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Air

ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP

IMPLEMENTATION DOCUMENT

ETHYLENE OXIDE
COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP IMPLEMENTATION DOCUMENT

Prepared for:

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Disclaimer

The information provided in this document is intended as supplemental information to the regulated community. In case of any discrepancy between information provided in this document and the codified National Emission Standards for Hazardous Air Pollutants for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O), information contained in the codified standards will apply.

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CHAPTER 1
INTRODUCTION

1.1 BACKGROUND

Under Section 112 of the Clean Air Act (CAA), the U. S. Environmental Protection Agency (EPA) is required to develop national emission standards for hazardous air pollutants (NESHAP) for source categories that have been identified as major sources of hazardous air pollutants (HAP). Section 112(b) of the CAA identifies ethylene oxide (EO) as a HAP because it is suspected to cause cancer in humans, is highly mutagenic and teratogenic, and has significant acute and subchronic exposure health effects. To meet the requirements of the CAA, EPA promulgated NESHAP for ethylene oxide commercial sterilization and fumigation operations in the December 6, 1994 *Federal Register* as subpart O of part 63 of the Code of Federal Regulations.

Under this NESHAP, the EPA has elected to regulate both major (i.e., sources that emit or have the potential to emit 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAP) and area sources (i.e., any HAP source that is not a major source) because of the high toxicity of EO. Therefore, consistent with section 112(d) of the CAA, existing and new major sources will control emissions to the level achievable by the maximum achievable control technology (MACT); existing and new area sources will control emissions using generally available control technology (GACT).

Commercial sterilization and fumigation sources using EO as a sterilant for heat and moisture sensitive products and as a fumigant to control microorganisms or insects are subject to the regulation. However, the regulation exempts EO sterilizers in hospitals. Products that are typically sterilized or fumigated with EO include medical equipment and supplies, pharmaceuticals, spices, books, museum artifacts, and cosmetics. Approximately 100 EO commercial sterilization and fumigation sources exist in the United States. The EPA estimates that full compliance with the regulation will reduce the amount of EO released into the air by 1,100 tons.

1.2 PURPOSE OF DOCUMENT

Under sections 112(d) and 112(l) of the CAA, EPA provides guidance useful to EPA Regional Office and State and local agency personnel who will be responsible for implementing NESHAP. The purpose of this document is to provide these personnel with implementation materials to assist them in conducting complete and efficient inspections at ethylene oxide commercial sterilization and fumigation operations to determine compliance with the NESHAP.

1.3 ORGANIZATION

Chapter 2 of this document presents a summary of the requirements of the regulation. Strategies for determining applicability of the regulation, including flowcharts, are provided in Chapter 3. Chapter 4 discusses the emission reductions and limits in the regulation and the control techniques that may be used to meet these standards. Requirements for demonstrating compliance with the regulation are discussed in Chapter 5. Chapter 6 summarizes the recordkeeping and reporting requirements of the regulation. Chapter 7 covers inspection procedures, including inspector checklists. A summary of commonly asked questions and answers are included in Chapter 8, and a list of other available implementation materials is included in Chapter 9. Appendix A contains a glossary of terms and nomenclature used in the regulation. A detailed “table of contents” of the regulation is included as Appendix B. A list of known facilities is included as Appendix C.

CHAPTER 2
SUMMARY OF THE REGULATION

The regulation affects sources using EO for commercial sterilization or fumigation operations. How a source is affected depends on the amount of EO that the source uses. Sterilization sources using less than 1 ton are not subject to the emission standards, but are subject to the recordkeeping requirements of the regulation.

In general, the regulation specifies:

- ✓ Compliance dates
- ✓ Emission reductions and limits
- ✓ Initial performance testing
- ✓ Ongoing monitoring
- ✓ Recordkeeping
- ✓ Reporting

Each of these requirements is summarized below. These requirements are discussed in more detail in subsequent chapters of this document. In addition, a detailed "table of contents" of the regulation is included in Appendix B of this document. It lists the requirements of the regulation and provides a cross-reference to the codified sections of the regulation where these requirements are found.

2.1 COMPLIANCE DATES

All existing sources (i.e., initial startup date before December 6, 1998) (see section 2.2 below) must be in compliance with the regulation by the following dates:

- Sterilization chamber vents subject to the emissions standards in Section 63.362 with an initial startup date before December 6, 1998, no later than December 6, 1998.

- Sterilization chamber vents subject to the emissions standards in Section 63.362 with an initial startup date on or after December 6, 1998, immediately upon initial startup of the source.

- Sterilization chamber vents at sources using less than 1 ton of ethylene oxide that increase their ethylene oxide usage after December 6, 1998 such that the sterilization chamber vent

becomes subject to the emissions standards in Section 63.362(c), immediately upon becoming subject to the emission standards.

- Aeration room vents subject to the emissions standards in Section 63.362 with an initial startup date before December 6, 2000, no later than December 6, 2000.
- Aeration room vents subject to the emissions standards in Section 63.362 with an initial startup date on or after December 6, 2000, immediately upon initial startup of the source.
- Aeration room vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2000, such that the aeration room vents become subject to the emissions standards in Section 63.362, immediately upon becoming subject to the emission standards.
- New sources (i.e., initial startup date on or after December 6, 1998) that are subject to emission standards must be in compliance with the regulation as stated in the previous paragraphs. Consult your enforcing agency if you have any questions regarding the applicable compliance date

for your source.

2.2 EMISSIONS REDUCTIONS AND LIMITS

The regulation specifies the following emission reductions and limits that depend on the piece of equipment and the amount of EO that the facility uses per year:

- ✓ For sterilization chamber vents (SCV's), at sources using 1 or more tons of EO per year, 99 percent reduction; and
- ✓ For aeration room vents (ARV's) at sources using 10 or more tons of EO per year, 99 percent reduction OR 1 part per million by volume (ppmv) concentration limit.

2.3 INITIAL PERFORMANCE TESTING

Initial performance testing is required to demonstrate that the source is meeting the emissions standards. This is a one-time test. The regulation contains the test methods that will be used to determine initial compliance. During this initial performance test, the source will also establish operating parameter values that will be the bases for demonstrating ongoing compliance through monitoring of these parameters.

2.4 ONGOING MONITORING

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 the source uses. If using an acid-water scrubber, the source must monitor the ethylene glycol concentration or the scrubber liquor tank level once per week. If using a catalytic or thermal oxidation unit, the source must monitor the temperature continuously to maintain the minimum temperature based on the manufacturer's design. In addition, if using a catalytic oxidizer, the source must periodically replace the catalyst or annually test the control device performance and, if necessary, restore the catalyst. For any type of emission reduction technique used to control emissions for ARV, the source may monitor the EO concentration once per hour.

2.5 RECORDKEEPING

The regulation requires that all sources keep records to document compliance with the regulation. Records for sources using 1 ton or more of EO per year include performance test results, monitoring and calibration data, and malfunctions and deviations data (i.e., deviations from any emission limitation, work practice, or operating limit). Records for sources using less than 1 ton of EO per year include annual usage data to demonstrate that they are not subject to the emission reduction requirements.

2.6 REPORTING

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

CHAPTER 3
APPLICABILITY OF THE REGULATION

3.1 APPLICABILITY

The regulation applies to commercial sterilization and fumigation sources that use EO as a sterilant for heat and moisture sensitive products or as a fumigant to control microorganisms or insects, regardless of size (see exemptions listed in section 3.2). Both major and area sources are covered by the regulation. (Major sources are sources emitting 10 or more tons per year of any HAP or 25 or more tons per year of any combination of HAP's. Area sources, also referred to as "nonmajor sources," are sources that do not qualify as major.) The Figure 3-1 flowchart may be used to determine the applicability of the requirements of the regulation to a particular source.

