ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2019–0178; FRL–7055–02–OAR]

RIN 2060–AU37

National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Commercial Sterilization Facilities source category regulated under national emission standards for hazardous air pollutants (NESHAP) under the Clean Air Act. The EPA is finalizing decisions concerning the RTR, including definitions for affected sources, emission standards for previously unregulated sources, amendments pursuant to the risk review to address ethylene oxide (EtO) emissions from certain sterilization chamber vents (SCVs), aeration room vents (ARVs), chamber exhaust vents (CEVs), and room air emissions, and amendments pursuant to the technology review for certain SCVs and ARVs. In addition, we are taking final action to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing exemptions for periods of SSM. We are also taking final action to require owners and operators to demonstrate compliance through the use of EtO continuous emissions monitoring systems (CEMS), with exceptions for very small users of EtO; add provisions for electronic reporting of performance test results and other reports; and include other technical revisions to improve consistency and clarity. We estimate that these final amendments will reduce EtO emissions from this source category by approximately 21 tons per year (tpy).

DATES: This final rule is effective on April 5, 2024. The incorporation by reference (IBR) of certain material listed in the rule is approved by the Director of the Federal Register April 5, 2024. The incorporation by reference (IBR) of certain other material listed in the rule was approved by the Director of the Federal Register before February 27, 2021.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2019–0178. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact U.S. EPA, Attn: Jonathan Witt, Mail Drop: E143–05, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–5645; and email address: *witt.jon@epa.gov.* For specific information regarding the risk modeling methodology, contact U.S. EPA, Attn: Matthew Woody, Mail Drop: C539–02, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–1535; and email address: *woody.matt@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ADAF age-dependent adjustment factor
AEGL acute exposure guideline level
APCD air pollution control device
ARV aeration room vent
ASME American Society of Mechanical Engineers
BTF Beyond-the-Floor
BMP best management practice
CAA Clean Air Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CEMS continuous emission monitoring system
CEV chamber exhaust vent
CFR Code of Federal Regulations
cfs cubic feet per second
dscfm dry standard cubic feet per minute
EJ environmental justice
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
EtO ethylene oxide
FDA Food and Drug Administration
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
FR Federal Register
FRFA final regulatory flexibility analysis
FTIR Fourier Transform Infrared Spectroscopy
GACT generally available control technology
HAP hazardous air pollutants(s)
HEM Human Exposure Model
HQ hazard quotient
ICR Information Collection Request
ID Interim Decision
IFU instructions for use
IRFA initial regulatory flexibility analysis
IRIS Integrated Risk Information System
ISO International Organization for Standardization
km kilometer
lb pound
lb/h pounds per hour
LEL lower explosive limit
LPL lower prediction limit
MACT maximum achievable control technology
MIR maximum individual risk
mg/L milligrams per liter
NAICS North American Industry Classification System
NDO natural draft opening
NESHAP national emission standards for hazardous air pollutants
OMB Office of Management and Budget
OPP Office of Pesticide Programs
OSHA Occupational Safety and Health Administration
PID Proposed Interim Decision
ppbv parts per billion by volume
ppm parts per million
ppmv parts per million by volume
PTE permanent total enclosure
REL reference exposure level
RDL Representative detection level
RFA Regulatory Flexibility Act
RIA regulatory impact assessment
RTR risk and technology review
SAB Science Advisory Board
SBA Small Business Administration
SBAR Small Business Advocacy Review
SCV sterilization chamber vent
SER small entity representative
SSM startup, shutdown, and malfunction
TOSHI target organ-specific hazard index
tpy tons per year
UPL upper prediction limit
$\mu g/m^3$ micrograms per cubic meter
UMRA Unfunded Mandates Reform Act
URE unit risk estimate
VCS voluntary consensus standards

Background information. On April 13, 2023, the EPA proposed revisions to the Commercial Sterilization Facilities NESHAP based on our RTR. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to

those comments is available in *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* Docket ID No. EPA–HQ–OAR–2019–0178. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

Exercising authority under multiple provisions of section 112 of the Clean Air Act (CAA), we are finalizing revisions to the NESHAP for Commercial Sterilization Facilities (40 CFR part 63, subpart O) by both amending the current standards and establishing standards for previously unregulated emissions within this source category. First, we are finalizing emission standards under CAA sections 112(d)(2)–(3) and (d)(5) for previously unregulated emission sources of EtO. Second, we are finalizing risk-based standards under CAA section 112(f)(2) to protect public health with an ample margin of safety. Third, we are finalizing emission standards under CAA section 112(d)(6) based on our review of developments in practices, processes, and control technologies for this source category.

This final rulemaking reflects the EtO toxicological assessment that EPA's Integrated Risk Information System (IRIS) Program completed in December 2016,[1] which indicated that EtO is a far more potent carcinogen than we had understood when the RTR for this source category was conducted in 2006. There are 88 commercial sterilization facilities in this source category, many of which are located near residences, schools, and other public facilities. Many of these facilities are also located in communities with environmental justice (EJ) concerns. We have determined that approximately 23 of these facilities pose high lifetime cancer risks to the surrounding communities, and some facilities pose exceptionally high risks that are among some of the highest for a CAA section 112(f)(2) risk assessment. Throughout this rulemaking process, we have engaged in outreach activities to these communities, along with their State and local governments, to discuss their concerns, along with the need and potential solutions for reducing emissions and increasing transparency on exposure and potential impacts to communities, which this final rule will achieve.

This important action will reduce EtO emissions and lifetime cancer risks in multiple communities across the country, including communities with EJ concerns, and it updates our standards using proven and cost-effective control technologies that are already in use at some facilities in this source category. The protections offered by these standards will be especially important for children. In addition, this rule will advance the President's Cancer Moonshot,[2] by preventing cancer before it starts. Recognizing that we now have additional information about the health risks of EtO that was not available at the time of the 2006 RTR, and in order to ensure that our standards for this source category adequately protect public health, we have conducted a second residual risk review under CAA section 112(f)(2), as discussed in section I.A.3 of this preamble.

In deciding to conduct this second residual risk review, we considered the health effects of EtO exposure, the impacts to surrounding communities, the advantages of EtO reductions, and the distribution of those reductions consistent with the clear goal of CAA section 112(f)(2) to protect the most exposed and susceptible populations. While commercial sterilizers provide a critical benefit for the health of all, protecting people who live near commercial sterilization facilities from the disproportionate risk of being significantly harmed by toxic air

[1] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide,* December 2016, EPA/635/R–16/350Fc.

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/13/fact-sheet-as-part-of-president-bidens-unity-agenda-white-house-cancer-moonshot-announces-new-actions-and-commitments-to-end-cancer-as-we-know-it/.*

pollution is also a core responsibility for the EPA under the CAA.

At the same time, we recognize that commercial sterilization facilities play a vital role in maintaining an adequate supply of sterilized medical devices for public health needs in the U.S. According to the U.S. Food and Drug Administration (FDA), ''Literature shows that about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide.'' FDA also notes that, ''For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process.'' [3] In developing this final rule, therefore, we carefully considered the important function these facilities serve, drawing from extensive engagement with industry stakeholders as well as Federal agencies with expertise in and responsibility for the medical device supply chain.

To ensure our actions with respect to this source category are based on the most accurate and complete information possible, we have had many interactions with the EtO commercial sterilization industry in recent years, including meetings, requests for information, and outreach specific to this final rulemaking. This has enabled us to work from the best possible information when conducting the analyses to support this final rulemaking, including the current configuration of facilities and the performance of control technologies that are currently used.

We have engaged with the U.S. Department of Health and Human Services, particularly FDA, regarding the potential impacts of this final rule on commercial facilities that sterilize medical devices. These discussions have focused on identifying and discussing any concerns regarding the potential impact on the availability of certain medical devices that are sterilized with EtO, in cases where alternative sterilization methods are not readily available, in particular, devices that are (1) experiencing or at risk of experiencing a shortage, (2) intended to provide life-supporting, life-sustaining care or that is intended for use in emergency medical care or during surgery, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility.

Mindful of the vital role that commercial sterilizers play in supplying the nation with sterile medical devices, and the core objective of protecting public health under CAA section 112, the EPA has carefully evaluated the feasibility and cost of compliance with this rule, and potential implications for the medical device supply chain.[4] The EPA notes that a number of the facilities covered by this final rule have already implemented one or more of the controls that will be needed for compliance. Moreover, the EPA's own experience working with facility owners, as well as State and local agencies that have regulated EtO emissions from these facilities, confirms that it is feasible for individual facilities to install the required controls well within the deadlines provided in this rule, and for multiple facilities to do so simultaneously.

In addition, as a result of the comments received, as well as the EPA's consultation with FDA and other Federal partners, the final rule incorporates several key changes from the proposed rule, including modifications to the format of certain standards and compliance flexibilities. We are also providing sufficient compliance time to enable these facilities to continue sterilizing products while installing and testing new control systems and associated equipment that will afford ample protection for nearby communities. These modifications to the proposed rule are intended to facilitate cost-effective compliance, and to avoid any impacts to the integrity of the medical device supply chain, while ensuring that these standards reduce cancer risks for communities exposed to EtO emissions.

Given that key industry players are already planning for compliance, and in light of the significant changes made between the proposal and this final rule, the EPA does not anticipate that the implementation of these standards will have any adverse impacts on the medical supply chain. However, as the Agency proceeds to implement this final rule, we intend to continue to work closely with FDA, the relevant trade associations, and facility owners 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. In addition, in order to increase the resilience of the medical supply chain, we support the development and implementation of viable, safe, and cost-effective alternatives to EtO sterilization.

On April 13, 2023, the Office of Pesticide Programs (OPP) published a notice announcing the availability of a proposed interim decision (PID) as part of its periodic review of the registration of EtO under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (88 FR 22447). The PID contained a number of measures aimed at protecting workers from excessive EtO exposure. Since the issuance of the PID, OPP has been actively collaborating with the Office of Air and Radiation to ensure that the requirements of the FIFRA Interim Decision (ID) do not interfere with the requirements of this rule, and vice versa. The ID will contain the final requirements to mitigate worker exposure to EtO, considering the comments received on the PID. Furthermore, OPP has been consulting regularly with other Federal agencies and with industry trade groups, to discuss how best to harmonize the requirements of the FIFRA ID with the requirements of this rule, and to ensure that the operative standards, once finalized, will protect both workers and neighboring communities from the risks of EtO exposure while mitigating and managing any risk to the supply chain for sterile medical devices.

2. Summary of the Major Provisions of the Regulatory Action in Question

We are finalizing numeric emission limits, operating limits, and management practices under CAA sections 112(d)(2)–(3), (d)(5), and (d)(6) for EtO emissions from certain emission sources, and also finalizing standards under CAA section 112(f)(2) for certain emission sources in order to ensure that the standards provide an ample margin of safety to protect public health.[5]

For the following, previously unregulated emission sources at commercial sterilization facilities, we are setting standards under CAA sections 112(d)(2)–(3) or (d)(5): SCVs and ARVs at facilities where EtO use is less than 1 tpy,[6] ARVs at facilities where

[3] *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices.*

[4] For more information, see the document *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this rulemaking.

[5] In 1992, pursuant to CAA section 112(c)(1), we published a list of major and area sources for regulation under CAA section 112, including major and area sources at commercial sterilization facilities. 57 FR 31576, 31586 (July 16, 1992). Area sources at commercial sterilization facilities were listed for regulation under CAA section 112(c)(3) based on our finding that they present a threat of adverse effects to human health or the environment (by such sources individually or in the aggregate) warranting regulation under that section. Id. at 31586.

[6] In developing the original rule, EPA considered potential standards for SCV and ARV at area source facilities where EtO use is less than 1 tpy but the Agency understood these sources at the time to have low emission contributions (*e.g.,* a facility

EtO use is at least 1 tpy but less than 10 tpy,[7] CEVs,[8] and room air emissions.[9]

Next, based on our assessment of the residual risk after considering the emission reductions from the previous standards in subpart O, as well as the standards under CAA sections 112(d)(2)–(3) or (d)(5) for the previously unregulated sources, we are finalizing more stringent standards under CAA section 112(f)(2) to address risk at the following types of sources:

- SCVs at facilities where EtO use is at least 30 tpy
- SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy
- ARVs at facilities where EtO use is at least 30 tpy
- CEVs at area source facilities [10] where EtO use is at least 400 tpy
- CEVs at area source facilities where EtO use is at least 60 but less than 400 tpy
- Group 1 room air emissions [11] at area source facilities where EtO use is at least 40 tpy
- Group 2 room air emissions [12] at area source facilities where EtO use is at least 20 tpy
- Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy

Finally, under CAA section 112(d)(6), we are revising current standards for the following sources that were regulated in the previous 40 CFR part 63, subpart O:

- SCVs at facilities where EtO use is at least 10 tpy
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy
- ARVs at facilities where EtO use is at least 10 tpy

Table 1 summarizes the final CAA section 112(d) and 112(f)(2) standards.

TABLE 1—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new	At least 30 tpy	99.99 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 30 tpy.	99.9 percent emission reduction	112(f)(2).
		At least 10 tpy	99.9 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99.8 percent emission reduction	112(f)(2) and 112(d)(6).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing	At least 30 tpy	99.9 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 30 tpy.	99.6 percent emission reduction	112(f)(2).
		At least 10 tpy	99.6 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 30 tpy	99.9 percent emission reduction	112(f)(2).
		At least 10 tpy	99.9 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEVs at major source facilities.	Existing and new	N/A	99.94 percent emission reduction [1]	112(d)(2) and 112(d)(3).
CEVs at area source facilities.	Existing and new	At least 400 tpy	99.9 percent emission reduction	112(f)(2).
		At least 60 but less than 400 tpy.	99.9 percent emission reduction	112(f)(2).
		Less than 60 tpy	99 percent emission reduction	112(d)(5).
Group 1 room air emissions at major sources.	Existing and new	N/A	97 percent emission reduction [2 3]	112(d)(2) and 112(d)(3).
Group 1 room air emissions at area sources.	Existing and new	At least 40 tpy	98 percent emission reduction [3]	112(f)(2).
		Less than 40 tpy	80 percent emission reduction [3]	112(d)(5).

with EtO use of 1,999 lb/yr would have roughly less than 167 lb/month of usage and emissions, and less than 41 lb/week usage and emissions.) At the time, EPA considered costs for monitoring, recordkeeping, and reporting under the rule. Threshold cutoffs for area sources are at the discretion of the Agency.

[7] EPA considered standards for ARV and CEV at area source facilities where EtO use is at least 1 tpy and less than 10 tpy. As noted, the Agency understood at the time that the largest emission source of EtO occurred from the SCV, and therefore finalized emission reduction standards for all SCV at facilities where EtO use is at least 1 tpy. At the time ARV sources were understood to have low emission contributions. As noted, threshold cutoffs for area sources are at the discretion of the Agency.

[8] The standards for CEVs were originally promulgated on December 6, 1994. Following promulgation of the rule, we suspended certain compliance deadlines and ultimately removed the standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at EtO commercial sterilization facilities using oxidizers to control emissions from the CEV. For CEVs, it was determined that the primary contributing issue leading to the explosions was that EtO concentrations were above a safe level (*i.e.,* above the lower explosive limit (LEL)) within the CEV gas streams. We could not conclude at the time that the CEVs could be safely controlled, so the standards for CEVs were removed on November 2, 2001 (66 FR 55583). However, as discussed in section III.B.5 of the proposal preamble (88 FR 22790), facilities with controlled CEVs have revised their operating procedures to address the explosion issue by not exceeding 10 to 25 percent of the LEL. We have, therefore, determined that CEVs can be safely controlled.

[9] As discussed in section III.A, room air emissions include emissions resulting from indoor EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material.

[10] As discussed in section III.B of the proposal preamble (88 FR 22790, April 13, 2023), CAA section 112(a) defines a major source as ''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 tpy or more of any HAP or 25 tpy or more of any combination of HAPs. . .''. It further defines an area source as ''any stationary source of HAPs that is not a major source''. A synthetic area source facility is one that otherwise has the potential to emit HAPs in amounts that are at or above those for major sources of HAP, but that has taken a restriction so that its potential to emit is less than the threshold amounts for major sources. Most of the EtO used at these facilities is released through SCVs and ARVs, and subpart O contains emission standards for these sources at facilities where EtO use is at least 10 tpy. Some State and local governments also regulate EtO emissions from these facilities. Based on these facts, as well as our review of the permits for these facilities, it is our understanding that all facilities that use more than 10 tpy are synthetic area sources.

[11] As discussed in section III.A, Group 1 room air emissions cover indoor EtO storage, EtO dispensing, vacuum pump operation, and pre-aeration handling of sterilized material.

[12] As discussed in section III.A, Group 2 room air emissions cover post-aeration handling of sterilized material.

TABLE 1—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)—Continued

Emission source	Existing or new?	EtO use	Standards	CAA section
Group 2 room air emissions at major sources.	Existing and new	N/A	86 percent emission reduction[1 3]	112(d)(2) and 112(d)(3).
Group 2 room air emissions at area sources.	Existing	At least 20 tpy	98 percent emission reduction[3]	112(f)(2).
		At least 4 but less than 20 tpy.	80 percent emission reduction[3]	112(f)(2).
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened[4].	112(d)(5).
	New	At least 20 tpy	98 percent emission reduction[3]	112(f)(2).
		At least 4 but less than 20 tpy.	80 percent emission reduction[3]	112(f)(2).
		Less than 4 tpy	80 percent emission reduction[3]	112(d)(5).

[1] MACT floor.
[2] Beyond-the-Floor (BTF) standard.
[3] To assure compliance with the emission limit, we are requiring each facility to operate area sources with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.
[4] Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).

To demonstrate compliance with the emission limits, we are finalizing capture requirements. We are also finalizing a requirement for facilities to monitor with an EtO continuous emissions monitoring system (CEMS), with exceptions for small users.

3. EPA Authority

We note that the EPA completed a residual risk and technology review under CAA sections 112(f)(2) and 112(d)(6), respectively, for this source category in 2006 (71 FR 17712). While CAA section 112(f)(2) requires only a one-time risk review, which is to be conducted within eight years of the date the initial standards are promulgated, it does not limit our discretion or authority to conduct another risk review should we consider that such review is warranted. As discussed in more detail in section IV.C of this preamble, as our understanding of the health effects of EtO developed, we conducted a second residual risk review under CAA section 112(f)(2) for commercial sterilization facilities using EtO in order to ensure that the standards provide an ample margin of safety to protect public health.

As discussed in further detail in section IV.C, this second residual risk review also encompasses certain area sources for which we did not evaluate residual risk in our 2006 rulemaking. Although CAA section 112(f)(5) states that a risk review is not required for categories of area sources subject to generally available control technology (GACT) standards, it does not prohibit such review. In 2006, we undertook a CAA section 112(f)(2) analysis only for area source emissions standards that were issued as maximum achievable control technology (MACT) standards and exercised our discretion under CAA section 112(f)(5) not to do a CAA section 112(f)(2) analysis for those emission points for which GACT standards were established (67 FR 17715). However, as we made clear in that prior risk assessment, ''[w]e have the authority to revisit (and revise, if necessary) any rulemaking if . . . significant improvements to science [suggest that] the public is exposed to significant increases in risk as compared to the [2006 risk assessment].'' *Id.* In light of the updated IRIS cancer unit risk estimate (URE) for EtO, which is approximately 60 times greater than the value we used in our previous risk assessment, we are now exercising our discretionary authority to conduct another CAA section 112(f)(2) analysis and to include in this analysis area source commercial sterilizers using EtO for which we have promulgated, or have considered, GACT standards.

Section 112(d)(6) of the CAA requires EPA to review and revise, as necessary, standards promulgated under CAA section 112 at least every eight years, taking into account developments in practices, processes, and control technologies. We last completed this required technology review for the Ethylene Oxide Commercial Sterilization NESHAP (40 CFR 63, subpart O) in 2006. Accordingly, in this final action, we are also conducting a CAA section 112(d)(6) review of the current standards in this source category.

4. Costs and Benefits

Table 2 of this preamble summarizes the costs of this final action for 40 CFR part 63, subpart O (Ethylene Oxide Commercial Sterilization NESHAP).

TABLE 2—TOTAL CAPITAL INVESTMENT AND TOTAL ANNUAL COST

[2021$]

Requirement	Number of facilities w/costs associated with new requirements	Total capital investment	Total annual costs
Permanent total enclosure	28	$77,500,000	$8,280,000
Additional control devices	83	187,000,000	43,000,000
Monitoring and testing	89	48,100,000	19,400,000
Recordkeeping and reporting	[1] 90	.....	[2] 2,600,000
Total	[1] 90	313,000,000	74,000,000

[1] This includes the 88 facilities that are currently operating, as well as two planned facilities that are expected to start operating within the next few years.
[2] This includes $763,000 of one-time annual costs for reading the rule and developing record systems.

The capital costs for permanent total enclosure (PTE) and additional gas/solid reactors were annualized to 20 years. We estimate that these amendments will reduce EtO emissions from this source category by 21 tpy. Table 3 of this preamble summarizes the cancer risk reductions that will result from the final amendments, which are updated based on revisions made in the final rule and described in more detail in section IV.C.2.

TABLE 3—SUMMARY OF CANCER RISK REDUCTIONS

	Current cancer risks—actual emissions	Current cancer risks—allowable emissions	Cancer risks after implementation of final amendments
Maximum Individual Risk (MIR)[1]	6,000-in-1 million	8,000-in-1 million[3]	100-in-1 million.
Number of People with Cancer Risks >100-in-1 million	19,000	260,000	0.
Number of People with Cancer Risks ≥1-in-1 million	8.5 million	62 million	700,000 to 1.4 million.[2]
Estimated Annual Cancer Incidence (cases per year)	0.9	8	0.1 to 0.2.[2]

[1] The MIR or maximum individual lifetime cancer risk is defined as the increase in estimated cancer risk associated with a 70-year lifetime of continuous exposure at the highest concentration of HAP where people are likely to live.

[2] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

As indicated in table 3, we project that the standards in the final rule will significantly reduce incremental lifetime cancer risks associated with emissions of EtO from this source category. We estimate that the current maximum increase in lifetime cancer risk associated with any facility in this source category is 6,000-in-1 million based on estimated actual emissions (or 8,000-in-1 million based on allowable emissions) under the existing standards, and that approximately 19,000 people are exposed to EtO from this source category at levels that would correspond to a lifetime cancer risk of greater than 100-in-1 million (which is our presumptive upper bound threshold for acceptable health risks), based on actual emissions. When considering allowable emissions, this number increases to 260,000. Under the final rule, no individual will be exposed to EtO at levels that correspond to a lifetime cancer risk of greater than 100-in-1 million, and the number of people with a potential risk of greater than or equal to 1-in-1 million will be reduced by approximately 92 percent.

See section V of this preamble for further discussion of the costs and a discussion of the benefits of the final standards. See section IV.F of this preamble for discussion of the revisions to monitoring, recordkeeping, reporting, and testing requirements. See section IV.C for a discussion of the risk assessment results.

B. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in table 4 of this preamble.

TABLE 4—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Industrial category	NESHAP	NAICS[1] code
Surgical and Medical Instrument Manufacturing	40 CFR part 63, subpart O	339112
Surgical Appliance and Supplies Manufacturing	40 CFR part 63, subpart O	339113
Pharmaceutical Preparation Manufacturing	40 CFR part 63, subpart O	325412
Spice and Extract Manufacturing	40 CFR part 63, subpart O	311942
Dried and Dehydrated Food Manufacturing	40 CFR part 63, subpart O	311423
Packaging and Labeling Services	40 CFR part 63, subpart O	561910

[1] North American Industry Classification System.

Table 4 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

D. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by June 4, 2024. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised

during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*). The discussion that follows identifies the relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology,* in the docket for this rulemaking. Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements. For area sources, CAA section 112(d)(5) allows the EPA to set standards based on GACT in lieu of MACT standards. For categories of major sources and any area source categories subject to MACT standards, the second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f). Section 112(f) specifically states that the EPA ''shall not be required'' to conduct risk review under this subsection for categories of area sources subject to GACT standards but does not limit the EPA's authority or discretion from conducting such review. As discussed in more detail in section III.C of this preamble, in light of the updated URE regarding EtO, the EPA is choosing to exercise that discretion.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). In conducting this review, the EPA is not required to recalculate the MACT floors that were established in earlier rulemakings. *Natural Resources Defense Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category, and any new MACT standards must be established under CAA sections 112(d)(2) and (3), or, in specific circumstances, CAA sections 112(d)(4) or (h). *Louisiana Environmental Action Network (LEAN)* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

The residual risk review in the second stage of the regulatory process focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of ''ample margin of safety'' developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Residual Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk

determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations, and the United States Court of Appeals for the District of Columbia Circuit upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. *See NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination ''considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR) [13] of approximately 1-in-10 thousand.'' (54 FR 38045). If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors. For more information on the statutory authority for this rule, see 88 FR 22790, April 13, 2023.

B. What is the Commercial Sterilization Facilities source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the EtO Commercial Sterilization Facilities NESHAP on December 6, 1994 (59 FR 62585). The standards are codified at 40 CFR part 63, subpart O. The EtO commercial sterilization industry consists of facilities operating a sterilizer process that uses EtO to sterilize or fumigate materials (*e.g.,* medical equipment and supplies, spices, and other miscellaneous products and items). The source category covered by this MACT standard currently includes 88 facilities.

The original 1994 rulemaking for this source category set standards for EtO emissions originating from three emission points: sterilization chamber vents (SCV), aeration room vents (ARV), and chamber exhaust vents (CEV). The SCV evacuates EtO from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes before the chamber door is opened. The ARV evacuates EtO-laden air from the aeration room or chamber that is used to facilitate off-gassing of the sterile product and packaging. The CEV evacuates EtO-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes. Other sources of emissions within this source category are room air emissions from equipment used to charge EtO into sterilization chambers, as well as EtO residuals desorbing from sterilized products within the facility, but the current EtO Commercial Sterilization NESHAP does not include standards for room air emissions.

In the chamber EtO sterilization process, items to be sterilized are placed in a chamber and exposed to EtO gas at a predetermined concentration, temperature, humidity, and pressure for a period of time known as the dwell period. Following the dwell period, the EtO gas is evacuated from the chamber, and the sterilized materials are then aerated to remove EtO residuals from the product. After the aeration step, sterilized materials are typically moved to a shipping/warehouse area for storage until they are ready to be distributed to the customer. Sterilizer process equipment and emission control configurations vary across facilities. The most common sterilizer process equipment configuration includes a separate sterilizer chamber, separate aeration room, and chamber exhaust on the sterilizer chamber (also referred to as a back-vent). Another common configuration includes a combination sterilizer where the sterilization and aeration steps of the process occur within the same chamber.

Another EtO sterilization process is single-item sterilization where small individual items are sterilized in sealed pouches. EtO gas is introduced into the sealed pouch, either by injection or use of an EtO ampule, and the sealed pouch is then placed in a chamber where the sterilization step and aeration step occur.

In 2006, we finalized a residual risk review and a technology review under CAA section 112(f)(2) and CAA section 112(d)(6), respectively (71 FR 17712, April 7, 2006). No changes were made to the EtO Commercial Sterilization NESHAP in that action.

The current emission standards for commercial sterilization facilities in 40 CFR part 63, subpart O are shown in table 5:

TABLE 5—CURRENT ETO STANDARDS FOR COMMERCIAL STERILIZERS

Existing and new sources subcategory (in any consecutive 12-month period) [1]	Sterilization chamber vent (SCV)	Aeration room vent (ARV)	Chamber exhaust vent (CEV) [2]
Sources using 10 tons or more of EtO ..	99 percent emission reduction (see 40 CFR 63.362(c)).	1 part per million (ppm) maximum outlet concentration or 99 percent emission reduction (see 40 CFR 63.362(d)).	No control.
Sources using 1 ton or more of EtO but less than 10 tons of EtO.	99 percent emission reduction (see 40 CFR 63.362(c)).	No control	No control.
Sources using less than 1 ton of EtO ...	No control required; minimal record-keeping requirements apply (see 40 CFR 63.367(c)).).	No control required; minimal record-keeping requirements apply (see 40 CFR 63.367(c)).).	No control required; minimal record-keeping requirements apply (see 40 CFR 63.367(c)).).

[1] Determined on a rolling 12-month basis.

[2] The CEV emission source was included in the original standard but was later eliminated from the 40 CFR part 63, subpart O regulation in 2001.

[13] Although defined as ''maximum individual risk,'' MIR refers only to cancer risk and reflects the estimated risk if an individual were exposed to the maximum level of a pollutant for a 70-year lifetime.

For more information on the commercial sterilization industry and the current standards under 40 CFR part 63, subpart O, see 88 FR 22790, April 13, 2023.

We note that hospital sterilizers are regulated under a different NESHAP (40 CFR part 63, subpart WWWWW), which is not addressed in this rulemaking.[14] We are aware of the potential risk posed by EtO emissions from this source category and will address hospital sterilizers in a future rulemaking.

C. What changes did we propose for the Commercial Sterilization Facilities source category in our April 13, 2023, RTR proposal?

On April 13, 2023, the EPA published a proposed rule in the **Federal Register** for the EtO Commercial Sterilization NESHAP, 40 CFR part 63, subpart O, that took into consideration the RTR analyses. In the proposed rule, we proposed emission standards under CAA sections 112(d)(2)–(3) or (d)(5) for a number of unregulated emission sources of EtO. We then proposed tightening certain of these proposed standards and existing standards with risk-based standards under CAA section 112(f)(2) in order to protect public health with an ample margin of safety. Finally, we proposed revisions to certain existing standards under CAA section 112(d)(6) based on our review of developments in practices, processes, and control technologies for this source category.

For the following emission sources that were unregulated, we proposed to set standards under CAA sections 112(d)(2)–(3) or (d)(5):

- SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy,
- ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- CEVs at facilities where EtO use is at least 10 tpy, and
- Room air emissions.

Next, based on our assessment of the residual risk after considering the emission reductions from the standards in subpart O, as well as the proposed standards for the unregulated sources, we proposed more stringent standards under CAA section 112(f)(2) to address risk for the following types of sources:

- SCVs at facilities where EtO use is at least 40 tpy,
- SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy,
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and
- Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy.

Finally, under CAA section 112(d)(6), we proposed to revise standards for the following sources that were regulated in the previous 40 CFR part 63, subpart O:

- SCVs at facilities where EtO use is at least 10 tpy,
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and
- ARVs at facilities where EtO use is at least 10 tpy.

Table 6 summarizes the proposed section CAA section 112(d) and 112(f)(2) standards.

TABLE 6—SUMMARY OF STANDARDS AFTER PROPOSED ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new	At least 40 tpy	99.94 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 40 tpy.	99.94 percent emission reduction	112(f)(2).
		At least 10 tpy	99.94 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99.8 percent emission reduction	112(f)(2) and 112(d)(6).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing	At least 10 tpy	99.6 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 10 tpy	99.9 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEV	Existing and new	At least 10 tpy	3.2E–4 lb/h	112(d)(2) and (3).
		At least 1 but less than 10 tpy.	99.9 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
Group 1 room air emissions.	Existing and new	N/A	1.3E–3 lb/h [1]	112(d)(2) and 112(d)(3).
Group 1 room air emissions at area sources.	Existing and new	N/A	1.3E–3 lb/h [1]	112(d)(5).
Group 2 room air emissions at major sources.	Existing and new	N/A	2.8E–3 lb/h [1]	112(d)(2) and 112(d)(3).
Group 2 room air emissions at area sources.	Existing	At least 20 tpy	2.8E–3 lb/h [1]	112(f)(2).
		Less than 20 tpy	Follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 (July 15, 2014) and ISO 11138–1:2017 (March 2017).	112(d)(5).

[14] Hospitals are defined at 40 CFR 63.10448 to mean facilities that provide medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day. Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis.

TABLE 6—SUMMARY OF STANDARDS AFTER PROPOSED ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)—Continued

Emission source	Existing or new?	EtO use	Standards	CAA section
	New	N/A	2.8E–3 lb/h [1]	112(d)(5).

[1] To assure compliance with the emission limit, we proposed requiring each facility to operate areas with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.

To demonstrate compliance with the emission limits, we proposed capture requirements. We also proposed that facilities either monitor with an EtO CEMS or conduct initial and annual performance tests with continuous parameter monitoring.

We also proposed the following amendments:

- Corrections and clarifications to regulatory provisions related to emissions during periods of SSM, including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate.
- Revisions to monitoring and performance testing requirements and addition of provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports.
- Requiring all area source facilities to obtain a title V operating permit, and
- Compliance requirements for facilities using combined emission streams.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Commercial Sterilization Facilities source category and amends the EtO Commercial Sterilization NESHAP based on those determinations. This action also finalizes other changes to the NESHAP, including adding requirements and clarifications for periods of SSM; requiring the use of CEMS to demonstrate compliance for facilities where EtO use is at least 100 pounds (lb)/year; adding provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports; and other minor editorial and technical changes. This action also reflects several changes to the April 2023 proposal in consideration of comments received during the public comment period described in section IV of this preamble.

A. What are the final rule amendments addressing the affected source definitions?

The previous subpart O did not contain definitions for affected sources, which meant that the definition of an ''affected source'' at 40 CFR 63.2 applied.[15] We did not believe that this was appropriate because a facility may not route all emissions from a particular type of point source to the same control system, thus making compliance demonstration with the standards difficult. For SCVs, ARVs, and CEVs, we are finalizing, as proposed, the affected source definition as the individual vent. For Group 1 and Group 2 room air emissions, we are finalizing, as proposed, the affected source definition as the collection of all room air emissions for each group at any sterilization facility. *Group 1 room air emissions* are defined as emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material. *Group 2 room air emissions* are defined as emissions from post-aeration handling of sterilized material.

Section IV.A.3 of this preamble provides a summary of key comments we received on the affected source definitions and our responses.

B. What are the final rule amendments pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) for the Commercial Sterilization Facilities source category?

We are finalizing EtO emissions standards pursuant to CAA sections 112(d)(2)–(3) and 112(d)(5) for major and area sources that were previously unregulated. Please note that the final standards for some of these sources are further tightened pursuant to CAA section 112(f)(2), as shown in table 1 in section I.A above and discussed in more detail below in sections III.C and IV.[16]

Pursuant to CAA section 112(d)(2)–(3) or 112(d)(5), we are establishing in this final rule the following emission standards for the previously unregulated sources:

- 99 percent reduction for new and existing SCVs at facilities where EtO use is less than 1 tpy,
- 99 percent reduction for new and existing ARVs facilities where EtO use is at least 1 tpy less than 10 tpy,
- 99 percent reduction for new and existing ARVs at facilities where EtO use is less than 1 tpy,
- 99.94 percent reduction for new and existing CEVs at major source facilities,
- 99 percent emission reduction for new and existing CEVs at area source facilities,
- 97 percent reduction for new and existing Group 1 room air emissions at major source facilities,
- 80 percent emission reduction for new and existing Group 1 room air emissions at area source facilities,
- 86 percent reduction for new and existing Group 2 room air emissions at major source facilities, and
- 80 percent emission reduction for new Group 2 room air emissions at area source facilities.

As discussed in more detail below in section IV.C.3 of this notice, we are not finalizing any of the alternative emission limits for percent reduction standards on which we had solicited comment as part of the proposed rulemaking. Further, based on comments received on the proposed rulemaking, we are finalizing a revised best management practice (BMP) as the GACT standard under CAA section 112(d)(5) for existing Group 2 room air emissions at area sources. The BMP requires the in-chamber EtO concentration to be lowered to 1 part per million (ppm) before the chamber can be opened, as opposed to the proposed measure that would have required these facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with International Organization for Standardization (ISO) 11135:2014 and ISO 11138–1:2017. In addition, we are finalizing, as proposed, a requirement that facilities operate all areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA

[15] 40 CFR 63.2 defines an affected source as ''the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a section 112(c) source category or subcategory for which a section 112(d) standard or other relevant standard is established pursuant to section 112 of the Act.''

[16] These sources include CEVs at area source facilities where EtO use is at least 60 tpy, Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, and Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy.

Method 204, irrespective of which CAA section 112 authority is invoked. Lastly, we are finalizing the removal of the 1 ppm alternative for ARVs at facilities where EtO use is at least 10 tpy. Section IV.B of this preamble provides in more detail the standards we are finalizing pursuant to CAA section 112(d)(2), 112(d)(3), and 112(d)(5), our rationales for the final standards and for changes since proposal, and a summary of key comments we received on the proposed standards and our responses.

C. What are the final rule amendments based on the risk review for the Commercial Sterilization Facilities source category?

This section introduces the final amendments to the Commercial Sterilization Facilities NESHAP being promulgated pursuant to CAA section 112(f). As in the proposal, we determined that the risks for this source category were unacceptable under the previous provisions, and we are making a final determination of unacceptability as part of this final action, warranting necessary emission reductions as directed under the provisions we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) in this rulemaking. When risks are unacceptable after considering the emission reductions from the standards in subpart O, we must determine the emissions standards necessary to reduce risk to an acceptable level. As such, we are promulgating final amendments to the Commercial Sterilization Facilities NESHAP pursuant to CAA section 112(f)(2) that will reduce risk to an acceptable level and will also provide an ample margin of safety to protect public health (see section IV.C of the preamble for further discussion). Based on comments received during the proposed rulemaking, we are finalizing the following EtO emissions standards under CAA section 112(f)(2):

- 99.99 percent reduction for SCVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.8 percent reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.9 percent reduction for ARVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent reduction for CEVs at area source facilities where EtO use is at least 60 tpy,
- 98 percent reduction for Group 1 room air emissions at area sources facilities where EtO use is at least 40 tpy,
- 98 percent reduction for Group 2 room air emissions at area sources facilities where EtO use is at least 20 tpy, and
- 80 percent reduction for Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy.

We are not finalizing alternative emission limits for percent reduction standards for the same reasons discussed in section III.B of this preamble. Further, based on comments received during the proposed rulemaking, we are not finalizing any of the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1''.[17] These standards would have required facilities to limit their Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dry standard cubic feet per minute (dscfm) and a maximum EtO concentration of 30 parts-per-billion by volume (ppbv).

Section IV.C.3 of this preamble provides a summary of key comments we received regarding the risk review and our responses.

D. What are the final rule amendments based on the technology review for the Commercial Sterilization Facilities source category?

We determined that there are developments in practices, processes, and control technologies that warrant revisions to the previous standards for this source category. Therefore, to satisfy the requirements of CAA section 112(d)(6), we are revising the standards to include, as in the proposed rule:

- 99.8 percent reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.6 percent reduction for existing ARVs at facilities where EtO use is at least 10 tpy, and
- 99.9 percent reduction for new ARVs at facilities where EtO use is at least 10 tpy.

Based on comments received during the proposed rulemaking, we are finalizing a 99.9 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy, which is different from the 99.94 percent emission reduction standard that was proposed (see section IV.D.3.a of this document for further discussion). We are not finalizing any of the alternative emission limits for percent reduction standards that we had solicited comment on as part of the proposed rulemaking. As part of the technology review, we also identified regulatory gaps (previously unregulated processes or pollutants) and are establishing new standards to fill those gaps as described in section III.B of this preamble. Section IV.D.3 of this preamble provides a summary of key comments we received regarding the technology review and our responses.

E. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

In its 2008 decision in *Sierra Club* v. *EPA, 551 F.3d 1019* (D.C. Cir. 2008), the United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in our CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously. We have eliminated the SSM exemption in this rule. Consistent with *Sierra Club* v. *EPA,* the EPA has established standards in this rule that apply at all times. We have also revised table 6 in subpart O (the General Provisions Applicability Table) in several respects as is explained in section III.G.1 of the proposal preamble (88 FR 22790). For example, we have eliminated and revised certain recordkeeping that is related to the SSM exemption as described in detail in the proposed rule and summarized again in section IV.E.1 of this preamble.

In establishing standards in this rule, we have considered startup and shutdown periods and, for the reasons explained in section III.G.1 of the proposal preamble and section IV.E of this preamble, have not established alternate standards for those periods.

The EPA is also finalizing provisions related to malfunctions as proposed. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead, they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. (40 CFR 63.2) (Definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112

[17] Refer to section III.D.1.b of the proposal preamble (88 FR 22790, April 13, 2023) for further discussion of Control Option 1.

standards. This reading has been upheld as reasonable by the D.C. Circuit in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016).

Section IV.E.3 of this preamble provides a summary of key comments we received on the SSM provisions and our responses.

F. What other changes have been made to the NESHAP?

This rule also finalizes, as proposed, revisions to several other requirements in the Commercial Sterilization Facilities NESHAP. We describe these revisions in this section as well as other proposed provisions that have changed since proposal.

1. Demonstrating Compliance

In the majority of instances, parametric monitoring is used to good effect as an ongoing means of ensuring that these devices continue to get necessary emission reductions.[18] However, given the nature of EtO, in which small amounts can have large risk impacts, parametric monitoring alone will not be sensitive enough to detect very small fluctuations in EtO concentration. Based on comments received during the proposed rulemaking, the EPA is finalizing a requirement to use EtO CEMS for demonstrating compliance. However, facilities where EtO use is less than 100 lb/year will have the option to use EtO CEMS or performance testing and parametric monitoring to demonstrate compliance. Based on comments received during the proposed rulemaking, we are promulgating the following requirements:

- Quarterly reporting of EtO CEMS data,
- Minimum data availability of 90 percent for EtO CEMS, and
- Use of either outlet volumetric flow rate monitors or differential pressure monitors to demonstrate continuous compliance with EPA Method 204.

Based on comments received during the proposed rulemaking, we are not finalizing a requirement for the mass of EtO being routed to a control device from an SCV to be determined through inlet testing. Based on comments received during the proposed rulemaking, we are finalizing revisions to parametric monitoring requirements, and we are finalizing technical edits to Performance Specification 19 and QA Procedure 7.

2. Electronic Reporting

To increase the ease and efficiency of data submittal and data accessibility, we are finalizing, as proposed, a requirement that owners or operators of commercial sterilization facilities submit compliance reports (being finalized at 40 CFR 63.366(b) and (c)), performance test reports (being finalized at 40 CFR 63.366(f)), and performance evaluation reports (being finalized at 40 CFR 63.366(g)) electronically through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). The final rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website [19] at the time of the test be submitted in the format generated through the use of the ERT and that other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, performance evaluation results of CEMS measuring relative accuracy test audit pollutants that are supported by the ERT at the time of the test must be submitted in the format generated through the use of the ERT and other performance evaluation results be submitted in PDF using the attachment module of the ERT. For compliance reports, the final rule requires that owners or operators use the appropriate spreadsheet template to submit information to CEDRI. The final version of the template for these reports is in the docket and will be located on the CEDRI website.[20] Furthermore, we are finalizing as proposed provisions that allow facility operators the ability to seek extensions for submitting electronic reports for circumstances beyond the control of the facility, *i.e.,* for a possible outage in the CDX or CEDRI or for a force majeure event in the time just prior to a report's due date, as well as the process to seek such an extension.

For a more detailed discussion of these final amendments to the Commercial Sterilization Facilities NESHAP, see section IV.G.2.g of the proposal preamble (88 FR 22790, April 13, 2023), as well as section VI.B below on compliance with the Paperwork Reduction Act. For a more thorough discussion of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2019–0178–0398).

3. Title V Permitting

Because of the lack of other Federal requirements under the CAA that commercial sterilization facilities are subject to, as well as the robust monitoring and reporting requirements of the final rule, we are not finalizing a requirement for area source facilities subject to subpart O to obtain a title V permit from the delegated authority in which the source is located.

4. Combined Emission Streams

To increase the ease and efficiency of complying with the revised NESHAP, we are finalizing, based on comments received during the proposed rulemaking, alternative compliance approaches for combined emission streams. For these streams, facilities will now be allowed to demonstrate compliance with a mass emission limit that is determined based on the emission standards to which the component streams are subject, as well as characteristics specific to those facilities. In addition, we are finalizing an option for owners and operators to demonstrate compliance with a site-wide emission limitation, as opposed to demonstrating compliance for each individual and combined emission stream.

5. Minor Clarifications and Corrections

We are including several additional minor clarifying edits in the final rule based on comments received during the public comment period. The comments and our specific responses to these items can be found in the document, *Summary of Public Comments and Responses for the 2024 Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

G. What are the effective and compliance dates of the standards?

The revisions to the standards being promulgated in this action are effective on April 5, 2024. The compliance date for the standards promulgated pursuant to CAA section 112(f)(2) for the following existing sources is April 6, 2026:

- SCVs at facilities where EtO use is at least 1 tpy,
- ARVs at facilities where EtO use is at least 30 tpy,

[18] Parametric monitoring is an approach that measures one or more key indicators of process operation or emission control device operation, typically on a continuous basis. The parameters are known to affect emission levels associated with the process or the control efficiency of the source's air pollution control device.

[19] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

[20] *https://www.epa.gov/electronic-reporting-air-emissions/cedri.*

- CEVs at area source facilities where EtO use is at least 60 tpy,
- Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, and
- Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy.

The compliance date for the standards promulgated pursuant to CAA section 112(d)(2)–(3), 112(d)(5) or 112(d)(6) for the following existing sources is April 5, 2027:

- SCVs at facilities where EtO use is less than 1 tpy,
- ARVs at facilities where EtO use is less than 30 tpy,
- CEVs at major source facilities,
- CEVs at area source facilities where EtO use is less than 60 tpy,
- Room air emissions at major source facilities,
- Group 1 room air emissions at area source facilities where EtO use is less than 40 tpy, and
- Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy.

As required by CAA section 112(i)(1), new sources must comply with each applicable standard immediately upon its effective date, which is April 5, 2024, or upon startup, whichever is later.

The compliance schedules for existing sources have changed since proposal. We had proposed an 18-months compliance deadline for all of the proposed standards for existing sources. Based on the comments received, we have determined that 18 months is not a sufficient period for sources to comply with the CAA section 112(d)(2)–(3), 112(d)(5) and 112(d)(6) standards for existing sources, for the following reasons:

- Most commercial sterilization facilities were not initially designed to be compliant with the PTE requirements of EPA Method 204. We have learned from the comments received that for these facilities, the capture requirements associated with the emission reduction standards for Group 1 and Group 2 room air emissions in the final rule will likely require a redesign of a portion if not all of the facility. Many facilities will also need to purchase additional equipment (*e.g.,* fans, transformers, variable frequency drives, etc.) to meet the capture requirements. Moreover, compliance with the final emission standards will likely require the installation of additional control devices. We have reviewed the time that it has taken for previous projects of this nature to be completed, from submission of the initial State or local permit application to installation of the continuous compliance mechanisms. Based on this analysis, we find that the process of bringing a facility into compliance with the PTE requirements of EPA Method 204, as well as installing and verifying additional emission controls, can take approximately a year from permit submission to project completion. However, this estimate does not account for the time needed to design and plan before the initial permit application is submitted, nor for the time needed to avoid impacts on medical device supply chains, to procure control devices from a limited number of vendors, and to account for the other complexities identified below.
- The process of redesigning a facility or installing additional controls will require some reduction in sterilization capacity. Moreover, the process of coming into compliance with the standards may require multiple facilities to reduce their sterilization capacity simultaneously. Based on comments received during the proposed rulemaking, the average reduction in capacity during the re-design and installation period can range from 10 percent [21] to 20 percent.[22] In addition, there is already strain on the medical device supply chain, and it is difficult for most facilities to absorb any additional demand for sterilized product. Three years is needed to ensure that owners and operators can come into compliance with the emissions standards while at the same time minimizing any potential impacts to the medical device supply chain, for which reliability is important to protect public health.
- There are a limited number of vendors that specialize in the redesign of facilities to be compliant with the PTE requirements of EPA Method 204. In addition, there are a limited number of control technology vendors that supply the types of advanced control systems that the EPA expects will be necessary for facilities to comply with the final standards. Three years is needed to ensure that all owners and operators can receive the necessary services and have the proper equipment in place by the compliance date.

For the same reasons explained above, existing sources will need more than the proposed 18 months to comply with the standards promulgated under CAA section 112(f)(2). As with standards promulgated under section 112(d)(2)–(3), 112(d)(5) and 112(d)(6), in most instances compliance with the section 112(f)(2) standards will require sources to plan, purchase, and install equipment for EtO control. For example, for SCVs at facilities where EtO use is at least 30 tpy, if an existing affected source currently does not achieve 99.99 percent control of EtO emissions and a new control system is needed to meet that limit, the facility will need time to properly engineer the project, obtain capital authorization and funding, procure the equipment, construct the equipment, start up the equipment, set up new software, develop operating procedures, and train operators on the new equipment. The additional factors identified above, such as avoiding impacts to medical device supply chains and securing control devices from a limited number of vendors, apply similarly to section 112(f)(2) standards as to standards promulgated under section 112(d)(2)–(3), 112(d)(5) and 112(d)(6).

If facilities commence work on these emissions reduction efforts immediately after this rule becomes effective, we believe that sources will be able to comply with the standards in this final rule within the two year compliance window set by § 112(f)(4), without substantial interruption in operations.

Specifically, we offer the following timeline as a general guide to completing the necessary upgrades in a timely manner:

- Step 1: Secure vendors for facility retrofits, control devices, EtO CEMS, and any other equipment and services that will be needed in order to comply with the NESHAP.
- Step 2: Work with vendors on (1) any new facility designs that will be required in order to meet the PTE requirements of EPA Method 204, (2) any new control system designs that will be required in order to meet the emission standards, (3) a schedule to ensure timely compliance with the NESHAP, and (4) purchase of the equipment that will be required in order to meet items (1) and (2), along with EtO CEMS.
- Step 3: Submit a permit application to the relevant permitting authority.
- Step 4: Complete the necessary facility retrofits, control device installations, and EtO CEMS installations.
- Step 5: Test the control systems and facility air handling systems in order to ensure that the NESHAP is being met.

We recognize that this is a significant undertaking for the industry, and we encourage facilities to engage in these

[21] Commenter provided the following statement: ''For example, a 10% reduction in capacity across the 83 commercial sterilizers in the U.S. implies that an additional 8 sterilization facilities will be required to maintain existing throughput'' (see Docket Item No. EPA–HQ–OAR–2019–0178–0618).

