SMALL ENTITY COMPLIANCE GUIDE
FOR
COMMERCIAL STERILIZATION FACILITIES

National Emission Standards for Hazardous Air Pollutants (NESHAP):

Ethylene Oxide Emissions Standards for Sterilization Facilities

40 CFR Part 63, Subpart O

April 2024

NOTICE

This guide was prepared pursuant to section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104-121 as amended by Pub. L. Number 110-28. THIS DOCUMENT IS NOT INTENDED, NOR CAN IT BE RELIED UPON, TO CREATE ANY RIGHTS ENFORCEABLE BY ANY PARTY IN LITIGATION WITH THE UNITED STATES. The statements in this document are intended solely as guidance to aid you in complying with the Ethylene Oxide Emissions Standards for Sterilization Facilities, 40 CFR Part 63, Subpart O.

The full text of the rule and additional information are available online at
https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

ABOUT THIS GUIDE

The U.S. Environmental Protection Agency (EPA) published this document as a compliance guide for small entities, as required by the Small Business Regulatory Enforcement Fairness Act. The guide is designed to help small businesses determine if and how they are affected by the Ethylene Oxide Emissions Standards for Sterilization Facilities, 40 CFR Part 63, Subpart O.

Who should use this guide?

If you own or operate a commercial sterilization facility, then you should use this guide. This guide will help you determine if and how your facility is affected by the Commercial Sterilization Facilities NESHAP.

How do I use this guide?

This guide is organized into four major sections:

- **SECTION 1: INTRODUCTION** presents the final rule Commercial Sterilization Facilities NESHAP, which affects owners and operators of commercial sterilization facilities. The final rule was published on April 5, 2024. The section presents an overview of the rule and identifies the types of affected sources.
- **SECTION 2: SUMMARY OF THE COMMERCIAL STERILIZATION FACILITIES RULE** summarizes the requirements of the Commercial Sterilization Facilities NESHAP.
- **SECTION 3: HOW TO COMPLY** helps you determine the group for each affected source, which is based on the facility's status as a major or area source, whether the affected source is new or existing, and facility EtO use. The section also describes tasks that you have to complete, depending on the groups for your affected sources.
- **SECTION 4: OTHER INFORMATION** presents the estimated benefits and costs of the Commercial Sterilization Facilities NESHAP, provides compliance assistance resources, and tells you where to obtain additional information on the rule.

This guide is intended to summarize rule requirements and provide some examples and clarifications where EPA anticipates that small entities will have questions about rule requirements. Throughout this guide, citations to the actual regulatory text are referenced for both the commercial sterilization facilities rule and the applicable overarching requirements from the General Provisions. You can use the Electronic Code of Federal Regulations (e-CFR) to find the appropriate sections regulatory language cited in this guide.

- Go here to access the e-CFR regulatory text for the Commercial Sterilization Facilities NESHAP.
- Go here to access the e-CFR regulatory text for the General Provisions.

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LIST OF ACRONYMS

ARV	aeration room vent
CAA	Clean Air Act
CD	calibration drift
CDX	Central Data Exchange
CEDRI	Compliance and Emissions Data Reporting Interface
CEMS	continuous emission monitoring systems
CEV	chamber exhaust vent
CGA	cylinder gas audit
CMS	continuous monitoring system
CPMS	continuous parameter monitoring system
DSA	dynamic spiking audit
e-CFR	electronic-Code of Federal Regulations
EG	ethylene glycol
EPA	Environmental Protection Agency
EtO	ethylene oxide
FDA	Food and Drug Administration
lb/hr	pounds per hour
lb/yr	pounds per year
LOD	level of detection
ME	measurement error
NESHAP	national emission standards for hazardous air pollutants
ppmv	parts per million by volume
PS	performance specification
PTE	permanent total enclosure
RAA	relative accuracy audit
RATA	relative accuracy test audit
QA/QC	quality assurance/quality control
SA	standard addition
SADL	standard addition detection level
SAR	standard addition response
SCV	sterilization chamber vent
tpy	ton per year

1.0 INTRODUCTION

EPA published the final Commercial Sterilization Facilities NESHAP in the Federal Register on April 5, 2024 (go here to access the fact sheet). This rule reduces ethylene oxide emissions from the following affected sources:

- Sterilization chamber vents
- Aeration room vents
- Chamber exhaust vents
- Group 1 room air emissions
- Group 2 room air emissions

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

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

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

- **Aeration** means, for the purposes of this rule, exposing sterilized material at elevated temperatures to drive EtO out of the material.
- **Aeration room** means any vessel or room that is used to facilitate off-gassing of EtO at a sterilization facility.

Chamber exhaust vent (CEV) means the point(s) through which EtO-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes. This may also be referred to as a "backvent" (or "back vent").

Group 1 room air emissions mean emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material.

- **Indoor EtO storage** means the storage of EtO within non-cartridge media (e.g., drums, cylinders) inside a sterilization building.
- **EtO dispensing** means charging a sterilization chamber or chambers with EtO from non-cartridge storage media (e.g., drums, cylinders) via the use of piping, lines, and other equipment. This includes injection rooms and post-injection handling of containers.

  - **Injection room** means any room where EtO is injected into containers (e.g., bags, pouches) that are filled with product to be sterilized.
  - **Post-injection handling of containers** means the storage and transportation of containers (e.g., bags, pouches) that have been injected with EtO but have not been placed in a sterilization chamber.

- **Vacuum pump operation** means the operation of vacuum pumps, excluding dry seal vacuum pumps, for the purpose of removing EtO from a sterilization chamber.
- **Pre-aeration handling of sterilized material** means the storage and transportation of material that has been removed from a sterilization chamber but has not been placed in an aeration room.

Group 2 room air emissions mean emissions from post-aeration handling of sterilized material.

- **Post-aeration handling of sterilized material** means the storage and transportation of material that has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility. Post-aeration handling of sterilized material ends when that vehicle is closed for the final time before leaving the facility. This definition does not include handling of material that has been both previously sterilized and not removed from aeration following re-sterilization.

Some commercial sterilization facilities use **combination sterilization units**, which are defined as any enclosed vessel in which both sterilization and aeration of the same product occur within the same vessel (i.e., the vessel is filled with EtO gas or an EtO/inert gas mixture for the purpose of sterilizing and is followed by aeration of EtO). For these units, there is a SCV but no ARV or CEV; therefore, emissions from these units are subject to the relevant SCV standard. If material is not moved out of the vessel between sterilization and aeration, then there is no pre-aeration handling of sterilized material from these units. As discussed above, if material has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility, then there are Group 2 room air emissions present at the sterilization facility.

This rule also applies to **single-item sterilization**, which is defined as a process in which one or more items are placed in a pouch, EtO is injected into the pouch, and the sealed pouch is placed in a vessel to allow sterilization to occur. There are no separate standards for single-item sterilization; however, any facility that conducts single-item sterilization must follow the applicable standards for the affected sources at the facility.

2.0 SUMMARY OF THE COMMERCIAL STERILIZATION FACILITIES NESHAP

2.1 Am I subject to this rule?

You are subject to the Commercial Sterilization Facilities NESHAP if you own or operate a sterilization facility, which is defined as any stationary source where EtO is used in the

sterilization or fumigation of materials, including but not limited to facilities that engage in single-item sterilization.

The following facilities are NOT subject to the Commercial Sterilization Facilities NESHAP:

- Beehive fumigators
- Research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.
- EtO sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals.