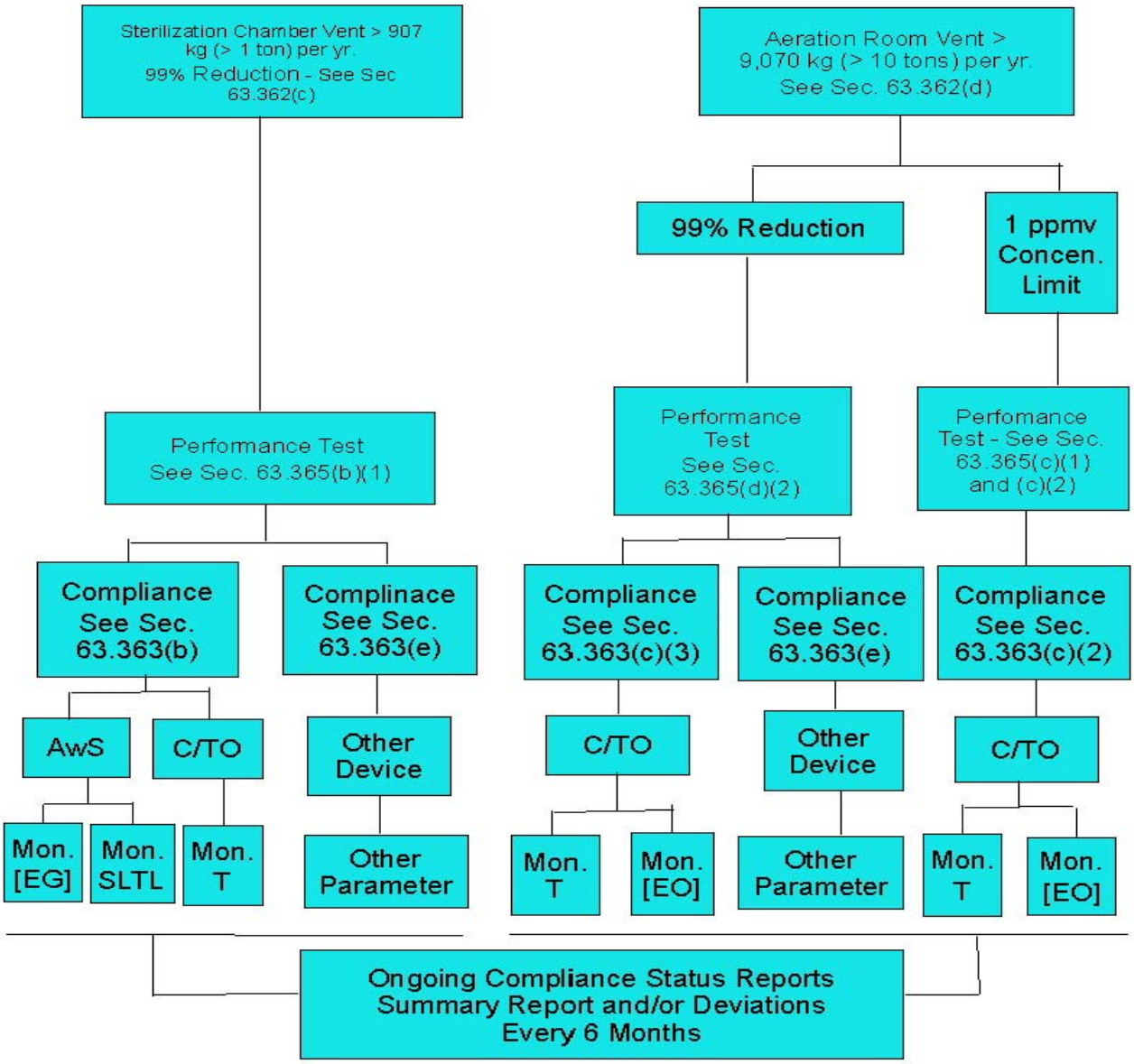
3.2 EXEMPTIONS

The regulation specifically exempts certain types of sources. These sources are:

- ✓ Beehive fumigators;
- ✓ Research and laboratory facilities, as defined in section 112(c)(7) of the CAA; and
- ✓ Medical facilities such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is providing medical services to humans or animals.

3.3 SOURCE DESCRIPTION

The commercial sterilization source category covers the use of EO as a sterilant/fumigant in the production of medical equipment supplies and in miscellaneous sterilization and fumigation operations. Commercial sterilization facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. Libraries and museums use EO to fumigate books and other historical items.



Key to Control Devices: AwS - Acid Water Scrubber; C/TO - Catalytic/Thermal Oxidizer; Other Device - Other Device.

Key to Parameters: [EG] - Ethylene Glycol Conc.; SLTL - Scubber Liquor Tank Level; T - Temp.; [EO] - Ethylene Oxide Conc.

Figure 3-1. Applicability Flowchart

There are two main types of EO sterilization processes: (1) bulk sterilization and (2) single-item sterilization. Using the single-item sterilization process, items are placed in a plastic pouch, sterilant gas is injected into the pouch, and the sealed pouch is placed into an aeration cabinet or room to allow sterilization to occur. Single-item sterilizers typically use much less than 1 ton of EO per year, and therefore, they may only be subject to minimal recordkeeping requirements of the NESHAP. Bulk sterilization is by far the more commonly used EO sterilization process. Using this process, products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.3.1 Equipment

A schematic of a gas sterilizer is shown in Figure 3-2. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3). A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete.

3.3.2 Sterilant Gases

Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping.

3.3.3 Sterilization Cycle

The typical sterilization cycle consists of six phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, (5) chamber exhaust, and (6) aeration. Each of these phases is discussed briefly below.

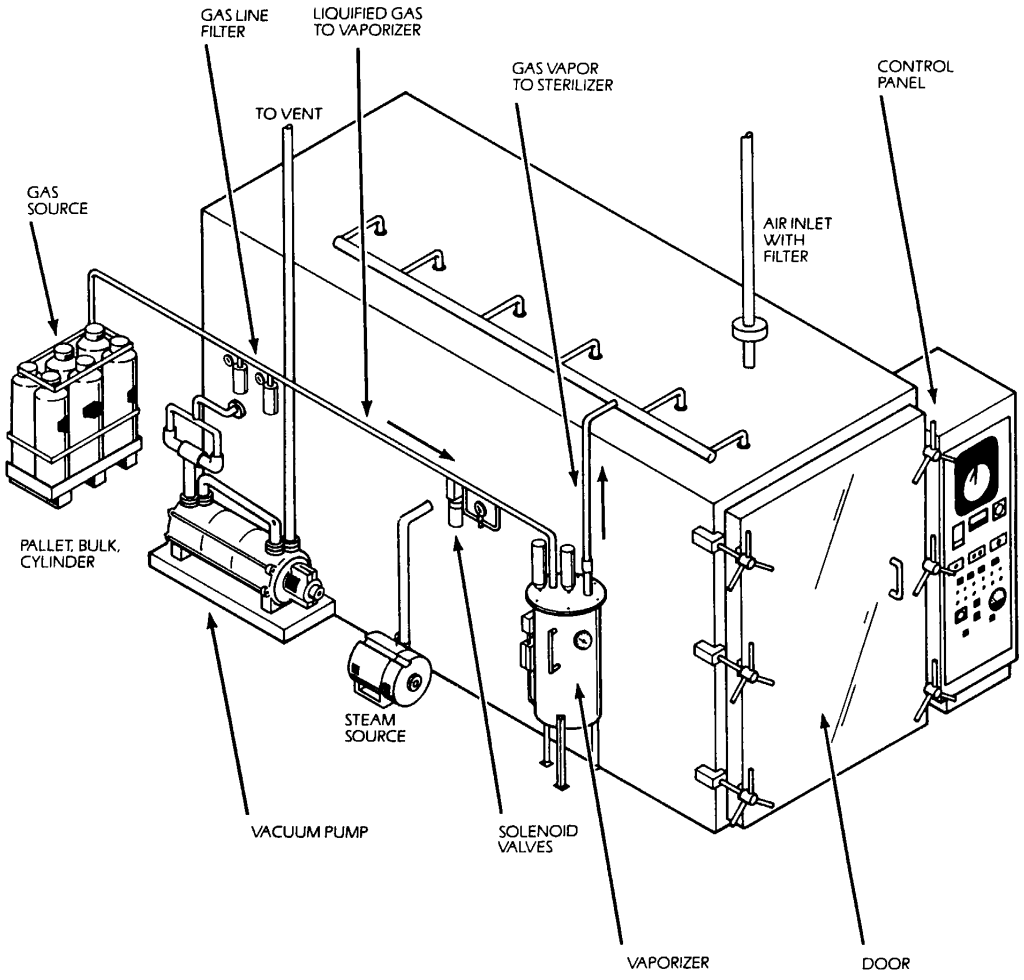


Figure 3-2. Schematic of a gas sterilizer.
(Courtesy of Union Carbide Corporation, Linde Division.)