[22] Commenter provided the following statement: ''During . . . upgrades, EtO sterilization capacity was reduced by more than 20 percent as emissions control equipment was installed and tested.'' (see Docket Item No. EPA–HQ–OAR–2019–0178–0566).

steps as early as practicable, as opposed to delaying action until closer to the end of the compliance period.

Although we believe sources that follow this timeline will be able to comply with these standards within two years, to minimize any potential impact to the medical device supply chain, we are allowing up to three years for existing sources to comply with section 112(d)(2)–(3), 112(d)(5) and 112(d)(6) standards, the maximum timeframe authorized under CAA section 112(i)(3)(A). Further, CAA section 112(i)(3)(B) and EPA's regulation at 40 CFR 63.6(i)(4)(i)(A) authorize States with delegated authority to implement and enforce this NESHAP to grant an existing source an additional year to comply with section 112(d) standards, if such additional period is necessary for the installation of controls.[23] In addition, for each standard, owners and operators will have 180 days after the end of the relevant compliance period to begin demonstrating compliance with that standard. See 40 CFR 63.7(a)(2).

Lastly, if more time is needed to comply with any standard in this final rule, CAA section 112(i)(4) provides that ''The President may exempt any stationary source from compliance with any standard or limitation under this section for a period of not more than 2 years if the President determines that the technology to implement such standard is not available and that it is in the national security interests of the United States to do so. An exemption under this paragraph may be extended for 1 or more additional periods, each period not to exceed 2 years. The President shall report to Congress with respect to each exemption (or extension thereof) made under this paragraph.''

IV. What is the rationale for our final decisions and amendments for the Commercial Sterilization Facilities source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket.

[23] This flexibility has been available since the NESHAP was first promulgated (59 FR 62585, December 6, 1994) and continues to be available in the current NESHAP.

A. Amendments Addressing the Affected Source Definitions

1. What amendments did we propose to address the affected source definitions?

For SCVs, ARVs, and CEVs, we proposed to define the affected source as the individual vent. For Group 1 and Group 2 room air emissions we proposed to define the affected source as the collection of all room air emissions for each group at any sterilization facility. More information concerning the affected source definitions is in section III.A. of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the affected source definitions change since proposal?

We are finalizing the affected source definitions as proposed (88 FR 22790, April 13, 2023).

3. What key comments did we receive on the affected source definitions and what are our responses?

Comment: Two commenters suggested that the definition of an affected source should be based on control system outlets, stating that when emission streams are combined, the limit must be based on the actual achievable rate of control with further consideration for the modeled risk of the facility. One commenter suggested that the affected source should be defined as the sterilization facility as a whole, and another commenter stated the affected source definition(s) should consider destruction efficiency. Additionally, commenters expressed concerns that the affected source definitions for point sources (*i.e.,* SCVs, ARVs, and CEVs) would disproportionately favor facilities with smaller capacity and facilities with multiple individual vents regardless of size. Specifically, one commenter stated that a facility with multiple individual vents would have a higher ''emission rate ceiling'' with respect to mass rate (*i.e.,* lb/h) emission limits.

Response: We disagree with the commenters' suggestion that the definition of an affected source should be based on control system outlets or the sterilization facility as a whole. There are many different ways in which emission sources can be combined and controlled at commercial sterilization facilities. If affected source definitions were based on control system outlets, it is not clear which outlets (and, by extension, emission source combinations) would be selected and what the criteria for selecting those outlets would be. It is not feasible to set an emission standard for every conceivable combination of emission sources. Furthermore, the commenters do not provide any suggestions on which control system outlets should be considered when defining affected sources. The most straightforward approach is to define the affected source as the emission source itself and to have owners and operators decide how best to combine and control emissions from affected sources at their facilities. With respect to defining the affected source as the sterilization facility as a whole, there is very limited data available where a performance test has been conducted for an entire facility. Furthermore, defining the affected source as the sterilization facility would require a compliance mechanism that some facilities may find unnecessarily complicated, given that compliance demonstration has typically been conducted on a source-by-source basis. It is not clear and the commenter does not provide any explanation on how to base an affected source definition on destruction efficiency.

Lastly, regarding the comment that the definition of affected sources for point sources is disproportionally favorable to facilities with smaller capacity or with multiple individual vents, this is not an issue in the final rule. All of the emission standards in this final rule are in a percent reduction format, which is the same regardless of facility size or how many vents are in place. Therefore, concerns regarding ''emission rate ceilings'' are no longer relevant.

Comment: One commenter stated that there is unnecessary complexity to the proposed definitions of Group 1 and Group 2 room air emissions due to the variability in size and facility configuration, particularly as they apply to the proposed format of the emission standards for these sources (*i.e.,* lb/h). The commenter also stated that the definitions favor facilities which have smaller capacity and noted that individual facility characteristics must be considered for Group 1 and Group 2 emissions. Specifically, the commenter stated that emission rates should be based on technological feasibility to control emissions, including feasibility limitations regarding low inlet concentrations.

Response: We disagree with one commenter's assertion that there is unnecessary complexity to the proposed definitions of Group 1 and Group 2 room air emissions due to the variability in size and facility configuration. All sterilization facilities, regardless of size or configuration, follow the same basic procedure: sterilization and its associated activities (*e.g.,* EtO storage and dispensing, vacuum pump

operation, handling of pre-aeration sterilized product), aeration, and shipping. Group 1 room air emissions simply cover all activities that occur prior to aeration, and Group 2 room air emissions cover all activities that occur after aeration. Combining room air emissions based on whether they occur before or after aeration is a clear way to defining room air emissions affected sources. It also reflects the most common controlled room air configuration that we have observed. With respect to considering individual facility characteristics The simplest breakdown of controlled room air emissions that we have observed involves capturing and routing all emissions from post-aeration handling of sterilization material to one control system, and then capturing and routing all other room air emission sources (*i.e.,* Group 1 room air emissions) to another control system. It is important to define the affected sources for room air emissions in this manner so that owners and operators can have flexibility in how they chose to control their emissions,[24] and so that facilities who have already chosen to control their emissions in this manner can continue to do so while minimizing any potential compliance issues. With respect to the comment that the definition of affected sources for room air emissions is disproportionally favorable to facilities with smaller capacity, the comment appears to pertain more to the setting of the emission standards themselves, rather than the affected source definition. As discussed in section IV.B.3.b of this preamble, we are no longer finalizing mass rate emission standards, and we are accounting for technical feasibility (*e.g.,* manufacturer guarantees, emission reductions achieved in performance tests) when finalizing emission standards. The emission standards in this final rule for room air emissions are in a percent reduction format, which is the same regardless of facility size.

4. What is the rationale for our final approach and final decisions to address the affected source definitions?

We evaluated the comments on our proposed affected source definitions. For the reasons explained in the proposed rule (88 FR 22790, April 13, 2023), we determined that these amendments are necessary because the definition of an ''affected source'' at 40 CFR 63.2 is not appropriate for this source category. More information concerning the amendments we are finalizing for affected source definitions is in the preamble to the proposed rule and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking. Therefore, we are finalizing the affected source definitions as proposed.

B. Amendments Pursuant to CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5) for the Commercial Sterilization Facilities Source Category

1. What did we propose pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) for the Commercial Sterilization Facilities source category?

We proposed to establish standards under CAA sections 112(d)(2)–(3) and 112(d)(5) for the following emission sources that were unregulated: SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy, ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs at facilities where EtO use is at least 10 tpy, and room air emissions. We also proposed a technical correction to the emission standard for ARVs at facilities where EtO use is at least 10 tpy. We proposed the following emission standards pursuant to CAA section 112(d)(2)–(3):

- 3.2E–4 lb/h for new and existing CEVs at facilities where EtO use is at least 10 tpy,
- 1.3E–3 lb/h for new and existing Group 1 room air emissions at major source facilities, and
- 2.8E–3 lb/h for new and existing Group 2 room air emissions at major source facilities.

For more information, see section III.B of the proposal preamble (88 FR 22790, April 13, 2023). We proposed the following emission standards pursuant to CAA section 112(d)(5):

- 99 percent emission reduction for new and existing SCVs at facilities where EtO use is less than 1 tpy,
- 99 percent emission reduction for new and existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99 percent emission reduction for new and existing ARVs at facilities where EtO use is less than 1 tpy,
- 99 percent emission reduction for new and existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99 percent emission reduction for new and existing CEVs at facilities where EtO use less than 1 tpy.
- 1.3E–3 lb/h emission limit for new and existing Group 1 room air emissions at area source facilities, and
- 2.8E–3 lb/h emission limit for new Group 2 room air emissions at area source facilities.

These are emissions standards that reflect the use of generally available control technologies. For more information, see section III.B of the proposal preamble (88 FR 22790, April 13, 2023).

For existing Group 2 room air emissions at area source facilities, pursuant to CAA section 112(d)(5), we proposed a requirement for facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. This is a BMP that would reduce EtO use per sterilization cycle (*i.e.,* pollution prevention). For more information, see section III.B.8.g of the proposal preamble (88 FR 22790, April 13, 2023). In order to ensure complete capture of EtO emissions and, in turn, compliance with the proposed standards, we proposed to require each facility to operate areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. For more information, see section III.B of the proposal preamble (88 FR 22790, April 13, 2023).

We addressed a necessary correction to the emission standards for these sources in 40 CFR 63.362(d) that allow facilities to either achieve 99 percent emission reduction or limit the outlet concentration to a maximum of 1 part per million by volume (ppmv), ''whichever is less stringent, from each aeration room vent.'' We proposed removing the less stringent 1 ppmv concentration alternative for these sources because it is not equivalent and therefore not an appropriate alternative to 99 percent emission reduction standard. For more information, see section III.B.2 of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the revisions pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) change since proposal for the Commercial Sterilization Facilities source category?

We are finalizing as proposed the following standards under CAA section 112(d)(5):

- 99 percent emission reduction for new and existing SCVs at facilities where EtO use is less than 1 tpy,
- 99 percent emission reduction for new and existing ARVs at facilities

[24] The EPA has not observed any instance where a facility is routing a portion of its Group 1 room air emissions to one control system, and the other portion to a different control system.

where EtO use is at least 1 tpy but less than 10 tpy, and

- 99 percent emission reduction for new and existing ARVs at facilities where EtO use is less than 1 tpy.

In addition, we are finalizing a requirement for each facility to operate areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We are also finalizing the removal of the 1 ppm alternative for ARVs at facilities where EtO use is at least 10 tpy, as proposed.

Based on comments received during the proposed rulemaking, we have revised the proposed standards for the following affected sources. The final emission standards pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) are as follows:

- 99.94 percent emission reduction for new and existing CEVs at major source facilities,
- 99 percent emission reduction for new and existing CEVs at area source facilities,
- 97 percent emission reduction for new and existing Group 1 room air emissions at major source facilities,
- 80 percent emission reduction for new and existing Group 1 room air emissions at area source facilities,
- 86 percent emission reduction for new and existing Group 2 room air emissions at major source facilities,
- For existing Group 2 room air emissions at area source facilities, lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened, and
- 80 percent emission reduction for new Group 2 room air emissions at area source facilities.

For new and existing CEVs at major source facilities, as well as new and existing room air emissions at major source facilities, based on comments received during the proposed rulemaking, we have re-calculated the MACT floor based on percent emission reduction, as opposed to mass rate emissions. The primary reason for finalizing this change is that there is a serious concern that mass rate emission standards could result in operational reductions that could adversely impact the medical supply chain. The revised MACT floor for new and existing CEVs at major source facilities is 99.94 percent emission reduction. Because we were unable to identify more stringent (*i.e.,* beyond the floor or ''BTF'') options that are cost-effective, we are finalizing 99.94 percent emission reduction as the MACT standard under CAA section 112(d)(2)–(3) for new and existing CEVs at major source facilities. The revised MACT floor for new and existing Group 1 room air emissions at major source facilities is 90 percent emission reduction. We were able to identify a more stringent (*i.e.,* 97 percent control) and cost-effective BTF option and, therefore, we are finalizing a 97 percent emission reduction standard as the MACT standard under CAA section 112(d)(2)–(3) for new and existing Group 1 room air emissions at major source facilities. The revised MACT floor for new and existing Group 2 room air emissions at major source facilities is 86 percent emission reduction. Because the concentration that corresponds to this emission reduction is three times the representative detection level (RDL) for EtO, there are no BTF options to consider due to the potential difficulty of demonstrating compliance with limits lower than the MACT floor. Therefore, we are finalizing 86 percent emission reduction as the MACT standards for new and existing Group 2 room air emissions at major source facilities. For more information, see section IV.B.3.b of this preamble.

For both new and existing Group 1 room air emissions at area source facilities, as well as new Group 2 room air emissions at area source facilities, based on comments received during the proposed rulemaking, we are finalizing an 80 percent emission reduction standard, consistent with the manufacturer guarantee for the control technology on which the standard is based. The primary reason for the change from mass rate to percent reduction is that there is a serious concern that mass rate emission standards could result in operational reductions in order to meet the standards while still ensuring work health and safety, but that could adversely impact the medical supply chain. In addition, while some sources have demonstrated emission reductions higher than 80 percent, those reductions are limited to facilities with higher EtO usage rates, and we cannot determine whether smaller users of EtO can meet those emission reductions. For more information, see section IV.B.3.b of this preamble.

For existing Group 2 room air emissions at area source facilities, based on comments received during the proposed rulemaking, we are finalizing a revised BMP due to concerns that the BMP that we proposed (as well as alternatives for which we solicited comment in the proposal), would adversely impact the medical supply chain due to inefficiencies that would arise, as well as having to lengthen cycle dwell times in order to ensure sterility. The final requirement reduces existing Group 2 room air emissions at area source facilities by 20 percent, does not interfere with sterility assurance, and is expected to impact only 20 percent of facilities. We do not anticipate any severe negative impacts to the medical supply chain as a result of finalizing this requirement. For more information, see section IV.B.3.a of this preamble.

3. What key comments did we receive on the proposal revisions pursuant to CAA section 112(d)(2), 112(d)(3), and 112(d)(5), and what are our responses?

This section provides comment and responses for the key comments received regarding BMPs, mass rate emission standards, PTE, and warehouses. Other comment summaries and our responses for additional issues raised regarding these activities, as well as issues raised regarding our proposed emission standards for SCVs and ARVs at facilities where EtO use is less than 1 tpy, ARVs at facilities where EtO use is a least 1 tpy but less than 10 tpy, room air emissions at major source facilities, and our proposed technical correction to the emission standard for ARVs at facilities where EtO use is at least 10 tpy can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

a. BMP

Comment: Several commenters contended that we should not require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. They stated that owners and operators should have the flexibility to optimize cycles using a variety of ISO/AAMI 11135 methods and that we should not limit or restrict the validation method that may be used.

One commenter stated that requiring facilities to follow the Cycle Calculation or Bioburden/Biological Indicator Approach would result in more dedicated product loads, more cycles needed to sterilize different project mixes, and most chambers not being filled to capacity. The commenter stated that de-consolidation of existing cycles to implement an appropriate Cycle Calculation or Bioburden/Biological Indicator approach would require (1) creation and validation of new product families, new process challenge devices, and biological indicators, (2) cycle development, and (3) maintenance through requalification and annual reporting. The commenter noted that the

extra burden associated with maintaining more cycles would create more work and require more chamber time, resulting in less sterilization capacity. Two commenters stated that requiring either the Cycle Calculation or Bioburden/Biological Indicator approach could limit research for product innovation as available development time in EtO sterilization chambers would be taken up for optimizing existing products.

Two commenters stated the ISO standards were intended for the process of EtO sterilization and not emission reduction or controls. One commenter further contended it is a faulty approach to base emission standards on international standards, as these standards are revised periodically and may continue to evolve. Another commenter noted that ISO/AAMI standards are currently being revised to be more flexible to achieve optimized cycles, while minimizing impact on sterilization capacity. The commenter contended that cycle validation must focus on achieving sterility required for patient safety and assuring product performance and reliability, and that reducing EtO use cannot take priority over patient safety.

One commenter stated that conducting Cycle Calculation studies for every product type or category would not be feasible with the current capacity. The commenter stated this would require effort to redesign sterilization cycles, evaluate product and packaging performance, and validate the redesigned cycles. The commenter also stated that the new validation work will impact sterilization capacity as sterilizer equipment is not available for production use during study times (*i.e.,* production capacity is diverted to cycle validation). The commenter further stated that sites that use more than one vendor would have to redesign sterilization cycles at each vendor and that, given the limited resources and expertise, this would not be possible to achieve on this scale. Another commenter stated they have not been able to ensure product sterility using Cycle Calculation approach.

Finally, one commenter stated that the Bioburden/Biological Indicator methods limit the number of products that can be validated in a single cycle. The commenter stated that the Bioburden/Biological Indicator approach may be limited to a range of products with similar attributes and drive up the number of required cycles. The commenter also stated that each validated cycle will require requalification every few years, and the additional testing at sterilizers and testing laboratories will decrease available sterilization capacity. The commenter stated that the inability to fill a sterilization chamber fully with product and waiting until full can lead to inefficient use of sterilization chambers and supply issues. Another commenter stated the Bioburden/Biological Indicator approach results in additional cost and delays, as it requires that the product bioburden levels be enumerated and characterized, and that consistency in the bioburden population and the bioburden's resistance to the sterilization process remain relatively stable over a multi-year period. The commenter also stated that it may take many years to establish the range in numbers and types of bioburden to properly perform a validation using this proposed Bioburden/Biological Indicator approach. Another commenter stated that the Bioburden approach would require upgrades to supplier facilities, manufacturing facility, and microbiological control practices.

Response: We agree with the commenters' concerns regarding potential inefficiencies in the sterilization process that may arise from requiring facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017, along with the potentially adverse impacts to the medical supply chain that could result from the proposed approach. These inefficiencies include reduced cycle optimization (*i.e.,* not being able to sterilize as much product per load or chamber), having to run more cycles overall in order to meet the demand for sterile medical devices, and diverting already strained resources away from normal operations to developing new cycle validations. We also agree with the commenters' concerns that requiring facilities to follow this requirement would limit research for product innovation. Given the current strain on resources, some companies may not be able to invest in additional chambers to conduct research. In addition, we agree with the commenters' concerns that because this requirement is based on international standards, which are revised periodically, this could result in potential future complications. Therefore, we are not including this requirement in the final rule.

Comment: As mentioned above, the EPA solicited comments on several other BMPs, including limiting EtO concentration limit and limiting packaging and pallet material. Two commenters stated that it is not technically feasible for facilities and products to meet a 290 milligrams per liter (mg/L) EtO concentration limit. One commenter stated that many industry guidelines and studies show that 400 mg/L is the minimum recommended concentration, and many products use higher concentrations to meet sterility assurance and product quality requirements as set forth by FDA. Another commenter stated that process efficiency is reduced with concentrations below 400 mg/L and that efficiency is constant at concentrations greater than 500 mg/L. One commenter indicated that an EtO concentration range of 400 to 650 mg/L is common practice because it achieves microbiological lethality for most products within a reasonable exposure time. Another commenter stated that product design, stability post-sterilization, and lethality are the drivers behind the choice of EtO concentration. The commenter also stated that research and development with biological indicators is routinely conducted using 600 mg/L cycles and that enforcing a lower limit may have an unintended negative consequence on the availability of biological indicators required for sterilization process validation and routine monitoring. One commenter stated we should not propose to limit the EtO concentration to 290 mg/L for small facilities and that we should, instead, allow performance-based standards. In addition, several commenters stated that an upper-bound limit on EtO concentration may lead to longer cycle times and dwell times and that longer dwell times would impact sterilization capacity and would lead to offshoring, as well as the construction of additional facilities.

One commenter stated limiting packaging and pallet material will interrupt trade, reduce innovation, increase the cost of medical devices, and disrupt the medical device manufacturing industry without a quantifiable reduction in EtO emissions. Two commenters stated that packaging and pallet material selection will drive the design of medical products. Two commenters noted that packaging requirements are in place to ensure a sterile barrier until use and to prevent product damage. One commenter stated packaging must pass rigorous test requirements, according to industry standards. Another commenter indicated that facilities use barcode instructions for use (IFUs) in place of paper IFUs when possible. However, paper IFUs are regulated by FDA. Two commenters noted that paper IFUs have not been documented to be a source of residual emissions. Another commenter

stated that there is no evidence that barcode materials would have less EtO retention than paper, and that labeling decisions have practical and legal considerations. One commenter noted that a minimal amount of plastic wrap is used to ensure the structural integrity of pallets during shipping and that excessive plastic is not in the interest of sterilization facilities, as it slows EtO penetration. The commenter also stated that kits are transported in cardboard to protect from punctures, and it is not possible to eliminate cardboard. A puncture to a kit means the kit needs to be re-sterilized, requiring use of additional EtO. One commenter stated that changes to pallet material could have supply chain issues given interoperability and weight requirements. Finally, another commenter stated that pallet materials impact the strength and design of pallet, and any issues would have implications for the entre medical device supply chain.

Response: We agree with the commenters' concerns regarding the issues with prescribing an upper-bound limit on in-chamber EtO concentration, as well as the negative impacts to the medical supply chain that could result from increasing the dwell time to maintain sterility as an outcome of such a requirement. Therefore, we are not including this requirement in the final rule. We also agree with the commenters' concerns regarding the need to ensure a sterile barrier through sufficient packaging, as well as the potential supply chain impacts from placing limits on the types of pallets that may be used. Therefore, we are not requiring limits on packaging or transport materials as part of this rulemaking.

Comment: One commenter recommended an end of sterilization cycle chamber limit of less than 1 ppm (with a zero mg/L reading) in the sterilization chamber (EtO remaining calculated measurement) as a BMP. The commenter stated that removing EtO from the sterilization chamber is the most efficient stage for EtO removal. The commenter further stated that longer EtO dwell times, as well as the potential for the elimination of nitrogen gas washes to keep total cycle time equivalent, could result in more EtO residual at aeration and the greater potential for room air emissions after aeration.

Response: We agree with the commenter's suggestion of a requirement to limit the in-chamber EtO concentration to 1 ppm. It does not interfere with sterility assurance, and, based on responses to the December 2019 questionnaire and September 2021 Information Collection Request (ICR), 80 percent of all commercial sterilization facilities, regardless of annual EtO use, are already meeting this limit. Those who are not meeting the limit currently are close to the limit,[25] so we do not anticipate any severe negative impacts to the medical device supply chain as a result of finalizing this requirement. We estimate that the emission reductions from applying this requirement to the source category would be 20 percent. In addition, since 80 percent of facilities are already meeting this limit, this would result in an 80 percent reduction in costs. We have evaluated the changes in cost, emissions, and cost-effectiveness for this BMP, and it is more cost-effective than the other options we considered. Therefore, for Group 2 room air emissions we are finalizing the BMP such that the in-chamber EtO concentration is to be lowered to 1 ppm before the chamber can be opened. We note that, even though this BMP is expected to result in fewer emission reductions than the BMP we proposed, this rule will still reduce EtO emissions (and, therefore, lifetime cancer risks) in multiple communities across the country. As discussed in section IV.C.2.a.iii, this BMP will ultimately apply only to facilities where EtO use is less than 4 tpy. We are finalizing the requirement that area source facilities whose EtO usage is at least 4 tpy but less than 20 tpy and area source facilities whose EtO usage is at least 20 tpy are required to reduce Group 2 room air emissions by 80 percent and 98 percent, respectively (see section IV.C.2.a.iii for more information). For SCVs and ARVs at facilities where EtO use is less than 1 tpy, as well as ARVs at facilities where EtO use is less than 10 tpy, our general rationale for proposing emission standards over the BMP was that emission standards would both achieve greater emission reduction and incur fewer annual costs than the BMP. However, even considering lower annual costs for the BMP, the emission standards would still achieve greater emission reduction. Therefore, for SCVs and ARVs at facilities where EtO use is less than 1 tpy, as well as ARVs at facilities where EtO use is less than 10 tpy, we are finalizing the emission standards as proposed pursuant to CAA section 112(d)(5). For CEVs at area source facilities, as well as room air emissions at area source facilities, we are also evaluating percent emission reduction standards, as opposed to mass rate emission standards. The revised GACT analyses for those emission sources are presented in section IV.B.3.b of this preamble.

Comment: Several commenters stated that we do not have the legislative authority or expertise to regulate sterilization cycles and that FDA is the Federal agency that has authority to regulate medical device sterilization. They stated that Congress gave FDA the authority to ensure the availability of safe and effective medical products and that we must not finalize any regulatory requirements that are under FDA purview.

Response: The EPA proposed the BMP (*i.e.,* require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach) pursuant to CAA section 112(d)(5), which authorizes the EPA to set standards for area sources that provide for the use of generally available control technologies or management practices to reduce emissions. In addition, CAA section 112(h)(1) authorizes the EPA to promulgate a design, equipment, work practice or operational standard, or a combination thereof, if the EPA does not think it can prescribe an emission standard. We have identified modification of the post-sterilization process (*e.g.,* reducing the EtO concentration within the sterilization chamber prior to opening the chamber) as a BMP that can reduce EtO emissions from certain affected sources at commercial sterilization area source facilities. Neither CAA section 112(d)(5) nor section 112(h)(1) limits the scope of management or work practices that the EPA may consider in setting standards to control HAP, nor did the commenter identify any such legal limitation in the CAA or other applicable legal authorities. As discussed above, we are not finalizing the proposed BMP; in response to comment, we are finalizing a requirement for area source facilities with existing Group 2 room air emissions to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened.[26] As discussed in

[25] The highest concentration that was reported prior to opening the chamber door was 20 ppm. While this may seem high, this is reduced from starting EtO concentrations of several thousand ppm (see section IV.F.3 of this preamble for further discussion).

[26] We have previously regulated the in-chamber EtO concentration when we established standards for CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (59 FR 62586, December 6, 1994). These requirements were removed initially due to safety concerns regarding the regulation of emissions from CEVs, not related to any limitations on our authority. See discussion in section III.B.5 of the proposal preamble (88 FR 22790, April 13, 2023) for more information regarding why safety is

Continued

section IV.C.2.a.iii of this preamble, this requirement will ultimately apply only to existing Group 2 room air emissions at facilities where EtO use is less than 4 tpy. Based on responses to the December 2019 questionnaire and the September 2021 ICR, we have not identified any facilities where EtO use is less than 4 tpy that are not currently meeting this requirement. Therefore, in general, we do not anticipate that any facilities will need to go through a new cycle validation as a result of this requirement. Based on our conversations with FDA, this requirement is not anticipated to have an adverse impact on the medical device supply chain.

b. Mass Rate Emission Standards

Comment: Several commenters were opposed to mass rate emission standards, stating that they do not account for the substantial variability among volumetric flow rates in sterilization operations. The commenters expressed concerns with potential operational reductions needed in order to meet the standards while still ensuring worker health and safety, as well as compliance with EPA Method 204. The commenters suggested that we finalize emission reduction and outlet concentration standards instead. In addition, these commenters recommended that these standards be based on control device manufacturer guarantees. One commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99 percent emission reduction standard for CEVs and an 80 percent emission reduction standard for room air emissions.

Response: We agree with the commenters' concerns regarding the potential impacts of mass rate emission standards. Given the low outlet EtO concentration of these streams, along with current EtO detection levels, a mass rate emission standard essentially functions as an upper-bound limit on volumetric flow rate. It may not be appropriate to limit volumetric flow rate in this fashion, as additional flow may be needed in order to demonstrate compliance with EPA Method 204 or to ensure worker health and safety. If volumetric flow rate is limited, a facility may be forced to reduce its sterilization capacity in order to meet the mass rate emission standards. However, we disagree with the commenters' suggestion that outlet concentration standards be considered. We are concerned that some owners and operators may choose to dilute the air flow of the emissions stream rather than control emissions, in order to meet an outlet concentration standard, which would not result in emission reductions. In order to ensure emission reductions from an outlet concentration standard, an upper-bound limit on the volumetric flow rate would be necessary. As we have discussed before, this may be inappropriate for the source category. Therefore, although we proposed mass emission rate standards, we are finalizing percentage emission reduction standards in their place, and those specific standards are discussed later in this section.

We re-calculated the MACT floor for existing CEVs at major source facilities. We ranked the percent reduction performance of the CEVs ''for which the EPA has emissions information'' and found the best performing 12 percent of CEVs consists of one CEV that is being controlled by a gas/solid reactor.[27] Because the variability and uncertainty associated using available, short-term data would tend to reduce the minimum percent reduction, we then used the lower, not upper, prediction limit approach to develop the MACT floor for existing sources.[28] The LPL approach predicts the level of emissions that the sources upon which the floor is based are expected to meet over time, considering both the average emissions level achieved as well as emissions variability and the uncertainty that exists in the determination of emissions variability given the available, short-term data. For LPLs, our practice is to use the first percentile, or LPL 1, as that is the level of emission reductions that we are 99 percent confident is achieved by the average source represented in a dataset over a long-term period based on its previous, measured performance history as reflected in short term stack test data. The LPL 1 value of the existing source MACT floor is 99.94 percent emission reduction. The LPL 1 EtO concentration that corresponds to this emission reduction rate is 49 ppbv. Based on our review of available EtO measurement instruments and our demonstration program, we find the in-stack detection level for EtO, given the current technology, and potential makeup of emission streams, is approximately 10 ppbv. Some EtO CEMS manufacturers claim instrument detection levels much lower than 10 ppbv. However, we believe at the current time, 10 ppbv is the lowest level that can be consistently demonstrated and replicated across a wide range of emission profiles. We expect that EtO CEMS manufacturers, measurement companies, and laboratories will continue to improve EtO detection levels (making them lower). In the meantime, consistent with our practice regarding reducing relative measurement imprecision by applying a multiplication factor of three to the RDL, the average detection level of the best performers, or, in this case, the better performing instruments, so that measurements at or above this level have a measurement accuracy within 10 to 20 percent—similar to that contained in the American Society of Mechanical Engineers (ASME) ReMAP study,[29] we apply a multiplication factor of three to the RDL of 10 ppbv, which yields a workable-in-practice lower measurable value of 30 ppbv. For reference, below is the equation that relates the percent emission reduction, inlet EtO concentration, and outlet EtO concentration:

$$ER = \frac{EtO_{IM} - EtO_{OM}}{EtO_{IM}}$$

Where, *ER* is the percent emission reduction, EtO_{IM} is the inlet EtO mass, and EtO_{OM} is the outlet EtO mass. Since

not a concern regarding the requirements finalized in this action.

[27] See CAA section 112(d)(3). See also, *National Ass'n of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1131 (2013) (citing *Sierra Club* v. *EPA,* 167 F.3d 658, 661 and 662) (''We accorded *Chevron* deference to EPA's . . . estimate of the MACT floor, noting that the requirement that the existing unit floors 'not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units' does not, on its own, dictate 'how the performance of the best units is to be calculated, . . . [and] recognizing that 'EPA typically has wide latitude in determining the extent of data gathering necessary to solve a problem.' '')

[28] The variability for a DRE format limit requires use of a lower prediction limit (LPL), the UPL template was therefore modified for use to determine the LPL; rather than use of the 99th percentile that captures the ''right tail'' of the data distribution, the LPL template uses the 1st percentile, *i.e.,* captures the ''left tail'' of the data distribution (the t-statistic is 0.01). The LPL differs from the more commonly used UPL in that variability and uncertainty associated with percent reduction limits tend to make the predicted limits smaller than their averages; for UPL applications, variability and uncertainty associated with emission limits tend to make those predicted limits larger than their averages. Both approaches—UPL and LPL—rely on the same set of equations developed for the UPL; they only differ in the selected percentile. In other words, the LPL relies on calculations associated with the first percentile (LPL 1) of the data distribution, which is below the fiftieth percentile (LPL 50), or average for data with a normal distribution, while the UPL relies on calculations associated with the ninety-ninth percentile (UPL 99) of the data distribution, which is above the fiftieth percentile (UPL 50), or average for data with a normal distribution. Also note that for data in a normal distribution, LPL 50 = UPL 50.

[29] See the discussion in the MATS rule preamble at 77 FR 9370, February 16, 2012.

the outlet EtO concentration that corresponds to the MACT floor of 99.94 percent emission reduction is above 3×RDL, there are more stringent (*i.e.,* BTF) options to consider.[30] We considered two BTF options for reducing EtO emissions from this source: the first option is 99.95 percent emission reduction, and the second option reflects the most stringent emission reduction for which compliance can be demonstrated. With respect to the second option, the most stringent emission reduction for which compliance can be demonstrated is that which corresponds to an outlet concentration of 30 ppbv (*i.e.,* 3xRDL). This emission reduction is 99.96 percent, which is lower than all of the reported emission reductions in the test runs that were used to calculate the MACT floor. The impacts of these options are presented in table 7. Because we have not identified any major source facilities with existing CEVs, the impacts are based on a model plant for existing CEVs at a synthetic area source facility with the following assumptions reflecting the average of each of the parameters at synthetic area source facilities:

- Annual EtO use: 200 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to CEVs: 1 percent.
- CEV flow rate: 278 cubic feet per second (cfs).

TABLE 7—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF BTF OPTIONS CONSIDERED UNDER CAA SECTIONS 112(d)(2) AND 112(d)(3) FOR CEVS AT MAJOR SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
MACT Floor ..	99.94 percent emission reduction	$830,000	$176,000	2.4E–2 [480 lb/yr]	$735,000 [$370/lb].
1	99.95 percent emission reduction	184,000	65,500	2.0E–4 [0.4 lb/year]	328,000,000 [$164,000/lb].
2	99.96 percent emission reduction	184,000	66,200	2.0E–4 [0.4 lb/year]	331,000,000 [$166,000/lb].

While we acknowledge that EtO is a highly toxic HAP, the cost estimates above are far outside the range of the cost-effectiveness values that we have determined to be cost-effective for highly toxic HAPs (*e.g.,* we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). Based on the estimates above, we find neither option to be cost effective. Therefore, the final MACT standard for existing CEVs at major source facilities is 99.94 percent emission reduction.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the CEV that is being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 99.94 percent emission reduction. As explained above, because this emission reduction limit is above the lowest level at which compliance can be demonstrated, the EPA considered more stringent (*i.e.,* BTF) options. We considered the same BTF options as those evaluated for existing CEVs at major source facilities, for the same reasons explained above. The first BTF option would require achieving 99.95 percent emission reduction, and the second BTF option would require achieving 99.96 percent emission reduction. The impacts of these options are presented in table 7 of this preamble. Because we have not identified any major source facilities with existing CEVs, the impacts are based on a model plant for existing CEVs at a synthetic area source facility. Based on the estimates above and for the reason explained above, we find neither option to be cost effective. Therefore, the final MACT standard for new CEVs at major source facilities is 99.94 percent emission reduction. For the reasons explained above, our final MACT standards under CAA sections 112(d)(2) and (3) for both new and existing CEVs at major source facilities require these facilities to reduce the EtO emissions from new and existing CEVs by 99.94 percent.

For existing CEVs at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on the CEVs, and the second option reflects applying a BMP to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened (*i.e.,* pollution prevention). With respect to the first option, because 34 out of 40 area source facilities with CEVs already using controls to reduce CEV emissions, and we have no reason to believe that the other six cannot do the same, we consider emission controls to be generally available for existing CEVs at these facilities. Evaluating the available information on controls, including the documented control efficiency for 12 facilities in the category, we determined that a control efficiency of 99 percent is generally available for existing CEVs at area source facilities. The second potential GACT option we considered was the same management practice discussed in section IV.B.3.a of this preamble, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these two options are presented in table 8.

[30] As Judge Williams explained in his concurring opinion in *Sierra Club* v. *EPA,* CAA ''Section 112(d)(2) calls for emissions standards that are the most stringent that the EPA finds to be 'achievable,' taking into account a variety of factors including cost. . . . The ''achievable'' standards have come to be known as the ''beyond-the-floor'' standards, . . . meaning, obviously, ones more stringent than the ''floors'' established under § 112(d)(3).'' 479 F.3d 875, 884 (D.C. Cir. 2007).

TABLE 8—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING CEVS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$1,750,000	$740,000	3.84 [7,680 lb/year]	193,000 [$96/lb]
2	BMP (estimated 20 percent emission reduction)	0	$3,560,000 (one-time annual cost) [1].	0.796 [1,590 lb/year]	$4,470,000 [$2,240/lb]

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as preparing and submitting the necessary paperwork to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. Such values include hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). We are finalizing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve much greater emission reduction than Option 2. Second, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing Option 1 for existing CEVs at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from existing CEVs by 99 percent.

For new CEVs at area source facilities, we considered two potential GACT options similar to those evaluated for existing CEVs at area source facilities. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described in section IV.B.3.a, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these options, which are presented in table 9 of this preamble, are based on a model plant for new CEVs at a new area source facility with the following assumptions reflecting the average of each of the parameters at existing area source facilities:

- Annual EtO use: 100 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to CEVs: 1 percent.
- CEV flow rate: 200 cubic feet per second (cfs).
- Number of unique cycles: nine.

TABLE 9—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW CEVS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$553,000	$142,000	0.99 [1,980 lb/year]	$144,000 [$72/lb]
2	BMP (estimated 20 percent emission reduction)	0	$80,000 (one-time annual cost) [1].	0.20 [400 lb/year]	$400,000 [$200/lb]

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness number of Option 2 is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2, and it is more cost-effective. Therefore, we are finalizing Option 1 as the standard for new CEVs at area source facilities under CAA section 112(d)(5). The standard requires these facilities to continuously reduce emissions from new CEVs by 99 percent.

We have re-calculated the MACT floor for existing Group 1 room air emissions at major source facilities. We ranked the performance of the facilities with Group 1 room air emissions for which data are available based on percent emission reduction. There are only three performance tests that are currently available, only one of which contains three test runs. Therefore, the best performing 12 percent of facilities for which data are available consists of one facility with three test runs that is controlling its Group 1 room air emissions with a gas/solid reactor. That facility reported an emission reduction of 98 percent. We then used the LPL approach, as mentioned previously, to develop the MACT floor for existing sources. The LPL 1 value of the existing source MACT floor is 90 percent emission reduction. The outlet EtO concentration (UPL 99 value) that corresponds to this emission reduction is 93 ppbv. Since this is above 3×RDL, there are more stringent (*i.e.,* BTF) options to consider. We considered two BTF options for reducing EtO emissions from this source: the first option we considered was 95 percent emission reduction. The first option reflects the lowest emission reduction that we have observed in performance tests, and The second option reflects the most stringent emission reduction for which compliance can be demonstrated. With respect to the second option, the most stringent emission reduction for which compliance can be demonstrated is that which corresponds to an outlet concentration of 30 ppbv (*i.e.,* 3xRDL). This emission reduction is 97 percent, which is lower than two of the three reported values in the test runs that were used to calculate the MACT floor. The impacts of these options are presented in table 10 (along with the MACT floor impacts). Because we have

not identified any major source facilities with existing Group 1 room air emissions, the impacts are based on a model plant for existing Group 1 room air emissions at a synthetic area source facility with the following assumptions reflecting the average of each of the parameters at synthetic area source facilities:

- Annual EtO use: 140 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to Group 1 RAE: 0.4 percent.
- Group 1 room air emission flow rate: 400 cubic feet per second (cfs).

TABLE 10—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF BTF OPTIONS CONSIDERED UNDER CAA SECTIONS 112(d)(2) AND 112(d)(3) FOR GROUP 1 ROOM AIR EMISSIONS AT MAJOR SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
MACT floor	90 percent emission reduction	$830,000	$176,000	0.168 [336 lb/year]	$1,050,000 [$525/lb].
1	95 percent emission reduction	553,000	129,000	2.80E–2 [56.0 lb/year]	$4,610,000 [$2,300/lb].
2	97 percent emission reduction	461,000	113,000	1.12E–2 [22.4 lb/year]	$10,100,000 [$5,040/lb].

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered BTF under CAA sections 112(d)(2), Option 2 would achieve greater emission reductions than Option 1. Therefore, the final MACT standard under CAA sections 112(d)(2) and (3) for existing Group 1 room air emissions at major source facilities is 97 percent emission reduction.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the Group 1 room air emissions that are being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 90 percent emission reduction. We considered the same BTF options as those evaluated for existing Group 1 room air emissions at major source facilities for the same reasons explained above. The first BTF option would require achieving 95 percent emission reduction, and the second BTF option would require achieving 97 percent emission reduction. The impacts of these options are presented in table 10 of this preamble. Because we have not identified any major source facilities with existing Group 1 room air emissions, the impacts are based on a model plant for new Group 1 room air emissions at a synthetic area source facility. Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered BTF under CAA sections 112(d)(2), Option 2 would achieve greater emission reductions than Option 1. Therefore, the final standard for new Group 2 room air emissions at major source facilities is 97 percent emission reduction. We also considered non-air quality health and environmental impacts and energy requirements when evaluating the BTF options. Further discussion of these considerations is presented in the document *MACT Floor Analysis for Ethylene Oxide Commercial Sterilization—Chamber Exhaust Vents and Room Air Emission Sources—Promulgation Rule Review for the Ethylene Oxide Commercial Sterilization Source Category,* available in the docket for this rulemaking.

For existing Group 1 room air emissions at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on Group 1 room air emissions, and the second option is the same BMP discussed above (lowering the in-chamber EtO concentration to 1 ppm before the chamber is opened). With respect to the first option, 32 out of 74 area source facilities with Group 1 room air emissions are already using controls to reduce those emissions.[31] We considered a standard of 80 percent emission reduction, which is the manufacturer guarantee for room air emissions controls provided by one of the commenters. We find this standard to be reasonable for existing Group 1 room air emissions at area source facilities because it is the manufacturer guarantee, which means that it is a level of emission reduction that all sources can achieve. While some sources have demonstrated emission reductions higher than 80 percent, those reductions are limited to facilities with higher EtO usage rates, and we cannot determine whether smaller users of EtO can meet those emission reductions. The second potential GACT option we considered was the same management practice discussed in section IV.B.3.a, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if more EtO is driven out of the product prior to opening the chamber, this can lead to a reduction in post-sterilization EtO emissions, including those from pre-aeration handling of sterilized material. The impacts of these options are presented in table 11.

[31] The Group 1 room air emission reduction at these facilities ranges from 52 percent to 99.8 percent. It should be noted that the facility with the emission reduction at the upper bound of this range uses 135 tpy of EtO.

TABLE 11—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING GROUP 1 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$91,000,000	$12,900,000	3.66 [7,320 lb/year] ..	$3,530,000 [$1,770/lb].
2	BMP (estimated 20 percent emission reduction).	$0	$5,040,000 (one-time annual cost) [1].	1.13 [2,260 lb/year] ..	$4,460,000 [$2,230/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost effective for highly toxic HAPs. We are finalizing Option 1 because while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing Option 1 for existing Group 1 room air emissions at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from existing Group 1 room air emissions by 80 percent.

For new Group 1 room air emissions at area source facilities, we considered the same two potential GACT options as those evaluated for existing Group 1 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option (Option 1) would require achieving an emission reduction of 80 percent. The second potential GACT option we considered (Option 2) is a BMP that would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these options, which are presented in table 12 of this preamble, are based on a model plant for new Group 1 room air emissions at an area source facility with the assumptions reflecting the average of each of the parameters at area source facilities with new Group 1 room air emissions as described in section III.B.8.c of the proposal preamble.

TABLE 12—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW GROUP 1 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$922,000	$192,000	0.288 [576 lb/year] ...	$666,000 [$333/lb].
2	BMP ..... (estimated 20 percent emission reduction)	0	$80,000 (one-time annual cost) [1].	7.20E–2 [144 lb/year]	$1,110,000 [$556/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing standards for new Group 1 room air emissions at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from new Group 1 room air emissions by 80 percent.

We re-calculated the MACT floor for existing Group 2 room air emissions at major source facilities. We ranked the performance of the facilities with Group 2 room air emissions for which data are available based on percent emission reduction. There are only three performance tests that are currently available, only one of which contains three test runs. Therefore, the best performing 12 percent of facilities for which data are available consists of one facility with three test runs that is controlling its Group 2 room air emissions with a gas/solid reactor. That facility reported an emission reduction of 96 percent. As mentioned previously, we then used the LPL approach to develop the MACT floor for existing sources. The LPL 1 value of the existing source MACT floor is 94 percent emission reduction. The outlet EtO concentration (LPL 1 value) that corresponds to this emission reduction is 10 ppbv. Since this is below 3×RDL, we adjusted the MACT floor by determining the emission reduction using 30 ppbv and the LPL 1 value of the inlet EtO concentration of the Group 2 room air emissions stream at the facility, which is 0.12 ppmv. This results in an adjusted MACT floor of 86 percent emission reduction. Since this represents 3×RDL, there are no more stringent (*i.e.,* BTF) options to consider, as there would be difficulty demonstrating compliance at any such lower limit. Therefore, the final MACT standard under CAA sections 112(d)(2) and (3) for existing Group 2 room air emissions at major source facilities is 86 percent emission reduction.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the Group 2 room air emissions that are being controlled by a gas/solid reactor and the data of which is used to determine the MACT

floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 86 percent emission reduction. As explained above, because this emission limit represents the lowest level at which compliance can be demonstrated, the EPA did not consider more stringent (*i.e.,* BTF) options. Therefore, the proposed standard for new Group 2 room air emissions at major source facilities is 86 percent emission reduction.

For existing Group 2 room air emissions at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on Group 2 room air emissions, and the second option is the same BMP discussed above (lowering the in-chamber EtO concentration to 1 ppm before the chamber is opened). With respect to the first option, 30 out of 80 area source facilities with Group 2 room air emissions are already using controls to reduce those emissions.[32] We considered a standard of 80 percent emission reduction, which is the manufacturer guarantee for room air emissions controls provided by one of the commenters. We find this standard to be reasonable for existing Group 2 room air emissions at area source facilities because it is the manufacturer guarantee, which means that it is a level of emission reduction that all sources can achieve. While some sources have demonstrated emission reductions higher than 80 percent, those reductions are limited to facilities with higher EtO usage rates, and we cannot determine whether smaller users of EtO can meet those emission reductions. The second potential GACT option we considered was the same management practice discussed in section IV.B.3.a, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if more EtO is driven out of the product prior to opening the chamber, this can lead to a reduction in post-sterilization EtO emissions, including those from post-aeration handling of sterilized material. The impacts of these options are presented in table 13.

TABLE 13—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING GROUP 2 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$236,000,000	$32,700,000	1.10 [2,200 lb/year]	$29,700,000 [$14,900/lb].
2	BMP (estimated 20 percent emission reduction).	0	$5,440,000 (one-time annual cost) [1].	0.311 [622 lb/year]	$17,500,000 [$8,750/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. Further, as discussed in section III.B.8.g of the proposal preamble (88 FR 28790, April 13, 2023), there are multiple factors we consider in assessing the cost of the emission reductions. See *NRDC* v. *EPA,* 749 F.3d 1055, 1060 (D.C. Cir. April 18, 2014) (''Section 112 does not command the EPA to use a particular form of cost analysis.''). These factors include, but are not limited to, total capital costs, total annual costs, cost-effectiveness, and annual costs compared to total revenue (*i.e.,* costs to sales ratios). Our established methodology for assessing economic impacts of regulations indicates that the potential for adverse economic impacts begins when the cost to sales ratio exceeds three percent. According to our estimates, the annual cost of the emission control option for most of the affected sources discussed above is well below three percent.[33] However, reducing existing Group 2 room air emissions at area source facilities using emission control devices (Option 1), would significantly impact several companies operating a total of nine area source facilities with Group 2 room air emissions. We estimate that the annual cost of controls at the level under Option 1 would exceed three percent of revenue for these companies.[34] Based on the available economic information, assuming market conditions remain approximately the same, we are concerned that these companies would not be able to sustain the costs associated with Option 1. In addition, according to FDA, six of these facilities could impact the availability of the medical devices described in section I.A.1 of this preamble. Therefore, pursuant to CAA section 112(d)(5), we are finalizing Option 2 as the GACT standard for existing Group 2 room air emissions at area source facilities. Specifically, this GACT standard requires facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened.[35]

For new Group 2 room air emissions at area sources facilities, we considered the same two potential GACT options as those evaluated for existing Group 1 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option (Option 1) would require achieving an emission reduction of 80 percent. The second potential GACT option we considered (Option 2) is a BMP that would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these options, which are presented in table 14 of this preamble, are based on a model plant for new Group 2 room air emissions at an area source facility with the assumptions reflecting the average of each of the parameters at area source facilities with

[32] The Group 2 room air emission reduction at these facilities ranges from 30 percent to 99.97 percent. It should be noted that the facility with the emission reduction at the upper bound of this range uses 135 tpy of EtO.

[33] See memorandum, *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

[34] The issue of high cost-to-sales ratios is present only for this option and, thus, is not discussed for other options.

[35] As discussed in section IV.C.2.a.iii of this preamble, this GACT standard will ultimately apply only to facilities where EtO use is less than 4 tpy. Facilities where EtO use is at least 4 tpy will be required to meet an emission standard established under CAA section 112(f)(2).

new Group 1 room air emissions as described in section III.B.8.h of the proposal preamble.

TABLE 14—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW GROUP 2 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$1,840,000	$332,000	3.6E–2 [72 lb/year]	$9,170,000 [$4,560/lb].
2	BMP (estimated 20 percent emission reduction).	0	$40,000 (one-time annual cost)[1].	9.1E–3 [18 lb/year]	$4,375,000 [$2,190/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. As discussed earlier in this section, this includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). Although both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve four times the emission reductions of Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing standards for new Group 2 room air emissions at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from new Group 2 room air emissions by 80 percent.

c. PTE

Comment: We received extensive comment on our proposal to require that each facility must operate areas with room air emissions subject to an emission standard under the PTE requirements of EPA Method 204. Some commenters were supportive of this requirement, stating that other regulatory bodies have already required this and that this is the correct protocol for ensuring that emissions are captured and routed to a control system. Other commenters were opposed to this requirement, stating that EPA Method 204 was established for smaller point source operations (*e.g.,* paint booths, spray coating), as opposed to larger sterilization facilities. Several commenters cited other technical concerns, including the fact that not every facility is currently configured to meet the PTE requirements of EPA Method 204. The commenters suggested broad alternatives, including a simple requirement to operate areas with room air emissions subject to an emission standard under negative pressure.