2.2 Summary of Requirements

EPA is regulating affected sources at commercial sterilization facilities based on three components: whether the source is located at a major or area source facility, whether the source is new or existing, and facility EtO use. Table 1 summarizes the standards:

Table 1. Summary of Standards for Commercial Sterilization Facilities

Emission source	Existing or new?	EtO use	Standards
SCV	Existing and new	At least 30 tpy	99.99% emission reduction[1]
		At least 10 tpy but less than 30 tpy	99.9% emission reduction[1]
		At least 1 but less than 10 tpy	99.8% emission reduction[1]
		Less than 1 tpy	99% emission reduction[2]
ARV	Existing	At least 30 tpy	99.9% emission reduction[1]
		At least 10 tpy but less than 30 tpy	99.6% emission reduction[1]
		Less than 10 tpy	99% emission reduction[2]
	New	At least 10 tpy	99.9% emission reduction[1]
		Less than 10 tpy	99% emission reduction[2]
CEVs at major source facilities	Existing and new	N/A	99.94% emission reduction
CEVs at area source facilities	Existing and new	At least 60 tpy	99.9% emission reduction[1]
		Less than 60 tpy	99% emission reduction[2]
Group 1 room air emissions at major sources	Existing and new	N/A	97% emission reduction[3]
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98% emission reduction[1,3]
		Less than 40 tpy	80% emission reduction[2,3]

Emission source	Existing or new?	EtO use	Standards
Group 2 room air emissions at major sources	Existing and new	N/A	86% emission reduction[3]
Group 2 room air emissions at area sources	Existing	At least 20 tpy	98% emission reduction[1,3]
		At least 4 but less than 20 tpy	80% emission reduction[1,3]
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened[2,4]
	New	At least 20 tpy	98% emission reduction[1,3]
		Less than 20 tpy	80% emission reduction[2,3]

[1] For existing sources, the standard applies if a facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025. The standard also applies if a facility with previous EtO use below the specified amount has subsequently increased its EtO use to the specified EtO use range for a consecutive 12-month period after April 7, 2025.

[2] For existing sources, the standard applies if a facility has used less than the specified EtO use within all consecutive 12-month periods after April 7, 2026.

[3] To ensure compliance with the emission limit, we are requiring each facility to operate sources with these emissions in accordance with the permanent total enclosure (PTE) requirements of EPA Method 204 of appendix M to 40 CFR part 51. (You can also go here to access a stand-alone version of the method).

[4] Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).

New sources are subject to emission standards beginning on April 5, 2024, or upon startup, whichever is later. Because most standards for new sources are dependent on the amount of EtO use per year, if a new source starts up on or after April 5, 2024, there will not be one year worth of actual EtO use data by the compliance deadline, in which case the standard that applies on the compliance date is based on how much EtO the facility is expected to use within 12 months of the new source being in operation. For example, if a facility has a new SCV that starts up May 1, 2024, and if the facility expects to use at least 30 ton per year (tpy) of EtO within the first 12 months of the new SCV being in operation (May 1, 2024, through April 30, 2025), then a 99.99% emission reduction standard applies to that new SCV on May 1, 2024. For a new source that started up before April 5, 2024, the standard that applies on April 5, 2024, is based on a combination of actual and expected EtO use for the first 12 months of the new source being in operation. For example, if a facility has a new SCV that started up January 1, 2024, the applicable standard is based on the total of the actual EtO use amount between January 1 and April 4, 2024, and expected use amount from April 5, 2024, through December 31, 2024. In both examples above, after the new source has been in operation for a year, the standard that applies is based on actual EtO use for the first 12 months of the new SCV being in operation.

To demonstrate compliance with the emission limits, we have also included capture requirements. We are also requiring facilities to monitor with an EtO continuous emissions

monitoring system (CEMS), with exceptions for small users (i.e., those using less than 100 pounds per year (lb/yr) of EtO). Small users have the option to either use EtO CEMS for demonstrating compliance, or they may conduct annual performance tests on the control equipment, establish operating limits during those tests, and conduct parametric monitoring. Until compliance is required with the above standards, facilities subject to the requirements that were in the previous rule must continue to comply with such requirements, which are as follows:

- SCVs at facilities where EtO use is at least 1 tpy: 99% emission reduction
- ARVs at facilities where EtO use is at least 10 tpy: 99% emission reduction

2.3 When Do I Need to Comply?

Initial Notification of Applicability: (§63.9(b))

- August 5, 2024, or within 120 days after source startup, whichever is later.
- In addition, if your facility subsequently increases its EtO usage amount and becomes subject to a different standard, you must submit an initial notification within 120 days of becoming subject to that standard.
- Initial Notifications are not required to be submitted electronically. However, if you wish to submit the notification electronically, you may do so via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) (https://cdx.epa.gov/).

Notification of Compliance Status: (§63.9(h))

- Within 60 days of completing the relevant compliance demonstration activity (e.g., performance test, operation of EtO CEMS)
- Beginning October 7, 2024, the Notification of Compliance Status must be submitted electronically via CEDRI

Compliance Dates (Tables 1 through 5 to Subpart O of Part 63)

- See Table 2.

What if I miss the notification deadline? Will I be penalized for submitting a late notification?

Please note that it is beyond the scope of this document to discuss any specific enforcement response. If for some reason you miss the notification deadline, please send in your forms as soon as possible.

Table 2. Summary of Compliance Dates

Emission source	Existing or new?	EtO use	Submit Initial Notification of Applicability by…	Demonstrate Compliance with Emission Standards by…	Submit Notification of Compliance Status by…
SCV	Existing	At least 1 tpy	August 5, 2024.	October 5, 2026	December 7, 2026
		Less than 1 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A[3]	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
ARV	Existing	At least 10 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 10 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
CEVs at major source facilities	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
CEVs at area source facilities	Existing	At least 60 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 60 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 1 room air	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.

Emission source	Existing or new?	EtO use	Submit Initial Notification of Applicability by…	Demonstrate Compliance with Emission Standards by…	Submit Notification of Compliance Status by…
emissions at major sources	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 1 room air emissions at area sources	Existing	At least 40 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 40 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 2 room air emissions at major sources	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 2 room air emissions at area sources	Existing	At least 4 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 4 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.

If you become subject to a more stringent standard due to an increase in EtO usage after the compliance date for that standard, then the following applies:

- You must comply with the standard immediately upon becoming subject to it,
- You must demonstrate compliance with the standard within 180 days of becoming subject to it, and

- You must submit a notification of compliance status within 60 days after demonstrating compliance with the standard (i.e., within 240 days of becoming subject to the more stringent standard).

3.0 HOW TO COMPLY

Your requirements depend on the groups that your affected sources fall into. To determine your requirements, identify those groups, and then see which tasks you must complete.

3.1 How Do I Determine the Group for Each Affected Source?

To determine the group for your affected sources, you may need to answer three questions:

- Is my facility a major source or an area source
- Is the affected source existing or new?
- What is the EtO use at my facility?

The first two bullets are discussed in detail in the sub-sections below. For EtO use, see Table 1 of this guide for the specific EtO use requirements that apply for each standard.

3.1.1 Major source vs. area source

Under the Clean Air Act (CAA), EPA classifies stationary sources by the amount of toxic pollution they emit. A "major source" is any stationary source or a group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit 10 or more tons per year of any single hazardous air pollutant (HAP) or 25 or more tons per year of any combination of HAP. Accordingly, a commercial sterilization facility that meets the emission threshold is a major source. Any facilities that are not major sources are classified as area sources.

3.1.2 New vs. existing affected source

An affected source is existing if construction or reconstruction of the affected source commenced on or before April 13, 2023. An affected source is new if construction or reconstruction of the affected source commenced after April 13, 2023.