3.3.3.1 Presterilization Conditioning. After the products have been loaded into the chamber and the airtight door is sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable gas mixtures are used, the removal of air reduces the potential for ignition. The initial drawdown takes from about 5 to 45 minutes, depending on the product being sterilized. The chamber temperature is adjusted to ensure proper sterilization, and the relative humidity is raised to ensure susceptibility of microorganisms to the sterilant gas.

3.3.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO. The chamber pressure, which depends on the type of sterilant gas used, is maintained for about 4 to 6 hours.

3.3.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. This postcycle vacuum phase typically lasts about 10 minutes.

3.3.3.4 Air Wash. The pressure in the chamber is bought to atmospheric pressure by introducing either air, nitrogen, or CO_2 (depending on the flammability of the sterilant gas mixture). The combination of evacuation and air wash phases is repeated from four to six times to remove as much of the EO from the product as possible. The purpose of the air washes is to allow residual EO to diffuse from the product to help meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the Occupational Safety and Health Administration (OSHA) standard for exposure in the workplace.

3.3.3.5 Chamber Exhaust. Prior to unloading the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is an exhaust system that evacuates EO-laden air from the chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust is a worker safety system that is responsible for removing EO from the void space in the sterilizer chamber. The chamber exhaust does not dramatically effect residual EO concentrations in the products being sterilized.

3.3.3.6 Aeration. Following their removal from the sterilization chamber, the sterile products are placed in an aeration room and kept there for several hours or days depending on the product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to shipping in order to comply with the FDA and EPA guidelines for residual EO. Ethylene oxide

concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour. Also, aeration rooms are frequently heated to aid in EO off gassing.

3.3.4 Emission Sources

The four principal sources of EO emissions from sterilization/fumigation processes are the following:

- ✓ Sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
- ✓ Sterilization chamber vacuum pump drain;
- ✓ Chamber exhaust vent(s); and
- ✓ Aeration room vent(s).

A schematic of these emission sources is shown in Figure 3-3.

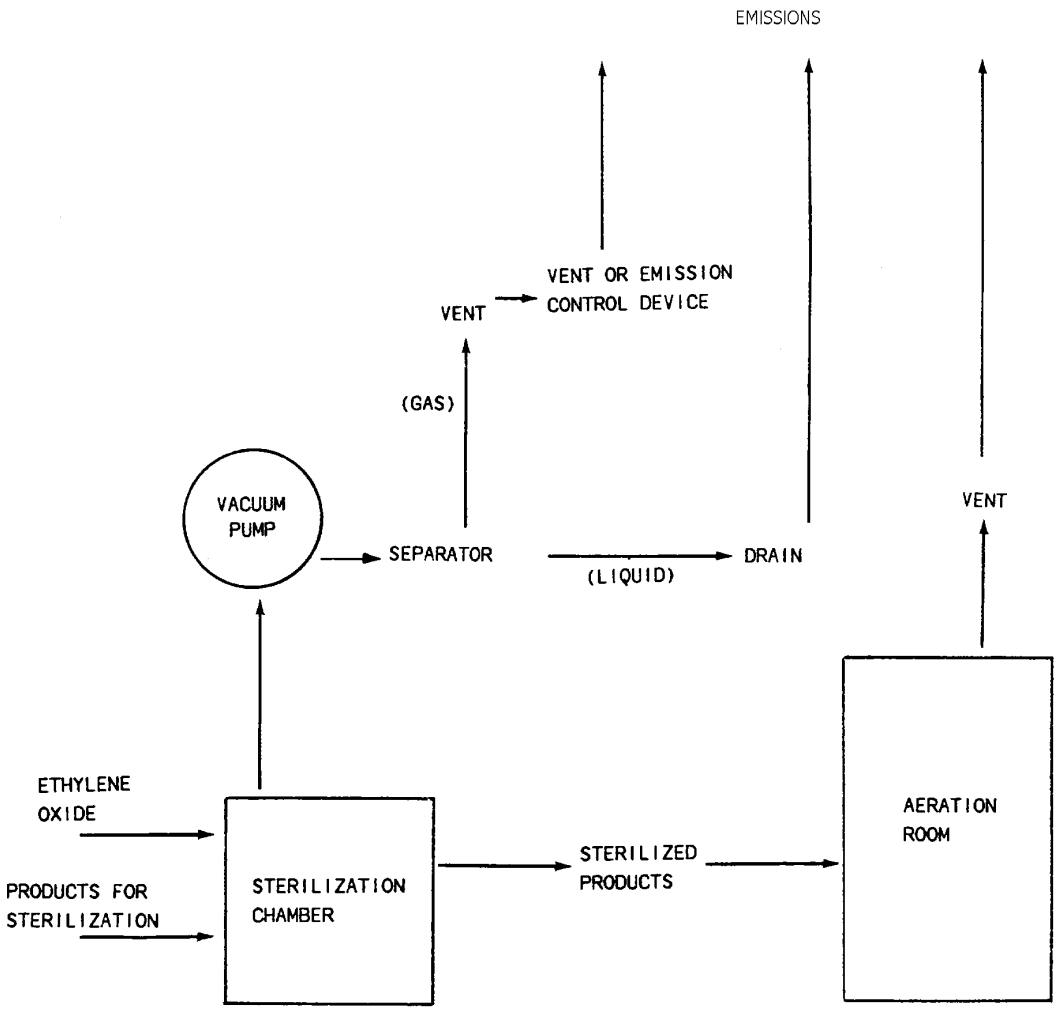


Figure 3-3. Schematic of emission sources at commercial sterilization facilities.

CHAPTER 4
EMISSION LIMITS AND CONTROL TECHNIQUES

4.1 EMISSION LIMITS

The regulation specifies emissions standards as shown in Table 4-1 and provides reference emission reduction techniques that may be used to comply with the requirements. However, a source may use other emission reduction techniques, as long as the level of emission reduction is the same or better.

Table 4-1. Emissions Reductions and Limits

Source size, yearly EO usage	Emissions standards for each source type	
	Sterilization chamber vent, SCV	Aeration room vent, ARV
<1 ton	No controls required; minimal recordkeeping requirements apply.	
≥1 ton and <10 tons	99% emission reduction	No control
≥10 tons	99% emission reduction	1 ppmv maximum outlet concentration --OR-- 99% emission reduction

4.2 CONTROL TECHNIQUES

As mentioned above, the emission reductions and limits are based on the use of certain control techniques. However, a source may choose to use an alternative control technique, as long as the emission reductions and limits are met. The following paragraphs discuss the control techniques upon which the emissions limits found in Table 4.1 are based.

