- http://www.epa.gov/ttn/atw/area/regional_contacts.pdf
- <http://www.smallbiz-enviroweb.org/sba/sbap.html>
- www.epa.gov/ttn/atw/eparules.html
- <http://www.epa.gov/ttn/atw/area/arearules.html>
- <http://www.epa.gov/ttn/atw/area/sterilizersb.pdf>
- <http://www.epa.gov/ttn/atw/area/hospitalsbs.doc>
- http://www.epa.gov/ttn/atw/area/inocs_example.doc

State Permitting Contacts

- Iowa: Doug Campbell (515) 281-8930
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Local Permitting Contacts

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