You commence construction or reconstruction if you have a contractual obligation to undertake and complete construction or have begun the act of construction on the affected source. An affected source is reconstructed if both reconstruction commenced after April 13, 2023, and the following criteria are met:

- The fixed capital cost of the new components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source; and
- It is technologically and economically feasible for the reconstructed source to meet the relevant standard for new sources. Upon reconstruction, an affected source is subject to

relevant standards for new sources, including compliance dates, irrespective of any change in HAP emissions from that source.

3.2 Task 1: Submit Initial Notifications

All owners and operators of a commercial sterilization facility must submit an Initial Notification of Applicability.

Notification of Applicability. Submit an Initial Notification of Applicability for:

- ***Existing Sources***: No later than August 5, 2024.
- ***New Sources***: Within 120 days after startup.

The Initial Notification of Applicability must contain the following information:

- The name and address of the owner or operator.
- The address (i.e., physical location) of the affected source.
- An identification of the relevant standard, or other requirement, that is the basis of the notification (i.e., 40 CFR part 63 subpart O) and the source's compliance date.
- Anticipated compliance date with the standard.
- A brief description of the nature, size, design, and method of operation of the source and an identification of the types of emission points within the affected source subject to the relevant standard.
- A statement of whether the affected source is a major source or an area source.
- The amount of EtO used at the facility during the previous consecutive 12-month period. For new sterilization facilities, the amount of EtO used at the facility shall be an estimate of expected use during the first consecutive 12-month period of operation.

Notification of Compliance Status. A notice certifying your compliance with the rule requirements is required. The notification must be submitted electronically using CEDRI on EPA's CDX (www.epa.gov/cdx). Submit the Notification of Compliance Status within 60 days of completing the relevant compliance demonstration activity (e.g., performance test, operation of EtO CEMS).

See section 4 of this compliance guide for links to addition resource support.

3.3 Task 2: Comply with Best Management Practice (if applicable)

If you own or operate an existing collection of Group 2 room air emissions at a facility where EtO use is less than 4 tpy, you must lower the EtO concentration within each sterilization chamber to 1 parts per million by volume (ppmv) before the chamber can be opened.

3.4 Task 3: Meet Emission Limits

3.4.1 What, When, and How Must I Monitor or Test?

All facilities must use EtO CEMS to demonstrate compliance with emission limits, with one exception for facilities where EtO use is less than 100 lb/yr. If you operate a facility where EtO use is less than 100 lb/yr, see section 3.4.1.2 of this compliance guide. Otherwise, see section 3.4.1.1.

The compliance dates for existing sources may be 2 years or 3 years.

Emission sources with a 2-year compliance date.

Existing emission sources with a 2-year compliance date include the following:

- SCV at facility where EtO use is at least 30 tpy,
- SCV at facility where EtO use is at least 10 tpy but less than 30 tpy.
- ARV at facility where EtO use is at least 30 tpy,
- ARV at facility where EtO use is at least 10 tpy but less than 30 tpy,
- CEV at area source facility where EtO use is at least 60 tpy,
- Group 1 room air emissions at area source facility where EtO use is at least 40 tpy,
- Group 2 room air emissions at area source facility where EtO use is at least 20 tpy,
- Group 2 room air emissions at area source facility where EtO use is at least 4 tpy but less than 20 tpy.

Emission sources with a 3-year compliance date.

Existing emission sources with a 3-year compliance date include the following:

- SCV at facility where EtO use is less than 1 tpy,
- ARV at facility where EtO use is less than 10 tpy,
- CEV at major source facility,
- CEV at area source facility where EtO use is less than 60 tpy,
- Group 1 room air emissions at major source facility,
- Group 1 room air emissions at area source facility where EtO use is less than 40 tpy,
- Group 2 room air emissions at major source facility,
- Group 2 room air emissions at area source facility where EtO use is less than 4 tpy.

Facilities subject to subpart O must meet the subtasks under this section 3.4.1 through 3.4.7 of this compliance guide.

3.4.1.1 Facilities using EtO CEMS

All facilities must use an EtO CEMS to demonstrate compliance with emission limits (except for facilities where EtO use is less than 100 lb/yr). You must certify the EtO CEMS using **Performance Specification 19[1] (PS 19)** in Appendix B (and following **Appendix A**[2] to subpart O), completing the initial performance test over the first 30 operating days after certification using PS 19, and conducting quality assurance and quality control (QA/QC) using **Procedure 7**[3] in Appendix F to Part 60.

***Emission Sources with a 2 year compliance date*.**

To demonstrate compliance using an EtO CEMS for emission sources that are subject to a 2-year compliance date, you must:

1. Demonstrate continuous compliance with emission limits using an EtO CEMS.
2. In conjunction with Appendix A to subpart O, certify EtO CEMS using Performance Specification 19 in Appendix B to part 60.
    a. Existing: Complete within 150 days after compliance date,[4] or September 7, 2026.
    b. New: Complete within 150 days after compliance date, or September 2, 2024, or 150 days after startup.
3. Initial performance test consists of first 30 operating days after certification of EtO CEMS.
    a. Existing: Complete within 180 days after compliance date, or October 5, 2026.
    b. New: Complete within 180 days after compliance date, or October 2, 2024, or 150 days after startup.
4. In conjunction with Appendix A to subpart O, operate EtO CEMS following Procedure 7 in Appendix F to part 60.
5. Develop a Performance Evaluation Plan (per §63.364(a)(5)), that also meets PS 19.

[1] Performance Specification 19. Performance Specifications and Test Procedures for Ethylene Oxide (ETO) Continuous Emission Monitoring Systems. 40 CFR part 60, Appendix B, Performance Specifications.
[2] Appendix A to Subpart O of Part 63. Monitoring Provisions for EtO CEMS.
[3] Procedure 7. Quality Assurance Requirements for Gaseous Ethylene Oxide (EtO) Continuous Emission Monitoring Systems Used for Compliance Determination. 40 CFR part 60, Appendix F, Quality Assurance Procedures.
[4] The 150-day timeframe is highlighted here to allow sufficient time for the facility to conduct the initial performance test over the first 30 operating days. While 180 days is provided for demonstrating compliance, the actual compliance demonstration is done using the first 30 operating days of data following certification. Therefore, data collection will need to begin at least 30 days prior to the deadline for demonstrating compliance. In addition, in order for the data collected by the EtO CEMS to be valid, the EtO CEMS must be certified in accordance with PS 19. This means that the certification must be done within 150 days of the relevant compliance date so that valid data can be used to demonstrate compliance with the standard.

For facilities with room air emissions subject to emission limits in subpart O, you must demonstrate initial compliance for PTE, §63.365(f).

Emission sources with a 3 year compliance date.

To demonstrate compliance using an EtO CEMS for emission sources that are subject to a 3-year compliance date, you must:

1. Demonstrate continuous compliance with emission limits using an EtO CEMS.
2. In conjunction with Appendix A to subpart O, certify EtO CEMS using Performance Specification 19 in Appendix B to part 60.
    a. Existing: Complete within 150 days after compliance date, or September 6, 2027.
    b. New: Complete within 150 days after compliance date, or September 2, 2024, or 150 days after startup.
3. Initial performance test consists of first 30 operating days after certification of EtO CEMS.
    a. Existing: Complete within 180 days after compliance date, or October 5, 2027.
    b. New: Complete within 180 days after compliance date, or October 2, 2024, or 150 days after startup.
4. In conjunction with Appendix A to subpart O, operate EtO CEMS following Procedure 7 in Appendix F to part 60.
5. Develop a Performance Evaluation Plan (per §63.364(a)(5)), that also meets PS 19.