Response: We strongly disagree with the commenters that EPA Method 204 is not appropriate to apply to this source category. The design requirements of EPA Method 204 are agnostic to the industry it is applied. It has been applied widely to any industrial processes that needs to control VOC emissions, including several existing commercial sterilizers that have already been complying with EPA Method 204. In order to meet the emission standards, it is necessary to ensure that all emissions are captured and routed to a control system. Our established protocol in numerous new source performance standards, NESHAPs, and federally enforceable State and local programs (*e.g.,* title V permits, State implementation plans) for ensuring complete capture of room air emissions is EPA Method 204. We recognize that many commercial sterilizers will need to retrofit their facilities to meet the PTE requirements of EPA Method 204, similar to facilities that have already done so. We have accounted for the cost to retrofit facilities by scaling the cost from a large facility that conducted a retrofit. Furthermore, based on our knowledge regarding the application of EPA Method 204 in general, retrofitting to meet this method can be complicated, depending on the size of the facility. However, commercial sterilization facilities tend to be simple buildings (in some cases, re-purposed warehouses) with a relatively small footprint, which helps the retrofitting process. The emission standards for room air emissions that we evaluated assume 100 percent capture of EtO emissions,[36] and the costs of complying with the PTE requirements of EPA Method 204 were included in our BTF and GACT evaluations. We found each emission standard that we evaluated to be cost-effective (see section IV.B.3.b of this preamble for more information). In addition, the term ''negative pressure'' is vague and can imply any capture efficiency between zero and 100 percent. The commenters did not provide specific suggestions for alternative capture efficiencies, nor did they provide the criteria that would be used to demonstrate that those efficiencies are being met, and we are unable to evaluate alternative negative pressure requirements as a result. Therefore, EPA Method 204 is appropriate to apply to this source category in order to ensure complete capture of room air emissions.

Comment: Several commenters requested various flexibilities and clarifications with respect to the PTE requirements of EPA Method 204. Several commenters expressed concern with Criterion 5.1 of EPA Method 204, stating that it would not be possible to always ensure that doors are ''at least four equivalent opening diameters'' from all EtO storage media or post-aeration sterilized product, particularly during loading and unloading operations. Two commenters recommended that we revise the standards to permit implementation of cascading air systems to capture room air emissions.[37] One commenter stated that these systems would provide greater flexibility to accommodate sterilization operations that could not implement a PTE, would offer EtO capture and control efficiency that was as effective as a PTE, and would have fewer manufacturing implications and potential adverse impacts. Finally, two

[36] Section 2 of EPA Method 204 states, in part, ''If the criteria are met and if all the exhaust gases from the enclosure are ducted to a control device, then the volatile organic compounds (VOC) capture efficiency (CE) is assumed to be 100 percent, and CE need not be measured.''

[37] These are systems that move air from ambient pressure, through warehouse ventilation, secondary aeration, primary aeration, the sterilizer chamber, and ultimately to an air pollution control device to capture and control EtO emissions. This is opposed to other systems where air from one source is captured and then directly sent to a control system.

commenters expressed concern with Criteria 5.2, 5.3, and 5.5 of EPA Method 204.

Response: Criterion 5.1 of EPA Method 204 states that ''Any natural draft opening (NDO) shall be at least four equivalent opening diameters from each VOC emitting point unless otherwise specified by the Administrator.'' [38] We disagree with the commenters' concerns that Criterion 5.1 of EPA Method 204 will not be possible to meet for doors where either EtO storage media is moved into a PTE or post-aeration sterilized material is moved out of a PTE. There may be certain facility designs where such an exemption is either necessary or unnecessary in order to ensure complete capture of room air emissions. However, the EPA does not have enough information to make that determination for all facilities within the source category as part of this rulemaking. Criterion 5.1 of EPA Method 204 allows delegated authorities to exempt any NDO from this requirement, as needed. Therefore, we are not exempting Criterion 5.1 of EPA Method 204 for doors where either EtO storage media is moved into a PTE or post-aeration sterilized material is moved out of a PTE as part of this final rule. Instead, we are relying on the delegated authorities to make that determination for their commercial sterilization facilities, as provided in Criterion 5.1., as they are in a better place to determine whether there are sufficient measures in place to capture any emission points within four equivalent opening diameters of an NDO. With respect to cascading air systems, we disagree with the commenters' suggestion that they be permitted in place of the PTE requirements of EPA Method 204, as they are insufficient on their own to ensure complete capture of room air emissions. However, it is not our intent to discourage or prohibit the use of these systems altogether. Cascading air systems may be used to capture and route room air emissions to a control device. However, in order to ensure complete capture of room air emissions, if such a system contains one or more areas that are subject to the PTE requirements of EPA Method 204, then the entire system must be treated as a single enclosure that is subject to those requirements.

For all other flexibilities suggested by the commenters, we provide the following responses:

- Criterion 5.2 of EPA Method 204 states that ''Any exhaust point from the enclosure shall be at least four equivalent duct or hood diameters from each NDO.'' One commenter stated that Criterion 5.2 may not be possible for all facilities due to preexisting layouts. This criterion only applies to temporary total enclosures, as opposed to PTEs, and is not required in the final rule.
- Criterion 5.3 of EPA Method 204 states that ''The total area of all NDO's shall not exceed 5 percent of the surface area of the enclosure's four walls, floor, and ceiling.'' One commenter stated that the presence of garage doors could exceed the requirement that NDOs not exceed five percent of the PTE total floor space. However, we note that facilities can be, and have been, re-designed in order to meet the PTE requirements of EPA Method 204, including Criterion 5.3. Therefore, we are not finalizing any exceptions for this criterion.
- Criterion 5.5 of EPA Method 204 states that ''All access doors and windows whose areas are not included in section 5.3 and are not included in the calculation in section 5.4 shall be closed during routine operation of the process''. Two commenters expressed concern with Criterion 5.4 of EPA Method 204. However, the commenters did not provide any explanation as to why exceptions for Criterion 5.5 of EPA Method 204 should be made. Therefore, we are not finalizing any exceptions for this criterion.

d. Warehouses

Comment: We received extensive comments on the regulation of warehouses, particularly stand-alone (*i.e.,* off-site) warehouses. Most commenters were supportive of regulating emissions from all warehouses, stating that sterilized materials can continue to off-gas significant quantities of EtO after being moved to a warehouse. Several commenters pointed to a stand-alone warehouse in Georgia, where the State estimated that potential pre-control EtO emissions were approximately 5,000 lb/year. One commenter was opposed to including standards for stand-alone warehouses as part of this final rule, stating that we could, instead, identify potentially applicable facilities, collect data from these facilities, and then determine if further regulation is necessary.

Response: It is our understanding that there are three types of warehouses within this industry: attached warehouses, co-located warehouses, and stand-alone warehouses. Attached warehouses are those that are part of an EtO sterilization building. Co-located warehouses are those that are detached from but ''contiguous'' (including adjacent) to and ''under common control'' with the EtO sterilization building, including leased properties.[39] Stand-alone warehouses are those that are not attached to or co-located with an EtO sterilization building. According to our record at the time of category listing, ''the Commercial Sterilization Facilities source category includes ''*facilities which use ethylene oxide* in any equipment which destroys bacteria, viruses, fungi, insects, or other unwanted microorganisms or materials when such facilities are engaged in the growth, manufacture, construction, transportation, retail or wholesale trade, or storage of commercial products, or when such facilities are engaged in the operation of museums, art galleries, arboreta, or botanical or zoological gardens or exhibits. Not included in this category are hospitals, doctor offices, veterinary offices, clinics, and other facilities where medical services are rendered'' (emphasis added).[40] Under this definition, warehouses that are part of facilities which use EtO, including attached and co-located warehouses, are part of the source category and, therefore, subject to the standards for Group 2 room air emissions. However, because stand-alone warehouses do not use EtO, they are not included in the source category definition. Furthermore, we do not have sufficient information to understand where these warehouses are located, who owns them, how they are operated, or what level of emissions potential they may have. While several commenters note that emissions information is available for at least one stand-alone warehouse, it is unknown whether the emissions information for this facility is representative of all stand-alone warehouses. Thus, standards for these facilities are not included as part of this final rule. However, as suggested by one commenter, we are planning to gather information from stand-alone warehouses as soon as possible to

[38] Per 40 CFR 51.100(s), EtO is a VOC.

[39] This final rule establishes standards under CAA section 112 for both major and area sources of commercial sterilization facilities. As the EPA explained in its final rule promulgating the General Provisions for NESHAP pursuant to section 112, ''[f]or the purposes of implementing section 112, the major/area source determination is made on a plant-wide basis; that is, HAP emissions from all sources located within a contiguous area and under common control are considered in the determination.'' 59 FR 12408, 12411 (March 16, 1994). The EPA noted that ''the common dictionary term ''contiguous'' consists, in part, of ''nearby, neighboring, adjacent,'' and that ''the EPA has historically interpreted 'contiguous property' to mean the same as 'contiguous or adjacent property' in the development of numerous regulations to implement the Act.'' *Id.* at 12412.

[40] *Documentation for Developing the Initial Source Category List, Final Report,* page A–83 (see EPA–450/3–91–030, July 1992).

understand what the source category looks like and its emission potential and, if necessary, develop a regulatory action that both lists a new source category and proposes standards for stand-alone warehouses handling EtO sterilized medical devices. This information gathering effort may include engaging with State and local agencies and non-governmental organizations, as well as conducting an ICR(s) pursuant to CAA section 114.

The remaining comments and our specific responses can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

4. What is the rationale for our final approach and final decisions for the revisions pursuant to CAA section 112(d)(2), 112(d)(3), and 112(d)(5)?

We evaluated the comments on our proposed standards for SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy, ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs at facilities where EtO use is at least 10 tpy, and room air emissions, as well as our proposed technical correction to the emission standard for ARVs at facilities where EtO use is at least 10 tpy. As explained above in section IV.B.3 and in Chapter 4 of the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* we made changes in the final rule based on comments received during the proposed rulemaking. More information and rationale concerning all the amendments we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) is in the preamble to the proposed rule (88 FR 22790, April 13, 2023), in section IV.B.3 of this preamble, and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* which is available in the docket for this rulemaking. Therefore, we are finalizing the proposed standards for SCVs and ARVs at facilities where EtO use is less than 1 tpy, finalizing the proposed standards for ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, finalizing standards for CEVs, finalizing the proposed emission standards for room air emissions at major sources facilities, finalizing emission standards for room air emissions at area source facilities, and finalizing the proposed revisions for ARVs at facilities where EtO use is at least 10 tpy.

C. Residual Risk Review for the Commercial Sterilization Facilities Source Category

1. What did we propose pursuant to CAA section 112(f) for the Commercial Sterilization Facilities source category?

Pursuant to CAA section 112(f), we conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the April 13, 2023, proposed rule for 40 CFR part 63, subpart O (88 FR 22790). The results of the risk assessment for the proposal are presented briefly in table 15 of this preamble. As discussed in section III.A of the proposed rule, all baseline risk results were developed using the best estimates of actual emissions, and we did not conduct a separate assessment of allowables at proposal. More detail is in the residual risk technical support document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2023 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2019–0178–0482).

TABLE 15—COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY BASELINE RISK ASSESSMENT RESULTS IN THE PROPOSAL

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer		Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI	Maximum screening acute noncancer hazard quotient (HQ)
		>100-in-1 million	≥1-in-1 million			
97 [3]	6,000	18,000	8,300,000	0.9	0.04	0.002 (REL).

[1] Number of facilities evaluated in the risk analysis.

[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.

[3] As part of the risk assessment for the proposed rulemaking, there were 86 facilities in the Commercial Sterilization Facilities source category in operation and 11 research and development facilities, for a total of 97 facilities. To exercise caution with respect to this source category, we included research facilities in our assessment because there was a lack of certainty over whether these were true research facilities, for which CAA section 112(c)(7) requires that a separate category be established. However, EtO use at these facilities tends to be very low (less than 1 tpy), and these facilities had low risk.

The results of the proposed chronic baseline inhalation cancer risk assessment at proposal indicated that, based on estimates of current actual emissions, the MIR posed by the source category was 6,000-in-1 million. At proposal, the total estimated cancer incidence from this source category was estimated to be 0.9 excess cancer cases per year, or one case in every 1.1 years. Approximately 8.3 million people were estimated to have cancer risks at or above 1-in-1 million from HAP emitted from the facilities in this source category. At proposal, the estimated maximum chronic noncancer target organ-specific hazard index (TOSHI) for the source category was 0.04, indicating low likelihood of adverse noncancer effects from long-term inhalation exposures.

As shown in table 15 of this preamble, the acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.002 for propylene oxide based on the reference exposure level (REL) acute health reference value.[41] For EtO, the maximum HQ is 0.0005 based on the acute exposure guideline level (AEGL)–2 acute health reference value.[42]

At proposal, the maximum lifetime individual cancer risk posed by the 97 modeled facilities, based on whole facility emissions, was 6,000-in-1 million, with EtO emissions from SCVs and Group 2 room air emissions from the Commercial Sterilization Facilities source category driving the risk. Regarding the noncancer risk

[41] Not to be confused with the ''recommended exposure limit'', which is used by the National Institute for Occupational Safety and Health.

[42] Acute RELs, ERPG–1, and AEGL–1 acute health reference values are not available for ethylene oxide.

assessment, the maximum chronic noncancer TOSHI posed by whole facility emissions was estimated to be 0.04 (for the neurological system as the target organ), driven by emissions of EtO from source category sources.

We weighed all health risk factors, including those shown in table 15 of this preamble, in our risk acceptability determination and proposed that the risks posed by this source category under the current provisions are unacceptable. At proposal, we identified several options to control EtO emissions from SCVs and Group 2 room air emissions.

To reduce risks, we considered two additional control options after implementation of controls under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). Control Option 1 would have required a 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 40 tpy, as well as a 2.8 E–3 lb/h standard for existing Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy. We determined that this would have resulted in a source category MIR of 400-in-1 million. Control Option 2 would have imposed the same requirements as Control Option 1, but it would also have required facilities where the MIR is greater than 100-in-1 million after Control Option 1 is imposed to limit their existing Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv. This would have resulted in a source category MIR of 100-in-1 million. We proposed Control Option 2 and solicited comment on Control Option 1.

We proposed that, after implementation of the proposed controls for SCVs and Group 2 room air emissions at commercial sterilization facilities, the resulting risks would be acceptable for this source category. In our proposal, we presented the risk impacts using health risk measures and information, including the MIR, cancer incidence, and associated uncertainty in emissions estimates after application of the proposed options to control EtO emissions from Group 2 room air emissions (88 FR 22790, April 13, 2023). At proposal, we determined application of the controls for SCVs and Group 2 room air emissions would reduce the estimated MIR from 6,000-in-1 million to 100-in-1 million.

We then considered whether the standards provide an ample margin of safety to protect public health and whether, taking into consideration costs, energy, safety, and other relevant factors, additional standards are required to prevent an adverse environmental effect. To determine whether the rule provides an ample margin of safety, we considered the requirements that we proposed to achieve acceptable risks. In addition, we considered more stringent controls for SCVs, as well as expanding the emission standard and work practice standards for existing Group 2 room air emissions to all facilities in the source category. In considering whether the standards should be tightened to provide an ample margin of safety to protect public health, we considered the same risk factors that we considered for our acceptability determination and also examined the costs, technological feasibility, and other relevant factors related to emissions control options that might reduce risk associated with emissions from the source category. Based on these considerations, we proposed that the standards that we proposed to achieve acceptable risks, along with a 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy and a 99.8 percent emission reduction standard for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, would provide an ample margin of safety to protect public health (section III.D.2 of the proposal preamble, 88 FR 22790, April 13, 2023). We also solicited comment on which of the available control options should be applied in order to provide an ample margin of safety to protect public health.

2. How did the risk review change for the Commercial Sterilization Facilities source category?

a. Commercial Sterilization Facilities Source Category Risk Assessment and Determination of Risk Acceptability (Step 1)

As part of the final risk assessment, the EPA reanalyzed risks to include allowable emissions (which we did not include at the proposal stage), changes since proposal to certain emission standards being finalized for previously unregulated sources, and three additional facilities identified by commenters. Allowable emissions are the maximum amount that facilities are allowed to emit under CAA section 112(d) standards. For previously unregulated sources, since there were no CAA section 112(d) standards in place, the allowable emissions in the baseline risk assessment are equal to the uncontrolled emissions from these sources. In some instances, the actual emissions for these sources are lower than the allowable emissions. This is because some facilities are already controlling these sources as a result of local requirements or through voluntary control measures.[43] The revised emissions used to reanalyze risks are available in the docket for this rulemaking (see section IV.C.3 of this preamble and Appendix 1 of the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule*).

Based on the actual emission estimates, the results of the chronic inhalation cancer risk from the risk assessment indicate that the maximum lifetime individual cancer risk posed by the 88 facilities could be as high as 6,000-in-1 million, with EtO as the major contributor to the risk. The total estimated cancer incidence from the revised risk assessment is 0.9 excess cancer cases per year, or one excess case in every 1.1 years. Of the approximately 115 million people that live within 50 kilometers (km) of the 88 facilities included in the risk assessment, 8.5 million people were estimated to have cancer risks greater than or equal to 1-in-1 million from HAP emitted from the facilities in this source category, and approximately 19,000 are estimated to have cancer risks greater than 100-in-1 million (table 16 of this preamble).

The estimated maximum chronic noncancer TOSHI for the source category remained unchanged from the proposal at 0.04, indicating low likelihood of adverse noncancer effects from long-term inhalation exposures. Additionally, the worst-case acute HQ remained unchanged from proposal (0.002 for propylene oxide based on the REL acute health reference value).

The maximum lifetime individual cancer risk based on whole facility emissions was 6,000-in-1 million driven by EtO emissions from the Commercial Sterilization Facilities source category. The maximum chronic noncancer TOSHI posed by whole facility emissions was estimated to be 0.04 (for the neurological system as the target organ), driven by emissions of EtO from source category sources.

[43] As discussed later in this section, for previously unregulated sources, the allowable emissions in the risk assessment that considers controls we are promulgating under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) are equal to the controlled emissions from these sources assuming that they are only controlled to the degree that we are requiring pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). In some instances, the actual emissions for these sources may still be lower than the allowable emissions. This is because some facilities are already controlling these sources to a degree greater than what we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as a result of local requirements or through voluntary control measures.

Based on allowable emission estimates, the maximum lifetime individual cancer risk could be as high as 8,000-in-1 million, with EtO driving the risk. The total estimated cancer incidence is 8 excess cancer cases per year, or 1 excess case in every 1.5 months. Approximately 62 million people were estimated to have cancer risks greater than or equal to 1-in-1 million from allowable emissions, and approximately 260,000 are estimated to have cancer risks greater than 100-in-1 million (table 16 of this preamble).

TABLE 16—COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY BASELINE RISK ASSESSMENT RESULTS BASED ON REVISED EMISSIONS IN FINAL RULE

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer		Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI	Maximum screening acute noncancer HQ
		>100-in-1 million	≥1-in-1 million			
Actual Emissions						
88 [3]	6,000	19,000	8,500,000	0.9	0.04	0.002 (REL).
Allowable Emissions						
88 [3]	8,000	260,000	62,000,000	8	0.05	

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Two of the 90 facilities identified in the source category are planned or under construction and therefore were not included in the risk assessment.

Risks were then estimated after application of the controls finalized in this rulemaking pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). A summary of those controls is presented in table 17.

TABLE 17—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), AND 112(d)(5)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new.	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy	99 percent emission reduction	Current standard.
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing and new.	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEV at major sources	Existing and new.	N/A	99.94 percent emission reduction [1]	112(d)(2) and 112(d)(3).
CEV at area sources	Existing and new.	N/A	99 percent emission reduction [1]	112(d)(5).
Group 1 room air emissions at major sources.	Existing and new.	N/A	97 percent emission reduction [1 2]	112(d)(2) and 112(d)(3).
Group 1 room air emissions at area sources.	Existing and new.	N/A	80 percent emission reduction [1 2]	112(d)(5).
Group 2 room air emissions at major sources.	Existing and new.	N/A	86 percent emission reduction [1 2]	112(d)(2) and 112(d)(3).
Group 2 room air emissions at area sources.	Existing	N/A	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened.[1]	112(d)(5).
	New	N/A	80 percent emission reduction [1 2]	112(d)(5).

[1] This standard is different from what was proposed.
[2] To assure compliance with the emission limit, we are requiring each facility to operate areas with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.

Based on the risk assessment considering controls finalized under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), the maximum lifetime individual cancer risk could be as high as 6,000-in-1 million, with EtO driving the risk. For previously unregulated sources, the allowable emissions in this risk assessment are equal to the controlled emissions from these sources assuming that they are only controlled to the degree that we are requiring pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). In some instances, the actual emissions for these sources may still be lower than the allowable emissions. This is because some facilities are already controlling these sources to a degree greater than what we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as a result of local requirements or through voluntary control measures. The total estimated

cancer incidence could be as high as 4 excess cancer cases per year, or 1 excess case in every 3 months. As many as 38 million people are estimated to have cancer risks greater than or equal to 1-in-1 million, and approximately 85,000 people are estimated to have cancer risks greater than 100-in-1 million (table 18 of this preamble).

However, as noted above, some facilities are currently performing better than the controls finalized under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), and in that case we estimate the maximum lifetime individual cancer risk as 5,000-in-1 million, with EtO driving the risk. The total estimated cancer incidence is estimated to be 0.4 excess cancer cases per year, or 1 excess case in every 2.5 years. Approximately 4.2 million people were estimated to have cancer risks greater than or equal to 1-in-1 million, and approximately 3,900 are estimated to have cancer risks greater than 100-in-1 million (table 18 of this preamble), based only on the application of the CAA section 112(d)(2), 112(d)(3), and 112(d)(5) actions being finalized.

TABLE 18—COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY RISK ASSESSMENT RESULTS BASED ON EMISSIONS AFTER CONTROLS PROMULGATED UNDER CAA SECTIONS 112(d)(2)–(3) AND 112(d)(5)

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer [2]		Estimated annual cancer incidence (cases per year) [2]
		>100-in-1 million	≥1-in-1 million	
88 [3]	[4] 5,000–6,000	[4] 3,900–260,000	[4] 4,200,000–62,000,000	[4] 0.4–4

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Two of the 90 facilities identified in the source category are planned or under construction and therefore were not included in the risk assessment.
[4] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

Based on the revised risk assessment results considering controls finalized under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), we continue to find that the risks are unacceptable, as we did during the proposal due to emissions of EtO from SCVs, ARVs, Group 1 room air emission, Group 2 room air emissions, and CEVs. Pursuant to CAA section 112(f)(2), the EPA must first determine the emission standards necessary to reduce risks to an acceptable level, and then determine whether further HAP emissions reductions are necessary to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. Immediately below is a discussion of the standards the EPA has evaluated for bringing risks to an acceptable level (step 1).

i. SCV Emissions

There are 26 facilities within the source category where the ''revised allowable emissions'' from SCVs (*i.e.,* allowable emissions after implementing existing and newly promulgated 112(d) standards in this final rule) contribute to the facilities' MIRs exceeding 100-in-1 million, and EtO usage at these facilities ranges from four tpy to 446 tpy. The previous subpart O required 99 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy. An emission reduction of 99 percent is also the final standard under CAA section 112(d)(5) for the previously unregulated SCVs, which were those at facilities where EtO use is less than 1 tpy (see section IV.B.2).

Our data do not identify any add-on controls beyond those we have already considered when promulgating or reviewing the SCV standards in the previous subpart O or finalizing the standards for the previously unregulated SCVs in section IV.B. However, our evaluation of the performance test data and manufacturer guarantees shows that these controls can achieve greater than 99 percent reduction. We therefore considered more stringent SCV standards for facilities where EtO use is at least 1 tpy, which would include all 26 facilities where the revised allowable emissions from SCVs contribute to the facilities' MIRs exceeding 100-in-1 million.

We evaluated 99.8 percent reduction of SCV emissions from facilities using at least 1 tpy but less than 10 tpy of EtO.[44] As discussed in section III.D.2 of the proposal preamble (88 FR 22790, April 13, 2023), 99.8 percent is the maximum emission reduction from SCV with which compliance can be demonstrated at all facilities with EtO usage within this range.[45] A 99.8 percent reduction would eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-1 million for facilities using at least 1 tpy but less than 10 tpy of EtO.[46] We have determined that a 99.8 percent emission reduction standard is feasible because of one commenter's statement that, based on their discussions with control device manufacturers, the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

For facilities using at least 10 tpy, further reduction would be needed to eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-a-million. We evaluated 99.9 percent reduction, which as mentioned above reflects the manufacturer guaranteed control level. A 99.9 percent reduction would eliminate SCV emissions as a contributor to facilities' MIRs exceeding 100-in-1 million for facilities using at least 10 tpy but less than 30 tpy of EtO. As discussed in section III.D.2 of the proposal preamble (88 FR 22790, April 13, 2023), we evaluated a 99.94 percent emission reduction standard for these facilities as part of Control Option A under the second step of the residual risk review. However, as discussed in section IV.C.3 of this preamble, several commenters stated that we do not have representative performance tests for SCVs. While this is not true for the whole source category, it is true for facilities where EtO use is at least 10 tpy but less than 30 tpy. Therefore, as part of this final rule, we did not evaluate an

[44] The MIRs of facilities with EtO usage less than 1 tpy are all below 100-in-a-million.

[45] *i.e.,* Based on facility characteristics, there is no compliance demonstration issue because the required EtO concentration to meet this limit would be at or above 30 ppbv (which is 3 × RDL).

[46] A facility with usage amount in this range may still have a MIR exceeding 100-in-a-million due to other emissions.

emission reduction standard more stringent than the manufacturer guarantee for SCVs at these facilities.

For facilities using at least 30 tpy, further reduction would be needed to eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-1 million. We evaluated 99.99 percent reduction based on a performance test showing this level of reduction from a facility within this group. A 99.99 percent reduction would eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-a-million for facilities using at least 30 tpy of EtO. We received comment on the technical feasibility of emission standards that exceed the manufacturer guarantee for SCVs (*i.e.,* 99.9 percent emission reduction), but we do not have any information suggesting that any facility within this group cannot achieve 99.99 percent emission reduction. See section IV.C.3 of this preamble for more information.

ii. ARV Emissions

There are three facilities where revised allowable ARV emissions contribute to the facility's MIR exceeding 100-in-1 million, and EtO use at these facilities currently ranges from 44 tpy to 446 tpy of EtO. The previous subpart O required a 1 ppm maximum outlet concentration or 99 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy. As discussed in section IV.B, we are removing the 1 ppm maximum outlet concentration alternative standard, and we are finalizing 99 percent emission reduction standards under CAA section 112(d)(5) for previously unregulated ARVs, which were those at facilities where EtO use is less than 10 tpy. As a result, the final 112(d) standard for ARV emissions at all facilities is 99 percent reduction.

Our data do not identify any add-on controls beyond those we have already considered when promulgating, or proposing revisions to the previous ARV standards in subpart O or finalizing the standards for the previously unregulated ARVs in section IV.B. However, as discussed in section III.F.3 of the proposal preamble (88 FR 22790, April 13, 2023), our evaluation of the performance test data shows that these controls can achieve greater than 99 percent emission reduction.[47] We evaluated 99.9 percent reduction of ARV emissions from facilities using at least 30 tpy of EtO,[48] which is feasible because it is currently achieved by one-third of these facilities. Of these 12 facilities that are currently achieving this emission reduction, nine use catalytic oxidizers, two use a catalytic oxidizer and gas/solid reactor in series, one uses a thermal oxidizer, and one uses a gas/solid reactor. Note that this does not sum to 12 because one facility uses two different types of control systems to reduce its ARV emissions.[49] A 99.9 percent emission reduction would eliminate ARV emissions as a contributor to a facility's MIR to exceed 100-in-1 million for facilities using at least 30 tpy of EtO.[50]

iii. Group 2 Room Air Emissions

There are 13 facilities, all area sources, where revised allowable Group 2 room air emissions contribute to the facilities' MIRs exceeding 100-in-1 million and the EtO usage at these facilities ranges from 4 tpy to 446 tpy.[51] Because Group 2 room air emissions contribute to unacceptable risks from existing area sources in this source category, we evaluated available control options for reducing risks from Group 2 room air emissions.

As discussed in section IV.B of this preamble, we are finalizing a GACT standard for previously unregulated Group 2 room air emissions at existing area source facilities. Specifically, we are finalizing under CAA section 112(d)(5) that area source facilities lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened.[52] Because there is still unacceptable risk from facilities where EtO usage is above 4 tpy, this requirement will ultimately apply only to existing Group 2 room air emissions at facilities where EtO use is less than 4 tpy.

In evaluating the appropriate GACT standard for previously unregulated existing Group 2 room air emissions at area source facilities, we considered an emission reduction of 80 percent that reflects the use of control devices (Option 1) but did not finalize that option under CAA section 112(d)(5) for reasons stated in section IV.B.3.b. However, having determined under CAA section 112(f)(2) that the risk for the source category is unacceptable, we are determining the emissions standards necessary to reduce risk to an acceptable level without considering costs. We evaluated 80 percent emission reduction of Group 2 room air emissions from area source facilities using at least 4 tpy but less than 20 tpy of EtO. As discussed in section IV.B.3.b of this preamble, 80 percent is the manufacturer guarantee for room air emissions controls provided by one of the commenters. We do not have any performance test data for Group 2 room air emissions at these facilities, so it is unknown whether these sources can achieve greater than 80 percent emission reduction. An 80 percent reduction would eliminate Group 2 room air emissions as a contributor to a facility's MIRs exceeding 100-in-1 million for area source facilities using at least 4 tpy but less than 20 tpy.

For area source facilities using at least 20 tpy, further reduction would be needed to eliminate Group 2 room air emissions as a contributor to a facility's MIR exceeding 100-in-a-million. Our data do not identify any add-on controls beyond those we have already considered when finalizing the standards for the previously unregulated Group 2 room air emission in section IV.B. However, our evaluation of the performance data shows that these controls can achieve greater than 80 percent emission reduction at area source facilities where EtO use is at least 20 tpy. We therefore considered a more stringent Group 2 room air emission standard for these facilities. We evaluated 98 percent reduction of Group 2 room air emissions from area source facilities using at least 20 tpy, which is the emission reduction that has been achieved in one-third of the

[47] While the types of controls used for ARVs are the same as those used for SCVs, the distribution of these controls is different. For example, the use of catalytic oxidizers and gas/solid reactors is more prominent when controlling ARV emissions, while the use wet scrubbers is more prominent when controlling SCV emissions. See memorandum, *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

[48] As discussed above, one of the facilities where allowable ARV emissions contribute to the facility's MIR exceeding 100-in-1 million uses 44 tpy. Evaluating the emission reduction for facilities where EtO use is at least 30 tpy provides a sufficient buffer in case the EtO use at this facility drops to below 40 tpy.

[49] As part of the proposed rulemaking, a similar analysis was conducted for ARVs at facilities where EtO use is at least 10 tpy. See section III.F.3.a of the proposal preamble for more details on that analysis (88 FR 22790, April 13, 2023).

[50] As part of the proposed rulemaking, we evaluated a 99.9 percent emission reduction standard for ARVs at facilities where EtO use is at least 10 tpy as part of the technology review (see section III.F.3 of the proposal preamble (88 FR 22790, April 13, 2023)). For existing sources, this option was rejected in favor of a more cost-effective option (*i.e.,* 99.6 percent emission reduction). However, we proposed a 99.9 percent emission reduction standard for new sources pursuant to CAA section 112(d)(6).

[51] As discussed earlier, the EPA has the authority to conduct an (f)(2) review of GACT standards and is exercising that authority in this action.

[52] As discussed in section IV.B of this preamble, we are finalizing an 80 percent emission reduction standard for all new Group 2 room air emissions at area source facilities, regardless of EtO use, under CAA section 112(d)(5).

available performance test runs for these facilities.[53] 98 percent reduction would eliminate Group 2 room air emissions as a contributor to a facility's MIR exceeding 100-in-a-million for area source facilities where EtO use is at least 20 tpy.

iv. CEV Emissions

There is one facility within the source category where revised allowable emissions from CEVs contribute to the facility's MIR exceeding 100-in-1 million, and this is an area source facility that currently uses 446 tpy of EtO. The previous subpart O did not regulate CEVs at area source facilities. As discussed in section IV.B of this preamble, we are finalizing a GACT standard for these sources. Specifically, pursuant to CAA section 112(d)(5), we are finalizing a 99 percent emission reduction standard for CEVs at area source facilities.

Our data do not identify any add-on controls beyond those we have already considered when finalizing the standards for CEVs in section IV.B. However, our evaluation of the performance test data shows that these controls can achieve greater than 99 percent reduction. We therefore considered a more stringent CEV emission standard for area source facilities where EtO use is at least 400 tpy. We evaluated 99.9 percent reduction of CEV emissions from facilities where EtO use is at least 400 tpy, which is the emission reduction that is currently achieved by 75 percent of these facilities.[54] A 99.9 percent reduction would eliminate CEV emissions as a contributer to a facility's MIR exceeding 100-in-1-million for facilities where EtO use is at least 400 tpy.

v. Group 1 Room Air Emissions

There are four area source facilities within the source category where revised allowable Group 1 room air emissions contribute to the facilities' MIRs exceeding 100-in-1 million, and the EtO usage at these facilities ranges from 44 to 446 tpy. The previous subpart O did not regulate Group 1 room air emissions at area source facilities. As discussed in section IV.B of this preamble, we are finalizing a GACT standard for these sources. Specifically, pursuant to CAA section 112(d)(5), we are finalizing an 80 percent emission reduction as the GACT standard for Group 1 room air emissions at area source facilities.

Our data do not identify any add-on controls beyond those we have already considered when finalizing the standards for Group 1 room air emissions in section IV.B. However, our evaluation of the performance test data shows that these controls can achieve greater than 80 percent reduction. We therefore considered a more stringent Group 1 room air emission standard for area source facilities where EtO use is at least 40 tpy. We evaluated 98 percent emission reduction of Group 1 room air emissions from area source facilities using at least 40 tpy, which is the emission reduction that has been achieved in all but one of the six available performance test runs for these facilities.[55] A 98 percent reduction would eliminate Group 1 room air emissions as a contributor to a facility's MIRs exceeding 100-in-1-million for area source facilities where EtO use is at least 40 tpy.

Considering all of the emission reductions that we evaluated above, the source category MIR would be reduced to 100-in-1 million. This means that all facilities would have an MIR at or below 100-in-1 million,[56] and the population exposed to risk levels greater 100-in-1 million would be reduced to zero. In addition, the population exposed to risk levels greater than or equal to 1-in-1 million living within 50 km of a facility would be reduced to between 710,000 (when considering some facilities are currently performing better than the standards) and 1.41 million people (when considering all facilities perform at the level of the standards). Finally, the cancer incidence would be reduced from 0.9 to between 0.1 (when considering some facilities are currently performing better than the standards) and 0.2 (when considering all facilities perform at the level of the standards), or from 1 cancer case every 1.1 years to 1 cancer case every 5 to 10 years. For these reasons, we find that the preceding emission reductions that we evaluated reduce risks to an acceptable level. These emission reduction measures are:

- 99.99 percent emission reduction for SCVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.9 percent emission reduction for ARVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent emission reduction for CEVs at facilities where EtO use is at least 400 tpy,
- 98 percent emission reduction for Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy,
- 98 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy, and
- 80 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy.

b. Ample Margin of Safety (Step 2)

At step 1 of our review of residual risks under CAA section 112(f)(2), we have identified a suite of standards and determined that they are necessary to reduce risks to an acceptable level. These include standards for SCVs at facilities with EtO usage of at least 1 tpy, ARVs at facilities with EtO usage of at least 30 tpy, CEVs at area source facilities with EtO usage of at least 400 tpy, Group 1 room air emissions at area source facilities with EtO usage of at least 40 tpy, and Group 2 room air emissions at area source facilities with EtO usage of at least four tpy. For step 2 of our review of residual risks, we evaluate whether more stringent standards are necessary to provide an ample margin of safety to protect public health. While we do not consider costs in the step 1 analysis, costs are a factor we consider in the step 2 analysis. For details on the assumptions and methodologies used in the costs and impacts analyses, see the technical memorandum titled *Ample Margin of Safety Analysis for Ethylene Oxide Commercial Sterilization—Promulgation Rule Review for the Ethylene Oxide Commercial Sterilization Source Category,* which is available in the docket for this rulemaking.

As part of the proposed rulemaking, we considered six options (which are identified in the proposal preamble table 22 (88 FR 22829) and proposed Control Options A and C as part of the ample margin of safety analysis. Control Option A would have required 99.94 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy. We are not finalizing Control Option A for the following reasons. First, this option is less stringent than the standard we have

[53] All of these facilities use gas/solid reactors to control their Group 2 room air emissions.

[54] There are three facilities that are currently achieving this emission reduction. Of these three facilities, two use catalytic oxidizers, and one uses a wet scrubber.

[55] All of these facilities use gas/solid reactors to control their Group 1 room air emissions.

[56] Considering actual emissions, most facilities (*i.e.,* 87 out of 88) would have an MIR less than 100-in-1 million.

already identified in Step 1 (99.99 percent emission reduction) for SCV emissions at facilities where EtO use is at least 30 tpy.[57] Second, for facilities where EtO use is less than 30 tpy, we do not have any performance tests showing that these facilities can perform better than the manufacturer guarantee (*i.e.,* 99.9 percent emission reduction for SCVs). For these reasons, we are not finalizing Control Option A as part of this rulemaking. Control Option C would have required 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. As discussed in section IV.C.2.a of this preamble (step 1 of risk review), Control Option C is one of the standards identified under the revised Step 1 analysis as necessary to reduce risks to an acceptable level.

In addition, we evaluated the following options but rejected them for the reasons discussed below:

○ For ARVs at facilities where EtO use is at least 30 tpy, we do not have data showing that it is technically feasible for all facilities to achieve greater than 99.9 percent emission reduction (which is the standard applicable to these sources that we have determined under step 1 as necessary to reduce risks to an acceptable level).

• For ARVs at facilities where EtO use is less than 10 tpy, we were unable to identify any cost-effective options that achieve emission reduction greater than the current 99 percent emission reduction standard (GACT). More information is presented in the technical memorandum titled *Ample Margin of Safety Analysis for Ethylene Oxide Commercial Sterilization—Promulgation Rule Review for the Ethylene Oxide Commercial Sterilization Source Category,* which is available in the docket for this rulemaking.

• For Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy, we do not have data indicating that it is technically feasible for all facilities to achieve greater than 98 percent emission reduction (which is the standard applicable to these sources that we have determined under step 1 as necessary to reduce risks to an acceptable level).

• For Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy, we do not have any performance tests showing that these facilities can perform better than the manufacturer guarantee (*i.e.,* 80 percent emission reduction for room air emissions, which is the standard for facilities using at least 4 tpy but less than 20 tpy of EtO that we have determined under step 1 as necessary to reduce risks to an acceptable level).

• For Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy, 80 percent emission reduction is not cost effective.[58]

• For Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, we do not have data indicating that it is technically feasible for all facilities to achieve greater than 98 percent emission reduction (which is the standard for these affected sources that we have identified in Step 1 as necessary to reduce risks to an acceptable level).

• For Group 1 room air emissions at area source facilities where EtO use is less than 40 tpy, we do not have any performance tests showing that these facilities can perform better than the manufacturer guarantee (*i.e.,* 80 percent emission reduction for room air emissions, which we have established in this final rule as the GACT standard for Group 1 room air emissions at these facilities).

However, there are two potential options. One potential option is 99.6 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy but less than 30 tpy. This is cost effective and is already being achieved by these facilities. The other potential option is to further reduce CEV emissions at area source facilities.[59] Under this option, which would reduce CEV emissions by 99.9 percent at area source facilities where EtO use is at least 60 tpy less than 400 tpy,[60] costs were found to be a $6,820,000 total capital investment and a $1,670,000 total annualized cost. The estimated EtO emissions reductions are 1.9 tpy (*i.e.,* 3,720 lb/year) with a cost effectiveness of $895,000 per ton of EtO (*i.e.,* $448 per lb of EtO). Considering EtO is a highly potent carcinogen, the cost-effectiveness number of this option is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. As explained in section IV.B.3.b of this preamble, this includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). While we do not know what the full extent of risk reductions would be, we estimate that, compared to the measures in step 1, this control option would further reduce the population exposed to risk levels greater than or equal to 1-in-1 million by additional 10,000–30,000 people. For area sources where EtO use is less than 60 tpy, we do not have any performance test data showing that existing controls can achieve greater than 99 percent reduction for CEVs (which is the GACT standard we have established in this final rule for CEV at area sources). In addition, for area source facilities where EtO use is at least 400 tpy, we were unable to identify any cost-effective options. Therefore, we did not consider a more stringent CEV standard for facilities where EtO use at least 400 tpy.

In the post control scenario (*i.e.,* with the implementation of the standards identified under step 1 and the two potential options discussed immediately above in this step 2 analysis, we estimated that the baseline cancer MIR of 6,000-in-1 million for actual emissions and 8,000-in-1 million for allowable emissions would be reduced to 100-in-1 million, with EtO driving the risk. While the MIR for the source category will be 100-in-1 million, we estimate that most facilities (*i.e.,* 87 out of 88) will have an MIR less than 100-in-1 million. There is an estimated reduction in cancer incidence to 0.2 excess cancer cases per year (or one excess case every 5 years), down from 0.9 excess cancer cases per year (or one excess cancer case every 1.1 years) for baseline actual emissions and down from 8 excess cancer cases per year (or one excess cancer case every 1.5 months) for baseline allowable emissions. We estimate that, after full implementation of this final rule, 0 people would have cancer risks greater than 100-in-1 million, down from 19,000 people for actual emissions and 260,000 people for allowable emissions. In addition, the number of people estimated to have a cancer risk greater than or equal to 1-in-1 million would be reduced to 1.38 million people, down from 8.5 million people for actual emissions and 62 million people for

[57] For facilities where use is less than 30 tpy, we do not have performance test data indicating that 99.99 percent emission reduction for SCVs is technical feasible.

[58] As discussed in section IV.B.3.b of this preamble, we analyzed this option as part of the GACT analysis and found it to be cost-effective. However, this analysis included all facilities in the source category (*i.e.,* not just those where EtO use is less than 4 tpy).

[59] As discussed in section IV.B.3.b of this preamble, pursuant to CAA sections 112(d)(2) and 112(d)(3), we are finalizing a 99.94 percent emission reduction standard for CEVs at major source facilities. We did not identify any cost-effective BTF options.

[60] As discussed in step 1 analysis, pursuant to CAA section 112(f)(2), this standard for CEVs at area source facilities where EtO usage is at least 400 tpy is necessary to reduce risks to an acceptable level.

allowable emissions (table 19 of this preamble).

Again, we note that some facilities are currently performing better than the controls finalized under CAA sections 112(f)(2), and in that case we estimate the maximum lifetime individual cancer risk as 100-in-1 million, with EtO driving the risk. The total estimated cancer incidence is estimated to be 0.1 excess cancer cases per year, or 1 excess case in every 10 years, with approximately 700,000 people estimated to have cancer risks greater than or equal to 1-in-1 million and 0 people estimated to have cancer risks greater than 100-in-1 million (table 19 of this preamble).

TABLE 19—BASELINE AND POST-CONTROL RISK (AFTER CONTROLS PROMULGATED UNDER CAA SECTIONS 112(F)(2) SUMMARY FOR THE COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY BASED ON EMISSIONS IN THE FINAL RULE

	Inhalation cancer risk		Population cancer risk		
	Maximum individual risk (in 1 million)	Risk driver	Cancer incidence (cases per year)	>100-in-1 million	≥1-in-1 million
Actual Emissions Baseline Risk	6,000	ethylene oxide	0.9	19,000	8,500,000
Allowable Emissions Baseline Risk	8,000	ethylene oxide	8	260,000	62,000,000
Post-control Risk	100	ethylene oxide	[1] 0.1–0.2	0	[1] 700,000–1,380,000

[1] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

Additional details of the analyzed risks can be found in the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* available in the docket for this rulemaking.

Based on our ample margin of safety analysis, including all health information and the associated cost and feasibility discussed above, we find that requiring the standards that, based on our analysis, would bring risks to an acceptable level, along with 99.6 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy but less than 30 tpy and 99.9 percent emission reduction for CEVs at area source facilities where EtO use is at least 60 tpy but less than 400 tpy, would provide an ample margin of safety to protect public health.

c. Environmental Effects

As explained in our proposed rule, the emissions data indicate that no environmental HAP are emitted by sources within this source category. In addition, we are unaware of any adverse environmental effects caused by HAP emitted by this source category. Therefore, we do not expect there to be an adverse environmental effect as a result of HAP emissions from this source category. For the reason stated above, it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

d. Rule Changes

Based on comments received on the proposed rulemaking, we are finalizing the following emissions standards pursuant to CAA section 112(f)(2):

- 99.99 percent emission reduction for SCVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.9 percent emission reduction for ARVs at facilities where EtO use is at least 30 tpy,
- 99.6 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.9 percent emission reduction for CEVs at area source facilities where EtO use is at least 60 tpy,
- 98 percent emission reduction for Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy,
- 98 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy, and
- 80 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy.

We are not finalizing the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1'', which would have required facilities to limit their existing Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv. We had proposed these standards based on the risk review we conducted during the proposal stage, which has been substantially revised. As discussed above, based on the revised risk review, we are finalizing a different suite of standards pursuant to CAA section 112(f)(2) to reduce risks to an acceptable level and provide an ample margin of safety to protect public health.

3. What key comments did we receive on the risk review, and what are our responses?

This section provides comment summaries and responses for the key comments received regarding our exclusion of allowable emissions from the risk assessment, the control requirements proposed for SCVs, and the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1'' evaluated in the residual risk assessment during the proposal stage, as well as the proposed GACT standards that were incorporated into the residual risk assessment. We received comments against the exclusion of allowable emissions from the risk assessment, the control requirements proposed for SCVs, and the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1.'' Other comments on these issues, as well as on additional issues regarding the residual risk review and our proposed changes based on the residual risk review, can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for*

Commercial Sterilization Facilities, available in the docket for this rulemaking.

Comment: Two commenters contended that we should use allowable emissions when conducting residual risk assessments. One commenter stated that actual emissions only provide a snapshot in time and that there is no legal requirement at the Federal level to maintain emissions beyond the NESHAP requirements in any given year. The commenter also referenced a 2010 Science Advisory Board (SAB) report that recommended we use ''facility-specific allowable emissions reflecting current regulatory limits.'' [61]

Response: We agree with commenters that allowable emissions should be considered as part of the residual risk assessment. As discussed in section III.C of the proposed rulemaking (88 FR 22790), because allowable emissions and risks were higher than actual emissions, and in light of our finding that risks were unacceptable based on actual emissions, we determined that a separate assessment of allowable emissions was unnecessary. However, for the reasons stated by the commenters, we have incorporated allowable emissions into our revised risk assessment as part of this final rulemaking.

Comment: Two commenters expressed the following concerns with the 99.94 percent emission reduction standard for SCVs:

- Our technical publications on reduction ranges for add-on control equipment for HAPs do not show that a destruction and removal efficiency of 99.94 percent is achievable under normal continuous operation.
- The proposed requirement does not require additional controls based on new technology, but requires achieving greater efficiency from existing controls. Specifically, one commenter stated that nothing in the proposal preamble suggests that the control systems installed in order to meet the current SCV standard need to be replaced or their performance upgraded. The commenter further stated that our cost estimates include nothing with respect to controls for SCVs.
- Emission control device manufacturers do not guarantee a destruction removal efficiency of 99.94 percent for SCVs.

Two commenters stated that emissions standards should be based on achievable, manufacturer guaranteed destruction removal efficiency of emission control equipment. One commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

Response: We disagree with the commenters that our technical publications on reduction ranges for add-on control equipment for HAPs do not show that an emission reduction of 99.94 percent (and, therefore, any greater emission reduction) is achievable under normal continuous operation for SCVs. Such a performance test was conducted for at least two systems that control SCV emissions, and the reported emission reduction for both of these systems was 99.99 percent. Below is a discussion on the relevant points for each performance test:

- The first performance test was conducted on November 17, 1999.[62] It is unknown what the EtO use at this facility was at the time of the performance test, but it is expected that it was somewhere between 10 tpy and 30 tpy. At the time of the performance test, the facility used a wet scrubber to control its SCV emissions.[63] Prior to November 2, 2001, we required facilities to test the both the first and last evacuations of the SCV. The SCV concentration decreases over time, so any emission reductions between the first and last evacuations are going to be at least as high as that of the last evacuation. For this performance test, the average emission reduction at the first evacuation was 99.9946 percent, and the average emission reduction at the last evacuation was 99.99 percent. This means that the emission reduction over all the SCV cycles exceeded 99.99 percent. While this performance test data is almost 25 years old, emission control technology has continued to improve over time, and emission reductions today are likely higher.
- The data from this performance test indicates that, for facilities where EtO use is at least 30 tpy, any SCV control system that is achieving higher than 99.9946 percent emission reduction on the first evacuation is likely achieving at least 99.99 percent emission reduction overall. Our current performance test data indicates that at least 15 facilities where EtO use is at least 30 tpy are currently achieving greater than 99.9946 percent emission reduction on the first evacuation, and the highest emission reduction on the first evacuation that we have observed is 99.99999982 percent. Of these 15 facilities that are currently achieving this emission reduction, eight use wet scrubbers, three use a wet scrubber and gas/solid reactor in series, two use thermal oxidizers, one uses a catalytic oxidizer, and one uses a wet scrubber and catalytic oxidizer in series.
- The second performance test was conducted on March 10, 11, and 12, 2020,[64] and EtO use at this facility is 229.2 tpy. This facility uses wet scrubbers and gas/solid reactors in series to control its SCV emissions. Due to the configuration of the control system at this facility, there is no mechanism to test the SCVs on their own. Therefore, this performance test was conducted for all emission sources at the facility. For lower concentration streams like ARVs, CEVs, and room air emissions, emission reductions tend to be lower. Therefore, it is likely that the SCV emission reduction at this facility exceeds 99.99 percent.

