National Emissions Standards for Hospital Ethylene Oxide Sterilizers
EPA Final Rule 40 CFR 63, Subpart W W W W W
Federal Register, Volume 72, No. 248, December 28, 2007 pp.73611- 73625

Attached is an EPA Final Rule setting forth hospital actions to control ethylene oxide emissions from their sterilizers. [40 CFR 63, Subpart W W W W W, December 28, 2007, pp. 73611-73625].

SUMMARY:

The Rule is set forth in its entirety on 3 pages (73623 to 73625). Hospital Central Service Managers should find that compliance is consistent with their current procedures for monitoring ethylene oxide sterilizer operations and recordkeeping. Hospitals may comply in one of two ways:

1. By a work practice in which ethylene oxide sterilizers are run fully loaded. The hospital can run a less-than-fully loaded sterilizer in those medically necessary circumstances when patient health must be protected, for example when there is a need to meet surgical schedules. The Central Service Manager or the sterilizer technician must note on the record for each sterilizer cycle whether the sterilizer has been run with a full load or not, and when the sterilizer has not been run fully loaded, note that it was medically necessary to do so and sign the record.

OR

2. The hospital may install an ethylene oxide emission control device and operate it in accordance with state or local regulations, as well as the manufacturer's recommended procedures. Typically, this has been done by hospitals in localities that mandate control of ethylene oxide emissions.

The Rule stipulates by what dates the hospital must comply. Compliance is demonstrated by providing the EPA and the local authorities, as appropriate, with a Notice of Initial Compliance Status; and by keeping sterilizer records for up to five years, of which two years must be onsite.

DETAILS follow below and are contained in the Rule itself, which is attached.

Who is covered? The Rule is set forth on pages 73623-73625. It specifies that if you own or operate an ethylene oxide [EO] sterilizer at a hospital that is an area source of hazardous air pollutants, you must comply with Part 63, Subpart W W W W W. [Section 63.10382]

What Management Practice Must I Meet? [Section 63.10390]

Unless you operate a sterilizer with an air pollution control device, you must sterilize full loads of items that require the same sterilizer cycle. [In the language of the Rule, "common aeration time". Most EO sterilizers can run only two cycles – a low temperature or a high temperature one. The low temperature cycle needs more aeration time. Most hospitals run low temperature cycles only a few times per year.]

You can run less than full loads if "medically necessary circumstances" require you to do so. This decision can be made by Hospital Central Service Staff[1], a Physician, or a Hospital Administrator. The decision is based on generally accepted medical practices, that running less than a full load is needed to "protect human health." [Also see Section 63.10448, Definitions - "Medically necessary."[2]]

When must I comply?

If your EO sterilizer was *INSTALLED, OR REBUILT*, before November 6, 2006, it is considered an existing source. The *COMPLIANCE DATE* is December 29, 2008. You have 180 calendar days from the *COMPLIANCE DATE*: December 29, 2008, to demonstrate Initial Compliance with this Rule. [Section 63.10384(a) and Section 63.10402] *[NOTE: Most sterilizers using Oxyfume® 2002 sterilant were installed or rebuilt before November 6, 2006.]*

If your EO sterilizer was *INSTALLED, OR REBUILT*, after November 6, 2006, but before December 28, 2007, it is considered a new source. The *COMPLIANCE DATE* is December 27, 2007. You have 180 calendar days from the *COMPLIANCE DATE*: December 27, 2007, to demonstrate Initial Compliance with this Rule. [Section 63.10384(b) and Section 63.10402]

If you start up a *NEW* EO sterilizer after December 28, 2007, it is considered a new source. The *COMPLIANCE DATE* is the start-up date of the EO sterilizer. You must demonstrate Initial Compliance with this Rule on the *COMPLIANCE DATE*. [Section 63.10384(c) and Section 63.10402]

How do I demonstrate Initial Compliance?

If you operate a sterilizer with an air pollution control device[3], follow certifying instructions in Section 63.10400 (b) or (c).

If you operate a sterilizer without an EO emission control device, follow the certifying instructions in Section 63.10400(a) and Section 63.10430.

If you are subject to the requirements of Section 63.10400 (a), (b) or (c), you must submit an Initial Notice of Compliance Status. In addition to the certification required in

[1] Hospital Central Service Staff" is defined as: "a healthcare professional, including manager and technician, who is either directly involved in or responsible for sterile processing . . ." [Section 63.10448]
[2] For more background of the EPA intent, see *V. Summary of Comments and Responses, 3. Exception to the Management Practice Requirement*, pp. 73614-15 of the attached Rule.
[3] Air pollution control device: a catalytic oxidizer, acid-water scrubber, or any other air pollution control that reduces the quantity of EO in the effluent gas stream from the sterilization processes and aeration processes (Section 63.10448)

Section 63.10400, include the following information in the notice [see Section 63.10430(a) for the complete requirement]:

1. Name and address of the hospital.
2. Address - and location - of the EO sterilizer [Usually the address is the same as the address of the hospital]
3. An identification of the applicable standard as "40CFR63, Subpart W W W W W".
4. Describe the facility:
    a. List each EO sterilizer and its size, preferably in cubic feet.
    b. Identify each sterilizer as "existing" or "new" source as defined above.
    c. Include the *COMPLIANCE DATE* for each sterilizer.
    d. List the number of aerators, if any.
    e. State the total pounds of EO the facility uses each year.

        i. Lbs. EO in Oxyfume 2002 used per year = # of cylinders/year x 13.5

        ii. Lbs. EO in Oxyfume 2000 used per year = # of cylinders/year x 11.6

    f. State the number of sterilization cycles typically run in a year.
    g. Specify how the gas is emitted [Usually gases from <u>all</u> EO sources are sent to a dedicated exhaust line to the roof. EO gases are sent from the chamber during post vacuum steps, from the chamber, or separate aerator if you have one, during aeration, from the safety relief valves on the chamber or aerator, and from capture boxes above [i] the drains and [ii] connections at the gas cylinder.]
5. A statement that the affected source is an area source of hazardous air pollutant emissions.

<u>Submit the initial Notification to the appropriate Authority:</u>

1. Submit to the EPA Office of Air Quality Planning and Standards via e-mail or US mail. e-mail and postal addresses are listed in Section 63.10430(b).
2. Additionally, when they are designated, you must submit to the designated State and local authorities for Part 63, Sub-part W W W W W. [Delegated authorities are identified in Part 63, Subpart E, Section 63.99][4]
3. Copies of the Initial Notification sent to the designated local authority must be sent to the Regional EPA Office. [Attached is a list of Regional EPA office addresses in Part 63, Subpart A, Section 63.13.][4]

[4] Part 63, Subparts A through Z may be found on the following link:
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;rgn=div5;view=text;node=40%3A9.0.1.1.1;idno=40;sid=ced006e1fbe09632c3f6c2bfaad3a774;cc=ecfr#PartTop

Each copy of Initial Notification of Compliance Status should be kept onsite, readily available for review.

What are the Continuous Compliance Requirements? [Section 63.10420]

For each sterilizer that does not have an EO emission control device, you must maintain records. They may be included in those you now keep for each sterilization cycle. The records should state:

1. Date and time of the sterilization cycle
2. Whether or not the cycle contains a full load of medical devices
3. If less than a full load, a signed notation from Central Service Staff[1], a hospital administrator, or a physician that it was medically necessary to run less than a full load.

Records, in a form suitable for review, must be kept for five [5] years – onsite for at least two [2] years. You may keep them offsite for the remaining three [3] years. [Section 63.10432]

§ 63.13 Addresses of State air pollution control agencies and EPA Regional Offices.

(a) All requests, reports, applications, submittals, and other communications to the Administrator pursuant to this part shall be submitted to the appropriate Regional Office of the U.S. Environmental Protection Agency indicated in the following list of EPA Regional Offices.

EPA Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont), Director, Air, Pesticides and Toxics Division, J.F.K. Federal Building, Boston, MA 02203-2211.

EPA Region II (New Jersey, New York, Puerto Rico, Virgin Islands), Director, Air and Waste Management Division, 26 Federal Plaza, New York, NY 10278.

EPA Region III (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia), Director, Air Protection Division, 1650 Arch Street, Philadelphia, PA 19103.

EPA Region IV (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee). Director, Air, Pesticides and Toxics Management Division, Atlanta Federal Center, 61 Forsyth Street, Atlanta, GA 30303-3104.

EPA Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin), Director, Air and Radiation Division, 77 West Jackson Blvd., Chicago, IL 60604-3507.

EPA Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas), Director, Air, Pesticides and Toxics, 1445 Ross Avenue, Dallas, TX 75202-2733.

EPA Region VII (Iowa, Kansas, Missouri, Nebraska), Director, Air, RCRA, and Toxics Division, U.S. Environmental Protection Agency, 901 N. 5th Street, Kansas City, KS 66101.

EPA Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming), Director, Air and Toxics Division, 999 18th Street, 1 Denver Place, Suite 500, Denver, CO 80202-2405.

EPA Region IX (Arizona, California, Hawaii, Nevada, American Samoa, Guam), Director, Air and Toxics Division, 75 Hawthorne Street, San Francisco, CA 94105.

EPA Region X (Alaska, Idaho, Oregon, Washington), Director, Office of Air Quality, 1200 Sixth Avenue (OAQ-107), Seattle, WA 98101.

(b) All information required to be submitted to the Administrator under this part also shall be submitted to the appropriate State agency of any State to which authority has been delegated under section 112(l) of the Act. The owner or operator of an affected source may contact the appropriate EPA Regional Office for the mailing addresses for those States whose delegation requests have been approved.

(c) If any State requires a submittal that contains all the information required in an application, notification, request, report, statement, or other communication required in this part, an owner or operator may send the appropriate Regional Office of the EPA a copy of that submittal to satisfy the requirements of this part for that communication. [59 FR 12430, Mar. 16, 1994, as amended at 63 FR 66061, Dec. 1, 1998; 67 FR 4184, Jan. 29, 2002; 68 FR 32601, May 30, 2003; 68 FR 35792, June 17, 2003]