4.2.1 Acid-water Scrubber

An acid-water scrubber, depicted in Figure 4-1, consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas contacts an

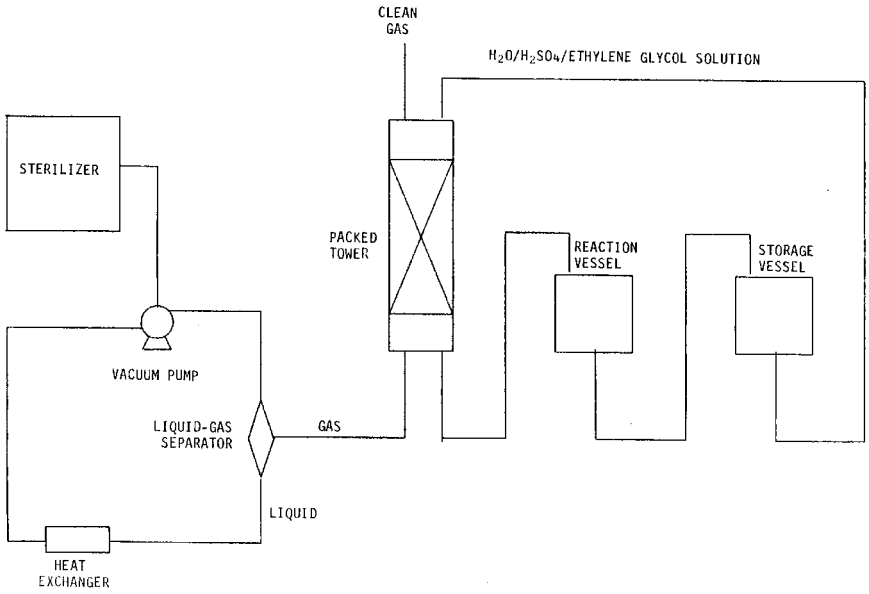


Figure 4-1. Schematic of a typical acid water scrubber system.

acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reaction vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of ethylene glycol in the liquor reaches a predetermined weight percentage. (At this point the scrubber efficiency declines.) The spent solution is neutralized and then disposed or sold. Typical EO removal efficiencies of acid-water scrubbers are at least 99 percent.

4.2.2 Catalytic Oxidation Unit

Figure 4-2 shows a schematic of a catalytic oxidation unit. If necessary, inlet gas is first mixed with a large volume of air to dilute the control device inlet EO concentration to 5,000 ppmv or less. This dilution prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and is preheated to the reaction temperature with steam or electricity.

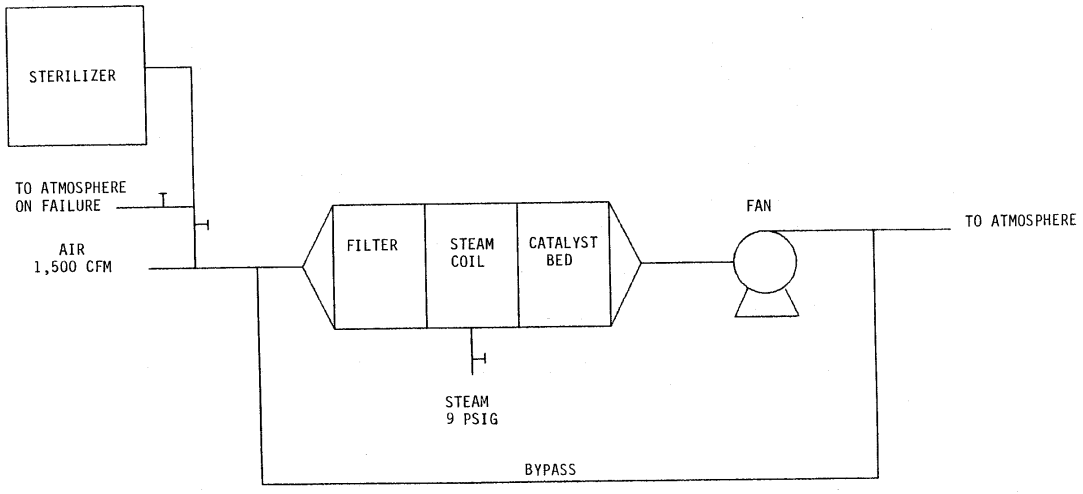


Figure 4-2. Schematic of a typical catalytic oxidation system.

The gas then enters the catalyst bed(s), where the EO is oxidized. Because catalytic oxidation is applicable to the control of lower EO concentrations, facilities can manifold several EO emission sources to one control device. In some situations, low-concentration emission sources can provide part or all of the necessary diluent air. Typical EO removal efficiencies of catalytic oxidation units are greater than 99 percent.

4.2.3 Thermal Oxidation Unit

A thermal oxidation unit is depicted in Figure 4-3. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air, can be easily and efficiently destroyed by thermal oxidation using flares. However, because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO. Flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent EO destruction efficiency.

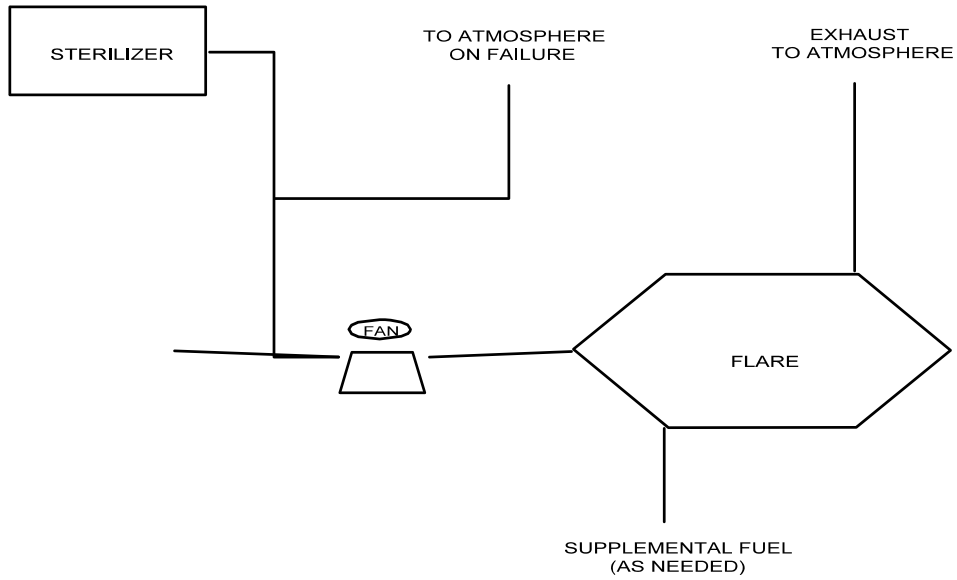


Figure 4-3. Schematic of a typical thermal oxidation system

CHAPTER 5
DEMONSTRATING COMPLIANCE

There are three components to demonstrating compliance with the emissions standards of this regulation:

- ✓ Initial performance testing
- ✓ Site-specific operating parameters setting
- ✓ Ongoing compliance monitoring

5.1 INITIAL PERFORMANCE TESTING

The initial performance test serves two primary purposes. First, it is necessary to determine if the source is in compliance with the emissions standards listed in Table 4-1 of this document. Second, the initial performance test establishes values for the air pollution control system operating parameters. Monitoring and recording these operating parameters during ongoing sterilization processes will indicate whether or not the source is in compliance with the emissions standards.

Each existing source that is subject to emissions standards is required to perform an initial performance test. For sources with an initial startup date of December 6, 1998 or later, the initial performance test must be completed within 180 days after initial startup. Section 63.365 of the regulation specifies test methods and procedures to be used to determine the efficiency of the control devices.

5.2 ESTABLISHING SITE-SPECIFIC OPERATING PARAMETERS

During initial performance testing, applicable air pollution control technique operating parameters must be recorded. These site-specific operating parameters are determined by the air pollution control technique or strategy that the source is using and are listed in Table 5-1. Table 5-1 also refers to the location in the NESHAP for the procedure to be used to establish the site-specific operating parameter.