For facilities with room air emissions subject to emission limits in subpart O, you must demonstrate initial compliance for PTE, §63.365(f).

3.4.1.2. Facilities where EtO use is less than 100 lb/yr conducting periodic performance tests of control devices.

Facilities where EtO use is less than 100 lb/yr may follow either the compliance and monitoring approach using EtO CEMS in section 3.4.1.1 of this compliance guide, or you may follow the compliance and monitoring approach using periodic performance testing and parametric monitoring for control devices in this section. To demonstrate compliance with the emission limits at facilities where EtO use is less than 100 lb/yr, you may:

1. Conduct initial performance tests on control devices.
    a. Existing: Complete within 180 days after compliance date, or October 5, 2026 (for emission sources with 2-year compliance date). (For emission sources with 3-year compliance date, October 5, 2027.)
    b. New: Complete within 180 days after compliance date, or October 7, 2024, or 180 days after startup.
2. Establish operating limits during the performance tests.
3. Monitor and collect data to demonstrate compliance with operating limits.
4. Conduct annual performance tests.

For facilities with room air emissions subject to emission limits in subpart O, you must demonstrate initial compliance for PTE, §63.365(f).

3.4.1.3. Additional Compliance Approaches for Combined Sources and Site-Wide at Facilities Using EtO CEMS.

Subpart O includes compliance alternatives for combined emission streams and for site-wide emission limits.

Combined Emission Streams.

A combined emission stream is when the emissions from more than one emission source are routed together using common ductwork prior to the control system. Facilities must comply with one of two options under §63.362(i) for combined emission streams.

Option to apply most stringent limit:

- Determine the mass of EtO entering the control device after the emission streams are combined (i.e., the 30-operating day rolling sum of inlet mass to the control system), and apply the most stringent emission reduction standards that the component streams are subject to. See §63.362(i)(1)(i) for the equation for calculating 30-operating day rolling sum of combined emission stream limit, and see §63.362(i)(1)(ii) and equation A-3 to Appendix A to subpart O for calculating the 30-operating day rolling sum of actual emissions from the combined streams.
- You must demonstrate the 30-operating day rolling mass of actual emissions is at or below the 30-operating day rolling sum of combined emission stream limit.

Option to apply the applicable limit to each component stream:

- Determine the mass of EtO entering the control device before the emission streams are combined (i.e., the 30-operating day rolling sum of inlet mass to the control device for each component stream), and apply the emission reduction standard that each component stream is subject to. See §63.362(i)(2)(i) for the equation for calculating 30-operating day rolling sum emission limit (sum of all component streams), and see §63.362(i)(2)(ii) and equation A-3 to Appendix A to subpart O for calculating the 30-operating day rolling sum of actual emissions at the outlet of the control system.
- You must demonstrate the 30-operating day rolling sum of actual emissions is at or below the 30-operating day rolling sum emission limit.

Site-wide Emission Limit.

A site-wide emission limit includes the emissions from all emission sources at the facility. Facilities must comply with one of two options under §63.362(j) for site-wide emission limits.

Option based on facility EtO usage and applying the SCV percent emission reduction limit:

- Determine the 30-operating day rolling sum of EtO use at the facility, multiply by 0.99, and then apply the required SCV percent emission reduction limit. See §63.363(j)(1)(i) for the equation calculating 30-operating day rolling sum emission limit, and see §63.362(j)(1)(ii) and equation A-3 of Appendix to subpart O for calculating the 30-operating day rolling sum of actual emissions across all stacks.
- You must demonstrate the emissions for each 30-operating day period are at or below the site-wide emission limit.

Option based on emission streams and the applicable limit for each component stream:

- Determine the mass of EtO sent to the control device, and apply the applicable emission reduction standard. See §63.362(j)(2)(i) for the equation for calculating 30-operating day rolling sum emission limit (sum of all non-SCV component streams and sum all SCV component streams), and see §63.362(j)(2)(ii) and equation 4 to that section for calculating the 30-operating day rolling sum of actual emissions across all stacks.
- You must demonstrate the emissions for each 30-operating day period are at or below the site-wide emission limit.

3.4.2 Develop and Follow a Site-specific Testing Plan

All facilities subject to subpart O must complete this subtask.

You must develop a site-specific test plan before conducting your required EtO CEMS certification and performance test. You do not have to submit the site-specific test plan to the EPA Administrator or delegated authority unless it is requested. If requested, the site-specific test plan must be submitted at least 60 days before your EtO CEMS certification or performance stack test. You must keep a copy of the site-specific test plan as a record.

The site-specific test plan must include:

- Test program summary
- Test schedule
- Data quality objectives (pretest expectations of precision, accuracy, and completeness)
- Internal and external quality assurance program.

3.4.3 Develop and Follow a Site-specific Monitoring Plan

A site-specific monitoring plan must include:

- EtO CEMS monitoring, as applicable;
- Parametric monitoring approach used under §63.363(d) and (e), as applicable;
- Monitoring approach for PTE under §63.364(g); and

- Monitoring approach for best management practice under §63.364(h) (for area sources where EtO use is less than 4 tpy).

The monitoring plan is required for any continuous emissions monitoring system (CEMS) or continuous parameter monitoring system (CPMS). These types of continuous monitors are referred to as continuous monitoring systems (CMS) in the remainder of this section.

3.4.3.1. Facilities using EtO CEMS

A site-specific monitoring plan is required if you monitor with EtO CEMS. The EtO CEMS must be operated according to PS 19 in Appendix B to part 60 and must meet the requirements of Appendix A to subpart O. Appendix A to subpart O includes:

- installation requirements;
- initial certification procedures;
- ongoing QA requirements that include following Procedure 7 in Appendix F to Part 60 and data validation; and
- a written QA/QC plan for EtO CEMS for preventive maintenance, recordkeeping and reporting, and maintenance, and data collection and reduction requirements.

For each emission source or sources monitored at a common stack, the Monitoring Plan for the EtO CEMS and other monitoring systems must contain information on associated CMS and how all EtO emissions are monitored and reported (e.g., concentration, stack gas volumetric flow rate, emission rate, certification and QA test records). The Monitoring Plan must also contain reporting provisions for the EtO CEMS and emissions.

3.4.3.2. Facilities where EtO use is less than 100 lb/yr conducting periodic performance tests of control devices

If you choose to demonstrate compliance through periodic performance testing of control devices and subsequent compliance with operating limits, then you must develop a site-specific monitoring plan. A monitoring plan is also required if you petition the EPA Administrator for alternative monitoring parameters under §63.363(e) and §63.8(f) of the General Provisions.

- Submit, if requested, the site-specific monitoring plan at least 60 days before your initial performance evaluation of your CMS.
- In the site-specific monitoring plan, address the installation location, performance and equipment specifications, performance evaluation procedures and acceptance criteria, ongoing operation and maintenance procedures, ongoing data quality assurance procedures, and ongoing recordkeeping and reporting procedures.
- Conduct a performance evaluation of each CMS per your site-specific monitoring plan.
- Operate and maintain the CMS according to the site-specific monitoring plan.

3.4.3.3. Best Management Practice for Existing Group 2 Room Air Emissions at Area source facilities where EtO use is less than 4 tpy.

For the best management practice for existing Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy, facilities must indicate whether they will monitor using parametric or direct measurement, and may also apply for an alternative monitoring approach. For the parametric approach, indicate the parameters used to monitor and calculate the end-cycle EtO concentration. For the measurement approach, indicate how the EtO concentration will be monitored. For the alternative monitoring, submit a request for approval by the Administrator under §63.8(f).