As a general matter, it is not our policy to simply rely on manufacturer guarantees when setting or revising emission standards. Typically, we evaluate performance tests to see what the controls are actually achieving in practice and then set or revise the standards based on that evaluation. However, if representative performance test data are not available, then manufacturer guarantees may be considered. We also note that it is common within this industry to combine different types of control devices in series when reducing emissions. Since these control devices are often made by different manufacturers, there is no manufacturer guarantee available for these systems. We do not share the commenters' concerns that emission control device manufacturers do not guarantee a destruction removal efficiency of 99.94 percent for SCVs, as representative performance test data is available and indicates that these emission reductions (and, in fact, higher emission reductions) are achievable for higher use facilities. However, such performance test data are not available for smaller users, and it is not known whether those facilities can meet the emission reduction that the higher use facility is demonstrating. Therefore, we agree with commenters that consideration of manufacturer guarantees is warranted for lower use facilities, and the

[61] Commenter provided the following reference: EPA Science Advisory Board, Review of EPA's draft entitled, ''Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing'', at ii, (May 7, 2010), *https://www.regulations.gov/document/EPA-HQ-OAR-2010-0682-0103.*

[62] *https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0297.*

[63] This facility continues to use a wet scrubber to control its SCV emissions to this day.

[64] *https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0349.*

standards that we are finalizing for SCVs at facilities where EtO use is less than 30 tpy do not exceed the manufacturer guarantee.

In addition, we disagree with one commenter's assertion that there is nothing in the proposal preamble to suggest that the control systems installed in order to meet the current SCV standard need to be replaced or their performance upgraded. Furthermore, the commenter's assertion that our cost estimates include nothing with respect to controls for SCVs is incorrect. As discussed in section II.A of this preamble, under the first step of the residual risk assessment, if risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. While we did not conduct a cost analysis for the SCV standards that we are finalizing pursuant to CAA section 112(f)(2) step 1 (risk acceptability analysis), we assume that new controls would be needed in order to achieve those standards, and the cost of those controls are included in the total costs of the rule. However, we note that the final standard is simply an emission reduction standard, and owners and operators may choose to meet the standard however they see fit (*e.g.,* either through process changes, the replacement of a control system, or the use of additional control devices to further reduce emissions from an existing control system). In some cases, existing controls may already be achieving the standard, and in that case, no changes are required.

Comment: Several commenters stated that reducing the volumetric flow rate from Group 2 room air emissions to 2,900 dscfm would be detrimental to sterilization operations and may make it impossible to achieve the proposed PTE requirement.

Response: Based on comments received on the proposed rulemaking, we revised the risk assessment, which resulted in different emission reduction measures than what we proposed to bring the risk to the acceptable level. The proposed work practice standards are no longer necessary to bring the MIR of Group 2 room air emissions at area source facilities to 100-in-1 million. Therefore, we are not including a work practice standard that would require any facilities to reduce their throughput as part of this final rule.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, we set standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive benchmark on MIR of approximately 1-in-10 thousand'' (88 FR 22790, April 13, 2023; see also 54 FR 38045, September 9, 1989). We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum TOSHI, the maximum acute HQ, the extent and the distribution of cancer and noncancer risks in the exposed population, multipathway risks, and the risk estimation uncertainties. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors.

Since proposal, our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects have not changed. The revised risk assessment (see document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking) shows that, after application of controls finalized in this rulemaking, the MIR for the source category is 100-in-1 million. Therefore, after application of the controls for SCVs at facilities where EtO use is at least 1 tpy, ARVs at facilities where EtO use is at least 30 tpy, CEVs at area source facilities where EtO use is at least 400 tpy, Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, and Group 2 room air emissions at area source facilities where EtO use is at least four tpy, we find that the risks are acceptable and that the final standards will achieve an ample margin of safety to protect public health.

D. Technology Review for the Commercial Sterilization Facilities Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Commercial Sterilization Facilities source category?

Based on our technology review for the Commercial Sterilization Facilities source category, we proposed under CAA section 112(d)(6) changes to the standards for SCVs where EtO use is at least 10 tpy, SCVs where EtO use is at least 1 tpy but less than 10 tpy, and ARVs where EtO use is at least 10 tpy. We provide a summary of our findings, as proposed, in this section. In general, while the types of controls have essentially remained the same since promulgation of subpart O, available information show greater emission reduction since then for some of these control options.

For SCVs, we proposed the following emission standards pursuant to CAA section 112(d)(6):

- 99.94 percent reduction for new and existing SCVs at facilities where EtO use is at least 10 tpy, and
- 99.8 percent reduction for new and existing SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy.

These are the maximum SCV emission reductions with which compliance can be demonstrated. We evaluated these standards against the maximum SCV emission reductions that all facilities are currently meeting within each subcategory. For more information, see sections III.F.1 and III.F.2 of the proposal preamble (88 FR 22790, April 13, 2023).

For ARVs, we proposed the following emission standards pursuant to CAA section 112(d)(6):

- 99.6 percent emission reduction for existing ARVs at facilities where EtO use is at least 10 tpy, and
- 99.9 percent emission reduction for new ARVs at facilities where EtO use is at least 10 tpy.

These are the emission reductions that have been demonstrated by 75 percent and 50 percent of all available performance tests, respectively. We evaluated both emission reductions for new and existing ARVs. For more information, see section III.F.3 of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the technology review change for the Commercial Sterilization Facilities source category?

We are finalizing the following emission standards as a result of the

technology review for the Commercial Sterilization Facilities source category, as proposed:

- 99.8 percent emission reduction for new and existing SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.6 percent emission reduction for existing ARVs at facilities where EtO use is at least 10 tpy, and
- 99.9 percent emission reduction for new ARVs at facilities where EtO use is at least 10 tpy.

For new and existing SCVs at facilities where EtO use is at least 10 tpy, based on comments received on the proposal, we are finalizing a 99.9 percent emission reduction, which is the manufacturer guarantee. There is a lack of representative performance test data for these SCVs, and we are unable to determine whether all facilities can achieve an emission reduction higher than the manufacturer guarantee. For more information, see section IV.D.3.a of this preamble.

3. What key comments did we receive on the technology review, and what are our responses?

This section provides comment and responses for the major comments on our proposed CAA section 112(d)(6) standards. Other comment summaries and our responses for additional issues raised regarding these activities, as well as issues raised regarding our proposed revisions, can be found in the document *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

a. SCVs at Facilities Where EtO Use Is at Least 10 tpy

Comment: Several commenters questioned whether the proposed emission standards for SCVs at facilities where EtO use is at least 10 tpy could be achieved with existing technology and stated that we should consider manufacturer guarantees when revising the standard, along with a maximum concentration limit. The commenters stated that we arrived at a 99.94 percent emission reduction standard based on performance tests that used the previous testing procedures in Subpart O. These consisted of one-hour test runs that occurred during the initial vacuum event, when EtO loading to the control system (and, therefore, emission reduction) is high. The commenters further stated that we proposed extending the duration of each test run to 24 hours, which would cover a variety of operating conditions, including periods of low inlet concentration, which have not been required to be tested. The commenters contended that the performance test results based on the proposed testing procedures would be lower than those under the previous testing procedures. One commenter stated that there are no data confirming whether state-of-the-art control systems can meet a 99.94 percent emission reduction standard for SCVs where each performance test run is 24 hours, and another commenter stated that we must ensure that any required emission reduction standards that are finalized for SCVs are proven and achievable as part of performance tests consisting of 24-hour test runs. One commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

Response: We agree with the commenters that it is not appropriate to use performance test data based on the previous testing procedures in Subpart O to justify revisions to the emission standards for SCVs. We disagree with one commenter's statement that there are no data confirming whether state-of-the-art control systems can meet a 99.94 percent emission reduction standard for SCVs where each test run is 24 hours. As discussed in section IV.C.3, such data exist for at least one system that controls SCV emissions. However, the EtO usage at this facility is fairly high, and we are unable to determine whether smaller users can meet this emission standard. With respect to the suggestion by some commenters that we consider a manufacturer guarantee reduction level, which one commenter stated is 99.9 percent emission reduction for SCVs, we have no data disputing such level or reason to question the manufacturer's guarantee. Further, as discussed in our response to the next comment below, we find the cost of this option to be reasonable. Therefore, pursuant to CAA section 112(d)(6), we are finalizing a 99.9 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy.[65]

We disagree with the commenter's suggestion that we should consider a maximum concentration limit along with the percentage reduction standard. As discussed in section IV.B.3.a, we are concerned that some owners and operators may dilute the air flow of the emissions stream to meet a concentration standard, which would not result in any actual emission reductions. Furthermore, it is not appropriate to establish upper-bound limitations on air flow within this source category, as additional flow may be necessary in order to mitigate any potential safety issues that may arise. Therefore, we are not finalizing any concentration standards as part of this rulemaking.

Comment: One commenter stated that, for the SCV technology rule under CAA section 112(d)(6), we merely referred back to, and repeated the proposed standards of, the residual risk review. The commenter further stated that we did not conduct the technology review as a separate analysis, but rather, it was inseparably intertwined with the residual risk review. Finally, the commenter stated there is no true technology review in the record and that cost considerations of the proposed CAA section 112(d)(6) emissions standard for existing SCVs at facilities where EtO use is at least 40 tpy were never considered, even though section 112(d)(6) requires considerations of cost.[66]

Response: We disagree with the commenter's statement that a ''true'' technology review was never conducted. In the proposal preamble (88 FR 22839–41), the EPA discussed control options that can achieve further emission reductions compared to the existing subpart O standards. While the types of controls have essentially remained the same, available information shows improvement in emission reduction potential for some of these control options, which we consider to be a development in control technologies; we analyzed this development and proposed revisions to the standards pursuant to CAA section 112(d)(6). The commenter appears to take issue with the fact that these are the same options as those we evaluated under CAA section 112(f)(2), specifically under step 2 (ample margin of safety) analysis. However, in evaluating whether we can achieve further emission reduction and thus lower risks, we naturally would

[65] We also note that, as discussed in section IV.F.3 of this preamble, we are finalizing a requirement for owners and operators to include a representative performance test period for SCVs, along with a justification, in their stack test protocol, so that the delegated authorities can review and approve or deny the protocol as appropriate. This will ensure that performance tests provide a more accurate representation of SCVs emission reductions.

[66] In support of its comment that control costs must be considered under section 112(d)(6) review, the commenter cited to *Nat'l Ass'n for Surface Finishing,* 795 F.3d at 5 (''in the technology review, EPA periodically assess, no less often than every eight years, whether standards should be tightened in view of developments in technologies and practices since the standard's promulgation or last revision, and, in particular, the cost and feasibility of developments and corresponding emissions savings'').

consider controls that reflect the current developments in processes and technology by this industry (*i.e.,* well performing air pollution control), which we are also required to evaluate under CAA section 112(d)(6). For the reason stated above, we find the comment that our technology review was not a ''true'' review to be without merit.

We acknowledge that in proposing a 99.94 percent standard pursuant to CAA section 112(d)(6) for SCV at facilities using at least 10 tpy EtO, we inadvertently evaluated the control costs for facilities using between 10 to 40 tpy only. However, as discussed in our comment response above, we no longer consider the proposed 99.94 percent emission reduction standard to be appropriate. As suggested by several commenters, we evaluated a manufacturer guarantee. Based on one commenter's discussions with control device manufacturers, the best and most advanced technologies will be guaranteed to meet 99.9 percent emission reduction for SCVs. The impacts of this option and the 99.6 percent reduction option that we considered during the proposal stage are presented below in table 20 for existing sources:

TABLE 20—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(6) FOR EXISTING SCVS AT FACILITIES WHERE ETO USE IS AT LEAST 10 TPY

Option	Standard evaluated	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.9 percent emission reduction	$1,840,000	$752,000	1.14 [2,280 lb]	$661,000 [$330/lb].
2	99.6 percent emission reduction	0	0	0	N/A.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness number of this option is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. As explained in section IV.B.3.b of this preamble, this includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). As part of the proposed rulemaking, the highest cost-effectiveness number that we found was $19,420,188/ton. We did not receive adverse comment on our finding that this is cost-effective. While Option 2 would prevent backsliding, it does not achieve additional emission reduction. Therefore, pursuant to CAA section 112(d)(6), we are revising the standard to require facilities where EtO use is at least 10 tpy to reduce their emissions from existing SCVs by 99.9 percent.

The impacts of these options for new sources, which are presented in table 21 of this preamble, are based on a model plant for new SCVs at a facility using at least 10 tpy of EtO with the following assumptions reflecting the average of each of the parameters at existing facilities using at least 10 tpy of EtO:

- Annual EtO use: 120 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to SCVs: 94.41 percent.
- SCV flow rate: 200 cfs.

TABLE 21—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(6) FOR NEW SCVS AT FACILITIES WHERE ETO USE IS AT LEAST 10 TPY

Option	Standard evaluated	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.9 percent emission reduction	$523,000	$136,000	1.02 [2,040 lb]	$134,000 [$67/lb].
2	99.6 percent emission reduction	348,000	106,000	0.68 [1,360 lb]	158,000 [$79/lb].

Based on the estimates above, we find both options to be cost effective. Option 1 would achieve greater emission reductions than Option 2, and Option 1 would be more cost-effective. Therefore, pursuant to CAA section 112(d)(6), we are revising the standard to require facilities where EtO use is at least 10 tpy to reduce their emissions from new SCVs by 99.9 percent.

Comment: In response to the EPA's solicitation of comment on whether to include a mass emission rate standard as an alternative to the percent emission reduction standard, two commenters were opposed to such an alternative. One commenter stated that mass emission rate standards for individual vents do not account for variability between facilities or variability within facilities. The commenter also stated that any standard that fails to reflect individual facility dynamics that materially affect the ability to comply is inappropriate and not achievable.

Response: We agree with the commenters' concerns regarding the alternative, equivalent mass rate emission standards. Therefore, they are not included in this final rule.

b. SCVs at Facilities Where EtO Use Is at Least 1 Tpy but Less Than 10 Tpy

Comment: One commenter stated that they support emission reduction standards based on manufacturer guarantees for control equipment, along with a maximum concentration limit, to ensure that compliance can be achieved and demonstrated. In addition, the commenter did not agree with our method to calculate alternative, equivalent mass rate emission standards. Another commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

Response: We agree with the commenter's suggestion that manufacturer guarantees be considered when finalizing the standard. Most of the performance tests that are currently available for SCVs are based on the previous testing procedures, which are not reflective of actual operating conditions. The one performance test we have that is based on actual operating conditions is for a facility

where EtO use exceeds 30 tpy and thus not appropriate for the group of facilities at issue here (*i.e.,* those using at least 1 tpy but less than 10 tpy of EtO). Therefore, a manufacturer guarantee is appropriate to consider in this instance, and a 99.8 percent emission reduction standard falls within the manufacturer guarantee range for SCV controls as provided by one of the commenters (99.9 percent emission reduction). However, this does not change our rationale for a 99.8 percent reduction standard during the proposal stage, which was that this is the maximum emission SCV reduction with which compliance can be demonstrated at all facilities where EtO use is at least 1 tpy but less than 10 tpy considering current emission profiles.

We disagree with the commenter's recommendation for a maximum concentration limit. As discussed in section IV.B.3.a, we are concerned that some owners and operators may dilute the air flow of the emissions stream to meet a concentration standard, which would not result in any actual emission reductions. Furthermore, it is not appropriate to establish upper-bound limitations on air flow within this source category, as additional flow may be necessary in order to mitigate any potential safety issues that may arise. Finally, as discussed in section IV.D.3.a, we are not including any alternative, equivalent mass rate emission standards in the final rule. Therefore, the commenter's concerns regarding the methodology used to calculate the limits are no longer relevant.

c. ARVs at Facilities Where EtO Use Is at Least 10 Tpy

Comment: Several commenters objected to the proposed emission reduction standards and stated that they are not achievable as written. One commenter stated that we should require emission reduction standards based on manufacturer guarantees, along with a maximum concentration limit. Another commenter stated that sterilization is a batch process and that the concentration from the aeration area is subject to constant fluctuation due to differences in product, cycles, facility design, and EtO decline curve, which makes a consistent emission reduction challenging to determine. Finally, several commenters expressed concerns with the use, and our development, of the alternative, equivalent mass rate emission standards due to the wide variations in ARV parameters across this group of facilities, as well as the difficulty in demonstrating compliance with this standard for larger facilities.

Response: We disagree with the commenters' position that the proposed emission reduction standards are not achievable. As discussed in section III.F.3.a of the proposal preamble (88 FR 22790, April 13, 2023), most existing sources (*i.e.,* 75 percent) are already achieving 99.6 percent emission reduction. In addition, 99.9 percent emission reduction has been demonstrated by 50 percent of existing sources. We also disagree with one commenter's suggestion that manufacturer guarantees be considered in this instance for two reasons. First, there is no need to rely on manufacturer guaranteed emission levels because there are available performance test data for ARVs that are representative of actual operating conditions. Unlike SCVs, which go through different active phases with wildly varying concentrations, fluctuations in ARV concentrations are slight; an aeration room serves one purpose, which is to hold product at an elevated temperature, and the resulting ARV concentration is relatively constant. Therefore, a one-hour test period for this source is appropriate, and the resulting performance test data are representative of actual operating conditions. To that end, we disagree with another commenter's statement that fluctuations in the ARV make it difficult to comply with an emission reduction standard. Second, performance test data for ARVs are plentiful. As discussed in section III.F.3.a of the proposal preamble, there are 47 facilities where EtO use is at least 10 tpy, 41 of which have ARVs. Of these 41 facilities, 32 (78 percent) have performance test data. Because the performance test data from ARVs at these facilities are both plentiful and representative of actual operating conditions, there is no need to rely on a manufacturer guaranteed emission reduction level in this instance. We also disagree with the commenters' recommendation for a maximum concentration standard. As discussed in section IV.B.3.a, we are concerned that some owners and operators may dilute the air flow of the emissions stream to meet a concentration standard, which would not result in any actual emission reductions. Furthermore, it is not appropriate to establish upper-bound limitations on air flow within this source category, as additional flow may be necessary in order to mitigate any potential safety issues that may arise. Finally, with respect to the alternative equivalent mass rate emission standards, we agree with the commenters' concerns, and we are not including these standards in the final rule.

Comment: One commenter stated that if the lowest practicably measured concentration is 30 ppbv (our presumed workable-in-practice detection limit for CEMS), then a source with an inlet concentration that is too low will be unable to show the required emission reduction, even if the control system is providing that level of reduction, because the monitoring approach will be unable to distinguish the true outlet concentration from 30 ppbv. The commenter further stated that existing sources would need to have pre-control aeration room concentrations of at least 7.5 ppmv to make this demonstration. Two commenters stated that the increased 99.6 percent (existing facilities) or 99.9 percent (new facilities) ARV emission reduction standards penalize facilities that have reduced EtO concentrations during the sterilization cycle. Several commenters noted that facilities have reduce EtO concentrations during the sterilization cycle (*i.e.,* use of vacuum and/or nitrogen wash cycles) prior to moving the sterilized load to aeration to reduce inlet ARV concentrations, and that removals, on a percent basis, are only achievable with elevated inlet concentrations.

Response: One commenter is correct that, given the lowest practicable measured concentration (30 ppbv), the pre-control concentration would need to be 7.5 ppmv in order to demonstrate compliance with the proposed standard for existing sources. The performance test data that are available for ARVs at these facilities consist of 86 test runs. Of these 86 test runs, only five (six percent) had a measured concentration less than 7.5 ppmv, which suggests low likelihood that facilities will have difficulty demonstrating compliance due to low pre-control concentration. based on the current operating conditions Furthermore, regarding the comment that these standards would penalize sources who have already worked to reduce their EtO concentrations during sterilization and, by extension, their inlet ARV concentrations, as discussed in section III.F.3 of the proposal preamble, 75 percent of existing sources are already meeting the proposed standard; it is unclear, and the commenter does not explain, why a requirement that retains facilities' status quo is a punishment to those facilities. Most of the industry is either (1) currently meeting the proposed standard or (2) capable of meeting the proposed standard based on current operating conditions. In addition, if a facility with existing ARVs

wishes to further reduce their EtO concentrations during sterilization, then operational changes can be made to the aeration room so that the facility can continue to demonstrate compliance with the emission reduction standard. Since new facilities are not currently in operation, there has been no reduction in EtO concentrations during sterilization and, therefore, no penalty has been incurred.

4. What is the rationale for our final approach for the technology review?

Our technology review focused on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the standards for Commercial Sterilization Facilities were originally promulgated on December 6, 1994 (59 FR 62585) and further amended on November 2, 2001 (66 FR 55577). Specifically, we focused our technology review on all previous standards for the various emission sources in the Commercial Sterilization Facilities source category, including SCVs at facilities where EtO use is at least 10 tpy, SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and ARVs at facilities where EtO use is at least 10 tpy. In the proposal, we identified developments for all emission sources, and we proposed to revise the standards for these emissions sources under the technology review. Further information regarding the technology review can be found in the proposed rule (88 FR 22790, April 13, 2023) and in the supporting materials in the rulemaking docket at Docket ID No. EPA–HQ–OAR–2019–0178.

During the public comment period, we received several comments on our proposed determinations for the technology review. No information presented by commenters has led us to change our proposed determination under CAA section 112(d)(6) for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and ARVs at facilities where EtO use is at least 10 tpy, and we are finalizing the changes to those standards as proposed. For SCVs at facilities where EtO use is at least 10 tpy, based on comments received on the proposal, we are finalizing a 99.9 percent emission reduction standard, which is the manufacturer guarantee. There is at least one representative performance test available for SCVs, but it was conducted at a facility with a higher EtO usage rate, and we are unable to determine whether smaller facilities can achieve the emission reduction from that performance test. The key comments and our specific responses can be found in section IV.D.3 of this preamble and in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

E. Amendments Addressing Emissions During Periods of SSM

1. What amendments did we propose to address emissions during periods of SSM?

For all emission points in the Commercial Sterilization Facilities source category, we proposed eliminating the SSM exemptions and to have the standards apply at all times. More information concerning the elimination of SSM provisions is in section III.G. of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the SSM provisions change since proposal?

We are finalizing the SSM provisions as proposed (88 FR 22790, April 13, 2023).

3. What key comments did we receive on the SSM revisions and what are our responses?

This section provides comment summaries and responses for the key comments received regarding our proposed revisions. Other comment summaries and the EPA's responses for additional issues raised regarding these activities as well as issues raised regarding our proposed revisions can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

Comment: One commenter stated that the EPA should consider other approaches to adequately account for SSM contingencies. The commenter suggested that the EPA classify sources in SSM states as sub-sources subject to different emissions limitations or work practice standards. Another commenter stated that EtO sterilizers do not create emissions during startup or shut down because, unlike other industrial processes regulated under the NESHAP program, EtO is not emitted as a byproduct of combustion or chemical reaction but is released intentionally in a highly controlled manner. The commenter further stated that sterilization never begins before control equipment is activated and always ends before control equipment is deactivated. Similarly, another commenter stated that the EPA inaccurately assumed that startup and shutdown are no different than normal operation. The commenter further stated that constructing and starting new abatement equipment includes periods of troubleshooting and acceptance testing. The commenter also stated that the proposal does not address the permit-to-construct process and related requirements before transferring to an operating permit. Finally, one commenter suggested that the malfunction exemption should not be eliminated because, due to the nature of sterilization operations and various stages of cycles, commercial sterilizers must be able to address malfunctions that could result in a potential risk to employees or the facility without the risk of being in noncompliance.

Response: As discussed in section III.G.1 of the proposal preamble (88 FR 22790, April 13, 2023), it is common practice in this source category to start an air pollution control device (APCD) prior to startup of the emissions source it is controlling, so the APCD would be operating before emissions are routed to it, which has been confirmed by one of the commenters. In addition, based on responses to the December 2019 questionnaire and the September 2021 ICR, many facilities already have measures in place to ensure that the emission standards are met during periods of SSM, including holding emissions within the process unit or the APCD itself, or the use of onsite generators in the event of a power outage.[67] The comments provided do not support establishing emission standards that apply only during periods of SSM. With respect to classifying sources in SSM states as sub-sources subject to different emissions limitations or work practice standards, the commenter does not provide any rationale for why this should be done or any suggestions for what those emission standards should be. With respect to emission spikes from troubleshooting control devices, as discussed in section IV.F.3 of this preamble, the EPA is finalizing a requirement for emission limits to be based on 30-operating day rolling sums of EtO entering the control system(s) for EtO CEMS, which will help to mitigate these spikes over time. However, the commenter does not provide any rationale for why the permitting process should be considering when evaluating SSM. Finally, we cannot agree with the commenter's recommendation to keep the malfunction exemption in

[67] See memorandum, *Review of Startup, Shutdown, and Malfunction of Process and APCD Equipment in the Ethylene Oxide Commercial Sterilization Source Category Technology Review Project,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

contradiction with *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), in which the court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. As discussed in section III.G.1 of the proposal preamble, in its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court held that emissions standards or limitations must be continuous in nature, which means that there cannot be exemptions for periods of malfunction. Further, while the EPA could consider establishing a different standard during malfunction if warranted and still be consistent with the *Sierra Club* decision, the commenter does not provide any specific information regarding instances where compliance with the standards during malfunction could result in potential risks to the employees or the facility or suggestions for what emission standards the EPA should consider to address the concern. Therefore, the EPA is not finalizing any emission standards that apply only during periods of SSM.

Comment: One commenter stated that a specific area of concern is the ability to demonstrate compliance during startup and shutdown, asserting that the proposed rule offered no means for a source to remain in compliance during the inevitable and foreseeable, but not predictable, failure of monitoring equipment. The commenter further suggested that the EPA should consider specific reporting and monitoring alternative requirements for these scenarios. The commenter provided the example of a requirement specific to releases from sterilizer pressure relief devices (PRDs) resulting from malfunctions or required during shutdown events that the commenter suggested could be modeled after recent PRD requirements in 40 CFR 63.648(j). Another commenter recommended that facilities should only be required to report malfunction events that result in unpermitted releases to the atmosphere. The commenter stated that, in the example situation where control equipment unexpectedly goes offline during operations but EtO remains trapped within the facilities ducts under negative pressure, there would be no need to create additional administrative compliance requirements for the facility.

Response: With respect to accounting for the failure of monitoring equipment when demonstrating compliance, as discussed in section IV.F.3 of this preamble, the EPA is finalizing a minimum data availability requirement of 90 percent for EtO CEMS. With respect to specific reporting and monitoring alternative requirements that apply during periods of SSM, the commenter did not provide any recommendations for what those requirements should be. In addition, we agree with one commenter's suggestion that facilities should only be required to report malfunction events that result in unpermitted releases to the atmosphere. However, to be clear, we are finalizing reporting requirements for malfunction events that occur with emissions or parametric monitoring equipment.

Comment: One commenter suggested that the EPA should not include the general duty clause in the final rule. The commenter stated that it is not clear on what basis the EPA is claiming authority to impose a general standard of behavior on regulated sources. The commenter asserted that CAA section 112 grants the EPA authority to set emissions limits and certain specific alternative standards but does not grant authority to impose a ''vague and subjective code of conduct.'' The commenter stated that the general duty clause is redundant to proposed amendment to 40 CFR 63.632(b) that would require compliance ''at all times.'' The commenter asserted that if compliance with the specific requirements of the rule will satisfy the general duty, then there is no need for the EPA to reserve the authority to evaluate a source's good air pollution control practices. Furthermore, the commenter asserted that the general duty provisions date back to a regulatory period during which air quality control rules lacked the specificity of monitoring, reporting, and recordkeeping that are included in the proposed rule. The commenter suggested that either the EPA should not finalize the proposed general duty clause at 40 CFR 63.632(j) or that the general duty clause from the General Provisions should be incorporated. The commenter stated that the General Provision contains language that more clearly explains the EPA's exercise of enforcement discretion during SSM periods.

Response: As part of the proposed rulemaking, we proposed to add the following general duty clause to 40 CFR 63.362(j):

''At all times, you must 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. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.''

We disagree with the commenter's suggestion to not finalize the general duty clause. We do not consider this duty clause to be redundant just because the emission standards apply at all times; the provision imposes a 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. Commenters did not provide data supporting the suggestion that this general duty clause is redundant. Even assuming it were redundant, which it is not, the commenter does not explain why it must be removed. In addition, the inclusion of a general duty clause like the one proposed is standard practice for other NESHAPs. Furthermore, we disagree with the commenter's suggestion to incorporate the general duty clause from Subpart A. As discussed in earlier in this section, in its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court held that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature, which means that there cannot be exemptions for periods of SSM. The general duty clause in Subpart A contains certain exemptions for periods of SSM. We are therefore finalizing the general duty provision as proposed.

4. What is the rationale for our final approach and final decisions to address emissions during periods of SSM?

We evaluated all of the comments on the EPA's proposed amendments to the SSM provisions. As explained in section III.G of the proposed rule (88 FR 22790, April 13, 2023), in its 2008 decision in *Sierra Club* v. *EPA,* the court held that under CAA section 302(k), emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously. In addition, as part of this rulemaking, we have gathered information that indicates many facilities already have measures in place to ensure that the emission standards are met during periods of

SSM. Therefore, we determined that these amendments, which remove and revise provisions related to SSM, are necessary to be consistent with the requirement that the standards apply at all times. More information concerning the amendments we are finalizing for SSM is in the preamble to the proposed rule and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking. Therefore, we are finalizing our approach for the SSM provisions as proposed.

F. Other Amendments to the Standards

1. What other amendments did we propose for the Commercial Sterilization Facilities source category?

We proposed that owners and operators would be required to demonstrate compliance via annual performance testing and parametric monitoring of EtO through the use of CEMS. As discussed in section III.G.2.c of the proposal preamble (88 FR 22790, April 13, 2023), we did not propose to include requirements for fenceline or ambient air monitoring as part of this rule for the following reasons:

- Typically for this type of monitoring, we require the fenceline monitor to be located at least 50 meters from the source of emissions to allow for some dispersion.
- In contrast to the large number of dispersed and difficult-to-monitor emission points for other source categories for which we have either finalized or proposed fenceline monitoring requirements (*e.g.,* refineries), current room air releases at commercial sterilization facilities are typically at ground-level and consist of uncontrolled building emissions through doorways, loading points, and ventilation exhausts, all of which can be captured while inside the building and routed through a vent to a control device.
- The proposed PTE design criteria, room air emission standards, and associated parametric monitoring would effectively and continuously ensure these previously uncontrolled emissions are captured and routed to exhaust points that are then subject to removal or emission rate standards.

With respect to fenceline monitoring, we solicited comment on (1) whether fenceline monitoring should be required regardless of the proposed PTE design criteria, proposed room air emission standards, and proposed continuous parametric monitoring; (2) the technical feasibility of fenceline monitoring and available technology able to measure at any potential action level; and (3) the potential cost of continuous fenceline monitoring and associated work practices if implemented.

With respect to ambient air monitoring, we solicited comment on how this could be used to screen for elevated concentrations of EtO above the ambient baseline and how this information could be used to trigger a root cause analysis to identify potential source(s) of emission and to perform corrective action, if a potential source of the emissions was part of an affected source under the commercial sterilization proposed rule. We also solicited comment on (1) the feasibility of other types of air monitoring that could be applied to this sector for compliance assurance and the costs associated with this type of monitoring, (2) how frequently this monitoring should occur, (3) the recordkeeping and reporting requirements for this type of monitoring, and (4) how should any action-level be defined.

We proposed various changes to the performance testing requirements to ensure that the results are as accurate as possible, including the approved test methods, requirements for SCV inlet testing, and 24-hour test runs for larger users. Furthermore, we proposed various changes to the parametric monitoring requirements, as well as requirements for demonstrating continuous compliance with the PTE requirements given in EPA Method 204.

We also proposed that owners or operators submit electronic copies of required compliance reports (at 40 CFR 63.366(b) and (c)), performance test reports (at 40 CFR 63.366(f)), and performance evaluation reports (at 40 CFR 63.366(g)) through the EPA's CDX using CEDRI, and we proposed two narrow circumstances in which owners or operators may, within five business days of the reporting deadline, seek extensions of that deadline if they are prevented from reporting by conditions outside of their control. We proposed at 40 CFR 63.366(h) that an extension may be warranted due to outages of the EPA's CDX or CEDRI that precludes an owner or operator from accessing the system and submitting required reports. We also proposed at 40 CFR 63.366(i) that an extension may be warranted due to a *force majeure* event, such as an act of nature, act of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

Finally, we proposed to reinstate title V permitting requirements for all area source facilities, and we proposed compliance mechanisms for owners and operators of combined emission streams. We also proposed revisions to clarify text or correct typographical errors, grammatical errors, and cross-reference errors.

2. How did the other amendments for the Commercial Sterilization Facilities source category change since proposal?

We are finalizing a requirement for owners and operators to use EtO CEMS to demonstrate compliance. In addition, for affected sources with a percent emission reduction standard, we are finalizing a requirement for source owners or operators to obtain and record hourly average ppbvd of EtO concentration, dscfm of flow rate, and weight differential in pounds of EtO used, to calculate and record each day of operation—where any operation less values obtained during periods of SSM constitute a day of operation—and the emission limit(s) based on the 30-operating day rolling sum of EtO entering the control system(s), as determined using values from the current operating day and the previous 29 operating days. However, owners and operators of facilities where EtO use is less than 100 lb/year will have the option to demonstrate compliance through annual performance testing and parametric monitoring. We are not including requirements for fenceline or ambient air monitoring in this final rule. For EtO CEMS, based on comments received during the proposed rulemaking, we are finalizing a requirement for quarterly reporting, as well as a minimum data availability of 90 percent. For performance testing, we are finalizing the incorporation of additional test methods. Based on comments received during the proposed rulemaking, we are also retaining currently approved test methods that we proposed to remove, and we are not finalizing a requirement to conduct SCV inlet testing. For performance test duration, based on comments received during the proposed rulemaking, we are not finalizing a requirement for 24-hour test runs. Instead, owners and operators may continue to conduct 1-hour test runs for ARVs, CEVs, room air emissions, or any combination thereof. For emission streams that contain an SCV, we are finalizing a requirement for owners and operators to include a representative test period as part of their test protocol, which is subject to approval from the delegated authority. Based on comments received during the proposed rulemaking, we are finalizing numerous revisions to the proposed requirements for parametric monitoring. Furthermore, based on comments received during the proposed

rulemaking, we are not finalizing a requirement for owners and operators that are required to comply with EPA Method 204 to conduct daily inspections of all applicable NDOs. Instead, we a finalizing a requirement for owners and operators to demonstrate continuous compliance with EPA Method 204 through the use of either outlet volumetric flow rate monitors or differential pressure monitors.

We are not finalizing a requirement for all area source facilities to obtain a title V operating permit. In addition, based on comments received during the proposed rulemaking, we are finalizing revised compliance mechanisms for combined emission streams. We are also finalizing an option for owners and operators to demonstrate compliance with a site-wide emission limitation, as opposed to demonstrating compliance for each individual and combined emission stream.

3. What key comments did we receive on the other amendments for the Commercial Sterilization Facilities source category and what are our responses?

Comment: We received extensive comment on our proposal to allow either the use of EtO CEMS or annual performance testing with parametric monitoring for demonstrating compliance with emission standards. Some commenters stated that EtO CEMS should be the only mechanism allowed for demonstrating compliance, as it will yield more real-time data that will allow for potential issues to be identified and resolved more quickly. Other commenters stated that EtO CEMS are a relatively new technology and that the available supply, reliability in industrial facilities, and maintenance support for EtO CEMS is questionable. Commenters also expressed concerns with parametric monitoring and pointed to our requirements for CEMS in other rules, as well as the fact that EtO CEMS are used in a number of sterilization facilities.

Response: In the majority of instances, parametric monitoring is used to good effect as an ongoing means of ensuring that control devices continue to get necessary emission reductions. However, given the nature of EtO, in which small amounts can have large risk impacts, parametric monitoring alone will not be sensitive enough to detect very small fluctuations. In addition, many facilities in this source category are controlling their EtO emissions using systems that contain one or more control devices, each with their own parametric monitoring requirements. While this has proven to be effective in reducing EtO emissions, it can lead to multiple, simultaneous parameter collection and processing, increasing system complexity and increasing the time necessary for diagnosis and correction of control device or process problems.

Therefore, the EPA is finalizing a requirement to only use CEMS for demonstrating compliance. However, facilities where EtO use is less than 100 lb/year will still have the option to use CEMS or performance testing and parametric monitoring to demonstrate compliance. This is because risk remains at acceptable levels for these facilities even when considering uncontrolled emissions. In addition, these facilities tend to have relatively simple control systems. Although EtO CEMS is a relatively new technology in this industry, it has been proven as a highly effective method for demonstrating compliance. While the use of these CEMS systems for low-level measurements of EtO is relatively new, they are in use in this sector; because of this, we find it technically feasible to require their use more broadly. Additionally, the EtO instruments used as part of these CEMS are readily available and although the low-level detection levels are recent, they have been demonstrated in the field.

Comment: We received extensive comments on our decision to not include fenceline or ambient air monitoring as part of the proposed rulemaking. Some commenters were supportive of this exclusion, stating that this source category is comprised of enclosed facilities with defined emission points (*e.g.,* windows, doors, ventilation exhaust) and that PTE is sufficient to ensure the containment of emissions. Other commenters were opposed to this exclusion, stating that fenceline and ambient air monitoring are necessary in order to ensure that commercial sterilization facilities are complying with the rule requirements, as well as to provide important information about emissions, exposure, and the efficacy of control equipment to nearby communities, regulatory agencies, and workers. The commenters pointed to other source categories where we have either required fenceline monitoring (*i.e.,* petroleum refineries) or proposed it (*i.e.,* the Synthetic Organic Chemical Manufacturing Industry and the Polymers and Resins industry).

Response: We acknowledge that many commenters expressed their strong support for fenceline monitoring requirements as part of this rule. As a general matter, fenceline monitoring is considered a particularly useful compliance monitoring approach if it is infeasible to enclose an emission source(s). This is the case for source categories where we have either required or proposed fenceline monitoring, such as refineries, because facilities within these source categories cover a wide variety of emission sources where PTE is not feasible. At such sources, it is frequently impossible to rapidly detect and remedy a leak or other unauthorized release without the use of fenceline monitoring.

By contrast, as discussed in section IV.B.3.c, PTE in accordance with EPA Method 204 has been demonstrated to be feasible for commercial sterilization facilities. As part of the PTE requirements the EPA is finalizing in this rule, the EPA is also requiring monitoring of either the volumetric flow rate from each outlet or differential pressure in order to ensure that the PTE is operating effectively on a continuous basis. Furthermore, as discussed above, we are requiring EtO CEMS at facilities where EtO use is at least 100 lb/year, which includes most facilities within the source category. The data from these CEMS will help to ensure that commercial sterilization facilities are complying with the rule requirements, and the data will be made available to the public, providing important information about emissions, exposure, and the efficacy of control equipment to nearby communities, regulatory agencies, and workers. As noted above, the physical configuration of commercial sterilizer facilities can also make the implementation of fenceline monitoring challenging at these sources. For these reasons, the EPA is not finalizing fenceline monitoring requirements as part of this rule.

Comment: We received extensive comments on our proposed requirement that EtO CEMS data be reported on a daily basis. Some commenters were supportive, stating that daily reporting provides assurance to the public that emission control devices are working as designed. Other commenters were opposed, stating that facilities need sufficient time to conduct QA/QC to verify the accuracy and reliability of the data and that reporting inaccurate data due to insufficient QA/QC would undermine public confidence of the CEMS monitoring and potentially adversely impact the medical supply chain if there is undue public concern. One commenter questioned whether there is a precedent for daily reporting, and another was unaware of any other NESHAP that requires daily reporting for CEMS. Several commenters stated that quarterly or semi-annual reporting is sufficient and more consistent with other NESHAPs.

Response: We agree with the commenters' concern that daily reporting of CEMS data is not appropriate. Sufficient time is needed so that the proper QA/QC procedures can be conducted to verify the accuracy and reliability of the data. Therefore, we are finalizing a requirement that CEMS data be reported quarterly, which is consistent with other NESHAPs that regulate pollutants of significant concern, as well as at least one sterilization facility that uses CEMS to demonstrate compliance with local requirements.

Comment: One commenter stated we did not address CEMS downtime and how downtime will be assessed or impact reporting. In addition, two commenters stated that there should be allowances or an exemption from sampling during periods of non-operation (*e.g.,* power outages, plant shutdowns).

Response: Our general policy is to require source owners and operators to have working monitoring while the emissions-producing process is operating and to identify those periods where monitoring is not working while the emissions-producing process is operating, as well as to quickly correct monitoring issues so that such periods are minimized. Recognizing that EtO CEMS are a newer technology that may pose challenges to users who may be unfamiliar with instrument characteristics, the rule will provide a period of data unavailability for up to ten percent of process operating time for EtO CEMS in operation before requiring additional corrective activity by owners or operators. Such an allowance, referred to as a minimum data availability requirement, has been used to good effect for other types of CEMS as they were introduced. As familiarity with those CEMS increased, so did their minimum data availability requirements; the EPA expects this pattern to continue for EtO CEMS such that in the future, the minimum data availability requirement for EtO CEMS will be replaced by the agency's general policy. Until then, the rule will have a minimum data availability for EtO CEMS of ninety percent. This means that EtO emissions data must be collected over at least ninety percent of the process operating time in order to avoid non-compliance and potential penalties. Data availability will be determined by assessment of the ratio of periods of valid EtO CEMS values to process operation periods, where valid EtO CEMS values occur when a minimum of 4 equally spaced values occur over an hour of process operation. Periods associated with normal quality assurance activities, such as daily calibrations, do not count as periods of data unavailability, however, periods of out-of-control monitor operation or when the EtO CEMS is unable to provide quality-assured data, such as those periods associated with monitor or data acquisition and handling system failure, do count as periods of data unavailability. Note that source owners or operators are to record EtO CEMS values during all periods of operation, include SSM, to the extent that the values are available. Source owners or operators will need to keep records of periods of process operation, EtO CEMS availability, and EtO CEMS unavailability; cause and duration of EtO CEMS unavailability; and of activity taken to correct and prevent future periods of EtO CEMS unavailability. Moreover, owners or operators will be required to provide immediate notice of failure to meet the data availability of 90 percent, as well as root cause analysis of periods of EtO CEMS monitor unavailability and specific corrective actions—along with schedule and enumerated expenditures—planned to address EtO CEMS unavailability.

Comment: Several commenters stated that the requirement to measure SCV inlets can create significant safety hazards. Two commenters stated that EtO concentrations in abatement system inlets coming from SCVs can reach several hundred thousand ppm. The commenters noted that these concentrations exceed the lower explosion limit of 30,000 ppm, thereby posing a significant explosion risk. Commenters noted that this situation could also expose workers to EtO levels above the Immediately Dangerous to Life or Health limit set by the U.S. Occupational Safety and Health Administration (OSHA), resulting in hazardous working conditions. Several commenters stated that we should retain the option to determine emission reduction using mass balance calculations and pounds of EtO injected into the sterilization chamber to ensure safe testing practices.

Response: We agree with the commenters' concerns regarding the safety risks associated with testing the SCV inlet. Therefore, we are removing this requirement for SCVs from the final rule. Owners and operators must instead determine the mass of EtO emissions from the SCV by measuring the daily change in weight of the EtO drums that are used to charge the sterilization chamber.

Comment: Several commenters were opposed to our proposed requirement for each performance test run to be conducted over a 24 hour period for facilities where EtO use is at least 10 tpy, stating that this requirement is difficult, infeasible, and of limited value. The commenters stated that there are a limited number of testing companies with both the experience to conduct performance tests of this length, as well as the personnel to remain at facilities during these long performance test periods. The commenters stated that multiple companies will be in demand for these limited services and that scheduling these performance tests so that the medical supply chain is not adversely impacted will be difficult. In general, the commenters agreed that a performance test run longer than one hour is necessary but were divided on what constitutes a representative period, with one commenter stating that eight to 10 hours is representative, and another stating that six to 12 hours is representative. Several commenters stated the performance test duration should be determined by the facility and accompanied with a justification of how normal operations are captured over this duration. One commenter stated that ARV and room air emissions are continuous in nature and that one-hour performance test runs are sufficient for these sources. The commenter also stated the CEV operations are started and completed within an hour and, therefore, one-hour performance test runs are appropriate for these sources as well. Finally, one commenter suggested that each performance test run for facilities where EtO use is less than 10 tpy should be longer than one hour.

Response: As discussed earlier, we are finalizing a requirement to only use EtO CEMS for demonstrating compliance. In addition, owners or operators of affected sources subject to a percent emission reduction standard will obtain and record EtO concentration in ppbvd, flow rate in dscfm, and daily EtO use in pounds; determine daily amounts of EtO entering and exiting control systems; use those daily amounts to calculate and record 30-operating day rolling sums; and calculate emission limits and determine compliance based on those rolling sums. However, facilities where EtO use is less than 100 lb/year will still have the option to use CEMS or performance testing and parametric monitoring to demonstrate compliance. Therefore, our proposal for each performance test run to be conducted over a 24-hour period for facilities where EtO use is at least 10 tpy is no longer applies and is not included in the final rule. For facilities where EtO use is less than 100 lb/year, we agree that a one-hour performance test period for

ARVs and room air emissions is appropriate, as these operations are continuous in nature, with minimal variations in emissions. We also agree that a one-hour performance test period is appropriate for CEVs, as these operations are typically started and concluded in less than one hour. For SCVs, the emissions profile can vary significantly depending on the number of chambers at a facility and how the emissions are staggered. Therefore, we are finalizing a requirement for owners and operators to include a representative performance test period for SCVs, along with a justification, in their stack test protocol, so that the delegated authorities can review and approve or deny the protocol as appropriate.

Comment: We received comments on continuous compliance requirements for verifying EPA Method 204. Several commenters contended that continuously verifying the direction of airflow through daily inspections of each NDO presents significant safety risks and are redundant or impractical. They noted that NDOs may be located at ceiling levels (such as a makeup air unit) in processing areas or in other hard to reach areas where EtO concentrations may require the use of specialized protective equipment. One commenter stated that streamers are not practical, may not be observable, and often get stuck or wrapped around objects. Another commenter noted that smoke testing in EtO facilities is discouraged due to safety concerns, as any indication of fire in an EtO facility is highly problematic, and seeing smoke within the facility should not be routine. Finally, two commenters questioned the value of daily NDO inspections when other relevant parameters are being continuously monitored.

One commenter recommended the use of differential pressure monitoring to verify EPA Method 204, accompanied by a data recording system to demonstrate continuous compliance. Other commenters were opposed to any continuous compliance requirements for verifying EPA Method 204, stating that they would be burdensome, expensive, and difficult to maintain. Two commenters stated that we should change the criteria for demonstrating continuous compliance with EPA Method 204 from ''maintained above 0.007 inches of water'' to ''at least 0.007 inches of water'' to align to the Method 204 definition of facial velocity equivalence.

Response: We agree with the commenters' concerns regarding the safety and practical aspects of daily NDO inspections. Therefore, we are not including this requirement in the final rule. In order to ensure that emissions are not leaving through uncontrolled spaces, it is critical to demonstrate continuous compliance with EPA Method 204. In the absence of daily NDO inspections, differential pressure monitoring and outlet volumetric flow rate monitoring are viable options for verifying the continuous flow of air into a control device, and both of these options were included in the proposed rulemaking. Therefore, we are finalizing a requirement for owners and operators to demonstrate continuous compliance with EPA Method 204 either through outlet volumetric flow rate monitoring or through differential pressure monitoring. We also agree with commenters that, if differential pressure monitoring is used, the pressure differential should be maintained at or above 0.007 inch of water in order to demonstrate continuous compliance, as this is what is required in EPA Method 204.

Comment: We received extensive comments on our proposed requirement for all area source facilities within the source category to obtain a title V operating permit. Several commenters were supportive, citing the serious health concerns of EtO. The commenters stated that facilities with title V operating permits tend to receive more oversight and that this, along with increased community engagement, will ensure that these facilities are complying with the rule requirements. Other commenters were opposed, stating the current and proposed NESHAP included substantial compliance, parametric monitoring, recordkeeping, and reporting obligations. One commenter stated that subjecting area source EtO commercial sterilizers to the title V permitting program requires additional regulatory fees; burdensome permitting, recordkeeping and reporting requirements; increased administrative costs; as well as Clean Air Act citizen suits. Two commenters suggested that the proposed requirements could be incorporated into a State minor source permit without the additional burden of title V permitting, and that title V permits should apply only to major sources. Multiple commenters also indicated that the four-factor balancing test still weighs in favor of continued exclusion of area source facilities within this source category from title V permitting requirements.

With respect to the first factor (*i.e.,* whether title V would result in significant improvements to the compliance requirements, including monitoring, recordkeeping, and reporting that are proposed for the area source category), several commenters stated that requiring title V operating permits would not provide significant improvements to compliance requirements. Two commenters agreed with our 2005 analysis that the NESHAP requirements applicable to area sources already subjected them to continuous monitoring and assessment, reporting, and certification of compliance status on a semiannual basis, which was similar to what was required by title V. Commenters stated that the proposed rule addressed increased transparency and further strengthened monitoring, recordkeeping, and reporting requirements, including developing a new performance specification and associated QA procedures for CEMS capable of detecting EtO at very low levels. One commenter stated that we recognized that modern NESHAPs have sufficient parametric monitoring. The commenter also stated that the only gain that we identified that was not already satisfied was the public comment period for title V permitting; however, the commenter noted that many facilities may need construction permits to come into compliance with the updated requirements, during which many States have an option to hold a public comment period and a public meeting(s) for changes that may be of interest to the community. The commenter noted that, as part of this rulemaking process, the EPA held numerous public meetings for local communities regarding specific facilities and additional public outreach meetings for transparency. This commenter stated these outreach efforts and the potential construction permitting actions will eliminate the need to have the title V public comment period. Three commenters stated that one of the primary purposes of the title V program was to clarify in a single document the various and complex regulations that applied to a facility in order to improve compliance. Two commenters stated that we agreed that EtO sterilizers were still subject only to a single NESHAP. Three commenters stated the benefit of requiring a title V permit to house all applicable regulations into a single document would not apply to those area sources and was not needed, and one commenter added that area sources should be exempt from title V on that basis alone. One commenter stated that, in response to a comment on our 2005 proposed rule, we also indicated that NESHAP provisions independently required schedules of compliance, provided inspection and entry

authority, and established emissions limitations and standards that were enforceable regardless of title V permitting. This commenter noted the proposed rule asserted that the compliance benefits of title V were greater today than in 2005 and so the benefits would be greater, but the commenter argued that we made these statements without providing supporting analysis.

