

EPA's NEW REGULATION CONTROLLING ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL STERILIZATION AND FUMIGATION

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BACKGROUND

In December 1994, the U.S. Environmental Protection Agency (EPA) issued national regulations to control air emissions of ethylene oxide, a hazardous air pollutant, from commercial sterilization and fumigation operations. The regulation, subpart O of 40 CFR part 63, appeared in the December 6, 1994, edition of the Federal Register [volume 59, beginning on page 62585].

Why is the EPA regulating commercial sterilization and fumigation operations?

The Clean Air Act (CAA) as amended in 1990 directs EPA to regulate emissions into the air of 189 toxic chemicals, including ethylene oxide, from a wide range of industrial sources. EPA is regulating the emissions of ethylene oxide from commercial sterilization and fumigation operations to meet the requirements of the CAA. Congress included ethylene oxide on its list of CAA toxic chemicals because it is suspected to cause cancer in humans, is highly mutagenic and teratogenic, and has significant acute and subchronic exposure health effects.

Commercial sterilization and fumigation sources that use ethylene oxide as a sterilant for heat and moisture sensitive products and as a fumigant to control microorganisms or insects are subject to the new regulation. Products that are typically sterilized or fumigated with ethylene oxide include medical equipment and supplies, pharmaceuticals, spices, books, museum artifacts, and cosmetics.

Approximately 200 ethylene oxide commercial sterilization and fumigation sources exist in the United States; approximately 150 of these sources are expected to be affected by the regulation. EPA estimates that full compliance with its new regulation will reduce the amount of ethylene oxide released into the air by 1,100 tons.

What is an affected source?

All sources that use ethylene oxide in sterilization or fumigation operations are affected sources (with the exceptions identified below). Affected sources that use less than 1 ton per year of ethylene oxide are required to demonstrate by recordkeeping that their ethylene oxide usage is actually below 1 ton per year. Affected sources using 1 ton per year or more of ethylene oxide are subject to the emissions reductions and limits of the regulation. The following sterilization sources are specifically exempted from this regulation and are therefore not "affected sources": beehive fumigators; research and laboratory facilities as defined in section 112(c)(7) of the CAA; and medical facilities whose primary purposes are to provide medical services to humans or animals.

How does the new Federal EPA regulation relate to State or local requirements?

State or local requirements that may have affected you prior to the new EPA regulation continue to apply. The new EPA regulation is the minimum emission reduction that is required nationally. Some State and local agencies do require stricter limits.

How does the new EPA regulation affect you?

The regulation affects sources using ethylene oxide for sterilization or fumigation operations. How you are affected depends on the amount of ethylene oxide you use.

In general, the regulation requires:

- Emissions reductions and limits
- Initial performance testing
- Ongoing monitoring
- Recordkeeping
- Reporting

These requirements are summarized in this pamphlet.

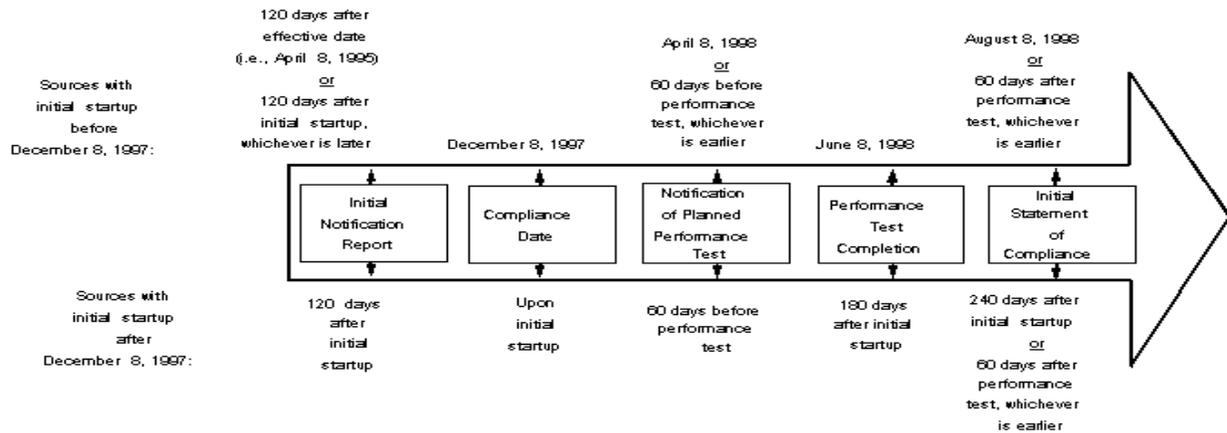
REGULATION

What about the General Provisions?

In addition to the requirements in the regulation, further requirements are located in the General Provisions, subpart A of 40 CFR part 63 [appeared in the March 16, 1994, edition of the Federal Register, volume 59, beginning on page 12430]. A table in the new EPA regulation identifies General Provisions requirements that are applicable to this industry. In general, these requirements include:

- **Construction/reconstruction:** Sources must submit an application for approval of any construction or reconstruction projects starting after December 8, 1994.
- **Compliance:** Sources must not exceed emissions levels specified in this regulation.
- **Performance test:** Sources must develop a test plan, conduct performance tests, get EPA approval for any alternate test methods to be used, analyze the data from the test, keep records of and report results of the test, or apply for a test waiver.
- **Monitoring:** Sources must install monitoring systems, evaluate the performance of the monitoring systems, get EPA approval for any alternate monitoring methods to be used, and convert data from monitoring systems to standard units.
- **Notification:** Sources using 1 ton or more of ethylene oxide must give EPA initial notification of their being subject to this regulation, notify EPA of upcoming performance tests of the emissions reduction equipment and evaluations of the monitoring equipment, and notify EPA of initial compliance with this regulation.
- **Recordkeeping:** Sources must keep records to document compliance with this regulation.
- **Reporting:** Sources must submit semi-annual compliance reports summarizing excess emissions, monitoring system performance, etc.