If a facility chooses to use a control technology other than an acid-water scrubber or catalytic or thermal oxidizer to comply with the emissions standards, the owner or operator of the facility

Table 5-1. Site-specific Operating Parameters

Air pollution control system or strategy	Site-specific operating parameter	Procedure in regulation
Sterilization Chamber Vent (SCV) Standard		
Acid-water scrubber	1. Maximum ethylene glycol concentration in scrubber liquor --OR--	§ 63.365(e)(1)
	2. Maximum scrubber liquor level in recirculation tank	§ 63.365(e)(2)
Catalytic or Thermal oxidizer	Minimum temperature during initial performance test –AND-- For catalytic oxidizer, perform work practice	Based on manufacturer's design
Aeration Room Vent (ARV) Standard		
Catalytic or Thermal oxidizer	1. Minimum temperature during initial performance test --AND– For catalytic oxidizer, perform work practice –OR-- 2. Outlet total EO concentration	Based on manufacturer's design §63.365(c)(1)

must submit to the Administrator or appropriate enforcement agency their own recommendations for operating parameters to be established and monitored to demonstrate continuous compliance. Based on this information, the Administrator or enforcement agency will determine the operating parameter(s) to be measured during the performance test. Using the methods approved in section 63.365(g) of the rule, facilities must determine site-specific operating limit(s) for the operating parameters approved by the Administrator.

5.3 ONGOING MONITORING

During performance testing, site-specific operating parameters are established, as discussed above. Facilities must continue to monitor these operating parameters to ensure ongoing continuous compliance with each emission limitation (including any operating limit) or work practice required, except during periods of startup, shutdown, and malfunction. By monitoring and recording the appropriate air pollution control system parameters and comparing the monitored values to the maximum or minimum value established during the performance test, the enforcing agency can determine if the facility is in compliance with the emissions standards. Tables 5-2 and 5-3 summarize the ongoing monitoring requirements associated with the sterilization chamber vent standard, and aeration room vent standard, respectively. Each of these tables includes the equipment specifications and the monitoring frequency, as well as indicators of a deviation of the standard for the various air pollution control systems and strategies that may be used.

If using a catalytic oxidizer, the following work practices apply: (1) Once per year after the initial compliance test, conduct a performance test during routine operations with product in the chamber using procedures in section 63.365(b) or (d) as appropriate. If percent efficiency is less than 99 percent, restore catalyst as soon as practicable but no later than 180 days after the performance test; or (2) Once per year after the initial compliance test, analyze ethylene oxide concentration data from section 63.364(e) or a CEMS and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or (3) Every 5 years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst material.

Table 5-2. Summary of Ongoing Monitoring Requirements for the Sterilization Chamber Vent Standard

Air pollution control system or strategy	Monitored parameter	Monitoring equipment	Frequency	Deviation
Acid-water scrubber	1. Ethylene glycol concentration in scrubber liquor --OR--		[a]Once per week	Deviation from maximum ethylene glycol concentration in scrubber liquor established during initial performance test
	2. Scrubber liquor level in recirculation tank	Liquid level indicator (e.g., marker on tank wall, dipstick, magnetic indicator)	Once per week	Deviation from maximum scrubber liquor level established during initial performance test
Catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [b] --AND--	Continuously	Oxidation temperature, averaged daily, more than 10°F below minimum temperature established during initial performance test
		2. Data acquisition system [c]		

[a]Monitoring is only required during weeks when the scrubber unit has been operated.

[b]Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor (traceable to NIST standards) or an independent temperature measurement device dedicated for this purpose. During accuracy testing, the probe of the reference device must be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

[c]The data acquisition system must compute and record, from 15-minute or shorter period temperature values, the daily average oxidation temperature. Strip chart data must be used to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

Table 5-3. Summary of Ongoing Monitoring Requirements for the Aeration Room Vent Standard

Air pollution control system or strategy	Monitored oarameter	Monitoring equipment	Frequency	Deviation
Catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [a] --AND-- 2. Data acquisition system [b]	Continuously	Oxidation temperature, averaged daily, more than 10°F below minimum temperature established during initial performance test
Direct measurement of EO concentration	EO concentration at outlet to atmosphere from ARV after any control device	Gas chromatograph [c]	Once per hour and compute 24-hour average daily	24-hour average EO concentration in excess of 1 ppmv EO concentration limit

[a] Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor (traceable to NIST standards) or an independent temperature measurement device dedicated for this purpose. During accuracy testing, the probe of the reference device must be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

[b] The data acquisition system must compute and record, from 15-minute or shorter period temperature values, the daily average oxidation temperature. Strip chart data must be used to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

[c] Facility must install, calibrate, operate, and maintain gas chromatograph consistent with performance specification (PS) 8 or 9 in 40 CFR part 60,

Appendix B. Daily calibration is only required on days when EO emissions are vented to a control device from the ARV.

CHAPTER 6
RECORDKEEPING AND REPORTING REQUIREMENTS

Most of the recordkeeping and reporting requirements are not detailed in the NESHAP. Instead, they are contained in the General Provisions to part 63 and simply referenced in Table 1 of Section 63.360 in the NESHAP. This table provides specific references to those sections of the General Provisions that apply to the commercial sterilization and fumigation NESHAP. The EPA chose to reference the recordkeeping and reporting requirements of the General Provisions to help reduce unnecessary repetitiveness, and to help provide consistency between the different NESHAP in part 63.

6.1 RECORDKEEPING

The regulation requires sources to keep records to document compliance status with the regulation. These records include:

- ✓ Records to demonstrate compliance, including work practice records
- ✓ Performance test results
- ✓ Continuous monitoring system records
- ✓ Documentation supporting initial notification and notification of compliance status
- ✓ EO usage records for sources not subject to emissions standards

These records must be maintained in a form suitable and readily available for expeditious inspection and review. They may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disks, magnetic tape disks, or microfiche. The files must be retained for at least 5 years, and the most recent 2 years of data must be retained on site.

6.1.1 Malfunction Records

Sources must maintain records of the occurrence and duration of each malfunction of the air pollution control equipment. Records of each period during which a CMS is malfunctioning or inoperative (including out-of-control periods) are also required.

6.1.2 Records to Demonstrate Compliance

Sources are also required to maintain records of all required measurements needed to demonstrate compliance with the standards and work practices, including records of the compliance test and data analysis, and if catalyst is replaced, proof of replacement.. These records should include the data compiled according to Tables 5-2 and 5-3 of this document, which detail the monitoring requirements of the NESHAP.

6.1.3 Performance Test Results

Sources must maintain records of all results of performance tests and CMS performance evaluations, as well as all measurements necessary to determine the conditions of performance tests and performance evaluations.

6.1.4 Continuous Monitoring System Records

Records relating to CMS must include: (1) all CMS calibration checks; (2) all adjustments and maintenance performed on CMS; (3) all required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods); (4) the date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks; (5) the specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances that occurs during periods other than startups, shutdowns, and malfunctions of the source; (6) the nature and cause of any malfunction (if known); the corrective action taken or preventive measures adopted; (7) the nature of the repairs or adjustment to the CMS that was inoperative or out of control; (8) the total process operating time during the reporting period; and (9) all procedures that are part of a quality control program developed and implemented for CMS.

6.1.5 Documentation Supporting Initial Notification and Notification of Compliance Status

Sources are required to maintain all documentation supporting the initial notifications and notifications of compliance status required by the NESHAP.

6.1.6 Records for Sources Not Subject to Emissions Standards

Sources that use 1 to 10 tons of EO per year and that are not subject to emissions standards (see Table 4-1 of this document) are only required to keep records of EO usage on a 12-month rolling basis. Sources that use less than 1 ton of EO per year are also only required to keep EO usage records on a 12-month rolling basis.

6.2 REPORTING

The regulation requires that sources submit reports and notifications, which include:

- ✓ Initial notification
- ✓ Notification of construction/reconstruction
- ✓ Notification of performance test and CMS performance evaluation
- ✓ Test plans (to be submitted upon request)
- ✓ Notification of compliance status
- ✓ Deviations and CMS performance report/summary report

All reports must be submitted to the Administrator (i.e., the appropriate EPA Regional Office or the delegated State or local authority). The required reports may be sent by U. S. Mail, fax, or by another courier (including electronic submission).