With respect to the second factor (*i.e.,* whether title V permitting would impose significant burdens on the area source category and whether the burdens would be aggravated by any difficulty in obtaining assistance from permitting authorities), several commenters noted that requiring area sources to obtain a title V permit would pose significant burdens on sterilization facilities, with one commenter stating that it would pose significant burden ''within the time frame being proposed.'' [68] Additionally, the commenter stated the State permitting agencies may be overly burdened in issuing title V permits at a facility with such low emissions. Several commenters stated that the proposed title V permitting requirement for area sources would be a significant burden for small businesses, as these permits required businesses to prepare significant amounts of paperwork, negotiate compliance with the permitting authority, and subject their operations and permit application to public comment or petitions that would potentially delay operations and create additional regulatory burdens that, per OMB analysis, may be biased against small businesses. One commenter noted that small businesses in this industry had no experience with title V permitting and that obtaining these permits would require additional resources. The commenter stated that we ignored the significant cost of uncertainty that title V permitting introduced to small business planning. The commenter explained that rather than hiring an engineer to determine how a facility could meet the requirements, a small business would have to engage in a process with multiple partners, develop supporting material that may or may not be sufficient in the eyes of the regulatory authority, and prepare a public relations strategy in anticipation of community opposition to their operations, and that this investment must be made without the certainty of an outcome that will allow continued operation. One commenter noted that many Small Business Environmental Assistance Programs are precluded from assisting with title V permitees and, as such, this rule could strip small businesses of the assistance mandated under CAA section 507. One commenter stated that our justification seemed premised on an expectation of noncompliance, although clarified that we had not alleged that small commercial sterilizers have a history of noncompliance. The commenter noted that recent controversies around EtO facilities had centered around large facilities owned by large businesses. The commenter indicated it was not clear how title V permitting of area sources would create additional incentives for compliance or give State enforcement authorities the resources and expertise they would not otherwise have to enforce this NESHAP. One commenter stated the addition of title V permitting for area sources formalized community involvement in the authorization of area source commercial sterilizers, and that this level of community review was unnecessary and overly burdensome. Another commenter noted that the public already had access to commercial sterilizer locations, emissions, and current standards to which they were subject via our website and regulations, as well as our community outreach to advise the public of the hazards of EtO.

With respect to the third factor (*i.e.,* whether the costs of title V permitting for area sources would be justified taking into consideration any potential gains in compliance likely to occur for such sources), two commenters stated there would be no justification for imposing the burden of title V permitting. One commenter stated that we could have separated the cost estimate for the 86 area sources in order to provide more accurate numbers. Additionally, the commenter stated that the 2019 cost estimates were not accurate, as the new rules would require facilities to change not only their equipment, but also their calculation methods, monitoring, and testing. The commenter stated that those costs needed to be considered in a title V cost analysis. Three commenters stated that our cost estimate for obtaining a title V permit underestimated the cost of this requirement and that we should not add to the burdens for area sources. One commenter stated that the time and cost of getting a title V permit did not correlate to the potential gains and that we provided no supporting data for our conclusion that the average costs associated with title V ($67,211 for the first year, as calculated in 2019) will likely be less for area sources. This commenter suggested that our cost determination did not align with the proposed rule, which said ''the rule amendments proposed provide for a greater degree of complexity and requirements to achieve and demonstrate compliance for area sources.'' One commenter noted that we stated that the burden was not insignificant, but justified the costs because it represented a small portion of the anticipated costs related to the amendments of the proposed rule. One commenter stated that the analysis on title V applicability did not ask how the burden compared to the cost of complying [with] some other measure, but that the question was whether the potential compliance benefits outweighed the steep costs, the answer to which we seemed to concede was ''no.''

With respect to the fourth factor (*i.e.,* whether adequate oversight by State and local permitting authorities could achieve high compliance with the NESHAP requirements without relying on title V permitting), one commenter stated that CAA sections 112, 113, and 114 required implementation and enforcement programs to be conducted by the EPA or delegated to the proper State authority and a small business assistance program to assist area sources exempted from title V with compliance. The commenter noted that States and the EPA routinely conducted voluntary compliance assistance outreach and education programs. The commenter noted that the EPA's review of State-provided empirical data demonstrated that area sources were adequately compliant with their requirements without title V permitting. The commenter stated that the proposed rule is silent on whether permitting authorities could effectively implement NESHAPs without title V, and that the EPA alluded to its 2019 ICR, implying that the responses thereto supported the EPA's title V decision, but the EPA never identified specific data or explained how it would support any of EPA's cursory statements. The commenter concluded that there was no more difficulty enforcing the single NESHAP for area sources now versus in 2005, when EPA unequivocally determined title V would provide no benefits to its ability to enforce CAA regulations in tandem with its State and local partners. The commenter stated that requiring title V now would only make enforcement more difficult, as State agencies would be flooded with

[68] Commenter provided the following statement: ''Requiring areas sources to obtain a title V permit would pose significant burdens on sterilization facilities especially within the time frame being proposed.'' (see Docket Item No. EPA–HQ–OAR–2019–0178–0632, Attachment 2, page 20).

title V applications that would require time and State funds to implement and could potentially shift attention away from major source compliance in a way that would compromise (and not improve) implementation of any final NESHAP program. Another commenter stated there was already sufficient oversight by State and local permitting authorities, as well as subpart O requirements. One commenter stated that, as a State regulatory agency, they had the ability to adequately ensure compliance with the proposed standard for facilities within their jurisdiction regardless of whether the facility is subject to title V permitting. Another commenter stated the proposed removal of the title V permitting exemption for area sources meant a significant number of small operations would be required to obtain title V permits for the first time, and as many of these area sources were subject to a limited set of applicable requirements and permits, there was little apparent benefit from the consolidation of these requirements within a title V permit. One commenter stated that the EPA failed to discuss whether there was a history of noncompliance with the EtO Commercial Sterilization NESHAP, which indicated that that there are few potential gains from the increased burdens. Finally, one commenter stated that State operating permits (*e.g.,* Synthetic Minor or Federally Enforceable State Operating Permits) are abundant and adequate to deal with these GACT sources without the added expense, complication, and delays associated with title V permitting.

Response: We agree with commenters that the four-factor balancing test continues to weigh in favor of exempting area source facilities from title V permitting. In particular, we agree with commenters that one of the primary benefits of the title V program is to clarify, in a single document, the various and complex regulations that apply to a facility in order to improve compliance, and that this benefit is not realized in this case because commercial sterilization facilities are subject to only one NESHAP (Subpart O). In addition, we agree with commenters that, in light of the robust monitoring, recordkeeping and reporting requirements in the final rule, a title V permit would likely not add any substantial monitoring, recordkeeping and reporting requirements. We further note that, even in the absence of title V permitting requirements, this final rule will ensure transparency around the emissions from these facilities by requiring that EtO CEMS data be reported on a quarterly basis, and this data will be made available to the public.

In summary, the benefits of requiring title V permitting for area source facilities are not outweighed by the concerns. For the reasons stated above, we agree with commenters that the four-factor balancing test continues to weigh in favor of exempting area source facilities from title V permitting on the basis that title V is unnecessarily burdensome. Therefore, we are not finalizing title V permitting requirements for area source facilities.

Comment: One commenter suggested that we require only a single combined performance test for the outlet point and that the most stringent applicable standard (*i.e.,* the control level required for the SCV) should be applied. Two commenters stated that our affected source proposal is unnecessarily complicated. One commenter stated that where control equipment has a single inlet and outlet, the facility should not be required to test individual source inlets or outlets. The commenter also stated that it is logical that point sources routed to the same emission control system should be defined as a single unit. The commenter stated it is important to set emission limits that reflect this reality and test methods that allow for combined system testing at the outlet of the system. The commenter also stated that the proposed language implies that the SCV, CEV, and ARV must be tested separately, which is challenging given the complexity in design of existing duct work and access to inlets. The commenter stated that testing the combined inlet to the APCD would be the safest, most accurate, and most cost-effective method for determining compliance for facilities with combined emissions. Another commenter stated that applying the most restrictive removal efficiency standard when different sources are combined is impractical.

Response: The EPA is finalizing approaches that will provide facilities with flexibility in terms of how they choose to demonstrate compliance with the standards for instances where emission streams are combined prior to entering a control system. Facilities can determine compliance via one of two options:

- *Option 1:* Determine the mass of EtO entering the control device at a point after the emission streams are combined, and apply the most stringent emission reduction standard that the component streams are subject to.
- *Option 2:* Determine the mass of EtO entering the control device at points before the emission streams are combined, and apply the emission reduction standards that the component streams are subject to.

Option 1 is consistent with what was proposed, and Option 2 has been added in order to provide more flexibility for facilities in terms of how they chose to demonstrate compliance. As an example, suppose an area source facility uses at least 30 tpy but less than 60 tpy, and the facility chooses to control all of its ARVs and CEVs with one control system. The emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. In this example, suppose the mass of EtO emissions from the ARVs is 4 lb, and the mass of EtO emissions from the CEVs is 1 lb, meaning that the mass of EtO emissions from the combined stream is 5 lb. Under Option 1, the facility would need to apply an emission reduction of 99.9% to the combined stream, resulting in an emission limit of 0.005 lb. Under Option 2, the facility would apply an emission reduction of 99.9% to the ARV stream and an emission reduction of 99% to the CEV stream, resulting in an emission limit of 0.014 lb. When an affected source is subject to a relatively high emission reduction standard, it can be difficult to demonstrate compliance with that standard when the concentration of pollutants going into the control device is low. By combining emission streams and increasing the concentration of pollutants in the air stream, it is easier to demonstrate compliance.

Comment: One commenter recommended the creation of the option for a site-wide emission limitation. This limitation could take the form of either overall removal efficiency, or a total mass rate per hour. Another commenter suggested a site-wide emission limitation based upon EtO usage and end-state emissions and identified as precedent an Illinois construction permit containing monthly and annual mass emissions caps. The commenter also suggested a compliance option by emission reduction or emission rate standards and identified as precedent Illinois legislation requiring 99.9 percent emission reduction at each exhaust point or limitation of EtO emissions to 0.2 ppm.

Response: We agree with the creation of an option for a site-wide emission limitation and have included this in the final rulemaking. Specifically, we are finalizing two options for determining compliance on a site-wide basis:

- *Option 1:* Determine the mass of EtO being used at the facility and apply the SCV emission reduction standard, which is the most stringent emission

reduction standard that any emission stream at the facility is subject to.

• *Option 2:* Determine the mass of EtO being emitted from each affected source, and apply the emission reduction standards that each affected source is subject to. For SCVs, the mass of EtO may be determined by measuring how much is used and then applying a facility-specific factor that accounts for EtO entering the control systems from other affected sources.

We disagree with the suggestion to set an emissions cap, as the amount of EtO that a facility will use in a given month is unknown.

4. What is the rationale for our final approach and final decisions for the other amendments for the Commercial Sterilization Facilities source category?

We are not finalizing a requirement for all area sources facilities to obtain a title V operating permit, and we are not including requirements for fenceline or ambient air monitoring as part of this final rule. Based on the comments received during the proposed rulemaking, we are requiring EtO CEMS for facilities where EtO use is at least 100 lb/year, and we are finalizing a requirement for EtO CEMS data to be reported quarterly. We are not finalizing a requirement for owners and operators to conduct SCV inlet testing, and we are not finalizing a requirement for each performance test run to be conducted over a 24-hour period. Lastly, we are finalizing revised compliance mechanisms for combined emission streams, as well as the option for facilities to demonstrate compliance with a site-wide emission limit, as opposed to having to demonstrate compliance for each individual and combined emission stream. See section IV.F.3 of this preamble for further discussion.

In a few instances, we received comments that led to additional minor editorial corrections and technical clarifications being made in the final rule, and our rationale for these corrections and technical clarifications can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

As part of the proposed rulemaking, we estimated that there were 86 existing commercial sterilization facilities and two planned facilities. However, based on comments received on the proposed rulemaking, we understand that one of the existing facilities has closed. In addition, the commenters identified three existing commercial sterilization facilities that were unknown during the proposed rulemaking. However, it should be noted that EtO use at the three facilities that were previously unknown is very small (*i.e.,* less than 1 tpy). A complete list of the known 88 Commercial Sterilization Facilities that are affected by this rulemaking is available in Appendix 1 of the document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

B. What are the air quality impacts?

At the current level of control prior to the amendments being finalized in this action, the EPA estimates that EtO emissions were approximately 23 tpy (actuals) and 160 tpy (allowables) from commercial sterilization facilities. At the level of control required by the amendments being finalized in this action, which includes standards for previously unregulated sources and amendments to all sources where standards were already in place, we estimated EtO emissions reductions of 21 tpy (actuals) and 150 tpy (allowables) for the source category.

C. What are the cost impacts?

The total capital investment cost of the final amendments and standards is estimated to be approximately $313 million in 2021 dollars. We estimate total annual costs of the final amendments to be approximately $74 million.

The present value (PV) of the estimated compliance costs over the 20-year timeframe from 2025 to 2044 for the final rule is $773 million in 2021 dollars, discounted at a 7 percent rate. The equivalent annualized value (EAV) of the costs is $88 million, using a 7 percent discount rate. Using a 3 percent discount rate, the PV and EAV of the costs from 2025 to 2044 are estimated to be $932 million and $63 million, respectively.

The nationwide costs of the different amendments being finalized in this action are presented in table 2 of this preamble. As described in this preamble, we are finalizing standards for previously unregulated sources, as well as amendments for sources where standards were already in place. Many of the emissions capture and control technologies that are needed to comply with the final rule will impact multiple sources at once, and those costs form the basis of our impact estimates. These costs are presented in table 2 of this preamble. There are 90 facilities (including the 88 existing facilities and the two planned facilities) affected by the amendments, and the number of facilities associated with each of the specific costs is indicated in table 2. The facility list was developed using methods described in section II.C of the proposal preamble (88 FR 22790, April 13, 2023). A complete list of known commercial sterilization facilities is available in Appendix 1 of the document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

D. What are the economic impacts?

The economic impact analysis is designed to inform decision makers about the potential economic consequences of the compliance costs outlined in section V.C of this preamble. The EPA performed a screening analysis that compared compliance costs to revenues at the ultimate parent company level (several companies own more than one affected facility). This is known as the cost-to-revenue or cost-to-sales test, or the ''sales test.'' The use of a sales test for estimating small business impacts for a rulemaking is consistent with EPA guidance on compliance with the Regulatory Flexibility Act (RFA) and is consistent with guidance published by the U.S. Small Business Administration's Office of Advocacy that suggests that cost as a percentage of total revenues is a metric for evaluating cost increases on small entities in relation to increases on large entities.

There are 88 existing commercial sterilization facilities and 2 planned commercial sterilization facilities, owned by 50 parent companies, affected by the final amendments. Of the parent companies, 22 companies, or 44 percent, are small entities based on the U.S. Small Business Administration's table of size standards. Next, we determined the magnitude of the costs of the amendments being finalized in this action for each entity and then calculated a cost-to-sales ratio for each entity by comparing estimated costs to the annual revenues of each parent company. We then assessed whether there would be potential for a significant impact on small entities based on the cost-to-sales ratios. For all entities, the average cost-to-sales ratio is approximately 8 percent; the median cost-to-sales ratio is 0.2 percent; and the

maximum cost-to-sales ratio is approximately 69 percent. For large firms, the average cost-to-sales ratio is approximately 0.2 percent; the median cost-to-sales ratio is 0.03 percent; and the maximum cost-to-sales ratio is 1.3 percent. This rule has potentially significant impacts on small entities. For small firms, the average cost-to-sales ratio is approximately 18 percent, the median cost-to-sales ratio is 4.7 percent, and the maximum cost-to-sales ratio is 69 percent. There are 13 small entities (59 percent of all affected small entities) with estimated cost-to-sales ratios of 3 percent or greater. See the Regulatory Impact Analysis for further detail on the cost estimates, small entity impact analysis, and a discussion of potential market and economic impacts.

The EtO sterilization industry is an integral part of the supply chain for many medical devices and capacity constraints have been reported. Based on the data we analyzed, we expect that the largest impacts of this rule are limited to a handful of the companies that play a key role in the availability of certain medical devices, and several of them are already in the planning stage for additional controls.

Some companies involved in medical device sterilization have installed, or are already planning for installation of, additional emissions controls. The controls necessary to meet the requirements of this final rule include PTEs and gas/solid reactors, along with (in some cases) alterations to facility design to ensure adequate capture of EtO emissions. Such controls rely on existing technologies that are commercially available from manufacturers and are already well established in this industry. In addition, a few companies have constructed, or are in the process of constructing, new facilities with state-of-the-art design and control installations to ensure full capture and control of EtO emissions. These early actions by industry demonstrate the feasibility of implementing the requirements in this final rule.

Over the last several years, the industry has demonstrated the capability to install controls on multiple facilities simultaneously without interfering with medical supply chains. For example, three companies re-designed their Illinois and Georgia facilities to comply with the PTE requirements of EPA Method 204, as well as installed emission controls at these facilities during overlapping timeframes from May 2019 through August 2020 without disruption to the medical supply chain. As discussed in section III.G of this preamble, we have reviewed the time that it has taken for these projects to be completed, from submission of the initial permit application to installation of the continuous compliance mechanisms. Based on this review, we found that the process of bringing a facility into compliance with the PTE requirements of EPA Method 204, as well as installing and verifying additional emission controls, takes approximately a year from permit submission to project completion.

The EPA has evaluated available information about the state of control installations at existing commercial sterilization facilities. Of the 88 existing facilities, seven appear have already met the emission standards and will not need to install additional emission controls. Another 55 facilities appear to only need additional abatement devices. We expect that 28 facilities still need to meet the PTE requirements of EPA Method 204 and install additional abatement devices. Table 22 presents the apparent compliance status with the final rule for each relevant emission source and facility EtO use combination, based on controls that are currently in place.

TABLE 22—APPARENT COMPLIANCE STATUS WITH FINAL RULE AND COMPLIANCE TIMEFRAMES

Emission source	Facility EtO use	Number of facilities with this affected source	Number of facilities appearing to achieve final standard [1]	Compliance timeframe
SCV	At least 30 tpy	38	19	Two years.
	At least 10 but less than 30 tpy.	9	9	Two years.
	At least 1 but less than 10 tpy.	18	16	Two years.
	Less than 1 tpy	23	22	Three years.
ARV	At least 30 tpy	36	12	Two years.
	At least 10 but less than 30 tpy.	5	5	Three years.
	At least 1 but less than 10 tpy.	10	7	Three years.
	Less than 1 tpy	4	2	Three years.
CEVs at major source facilities	N/A	0	N/A	Three years.
CEVs at area source facilities	At least 60 tpy	25	12	Two years.
	Less than 60 tpy	15	8	Three years.
Group 1 room air emissions at major sources	N/A	0	N/A	Three years.
Group 1 room air emissions at area sources	At least 40 tpy	36	16	Two years.
	Less than 40 tpy	38	7	Three years.
Group 2 room air emissions at major sources	N/A	1	0	Three years.
Group 2 room air emissions at area sources	At least 20 tpy	44	17	Two years.
	At least 4 but less than 20 tpy.	13	1	Two years.
	Less than 4 tpy	27	27	Three years.

[1] The phrase ''appearing to achieve'' is used (as opposed to ''achieving'') to account for uncertainties in the data. A notable example is the SCVs where, for a given facility, the emission reduction on the first evacuation may not high enough to ensure that the standard is being met across all evacuations. Another uncertainty is the fraction of EtO going to each emission stream. In some instances, there is facility-specific information available, and in others, there is no information available and default fractions are applied as a result.

E. What are the benefits?

The EPA did not monetize the benefits from the estimated emission reductions of HAP associated with this final action. The EPA currently does not have sufficient methods to monetize benefits associated with HAP, HAP reductions, and risk reductions for this rulemaking. However, we estimate that the final rule amendments would reduce EtO emissions by 21 tons per year and expect that these reductions will lower the risk of adverse health effects, including cancer, for individuals in communities near commercial sterilization facilities. For example, the estimated cancer incidence due to emissions from the source category would be reduced from 0.9 to between 0.1 to 0.2, or from 1 cancer case every 1.1 years to 1 cancer case every 5 to 10 years.

F. What analysis of environmental justice did we conduct?

Consistent with applicable executive orders and EPA policy, the EPA has carefully analyzed the environmental justice implications of the benefits associated with the reductions in EtO emissions as a result of this final rule. The EPA conducted this analysis for the purpose of providing the public with as full as possible an understanding of the potential impacts of this final action. The EPA believes that analyses like this can inform the public's understanding, place EPA's action in context, and help, identify and illustrate the extent of potential burdens and protections.

As part of understanding the impacts of this source category and of this final rule, we examined the potential for the 88 facilities that were assessed to pose concerns to communities with EJ concerns both in the baseline *i.e.,* under the current standards) standards considered in this final rule.

To examine the potential for EJ concerns in the pre-control baseline, we conducted two baseline demographic analyses, a proximity analysis and a risk-based analysis. The baseline proximity demographic analysis is an assessment of individual demographic groups in the total population living within 10 kilometers (km) and 50 km of the facilities. In this preamble, we focus on the 10 km radius for the health risk assessment and for the demographic analysis because it encompasses all the facility MIR locations and captures 100 percent of the population with risks greater than 100-in-1 million. The results of the proximity analysis for populations living within 50 km are included in the technical report included in the docket for this final rule for the public's understanding.

The baseline risk-based demographic analysis is an assessment of risks to individual demographic groups in the population living within the 10 km and 50 km radii around the facilities prior to the implementation of any controls finalized by this action (''baseline''). Again, in this preamble, we present for the public's understanding the results for populations living within 10 km of facilities. Results for populations living within 50 km are included in the technical report included in the docket for this final rule.

Overall, the results of the proximity demographic analysis (see first three columns of table 23) indicate that the percent of the population living within 10 km of the 88 facilities that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven largely by the seven facilities in Puerto Rico. The baseline proximity analysis indicates that the proportion of other demographic groups living within 10 km of commercial sterilizers is closer to the national average. The baseline risk-based demographic analysis (see ''baseline'' column in tables 23 to 25), which presents information for individuals that are expected to have higher cancer risks (greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million), suggests that the African American, Hispanic or Latino, below the poverty level, over 25 and without a high school diploma, and linguistically isolated demographic groups are also disproportionally represented at the higher risk levels.

The post-control risk-based demographic analysis presents information on current health risks and how the standards considered in this final regulatory action would affect the distribution of these risks across the populations and communities identified in the baseline. The CAA section 112(d)(2), (3), and (5) post-control scenario is shown in tables 23 to 25 and the residual risk post-control options are shown in tables 26 to 28. The post-control options show a substantial reduction in the number of individuals at each risk level, as well as a significant reduction in the proportion of African Americans that experience higher risk levels from facilities in this source category. We project that a majority of the individuals that would remain at risk after implementation of the final standards are Hispanic or Latino, driven largely by the facilities in Puerto Rico.

These three distinct but complementary analyses indicate the potential for EJ concerns associated with this source category in the baseline, as well as the substantial anticipated benefits these final standards will have in reducing EtO emissions and associated health risks for all of the affected public, including people living in communities with EJ concerns. Those benefits include that no individual is expected to be exposed to inhalation cancer risk levels above 100-in-1 million due to emissions from this source category after implementation of all the CAA standards finalized in this action.

The methodology and detailed results of the demographic analysis are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action, but a synopsis is provided below. We also received comments on the demographic analysis. Those comments and our specific responses can be found in the document, *Summary of Public Comments and Responses for the 2024 Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

1. Demographics

The first three columns of tables 23, 24, and 25 of this document show the total population, population percentages, and population count for each demographic group for the nationwide population and the total population living within 10 km of EtO sterilization facilities. A total of 17.3 million people live within 10 km of the 88 facilities that were assessed. The results of the proximity demographic analysis indicate that the percent of the population that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities in PR are Hispanic or Latino. The percent of the population that is ''Other and multiracial'' (11 percent) is higher than the national average (8 percent). The percent of people living below the poverty level (15 percent) and those over the age of 25 without a high school diploma (16 percent) are higher than the national averages (13 percent and 12 percent, respectively). The percent of people living in linguistic isolation [69] is double

[69] Linguistic Isolation is defined in the U.S. Census Bureau's American Community Survey as ''a household in which all members age 14 years and over speak a non-English language and also

Continued

the national average (10 percent versus 5 percent). We note that this estimate of linguistic isolation is largely driven by the facilities in Puerto Rico, where an average of 67 percent of the population is in linguistic isolation in comparison to the national average.

In summary, the baseline proximity analysis indicates that the percent of Hispanic or Latino populations living near commercial sterilizers (within 10 km) is higher than what would be expected based on the national average distribution. This is largely driven by the seven facilities located in Puerto Rico where, on average, the population of 658,000 people living within 10 km of these seven facilities is 99 percent Hispanic or Latino. In addition, the population around the facilities in Puerto Rico has 67 percent living in linguistic isolation, 45 percent living below the poverty level, and 24 percent over 25 without a high school diploma.

2. Baseline Risk-Based Demographics

The baseline risk-based demographic analysis results are shown in the ''baseline'' column of tables 23, 24, and 25. This analysis presented information on the populations living within 10 km of the facilities with estimated actual cancer risks greater than or equal to 1-in-1 million (table 23), greater than or equal to 50-in-1 million (table 24), and greater than 100-in-1 million (table 25). The risk analysis indicated that emissions from the source category, prior to the reductions we are finalizing, expose a total of 5.3 million people to a cancer risk greater than or equal to 1-in-1 million around 75 facilities, 124,000 people to a cancer risk greater than or equal to 50-in-1 million around 38 facilities, and 19,000 people to a cancer risk greater than 100-in-1 million around 16 facilities. The demographics of the baseline population with estimated cancer risks greater than or equal to 1-in-1 million are very similar to the total population within 10 km. Specifically, the percent of the population that is Hispanic or Latino is more than two times larger than the national average (39 percent versus 19 percent), the percent below the poverty level is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (18 percent versus 12 percent), and the percent linguistic isolation is two times the national average (11 percent versus 5 percent).

In contrast, the smaller populations with baseline cancer risk greater than or equal to 50-in-1 million (124,000 people), and greater than 100-in-1 million (19,000 people) are predominantly made up of African Americans (43 and 31 percent versus 12 percent nationally), and have a higher percentage of the population below the poverty level (22 and 25 percent versus 13 percent nationally). For this same group, the percent over 25 without a high school diploma is above the national average (17 and 18 percent versus 12 percent), and linguistic isolation is above the national average (9 and 16 percent versus 5 percent). This shows that risks tend to be higher both where more African American residents reside, and where poverty is higher than in the rest of the area within 10 km. It should be noted that the higher percentage African American population with baseline cancer risk greater than or equal to 50-in-1 million is driven largely by seven facilities located in or near communities that have African American populations that are between two and eight times the national average. The higher percentage African American population with baseline cancer risk greater than 100-in-1 million is driven largely by three facilities that are located in communities where the proportion of African American residents is between 2.5 and 8 times the national average. The population with higher baseline cancer risks living within 10 km of the facilities consists of a substantially smaller percentage of Hispanic or Latino (22 and 26 percent) than the total population living within 10 km (36 percent Hispanic or Latino) and is above the national average (19 percent).

In summary, the baseline risk-based demographic analysis, which presents information on those specific locations that are expected to have higher cancer risks, suggests that African Americans, those living below poverty, and those living in linguistic isolation are disproportionally represented where risk is highest. The population with risks greater than 100-in-1 million living within 10 km of a commercial sterilizer has a proportion of African Americans (31 percent), those living below poverty (25 percent) and those living in linguistic isolation (16 percent) that is more than twice as large as the respective national average.

3. Risks Across Demographics Anticipated After Standards Under CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5)

This analysis presented information on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (table 23), greater than or equal to 50-in-1 million (table 24), and greater than 100-in-1 million (table 25) after implementation of standards that we are finalizing under CAA sections 112(d)(2), (3), and (5). The results of our analysis of risk-based demographics considering standards under CAA sections 112(d)(2), (3), and (5) are shown in the last column of tables 23, 24, and 25 titled ''Baseline and CAA Section 112(d)(2), (3), and (5).'' In this analysis we evaluated how the final CAA sections 112(d)(2), (3), and (5) emission reductions in this final regulatory action affect the distribution of risks identified in the baseline. This enables us to characterize the post-control risks and to illustrate for the public's understanding whether this part of the final action affects, creates or mitigates potential EJ concerns as compared to the baseline.

The risk analysis indicated that the emissions from the source category, after implementation of the standards (resulting in emissions reductions) that we are finalizing under CAA sections 112(d)(2), (3), and (5), reduces the number of people living within 10 km of a facility and with a cancer risk greater than or equal to 1-in-1 million from 5.3 million people around 75 facilities to 3.2 million people around 70 facilities, reduces the number of people living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million from 124,000 people around 38 facilities to 23,000 people around 23 facilities, and reduces the number of people living within 10 km of a facility and with a cancer risk greater than 100-in-1 million from 19,000 people around 16 facilities to 3,900 people around 13 facilities.

The demographics of the population with estimated cancer risks greater than or equal to 1-in-1 million considering the standards we are finalizing under CAA sections 112(d)(2), (3), and (5) are very similar to both the total population within 10 km and to the baseline population with risks greater than or equal to 1-in-1 million. Specifically, the percent of the population that is Hispanic or Latino is twice the national average (38 percent versus 19 percent), the percent below the poverty level is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (18 percent versus 12 percent), and the percent linguistic isolation is two times the national average (11 percent versus 5 percent).

After implementation of the standards that we are finalizing under CAA sections 112(d)(2), (3), and (5), the percentage and number of African Americans at cancer risks greater than

speak English less than ''very well'' (have difficulty with English).''

or equal to 50-in-1 million and greater than 100-in-1 million is significantly reduced. For example, African Americans exposed to risks greater than 100-in-1 million went from 31 percent or 5,900 people in the baseline to 6 percent or 220 people after implementation of the final CAA section 112(d)(2), 112(d)(3), and 112(d)(5) emissions reductions. It should be noted that while the number of Hispanic or Latino people with risks greater than 100-in-1 million was reduced from 4,900 to 2,600 people, the percentage of the remaining population at >100-in-1 million risk that is Hispanic or Latino went up from 26 percent in the baseline to 68 percent after the final CAA section 112(d)(2), 112(d)(3), and 112(d)(5) emissions reductions. However,. Similarly, the number of people below the poverty level or linguistically isolated with a cancer risk >100-in-1 million decreased significantly; however, the percentage of the remaining population at risk post-emission controls that are in these demographics went up from the baseline. For example, the proportion of the population with risks greater than 100-in-1 million that were below the poverty level was much higher than the baseline (38 percent versus 25 percent), but the number of people was reduced from 4,700 people to 560 people.

In summary, implementation of the final CAA sections 112(d)(2), (3), and (5) standards would significantly reduce the number of people in all demographic groups that are exposed to risks greater than or equal to 1-in-1 million, greater than and equal to 50-in-1 million, and greater than 100-in-1 million. Specifically, the percent of the population that is African American who are at a cancer risk greater than or equal to 50-in-1 million and greater than 100-in-1 million was reduced from 43 percent in the baseline to about 13 percent after the CAA section 112(d)(2), 112(d)(3), and 112(d)(5) controls. The percentage of Hispanic or Latino people increased as the higher risk facilities in Puerto Rico make-up an increasing portion of the remaining populations with higher cancer risks.

TABLE 23—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥ 1-in-1 million	
			Baseline	Post-control
Total Population	328M	17.3M	5.3M	3.2M
Number of Facilities	.....	88	75	70
Race and Ethnicity by Percent [Number of People]				
White	60 percent [197M]	40 percent [6.9M]	40 percent [2.1M]	40 percent [1.3M]
African American	12 percent [40M]	13 percent [2.3M]	15 percent [770K]	16 percent [520K]
Native American	0.7 percent [2M]	0.3 percent [51K]	0.3 percent [17K]	0.3 percent [9K]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	36 percent [6.2M]	39 percent [2.1M]	38 percent [1.2M]
Other and Multiracial	8 percent [27M]	11 percent [1.9M]	7 percent [350K]	6 percent [190K]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	15 percent [2.5M]	16 percent [840K]	16 percent [520K]
Above Poverty Level	87 percent [284M]	85 percent [14.8M]	84 percent [4.5M]	84 percent [2.7M]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	16 percent [2.7M]	18 percent [960K]	18 percent [590K]
Over 25 and with a High School Diploma	88 percent [288M]	84percent [14.6M]	82 percent [4.3M]	82 percent [2.7M]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [1.8M]	11 percent [570K]	11 percent [360K]

Notes:

- Nationwide population and demographic percentages are based on the Census Bureau's (Census) 2015–2019 American Community Survey (ACS) 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
- To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
- The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
- The sum of individual populations with a demographic category may not add up to total due to rounding.

TABLE 24—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 50-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥ 50-in-1 million	
			Baseline	Post-control
Total Population	328M	17.3M	124,000	23,000
Number of Facilities	.....	88	38	23
Race and Ethnicity by Percent [Number of People]				
White	60 percent [197M]	40 percent [6.9M]	31 percent [39K]	30 percent [7K]
African American	12 percent [40M]	13 percent [2.3M]	43 percent [54K]	13 percent [2.9K]
Native American	0.7 percent [2M]	0.3 percent [51K]	0.1 percent [190]	0.1 percent [<100]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	36 percent [6.2M]	22 percent [27K]	56 percent [13K]
Other and Multiracial	8 percent [27M]	11 percent [1.9M]	3 percent [3.9K]	2 percent [400]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	15 percent [2.5M]	22 percent [28K]	29 percent [6.6K]
Above Poverty Level	87 percent [284M]	85 percent [14.8M]	78 percent [96K]	71 percent [17K]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	16 percent [2.7M]	17 percent [21K]	21 percent [5K]
Over 25 and with a High School Diploma	88 percent [288M]	84 percent [14.6M]	83 percent [103K]	79 percent [18K]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [1.8M]	9 percent [11K]	30 percent [6.9K]

Notes:

• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.

• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.

• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.

• The sum of individual populations with a demographic category may not add up to total due to rounding.

• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100.''

TABLE 25—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk > 100-in-1 million	
			Baseline	Post-control
Total Population	328M	17.3M	19,000	3,900
Number of Facilities	.....	88	16	13
Race and Ethnicity by Percent [Number of People]				
White	60 percent [197M]	40 percent [6.9M]	40 percent [7.7K]	25 percent [1K]
African American	12 percent [40M]	13 percent [3M]	31 percent [5.9K]	6 percent [200]
Native American	0.7 percent [2M]	0.3 percent [51K]	0.1 percent [<100]	0 percent [0]

TABLE 25—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED—Continued

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk > 100-in-1 million	
			Baseline	Post-control
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	36 percent [6.2M]	26 percent [4.9K]	68 percent [2.6K]
Other and Multiracial	8 percent [27M]	11 percent [1.9M]	3 percent [500]	1 percent [<100]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	15 percent [2.5M]	25 percent [4.7K]	38 percent [1.4K]
Above Poverty Level	87 percent [284M]	85 percent [14.8M]	75 percent [14K]	62 percent [2.4K]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	16 percent [2.7M]	18 percent [3.5K]	22 percent [900]
Over 25 and with a High School Diploma	88 percent [288M]	84 percent [14.6M]	82 percent [16K]	78 percent [3K]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [1.8M]	16 percent [3K]	44 percent [1.7K]

Notes:
- Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
- To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
- The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
- The sum of individual populations with a demographic category may not add up to total due to rounding.
- To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100.''

4. Demographics of Affected Populations Anticipated After Implementation of Residual Risk Standards (Post-Control)

This analysis presented information on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (table 26), greater than or equal to 50-in-1 million (table 27), and greater than 100-in-1 million (table 28) after implementation of the standards being finalized under CAA section 112(f)(2) as described in section IV.C of this preamble. The demographic results for the risks after implementation of the residual risk-based controls are in the column titled ''Residual Risk Standards.'' These standards will be implemented in addition to the CAA section 112(d)(2), (3), and (5) standards and are anticipated to result in additional post-control emissions reductions. Therefore, in this analysis, we evaluated how all of the final standards and emission reductions described in this action affect the reduction and distribution of risks. This enables us to characterize the post-control risks and to understand whether the final action affects, creates or mitigates potential EJ concerns as compared to the baseline.

The risk analysis indicated that the number of people exposed to risks greater than or equal to 1-in-1 million within 10 km of a facility (table 26) is reduced from 3.2 million people after implementation of the CAA section 112(d)(2), (3), and (5) controls to approximately 700,000 people after implementation of the residual risk standards. This represents a significant reduction (about 80 percent reduction) in the size of the population facing this level of risk after implementation of the residual risk standards being finalized, when compared to the population facing this level of risk after implementation of just the CAA section 112(d)(2), (3), and (5) controls. The people with a cancer risk greater than or equal to 1-in-1 million are located around 67 facilities after implementation of the residual risk standard-based controls.

The demographics of the post-control population living within 10 km of a facility and with an estimated cancer risks greater than or equal to 1-in-1 million after implementation of the residual risk standards and resulting controls (table 26) are very similar to the CAA section 112(d)(2), (3), and (5) post-control population with risks greater than or equal to 1-in-1 million. Specifically, the percent of the population that is Hispanic or Latino is nearly twice the national average (34 percent versus 19 percent), the percent below poverty is above national average (15 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (15 percent versus 12 percent), and the percent linguistic isolation is almost two times the national average (11 percent versus 5 percent).

The risk analysis indicated that the number of people living within 10 km of a facility and exposed to risks greater than or equal to 50-in-1 million (table 27) is reduced from 23,000 people after implementation of the CAA section

112(d)(2), (3), and (5)-based controls to 170 people after implementation of the residual risk-based controls. This represents a 99 percent reduction in the size of the populations at risk. The people living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million after implementation of the final rule are located around 11 facilities.

The demographic breakdown of the much smaller post-control population living within 10 km of a facility and with estimated cancer risks greater than or equal to 50-in-1 million for the residual risk controls (table 27) is significantly different from the population after implementation of the CAA section 112(d)(2), (3), and (5) controls. Specifically for the 170 individuals still at greater than or equal to 50-in-1 million risk, the percent of the population that is Hispanic or Latino is significantly higher at 76 percent for the residual risk controls. This higher percentage is driven by two facilities in Puerto Rico, for which the population is over 99 percent Hispanic or Latino. However, the number of Hispanic or Latino people with risks greater than or equal to 50-in-1 million was reduced by about 99 percent from 13,000 people to 130 people after anticipated implementation of the residual risk standard-based controls. Similarly, the percentage of the population that is below the poverty level or linguistically isolated went up from the CAA section 112(d)(2), (3), and (5) post-control population, but the number of people in each demographic decreased significantly.

The risk analysis indicated that the number of people living within 10 km of a facility and exposed to risks greater than 100-in-1 million (table 28) is reduced from 3,900 people after implementation of the CAA section 112(d)(2), (3), and (5)-based controls to zero people for residual risk-based controls. After implementation of the residual risk standards, there are no facilities or people with risks greater than 100-in-1 million. Therefore, there are no greater than 100-in-1 million risk populations or demographics to discuss.

In summary, as shown in the residual risk post-control risk-based demographic analysis, the standards being finalized will reduce the number of people and facilities expected to have cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million significantly. Under residual risk-based controls, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 1-in-1 million is reduced by 80 percent, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 50-in-1 million is reduced by 99 percent, and the number of Hispanic or Latino people that are exposed to risks greater than 100-in-1 million is reduced by 100 percent. We note that, primarily driven by the higher risk facilities in Puerto Rico, the percentage of population that is Hispanic or Latino, below the poverty level, over 25 without a high school diploma, or in linguistic isolation increases as the cancer risk increases from greater than or equal to 1-in-1 million to greater than 50-in-1 million. Under residual risk-based controls, there are no facilities or people with risks greater than 100-in-1 million.

TABLE 26—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL STANDARDS

Demographic group	Nationwide	Cancer risk ≥1-in-1 million	
		Post-control CAA section 112(d)(2), (3), and (5) standards	Residual risk standards (CAA section 112(f)(2))
Total Population	328M	3.2M	700K
Number of Facilities with Pop. Above Cancer Level	.....	70	67
Race and Ethnicity by Percent [Number of People]			
White	60 percent [197M]	40 percent [1.3M]	40 percent [280K]
African American	12 percent [40M]	16 percent [520K]	18 percent [130K]
Native American	0.7 percent [2M]	0.3 percent [9K]	0.2 percent [2.2K]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	38 percent [1.2M]	34 percent [240K]
Other and Multiracial	8 percent [27M]	6 percent [190K]	8 percent [53K]
Income by Percent [Number of People]			
Below Poverty Level	13 percent [44M]	16 percent [520K]	15 percent [100K]
Above Poverty Level	87 percent [284M]	84 percent [7M]	85 percent [600K]
Education by Percent [Number of People]			
> 25 w/o a HS Diploma	12 percent [40M]	18 percent [590K]	15 percent [110K]
> 25 w/HS Diploma	88 percent [288M]	82 percent [2.7M]	85 percent [590K]

TABLE 26—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL STANDARDS—Continued

Demographic group	Nationwide	Cancer risk ≥1-in-1 million	
		Post-control CAA section 112(d)(2), (3), and (5) standards	Residual risk standards (CAA section 112(f)(2))
Linguistically Isolated by Percent [Number of People]			
Linguistically Isolated	5 percent [18M]	11 percent [360K]	11 percent [80K]

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.

TABLE 27—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 50-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL RULE

Demographic group	Nationwide	Cancer risk ≥50-in-1 million post-control	
		CAA section 112(d)(2), (3), and (5) standards	Residual risk standards (112(f)(2))
Total Population	328M	23,000	170
Number of Facilities with Pop. Above Cancer Level	.....	23	11
Race and Ethnicity by Percent [Number of People]			
White	60 percent [197M]	30 percent [7K]	12 percent [<100]
African American	12 percent [40M]	13 percent [2.9K]	11 percent [<100]
Native American	0.7 percent [2M]	0.1 percent [190]	0.3 percent [<100]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	56 percent [13K]	76 percent [130]
Other and Multiracial	8 percent [27M]	2 percent [400]	0.4 percent [<100]
Income by Percent [Number of People]			
Below Poverty Level	13 percent [44M]	29 percent [6.6K]	30 percent [<100]
Above Poverty Level	87 percent [284M]	71 percent [17K]	70 percent [120]
Education by Percent [Number of People]			
>25 w/o a HS Diploma	12 percent [40M]	21 percent [5K]	31 percent [<100]
>25 w/HS Diploma	88 percent [288M]	79 percent [18K]	69 percent [120]
Linguistically Isolated by Percent [Number of People]			
Linguistically Isolated	5 percent [18M]	30 percent [6.9K]	47 percent [<100]

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.

• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.
• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100''.

TABLE 28—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL RULE

Demographic group	Nationwide	Cancer risk >100-in-1 million	
		CAA section 112(d)(2), (3), and (5) post-control	Residual risk controls
Total Population	328M	3,900	0
Number of Facilities with Pop. Above Cancer Level	.....	13	0
Race and Ethnicity by Percent [Number of People]			
White	60 percent [197M]	25 percent [1K]	.....
African American	12 percent [40M]	6 percent [200]	.....
Native American	0.7 percent [2M]	0 percent [0]	.....
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	68 percent [2.6K]	.....
Other and Multiracial	8 percent [27M]	1 percent [<100]	.....
Income by Percent [Number of People]			
Below Poverty Level	13 percent [44M]	38 percent [1.4K]	.....
Above Poverty Level	87 percent [284M]	62 percent [2.4K]	.....
Education by Percent [Number of People]			
>25 w/o a HS Diploma	12 percent [40M]	22 percent [900]	.....
>25 w/HS Diploma	88 percent [288M]	78 percent [3K]	.....
Linguistically Isolated by Percent [Number of People]			
Linguistically Isolated	5 percent [18M]	44 percent [1.7K]	.....

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.
• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100''.

VI. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a ''significant regulatory action'', as defined under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations,* is also available in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1666.12. You can find a copy of the ICR in the docket for this rulemaking, and it is briefly summarized here.

We are amending the reporting and recordkeeping requirements for several

emission sources at commercial sterilization facilities (*e.g.,* SCV, ARV, CEV, and room air emissions). The amendments also require electronic reporting, removes the SSM exemption, and imposes other revisions that affect reporting and recordkeeping. This information was be collected to assure compliance with 40 CFR part 63, subpart O.

Respondents/affected entities: Owners or operators of commercial sterilization facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart O).

Estimated number of respondents: 88 facilities.

Frequency of response: Quarterly, semiannual, or annual. Responses include notification of compliance status reports and semiannual compliance reports.

Total estimated burden: 34,351 hours (per year) for the responding facilities and 9,174 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $5,140,563 (per year), which includes $2,549,368 annualized capital and operation and maintenance costs for the responding facilities.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) that examines the impact of the rule on small entities along with regulatory alternatives that could minimize the impact. The complete FRFA is available for review in the docket and is summarized here.

1. Statement of Need and Rule Objectives

This industry is regulated by the EPA because pollutants emitted from EtO sterilization and fumigation facilities are considered to cause or contribute significantly to air pollution that may reasonably be anticipated to endanger public health. This action is being finalized to comply with CAA section 112 requirements, which direct the EPA to complete periodic reviews of NESHAPs following initial promulgation. The requirements are being finalized to address unacceptable health risks linked to emissions from subpart O facilities and to provide an ample margin of safety to protect public health.

The EPA is required under CAA section 112(d) to establish emission standards for each category or subcategory of major and area sources of HAPs listed for regulation in section 112(b). These standards are applicable to new or existing sources of HAPs and require the maximum degree of emission reduction. The EPA is required to review these standards set under CAA section 112 every eight years following their promulgation and revise them as necessary, taking into account any ''developments in practices, processes, or control technologies.'' This review is known as the technology review. It has been over 25 years since the initial NESHAP for this source category was promulgated in 1994 and roughly 15 years since the last technology review. As such, this final rule is overdue. This rule also establishes standards for currently unregulated sources of EtO emissions at subpart O facilities under CAA section 112(d), such as room air emissions. The decision in *Louisiana Environmental Action Network* v. *EPA, 955 F.3d 1088* (D.C. Cir. 2020) concluded that the EPA is required to address regulatory gaps (*i.e.,* ''gap-filling'') when conducting NESHAP reviews. Finally, the EPA determined that a risk review was warranted (despite not being required) due to the updated unit risk estimate associated with EtO, which is significantly higher than it was during the last review of this NESHAP in 2006. Therefore, the EPA is finalizing requirements under CAA section 112(f) to address unacceptable health risk attributed to emissions from subpart O facilities and to provide an ample margin of safety to protect public health.

2. Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis (IRFA) and EPA Response

While the EPA did not receive any comments specifically in response to the IRFA, we did receive comments from the Office of Advocacy within the Small Business Administration (SBA), and a summary of the major comments and our responses is provided in the next section. The issues raised by SBA were also reflected in comments from small businesses and organizations with small business interests.

3. SBA Office of Advocacy Comments and EPA Response

The SBA's Office of Advocacy (hereafter referred to as ''Advocacy'') provided substantive comments on the April 2023 Proposal. Those comments made the following claims: (1) the proposed compliance period for existing sources (18 months) would disadvantage small business; (2) the proposed requirement for area source commercial sterilization facilities to obtain a title V permit would impose significant costs and uncertainty for small businesses; and (3) EPA should adopt the BMP alternatives for GACT at area source facilities. Based on those claims, Advocacy insisted that EPA reconsider these policies to reduce the impact on small entities and reduce the likelihood they will leave the market.

In response to Advocacy's comments, EPA agrees that the proposed compliance timeframe is too short and that more time is needed to comply with the rule. Therefore, as part of the final rulemaking, EPA is providing the maximum amount of time that is allowed under the CAA to comply with the emission standards, which is three years for standards that are promulgated pursuant to CAA section 112(d) and two years for standards that are promulgated pursuant to CAA section 112(f)(2). With respect to title V permitting, because of the lack of other Federal requirements under the CAA that commercial sterilization facilities are subject to, as well as the robust monitoring and reporting requirements of the final rule, the EPA is not finalizing a requirement for area source facilities to obtain a title V permit. In addition, with respect to GACT, emission standards were evaluated against the BMP on a source-by-source basis. In general, we are finalizing the emission standards for each source pursuant to CAA section 112(d)(5), with the exception of existing Group 2 room air emissions at areas source facilities, because they achieve higher emission reductions than the BMP. Further discussion is available in section IV.B.3.

More detailed responses to Advocacy's comments can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

4. Estimate of the Number of Small Entities to Which the Final Rule Applies

For purposes of assessing the impacts of this rule on small entities, a small entity is defined as a small business in the commercial EtO sterilization

industry whose parent company has revenues or numbers of employees below the SBA Size Standards for the relevant NAICS code. We have identified 20 different NAICS codes within this source category. A complete list of those NAICS codes and SBA Size Standards is available in section 5.2 of the RIA. The rule contains provisions that will affect 22 small entities. These small entities are involved in sterilizing various types of medical devices and spices. In addition, at least 12 of these small entities are involved in sterilizing the types of medical devices discussed in section I.A.1 of this preamble.

5. Projected Reporting, Recordkeeping and Other Compliance Requirements of the Final Rule

Under the rule requirements, small entities will be required to comply with various emission standards, which may require the use of one or more new control devices. Small entities will also need to demonstrate compliance with the emission standards through the use of an EtO CEMS or through periodic performance testing and parametric monitoring. This rule includes reporting, recordkeeping, and other administrative requirements. Under the rule, the EPA estimates that approximately 13 small entities (60 percent of small entities) could incur total annual costs associated with the proposal that are at least three percent of their annual revenues. Considering the level of total annual costs relative to annual sales for these small entities, the EPA determined that there is potential for the requirements to have a 'Significant Impact on a Substantial Number of Small Entities'. See section 5.2 of the RIA for more information on the characterization of the impacts under the rule.

6. Steps Taken To Minimize Economic Impact to Small Entities

a. Small Business Advocacy Review Panel

As required by section 609(b) of the RFA, the EPA also convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to the rule's requirements. On November 25, 2020, the EPA's Small Business Advocacy Chairperson convened the Panel, which consisted of the Chairperson, the Director of the Sector Policies and Programs Division within the EPA's Office of Air Quality Planning and Standards, the Administrator of the Office of Information and Regulatory Affairs within OMB, and the Chief Counsel for Advocacy of the SBA.