3.4.4 Conduct Initial and Annual Performance Tests

3.4.4.1. Facilities using EtO CEMS

Facilities using EtO CEMS to demonstrate compliance must follow Appendix A to subpart O and PS 19 in Appendix B to certify the CEMS. Following certification, facilities must complete the initial performance test over the first 30 operating days, and conduct ongoing QA/QC using Procedure 7 in Appendix F to part 60.

3.4.4.2. Facilities where EtO use is less than 100 lb/yr conducting periodic performance tests for control devices

You may conduct an initial performance test of the control devices to demonstrate initial compliance and to establish operating parameters that you will follow until the next performance test, which must be conducted annually.

You must conduct all performance tests according to §63.365 and to §63.7 according to Table 6 to subpart O, which specify test methods for selecting sampling ports, determining stack gas velocity and flow rate, determining O_2 and CO content, measuring moisture content, and measuring emissions.

If you own or operate an area source facility where EtO use is less than 100 lb/yr and where an existing collection of Group 2 room air emission is operated in accordance with the PTE requirements of EPA Method 204 of Appendix M to part 51, you may instead conduct these performance tests once every three years.

You must conduct the performance tests under normal operating conditions, and you must account for the control system residence time when conducting the performance test.

Depending on the configuration of your facility, you may need to conduct more than one performance stack test. You must follow the requirements in the General Provisions, which include:

- Completing a test method performance audit during the performance test (using blind audit samples, supplied by an accredited audit sample provider and analyzed during the performance test, to provide a measure of test data bias).
- Providing testing facilities that are adequate and safe to conduct stack testing.
- Conducting tests under representative conditions.
- Requesting to use an alternative test method, if desired.

In addition, you must:

- Conduct a minimum of three separate test runs for each performance stack test.
- If you are testing equipment other under §63.363(e) and §63.364(e), §63.365(e)(5) you must submit information at least 60 days before the performance test is scheduled to begin.

3.4.5 Establish Operating Limits during the Performance Test

3.4.5.1. Facilities where EtO use is less than 100 lb/yr conducting periodic performance tests.

During the 3-run performance stack test(s), you must establish operating limits for your air pollution control device(s). Section §63.365(e) of subpart O specifies how to establish operating parameters.

Acid-Water Scrubber:

- Establish operating limits for maximum ethylene glycol (EG) concentration, maximum scrubber liquor tank level, or pH. If you conduct multiple stack tests, you must set the operating limits at the highest minimum values established during the multiple tests.

Catalytic Oxidizer:

- Establish operating limits for minimum inlet temperature to the catalyst bed, and minimum temperature increase across the catalyst bed (i.e., minimum temperature difference).

Thermal Oxidizer:

- Establish minimum outlet temperature from the firebox.

Gas Solid Reactor:

- Establish maximum pressure drop across the media beds.

Other control device type:

- Propose monitoring parameters and submit for approval to the Administrator, using §63.365(e).

3.4.5.2. All Facilities.

PTE for Room Air Emissions*:*

For facilities with room air emissions subject to emission limits in subpart O and that choose to monitor volumetric flow rate, during the 3-run performance stack test(s), you must establish the operating limit for your PTE.

- If monitoring volumetric flow rate from PTE, establish minimum volumetric flow rate through affected stacks using §63.365(f)(1).

3.4.6 Monitor and Collect Data to Demonstrate Continuous Compliance with the Emission Limits

3.4.6.1. Facilities using EtO CEMS

Facilities using EtO CEMS must follow Appendix A to subpart O and Performance Specification 19 in Appendix B to certify the CEMS. Following certification, the facility must complete the initial performance test over the first 30 operating days, and conduct ongoing QA/QC using Procedure 7 in Appendix F to part 60.

3.4.6.2. Facilities where EtO use is less than 100 lb/yr conducting periodic performance tests of control devices.

Demonstrate continuous compliance with the emission limits and operating limits by continuously monitoring your operating parameters according to the methods in §63.364, and comply with monitoring requirements in §63.8 according to Table 6 to subpart O.

Acid-Water Scrubber EG Concentration, Scrubber liquor tank level, or pH:

EG concentration:

- For EG concentration, sample and analyze scrubber liquor once per week, if acid-water scrubber was operated during the week.
- Maintain weekly EG concentration below the operating limit established during the most recent performance test.

Scrubber liquor tank level:

- For scrubber liquor tank level, measure level once per day, if acid-water scrubber was operated during the day.

- Maintain daily tank level below the operating limit established during the most recent performance test.

pH:

- Collect pH data every 15 minutes while acid-water scrubber is operating.
- Calculate 1-hour average readings over each clock hour for pH data.
- Calculate the average of previous 3 operating hours to determine 3-hour rolling average pH.
- Maintain 3-hour rolling average below the operating limit established during the most recent performance test.

Catalytic Oxidizer Inlet Temperature and Temperature Increase across Catalyst Bed:

- Collect inlet temperature data and temperature increase data every 15 minutes while the catalytic oxidizer is operating.
- Calculate 1-hour average readings over each clock hour for inlet temperature data.
- Calculate 1-hour average readings by first computing difference in outlet temperature minus inlet temperature, and then averaging the 1-hour average temperature difference.
- Calculate the average of previous 3 operating hours to determine 3-hour rolling average inlet temperature, and 3-hour rolling average temperature increase.
- Maintain 3-hour rolling average at or above the operating limit established during the most recent performance test.

Thermal Oxidizer Outlet Temperature:

- Collect outlet temperature data every 15 minutes while thermal oxidizer is operating.
- Calculate 1-hour average for readings over each clock hour.
- Calculate the average of previous 3 operating hours to determine 3-hour rolling average outlet temperature.
- Maintain 3-hour rolling average at or above the operating limit established during the most recent performance test

Gas Solid Reactor Pressure drop and Media sample:

- Collect pressure drop data every 15 minutes while gas-solid reactor is operating.
- Calculate 1-hour average for readings over each clock hour.
- Calculate the average of previous 3 operating hours to determine 3-hour rolling average pressure drop.

- Maintain 3-hour rolling average below the operating limit established during the most recent performance test.
- Sample and analyze media once per week, if gas/solid reactor was operated during the week.

Other control device type:

- Monitor the parameters approved by the Administrator, using the methods and procedures in §63.365(e).

3.4.6.3. All Facilities.

All facilities subject to subpart O must monitor and collect data for facility EtO usage and PTE.[5]

EtO Usage:

- Collect total mass of EtO usage daily.
- Calculate the sum of previous 30 days to determine the 30-operating day rolling EtO usage.
- Calculated the total mass of EtO usage for each calendar month.

PTE Flow rate or Pressure difference:

Flow rate, at each outlet where air from the PTE is routed:

- Collect volumetric flow rate data every 15 minutes while the commercial sterilization facility is operating, including portions of the facility covered by PTE that are not operating.
- Calculate 1-hour average for readings over each clock hour.
- Calculate the average of previous 3 operating hours to determine 3-hour rolling average volumetric flowrate.
- Maintain 3-hour rolling average above the operating limit established during the most recent compliance demonstration.

Pressure difference:

- Collect pressure difference data every 5 minutes while the commercial sterilization facility is operating.
- Calculate 1-hour average for readings over each clock hour.

[5] For PTE, this does not apply to existing Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy.

- Calculate the average of previous 3 operating hours to determine 3-hour rolling average pressure difference.
- Maintain 3-hour rolling average at or above the 0.007 inches of water difference.

3.4.6.4. Best management Practice for Existing Group 2 Room Air Emissions at Area source facilities where EtO use is less than 4 tpy.