6.2.1 Initial Notification

Sources with an initial startup date before December 6, 1994 were required to submit an initial notification to the Administrator on or before April 5, 1995 (120 days after the effective date of the standards). New or reconstructed sources with an initial startup date after December 6, 1994 are required to submit an initial notification within 120 calendar days after the source becomes subject to the standards. The initial notification includes the following information: (1) the name and address of the owner or operator; (2) the physical address of the source; (3) an identification of the relevant standard or other requirement and the source's compliance date; (4) a brief description of the nature, size, design, and method of operation of the source; and (5) a statement of whether the source is a major source or an area source.

6.2.2 Notification of Construction/Reconstruction

Sources must apply for approval of the construction of a new affected source. Sources must also apply prior to the reconstruction of a nonaffected source if the reconstruction would result in the source being an affected source. All applications must be submitted to the Administrator as soon as practicable to ensure timely review.

6.2.3 Notification of Performance Test and CMS Performance Evaluation

Sources must notify the Administrator in writing of intent to conduct an initial performance test at least 60 calendar days before the scheduled date of the test to allow the Administrator to review and approve their site-specific test plan and to have an observer present at the test. Simultaneously with this notification, the source will also notify the Administrator of the date of the continuous monitoring system (CMS) performance evaluation. The Administrator may or may not choose to have an observer present. If the scheduled date for the test is changed for unforeseen reasons, the source will inform the Administrator within 5 calendar days of the originally scheduled test date and will specify the date of the rescheduled test.

6.2.4 Test Plans

Before conducting the initial performance test, sources are required to develop and, if requested by the Administrator, submit a site-specific test plan and a CMS performance evaluation test plan to the Administrator for approval. The test plan will include: (1) a test program summary, (2) the test schedule, (3) data quality objectives (i.e., pretest expectations of precision, accuracy, and completeness of data), (4) an internal and external quality assurance (QA) program. The CMS performance evaluation test plan will include: (1) the evaluation program summary, (2) the performance evaluation schedule, (3) data quality objectives, and (4) both an internal an external QA program. If requested by the Administrator, the source will submit these test plans at least 60 calendar days before the performance test is scheduled to take place. The Administrator will then either approve or disapprove the test plans within 30 calendar days after receipt of the plans.

6.2.5 Notification of Compliance Status

Sources are required to submit a notification of compliance status within 60 days after the initial performance test. The notification must include: (1) the methods that were used to determine compliance; (2) the results of the performance test and the CMS performance evaluation; (3) the methods that will be used for determining continuing compliance; (4) the type and quality of HAPs emitted, reported in units and averaging times specified in the regulation; (5) an analysis demonstrating whether the source is a major source or an area source; (6) a description of the air pollution control equipment (or method) for each emission point, including the control efficiency

for each control device (or method); and (7) a statement as to whether the source has complied with the relevant standard or other requirements.

6.2.6 Deviations and CMS Performance Report/Summary Report

Sources are required to submit all deviations and CMS performance reports and/or a summary report to the Administrator semiannually . These reports must be delivered or postmarked within 30 calendar days after the end of each calendar half (i.e., July 30 and January 30), or quarter as appropriate. A summary report may be submitted in lieu of the full deviations and CMS performance report if the total duration of deviations for the reporting period is less than 1 percent of the total operating time for the reporting period, and if the CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period. Otherwise, the summary report and the deviations and CMS performance report is required.

The summary report must include: (1) the company name and address of the source; (2) an identification of each HAP monitored at the source; (3) the beginning and ending dates of the reporting period; (4) a brief description of the process units; (5) the relevant emission and operating parameter limitations specified in the NESHAP; (6) the monitoring equipment and manufacturer(s) and model number(s); (7) the date of the latest CMS certification or audit; (8) the total operating time of the source during the reporting period; (8) an emission data summary, including the total duration of deviations during the reporting period, the total duration of deviations expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total duration of deviations during the reporting period into those that are due to startup/shutdown, control equipment problems, process problems, other known causes, and other unknown causes; (9) a CMS performance summary, including the total CMS down time during the reporting period, the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, quality assurance/quality control calibration, other known causes, and other unknown causes; (10) a description of any changes in CMS, processes, or controls since the last reporting period; (11) the name, title, and signature of the responsible official who is certifying the accuracy of the report; and (12) the date of the report.

The deviations and CMS performance report must include: (1) the name, title, and signature of the responsible official who is certifying the accuracy of the report; (2) information from any calibration tests in which the monitoring equipment is not in compliance with performance specification (PS) -9 of 40 CFR part 60 or the method used for temperature calibration; (3) the date and time identifying each period during which the CMS was inoperative, except for zero (low-level) and high-level checks; (4) the date and time of commencement and completion of each time period of deviations that occurs during periods other than startups, shutdowns, and malfunctions of the source; (5) the nature and cause of any malfunction (if known); (6) the corrective action taken or preventive measures adopted; (7) the nature of the repairs or adjustment to the CMS that was inoperative; and (8) the total process operating time during the reporting period. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information must be stated in the report.

CHAPTER 7
INSPECTION PROCEDURES

The following comprise sample checklists that may be used during inspections of affected sources.

INSPECTION CHECKLIST

PART A. GENERAL PROCESS INFORMATION

Applicable Rule: 40 CFR Part 63, Subpart O—NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations.

Plant Name _____

Plant Address _____

_____

City_____ State_____ Zip Code_____

Plant Contact/Title_____Plant Phone number _____

Owner/Operator, Title_____

Street Address (if different than plant's)_____

_____

City_____ Sate_____ Zip Code _____

1. Inspection Date: ___/___/___ Time:_____
2. Indicate whether a facility is a new or existing source:

   ___ New source ___ Existing source
3. Indicate the facility's compliance date: ___/___/___
4. Indicate the facility's annual EO use in previous 12 months: _____
5. Indicate the facility's compliance approach

   Sterilization chamber vent:

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

   Aeration room vent:

   ___ 1 ppm max ___ Percent Reduction ___ Dedicated control device

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

Investigator/Title:_____Date:___/___/___

PART B. MONITORING REQUIREMENTS FOR STERILIZATION CHAMBER VENTS

Inspection steps	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the dedicated control device used to comply with the standard.				
2. Determine that source has complied with the requirements for the appropriate dedicated control device; follow the inspection steps listed on the appropriate forms:				

Inspection steps	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source deviated from the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source deviated from the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the deviations to the Administrator? Stop here.				

Inspection steps	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Obtain and enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor or a dedicated independent temperature measurement device?				
4. Does the source operate a data acquisition system that computes and records the daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature?				
5. Has the oxidation temperature been more than 10°F below the minimum temperature established during the initial performance test?				
6. If using a catalytic oxidizer, has the source replaced the catalyst and is there a record of replacement?				
7 If the answer to step 5 is "Yes," has the source reported the deviations to the Administrator? Stop here.				

Inspection steps	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown deviations of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the deviations to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART C. MONITORING REQUIREMENTS FOR AERATION ROOM VENTS

Step in inspection	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the method of compliance: (a) Monitor EO concentration. Go to Step 2. (b) Manifold emissions to control device. Go to Step 5. (c) Emissions controlled via dedicated control device. Go to Step 6.				
2. Obtain records of ongoing monitoring data.				
3. Has the ethylene oxide concentration deviated from the 1 ppm limit?				
4. If the answer to step 3 is "Yes," has the source reported the deviations to the Administrator? Stop here.				
5. Determine that source has complied with the requirements for that control device on that emissions point (continue on Part B, or Part C as appropriate).				
6. Determine that source has complied with the requirements for the appropriate device as follows:				

RECORDING AND REPORTING REQUIREMENTS

Step in inspection	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source deviated from the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source deviated from the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the deviations to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor or a dedicated independent temperature measurement device?				
4. Does the source operate a data acquisition system that computes and records the daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature?				
5. Has the oxidation temperature, been more than 10°F below the minimum temperature established during the initial performance test?				
6. If using a catalytic oxidizer, has the source replaced the catalyst and is there a record of replacement?				
7. If the answer to step 5 is "Yes," has the source reported the deviations to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown deviations of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the deviations to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART D. RECORDKEEPING REQUIREMENTS

Step in inspection	Y	N	Inspector notes
1. Does the source use less than 10 tons of ethylene oxide per year? If "Yes," go to Step 2. If "No," go to Step 4.			
2. Is the source subject to emissions limitations in the regulation? If "Yes," go to Step 4. If "No," go to Step 3.			
3. Does the source maintain records of EO usage on a 12-month rolling basis? Stop here.			
4. Does the source maintain the following malfunction records: (a) The occurrence and duration of each malfunction of the air pollution control equipment; AND (b) Records of each period during which a continuous monitoring system is malfunctioning or inoperative (including out-of-control periods)?			
5. Does the source maintain work practice records and records of all required measurements needed to demonstrate compliance with the standard?			
6. Does the source maintain records of all results of performance tests and CMS performance evaluations, as well as all measurements as may be necessary to determine the conditions of the performance tests and evaluations?			