Prior to convening the Panel, the EPA conducted outreach and solicited comments from the SERs. After the Panel was convened, the Panel provided additional information to the SERs and requested their input. In light of the SERs' comments, the Panel considered the regulatory flexibility issues and elements of the IRFA specified by RFA/Small Business Regulatory Enforcement and Fairness Act and developed the findings and discussion summarized in the SBAR report. The report was finalized on April 26, 2021, and transmitted to the EPA Administrator for consideration. A copy of the full SBAR Panel Report is available in the rulemaking docket.

b. Alternatives Considered

The SBAR Panel recommended several flexibilities relating to the format of the standards, room air emissions requirements, subcategorization, the compliance timeframe, the consideration of GACT standards, incentivizing lower EtO use, a compliance alternative for combined emission streams, proximity requirements, and the consideration of interactions with OSHA standards. The EPA is including some of these flexibilities as a part of the rule requirements.

As discussed in section VI.C.3, the EPA is providing the maximum amount of time that is allowed under the CAA to comply with the emission standards. In addition, as discussed in section IV.B.3.b, the EPA is not any finalizing any mass rate emission standards and is finalizing percent emission reduction standards in their place. Finally, as discussed in section IV.F.3, the EPA is finalizing compliance flexibilities for combined emission streams, as well as the option to demonstrate compliance with a site-wide emission limit, as opposed to having to demonstrate compliance with each individual or combined emission stream.

In addition, the EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. The Small Entity Compliance Guide will be available on the same date as the date of publication of the final rule or as soon as possible after that date and will be available on the rule web page at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.*

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. None of the commercial sterilization facilities that have been identified as being affected by this final action are owned or operated by Tribal governments or located within Tribal lands within a 10-mile radius. Thus, Executive Order 13175 does not apply to this action. We conducted an impact analysis using the latitude and longitude coordinates from the risk modeling input file to identify Tribal lands within a 10- and 50-mile radius of commercial sterilization facilities to determine potential air quality impacts on Tribes. Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, although there were no Tribal lands located within a 10-mile radius of commercial sterilization facilities, the EPA offered consultation with all Tribes that were identified within a 50-mile radius of an affected facility, however, only one Tribal official requested consultation. Additional details regarding the consultation letter and distribution list can be found in the memorandum, *Commercial Sterilization Facilities RTR Consultation Letter,* which is available in the docket for this rulemaking. The EPA also participated on a phone call with the National Tribal Air Association on May 25, 2023, and presented an overview of the rulemaking.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health

and safety standards and explain why the regulation is preferable to potentially effective and reasonable feasible alternatives. This action is subject to Executive Order 13045 because it is a 3(f)(1) significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. The EPA's Policy on Children's Health also applies to this action. Accordingly, we have evaluated the environmental health or safety effects of EtO emissions and exposures on children. The protection offered by these standards may be especially important for children.

Because EtO is mutagenic (*i.e.,* it can damage DNA), children are expected to be more susceptible to its harmful effects. To take this into account, as part of the risk assessment in support of this rulemaking, the EPA followed its guidelines and applied age-dependent adjustment factors (ADAFs) for early lifestage exposures (from birth up to 16 years of age). With the ADAF applied to account for greater susceptibility of children, the adjusted EtO inhalation URE is $5 \times 10-3$ per $\mu g/m^3$. It should be noted that, because EtO is mutagenic, emission reductions in this preamble will be particularly beneficial to children. In addition, children are at increased risk if they live, play, or attend school in close proximity to a commercial sterilization facility, of which there are many cases noted by the public to be the case. For these reasons, there is both increased susceptibility and increased exposure for early lifestages as a result of EtO emissions from commercial sterilization facilities.

A total of 3.97 million children ages 0–17 live within 10km of commercial sterilization facilities. Due to baseline emissions from commercial sterilization facilities (prior to application of controls in this action), there are approximately 1.25 million children (0–17 years) with increased lifetime cancer risks of greater than or equal to 1-in-1 million, 30,000 with increased lifetime cancer risks greater than or equal to 50-in-1 million, and 4,300 with increased lifetime cancer risks greater than 100-in-1 million. After application of the controls in this action, lifetime cancer risks to children from commercial sterilization facility emissions decrease significantly to approximately 162,300 children with increased lifetime cancer risks of greater than or equal to 1-in-1 million, less than 100 with increased lifetime cancer risks of greater than or equal to 50-in-1 million, and none with increased lifetime cancer risks greater than 100-in-1 million. The methodology and detailed results of the demographic analysis are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action.

More detailed information on the evaluation of the scientific evidence and policy considerations pertaining to children, including an explanation for why the Administrator judges the standards to be requisite to protect public health, including the health of children, with an adequate margin of safety, in addition to the summaries of this action's health and risk assessments are contained in sections II.A and IV.C of this preamble and further documented in the risk report, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in Docket ID No. EPA–HQ–OAR–2019–0178.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The overall energy impact of this rule should be minimal for commercial sterilization facilities and their parent companies. EPA was unable to quantify the degree to which manufacturers will need to switch sites, so we cannot estimate potential energy impacts related to transportation. The EPA solicited comment on any potential impacts the proposed standards may have in relation to energy use for transportation but did not receive any comments that would help to quantify such impacts.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking involves technical standards. The EPA conducted searches for the standards through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 1A, 2, 2A, 2C, 3A, 3B, and 4 of 40 CFR part 60, Appendix A, EPA Method 204 of 40 CFR part 51, Appendix M, and EPA Methods 301 and 320 in 40 CFR part 63, Appendix A. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's reference method, the EPA reviewed it as a potential equivalent method.

The EPA incorporates by reference VCS ANSI/ASME PTC 19.10–1981 Part 10, ''Flue and Exhaust Gas Analyses,'' a method for quantitatively determining the gaseous constituents of exhausts resulting from stationary combustion and includes a description of the apparatus, and calculations used which are used in conjunction with Performance Test Codes to determine quantitatively, as an acceptable alternative to EPA Method 3B of appendix A to 40 CFR part 60 for the manual procedures only and not the instrumental procedures. The ANSI/ASME PTC 19.10–1981 Part 10 method incorporates both manual and instrumental methodologies for the determination of oxygen content. The manual method segment of the oxygen determination is performed through the absorption of oxygen. This method is available at the American National Standards Institute (ANSI), 1899 L Street NW, 11th floor, Washington, DC 20036 and the American Society of Mechanical Engineers (ASME), Three Park Avenue, New York, NY 10016–5990. See *https://www.ansi.org* and *https://www.asme.org.*

The EPA incorporates by reference VCS ASTM D6348–12 (Reapproved 2020), ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,'' as an acceptable alternative to EPA Method 320 of appendix A to 40 CFR part 63 with caveats requiring inclusion of selected annexes to the standard as mandatory. The ASTM D6348–12 (R2020) method is an extractive FTIR spectroscopy-based field test method and is used to quantify gas phase concentrations of multiple target compounds in emission streams from stationary sources. This field test method provides near real time analysis of extracted gas samples. In the September 22, 2008, NTTAA summary, ASTM D6348–03(2010) was determined equivalent to EPA Method 320 with caveats. ASTM D6348–12 (R2020) is a revised version of ASTM D6348–03(2010) and includes a new section on accepting the results from direct measurement of a certified spike gas cylinder, but still lacks the caveats we placed on the D6348–03(2010) version. We are finalizing that the test plan preparation and implementation in the Annexes to ASTM D 6348–12 (R2020), Sections Al through A8 are mandatory;

and in ASTM D6348–12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). We are finalizing that, in order for the test data to be acceptable for a compound, %R must be 70% ≤ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the following equation:

$$Reported\ Results = \frac{Stack\ Concentration}{\%R} = 100$$

The ASTM D6348–12 (R2020) method is available at ASTM International, 1850 M Street NW, Suite 1030, Washington, DC 20036. See *https://www.astm.org/.*

ASTM D3695–88 is already approved for the locations in which it appears in the amendatory text.

While the EPA identified 12 other VCS as being potentially applicable, the Agency decided not to use them because these methods are impractical as alternatives due to lack of equivalency, documentation, validation data, and other important technical and policy considerations. The search and review results have been documented and are in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review,* which is available in the docket for this rulemaking.

Under 40 CFR 63.7(f) and 40 CFR 63.8(f), subpart A—General Provisions, a source may apply to the EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. A total of 17.3 million people live within 10 km of the 88 facilities that were assessed. The percent of the population that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities are Hispanic or Latino. The proportion of other demographic groups living within 10 km of commercial sterilizers is similar to the national average. The EPA also conducted a risk assessment of possible cancer risks and other adverse health effects, and found that prior to the implementation of this regulation, cancer risks are unacceptable for several communities. See section VI.F for an analysis that characterizes communities living in proximity to facilities and risks prior to implementation of the final regulation.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. This action establishes standards for SCVs and ARVs at facilities where EtO use is less than 1 tpy, ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs, and room air emissions. In addition, it tightens standards for SCVs at facilities where EtO use is at least 1 tpy, as well as ARVs at facilities where EtO use is at least 10 tpy. This action also finalizes amendments to correct and clarify regulatory provisions related to emissions during periods of SSM, including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate. As a result of these changes, we expect zero people to be exposed to cancer risk levels above 100-in-1 million. See section IV for more information about the control requirements of the regulation and the resulting reduction in cancer risks.

The EPA additionally identified and addressed environmental justice concerns by engaging in outreach activities to communities we expect to be impacted most by the rulemaking The EPA is also requiring owners and operators of commercial sterilization facilities to submit electronic copies of required compliance reports, performance test reports, and performance evaluation reports, which will increase transparency and will provide greater access to information for the public, including impacted communities.

The information supporting this Executive order review is contained in section VI.F of this preamble, as well as in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 60

Environmental protection, Administrative practice and procedures, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR parts 60 and 63 as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Appendix B to Part 60—Performance Specifications

■ 2. Appendix B to part 60 is amended by adding Performance Specification 19 to read as follows:

Appendix B to Part 60—Performance Specifications

* * * * *

Performance Specification 19-Performance Specifications and Test Procedures for Ethylene Oxide (ETO) Continuous Emission Monitoring Systems

1.0 Scope and Application

1.1 Analyte. This performance specification (PS) is applicable for measuring gaseous concentrations of Ethylene Oxide (EtO), CAS: 775–21–8, on a continuous basis in the units of the applicable standard or in units that can be converted to units of the applicable standard(s) (*e.g.,* lbs/hr,). This performance specification may be approved for the measurement of other pollutants and/or in other sectors by the Administrator on a case-by-case basis if not otherwise allowed or denied in an applicable subpart of the regulations.

1.2 Applicability.

1.2.1 This specification is used to evaluate the acceptability of EtO continuous emission monitoring systems (CEMS) at the time of installation or soon after and whenever specified in the regulations. The specification includes requirements for initial acceptance including instrument accuracy and stability assessments and use of audit samples if they are available.

1.2.2 The Administrator may require the operator, under section 114 of the Clean Air Act, to conduct CEMS performance evaluations at other times besides the initial test to evaluate the CEMS performance. See 40 CFR part 60, § 60.13(c) and § 63.8(e)(1).

1.2.3 A source that demonstrates their CEMS meets the criteria of this PS may use the system to continuously monitor gaseous EtO under any regulation or permit that requires compliance with this PS. If your CEMS reports the EtO concentration in the units of the applicable standard, no additional CEMS components are necessary. If your CEMS does not report concentrations in the units of the existing standard, then other CEMS (*i.e.,* oxygen) or CEMS components (*e.g.,* temperature, stack gas flow, moisture, and pressure) may be necessary to convert the units reported by your CEMS to the units of the standard.

1.2.4 These specification test results are intended to be valid for the life of the system. As a result, the EtO measurement system must be tested and operated in a configuration consistent with the configuration that will be used for ongoing continuous emissions monitoring.

1.2.5 Substantive changes to the system configuration require retesting according to this PS. Examples of such conditions include but are not limited to: major changes in dilution ratio (for dilution-based systems); changes in sample conditioning and transport, if used, such as filtering device design or materials; changes in probe design or configuration and changes in materials of construction. Changes consistent with instrument manufacturer upgrade that fall under manufacturer's certification do not require additional field verification. Manufacturer's upgrades (*e.g.,* changes to the quantification algorithm) require recertification by the manufacturer for those requirements allowed by this PS, including interference, and level of detection (LOD).

1.2.6 This specification is not designed to evaluate the ongoing CEMS performance, nor does it identify specific calibration techniques and auxiliary procedures to assess CEMS performance over an extended period of time. The requirements in Procedure 7 to Appendix F of this part are designed to provide a way to assess CEMS and CEMS components (if applicable) performance over an extended period of time. The source owner or operator is responsible to calibrate, maintain, and operate the CEMS properly.

2.0 Summary of Performance Specification

2.1 This specification covers the procedures that each EtO CEMS must meet during the performance evaluation test. Installation and measurement location specifications, data reduction procedures, and performance criteria are included.

2.2 The technology used to measure EtO must provide a distinct response and address any appropriate interference correction(s). It must accurately measure EtO in a representative sample of stack effluent.

2.3 The relative accuracy (RA) must be established against a reference method (RM) (*i.e.,* Method 320, or other alternative approved as a RM by the Administrator) on a case-by-case basis if not otherwise allowed or denied in an applicable subpart of the regulations.

2.4 A standard addition (SA) procedure using a reference standard is included in appendix A to this performance specification for use in verifying LOD. For extractive CEMS, where the SA is done by dynamic spiking (DS), the appendix A procedure is allowed as an option for assessing calibration drift and is also referenced by Procedure 7 of appendix F to this part for ongoing quality control tests.

3.0 Definitions

3.1 *Calibration drift* (CD) means the absolute value of the difference between the CEMS output response and an upscale reference gas or a zero-level gas, expressed as a percentage of the span value, when the CEMS is challenged after a stated period of operation during which no unscheduled adjustments, maintenance or repairs took place. For other parameters that are selectively measured by the CEMS (*e.g.,* temperature, velocity, pressure, flow rate) to measure in the units of the applicable standard, use two analogous values (*e.g.,* Low: 0–20% of full scale, High: 50–100% of full scale). 3.2 *Calibration Span* means the calibrated portion of the measurement range as specified in the applicable regulation or another requirement. If the span is not specified in the applicable regulation or other requirement, then it must be a value approximately equivalent to three times the applicable emission standard. When the emission standard is expressed as mass emissions, use the average flow rate in the duct to calculate the concentration equivalent of the emission standard.

3.3 *Centroidal area* means a central area that is geometrically similar to the stack or duct cross section and is no greater than 10 percent of the stack or duct cross-sectional area.

3.4 *Continuous Emission Monitoring System* (CEMS) means the total equipment required to measure the pollutant concentration or emission rate continuously. The system generally consists of the following three major subsystems:

3.4.1 *Sample interface* means that portion of the CEMS used for one or more of the following: Sample acquisition, sample transport, sample conditioning, and protection of the monitor from the effects of the stack effluent.

3.4.2 *EtO analyzer* means that portion of the EtO CEMS that measures the total vapor phase EtO concentration and generates a proportional output.

3.4.3 *Data recorder* means that portion of the CEMS that provides a permanent electronic record of the analyzer output. The data recorder may record other pertinent data such as effluent flow rates, various instrument temperatures or abnormal CEMS operation. The data recorder may also include automatic data reduction capabilities and CEMS control capabilities.

3.5 *Diluent gas* means a major gaseous constituent in a gaseous pollutant mixture. For combustion sources, either carbon dioxide (CO_2) or oxygen (O_2) or a combination of these two gases are the major gaseous diluents of interest.

3.6 *Dynamic spiking (DS)* means the procedure where a known concentration of EtO gas is injected into the probe sample gas stream for extractive CEMS at a known flow rate to assess the performance of the measurement system in the presence of potential interference from the flue gas sample matrix.

3.7 *Flow Rate Sensor* means that portion of the CEMS that senses the volumetric flow rate and generates an output proportional to that flow rate. The flow rate sensor shall have provisions to check the CD for each flow rate parameter that it measures individually (*e.g.,* velocity, pressure).

3.8 *Independent measurement(s)* means the series of CEMS data values taken during sample gas analysis separated by two times the procedure specific response time (RT) of the CEMS.

3.9 *Interference* means a compound or material in the sample matrix other than EtO whose characteristics may bias the CEMS measurement (positively or negatively). The interference may not prevent the sample measurement but could increase the analytical uncertainty in the measured EtO concentration through reaction with EtO or by changing the electronic signal generated during EtO measurement.

3.10 *Interference test* means the test to detect CEMS responses to interferences that are not adequately accounted for in the calibration procedure and may cause measurement bias.

3.11 *Level of detection (LOD)* means the lowest level of pollutant that the CEMS can

detect in the presence of the source gas matrix interferents with 99 percent confidence.

3.12 *Measurement error (ME)* is the mean difference between the concentration measured by the CEMS and the known concentration of a reference gas standard, divided by the span, when the entire CEMS, including the sampling interface, is challenged.

3.13 *Reference gas standard* means the gas mixture containing EtO at a known concentration and produced and certified in accordance with ''EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards,'' September 1997, as amended August 25, 1999, EPA–600/R–97/121 or more recent updates. The tests for analyzer measurement error, calibration drift, and system bias require the use of calibration gas prepared according to this protocol. If a zero gas is used for the low-level gas, it must meet the requirements under the definition for ''zero air'' in 40 CFR 72.2. Alternatively, if the ''protocol'' gas is not commercially available, you must use a reference gas that has been prepared according to the procedures in appendix B of this PS.

3.14 *Relative accuracy (RA)* means the absolute mean difference between the gas concentration, or the emission rate determined by the CEMS, and the value determined by the RM, plus the confidence coefficient of a series of nine test runs, divided by the average of the RM or the applicable emission standard.

3.15 *Response time (RT)* means the time it takes for the measurement system, while operating normally at its target sample flow rate, dilution ratio, or data collection rate to respond to a known step change in gas concentration, either from a low- or zero-level to a high-level gas concentration or from a high-level to a low or zero-level gas concentration, and to read 95 percent of the change to the stable instrument response. There may be several RTs for an instrument related to different functions or procedures (*e.g.,* DS, LOD, and ME).

3.16 *Span value* means an EtO concentration approximately equal to two times the concentration equivalent to the emission standard unless otherwise specified in the applicable regulation, permit or another requirement. Unless otherwise specified, the span may be rounded up to the nearest multiple of 5.

3.17 *Stable value* means the measure of two or more values that are statistically the same and the absence of measurement system drift.

3.18 *Standard addition* means the addition of known amounts of EtO gas (either statically or dynamically) measured sample gas stream.

3.19 *Zero gas* means a gas with an EtO concentration that is below the LOD of the measurement system.

4.0 Interferences

Sample gas interferences will vary depending on the instrument or technology used to make the measurement. Interferences must be evaluated through the interference test in this PS. Several compounds including carbon dioxide (CO_2), carbon monoxide (CO), methane (CH_4), and water (H_2O) are potential optical interferences with certain types of EtO monitoring technology.

Note: Interferences may be mitigated though the use of dilution systems, however this approach could also affect the sensitivity of the measurement.

5.0 Safety

The procedures required under this PS may involve hazardous materials, operations, and equipment. This PS may not address all the safety issues associated with these procedures. It is the responsibility of the user to establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. The CEMS user's manual and as well as cautions within and materials recommended by the RM should be consulted for specific precautions to be taken in regard to the relative accuracy testing.

6.0 Equipment and Supplies

The equipment and supplies are the same as in section 6 of PS 18, except replace HCl for EtO where appropriate. The following definitions are added and/or revised:

6.1 Moisture Measurement System. If correction of the measured EtO emissions for moisture is required, you must install, operate, maintain, and quality assure a continuous moisture monitoring system for measuring and recording the moisture content of the flue gases. The following continuous moisture monitoring systems are acceptable: Any optical measurement system validated according to Method 301 or section 13.0 of Method 320 in appendix A to part 63 of this chapter; a continuous moisture sensor; an oxygen analyzer (or analyzers) capable of measuring O_2 both on a wet basis and on a dry basis; or other continuous moisture measurement methods approved by the Administrator.

7.0 Reagents and Standards

7.1 Reference Gases means the gas mixture containing EtO at a known concentration and produced and certified in accordance with ''EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R–12/531) or more recent updates. The tests for analyzer measurement error, calibration drift, and system bias require the use of calibration gas prepared according to this protocol. If a zero gas is used for the low-level gas, it must meet the requirements under the definition for ''zero air'' in 40 CFR 72.2. Alternatively, if the ''protocol'' gas is not commercially available, you must use a reference gas that has been prepared according to the procedures in appendix B of this PS and meeting the requirements in section 12.2 of appendix B of this PS, if applicable.

7.2 Cylinder gas may be diluted for use in this specification, including measurement error testing. You must document the quantitative introduction of EtO standards into the system using Method 205, found in 40 CFR part 51, appendix M, or other procedure approved by the Administrator. The laboratory/field evaluations in Method 205 must be conducted at least quarterly and prior to any audit test (*e.g.,* CGA, RAA) required in QA Procedure 7 (40 CFR part 60, appendix F). Calibration must be conducted on an annual basis or whenever significant changes are made to the dilution system. In addition to the requirements in Method 205, when in use, you must document gas flow rates through each of the channels; if the dilution system records these values electronically, this is considered the documentation. For the purpose of this PS, cylinder gas should not be diluted beyond a dilution ratio of 500:1 using Method 205.

8.0 CEMS Measurement Location Specifications and Pretest Preparation

8.1 Prior to the start of your initial PS tests, you must ensure that the CEMS is installed according to the manufacturer's specifications and the requirements in this section.

8.2 CEMS Installation. Install the CEMS at an accessible location where the pollutant concentration or emission rate measurements are directly representative of the EtO emissions. If the units of the emission standard are expressed as a mass (*e.g.,* lb/hr), then the CEMS probe must also be located within 0.5 equivalent diameters of the flow sensor and the CEMS must be located (1) at least two equivalent diameters downstream from the nearest control device, the point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur and (2) at least a half equivalent diameter upstream from the effluent exhaust or control device. If the CEMS are to utilize time-sharing, the distance between each measurement point and the CEMS should be approximately the same. The CEMS need not be installed at the same location as the relative accuracy test location. If you fail the RA requirements in this specification due to the CEMS measurement location and a satisfactory correction technique cannot be established, the Administrator may require the CEMS to be relocated.

8.2.1 Single point sample gas extraction should be (1) no less than 1.0 m (3.3 ft.) from the stack or duct wall or (2) within the centroidal area of the stack or duct cross section.

8.2.2 CEMS and Data Recorder Scale Check. After CEMS installation, record and document the measurement range of the EtO CEMS. The CEMS operating range and the range of the data recording device must encompass all potential and expected EtO concentrations, including the concentration equivalent to the applicable emission limit and the span value.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization—Reserved

11.0 Performance Specification Test Procedure

After completing the CEMS installation, setup, and calibration, you must complete the PS test procedures in this section. You must perform the following procedures and meet the performance requirements for the initial demonstration of your CEMS:

a. Interference Test;

b. Level of Detection Determination;

c. Response Time Test;

d. Measurement Error Test;
e. Calibration Drift Test; and
f. Relative Accuracy Test.
g. If CEMS is to be time-shared, determine the response time to each measurement point, the sampling time at each measurement point, and the cycle time at each measurement point. The sampling time at each measurement point shall be at least 3 times as long as the system response time (RT), and the maximum number of measurement points shall not exceed the quotient, rounded down to the next whole number, of 15 minutes divided by the longest cycle time of the measurement point.

11.1 *Interference Test*

11.1.1 Prior to its initial use in the field, you must demonstrate that your monitoring system meets the performance requirements of the interference test in section 13.5 of this PS to verify that the candidate system measures EtO accurately in the presence of common interferences in emission matrices from commercial sterilizers. In the event this performance specification is applied in other emission sources, the interference test must evaluate any other predominant gases is the emission matrices of those sources.

11.1.2 Your interference test must be conducted in a controlled environment. The equipment you test for interference must include the combination of the analyzer, related analysis software, and any sample conditioning equipment (*e.g.,* dilution module, moisture removal equipment or other interferent scrubber) used to control interferents.

11.1.3 If you own multiple measurement systems with components of the same make and model numbers, you need only perform this interference test on one analyzer and associated interference conditioning equipment combination. You may also rely on an interference test conducted by the manufacturer or a continuous measurement system integrator on a system having components of the same make(s) and model(s) of the system that you use.

11.1.4 Perform the interference check using an EtO reference gas concentration of approximately ten times the LOD or at 50 parts per billion, whichever is greater.

11.1.5 Introduce the interference test gases listed in table 1 in section 17.0 of this PS to the analyzer/conditioning system separately or in any combination. The interference test gases need not be of reference gas quality.

11.1.6 The interference test must be performed by combining an EtO reference gas with each interference test gas (or gas mixture). You must measure the baseline EtO response, followed by the response after adding the interference test gas(es) while maintaining a constant EtO concentration. You must perform each interference gas injection and evaluation in triplicate.

Note: The baseline EtO gas may include interference gases at concentrations typical of ambient air (*e.g.,* 21 percent O_2, 400 parts per million (ppm) CO_2, 2 percent H_2O), but these concentrations must be brought to the concentrations listed in table 1 of this PS when their interference effects are being evaluated.

11.1.7 You should document the gas volume/rate, temperature, and pressure used to conduct the interference test. A gas blending system or manifold may be used.

11.1.8 Ensure the duration of each interference test is sufficient to condition the EtO measurement system surfaces before a stable measurement is obtained.

11.1.9 Measure the EtO response of the analyzer/sample conditioning system combination to the test gases in ppbv. Record the responses and determine the overall interference response using table 2 in section 17.0 of this PS.

11.1.10 For each interference gas (or mixture), calculate the mean difference (ΔMC_{avg}) between the measurement system responses with and without the interference test gas(es) using equation 1 in section 12.2 of this PS. Summarize the results following the format contained in table 2 in section 17.

11.1.11 Calculate the percent interference (I) for the gas runs using equation 2 in section 12.2 of this PS.

11.1.12 The total interference response (*i.e.,* the sum of the interference responses of all tested gaseous components) must not exceed the criteria set forth in section 13.5 of this PS.

11.2 Level of Detection Determination

11.2.1 You must determine the minimum amount of EtO that can be detected above the background in a representative gas matrix.

11.2.2 You must perform the LOD determination in a controlled environment such as a laboratory or manufacturer's facility.

11.2.3 You must add interference gases listed in table 1 of this PS to a constant concentration of EtO reference gas.

11.2.3.1 You may not use an effective reference EtO gas concentration greater than ten times the estimated instrument LOD.

11.2.3.2 Inject the EtO and interferents described in section 11.1.5 of this PS directly into the inlet to the analyzer, allow time for the value to stabilize and then collect measurement data for 15 minutes and average those results. Repeat this procedure to obtain a total of seven or more of these runs, purging the measurement system with ambient air between each run, to determine the LOD.

11.2.4 Calculate the standard deviation of the measured values and define the LOD as three times the standard deviation of these measurements.

11.2.5 You must verify the controlled environment LOD of section 11.2.2 of this PS for your CEMS during initial setup and field certification testing using the SA procedure in appendix A of this PS with the following exceptions:

11.2.5.1 You must make three independent SA measurements spiking the native source concentration by no more than five times the controlled environment LOD concentration determined in section 11.2.4.

11.2.5.2 You must perform the SA as a dynamic spike by passing the spiked source gas sample through all filters, scrubbers, conditioners, and other monitoring system components used during normal sampling, and as much of the sampling probe as practical.

11.2.5.3 The amount detected, or standard addition response (SAR), is based on the average difference of the native EtO concentration in the stack or duct relative to the native stack concentration plus the SA. You must be able to detect the effective spike addition (ESA) above the native EtO present in the stack gas matrix. The ESA is calculated using equation A7 in appendix A of this PS.

11.2.5.4 If the field verification of your system LOD does not demonstrate a SAR greater than or equal to your initial controlled environment LOD, you must increase the SA concentration incrementally and repeat the field verification procedure until the SAR is equal to or greater than LOD. The site-specific standard addition detection level (SADL) is equal to the standard addition needed to achieve the acceptable SAR, and the SADL replaces the controlled environment LOD. The SADL is calculated as the ESA using equation A7 in appendix A of this PS. As described in section 13.1 of this PS, the controlled environment LOD or the SADL that replaces a controlled environment LOD must be less than 20 percent of the applicable emission limit.

11.3 Response Time Determination. You must determine ME– and SA–RT.

11.3.1 For ME–RT, start the upscale RT determination by injecting zero gas into the measurement system as required by the procedures in section 11.4 of this PS. For the SA–RT start the upscale RT determination at native stack concentration of EtO. Allow the value to stabilize, which for the purpose of this PS is a change no change greater than 1.0 percent of span or 10 ppbv (whichever is greater) for 30 seconds.

11.3.2 When the CEMS output has stabilized, record the response in ppbv, record the time (hh:mm:ss), and immediately introduce an upscale (high level) or spike reference gas as required by the relevant (ME–RT or SA–RT) procedure. Record the time (hh:mm:ss) required for the measurement system to reach 95 percent of the change to the final stable value, the difference in these times is the upscale RT.

11.3.3 Reintroduce the zero gas for the ME–RT or stop the upscale gas flow for the SA–RT and immediately record the time (hh:mm:ss). Record the time (hh:mm:ss) required to reach within 95 percent of the previous stable response in 11.3.1 or 10 ppbv (whichever is greater); the difference in these times is the downscale RT.

Note: For CEMS that perform a series of operations (purge, blow back, sample integration, analyze, etc.), you must start adding reference or zero gas immediately after these procedures are complete.)

11.3.4 Repeat the entire procedure until you have three sets of data, then determine the mean upscale and mean downscale RTs for each relevant procedure (from each measurement point if the CEMS is time-sharing). Report the greater of the average upscale or average downscale RTs as the RT for the system.

11.4 Measurement Error (ME) Test

11.4.1 The measurement error test must be performed at the same time as the calibration drift test when the system is being placed in service. The measurement error test must be performed any time a substantive change (see section 1.2.5) has been made to the measurement system.

11.4.1.1 Introduce reference gases to the CEMS probe, prior to the sample

conditioning and filtration system. You may use a gas dilution system meeting the requirement in section 7.2 of this PS.

11.4.1.2 Challenge the measurement system with a zero gas and at the three upscale EtO reference gas concentrations in the range shown in table 3 of this PS. You may introduce different reference gas concentrations in any order, but you must not introduce the same gas concentration twice in succession.

11.4.1.3 Introduce the calibration gas into the sampling probe with sufficient flow rate to replace the entire source gas sample and continue the gas flow until the response is stable, as evidenced when the difference between two consecutive measurements is within 1.0 percent of span or 5 ppbv (whichever is less). Record this value and inject the next calibration gas.

11.4.1.4 Make triplicate measurements for each reference gas for a total of twelve measurements.

11.4.1.5 At each reference gas concentration, determine the average of the three CEMS responses (MC_l). Calculate the ME using equation 3A in section 12.3.

11.4.1.6 For non-dilution systems, you may adjust the system to maintain the correct flow rate at the analyzer during the test, but you may not make adjustments for any other purpose. For dilution systems, you must operate the measurement system at the appropriate dilution ratio during all system ME checks, and you may make only the adjustments necessary to maintain the proper ratio.

11.4.2 You may use table 5 in section 17.0 to record and report your ME test results.

11.4.3 If the ME specification in section 13.3 is not met for all four reference gas concentrations, take corrective action, and repeat the test until an acceptable 4-level ME test is achieved.

11.5 Seven-Day Calibration Drift (CD) Test

11.5.1 The CD Test Period. Prior to the start of the RA tests, you must perform a seven-day CD test. The purpose of the seven-day CD test is to verify the ability of the CEMS to maintain calibration for each of seven consecutive unit operating days as specified in section 11.5.5 of this PS.

11.5.2 The CD tests must be performed using the zero gas and high-level reference gas standards as defined in table 3 of this PS.

11.5.3 Conduct the CD test on each day during continuous operation of the CEMS and normal facility operations following the procedures in section 11.7 of this PS, except that the zero gas and high-level gas need only be introduced to the measurement system once each for the seven days.

11.5.4 If periodic automatic or manual adjustments are made to the CEMS zero and upscale response factor settings, conduct the CD test immediately before these adjustments.

Note: Automatic signal or mathematical processing of all measurement data to determine emission results may be performed throughout the entire CD process.

11.5.5 Determine the magnitude of the CD at approximately 24-hour intervals, for 7 consecutive unit operating days. The 7 consecutive unit operating days need not be 7 consecutive calendar days.

11.5.6 Record the CEMS response for single measurements of zero gas and high-level reference gas. You may use table 6 in section 17 of this PS to record and report the results of your 7-day CD test. Calculate the CD using equation 3B in section 12.3. Report the absolute value of the differences as a percentage of the span value.

11.5.7 The zero-level and high-level CD for each day must be less than 5.0 percent of the span value or an absolute difference of 10 ppbv, as specified in section 13.2 of this PS. You must meet this criterion for 7 consecutive operating days.

11.5.8 Dynamic Spiking Option for Seven-Day CD Test. You have the option to conduct a high-level dynamic spiking procedure for each of the 7 days in lieu of the high-level reference gas injection described in sections 11.5.2 and 11.5.3. If this option is selected, the daily zero CD check is still required.

11.5.8.1 To conduct each of the seven daily mid-level dynamic spikes, you must use the DS procedure described in appendix A of this PS using a single spike chosen to yield the range as indicated in table 3.

11.5.8.2 You must perform the dynamic spike procedure by passing the spiked source gas sample through all filters, scrubbers, conditioners, and other monitoring system components used during normal sampling, and as much of the sampling probe as practical.

11.5.8.3 Calculate the high-level CD as a percent of span using equation A6 of appendix A to this PS and calculate the zero-drift using equation 3B in section 12.3. Record and report the results as described in sections 11.5.6 and 11.5.7.

11.6 Relative Accuracy Test

11.6.1 Unless otherwise specified in an applicable regulation, use Method 320 as the RM for EtO measurement. Conduct the RM tests in such a way that they will yield results representative of the emissions from the source that can be compared to the CEMS data. You must collect gas samples that are at stack conditions (hot and wet), and you must traverse the stack or duct as required in section 11.6.3.

11.6.2 Conduct the diluent (if applicable), moisture (if needed), and pollutant measurements simultaneously. If the emission standard is expressed in a mass unit (*i.e.,* lb/hr) you must also determine the flowrate simultaneously with each test using Method 2, 2A, 2B, 2C or 2D in appendix A–1 to this part, as applicable.

11.6.3 Reference Method Measurement Location and Traverse Point(s) Selection.

11.6.3.1 Measurement Location. Select, as appropriate, an accessible RM measurement location at least two equivalent diameters downstream from the nearest control device, point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur, and at least one-half equivalent diameter upstream from the effluent exhaust or a control device. When pollutant concentration changes are due solely to diluent leakage (*e.g.,* air heater leakages) and pollutants and diluents are simultaneously measured at the same location, a half diameter may be used in lieu of two equivalent diameters. The equivalent duct diameter is calculated according to Method 1 in appendix A–1 to this part. The CEMS and RM sampling locations need not be the same.

11.6.3.2 Traverse Point Selection. Select traverse points that assure acquisition of representative RM samples over the stack or duct cross section according to one of the following options: (a) sample at twelve traverse points located according to section 11.3 of Method 1 in appendix A–1 to this part or (b) sample at the three traverse points at 16.7, 50.0, and 83.3 percent of the measurement line. Alternatively, you may conduct a stratification test following the procedures in sections 11.6.3.2.1 through 11.6.3.2.4 to justify sampling at a single point. Stratification testing must be conducted at the sampling location to be used for the RM measurements during the RA test and must be made during normal facility operating conditions. You must evaluate the stratification by measuring the gas on the same moisture basis as the EtO CEMS (wet or dry). Stratification testing must be repeated for each RA test program to justify single point.

11.6.3.2.1 Use a probe of appropriate length to measure the EtO concentration, as described in this section, using 12 traverse points located according to section 11.3 of Method 1 in appendix A–1 to this part for a circular stack or nine points at the centroids of similarly shaped, equal area divisions of the cross section of a rectangular stack.

11.6.3.2.2 Calculate the mean measured concentration for all sampling points (MN_{avg}).

11.6.3.2.3 Calculate the percent stratification (S_t) of each traverse point using equation 5 in section 12.5.

11.6.3.2.4 The gas stream is considered to be unstratified and you may perform the RA testing at a single point that most closely matches the mean if the concentration at each traverse point differs from the mean measured concentration for all traverse points by no more than 5.0 percent of the mean concentration of EtO or 10 ppbv, whichever is less restrictive.

11.6.4 In order to correlate the CEMS and RM data properly, record the beginning and end of each RM run (including the time of day in hours, minutes, and seconds) using a clock synchronized with the CEMS clock used to create a permanent time record with the CEMS output.

11.6.5 You must conduct the RA test during representative process and control operating conditions or as specified in an applicable regulation, permit or subpart.

11.6.6 Conduct a minimum of nine RM test runs.

Note: More than nine RM test runs may be performed. If this option is chosen, up to three test run results may be excluded so long as the total number of test run results used to determine the CEMS RA is greater than or equal to nine. However, all data must be reported including the excluded test runs.

11.6.7 Analyze the results from the RM test runs using equations 9 through14 in section 12.6. Calculate the RA between the CEMS results and the RM results.

11.7 Record Keeping and Reporting

11.7.1 Record the results of the CD test, the RT test, the ME test, and the RA test. Also keep records of the RM and CEMS field data, calculations, and reference gas certifications necessary to confirm that the performance of the CEMS met the performance specifications.

11.7.2 For systems that use Method 205 to prepare EtO reference gas standards, record results of Method 205 performance test field evaluation, reference gas certifications, and gas dilution system calibration.

11.7.3 Record the LOD and field verified SADL for the CEMS in ppbv.

11.7.4 Record the results of the interference test.

11.7.5 Report the results of all certification tests to the appropriate regulatory agency (or agencies), in hardcopy and/or electronic format, as required by the applicable regulation or permit.

12.0 Calculations and Data Analysis

12.1 Nomenclature.

C_i = Zero or EtO reference gas concentration used for test i (ppbv);

CC = Confidence coefficient (ppbv);

CD = Calibration drift (percent);

d_{avg} = Mean difference between CEMS response and the reference gas (ppbv);

d_i = Difference of CEMS response and the RM value (ppbv or units of emission standard, as applicable);

I = Total interference from major matrix stack gases (percent);

ΔMC_{avg} = Average of the 3 absolute values of the difference between the measured EtO calibration gas concentrations with and without interference from selected stack gases (ppbv);

MC_i = Measured EtO (or zero) reference gas concentration i (ppbv);

$\overline{MC}_i$ = Average of the measured EtO (or zero) reference gas concentration i (ppbv);

MC_{int} = Measured EtO concentration of the EtO reference gas plus the individual or combined interference gases (ppbv);

ME = Measurement error for CEMS (percent);

MN_{avg} = Average concentration at all sampling points (ppbv);

MN_{bi} = Measured native concentration bracketing each calibration check measurement (ppbv);

MN_i = Measured native concentration for test or run I (ppbv);

n = Number of measurements in an average value;

RA = Relative accuracy of CEMS compared to a RM (percent);

RM_{avg} = Mean measured RM value (ppbv) or units of the emission standard);

RM_i = RM concentration for test run i (ppbv or units of the emission standard);

S = Span value (ppmv);

S_d = Standard deviation of the differences (ppmv);

S_{ti} = Stratification at traverse point i (percent);

SADL = Standard addition detection level (ppmv);

$t_{0.975}$ = One-sided t-value at the 97.5th percentile obtained from table 4 in section 17.0 for n-1 measurements;

12.2 Calculate the difference between the measured EtO concentration with and without interferents for each interference gas (or mixture) for your CEMS as:

$$\Delta MC_{avg}=\frac{\sum_{i=1}^{3}|MC_i-MC_{int}|}{3} \quad \text{Eq. 1}$$

Calculate the total percent interference as:

$$I=\sum_{i=1}^{n}\frac{\Delta MC_{avg}}{\overline{MC}_i}x100 \quad \text{Eq. 2}$$

12.3 Calculate the ME or CD at Concentration i as:

$$ME=\frac{|C_i-\overline{MC}_i|}{S} \quad \text{Eq. 3A}$$

$$CD=\frac{|C_i-MC_i|}{S} \quad \text{Eq. 3B}$$

12.4 Calculate the average native concentration before and after each calibration check measurement as:

$$MN_{bi}=\frac{MN_i+MN_{i+1}}{2} \quad \text{Eq. 4}$$

12.5 Calculate the Percent Stratification at Each Traverse Point as:

$$S_{ti}=\frac{|MN_i-MN_{avg}|}{MN_{avg}} \quad \text{Eq. 5}$$

12.6 Calculate the RA Using RM and CEMS Data

12.6.1 Determine the CEMS final integrated average pollutant concentration or emission rate for each RM test period. Consider system RT, if important, and confirm that the results have been corrected to the same moisture, temperature, and diluent concentration basis, as applicable. If the emission standard is based on a mass emission (*i.e.,* lbs/hr), confirm the results have been calculated correctly.

12.6.3 Make a direct comparison of the average RM results and CEMS average value for identical test periods.

12.6.4 For each test run, calculate the arithmetic difference of the RM and CEMS results using equation 6.

$$d_i = RM_i - MN_i \qquad \text{Eq. 6}$$

12.6.5 Calculate the standard deviation of the differences (S_d) of the CEMS measured results and RM results using equation 7.

$$S_d = \sqrt{\frac{\sum_i^n \left(d_i - \left(\sum_{i=1}^n d_i\right)\right)^2}{n-1}} \qquad \text{Eq. 7}$$

12.6.6 Calculate the confidence coefficient (CC) for the RA test using equation 8.

$$CC = t_{0.975}\left(\frac{S_d}{(n^{1/2})}\right) \qquad \text{Eq. 8}$$

12.6.7 Calculate the mean difference (d_{avg}) between the RM and CEMS values in the units of ppbv or of the emission standard using equation 9.

$$d_{avg} = \frac{1}{n}\sum_{i=1}^{n} d_i \qquad \text{Eq. 9}$$

12.6.8 Calculate the average RM value using equation 10.

$$RM_{avg} = \frac{1}{n}\sum_{i=1}^{n} RM_i \qquad \text{Eq. 10}$$

12.6.9 Calculate RA of the CEMS using equation 11.

$$RA = \left[\frac{(|d_{avg}| + CC)}{RM_{avg}}\right] x100 \qquad \text{Eq. 11}$$

13.0 Method Performance

13.1 Level of Detection. You may not use a CEMS whose LOD or SADL is greater than 20 percent of the applicable regulatory limit or other action level for the intended use of the data. If the regulatory limit is not based on a concentration, document the calculated concentration equivalent as required in section 11.7.

13.2 Calibration Drift. The zero- and high-level calibration drift for the CEMS must not exceed 5.0 percent of the span value or an absolute difference of 10.0 ppbv for 7 consecutive operating days.

13.3 Measurement Error. The ME must be less than or equal to 5.0 percent of the span or an absolute difference of 10.0 ppbv value at the low-, mid-, and high-level reference gas concentrations.

13.4 Relative Accuracy. Unless otherwise specified in an applicable regulation or permit, the RA of the CEMS, whether calculated in units of EtO concentration or in units of the emission standard, must be less than or equal to 20.0 percent of the RM when RM_{avg} is used in the denominator of equation 11.

13.4.1 In cases where the RA is calculated on a concentration (ppmv) basis, if the average RM emission level for the test is less than 50 percent of the EtO concentration equivalent to the emission standard, you may substitute the EtO concentration equivalent to the standard in the denominator of equation 14 in place of RM_{avg}.

13.4.2 Similarly, if the RA is calculated in units of the emission standard and the EtO emission level measured by the RMs is less than 50 percent of the emission standard, you may substitute the emission standard in the denominator of equation 14 in place of RM_{avg}.

13.4.3 The alternative calculated RA in paragraph 13.4.1 or 13.4.2 must be less than or equal to 15.0 percent.

13.5 Interference Test.

13.5.1 The sum of the interference response(s) from equation 2 must not be greater than 2.5 percent of the calibration span or ±3.0 percent of the equivalent EtO concentration used for the interference test, whichever is less restrictive. The results are also acceptable if the sum of the interference response(s) does not exceed ten times the LOD or 30 ppbv.

14.0 Pollution Prevention—[Reserved]

15.0 Waste Management—[Reserved]

16.0 Bibliography

1. ''Method 301—Field Validation of Pollutant Measurement Methods from Various Waste Media,'' 40 CFR part 63, appendix A.

2. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, U.S. Environmental Protection Agency office of Research and Development, EPA/600/R–12/531, May 2012.

17.0 Tables, Diagrams, Flowcharts, and Validation Data

TABLE 1—INTERFERENCE TEST GAS CONCENTRATIONS

Potential interferent gas [1]	Approximate concentration (balance N_2)
CO_2	1% ± 0.2% CO_2.
CH_4	20 ± 5 ppm.
H_2O	5% ± 1% H_2O.[1]
N_2	Balance.[1]

[1] Any of these specific gases can be tested at a lower level if the manufacturer has provided reliableness for limiting or scrubbing that gas to a specified level in CEMS field installations.

TABLE 2—EXAMPLE INTERFERENCE TEST DATA SHEET

Date of Test	
Analyzer type	
Model Number	
Serial Number	
Span	
Test Organization	
Test Personnel	

Interference gas or combination	EtO concentration (ppbv)	EtO concentration w/interference (ppbv)	Absolute difference (ppbv)	Average absolute difference (ppbv)

Interference gas or combination	EtO concentration (ppbv)	EtO concentration w/interference (ppbv)	Absolute difference (ppbv)	Average absolute difference (ppbv)

TABLE 3—PERFORMANCE SPECIFICATION TEST ZERO AND REFERENCE GAS RANGES

Test	Units	EtO zero and reference gas concentrations in terms of percent of span [a]				Section
		Zero	Low level	Mid-level	High level	
Calibration Drift	% Of Span	<LOD	NA		[b] 80–100	11.5
Measurement Error	% Of Span	NA	20–30	50–60	80–100	11.4

[a] Reference gas concentration must be NIST traceable. (See section 7.1)
[b] High-level is required. For DS calibration drift option, choose a concentration that yields a value in this range at the analyzer.

TABLE 4—STUDENT'S t-VALUES

n – 1 [a]	t-value	n – 1 [a]	t-value	n – 1 [a]	t-value
1	12.71	11	2.201	21	2.080
2	4.303	12	2.179	22	2.074
3	3.182	13	2.160	23	2.069
4	2.776	14	2.145	24	2.064
5	2.571	15	2.131	25	2.060
6	2.447	16	2.120	26	2.056
7	2.365	17	2.110	27	2.052
8	2.306	18	2.101	28	2.048
9	2.262	19	2.093	29	2.045
10	2.228	20	2.086	30	2.042

[a] The value n is the number of independent pairs of measurements. Either discrete (independent) measurements in a single run or run averages can be used.

TABLE 5—MEASUREMENT ERROR TEST DATA

Source:			Date:		
CEMS:			Location:		
Serial Number:			Span:		
Run number	Reference gas value (ppbv)	CEMS response (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)
1					
2					
3					
4					
5					
6					
7					
8					

TABLE 5—MEASUREMENT ERROR TEST DATA—Continued

Source:			Date:		
CEMS:			Location:		
Serial Number:			Span:		
Run number	Reference gas value (ppbv)	CEMS response (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)
9					
Mean Difference—ppbv					
Measurement Error—%					

TABLE 6—CALIBRATION DRIFT TEST DATA

Source/Location:						
CEMS:						
Instrument Serial Number:						
Instrument Span:						
Day	Date	Time	Reference gas value (ppbv)	CEMS response (ppbv)	Difference (ppbv)	Percent of span
Zero Gas						
1			0			
2			0			
3			0			
4			0			
5			0			
6			0			
7			0			
High-Level Gas						
1						
2						
3						
4						
5						
6						
7						

PS–19 Appendix A Standard Addition Procedures

1.0 Scope and Application

1.1 This appendix A (appendix PS–19A) to Performance Specification 19 (PS–19) describes the procedure and performance requirements for standard addition (SA) as a quality check for ethylene oxide (EtO) continuous emission monitoring systems (CEMS).

1.2 This procedure must be used, as a level of detection (LOD) verification of all field-installed CEMS. Additionally, it is allowed by Procedure 7 in appendix F to this part as an alternative to upscale calibration drift (CD) tests, cylinder gas audits and relative accuracy audits (RAAs), and may be used for quality assurance purposes under other applicable regulations or permits that require EtO monitoring.

2.0 Summary of the Appendix for Standard Addition

As used here, SA is a gas phase method of standard additions (either static or dynamic) used to verify the accuracy of CEMS measurements in the presence of the sample matrix. For extractive CEMS, it consists of spiking a known quantity of EtO dynamically into the measurement system as an addition to the native EtO and the native source gas matrix.

3.0 Definitions

(See PS–19 and Procedure 7 of appendix F to this part for the Definitions Used in this appendix.)

4.0 Interferences

Interferences are discussed in PS–19, section 4.0.

5.0 Safety

The procedures required under this appendix may involve hazardous materials,

operations, and equipment. This procedure may not address all of the safety problems associated with these procedures. You as the facility or operator must establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. As the CEMS user, you should consult instrument operation manuals, material safety data sheets, compressed gas safety requirements, and other Occupational Safety and Health Administration regulations for specific precautions to be taken.

6.0 Equipment and Supplies

An example of equipment and supplies is described in section 6 of PS–18.

7.0 Reagents and Standards

SA materials must meet the requirements defined for reference gases in section 7 of PS–19 to perform this procedure.

8.0 Standard Addition and Dynamic Spiking Procedure

The standard addition procedure consists of measuring the native source gas concentration, addition of reference gas, and measurement of the resulting SA elevated source gas concentration. EtO is spiked dynamically and thus, one must account for the dilution of sample gas from the addition of the EtO reference gas.

8.1 SA Concentration and Measurement Replicates.

8.1.1 You must inject EtO gas to create a measured concentration based on the requirements of the particular performance test (*e.g.,* LOD verification, CD).