For the best management practice for existing Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy, facilities must monitor using parametric, direct measurement, or may also apply for an alternative monitoring approach.

Parametric approach for sterilization chamber end-cycle EtO concentration:

- Monitor the parameters and conduct calculations to determine end-cycle EtO concentration, as described in the facility's Site-specific Monitoring Plan.

Measurement approach for sterilization chamber end-cycle EtO concentration:

- Monitor the EtO concentration for sterilization chamber end-cycle EtO concentration, as described in the facility's Site-specific Monitoring Plan.

Alternative monitoring approach:

- Monitor the parameters, using the methods and procedures approved by the Administrator in §63.8(f).

3.4.7 CMS Installation, Operation, Calibration, and Maintenance Requirements

You must comply with the CMS requirements in §63.363 and §63.364.

3.4.7.1 Facilities using EtO CEMS

- You must comply with the EtO CEMS configuration requirement in §63.364(f).
- You must install and operate EtO CEMS on each control system inlet according to Appendix A to subpart O, with the following exceptions:
    - For emissions streams that are comprised only of SCVs, you may use the procedures in §63.364(f)(1)(i) as an alternative to monitoring the inlet emission stream to determine the mass emissions of EtO being emitted via SCV(s) prior to the controls. This does not apply to single-item sterilization facilities.
    - For room air emissions are subject to an emission standard and split across 2 or more control systems, monitoring must be conducted for room air emissions before being combined with other streams, §63.364(f)(1)(ii).
- You must install and operate EtO CEMS on each control system outlet according to Appendix A to subpart O. In addition:

- For a single unit with single stack, you must install the EtO CEMS in the stack or ductwork downstream of all emission control devices, and must be installed in a position to provide representative measurement of pollutant and diluent emissions to the atmosphere.
- For units with a common stack with other emission sources that are also subject to subpart O, you must install EtO CEMS in the duct from each emission source, or install in a common stack.
- For units with a common stack that also serves non-commercial sterilization sources, you must install EtO CEMS in the duct from each emission source subject to subpart O, or install EtO CEMS in the common stack and attribute all emissions to the subpart O emission sources.
- For units with multiple parallel control devices with multiple stacks, you must install EtO CEMS in each of the multiple stacks.

3.4.7.2 Facilities where EtO use is less than 100 lb/yr conducting periodic performance tests.

All monitoring equipment must be installed to provide representative measurements or emissions or process parameters from the source, §63.364(a). The operational status of monitoring equipment must be verified using manufacturer written specifications for installation, operation, and calibration, §63.364(a). In addition, for the following CMS you must:

Acid-Water Scrubber (pH):

- pH sensor must be installed in a position to provide representative measurement of scrubber liquor pH;
- Sample must be properly mixed and representative of the fluid to be measured;
- A performance evaluation of pH monitoring system must conducted at least quarterly, and at the time of each performance test.

Catalytic Oxidizer and Thermal Oxidizer:

- Verify accuracy of temperature monitor two times each calendar year (at least 5 months apart), using a reference temperature monitor, at the same location of the temperature monitor being tested for accuracy.
- For catalytic oxidizers, if monitoring shows the temperature is below the operating limit, you must take corrective action, §63.364(c)(5).

3.4.7.3 All Facilities, PTE Monitoring.

For facilities with room air emissions subject to emission limits in subpart O:

Volumetric Flow rate:

- You must comply with the flow rate monitor configuration requirements in §63.364(g)(3).

Pressure difference:

- You must comply with the pressure differential monitor configuration requirements in §63.364(g)(4)(i).

3.5 Task 4: Keep Records and Report

See Task 1 for information on the Initial Notification of Applicability and Notification of Compliance Status. This section addresses the remaining recordkeeping requirements.

3.5.1 General Requirements for Records, Certifications, and Reports

You must keep a copy of each notification and report prepared to comply with this rule. You must also keep all documentation supporting any submitted documents. See Sections 3.5.2 and 3.5.3 of this compliance guide for details on the records required for your facility, based upon your affected sources, applicable standards (as indicated in Section 3.1 of this compliance guide), and method of compliance demonstration (as discussed in Section 3.4 of this compliance guide). Your records must be maintained in a manner that be readily accessed and suitable for inspection. You must keep each record for 5 years after the date of the recorded action. Any records that are submitted electronically via the EPA's Compliance and Emissions Data Reporting Interface (CEDRI) may be maintained in electronic format, provided that the records are available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation. You must keep each record on site or accessible from a central location by computer or other means of instant access at the site for at least 2 years after the date of each recorded action. For the remaining 3 of the 5 years, the records may be kept off site. In summary, you must keep copies of:

- Each notification and report, and all their supporting documentation.
- Control system monitored parameters.
- Daily and 30-operating day EtO usage records.
- The initial and quarterly compliance reports.
- Compliance tests and associated data analysis.
- If applicable, EtO CEMS certification and QA tests.
- Records of the occurrence and duration of each deviation from an emission limit, operating limit, or best management practice. At a minimum, these records must include:
    - The occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment.

- In the event that an affected unit does not meet an applicable standard, record the number of deviations. For each deviation, record the date, time, cause, and duration of each deviation.
- For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.
- Record actions taken to minimize emissions in accordance with §63.362(k) (i.e., the general duty to operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

Initial and Quarterly Compliance Reports

You must submit an initial compliance report that includes summary, monitoring system performance, and deviation information through CEDRI on April 5, 2027. You must also submit quarterly compliance reports containing this information within 30 days following the end of each calendar quarter. Your initial and quarterly compliance reports must include the following information:

- Date that facility commenced construction or reconstruction.
- Hours of commercial sterilization operation over the previous 12 months.
- Monthly EtO use, in tons, over the previous 36 months.
- Emission limit related information discussed in Section 3.5.3 of this compliance guide. If you are demonstrating continuous compliance through the use of an EtO CEMS, this information includes the information discussed in Section 3.5.4 of this compliance guide.
- If you are demonstrating continuous compliance through periodic performance testing, your reports must include:
  - Control system ID;
  - Control device ID;
  - Control device type; and
  - Recirculation tank ID if an acid-water scrubber is used to meet the emission standard and you elect to comply with the maximum scrubber liquor height limit.
- For each sterilization chamber: the sterilization chamber ID, the ID of each control system that the SCV is routed to, the portion of SCV exhaust that is routed to each control system, the ID of each EtO CEMS that is used to monitor SCV emissions (if applicable), the portion of SCV exhaust that is monitored by each EtO CEMS, the ID of each control system that the CEV is routed to, the portion of CEV exhaust that is routed to each control system, the ID of each EtO CEMS that is used to monitor CEV emissions (if applicable), and the portion of CEV exhaust that is monitored by each EtO CEMS.

- For each room subject to an emission standard: the room ID, documentation of the emissions occurring within the room (e.g., aeration, EtO storage, EtO dispensing, pre-aeration handling of sterilized material, post-aeration handling of sterilized material), the ID of each control system that the room air is routed to, the portion of room air exhaust that is routed to each control system, the ID of each EtO CEMS that is used to monitor room air emissions (if applicable), and the portion of room air exhaust that is monitored by each EtO CEMS.
- For each portion of your facility required to be operated with PTE:
    - If you are choosing to demonstrate continuous compliance through the use of volumetric flow rate monitoring: the 3-hour rolling average (rolled hourly) volumetric flow from each outlet where air from the PTE is sent.
    - If you are choosing to demonstrate continuous compliance through the use of differential pressure monitoring: the 3-hour rolling average (rolled hourly) pressure differential readings.
- If you are required to comply with the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, a certification from your responsible official that this approach is being followed and you are meeting the associated monitoring requirements.
- For each collection of existing Group 2 room air emissions at an area source facility where EtO use is less than 4 tpy: the room ID, number of room air changes per hour, room temperature, and EtO concentration. If you are complying with the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door and following the requirements of §63.363 you do not need to include the room air parameters under this bullet in your reports.