Step in inspection	Y	N	Inspector notes
7. Does the source maintain the following records relating to CMS: (a) All CMS calibration checks; (b) All adjustments and maintenance performed on CMS; (c) All required CMS measurements; (d) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks; (e) The specific identification (i.e., the date and time of commencement and completion) of each time period of deviations that occur during periods other than startups, shutdowns, and malfunctions of the source; (f) The nature and cause of any malfunction (if known); the corrective action taken or preventive measures adopted; (g) The nature of the repairs or adjustment to the CMS that was inoperative; (h) The total process operating time during the reporting period; and (I) All procedures that are part of a quality control program developed and implemented for CMS?			

CHAPTER 8
COMMONLY ASKED QUESTIONS AND ANSWERS

Q: In terms of the requirements of this standard, 40 CFR Part 63, Subpart O, does it matter whether I am a major or area source?

A: No. Some of the National Emission Standards for Hazardous Air Pollutants (NESHAP) do differentiate between major and area sources and some only regulate the major sources. However, this standard, 40 CFR Part 63, Subpart O (Sterilizer NESHAP), regulates both major and area sources.

Q: Does my ethylene oxide usage have an impact on the requirements of the Sterilizer NESHAP?

A: Yes. If your facility uses less than 1 ton of ethylene oxide per year (all consecutive 12-month periods, you are subject to only the recordkeeping requirements of the standard (Section 63.367). If you use 1 or more tons of ethylene oxide per year, you are also subject to the emission standards for sterilization chamber vents in the NESHAP. Which emission standards apply to you depend on whether or not you use 10 or more tons of ethylene oxide per year. Please note that how the standards apply to you is based on ethylene oxide usage, not ethylene oxide emissions. The basis here is different from that used to determine whether you are a major or area source.

Q: When do I need to comply with the Sterilizer NESHAP?

A: You should refer to Chapter 2, Section 2.1, for your applicable compliance date for emission standards for sterilization vents and aeration room vents. As of your compliance date, you are required to meet all standards that apply to you, depending on your ethylene oxide usage (see Question 3). You should contact your enforcement agency if you have questions regarding the compliance date.

If the Sterilizer NESHAP emission standards apply to your facility, you will need to conduct initial performance testing within 180 days of your compliance date. The performance testing is conducted with the methods and procedures in Sections 63.7 and 63.365. Performance testing will determine the values to be used for compliance monitoring at your facility. Monitoring requirements are described in Section 63.364 of the Sterilizer NESHAP and come into effect on the date of completion of the initial performance test.

Q: What does the Title V permit deferral I've heard about have to do with what I'm required to do for this standard (Sterilizer NESHAP)?

A: In its original form, the Sterilizer NESHAP required that subject sources using 1 ton or more obtain a Title V permit. Section 63.360(f) of the NESHAP was revised to state that you are subject to title V permitting requirements under 40 CFR parts 70 or 71, as applicable. Your title V permitting authority may defer your source from these permitting requirements until December 9, 2004, if your source is not a major source and is not located at a major source as defined under 40 CFR 63.2, 70.2, or 71.2, and is not otherwise required to obtain a title V permit. If you receive a deferral under this section, you must submit a title V permit application by December 9, 2005. You must continue to comply with the provisions of the NESHAP applicable to area sources, even if you receive a deferral from title V permitting requirements.

Q: How does combining my emissions from two or more emissions points to one control device affect my initial compliance test and ongoing monitoring?

A: In certain circumstances, it is possible to combine the emissions flows from multiple emissions points to a single emissions control device (e.g., combine the emissions from the sterilizer vent and aeration room to a catalytic oxidizer). If such an approach were attempted, the owner or operator would need to obtain prior approval from the delegated State agency. In addition, during the initial compliance test, the emissions points would need to be isolated so that the monitoring parameters may be accurately determined. After initial compliance is determined, the emissions may be manifolded to a common control device provided that the monitoring parameter limits determined during the initial compliance test are not exceeded.

Q: I determined initial compliance with the aeration room vent standards by calculating the percent reduction in emissions, must I continue to calculate the percent reduction to satisfy the ongoing monitoring requirements?

A: No. Achievement of emission limits is demonstrated during the initial compliance test. Subsequent to the tests, facilities must meet parametric limits on an ongoing basis. (Operating parameter limits are determined during the performance test.)

CHAPTER 9
AVAILABLE IMPLEMENTATION MATERIALS

The following are several resources available to EO NESHAP implementation officials as well as to the regulated community. These resources have been prepared by a variety of sources. The listing of these sources in this chapter should not imply any endorsement by the U. S. Environmental Protection Agency. Unless noted in the referenced documents, the U. S. Environmental Protection Agency has not reviewed these documents, and is not responsible for their content.

Ethylene Oxide Sterilization (EtO) Facilities. in: NSR BACT Guidelines (an Internet-based publication). Texas Natural Resources Conservation Commission, Office of Policy and Regulatory Development. This Internet site may be found at

http://www.tnrcc.state.tx.us/air/nsr_permits/bact.htm

Ethylene Oxide Sterilizers. in: (an Internet-based publication). U. S. Environmental Protection Agency, Region 5. This Internet site may be found at

http://www.epa.gov/docs/ARD-R5/enforce/ethyl.htm

Model Implementation Plan for MACT Standards (draft No. 1). Illinois EPA. October 4, 1996.

National Emission Standards for Hazardous Air Pollutants for: Chromium Emissions from hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; Ethylene Oxide Commercial Sterilization and Fumigation Operations; Perchloroethylene Dry Cleaning Facilities; and Secondary Lead Smelting: Final Amendment. in *Federal Register*: 61 FR 27785. June 3, 1996.

National Emission Standards for Hazardous Air Pollutants for: Chromium Emissions from hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; Ethylene Oxide Commercial Sterilization and Fumigation Operations; Perchloroethylene Dry Cleaning Facilities; and Secondary Lead Smelting: Proposed Rule Amendment. in *Federal Register*: 60 FR 64002. December 13, 1995.

National Emissions Standards for Commercial Sterilization and Fumigation Facilities: Guidance Information. U. S. Environmental Protection Agency, Emission Standards Division. February, 1995. (Available on EPA's Technology Transfer Network)

New Regulation Controlling Air Emissions from Ethylene Oxide Commercial Sterilization and Fumigation. U. S. Environmental Protection Agency; Emission Standards Division. February, 1995. Publication Number: EPA-453/F-95-002. (Available on EPA's Technology Transfer Network)

AVAILABLE IMPLEMENTATION MATERIALS

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations: Final Rule (40 CFR Parts 9 and 63, Subpart O). in *Federal Register*: 59 FR 62585. December 6, 1994.

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations: Background Information for Final Standards. U. S. Environmental Protection Agency, Emission Standards Division. November, 1994. Publication Number: EPA-453/R-94-084b.

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations: Proposed Rule (40 CFR Parts 9 and 63, Subpart O). in *Federal Register*: 59 FR 10591. March 7, 1994.