8.1.2 Each dynamic spike (DS) or standard addition (SA) replicate consists of a measurement of the source emissions concentration of EtO (native stack concentration) with and without the addition of EtO. With a single CEMS, you must alternate the measurement of the native and SA-elevated source gas so that each measurement of SA-elevated source gas is immediately preceded and followed by a measurement of native stack gas. Introduce the SA gases in such a manner that the entire CEMS is challenged. Alternatively, you may use an independent continuous EtO monitor to measure the native source concentration before and after each standard addition as described in section 8.1.4.

8.1.3 Unless specified otherwise by an applicable rule, your SA-elevated concentration may not exceed 100 percent of span when the SA and native EtO concentration are combined.

8.1.4 As an alternative to making background measurements pre- and post-SA, you may use an independent continuous EtO monitor as a temporary unit to measure native stack EtO concentration while simultaneously using the CEMS to measure the SA-elevated source concentration. If you use an independent continuous EtO monitor you must make one concurrent background or native EtO measurement using both the installed CEMS and the independent continuous EtO monitor, immediately before the SA procedure in section 8.2 or 8.3 begins, to confirm that the independent monitoring system measures the same background concentration as the CEMS being qualified with this PS.

8.2 Dynamic Spiking Procedure.

8.2.1 Your EtO spike addition must not alter the total volumetric sample system flow rate or basic dilution ratio of your CEMS (if applicable).

8.2.2 Your spike gas flow rate must not contribute more than 10 percent of the total volumetric flow rate through the CEMS.

8.2.3 You must determine a dilution factor (DF) or relative concentration of EtO for each dynamic spike. Calibrated, NIST-traceable flow meters accurate to within 2.0 percent or highly accurate tracer gas measurements are required to make the necessary DF determinations at the accuracy required for this PS. Calibrated, NIST-traceable flow meters (*e.g.,* venturi, orifice) accurate to within 2.0 percent should be recertified against an NIST-traceable flow meter annually. Note: Since the spiking mass balance calculation is directly dependent on the accuracy of the DF determination, the accuracy of measurements required to determine the total volumetric gas flow rate, spike gas flow rate, or tracer gas standard addition concentration is critical to your ability to accurately perform the DS procedure and calculate the results.

8.2.4 You must monitor and record the total sampling system flow rate and sample dilution factor (DF) for the spiking and stack gas sampling systems to ensure they are known and do not change during the spiking procedure. Record all data on a data sheet similar to table A1 in section 13 of this appendix.

8.2.4.1 You may either measure the spike gas flow and the total flow with calibrated flow meters capable of NIST traceable accuracy to ±2.0 percent or calculate the flow using a stable tracer gas included in your spike gas standard.

8.2.4.2 If you use flow measurements to determine the spike dilution, then use equation A1 in section 11.2.1 of this appendix PS–19A to calculate the DF. Determination of the spike dilution requires measurement of EtO spike flow (Q_{spike}) and total flow through the CEM sampling system (Q_{probe}).

8.2.4.3 If your CEMS is capable of measuring an independent stable tracer gas, you may use a spike gas that includes the tracer to determine the DF using equation A2 or A3 (sections 11.2.2 and 11.2.3 of this appendix PS–19A) depending on whether the tracer gas is also present in the native source emissions.

8.2.4.4 For extractive CEMS, you must correct the background measurements of EtO for the dilution caused by the addition of the spike gas standard. For spiking systems that alternate between addition of EtO and zero gas at a constant DF, the background measurements between spikes will not be equal to the native source concentration.

8.2.5 Begin by collecting unspiked sample measurements of EtO. You must use the average of two unspiked sample measurements as your pre-spike background.

Note: Measurements should agree within 5.0 percent or three times the level of detection to avoid biasing the spike results.

8.2.5.1 Introduce the EtO gas spike into the permanent CEMS probe, upstream of the particulate filter or sample conditioning system and as close to the sampling inlet as practical.

8.2.5.2 Maintain the EtO gas spike for at least twice the DS response time of your CEMS or until the consecutive measurements agree within 5.0 percent. Collect two independent measurements of the native plus spiked EtO concentration.

8.2.5.3 Stop the flow of spike gas for at least twice the DS response time of your CEMS or until the consecutive measurements agree within 5.0 percent. Collect two independent measurements of the native EtO concentration.

8.2.6 Repeat the collection of sample measurements in section 8.2.5 until you have data for each spike concentration including a final set of unspiked sample measurements according to section 8.2.5.3.

8.2.7 Verify that the CEMS responded as expected for each spike gas injection, and that the data quality is not impacted by large shifts in the native source concentration. Discard and repeat any spike injections as necessary to generate a complete set of the required replicate spike measurements.

8.2.8 Calculate the standard addition response (SAR) for extractive CEMS, using equation A4 in section 11.2, of this appendix PS–19A.

8.2.9 If the DS results do not meet the specifications for the appropriate performance test in PS–19 or Procedure 7 of appendix F of this part, you must take corrective action and repeat the DS procedure.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization—Reserved

11.0 Calculations and Data Analysis

Calculate the SA response for each measurement and its associated native EtO measurement(s), using equations in this section. (Note: For cases where the emission standard is expressed in units of lb/hr or corrected to a specified O_2 or CO_2 concentration, an absolute accuracy specification based on a span at stack conditions may be calculated using the average concentration and applicable conversion factors. The appropriate procedures for use in cases where a percent removal standard is more restrictive than the emission standard is the same as in PS–2, sections 12 and 13, in this appendix.)

11.1 Nomenclature.

C_{spike} = Actual EtO reference gas concentration spiked (*e.g.,* bottle or reference gas concentration) ppmv;

$C_{tracer\ spiked}$ = Tracer gas concentration injected with spike gas (''reference concentration'') ppmv;

DF = Spiked gas dilution factor;

DSCD = Calibration drift determined using DS procedure (percent);

DSE = Dynamic spike error (ppmv);

ESA = Effective spike addition (ppmv);

MC_{SA} = Measured SA-elevated source gas concentration (ppmv);

MC_{spiked} = Measured EtO reference gas concentration i (ppmv);

MC_{native} = Average measured concentration of the native EtO (ppmv);

$M_{native\ tracer}$ = Measured tracer gas concentration present in native effluent gas (ppmv);

$M_{spiked\ tracer}$ = Measured diluted tracer gas concentration in a spiked sample (ppmv);

Q_{spike} = Flow rate of the dynamic spike gas (Lpm);

Q_{probe} = Average total stack sample flow through the system (Lpm);

S = Span (ppmv);

SAR = Standard addition response (ppmv)

11.2 Calculating Dynamic Spike Response and Error.

11.2.1 If you determine your spike DF using spike gas and stack sample flow measurements, calculate the DF using equation A1:

$$DF=\frac{Q_{spike}}{Q_{probe}} \quad \text{Eq. A1}$$

11.2.2 If you determine your spike DF using an independent stable tracer gas that is not present in the native source emissions, calculate the DF for DS using equation A2:

$$DF=\frac{M_{spiked\ tracer}}{C_{tracer\ spiked}} \quad \text{Eq. A2}$$

11.2.3 If you determine your spike dilution factor using an independent stable tracer that is present in the native source emissions, calculate the dilution factor for dynamic spiking using equation A3:

$$DF=\frac{M_{spiked\ tracer} - M_{native\ tracer} -}{C_{tracer\ spiked} - M_{native\ tracer}} \quad \text{Eq. A3}$$

11.2.4 Calculate the SA response using equation A4:

$$SAR=MC_{spiked}-(1-DF)xMC_{native} \quad \text{Eq. A4}$$

11.2.5 Calculate the DS error using equation A5.

$$DSE=MC_{spiked}-MC_{native}-DFx(C_{spike}-MC_{native}) \quad \text{Eq. A5}$$

11.2.6 Calculating CD using DS. When using the DS option for determining mid-level CD, calculate the CD as a percent of span using equation A6:

$$DCSD=\frac{|DSE|}{S} \quad \text{Eq. A6}$$

11.2.7 The effective spike addition (ESA) is the expected increase in the measured concentration as a result of injecting a spike. Calculate ESA using equation A7:

$$ESA=DF(C_{spike}-MC_{native}) \quad \text{Eq. A7}$$

12.0 Reserved

13.0 Tables and Figures

TABLE A13—1—SPIKE DATA SHEET

Facility Name:	Date:	Time:
Unit(s) Tested:	Personnel:	
Analyzer Make and Mode		

TABLE A13—1—SPIKE DATA SHEET—Continued

Serial Number		
Calibration Span		

Q_{probe} (lpm)	Q_{spike} (lpm)	DF [1]	MC_{native}			Actual value (ppb)		DSE (ppbv)
			Pre	Post	Avg.	C_{spike} [2]	MC_{spike} [3]	
							Average	
							SD	

[1] DF must be less than or equal to 10%.
[2] C_{spike} = Actual EtO concentration of the spike gas, ppbv.
[3] MC_{spike} = Measured EtO concentration of the spiked sample at the target level, ppbv.

PS–19 Appendix B Preparation and Certification of Ethylene Oxide Gas Standards

1.0 Scope and Application

1.1 This appendix (appendix PS–19B) to Performance Specification 19 (PS–19) describes the procedure and performance criteria for the preparation and certification of EtO Gas Manufacturer Primary Standards (GMPS) and Gas Manufacturer Alternative Certified Standards (GMACS). These procedures are not specific to ethylene oxide and could be transferable to the preparation of gas standards for other pollutants regulated under 40 CFR parts 59, 60, 61, 63, and 65.

2.0 Summary of the Appendix

EPA requires the use of EPA Protocol gas standards for emissions monitoring. These gases are established following the EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R–12/531) otherwise referred in this appendix PS–19B as the EPA Traceability Protocol. The EPA Traceability Protocol requires the use of certified reference gas standards directly traceable to National Institute of Standards and Technology (NIST) or other recognized national metrology institute (NMI) reference gas standards. A NIST certified value is a value for which NIST has the highest confidence in that all known or suspected sources of bias and imprecision have been accounted for. Without NIST or other NMI reference gas standards, the necessary EPA Protocol gas standards cannot be prepared. An alternative approach is needed to establish a gas standard functionally equivalent to the EPA Protocol gas standard when NIST or NMI reference gas standard are not available. This appendix PS–19B is intended to provide procedures and performance criteria for the establishment of Gas Manufacturer Alternative Certified Standards (GMACS), the functional equivalent of EPA Protocol gas standards. GMACS and Gas Manufacturer Primary Standards (GMPS), the functional equivalent of the NIST or NMI reference gas standards. The GMPS are the reference gases used to establish the certified concentrations of the GMACs. The GMPS are established using a dual certification approach where the gravimetrically prepared reference value is confirmed using an independent measurement approach traceable to the International System of Units (SI) and references materials or devices.

2.1 This appendix PS–19B is intended to be performance-based and allow specialty gas manufacturers (SGM) flexibility in the preparation and certification of GMPS and GMACS.

2.2 This appendix PS–19B is not intended to be a replacement for the EPA Protocol gases established according to the EPA Traceability Protocol when calibration gases that meet EPA Traceability Protocol requirements are available. When NIST or other recognized NMI reference gas standards are manufactured and readily available, those gases must be used.

2.3 This appendix PS–19B is reliant on the procedures included the EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R–12/531). Users of this appendix PS–19B for the preparation of GMPS and GMACS must be proficient with the preparation protocol cylinders using this standard.

Note: This appendix PS–19B does not require the user to participate in any protocol gas verification program.

2.4 Any alternatives to the procedures in this appendix PS–19B are subject to Administrator review under the alternative test method the authority to approve alternatives or changes to test methods specified in the General Provisions to 40 CFR parts 60, 61, and 63 (§§ 60.8(b)(2), 61.13(h)(1)(ii), and 63.7(e)(2)(ii)). Requests for alternative to the procedures must be submitted to the agency according to Guideline Document 22 (*https://www.epa.gov/system/files/documents/2022-09/gd-022r5.pdf*).

3.0 Definitions

3.1 *Certification* means a set of procedures and performance criteria used by a SGM to prepare and certify a GMPS and/or GMACS for commercial sale.

3.2 *Certified Reference Material or CRM* means a material that has been certified or verified by either NIST or other NMI (*e.g.,* VSL, NPL) and may be used for traceability purposes.

3.3 *Dual Method Certification* means a process in which the gravimetric value is independently confirmed by a measured value.

3.4 *EPA Protocol Gas means* a calibration or reference gas required for emissions monitoring directly traceable to NIST or

other accepted NMI reference gas standards, prepared following the EPA Traceability Protocol

3.5 *EPA Traceable Protocol for Assay and Calibration Gas Standards or commonly referred to as the ''EPA Traceability Protocol''* means the document The protocol allows producers of these standards, users of gaseous standards, and other analytical laboratories to establish traceability of EPA Protocol Gases to gaseous reference standards produced by the National Institute of Standards and Technology (NIST).

3.6 *Gas Calibration Cylinder means* a refillable cylinder that meets the applicable DOT/TC specifications for high pressure cylinders. The cylinders shall be permanently stamped with a unique value.

3.7 *Gas Manufacturer Alternative Certified Standards or GMACS* means a gas that has been prepared according to this procedure and serves as a functional substitute for an EPA Protocol Gas where EPA Protocol gases are not available.

3.8 *Gas Manufacturer Intermediate Standard* means a gas reference standard made by a gas supplier and certified according to the U.S. EPA protocol rules for GMISs. For the purpose of this Appendix, GMISs may be assayed against a GMPS.

3.9 *Gas Manufacturer Primary Standards or GMPS* means a reference gas standard prepared and certified by the SGM that serves as a functional substitute for the reference gas standards established by, but not yet available from NIST or other accepted NMI and required by the EPA Traceability Protocol to produce EPA Protocol gases.

3.10 *Gravimetry* means the quantitative measurement of an analyte by weight.

3.11 *NIST* means the National Institute of Standards and Technology, located in Gaithersburg, Maryland.

3.12 *NIST Traceable Reference Material or NTRM* means is a reference material produced by a commercial supplier with a well-defined traceability linkage to NIST and named by NIST procedures, on a batch rather than individual basis. This linkage is established via criteria and protocols defined by NIST that are tailored to meet the needs of the metrological community to be served.

3.13 *Primary Reference Materials or PRM* means a mixture composition is verified against VSL's own primary standard gas mixtures to confirm the assigned value.

3.14 *Protocol Gas* means a calibration or reference gas required for emissions monitoring traceable to NIST or other accepted NMI, prepared following the EPA Traceability Protocol.

3.15 *Research Gas Mixture or RGMs* means a reference material produced by a commercial supplier certified by NIST on an individual basis, often using non routine procedures, are called Research Gas Mixtures (RGMs), and may be used for traceability purposes.

3.16 *Specialty Gas Manufacturer or SGM* means an organization that prepares and certified gas calibration gas mixtures.

3.17 *International System of Units or SI* means the standards for international measurement and are comprised of length (meter), time (second), amount of substance (mole), electric current (ampere), temperature (kelvin), luminous intensity (candela), and mass (kilogram).

3.18 *Standard Reference Material or SRM* means a material or substance issued by NIST that meets NIST-specific certification criteria and is issues with that with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material.

3.19 *Uncertainty* means the expression of the statistical dispersion of the values attributed to a measured quantity. For the purpose of this appendix, uncertainty is calculated using the root sum square of all uncertainty budget items associated with each procedure at k=2 (*i.e.,* approximately 95 confidence).

3.20 VSL means Van Swinden National Lab, located in Delft, Netherlands.

4.0 Interferences—Reserved

5.0 Safety

The procedures required under this appendix may involve hazardous materials, operations, and equipment. This procedure may not address all of the safety problems associated with these procedures. You as the facility or operator must establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. You should consult instrument operation manuals, material safety data sheets, compressed gas safety requirements, and other Occupational Safety and Health Administration regulations for specific precautions to be taken.

6.0 Equipment and Supplies

This procedure is not prescriptive on the type of equipment or the supplies necessary for the preparation of GMPS and GMACS gaseous cylinder standards, however SGM must use the appropriate equipment and supplies necessary to meet the uncertainty requirements in this appendix.

7.0 Reagents and Standards—Reserved

8.0 Procedures.

The exact procedures used will depend on the gas manufacturer and the physical characteristics of the compound being prepared as a gaseous calibration standard. Any procedure is deemed appropriate so long as the criteria in section 8.1 for GMPS and section 8.2 for GMACS are met.

8.1 *Preparation and Certification of the GMPS.*

The GMPS certified value is established using the dual certification approach. A candidate GMPS cylinder is prepared gravimetrically, and its established reference value is confirmed by an independent measurement traceable to SI units as well as other appropriate reference materials. The level of agreement between the gravimetric reference value and the SI-based independent measurements along with the average value and associated, combined, expanded uncertainties serve to establish the certified reference value. If high purity reference material is not readily available for a gravimetric preparation, a user may petition the Administrator for an alternative method for preparation of a GMPS.

The procedures for the gravimetric preparation, stability evaluation, and independent verification of GMPS must meet the criteria in this section following the procedures in 8.1*(a)* through *(g).*

(a) Raw Materials

(b) GMPS Cylinder Preparation/Creation

(c) GMPS Cylinder Independent Verification

(d) GMPS Cylinder Certification

(e) GMPS Cylinder Stability

(f) GMPS Cylinder Expiration Period

(g) GMPS Documentation

8.1.1 Raw Materials. Raw materials used in the production of GMPS must be of high quality (*e.g.,* 99+% purity recommended). Additionally, because raw material purity is the largest component of uncertainty in gas gravimetry, SGMs must substantiate the purity of the raw material prior to use, either via (1) a validated certificate of analysis for the actual lot number purchased provided by the raw material vendor, or (2) a purity assay conducted by the SGM on the actual raw material to be used. The uncertainty of the raw material (U_r) assay must be included as one of the components of the total combined uncertainty for the mixture.

8.1.2 GMPS Gravimetric Cylinder Preparation/Creation. The GMPS standards shall be based on a gravimetric preparation. The gravimetric preparation shall yield an expected concentration for the target component, and with the required statistical controls in place to calculate the uncertainty of that concentration.

8.1.2.1 The scale used to generate the gravimetric reference standard must be independently calibrated over the range of target masses with ASTM E617–13 Class-1 weights on no less than a yearly basis. For such certifications, a high accuracy mass comparator (electronic or pendulum-type scale) is employed as the ''scale.'' The resolution of the scale should be sufficient to be able to calculate the overall uncertainty of any concentration derived from these steps.

8.1.2.1.1 The scale used for the gravimetric operation must be independently calibrated and traceable to NIST standards with a defined uncertainty (u_t).

8.1.2.1.2 The scale calibration must be checked before the start of each new weighing operation (*i.e.,* the day of) with a weight in the appropriate range that also meets ASTM E617–13 Class-1 requirements.

8.1.2.1.3 All material and equipment associated with the gravimetric analysis shall have or apply a procedure to estimate the uncertainty of the measurement, including but not limited to the balance(s) used (u_{ca}) standard weight (u_w).

8.1.2.1.4 The assay purity and associated material uncertainty (u_r) of the assay for each component raw material and the balance gas must be known. This purity deviation is factored into the uncertainty of the mass of each material blended into the mixture.

8.1.2.1.5 The procedures below are minimum requirements and do not speak to all of the details an SRM would do to ensure the preparation of a high-accuracy gravimetric candidate GMPS, (*e.g.,* controls for external factors that would influence scale reading accuracy buoyancy effects, moisture/dust adsorption on the cylinder

surface, and errors caused by the location of the cylinder on the scale). The SGM should develop and follow and internal standard operation procedures (SOP) for the preparation of the candidate GMPS.

8.1.2.1.6 Record the Target cylinder identification number, blend date, and balance gas on the appropriate form (see figure B–1). Additionally, record the intended component(s) to be used in the preparation for this candidate GMPS, identifying the standard type, material name (*e.g.,* Ethylene Oxide), MW (g/mol), and purity (wt%).

8.1.2.1.7 Add the components to the candidate GMPS, recording the weight of each component added.

8.1.2.1.8 GMPS Gravimetric Uncertainty. Calculate and document the gravimetric concentration (GMPS–C_g) for each component of the candidate GMPS. You must also document the combined uncertainty, expressed as the root sum of the uncertainty budget items identified, for the candidate GMPS value (GMPS–C_{gu}). Gravimetric preparation uncertainty budget items include:

(a) The purity of the raw material and the balance gas;

(b) The measured accuracy of the (electronic) balance including consideration the uncertainty of the calibration weights, the calibration uncertainty, and its linearity;

(c) The repeatability of the balance readings including errors caused by the location of the cylinder on the balance;

(d) Balance Buoyancy effects;

(e) Effects of moisture adsorption and dust on the outer surface of the cylinder;

(f) Cylinder dilutions, if any, used to prepare target concentrations, including propagated uncertainties.

8.1.3 *GMPS Independent Verification.* The certification of the candidate GMPS is based on independent measurements verifying the reference concentration of the gravimetrically prepared GMPS candidate. The independent verification must be based on a measurement approach traceable to the SI and may include the use of intrinsic NIST or accepted NMI reference materials to establish said traceability. Candidate independent verification measurement approaches include classical chemistry, spectroscopic approaches, as well as other instrumental approaches as long as adequate and appropriate SI traceability can be incorporated. The approach must be performed using NIST (or equivalent) traceable calibrations materials and using procedures that would allow the user to determine the overall uncertainty of the measurement. In some instances, a component may not be suitable to analysis using a classical approach, in those instances alternative approaches may be used do long as they (1) yield a concentration for the target com, (2) have a calculated uncertainty, (3) have traceability to the SI, and (4) documented conformity to the general metrological principles for primary methods outlined above.

8.1.3.1 *GMPS Independent Verification Measurement Uncertainty.* The cumulative uncertainty of the GMPS independent verification measurement approach is integral to the ability to assess the overall quality of the independent verification measurement. You must also document the combined uncertainty, expressed as the root sum of the uncertainty budget items identified. Ensure that all known or suspected sources of bias and imprecision have been accounted for. The following elements are examples of sources of measurement error that must be included in the overall uncertainty calculation for the GMPS independent verification measurement:

(a) The uncertainty of the certified reference solution (the traceability source);

(b) Any propagated uncertainties through serial dilutions;

(c) The errors in volumetric sampling of the candidate GMPS mixture;

(d) The uncertainty of the instrument calibration curve (least squares fit and residual);

(e) The bias or error associated with any measurement interferences;

(f) The repeatability of replicate aliquot injections from the same sample;

(g) The repeatability of replicate samples of the mixture;

(h) Any external factors influencing sampling or instrument accuracy;

(i) The uncertainty of measured volumetric gas flows;

(j) The bias or uncertainty associated with quantitative gas flow delivery;

(k) The error associated with instrumental measurement analyzers;

(l) Replicate measurement instrument error and precision.

8.1.4 GMPS Certification. The candidate GMPS certified value is based on three factors:

(a) The relative agreement between the gravimetric reference value and the independent, measured value of the gravimetrically-prepared GMPS candidate;

(b) The combined, expanded uncertainty (k=2) of the gravimetric value and independently measured concentrations values;

(c) The average of the independently measured concentrations values.

8.1.4.1 GMPS Relative Agreement. Calculate the relative agreement according to equation B–1, expressed as Relative Percent Difference (RPD) between the gravimetric concentration (GMPS–C_g) the independently measured concentrations (GMPS–C_a). The results of these two analyses must agree within 4.0 percent (%).

$$RPD = \frac{\text{GMPS-}C_g - \text{GMPS-}C_a}{\left(\frac{\text{GMPS-}C_g + \text{GMPS-}C_a}{2}\right)} \qquad \text{Eq. B1}$$

8.1.4.2 GMPS Combined, Expanded Uncertainty. Determine the individual uncertainties for the gravimetric approach (GMPS–C_{ug}) and the independent measurement verification approach (GMPS–C_{ua}) according to equation B–2. Establish the GMPS combined, expanded uncertainty (GMPS–C_{uc}) as the root sum of the two individual uncertainties with a coverage factor k=2. The combined uncertainty must ≤5.0 percent (%). If these objectives are not met, the candidate GMPS is not acceptable, and must not be used.

$$\text{GMPS-}C_{ug} \text{ or GMPS-}C_{ua} = \sqrt{u_1^2 + u_2^2 + \cdots + u_i^2} \qquad \text{Eq. B2}$$

8.1.4.3 GMPS Certified Concentration Value. If the GMPS meets the Relative Agreement criteria in section 8.1.5.3 and the combined, expanded uncertainty criteria in section 8.1.5.4, the GMPS is valid. The GMPS certified value (GMPS–C_C) is based on the independently measurement concentration (GMPS–C_a). The certification date is the date of the last confirmatory measurement.

8.1.4.4 An SGMs may propose to Administrator an alternative acceptance values for section 8.1.5.1 or 8.1.5.2 for those components that are unable to meet the documented criteria. These proposals must include sufficient documentation that the objectives are unreasonable for a given component and concentrations.

8.1.5 GMPS Stability Testing. The SGM must test and document mixture stability of the GMPS to assure that the mixture stays within claimed accuracy bounds for the entire claimed expiration period. Alternatively, once a preparation process has been developed, the SGM can perform a stability study consisting not less than three cylinders prepared using the defined process and at the concentration(s) defined by the process. Once the stability study cylinders have demonstrated acceptable stability for

the minimum expiration period (6-months), additional GMPS cylinders can be prepared under identical process conditions.

8.1.5.1 The SGM may select the sampling frequency based on the targeted expiration period, the gas consumed in the analysis and expected component behavior. Stability testing data must consist of at least:

(a) Five discrete samplings of the retained mixture for an expiration period of 6-months to 1-year;

(b) Ten discrete samplings for an expiration period of 1–3 years; and

(c) Twenty for any period greater than 3 years.

8.1.5.2 Stability testing must be conducted for each cylinder size/type and at a similar concentration as the candidate GMPS. Stability analyses must be performed using methods that assure consistent results can be achieved. If instrumental analysis using a gas standard is employed, use of a GMPS standard is highly recommended. In the absence of a certified GMPS, stability testing must be conducted using the same independent verification measurement procedures and methodology used in section 8.1.4, or using another known-to-be-stable gas standard containing the target component in a similar concentration range.

8.1.5.3 Stability testing data must not show any upward or downward trends that would cause the mixture to become out of specification prior to the claimed expiration period.

8.1.6 GMPS Expiration Period. The expiration period for the GMPS mixture based must be based on the empirical stability test data. The expiration periods for reactive gases must not exceed the length of the stability test, however for non-reactive gases you may forecast an expiration period not to exceed two times the actual stability testing duration. The maximum expiration period for a GMPS is time span from the date of preparation to the date of the last/most recent stability study may not be less than 6-months. Provided that acceptable stability is observed, the maximum expiration period may be extended by retaining the stability study cylinders and performing additional analyses.

8.1.7 GMPS Documentation. You must document the preparation of the GMPS through the appropriate record keeping and document the certification of a GMPS. The information is section 8.1.8.1 and 8.1.8.2 must be maintained as a record by the SGM for the purpose of maintaining traceability and to verify the preparation. The information in section 8.1.8.3 must be documented and maintained by the SGM. This documentation and the records of the preparation and certification must be made available upon request by the appropriate delegated authority.

8.1.7.1 The following information for the gravimetric preparation information of the GMPS must be documented and maintained as a record. This record should include but is not limited to the: blend date, gravimetric concentration, gravimetric concentration uncertainties as a percentage and absolute, reference material information and purity, scale ID, scale accuracy, and calculated gravimetric uncertainties associated with material, balance, and environmental effects. You must include sufficient information that will allow a 3rd party to recalculate the prepared concentration and expanded uncertainties.

8.1.7.2 The following information for the analytical verification of the GMPS must be recorded and maintained as a record. This record should include the confirming methodology and any associated SOPs, confirming concentration(s), instrumentation used, calibration standards used and associated COAs, calibration curve data, replicate analysis calculated, and expanded uncertainties.

8.1.7.3 The following information must be documented for inclusion on the COA for the GMACS.

(a) Manufacturer's company name and address of the producing location

(b) Manufacturer's part number for the GMPS, lot number, and/or production record.

(c) Cylinder number, cylinder type, cylinder preparation ID, moisture dew point and cylinder pressure.

(d) Certification date and claimed expiration date.

(e) GMPS component(s) name, final certified concentration(s) (GMPS–C_c), and balance gas.

(f) Gravimetric value and uncertainty

(g)Verification value and uncertainty

(h) GMPS final certified value and uncertainty absolute as a percentage (GMPS–C_u)

8.2 Preparation and Certification of the GMACS. The preparation and certification of the candidate GMACS is also based on the independent verification of the gravimetrically prepared reference value. However, the independent verification utilizes the GMPS to perform the independent verification. This is accomplished by following the procedures in section 2.1 and 2.2 of the EPA Traceability Protocol, using the GMPS as the certified reference material. The measured value of the independent verification following the EPA Traceability Protocol procedures also establishes the certified reference value, providing the relative agreement performance criteria are met.

8.2.1 GMACS Gravimetric Cylinder Preparation/Creation. The gravimetric preparation of the GMACS is identical to the procedures used to gravimetrically prepare the GMPS. You must maintain the same information required for the gravimetric preparation of GMPS, as found in section 8.1.8.1 for GMACS, as a record.

8.2.2 GMACS Independent Verification and Certification. The candidate GMACS independent verification of the gravimetrically prepared reference value is contingent on the SGM following the procedures in sections 2.1 and 2.2 of the EPA Traceability Protocol. In addition, the EtO candidate GMACS certified reference value and associated expanded uncertainty is based on the EPA Traceability Protocol measured value. This is contingent upon the gravimetric and measured values meeting the relative agreement performance criteria established in section 8.1.5.3 and the uncertainty criteria established in section 8.1.5.4. Gas Manufacturers Intermediate Standards (GMIS) can be prepared by direct comparison to a GMPS that has been prepared and certified according to section 2.1.3.1 and 2.2 of the EPA Traceability Protocol. The tagged value of the GMACS must be based on the EPA Traceability Protocol measured value as long as the performance criteria in sections 12.1 and 12.2 are met.

8.2.3 GMACS Stability Testing. The SGM must test and document the stability of the GMACS to assure that the mixture stays within claimed certified bounds for the entire claimed expiration period. Use the procedures in section 8.1.6 to assess stability. The GMACS must also meet the requirements in section 2.1.5.2 of the EPA Traceability Protocol.

8.2.4 GMACS Expiration Date. The certification period of the GMACS shall be based on the documented stability tests of the GMPS in section 8.1.6. The expiration date shall be based on the certification date, plus the certification period plus one day. There is not a maximum period of expiration; however, expiration periods must not be less than six months.

8.2.5 GMACS Documentation You must document and maintain the same information required for the analytical verification of the GMPS, as found in section 8.1.8 for GMACS, as a record. The records of the preparation and certification must be made available upon request by the appropriate delegated authority.

8.2.6 GMACS Certificate of Analysis (COA). You must provide comprehensive documentation of the GMPS and GMACS development process in the form of a GMACS Certificate of Analysis (COA) that accompanies each commercially distributed GMACS. As a minimum, the COA must contain the following information:

(a) Identification of the gas as a Gas Manufacturer Alternative Certified Standard;

(b) The cylinder number;

(c) The certified concentration of the GMACS;

(d) The combined expanded uncertainty (k=2) of the GMACS reference value (both absolute and relative);

(e) The expiration date;

(f) The reference materials or standards used (*i.e.,* GMPS and GMIS);

(g) The same information (cylinder number, certified concentration, uncertainties, expiration dates, etc. for these cylinders);

(h) The gravimetric and independent measured verification reference concentration values and associated uncertainties for each GMPS used;

(i) Associated measurement principles and uncertainties;

(j) Any additional information stipulated by the EPA Traceability Protocol;

(k) Any comments/special instructions.

The SGM GMACS provider is encouraged to include additional relevant information to the COA, as appropriate. An example GMACS COA can be found in section 14 of this appendix.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization

There is a myriad of instrumental and mechanical techniques used in the

performance of this Appendix B. When reference methods are used, you must follow the calibration requirements of those methods and as defined in this appendix. For all other approaches, it is recommended to develop internal SOPs and develop.

11.0 Calculations and Data Analysis—Reserved

12.0 Method Performance

12.1 GMPS/GMACS Relative Agreement. As part of the certification/verification procedures for the candidate GMPS and GMACS, the relative agreement between the gravimetrically prepared reference value and the independently measured verification value must agree within 4.0 percent (%).

12.2 GMACS/GMPS Uncertainty. Final certification of the GMPS and GMACS reference concentrations must meet the combined expanded uncertainty (k=2) of ≤5.0 percent (%).

13.0 Pollution Prevention—Reserved

14.0 Waste Management—Reserved

15.0 Bibliography

1. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, Office of Research and Development, National Risk Management Research Laboratory, May 2012, EPA 600/R–12/531. *https://www.epa.gov/air-research/epa-traceability-protocol-assay-and-certification-gaseous-calibration-standards.*

2. EPA Alternative Method 114, Approval of Alternative Method for preparation of HCl Gas Standards for PS–18 and Procedure 6, February 22, 2016, *https://www.epa.gov/sites/default/files/2020-08/documents/alt114.pdf.*

3. Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement, JCGM 100:2008, *https://www.bipm.org/documents/20126/2071204/JCGM_100_2008_E.pdf/cb0ef43f-baa5-11cf-3f85-4dcd86f77bd6.*

16.0 Tables and Figures

Figure B–1 Example Gravimetric Preparation Sheet for GMPS and GMACS

BILLING CODE 6560–50–P

General Information

Project	Operator	Blend Date	Cylinder Number
Phase	Valve Connection	Blend Pressure	Headspace

Component Parameters

	Component 1	Component 2	Component 3	Component 4	Component 5
Material Name					
Material molecular weight (g/mol)					
Dilution Standard or Pure Cylinder Number					
Lot Number					
Dilution Standard Weight Concentration or Pure Weight % Assay (wt%)					
Dilution Standard Weight Accuracy, relative or +/- weight% uncertainty (wt%)					
Dilution Standard or Pure Weight (g)					
Mechanical Effects - u_m (g)					
Scale Capacity Selection (g)					
Scale Calibration Uncertainty - u_{sca} (g)					
Scale Accuracy - u_s (g)					
Weight Standard - u_{std} (g)					
Material Weight Added (g)					
Material Uncertainty - u_c (g)					
Total Weight Uncertainty (g)					
Additional Weight Uncertainty (g)					

Dilution Standard or Cross Contaminant Additions

Contributing Component #					
Weight Added (g)					
Uncertainty (g)					
Contributing Component #					
Weight Added (g)					
Uncertainty (g)					

Totals Calculations

Total Weight from all additions (g)					
Total moles					

Concentrations and Accuracy Calculations

Weight Concentration (%)					
Weight Accuracy Relative (%)					
Mole Concentration (%)					
Standard Uncertainty - u_i (%)					

Figure B–2 Apparatus for the assay of the GMACs

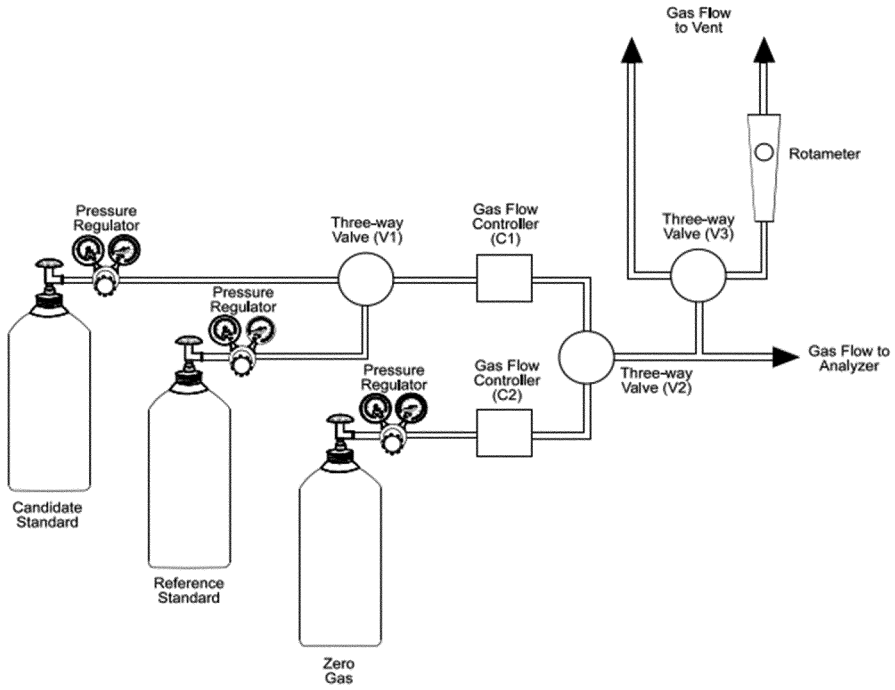
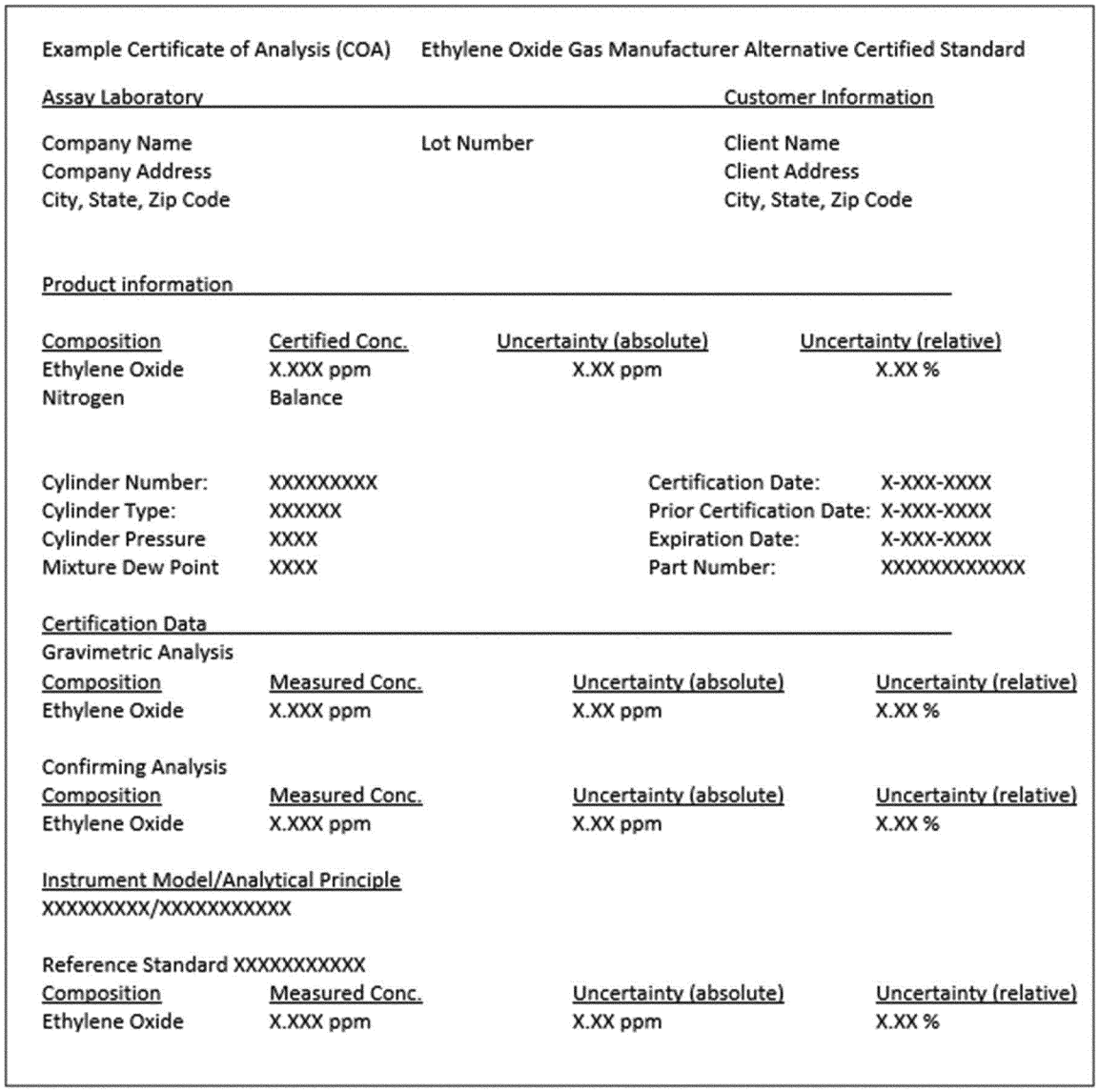


Figure B–3 Examples COA



Example Certificate of Analysis (COA) Ethylene Oxide Gas Manufacturer Alternative Certified Standard

Assay Laboratory — Customer Information

Company Name — Lot Number — Client Name
Company Address — Client Address
City, State, Zip Code — City, State, Zip Code

Product information

Composition	Certified Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %
Nitrogen	Balance		

Cylinder Number:	XXXXXXXXX	Certification Date:	X-XXX-XXXX
Cylinder Type:	XXXXXX	Prior Certification Date:	X-XXX-XXXX
Cylinder Pressure	XXXX	Expiration Date:	X-XXX-XXXX
Mixture Dew Point	XXXX	Part Number:	XXXXXXXXXXXX

Certification Data

Gravimetric Analysis

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Confirming Analysis

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Instrument Model/Analytical Principle
XXXXXXXXX/XXXXXXXXXXX

Reference Standard XXXXXXXXXXX

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

BILLING CODE 6560–50–C

■ 3. Appendix F to part 60 is amended by adding Procedure 7 to read as follows:

Appendix F to Part 60—Quality Assurance Procedures

* * * * *

Procedure 7. Quality Assurance Requirements for Gaseous Ethylene Exide (ETO) Continuous Emission Monitoring Systems Used for Compliance Determination

1.0 Applicability and Principle

1.1 Applicability. Procedure 7 is used to evaluate the effectiveness of quality control (QC) and quality assurance (QA) procedures and to evaluate the quality of data produced by any ethylene oxide (EtO) gas, CAS: 75–21–8, continuous emission monitoring system (CEMS) that is used for determining compliance with emission standards for EtO on a continuous basis as specified in an applicable permit or regulation.

1.1.1 This procedure specifies the minimum QA requirements necessary for the control and assessment of the quality of CEMS data submitted to the Environmental Protection Agency (EPA) or a delegated authority. If you are responsible for one or more CEMS used for EtO compliance monitoring you must meet these minimum requirements and you are encouraged to develop and implement a more extensive QA program or to continue such programs where they already exist.

1.1.2 Data collected as a result of QA and quality control (QC) measures required in this procedure are to be submitted to the EPA or the delegated authority in accordance with the applicable regulation or permit. These data are to be used by both the delegated authority and you, as the CEMS operator, in assessing the effectiveness of the CEMS QC and QA procedures in the maintenance of acceptable CEMS operation and valid emission data.

1.2 Principle

1.2.1 The QA procedures consist of two distinct and equally important functions. One function is the assessment of the quality of the CEMS data by estimating accuracy. The other function is the control and improvement of the quality of the CEMS data by implementing QC policies and corrective actions. These two functions form an iterative control loop. When the assessment function indicates that the data quality is inadequate, the control effort must be increased until the data quality is acceptable. In order to provide uniformity in the assessment and reporting of data quality, this procedure specifies the assessment procedures to evaluate response drift and accuracy. The procedures specified are based on Performance Specification 19 (PS–19) in appendix B to this part.

Note 1 to section 1.0: Because the control and corrective action function encompasses a variety of policies, specifications, standards and corrective measures, this procedure treats QC requirements in general terms to allow you, as source owner or operator to develop the most effective and efficient QC system for your circumstances.

2.0 Definitions

See PS–19 in appendix B to this part for the primary definitions used in this Procedure.

3.0 QC Requirements

3.1 You, as a source owner or operator, must develop and implement a QC program. At a minimum, each QC program must include written procedures and/or manufacturer's information which should describe in detail, complete, step-by-step procedures and operations for each of the following activities:

(a) Calibration Drift (CD) checks of CEMS;

(b) CD determination and adjustment of CEMS;

(c) Routine and preventative maintenance of CEMS (including spare parts inventory);

(d) Data recording, calculations, and reporting;

(e) Accuracy audit procedures for CEMS including reference method(s); and

(f) Program of corrective action for malfunctioning CEMS.

3.2 These written procedures must be kept on site and available for inspection by the delegated authority. As described in section 5.4, whenever excessive inaccuracies occur for two consecutive quarters, you must revise the current written procedures, or modify or replace the CEMS to correct the deficiency causing the excessive inaccuracies.

4.0 Daily Data Quality Requirements and Measurement Standardization Procedures

4.1 CD Assessment. An upscale gas, used to meet a requirement in this section must be a gas meeting the requirements in section 7.1 of PS–19 of appendix B to this part.

4.1.1 CD Requirement. Consistent with § 60.13(d) and with § 63.8(c) of this chapter, you, as source owners or operators of CEMS must check, record, and quantify the CD at two levels, using a zero gas and high-level gas at least once daily (approximately every 24 hours). Perform the CD check in accordance with the procedure in the applicable performance specification (*e.g.,* section 11.3 of PS–19 in appendix B to this part). The daily zero- and high-level CD must not exceed two times the drift limits specified in the applicable performance specification (*e.g.,* section 13.2 of PS–19 in appendix B to this part.)

4.1.2 Recording Requirement for CD Corrective action. Corrective actions taken to bring a CEMS back in control after exceeding a CD limit must be recorded and reported with the associated CEMS data. Reporting of a corrective action must include the unadjusted concentration measured prior to resetting the calibration and the adjusted value after resetting the calibration to bring the CEMS back into control.

4.1.3 Dynamic Spiking Option for high-level CD. You have the option to conduct a daily dynamic spiking procedure found in section 11.5.8 of PS–19 of appendix B to this part in lieu of the daily high-level CD check. If this option is selected, the daily zero CD check is still required.

4.1.4 Out of Control Criteria for Excessive CD. Consistent with § 63.8(c)(7)(i)(A) of this chapter, an EtO CEMS is out of control if the zero or high-level CD exceeds two times the applicable CD specification in the applicable performance specification or in the relevant standard. When a CEMS is out of control, you as owner or operator of the affected source must take the necessary corrective actions and repeat the tests that caused the system to go out of control (in this case, the failed CD check) until the applicable performance requirements are met.

4.1.5 Additional Quality Assurance for Data Above Span. This procedure must be used when required by an applicable regulation and may be used when significant data above span are being collected. Furthermore, the terms of this procedure do not apply to the extent that alternate terms are otherwise specified in an applicable rule or permit.

4.1.5.1 Any time the average measured concentration of EtO exceeds 200 percent of the span value for two consecutive one-hour averages, conduct the following 'above span' CEMS response check.

4.1.5.1.1 Within a period of 24 hours (before or after) of the 'above span' period, introduce a higher, 'above span' EtO reference gas standard to the CEMS. Use 'above span' reference gas that meets the requirements of section 7.0 of PS–19 in appendix B to this part and target a concentration level between 75 and 125 percent of the highest hourly concentration measured during the period of measurements above span or 5 ppmv whichever is greater.

4.1.5.1.2 Introduce the reference gas at the probe for extractive CEMS.

4.1.5.1.3 At no time may the 'above span' concentration exceed the analyzer full-scale range.

4.1.5.2 Record and report the results of this procedure as you would for a daily calibration. The 'above span' response check is successful if the value measured by the CEMS is within 20 percent of the certified value of the reference gas.

4.1.5.3 If the 'above span' response check is conducted during the period when measured emissions are above span and there is a failure to collect at least one data point in an hour due to the response check duration, then determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour.

4.1.5.4 In the event that the 'above span' response check is not successful (*i.e.,* the CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the 'above span' response check for reporting based on the CEMS response to the reference gas as shown in Eq. 7–1:

Eq. 7-1

$$\text{Normalized stack gas result} = \frac{\textit{Certified reference gas value}}{\textit{Measured value of reference gas}} \; x \; \textit{Measured stack gas result}$$

4.2 Out of Control Period Duration for Daily Assessments. The beginning of the out-of-control period is the hour in which the owner or operator conducts a daily performance check (*e.g.,* calibration drift) that indicates an exceedance of the performance requirements established under this procedure. The end of the out-of-control period is the completion of daily assessment of the same type following corrective actions, which shows that the applicable performance requirements have been met.

4.3 CEMS Data Status During Out-of-Control Period. During the period the CEMS is out-of- control, the CEMS data may not be used in calculating compliance with an emissions limit nor be counted towards meeting minimum data availability as required and described in the applicable regulation or permit.

5.0 Data Accuracy Assessment

You must audit your CEMS for the accuracy of EtO measurement on a regular basis at the frequency described in this section, unless otherwise specified in an applicable regulation or permit. Quarterly audits are performed at least once each calendar quarter. Successive quarterly audits, to the extent practicable, shall occur no closer than 2 months apart. Annual audits are performed at least once every four consecutive calendar quarters.

5.1 Concentration Accuracy Auditing Requirements. Unless otherwise specified in an applicable regulation or permit, you must audit the EtO measurement accuracy of each CEMS at least once each calendar quarter, except in the case where the affected facility is off-line (does not operate). In that case, the audit must be performed as soon as is practicable in the quarter in which the unit recommences operation. Successive quarterly audits must, to the extent practicable, be performed no less than 2 months apart. The

accuracy audits shall be conducted as follows:

5.1.1 Relative Accuracy Test Audit (RATA). A RATA must be conducted at least once every four calendar quarters, except as otherwise noted in sections 5.1.5 or 5.5 of this procedure. Perform the RATA as described in section 11.6 of PS–19 in appendix B to this part. If the EtO concentration measured by the RM during a RATA (in ppmv or other units of the standard) is less than or equal to 20 percent of the concentration equivalent to the applicable emission standard, you must perform a Cylinder Gas Audit (CGA) or a Dynamic Spike Audit (DSA) for at least one subsequent (one of the following three) quarterly accuracy audits.

5.1.2 Quarterly Relative Accuracy Audit (RAA). A quarterly RAA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three quarters in succession. To conduct an RAA, follow the test procedures in section 11.6 of PS–19 in appendix B to this part, except that only three test runs are required. The difference between the mean of the RM values and the mean of the CEMS responses relative to the mean of the values (or alternatively the emission standard) is used to assess the accuracy of the CEMS. Calculate the RAA results as described in section 6.2. As an alternative to an RAA, a cylinder gas audit or a dynamic spiking audit may be conducted.