3.5.2 Best Management Practice Recordkeeping and Reporting (if applicable)

If you are subject to the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must document and maintain records of your approach for determining the EtO sterilization chamber concentration. You may choose to use either a parametric or direct measurement approach.

If you choose a parametric approach, you must document and maintain records of the parameters used in the calculation to determine the EtO sterilization chamber concentration. Your monitoring plan must include the following for each instrument used for parametric monitoring:

- Parameter measured and measurement principle of the monitor.
- Instrument name, model number, serial number, and range.
- Manufacturer recommended operation practices, including daily operational check.
- Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

- Description for how the information from the parameter monitor is being collected and stored.

If you choose a direct measurement approach, you must document and maintain records of the procedures used for the operation of the associated instruments. Your monitoring plan must include the following for each instrument used for direct measurement of EtO:

- Instrument name, model number, serial number, and range.
- Description of the measurement principle and any potential interferences.
- If applicable, the description of the sampling condition system.
- Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.
- Description for how the information from the parameter monitor is being collected and stored.

As part of your initial and quarterly compliance reporting, you must submit a certification from your responsible official that the approach is being followed and that you are meeting the monitoring requirements discussed Section 3.3.

3.5.3 Emission Limits Recordkeeping and Reporting

Recordkeeping Requirements

You must keep records of your daily usage of EtO, the 30-operating day rolling total usage of EtO for each operating day, and the total usage of EtO in each calendar month.

If you are demonstrating continuous compliance through the use of an EtO CEMS, you must also meet the recordkeeping requirements discussed in Section 3.5.4 of this compliance guide.

If you are electing to determine the mass of EtO sent to a control device from the SCV using the alternative procedures of §63.364(f)(1)(i) (i.e., you determine the mass by weighing EtO gas cylinders or using a calibrated rate meter at the sterilizer inlet), you must keep records of each measurement and calculation required by that paragraph.

Reporting Requirements

As part of your initial and quarterly compliance reports, you must include the following:

- If you are electing to determine the mass of EtO sent to the control device from the SCV(s) via the procedure in §63.364(f)(1)(i) (i.e., you determine the mass by weighing EtO gas cylinders or using a calibrated rate meter at the sterilizer inlet) you must report the daily EtO use from each applicable chamber for the previous 7 months.
- If you are required to comply with one or more combined emission stream limitations (i.e., the emission streams from two or more emission sources are combined), you must

indicate that in your report and indicate the affected sources that are included in each combined emission stream limitation.

- If you are electing to comply with a site-wide emission limit, you must indicate that in your report and report the daily EtO use from the facility over the previous 7 months.
- If an EtO CEMS was used to demonstrate continuous compliance with an emission standard for more than 30-operating days, you must report the following:
  - The information specified in section 11 of appendix A to subpart O. This information is discussed in Section 3.5.4 of this compliance guide.
  - The affected sources that are included in each inlet that is being monitored with an EtO CEMS.
  - The IDs of each inlet(s) to and outlet(s) from each control system.
  - The daily sum of EtO for each inlet, along with 30-operating day rolling sums.
  - The daily sum of EtO emissions from each outlet of the control system, along with 30-operating day rolling sums.
  - For each operating day, report the daily mass emission limit that the control system must achieve based on the previous 30 days of data. For control systems used to comply with a combined emission stream limitation or a site-wide emission limitation, report the daily 30-operating day mass emission limit as determined in accordance with §63.362(i)(1)(i), (i)(2)(i), (j)(1)(i), or (j)(2)(i), as applicable.
  - For each operating day, the mass of EtO emitted from the control system over the previous 30 operating days.

3.5.4 EtO CEMS Recordkeeping and Reporting

If you are using one or more EtO CEMS to demonstrate compliance with an emission standard, you must meet the recordkeeping and reporting requirements of Appendix A to subpart O.

Recordkeeping Requirements

Your records must be maintained in a form suitable for inspection. You must keep each record for 5 years after the date of the recorded action. The records required to be kept under Appendix A include:

- A quality assurance/quality control (QA/QC) written plan that describes in detail complete, step-by-step procedures and operations for the most important QA/QC activities. You must also keep a written record of the procedures used for each type of QA test required for each EtO CEMS that explains how the results of each type of QA test are calculated and evaluated. You must also provide explanation of how each component of the EtO CEMS will be adjusted to provide correct responses to calibration gases after routine maintenance, repairs, or corrective actions.

- A preventative maintenance plan consisting of a written record of procedures needed to maintain the EtO CEMS in proper operating condition and a schedule for those procedures. At a minimum, the plan must include procedures specified by the manufacturers of the equipment and, if applicable, additional or alternate procedures developed for the equipment.
- A written record describing procedures that will be used to implement the recordkeeping and reporting requirements of Appendix A to subpart O.
- Maintenance records that include all testing, maintenance, or repair activities performed on any EtO CEMS.
- Monitoring plan records that explain how the data derived from these systems ensure that all EtO emissions from the unit or stack are monitored and reported.
- The monitoring plan must be updated whenever a replacement, modification, or change in a certified continuous EtO monitoring system is made which affects information reported in the monitoring plan.
- For each unit or stack operating hour, the following EtO emission records must be maintained:
    - The date and hour;
    - Monitoring system and component identification codes, as provided in the electronic monitoring plan, for each hour in which the EtO CEMS provides a quality-assured value of EtO concentration (as applicable);
    - The pollutant concentration, for each hour in which a quality-assured value is obtained;
    - A special code, indicating whether or not a quality assured EtO concentration value is obtained for the hour; and
    - Monitor data availability, as a percentage of unit or stack operating hours, calculated according to 40 CFR §75.32.
- For each unit or stack operating hour, you must maintain hourly measurements of stack gas volumetric flow rate.
- For each unit or stack operating hour, the following EtO emission rate records must be maintained:
    - The date and hour;
    - The hourly EtO emissions rate (lb/hr), for each hour in which valid values of EtO concentration and stack gas volumetric flow rate are obtained for the hour; and
    - A code indicating that the EtO emission rate was not calculated for the hour, if valid data for EtO concentration and/or any of the other necessary parameters are not obtained for the hour. For the purposes of this appendix, the substitute data values

required under part 75 of this chapter for stack gas flow rate are not considered to be valid data.