Compliance Schedule



Emissions Reductions And Limits

The regulation specifies emissions standards and provides reference emission reduction techniques that may be used to comply with the requirements. However, you may use another emission reduction technique as long as the level of emission reduction is the same or better.

Vent type*	Emissions Standard (see §3.362)		Emission reduction technique (see §3.363)
	>10 tons per year EO usage	1 to 10 tons per year EO usage	
SCV	99% emission reduction		Acid-water scrubber; OR Catalytic or thermal oxidation unit
ARV	99% emission reduction OR 1 ppmv concentration limit	no control	Catalytic or thermal oxidation unit
CEV	Manifold to emission reduction device used to control SCV or ARV OR 99% emission reduction	5,300 ppmv chamber concentration limit prior to activation of chamber exhaust	Acid-water scrubber; OR Catalytic or thermal oxidation unit

* SCV = sterilization chamber vent

ARV = aeration room vent

CEV = chamber exhaust vent/backdraft vent

Initial Testing

Initial testing is required by June 8, 1998, for sources with initial startup before December 8, 1997, to demonstrate that you are meeting the emission requirement for each vent type. During testing you will also establish operating parameter values (e.g., ethylene glycol concentration, scrubber liquor tank level, or temperature) that correspond to compliance with the emission requirement. The regulation contains test methods for measuring performance of the emission reduction device.

Vent type		Performance test method	
		>10 tons per year EO usage	1 to 10 tons per year EO usage
SCV	First evacuation	see §3.365(b)(1) for percent reduction	
	Last evacuation	see §3.365(b)(2) for percent reduction	
ARV		see §3.365(c)(1) for concentration limit; OR see §3.365(d)(1) for percent reduction	none required
CEV		see §3.365(d)(2) for percent reduction	see §3.365(c)(2) for concentration limit

Ongoing Monitoring

Continuous compliance with the regulation is demonstrated through ongoing monitoring of the operating parameter values established during initial testing. The monitoring requirements vary depending on the type of emission reduction technique that you use.

Emission reduction technique	What to monitor?	How often?	Procedure for establishing monitoring parameters
Acid-water scrubber	Ethylene glycol concentration; OR Scrubber liquor tank level	once per week	see §3.365(e)
Catalytic or thermal oxidation unit	Temperature	continuously	see §3.365(f)
For any type of emission reduction technique used to control emissions for ARV and for CEV (1 to 10 tons)	Ethylene oxide concentration may be monitored	once per hour for ARV; before activating the chamber exhaust for CEV	see §3.365(c)(1) for ARV; see §3.365(c)(2) for CEV

Recordkeeping

The regulation requires that sources keep records to document compliance with the regulation. Records for sources using 1 ton or more of ethylene oxide per year include performance test results, monitoring and calibration data, and malfunctions and exceedances data. Records for sources using less than 1 ton of ethylene oxide per year include annual usage data to demonstrate that you are not subject to the regulation. (You do not have to submit this data, but you must keep in on file.) All records must be kept for 5 years.

Reporting

Reports for sources using 1 ton or more of ethylene oxide per year include initial notification that the source is subject to this regulation, notification of performance tests and monitoring system evaluations, initial statement of compliance, and semi-annual compliance reports (on-going) that contain information on the compliance status of the source.

Whom can you contact for additional information?

For more information on this regulation, please call your State or local air pollution control agency; your State Small Business Assistance Program; or your State Small Business Ombudsman.

Another source of information is the Regional Office where your State or territory resides.

Region	Telephone #	States covered
1	(617) 565-4044	CT, ME, MA, NH, RI & VT
2	(212) 264-6819	NJ, NY, Puerto Rico & Virgin Islands
3	(215) 597-9162	DE, MD, PA, VA, WV & District of Columbia
4	(404) 347-3555	AL, FL, GA, KY, MS, NC, SC & TN
5	(312) 353-5546 (312) 886-6188 (312) 886-1425	IL, IN, MI, MN, OH, & WI
6	(214) 665-7549	AR, LA, NM, OK & TX
7	(913) 551-7097	IA, KS, MO & NE
8	(303) 293-1886	CO, MT, ND, SD, UT & WY
9	(415) 744-1145	AZ, CA, HI, NV, American Samoa & Guam
10	(206) 553-1949	AK, ID, WA & OR

Information related to this regulation may be obtained from EPA's Technology Transfer Network (TTN):

Data Transfer (919) 541-5742

Information (919) 541-5384

Documents that have been placed on the TTN include this pamphlet, the final preamble and regulation, and the Background Information for Final Standards (EPA-453/R-94-084b).

The information in this pamphlet is intended for general reference only; it is not a full and complete statement of the technical or legal requirements associated with the regulation. Consult the Federal Register for the full text of the regulation.