What Is The Compliance Date?

- Existing Sources: December 29, 2008.
- New Sources: Upon initial startup.

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.

What Are The Permitting Requirements?

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

What Records Are 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.
- Please send INOCS to EPA Headquarters (U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460), your EPA regional office and to the delegated state agency found at the following link: **http://www.4cleanair.org/contactUsaLevel.asp**
- No ongoing compliance reports 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.

You can also contact your Regional EPA air toxics office at the following numbers:

Address	States	Website/ Phone Number
Region 1 1 Congress Street Suite 1100 Boston, MA 02114-2023	CT, MA, ME, NH, RI, VT	www.epa.gov/region1 (888) 372-7341 (617) 918-1650
Region 2 290 Broadway New York, NY 10007-1866	NJ, NY, PR, VI	www.epa.gov/region2 (212) 637-4023
Region 3 1650 Arch Street Philadelphia, PA 19103-2029	DE, MD, PA, VA, WV, DC	www.epa.gov/region3 (800) 241-1754 (215) 814-2196
Region 4 Atlanta Federal Center 61 Forsyth Street, SW Atlanta, GA 30303-8960	FL, NC, SC, KY, TN, GA, AL, MS	www.epa.gov/region4 (404) 562-9131
Region 5 77 West Jackson Blvd. Chicago, IL 60604-3507	IL, IN, MI, WI, MN, OH	www.epa.gov/region5 (312) 353-3575 (312) 353-4145 (312) 886-3850
Region 6 1445 Ross Avenue Suite 1200 Dallas, TX 75202-2733	AR, LA, NM, OK, TX	www.epa.gov/region6 (800) 621-8431* 214-665-7171
Region 7 901 North Fifth Street Kansas City, KS 66101	IA, KS, MO, NE	www.epa.gov/region7 (800) 223-0425 (913) 551-7003
Region 8 1595 Wynkoop St. Denver, CO 80202-1129	CO, MT, ND, SD, UT, WY	www.epa.gov/region8 (800) 227-8917* (303) 312-6460
Region 9 75 Hawthorne Street San Francisco, CA 94105	CA, AZ, HI, NV, GU, AS, MP	www.epa.gov/region9 (415) 744-1197
Region 10 1200 6th Ave. Suite 900, AWT-107 Seattle, WA 98101	AK, ID, WA, OR	www.epa.gov/region10 (800) 424-4372* (206) 553-6220

*For sources within the region only.

For More Information

Copies of the rule and other materials are located at :
http://www.epa.gov/ttn/atw/area/arearules.html

For more information on state requirements, please contact your state representative found at the following link:
http://www.4cleanair.org/contactUsaLevel.asp

United States Environmental Protection Agency
February 2008
www.epa.gov/ttn/atw/eparules.html

Office of Air Quality Planning & Standards (EI 43-02)

EPA

Summary of Regulations Controlling Air Emissions from the

HOSPITAL STERILIZERS USING ETHYLENE OXIDE

NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS NESHAP (SUBPART WWWWW) FINAL RULE

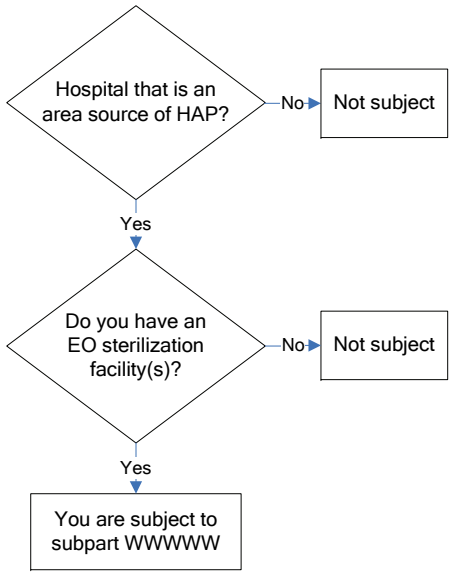
HOSPITAL STERILIZERS
(SUBPART WWWWW)

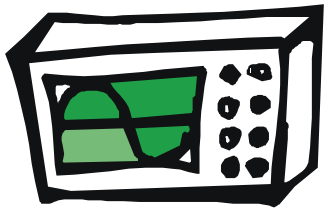
What Is an Area Source?

- Any source that is not a major source. (A major source is a facility that emits, or has the potential to emit in the absence of controls, at least 10 tons per year (TPY) of individual hazardous air pollutants (HAP) or 25 TPY of combined HAP.)

Who Does This Rule Apply To?

- Hospitals that are area sources of HAP emissions and own or operate an ethylene oxide (EO) 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. 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.





What Am I Required To Do?

- Hospitals must implement 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, a hospital administrator, or a physician, based on generally accepted medical practices.
- Hospitals which route EO to an air pollution control device (APCD) are in compliance with the rule requirements.

What Are The Impacts?

- Approximately 630 hospitals 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 was run full or not,
- If not run full, a note from hospital staff that it was medically necessary.

Initial Notification of Compliance Status

- Name and address of owner or operator.
- Address (physical location) of the hospital facility.
- Indicate that you are subject to 40 CFR, part 63, subpart WWWWW.
- Indicate that you are an existing or new sterilization facility, and include the date of construction or reconstruction.
- Compliance date.
- Description of the sterilization facility, include Number of EO sterilization units, the volume of each, number of aeration units, annual amount of EO usage, add-on APCD used to control EO emissions to the atmosphere for each sterilizer, if applicable, and number of sterilization cycles per year.
- **Certify to one of the following:**
  - ◊ Sterilizing full loads of items with common aeration time except under medically necessary circumstances; or
  - ◊ Operating the sterilization units with an add-on APCD required by a State or local regulation and that you are operating in accord with the State or local regulation and following APCD manufacturer recommended procedures; or
  - ◊ Operating the sterilization units with an add-on APCD (but are not subject to a State or local requirement to do so), venting EO emissions from each sterilization unit to the add-on APCD, operating the APCD during all sterilization processes, and following APCD manufacturer recommended procedures.