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations: Background Information for Proposed Standards. U. S. Environmental Protection Agency, Emission Standards Division. October, 1992. Publication Number: EPA-453/D-93-016.

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations: Final Amendments (40 CFR Part 63, Subpart O), in *Federal Register:* 66 FR 55577. November 2, 2001.

APPENDIX A

GLOSSARY OF TERMS

Administrator means the Administrator of the United States Environmental Protection Agency of his or her authorized representative (e.g., a State that has been delegated the authority to implement the provisions of 40 CFR part 63).

Aeration room means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Area source means any stationary source of hazardous air pollutants that is not a major source as defined below in this appendix. Another term for area source is "nonmajor source."

Baseline temperature means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation ~~unit~~ control device or at the exhaust point from the combustion chamberof a thermal oxidation ~~unit~~ control device.

Chamber exhaust vent means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Compliance date means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

Deviation means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standards;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

Effective date means the date of promulgation in the *Federal Register* notice (December 6, 1994).

Initial startup date means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

Major source means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls in the aggregate, 10 tons per year or more of any hazardous air pollutant, or 25 tons per year or more of any combination of hazardous air pollutants.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Maximum ethylene glycol concentration means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Operating parameter value means a minimum or maximum value established for a control device or process parameter which, if achieved by itself or in combination with one or more other operating parameter values, determines that an owner or operator is in continual compliance with the applicable emission limitation standard.

Oxidation temperature means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Research or laboratory operation means an operation whose primary purpose is for research and development of new processes and products, that is conducted under the close supervision of technically trained personnel, and that is not involved in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

Source(s) using less than 1 ton means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

Source(s) using 1 ton means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

Source(s) using 1 to 10 tons means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using less than 10 tons means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using 10 tons means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Sterilization operation means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

Thermal oxidizer means all combustion devices except flares.

APPENDIX B.
DETAILED TABLE OF CONTENTS OF THE REGULATION

Table B-1. Detailed Table of Contents of the Regulation

Section in regulation	Contents or Requirement
§ 63.360 Applicability	
§ 63.360(a)	Sources using ≥1 ton EO per year subject to rule (including subpart A)
§ 63.360(b)	Sources using <1 ton EO per year only subject to recordkeeping in § 63.367(c)
§ 63.360(c)	Exemption for beehive fumigation sources
§ 63.360(d)	Exemption for research and development sources
§ 63.360(e)	Exemption for medical facilities
§ 63.360(f)	Sources using ≥1 ton EO per year must obtain title V permit
§ 63.360(g)	Compliance dates (CD)
§ 63.361 Definitions	
§ 63.361	Definitions of terms used in regulation
§ 63.362 Standards	
§ 63.362(a)	Comply with standards as of CD for source
§ 63.362(b)	Standards apply only during sterilization operation, not during malfunctions
§ 63.362(c)	Sterilization chamber vent (SCV) (sources using ≥ 1 ton) ⇒ 99 percent reduction
§ 63.362(d)	Aeration room vent (ARV) (sources using ≥ 10 tons) ⇒ 99 percent reduction or 1 ppmv EO
§ 63.362(e)	Reserved
§ 63.363 Compliance	
§ 63.363(a)	Initial performance test required within 180 days after CD
§ 63.363(b)	Determining compliance with SCV standard:
§ 63.363(b)(1)	• Use test method in § 63.365(b) to determine efficiency
§ 63.363(b)(2)	•• Establish site-specific operating parameters for acid-water scrubbers ⇒ ethylene glycol concentration [EG] or scrubber liquor tank level
§ 63.363(b)(3)	•• Establish site-specific operating parameter for catalytic/thermal oxidizers ⇒ minimum oxidation temperature based on manufacturer's design
§ 63.363(b)(4)	• Perform work practices for catalytic oxidizers
§ 63.363(c)	Determining compliance with ARV standard:

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.363(c)(1) § 63.363(c)(2) § 63.363(c)(3)	• Comply with operating parameter established during performance test • Determine EO concentration into atmosphere (after control device) using methods in §63.365(c)(1); or • Determine control device efficiency using test methods and procedures in §63.365(d)(2)
§ 63.363(d)	Reserved
§ 63.363(e)	Compliance procedures for sources using other control devices
§ 63.363(f)	Requires continuous compliance with each operating limit and work practice standard required, except during periods of startup, shutdown, and malfunction

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.364 Monitoring	
§ 63.364(a)	Sources must comply with this section and subpart A
§ 63.364(b)	Acid-water scrubber monitoring:
§ 63.364(b)(1)	• [EG] - weekly
§ 63.364(b)(2)	• Scrubber liquor tank level - weekly, only if scrubber has been operated
§ 63.364(c)	Catalytic/thermal oxidizer monitoring, only when oxidation unit is operated: 1. [EO] concentration as described in 63.364(e); OR 2. [T] from 15-minute or shorter period temperature values, a daily average minimum oxidation temperature
~~§63.364(c)(1)~~	[Reserved]
~~§63.364(c)(2)~~	[Reserved]
~~§ 63.364(c)(3)~~	[Reserved]
§ 63.364(c)(4)	• Verify accuracy of [T] monitor every 6 months
§ 63.364(d)	Other control device monitoring according to § 63.365(g)
§ 63.364(e)	Monitoring of [EO]: hourly, a 24-hour average daily, install gas chromatograph and calibrate daily, only on days when [EO] emissions are vented to the control device
§ 63.364(f)	[Reserved]
§ 63.365 Test Methods and Procedures	
§ 63.365(a)	Sources subject to this section and subpart A
§ 63.365(b)	SCV - efficiency and parameter determination:
§ 63.365(b)(1)	• First evacuation of SCV - efficiency and parameter
§ 63.365(b)(2)	[Reserved]
§ 63.365(c)	[EO] Concentration determination for ARV:
§ 63.365(c)(1)	• Parameter determination
§ 63.365(c)(2)	• Determine overall outlet concentration from control device
§ 63.365(d)	Efficiency and parameter determination for ARV vent (not manifolded):
§ 63.365(d)(1)	• Determine [EO] concentration at inlet and outlet of control device
§63.365(d)(2)&(d)(3)	• Determine control device efficiency

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.365(e)	Parameter determination for acid-water scrubber:
§ 63.365(e)(1) § 63.365(e)(2)	• [EG] (any vent type) • Scrubber liquor tank level (any vent type)
§ 63.365(f)	[Reserved]
§ 63.365(g)	Efficiency and parameter determination for other control devices
§ 63.365(h)	Alternative to gas chromatography for ARV standards
§ 63.366 Reporting	
§ 63.366(a)	Sources subject to this section and subpart A; content and submittal dates for summary, deviations, and monitoring system performance reports
§ 63.366(b)	Construction/reconstruction reporting
§ 63.366(c)	Notification reports
§ 63.367 Recordkeeping	
§ 63.367(a)	Sources subject to this section and subpart A
§ 63.367(b)	Sources using 1 to 10 tons maintain records of EO usage on 12-month rolling basis
§ 63.367(c)	Sources using <1 ton maintain records of EO usage on 12-month rolling basis
§ 63.367(d)	Maintain work practice records if catalytic oxidizer is used: records of compliance test, data analysis, and if catalyst has been replaced, proof of replacement

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16. ABSTRACT

National emissions standards to control emissions of HAP from new and existing ethylene oxide commercial sterilization and fumigation operations were promulgated in 1994. This document contains information to assist State and local air pollution control agencies as well as the regulated community in the implementation of these standards. This document provides a common sense summary of the NESHAP requirements, describes the most frequently encountered emissions points, and describes the most commonly used emissions control devices. Sample inspection sheets are also provided as is a bibliography of Federal, State and private sources of additional information related to these standards.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Air pollution Air pollution control National emissions standards Hazardous air pollutants Ethylene oxide Commercial sterilization and fumigation industry Implementation guidance	Air pollution control Ethylene oxide Stationary sources	13B

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