- The following information for all required certification, recertification, diagnostic, and quality assurance tests:
    - For each required 7-day and daily calibration drift (CD) test or daily calibration error test (including daily calibration transfer standard tests) of the EtO CEMS, record the test date(s) and time(s), reference gas value(s), monitor response(s), and calculated calibration drift or calibration error value(s). If you use the dynamic spiking option for the mid-level calibration drift check under PS 19, you must also record the measured concentration of the native EtO in the flue gas before and after the spike and the spiked gas dilution factor.
    - For each required relative accuracy test audit (RATA) of an EtO CEMS, record the beginning and ending date and time of each test run, the reference method(s) used, and the reference method and EtO CEMS run values. Keep records of stratification tests performed (if any), all of the raw field data, relevant process operating data, and all of the calculations used to determine the relative accuracy.
    - For each required measurement error (ME) test of an EtO monitor, record the date and time of each gas injection, the reference gas concentration (low, mid, or high) and the monitor response for each of the three injections at each of the three levels. Also record the average monitor response and the ME at each gas level and the related calculations.
    - For each required level of detection (LOD) test of an EtO monitor performed in a controlled environment, record the test date, the concentrations of the reference gas and interference gases, the results of the seven (or more) consecutive measurements of EtO, the standard deviation, and the LOD value. For each required LOD test performed in the field, record the test date, the three measurements of the native source EtO concentration, the results of the three independent standard addition (SA) measurements known as standard addition response (SAR), the effective spike addition gas concentration, the resulting standard addition detection level (SADL) value and all related calculations. For extractive CEMS performing the SA using dynamic spiking, you must record the spiked gas dilution factor.
    - For each required ME/level of detection response time test of an EtO monitor, record the test date, the native EtO concentration of the flue gas, the reference gas value, the stable reference gas readings, the upscale/downscale start and end times, and the results of the upscale and downscale stages of the test.
    - For each required interference test of an EtO monitor, record (or obtain from the analyzer manufacturer records of): the date of the test; the gas volume/rate, temperature, and pressure used to conduct the test; the EtO concentration of the reference gas used; the concentrations of the interference test gases; the baseline EtO responses for each interferent combination spiked; and the total percent interference as a function of span or EtO concentration.

- For each quarterly relative accuracy audit (RAA) of an EtO monitor, record the beginning and ending date and time of each test run, the reference method used, the EtO concentrations measured by the reference method and CEMS for each test run, the average concentrations measured by the reference method and the CEMS, and the calculated relative accuracy. Keep records of the raw field data, relevant process operating data, and the calculations used to determine the relative accuracy.
- For each quarterly cylinder gas audit (CGA) of an EtO monitor, record the date and time of each injection, and the reference gas concentration (zero, mid, or high) and the monitor response for each injection. Also record the average monitor response and the calculated ME at each gas level.
- For each quarterly dynamic spiking audit (DSA) of an EtO monitor, record the date and time of the zero gas injection and each spike injection, the results of the zero gas injection, the gas concentrations (mid and high) and the dilution factors and the monitor response for each of the six upscale injections as well as the corresponding native EtO concentrations measured before and after each injection. Also record the average dynamic spiking error for each of the upscale gases, the calculated average DSA Accuracy at each upscale gas concentration, and all calculations leading to the DSA Accuracy.
- For the stack gas flow rate monitoring system, you must keep records of all certifications, recertification, diagnostic, and on-going quality-assurance tests of these systems.

Reporting Requirements

The required report elements of Appendix A to subpart O must be included as part of the initial and quarterly compliance reports discussed in Section 3.5.1 of this compliance guide. The applicable reporting requirements submitted as part of the initial and quarterly compliance reports include:

- The date of report generation;
- Facility identification information;
- EtO emissions records
- Stack gas volumetric flow rate records
- EtO emission rate records
- The results of all daily calibrations (including calibration transfer standard tests) of the EtO monitor.
- If applicable, the results of all daily flow monitor interference checks.
- A compliance certification statement by a responsible official with that official's name, title, and signature, certifying that, to the best of his or her knowledge, the report is true, accurate, and complete.

In addition to the elements listed above, you must fulfill the following reporting requirements of Appendix A to subpart O:

- Submit notifications for each affected unit (or group of units monitored at a common stack)
- Submit the monitoring plan prior for each affected unit (or group of units monitored at a common stack).
    - For a previously certified EtO CEMS, this is required prior to or concurrent with the first required quarterly emissions report.
    - For a new sterilization facility, this report is required at least 21 days prior to the start of initial certification testing of the EtO CEMS.
    - Also submit the monitoring plan information pertaining to any required flow rate monitoring systems if the records are not already in place.
    - Submit updated monitoring plans when required. An electronic monitoring plan information update must be submitted either prior to or concurrent with the quarterly report for the calendar quarter in which the update is required.
- Submit all required certification, recertification, quality-assurance, and diagnostic tests of the monitoring systems electronically. The test results must be submitted concurrent with the quarterly electronic emissions report.
    - For RATAs of the EtO monitor, if submission with the quarterly electronic emissions report is not possible, you have up to 60 days after the test completion date to submit test results. In this case, you may claim provisional status for the emissions data affected by the test, starting from the date and hour in which the test was completed and continuing until the date and hour in which the test results are submitted. If the test is successful, the status of the data in that time period changes from provisional to quality-assured, and no further action is required. However, if the test is unsuccessful, the provisional data must be invalidated and resubmission of the affected emission report(s) is required.
    - Required certification, recertification, quality-assurance, and diagnostic tests include the following:
        - Daily CD (or calibration error) assessment
        - RATA
        - ME test
        - Interference test
        - LOD test
        - ME or LOD response time test
        - Quarterly RAA
        - Quarterly CGA
        - Quarterly DSA

- For each diluent gas, flow rate, and moisture monitoring systems, report the results of each certification, recertification, diagnostic, and QA test.

4.0 OTHER INFORMATION

4.1 Compliance Assistance Resources

EPA believes that through awareness, education and reasonable options, both public and private members of the regulated community will choose to be proactive in voluntary efforts to comply with pollution control regulations. Compliance assistance providers help regulated communities and businesses understand and comply with environmental laws through one-to-one counseling, online resource centers, fact sheets, guides, and training. Assistance providers include EPA regional office staff; state, local and tribal governments; federal and state small business and pollution prevention technical assistance extension agents, consultants, and trade associations.

Find out what laws apply to you, what you need to do to comply, and tools and resources that can help you comply with environmental regulations by visiting the following websites:

EPA Compliance Assistance: https://www.epa.gov/compliance/resources-and-guidance-documents-compliance-assistance

EPA National Compliance Assistance Centers: https://www.epa.gov/compliance/compliance-assistance-centers

State-by-state Resource Locator: http://www.envcap.org/statetools/

National Small Business Environmental Assistance Program (SBEAP): https://nationalsbeap.org/

EPA Resources for Small Businesses: https://www.epa.gov/resources-small-businesses

EPA Hazardous Air Pollutants: https://www.epa.gov/haps

Emissions Standards for Commercial Sterilization Facilities: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

EPA Asbestos and Small Business Ombudsman: https://www.epa.gov/resources-small-businesses/asbestos-small-business-ombudsman

EPA Small Business Compliance and Enforcement:
https://www.epa.gov/compliance/small-business-compliance
https://www.epa.gov/enforcement/small-businesses-and-enforcement

EPA Compliance Incentives and Auditing: https://www.epa.gov/compliance/epas-audit-policyEPA Compliance Incentives and Auditing: https://www.epa.gov/compliance/epas-audit-policy

4.2 Other Governmental Support

As EPA proceeds to implement this final rule, we intend to continue to work closely with the Food and Drug Administration (FDA) to monitor the process of planning for compliance, to proactively identify any anticipated changes in facility operations that might implicate the medical supply chain, and to take appropriate steps to address any such impacts.

4.3 What Other Resources are Available?

State and local contacts can be found at the National Association of Clean Air Agencies web site at http://www.4cleanair.org/. State Small Business Assistance Program contacts can be found at https://nationalsbeap.org/.

4.4 For More Information

The full text of the Federal Register notices containing the rule and additional information are available online at: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.

A link to the commercial sterilization facilities rule text and General Provisions in the Electronic Code of Federal Regulations (e-CFR) is available online.

Other background information is also available at https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities and in the rulemaking docket (Docket ID: EPA-HQ-OAR-2019-0178) either electronically at http://www.regulations.gov, EPA's electronic public docket and comment system, or in hardcopy at the EPA Docket Center's Public Reading Room.