5.1.3 Cylinder Gas Audit. A quarterly CGA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three consecutive quarters. To perform a CGA, challenge the CEMS with a zero-level and two upscale level audit gases of known concentrations within the following ranges:

Audit point	Audit range
1 (Mid-Level)	50 to 60% of span value.
2 (High-Level)	80 to 100% of span value.

5.1.3.1 Inject each of the three audit gases (zero and two upscale) three times each for a total of nine injections. Inject the gases so that the entire measurement system is challenged. Do not inject the same gas concentration twice in succession.

5.1.3.2 Use EtO audit gases that meet the requirements of section 7 of PS–19 in appendix B to this part.

5.2.3.3 Calculate results as described in section 6.3.

5.1.4 Dynamic Spiking Audit. A quarterly DSA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three quarters in succession.

5.1.4.1 To conduct a DSA, you must challenge the entire EtO CEMS with a zero gas in accordance with the procedure in section 11.8 of PS–19 in appendix B of this part. You must also conduct the DS procedure as described in appendix A to PS–19 of appendix B to this part. You must conduct three spike injections with each of two upscale level audit gases. The upscale level gases must meet the requirements of section 7 of PS–19 in appendix B to this part and must be chosen to yield concentrations at the analyzer of 50 to 60 percent of span and 80 to 100 percent of span. Do not inject the same spike gas concentration twice in succession.

5.1.4.2 Calculate results as described in section 6.4. To determine CEMS accuracy, you must calculate the dynamic spiking error (DSE) for each of the two upscale audit gases using equation A5 in appendix A to PS–19 and equation 7–3 in section 6.4 of this Procedure.

5.1.5 Other Alternative Quarterly Audits. Other alternative audit procedures, as approved by the Administrator, may be used for three of four calendar quarters.

5.2 Out of Control Criteria for Excessive Audit Inaccuracy. If the results of the RATA, RAA, CGA, or DSA do not meet the applicable performance criteria in section 5.2.4, the CEMS is out-of-control. If the CEMS is out-of-control, take necessary corrective action to eliminate the problem. Following corrective action, the CEMS must pass a test of the same type that resulted in the out-of-control period to determine if the CEMS is operating within the specifications (*e.g.,* a RATA must always follow an out-of-control period resulting from a RATA).

5.2.1 If the audit results show the CEMS to be out-of-control, you must report both the results of the audit showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

5.2.2 Out-Of-Control Period Duration for Excessive Audit Inaccuracy. The beginning of the out-of-control period is the time corresponding to the completion of the sampling for the failed RATA, RAA, CGA or DSA. The end of the out-of-control period is the time corresponding to the completion of the sampling of the subsequent successful audit.

5.2.3 CEMS Data Status During Out-Of-Control Period. During the period the CEMS is out-of- control, the CEMS data may not be used in calculating emission compliance nor be counted towards meeting minimum data availability as required and described in the applicable regulation or permit.

5.2.4 Criteria for Excessive Quarterly and Yearly Audit Inaccuracy. Unless specified otherwise in the applicable regulation or permit, the criteria for excessive inaccuracy are:

5.2.4.1 For the RATA, the CEMS must meet the RA specifications in section 13.4 of PS–19 in appendix B to this part.

5.2.4.2 For the CGA, the accuracy must not exceed 10.0 percent of the span value at the zero gas and the mid- and high-level reference gas concentrations.

5.2.4.3 For the RAA, the RA must not exceed 20.0 percent of the RMavg as calculated using equation 7–2 in section 6.2 of this procedure whether calculated in units of EtO concentration or in units of the emission standard. In cases where the RA is calculated on a concentration (ppbv) basis, if the average EtO concentration measured by the RM during the test is less than 75 percent of the EtO concentration equivalent to the applicable standard, you may substitute the equivalent emission standard value (in ppbw) in the denominator of equation 7–2 in the place of RM_{avg} and the result of this alternative calculation of RA must not exceed 15.0 percent.

5.2.4.4 For DSA, the accuracy must not exceed 5.0 percent of the span value at the zero gas and the mid- and high-level reference gas concentrations or 20.0 percent of the applicable emission standard, whichever is greater.

5.3 Criteria for Acceptable QC Procedures. Repeated excessive inaccuracies (*i.e.,* out-of-control conditions resulting from the quarterly or yearly audits) indicate that the QC procedures are inadequate or that the CEMS is incapable of providing quality data. Therefore, whenever excessive inaccuracies occur for two consecutive quarters, you must revise the QC procedures (see section 3.0) or modify or replace the CEMS.

5.4 Criteria for Optional QA Test Frequency. If all the quality criteria are met in sections 4 and 5 of this procedure, the CEMS is in-control.

5.5.1 Unless otherwise specified in an applicable rule or permit, if the CEMS is in-control and if your source emits ≤75 percent of the EtO emission limit for each averaging period as specified in the relevant standard for eight consecutive quarters that include a minimum of two RATAs, you may revise your auditing procedures to use CGA, RAA or DSA each quarter for seven subsequent quarters following a RATA.

5.5.2 You must perform at least one RATA that meets the acceptance criteria every 2 years.

5.5.3 If you fail a RATA, RAA, CGA, or DSA, then the audit schedule in section 5.2 must be followed until the audit results meet the criteria in section 5.3.4 to start requalifying for the optional QA test frequency in section 5.5.

6.0 Calculations for CEMS Data Accuracy

6.1 RATA RA Calculation. Follow equations 9 through 14 in section 12 of PS–19 in appendix B to this part to calculate the RA for the RATA. The RATA must be calculated either in units of the applicable emission standard or in concentration units (ppbv).

6.2 RAA Accuracy Calculation. Use equation 7–2 to calculate the accuracy for the RAA. The RA may be calculated in concentration units (ppmv) or in the units of the applicable emission standard.

$$RA = \frac{MN_{avg} - RM_{avg}}{RM_{avg}} \times 100 \qquad \text{Eq. 7-2}$$

Where:

RA = Accuracy of the CEMS (percent)

MN_{avg} = Average measured CEMS response during the audit in units of applicable standard or appropriate concentration.

RM_{avg} = Average reference method value in units of applicable standard or appropriate concentration.

6.3 CGA Accuracy Calculation. For each gas concentration, determine the average of the three CEMS responses and subtract the average response from the audit gas value. For extractive CEMS, calculate the ME at each gas level using equation 3A in section 12.3 of PS–19 of appendix B to this part.

6.4 DSA Accuracy Calculation. DSA accuracy is calculated as a percent of span. To calculate the DSA accuracy for each upscale spike concentration, first calculate the DSE using equation A5 in appendix A of PS–19 in appendix B to this part. Then use equation 7–3 to calculate the average DSA accuracy for each upscale spike concentration. To calculate DSA accuracy at the zero level, use equation 3A in section 12.3 of PS–19 in appendix B to this part.

$$\text{DSA Accuracy} = \frac{\sum_1^3 \left[\frac{|DSEi|}{S}\right]}{3} x100 \qquad \text{Eq. 7-3}$$

7.0 Reporting Requirements

At the reporting interval specified in the applicable regulation or permit, report for each CEMS the quarterly and annual accuracy audit results from section 6 and the daily assessment results from section 4. Unless otherwise specified in the applicable regulation or permit, include all data sheets, calculations, CEMS data records (*i.e.,* charts, records of CEMS responses), reference gas certifications and reference method results necessary to confirm that the performance of the CEMS met the performance specifications.

7.1 Unless otherwise specified in the applicable regulations or permit, report the daily assessments (CD and beam intensity) and accuracy audit information at the interval for emissions reporting required under the applicable regulations or permits.

7.1.1 At a minimum, the daily assessments and accuracy audit information reporting must contain the following information:

a. Company name and address.

b. Identification and location of monitors in the CEMS.

c. Manufacturer and model number of each monitor in the CEMS.

d. Assessment of CEMS data accuracy and date of assessment as determined by a RATA, RAA, CGA or DSA described in section 5 including:

i. The RA for the RATA;

ii. The accuracy for the CGA, RAA, or DSA;

iii. The RM results, the reference gas certified values;

iv. The CEMS responses;

v. The calculation results as defined in section 6; and

vi. Results from the performance audit samples described in section 5 and the applicable RMs.

e. Summary of all out-of-control periods including corrective actions taken when CEMS was determined out-of-control, as described in sections 4 and 5. 7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

8.0 Bibliography

1. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, U.S. Environmental Protection Agency office of Research and Development, EPA/600/R–12/531, May 2012.

2. Method 205, ''Verification of Gas Dilution Systems for Field Instrument Calibrations,'' 40 CFR part 51, appendix M.

9.0 [Reserved]

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 4. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart A—General Provisions

■ 5. Section 63.14 is amended by:

■ a. Revising paragraphs (a) and (f) and paragraph (i) introductory text;

■ b. Redesignating paragraphs (i)(88) through (119) as paragraphs (i)(89) through (120), and;

■ c. Adding new paragraph (i)(88) and note 2 to paragraph (i).

The revisions and additions read as follows:

§ 63.14 Incorporations by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the EPA must publish a document in the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact the EPA at: EPA Docket Center, Public Reading Room, EPA WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC, telephone: 202–566–1744. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the sources in the following paragraphs of this section.

* * * * *

(f) American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016–5990; phone: (800) 843–2763; email: *CustomerCare@asme.org;* website: *www.asme.org.*

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981; IBR approved for §§ 63.309(k); 63.365(b); 63.457(k); 63.772(e) and (h); 63.865(b); 63.997(e); 63.1282(d) and (g); 63.1625(b); table 5 to subpart EEEE; §§ 63.3166(a); 63.3360(e); 63.3545(a); 63.3555(a); 63.4166(a); 63.4362(a); 63.4766(a); 63.4965(a); 63.5160(d); table 4 to subpart UUUU; table 3 to subpart YYYY; §§ 63.7822(b); 63.7824(e); 63.7825(b); 63.8000(d); 63.9307(c); 63.9323(a); 63.9621(b) and (c); 63.11148(e); 63.11155(e); 63.11162(f); 63.11163(g); 63.11410(j); 63.11551(a); 63.11646(a); 63.11945; table 4 to subpart AAAAA; table 5 to subpart DDDDD; table 4 to subpart JJJJJ; table 4 to subpart KKKKK; table 4 to subpart SSSSS; tables 4 and 5 of subpart UUUUU; table 1 to subpart ZZZZZ; and table 4 to subpart JJJJJJ.

(2) [Reserved]

* * * * *

(i) ASTM International, 100 Barr Harbor Drive, P.O. Box CB700, West Conshohocken, Pennsylvania 19428–2959; phone: (800) 262–1373; website: *www.astm.org.*

* * * * *

(88) ASTM D6348–12 (Reapproved 2020), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,

Approved December 1, 2020; IBR approved for § 63.365(b).

* * * * *

Note 2 to paragraph (i): Standards listed in this paragraph (i) may also be available from standards resellers including the Standards Store, *https://global.ihs.com.*

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■ 6. Subpart O is revised and republished to read as follows:

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

Sec.

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

§ 63.360 Applicability.

(a) You are subject to the requirements of this subpart if you own or operate a sterilization facility that has an affected source specified in paragraph (b) of this section. Table 6 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

(b) The affected sources subject to this subpart are:

(1) Each SCV at any sterilization facility;

(2) Each ARV at any sterilization facility;

(3) Each CEV at any sterilization facility;

(4) The collection of all Group 1 room air emissions at any sterilization facility; and

(5) The collection of all Group 2 room air emissions at any sterilization facility.

(c) An existing affected source is one the construction or reconstruction of which was commenced on or before April 13, 2023.

(d) A new affected source is one the construction or reconstruction of which is commenced after April 13, 2023.

(e) An SCV, ARV, or CEV is reconstructed if you meet the reconstruction criteria as defined in § 63.2, and if you commence reconstruction after April 13, 2023.

(f) This subpart does not apply to beehive fumigators.

(g) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(h) This subpart does not apply to EtO sterilization operations at stationary sources such as hospitals, doctor's offices, clinics, or other facilities whose primary purpose is to provide medical or dental services to humans or animals.

(i) If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart. Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart applicable to area sources.

(j) You must comply with the provisions of this subpart no later than the dates specified in paragraphs (j)(1) through (17) of this section:

(1) If you own or operate an existing affected source, you must comply with the applicable provisions of this subpart no later than the dates specified in tables 1 through 5 to this subpart, as applicable.

(2) If you own or operate a new affected source, and the initial startup of your affected source is on or before April 5, 2024, you must comply with the provisions of this subpart no later than April 5, 2024.

(3) If you own or operate a new affected source, and the initial startup is after April 5, 2024, you must comply with the provisions of this subpart upon startup of your affected source.

(4) If existing SCV, ARV, or CEV or parts of an existing collection of Group 1 or Group 2 room air emissions are replaced such that the replacement meets the definition of reconstruction in § 63.2 and the reconstruction commenced after April 13, 2023, then the existing affected source becomes a new affected source. The reconstructed source must comply with the requirements for a new affected source upon initial startup of the reconstructed source or by April 5, 2024, whichever is later.

(5) All existing SCVs at facilities that meet or exceed 1 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(6) All existing SCVs at facilities that do not exceed 1 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(7) All new SCVs at facilities that increase their EtO use over a year after startup such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(8) All existing ARVs at facilities that meet or exceed 10 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(9) All existing ARVs at facilities that do not exceed 10 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use after thereafter, such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(10) All new ARVs at facilities that increase their EtO use over a year after startup such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(11) All existing CEVs at facilities that do not exceed 60 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the CEV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(12) All new CEVs at facilities that increase their EtO use over a year after startup such that the CEV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(13) All existing collections of Group 1 room air emissions at facilities that do not exceed 40 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the collection of Group 1 room air emissions becomes subject to a more stringent emission

standard, immediately upon becoming subject to the more stringent emission standard.

(14) All new Group 1 room air emissions at facilities that increase their EtO use over a year after startup such that the Group 1 room air emissions become subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(15) All existing collections of Group 2 room air emissions at facilities that meet or exceed 4 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the collection of Group 2 room air emissions becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(16) All existing collections of Group 2 room air emissions at facilities that do not exceed 4 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the collection of Group 2 room air emissions becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(17) All new Group 2 room air emissions at facilities that increase their EtO use over a year after startup such that the Group 2 room air emissions become subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

§ 63.361 Definitions.

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§ 63.2 and 63.3, or in this section. For the purposes of this subpart, if the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section.

Acid-water scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to absorb and neutralize acid gases.

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. If a facility uses only combination sterilization units, for the purposes of this rule, there are no aeration rooms at the facility.

Aeration room vent (ARV) means the point(s) through which the evacuation of EtO-laden air from an aeration room occurs. For combination sterilization units, there is no ARV.

Catalytic oxidizer means a combustion device that uses a solid-phase catalyst to lower the temperature required to promote the oxidization and achieve adequate reduction of volatile organic compounds, as well as volatile hazardous air pollutants.

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''). For combination sterilization units, there is no CEV.

Combination sterilization unit means 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 ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by aeration of ethylene oxide.

Combined emission stream means when the emissions from more than one emission source are routed together using common ductwork prior to the control system.

Continuous monitoring system (CMS) means, for the purposes of this rule, the equipment necessary to continuously samples the regulated parameter specified in § 63.364 or § 63.365 of this subpart without interruption, evaluates the detector response at least once every 15 seconds, and computes and records the average value at least every 60 seconds, except during allowable periods of calibration and except as defined otherwise by the continuous emission monitoring system (CEMS) performance specifications (PS) in appendix B to part 60 of this chapter.

Control System Residence Time means the time elapsed from entrance of flow into the control system until gaseous materials exit the control system. For control systems with multiple exhaust streams whereby the residence time may vary for the streams, the residence time for purposes of complying with this subpart means the longest residence time for any exhaust stream in use. If a peak shaver is used, it is part of the control system, and its residence time must be considered.

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

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation, parameter value, or best management practice; or

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

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.

Gas/solid reactor means an add-on air pollution control device that uses a dry, solid-phase system to chemically convert EtO so that it becomes bound to the solid packing. This may also be referred to as a ''dry bed reactor'' or a ''dry bed scrubber.''

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

Group 2 room air emissions mean emissions from post-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.

Initial startup means the moment when an affected source subject to an emissions standard in § 63.362 first begins operation.

Injection room means any room where EtO is injected into containers (*e.g.,* bags, pouches) that are filled with product to be sterilized.

Maximum ethylene glycol concentration means the concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum gas/solid reactor pressure drop means the pressure drop of the gas/solid reactor established during a performance test when the gas/solid reactor achieves the appropriate control of EtO emissions.

Maximum liquor tank level means the level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum scrubber liquor pH means the pH of the acid-water scrubber liquor established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Minimum stack volumetric flow rate means the stack volumetric flow rate corrected established during a compliance demonstration when

permanent total enclosure (PTE) requirements are met.

Minimum temperature at the inlet to the catalyst bed means the temperature at the inlet to the catalyst bed established during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum temperature difference across the catalyst bed means the temperature difference across the catalyst bed established during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum temperature in or immediately downstream of the firebox means the temperature in or immediately downstream of the firebox established during a performance test when the thermal oxidizer achieves the appropriate control of EtO emissions.

Natural draft opening (NDO) means any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct in which a fan is installed.

Operating day means any day that a facility is engaged in a sterilization operation.

Peak shaver means a device that is used to reduce high EtO concentrations within an exhaust stream such that the downstream control device is not overwhelmed.

Permanent total enclosure (PTE) means a permanently installed enclosure that meets the criteria of Method 204 of appendix M, 40 CFR part 51 for a PTE. A PTE completely surrounds a source of emissions such that all EtO emissions are captured, contained, and directed to a control system or to an outlet(s).

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.

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.

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. If only combination sterilization units are used, and if material is not moved out of the vessel between sterilization and aeration, then emissions from this source do not exist. This does not include post-injection handling of containers.

Rolling sum means the weighted sum of all data, meeting QA/QC requirements or otherwise normalized, collected during the applicable rolling time period. The period of a rolling sum stipulates the frequency of data collection, summing, and reporting. As an example, to demonstrate compliance with a rolling 30-operating day sum emission reduction standard determined from hourly data, you must (1) determine the total mass of ethylene oxide prior to control and following control for each operating day; (2) then sum the current daily total mass prior to control with the previous 29 operating day total mass values and repeat the same process for the current daily total mass following control; and (3) then divide the 30-operating day total mass emissions following control by the 30-operating day total mass prior to control and subtract the resulting value from one to obtain the 30-operating day emission reduction achieved.

Single-item sterilization means 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.

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. This does not include injection rooms.

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 facility means 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.

Sterilization operation means any time when EtO is removed from the sterilization chamber through the SCV or the chamber exhaust vent, when EtO is removed from the aeration room through the aeration room vent, when EtO is stored within the building, when EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration.

Thermal oxidizer means all combustion devices except flares.

Vacuum pump operation means the operation of vacuum pumps, excluding dry seal vacuum pumps, for the purpose of removing EtO from a sterilization chamber.

§ 63.362 Standards.

(a) *Compliance date.* If you own or operate an affected source, you must comply with the applicable requirement by the compliance date specified in § 63.360(j). The standards of this section are summarized in tables 1 through 5 to this subpart.

(b) *Applicability of standards.* The standards in paragraphs (c) through (k) of this section apply at all times. If using EtO CEMS to determine compliance with an applicable standard, this compliance demonstration is based on the previous 30-operating days of data. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraphs (c) through (g) and (i) of this section for each operating day, you must determine the total inlet mass to and outlet mass from the control system using the procedures laid out in § 63.364(f) and appendix A to this subpart, and you must maintain the emission limit based on the inlet mass and the applicable emission reduction standard. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraph (j) of this section, you must continuously comply with the requirements of that paragraph.

(c) *SCV.* You must comply with each applicable standard in table 1 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a SCV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(d) *ARV.* You must comply with each applicable standard in table 2 to this subpart, and you must meet each applicable requirement specified in § 63.363. If an ARV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(e) *CEV.* You must comply with each applicable standard in table 3 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a CEV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(f) *Group 1 room air emissions.* You must comply with the applicable

standard in table 4 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 1 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(g) *Group 2 room air emissions.* You must comply with the applicable standard in table 5 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 2 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section. If you are required to limit the sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must meet the monitoring requirements specified in § 63.364(h).

(h) *Capture systems.* Room air emissions for which numerical limits are prescribed must be captured and routed under negative pressure to a control system. You may assume the capture system efficiency is 100 percent if both conditions in paragraphs (h)(1) and (2) of this section are met:

(1) The capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and directs all the exhaust gases from the enclosure to an add-on control system.

(2) All sterilization operations creating exhaust gases for which the compliance demonstration is applicable are contained within the capture system.

(i) *Requirements for combined emission streams.* When streams from two or more emission sources are combined, you must demonstrate compliance by either the approach specified in paragraph (i)(1) of this section or the approach specified in paragraph (i)(2) of this section in lieu of the applicable standards in paragraphs (c) through (g) of this section for the affected source. The combined emission stream limit is based on as 30-operating day rolling sum. In order to elect to comply with a combined emission streams limit, you must use a CEMS on each exhaust stack at the facility to determine compliance.

(1) *Monitoring after emission streams are combined.* You must follow requirements of paragraphs (i)(1)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine the 30-operating day rolling sum of mass inlet to the control system. Then, the emission limitation is determined by applying the most stringent emission reduction standard to the 30-operating day rolling sum of the inlet mass. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. Further suppose that the mass of uncontrolled EtO emissions from the combined stream is 5 lb during the 30-operating day period. Under this approach, the facility would need to apply an emission reduction of 99.9% to the combined stream, resulting in an emission limit of 0.005 lb for the 30-operating day period.

(i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 1 to this paragraph.

Equation 1 to paragraph (i)(2)(i)

$$CES_{Combined} = M_{30day} * (1 - Max(ER)) \quad \text{(Eq. 1)}$$

Where:

$CES_{Combined}$ = The combined emission stream limit based upon monitoring after the emission streams are combined, in pounds.

M_{30day} = The 30-operating day total mass sent to controls for the combined emission stream (*i.e.,* monitoring data at the inlet of the control system), as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''M_{30day}'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

Max(ER) = The most stringent emission reduction standard specified in tables 1 through 5 of this subpart applicable to any of the constituent streams, in decimal format.

(ii) The 30-operating day rolling sum of emissions for the combined emission stream (*i.e.,* monitoring data at the outlet of the control system) is calculated daily using equation A–3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as $E_{Combined}$. If the combined emission stream is split between two or more control systems, further sum the 30-operating day rolling sum of emissions from each control system to obtain $E_{Combined}$.

(iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that $E_{Combined}$, as calculated in accordance with paragraph (i)(1)(ii) of this section, for each 30-operating day period is at or below $CES_{Combined}$, as calculated in paragraph (i)(1)(i) of this section.

(2) *Monitoring before emission streams are combined.* You must follow requirements of paragraphs (i)(2)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine 30-operating day rolling sum of inlet mass to the control system for each component stream. Then, the emission limitation is determined by applying the applicable emission reduction standards to the 30-operating day rolling sum of each component stream and summing across the components. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. Further suppose that during a 30-operating day period the mass of uncontrolled EtO emissions from the ARVs is 4 lb and the mass of uncontrolled EtO emissions from the CEVs is 1 lb. Under this approach, the facility would need to apply an emission reduction of 99.9% to the ARV stream and an emission reduction of 99% to the CEV stream, resulting in an emission limit of 0.014 lb for the 30-operating day period.

(i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 2 to this paragraph.

Equation 2 to paragraph (i)(2)(i)

$$CES_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \quad \text{(Eq. 2)}$$

Where:

$CES_{Streams}$ = The combined emission stream limit based upon monitoring before the emission streams are combined, in pounds.

$M_{c,i}$ = The 30-operating day total mass sent to controls for each non-SCV constituent emission stream (*i.e.,* monitoring data at the inlet of the control system), as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''$M_{c,i}$'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

ER_i = The applicable emission reduction standard from tables 2 through 5 of this subpart to each non-SCV constituent emission stream *i.*

i = Non-SCV constituent emission stream index.

n = Total number of non-SCV constituent emission streams.

$M_{c,j}$ = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 10 of § 63.364(f)(1)(i)(C)(*1*).

ER_j = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

j = SCV emission stream index.

m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum emissions for the combined emission stream (*i.e.,* monitoring data at the outlet of the control system) is calculated daily using equation A–3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as $E_{Combined}$. If the combined emission stream is split between two or more control systems, then further sum the 30-operating day rolling sum emissions from each control system to obtain $E_{Combined}$.

(iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that $E_{Combined}$, as calculated in accordance with paragraph (i)(2)(ii) of this section, for each 30-operating day period is at or below $CES_{Streams}$, as calculated paragraph (i)(2)(i) of this section.

(3) If room air emissions are both subject to an emission standard and split between two or more control systems, then these control systems must be treated as part of the same control system.

(j) *Site-wide emission limitation.* You may choose to comply with a site-wide emission limitation (SWEL) specified in this paragraph (j) in lieu of the applicable standards in paragraphs (c) through (g) of this section for the facility. The SWEL, which is calculated daily, is based on the previous 30 operating days of data. In order to elect to comply with a SWEL, you must utilize an EtO CEMS on each exhaust stack at the facility to determine compliance. The owner or operator may demonstrate compliance via one of the two SWEL approaches in lieu of the applicable standard(s) in paragraphs (c) through (g) of this section for the facility. If electing to comply with a SWEL, you must comply with paragraph (j)(3) of this section.

(1) *SWEL based upon facility EtO use.* If you elect to comply with a SWEL based upon facility EtO use, you must follow requirements of paragraphs (j)(1)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, you first determine the 30-operating day rolling sum of EtO use. The SWEL is determined by multiplying by 0.99 and then applying the required SCV percent emission reduction standard in table 1 to this subpart to the 30-operating day rolling sum of EtO usage. Then, for each CEMS at the outlet of the control systems at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 3 to this paragraph.

Equation 3 to paragraph (j)(1)(i)

$$SWEL_{Fac} = M_{Fac} * 0.99 * (1 - ER_{SCV}) \quad \text{(Eq. 3)}$$

Where:

$SWEL_{Fac}$ = SWEL based upon facility EtO use, in pounds.

M_{Fac} = Facility EtO use over the previous 30 operating days, in pounds, as determined in accordance with equation 11 of § 63.364(i)(2).

0.99 = Adjustment factor for EtO residual in sterilized product.

ER_{SCV} = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this paragraph.

Equation 4 to paragraph (j)(1)(ii)

$$E_{Fac} = \sum_{i=1}^{n} E_{o,i} \quad \text{(Eq. 4)}$$

Where:

E_{Fac} = The total emissions from the facility over the previous 30-operating days, in pounds.

$E_{o,i}$ = The 30-operating day rolling sum of emissions calculated at each exhaust stack, *i,* monitored by an EtO CEMS, as calculated using equation A–3 of appendix A to this subpart.

i = Exhaust stack index

n = Total number of exhaust stacks

(iii) Compliance with the SWEL based upon facility EtO usage shall be

determined by demonstrating that E_{Fac}, as calculated in accordance with paragraph (j)(1)(ii) of this section, for each 30-operating day period is at or below the SWEL, as calculated paragraph (j)(1)(i) of this section.

(2) *SWEL based upon emissions streams.* If you elect to comply with a SWEL based upon emissions streams, you must follow requirements of paragraphs (j)(2)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, for each non-SCV affected source, you must determine the mass of EtO sent to controls and apply the applicable emission reduction standard. For each SCV affected source, you must determine the mass of EtO sent to controls as specified in § 63.364(f)(1)(i)(C)(*1*) and apply the applicable emission reduction standard. The SWEL is determined by summing across the result of this calculation for each affected source (both non-SCV and SCV). Then, for each CEMS at the outlet of the control system(s) at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 5 to this paragraph.

Equation 5 to paragraph (j)(2)(i)

$$SWEL_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \qquad \text{(Eq. 5)}$$

Where:

$SWEL_{Streams}$ = SWEL based upon individual emissions streams, in pounds.

$M_{c,i}$ = The 30-operating day total mass sent to controls (*i.e.,* monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''$M_{c,i}$'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

ER_i = The applicable emission reduction standard to each non-SCV emission stream, *i,* specified in tables 1 through 5 of this subpart, in decimal format.

i = Non-SCV emission streams index.

n = Total number of non-SCV emission streams.

$M_{c,j}$ = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 10 in § 63.364(f)(1)(i)(C)(*1*).

ER_j = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

j = SCV emission stream index.

m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this section.

(iii) Compliance with the SWEL based upon emission streams shall be determined by demonstrating that E_{Fac}, as calculated in accordance with paragraph (j)(2)(ii) of this section, for each 30-operating day period is at or below $SWEL_{Streams}$, as calculated in paragraph (j)(2)(i) of this section.

(3) *Boundary.* The boundary for this approach includes all affected sources at the facility.

(k) *General duty.* At all times, you must 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. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

§ 63.363 Compliance and performance provisions.

(a) *Continuous compliance.* You must demonstrate continuous compliance with the applicable emission standard(s) using an EtO CEMS, including a shared EtO CEMS, installed and operated in accordance with the requirements of Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter. Alternatively, if you own or operate a facility where EtO use is less than 100 pounds/yr, you may demonstrate continuous compliance by conducting annual performance tests using the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365. If you elect to demonstrate compliance through periodic performance testing, you must also demonstrate continuous compliance with each operating limit required under this section according to the methods specified in § 63.364. If you own or operate an area source facility where EtO use is less than 100 pounds/yr 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 of this chapter, you may instead conduct these performance tests once every three years.

(b) *Initial compliance for Facilities that use EtO CEMS.* To demonstrate initial compliance with an emission standard using a CEMS that measures HAP concentrations directly (*i.e.,* an EtO CEMS), the initial performance test must consist of the first 30 operating days after the certification of the CEMS according to Performance Specification 19 in Appendix B to part 40 of this chapter. The initial compliance demonstration period must be completed on or before the date that compliance must be demonstrated (*i.e.,* 180 days after the applicable compliance date). You must follow the procedures in appendix A to this subpart.

(1) The CEMS performance test must demonstrate compliance with the applicable EtO standards in tables 1 through 5 to this subpart. Alternatively, the CEMS performance test may demonstrate compliance with § 63.362(i) or (j).

(i) You may time-share your CEMS among different measurement points provided that:

(A) The measurement points are approximately equidistant from the CEMS;

(B) The sampling time at each measurement point is at least 3 times as long as the CEMS response time;

(C) The CEMS completes at least one complete cycle of operation for each shared measurement point within a 15-minute period; and

(D) The CEMS meets the other requirements of PS 19.

(2) You must collect hourly data from auxiliary monitoring systems during the performance test period, to convert the pollutant concentrations to pounds per hour.

(c) *Initial compliance demonstration where facility EtO use is less than 100 pounds per year.* If you own or operate an affected source that is both subject to an emission standard in § 63.362 and located within a facility where EtO use is less than 100 pounds per year, you may comply with paragraphs (c)(1) and (2) of this section:

(1) Conduct an initial compliance demonstration using the procedures listed in § 63.7 of this part according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365;

(2) Complete the initial compliance demonstration within 180 days after the compliance date for the affected source as determined in § 63.360(j).

(d) *Operating limits for facility where EtO use is less than 100 lb/yr.* If annual EtO use at the facility is less than 100 lb, the procedures in paragraphs (d)(1) through (5) of this section may be used to determine compliance with the standard(s) under § 63.362(c) through (g) and to establish operating limits for each of the control devices, as applicable:

(1) You must determine the percent emission reduction of the control system used to comply with § 63.362(c) through (g) using the test methods and procedures in § 63.365(d)(1).

(2) If an acid-water scrubber(s) is used to comply with a standard, then you must establish as an operating limit:

(i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1)(i);

(ii) The maximum liquor tank level using the procedures described in § 63.365(e)(1)(ii); or

(iii) The maximum scrubber liquor pH using the procedures described in § 63.365(e)(1)(iii).

(3) If a thermal oxidizer(s) is used to comply with a standard, you must establish as an operating limit the minimum temperature in or immediately downstream of the firebox using the procedures described in § 63.365(e)(2).

(4) If a catalytic oxidizer(s) is used to comply with the standard, you must establish as operating limits both:

(i) The minimum temperature at the inlet to the catalyst bed using the procedures described in § 63.365(e)(3); and

(ii) The minimum temperature difference across the catalyst bed using the procedures described in § 63.365(e)(3).

(5) If a gas/solid reactor(s) is used to comply with the standard, you must establish as an operating limit the pressure drop across the media beds and conduct weekly sampling and analysis of the media. Determine the maximum gas/solid reactor pressure drop using the procedures described in § 63.365(e)(4).

(e) *Other control technology for facility where EtO use is less than 100 lb/yr.* If you are conducting a performance test using a control technology other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator information describing the design and operation of the air pollution control system, including recommendations for the parameters to be monitored that will demonstrate continuous compliance. Based on this information, the Administrator will determine the parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(e)(5), you must determine the site-specific operating limit(s) for the operating parameters approved by the Administrator. You must submit the information at least sixty days before the performance test is scheduled to begin. The information on the control technology must include the five items listed in paragraphs (1) through (5) of this section:

(1) Identification of the specific parameters you propose to use as additional operating limits;

(2) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(3) A discussion of how you will establish the upper and/or lower values which will establish the operating limits for these parameters;

(4) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(5) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

(f) *Other emission streams.* If the emission stream does not consist only of an SCV(s), the procedures in paragraphs (f)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d) through (g), as applicable:

(1) You must comply with paragraph (c) of this section, as applicable.

(2) If you are complying with a percent emission reduction standard as specified in tables 1 through 5 to this subpart, you must determine compliance with § 63.362(c) through (g), as applicable, using the test methods and procedures in § 63.365(d)(1).

(3) If you are required to operate any portion of the facility under PTE, you must initially demonstrate that the PTE meets the requirements of Method 204 of 40 CFR part 51, appendix M, and that all exhaust gases from the enclosure are delivered to a control system or stack(s). You must also meet the requirements in § 63.363(f)(3)(i) and either § 63.363(f)(3)(ii) or (iii):

(i) Maintain direction of the airflow into the enclosure at all times, verifying daily using the procedures described in § 63.364(f)(5) and meet either of the requirements.

(ii) Establish as an operating limit the *minimum volumetric flow rate through the affected stack(s)* using the procedures described in § 63.365(f)(1); or

(iii) Install, operate, calibrate, and maintain a continuous pressure differential monitoring system using the procedures described in § 63.364(f)(4).

§ 63.364 Monitoring requirements.

(a) *General requirements.* (1) If you own or operate an affected source subject to an emission standard in § 63.362, you must comply with the monitoring requirements in § 63.8, according to the applicability in table 6 to this subpart, and in this section.

(2) If you own or operate an affected source at a facility where EtO use is less than 100 lb/yr that is subject to an emission standard in § 63.362, you may monitor the parameters specified in paragraphs (b), (c), (d), (e), (g), and (i) of this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(3) If you own or operate an affected source that is subject to an emission standard in § 63.362 and that is required to monitor using EtO CEMS, you must

comply with paragraphs (f), (g), and (i) of this section.

(4) If you comply with the management practice for Group 2 room air emissions at area sources, you must comply with paragraph (h) of this section.

(5) You must keep the written procedures required by § 63.8(d)(2) on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you must keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(b) *Acid-water scrubbers.* If you are demonstrating continuous compliance through periodic performance testing on an acid-water scrubber(s), you must:

(1) *Ethylene glycol concentration.* Sample the scrubber liquor from the acid-water scrubber(s) and analyze and record at least once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in § 63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated. You must maintain the weekly ethylene glycol concentration below the operating limit established during the most recent performance test;

(2) *Scrubber liquor tank level.* Measure and record at least once per day the level of the scrubber liquor in the recirculation tank(s). You must install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (*i.e.,* a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a day only if the scrubber unit has been operated. You must maintain the daily scrubber liquor height in each recirculation tank below the applicable operating limit established during the most recent performance test; or

(3) *pH.* Monitor and record at least every 15 minutes the scrubber liquor pH. Monitoring is required when the scrubber is operating. A data acquisition system for the pH monitor shall compute and record each 3-hour average scrubber liquor pH value, rolled hourly. This must be done by first averaging the scrubber liquor pH readings obtained over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the scrubber unit is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average scrubber liquor pH. You must maintain the 3-hour rolling average scrubber liquor pH below the applicable operating limit established during the most recent performance test. You must ensure the pH monitoring system meets the following requirements:

(i) The pH sensor must be installed in a position that provides a representative measurement of scrubber liquor pH;

(ii) The sample must be properly mixed and representative of the fluid to be measured; and

(iii) A performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system must be conducted in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(c) *Oxidizers.* If you are demonstrating continuous compliance through periodic performance testing on a catalytic oxidizer or thermal oxidizer, the requirements in paragraphs (c)(1) and (2) of this section apply:

(1) For thermal oxidizers, you must monitor and record at least every 15 minutes the temperature in or immediately downstream of the firebox using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the thermal oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature value, rolled hourly. This must be done by first averaging the temperature readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the thermal oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature in or immediately downstream of the firebox. You must maintain the 3-hour rolling average temperature above the operating limit established during the most recent performance test.

(2) For catalytic oxidizers, you must monitor and record at least every 15 minutes the temperature at the inlet to the catalyst bed using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the catalytic oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature, rolled hourly. This must be done by first averaging the temperature readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the catalytic oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature at the inlet to the catalyst bed. You must maintain the 3-hour rolling average temperature above the operating limit established during the most recent performance test.

(3) For catalytic oxidizers, you must monitor and record at least every 15 minutes the temperature increase across the catalyst bed, immediately downstream of the catalytic bed, using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the catalytic oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature increase, rolled hourly. This must be done by first computing the difference in outlet temperature minus inlet temperature (monitored under paragraph (c)(2)), and second averaging the temperature difference values over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the catalytic oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature increase across the catalyst bed. You must maintain the 3-hour average temperature increase above the operating limit established during the most recent performance test.

(4) You must install, calibrate, operate, and maintain a temperature monitor with a minimum accuracy of ±1 percent over the normal range of the temperature measured, expressed in degrees Celsius, or 2.8 degrees Celsius, whichever is greater. You must verify the accuracy of the temperature monitor twice each calendar year at least five months apart with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy of the temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(5) For catalytic oxidizers, if the monitor indicates that the temperature is below the operating limit, within 7 calendar days you must:

(i) Correct the temperature or temperature increase so that it falls within the established operating range; or

(ii) Replace the catalyst bed. Following replacement of the catalyst bed, you must conduct a new performance test within 180 days and re-establish the operating limits.

(d) *Gas-solid reactors.* If you are demonstrating continuous compliance through periodic performance testing on a gas/solid reactor(s), you must:

(1) *Media analysis.* Sample the media from the gas/solid reactor(s) and have the manufacturer analyze at least once per week. Monitoring is required during a week only if the gas/solid reactor unit has been operated; and

(2) *Pressure drop.* Monitor and record at least every 15 minutes the pressure drop. Monitoring is required when the gas/solid reactor is operating. A data acquisition system for the pressure drop monitor shall compute and record each 3-hour average gas/solid reactor pressure drop value, rolled hourly. This must be done by first averaging the gas/solid reactor pressure drop readings obtained over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the gas/solid reactor unit is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average gas/solid reactor pressure drop. You must maintain the 3-hour rolling average gas/solid reactor pressure drop below the applicable operating limit established during the most recent performance test.

(e) *Performance testing, other control technology.* If you are complying with § 63.363(d) or (e) using periodic performance testing and the use of a control device other than acid-water scrubbers, catalytic or thermal oxidizers, or gas/solid reactors, you must monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(e).

(f) *EtO CEMS configurations.* If you are using EtO CEMS to demonstrate compliance with an emission standard, you must install and operate an EtO CEMS on each outlet for the control system in accordance with the requirements of Appendix A to subpart O of this part. You must also conduct monitoring for each inlet to the control system that is used to demonstrate compliance with the emission reduction standard in accordance with the requirements of appendix A to this subpart, with the exception for SCV emission streams to the control system.

(1) *EtO CEMS inlet configuration.* The following caveats apply:

(i) *SCVs.* If you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to monitoring the inlet emission stream to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(A) Determine the mass ($M_{SCV,n}$) of EtO used for each charge and at each sterilization chamber used during the previous 30 days using the procedures in either paragraph (f)(1)(i)(A)(*1*) or (*2*) of this section.

(*1*) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass (M_c) vented to the controls using equation 1 to this paragraph.

Equation 1 to paragraph (f)(1)(i)(A)(1)

$$M_{SCV,n} = M_{charge} \times \%EO_w \quad \text{(Eq. 1)}$$

Where:

$M_{SCV,n}$ = Theoretical total mass of EtO vented to controls per charge, g (lb)

M_{charge} = total mass of sterilizer gas charge, g (lb)

$\%EO_w$ = weight percent of EtO

(*2*) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Q_m) and duration of each sterilizer charge. Calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 2 to this paragraph.

Equation 2 to paragraph (f)(1)(i)(A)(2)

$$M_{SCV,n} = (Q_m \times T_n \times \%EO_v \times \frac{MW}{SV}) \quad \text{(Eq. 2)}$$

Where:

$M_{SCV,n}$ = theoretical total mass of EtO sent to controls per charge

Q_m = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))

T_n = time duration of each charge, min

$\%EO_v$ = volume fraction percent of EtO

n = number of EtO charges

MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))

SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(B) Determine the adjustment factor (*f*) using equation 8 to this paragraph. Determine the mass of EtO sent to controls from all non-SCV affected sources, *I,* using equation 4 to this paragraph. For facilities where EtO use is less than 4 tpy, if not all Group 2 room air emissions are routed to a control device, do not include Group 2 room air emissions in *I,* and subtract 0.002 from this factor.

Equations 3 and 4 to paragraph (f)(1)(i)(B)

$$f = 0.99 - \frac{I}{M_{Fac}} \quad \text{(Eq. 3)}$$

Where:

f = Adjustment factor.

I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days

M_{Fac} = Facility EtO use over the previous 30-operating days, in pounds, as determined in accordance with equation 11 of § 63.364(i)(2)

$$I = \sum_{i=1}^{n} M_{c,i} \quad \text{(Eq. 4)}$$

Where:

I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days

$M_{c,i}$ = The 30-operating day total mass sent to controls (*i.e.,* monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''$M_{c,i}$'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

i = Non-SCV emission stream index.

n = Total number of non-SCV emission streams.

(C)(*1*) Determine the mass rate of EtO sent to controls during the previous 30 days using equation 5 to this paragraph.

Equation 5 to paragraph (f)(1)(i)(C)(1)

$$M_{SCV} = f \times \sum_{i=1}^{n} M_{SCV,n} \quad \text{(Eq. 5)}$$

Where:

M_{SCV} = Total mass of EtO sent to controls over the previous 30 operating days, g/hr (lb/hr)

f = Adjustment factor

$M_{SCV,n}$ = Theoretical mass of EtO sent to controls per charge per chamber, g (lb)

n = Total number of charges during the previous 30 operating days

(*2*) If both this approach is chosen and the SCV is (or SCVs are) combined with another emission stream, then the owner or operator cannot monitor the point after the combination occurs.

(ii) *Room air emissions.* If room air emissions are both subject to an emission standard and split between two or more control systems, then monitoring must be conducted for room air emissions before they are combined with other streams.

(2) *EtO CEMS on exhaust configurations.* Exhaust gases from the emission sources under this subpart exhaust to the atmosphere through a variety of different configurations, including but not limited to individual stacks, a common stack configuration, or a main stack plus a bypass stack. For the CEMS used to provide data under this subpart, the continuous monitoring system installation requirements for these exhaust configurations are as follows:

(i) *Single unit-single stack configurations.* For an emission source that exhausts to the atmosphere through a single, dedicated stack, you shall either install the required CEMS in the stack or at a location in the ductwork downstream of all emissions control devices, where the pollutant and diluents concentrations are representative of the emissions that exit to the atmosphere.

(ii) *Unit utilizing common stack with other emission source(s).* When an emission source utilizes a common stack with one or more other emission sources, but no emission sources not subject to this rule, you shall either:

(A) Install the required CEMS in the duct from each emission source, leading to the common stack; or

(B) Install the required CEMS in the common stack.

(iii) *Unit(s) utilizing common stack with non-commercial sterilization emission source(s).* (A) When one or more emission sources shares a common stack with one or more emission sources not subject to this rule, you shall either:

(*1*) Install the required CEMS in the ducts from each emission source that is subject to this rule, leading to the common stack; or

(*2*) Install the required CEMS described in this section in the common stack and attribute all of the emissions measured at the common stack to the emission source(s).

(B) If you choose the common stack monitoring option:

(*1*) For each hour in which valid data are obtained for all parameters, you must calculate the pollutant emission rate; and

(*2*) You must assign the calculated pollutant emission rate to each of the units subject to the rule that share the common stack.

(iv) *Unit with multiple parallel control devices with multiple stacks.* If the exhaust gases from an emission source, which is configured such that emissions are controlled with multiple parallel control devices or multiple series of control devices are discharged to the atmosphere through more than one stack, you shall install the required CEMS described in each of the multiple stacks. You shall calculate hourly, flow-weighted, average pollutant emission rates for the unit as follows:

(A) Calculate the pollutant emission rate at each stack or duct for each hour in which valid data are obtained for all parameters;

(B) Multiply each calculated hourly pollutant emission rate at each stack or duct by the corresponding hourly gas flow rate at that stack or duct;

(C) Sum the products determined under paragraph (f)(2)(iv)(B) of this section; and

(D) Divide the result obtained in paragraph (f)(2)(I(C) of this section by the total hourly gas flow rate for the unit, summed across all of the stacks or ducts.

(g) *PTE monitoring.* If you are required to operate all or a portion of your sterilization facility under PTE conditions, you must:

(1) *Initial compliance.* Demonstrate initial procedures in § 63.365(g)(1) and continued compliance with the provisions in this section. You must follow the requirements of either paragraphs (g)(2) and (3) of this section or paragraph (g)(4) of this section.

(2) *Continuous compliance.* If you choose to demonstrate continuous compliance through volumetric flow rate monitoring, you must monitor and record at least every 15 minutes the volumetric flow rate from each outlet where air from the PTE is sent using a flow rate monitoring system described in paragraph (g)(3) of this section. Monitoring is required when the portion of the facility covered by PTE is operated. A data acquisition system for the flow rate monitoring system shall compute and record each 3-hour average flow rate value, rolled hourly. This must be done by first averaging the flow rate readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even the portion of the facility covered by PTE is not operated for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average flow rate. You must maintain the 3-hour rolling average flow rate above the applicable operating limits established during the most recent compliance demonstration.

(3) *Continuous flow rate monitoring system for PTE.* You must install, operate, calibrate, and maintain instruments, according to the requirements in paragraphs (g)(3)(i) through (ix) of this section, for continuously measuring and recording the stack gas flow rate to allow determination of compliance with the minimum volumetric flow rate through the affected stack operating limit(s).

(i) You must install each sensor of the flow rate monitoring system in a location that provides representative measurement of the exhaust gas flow rate. The flow rate sensor is that portion of the system that senses the volumetric flow rate and generates an output proportional to that flow rate.

(ii) The flow rate monitoring system must be designed to measure the exhaust flow rate over a range that extends from a value of at least 20 percent less than the lowest expected exhaust flow rate to a value of at least 20 percent greater than the highest expected exhaust flow rate.

(iii) The flow rate monitoring system must be equipped with a data acquisition and recording system that is capable of recording values over the entire range specified in paragraph (g)(3)(ii) of this section.

(iv) The signal conditioner, wiring, power supply, and data acquisition and recording system for the flow rate monitoring system must be compatible with the output signal of the flow rate sensors used in the monitoring system.

(v) The flow rate monitoring system must be designed to complete a minimum of one cycle of operation for each successive 15-minute period.

(vi) The flow rate sensor must have provisions to determine the daily zero and upscale calibration drift (CD) (*see* sections 3.1 and 8.3 of Performance Specification 2 in appendix B to Part 60 of this chapter for a discussion of CD).

(A) Conduct the CD tests at two reference signal levels, zero (*e.g.,* 0 to 20 percent of span) and upscale (*e.g.,* 50 to 70 percent of span).

(B) The absolute value of the difference between the flow monitor response and the reference signal must be equal to or less than 3 percent of the flow monitor span.

(vii) You must perform an initial relative accuracy test of the flow rate monitoring system according to section 8.2 of Performance Specification 6 of appendix B to part 60 of the chapter with the exceptions in paragraphs (g)(3)(vii)(A) and (B) of this section.

(A) The relative accuracy test is to evaluate the flow rate monitoring system alone rather than a continuous emission rate monitoring system.

(B) The relative accuracy of the flow rate monitoring system shall be no greater than 10 percent of the mean value of the reference method data.

(viii) You must verify the accuracy of the flow rate monitoring system at least once per year by repeating the relative accuracy test specified in paragraph (g)(3)(vii) of this section.

(ix) You must operate the flow rate monitoring system and record data during all periods of operation of the affected facility including periods of startup, shutdown, and malfunction.

(4) *Pressure differential monitor.* You must instead install, operate, calibrate, and maintain a continuous pressure differential monitoring system, as follows, to verify the presence of PTE. You must operate this system whenever the facility is in operation. You must also maintain the pressure differential at or above 0.007 inches of water over a three-hour rolling average.

(i) This monitoring system must measure the pressure differential between the interior and exterior of the PTE, with at least one monitoring device located in each room that borders the PTE. These monitoring devices shall be designed to provide measurements of pressure differential to at least the nearest 0.001 inches of water and having a complete cycle time no greater than 5 minutes.

(ii) A data acquisition system for the monitoring system shall compute and record each 3-hour average pressure differential value, rolled hourly. This must be done by first averaging the pressure differential readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even in portions of the facility covered by PTE that are not operated for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average pressure differential. If data are not recorded from an alternative monitoring device, during any malfunction of the principal monitoring device(s) or the automatic recorder, you must manually record the measured data at least hourly.

(h) *Sterilization chamber end-cycle EtO concentration.* As part of your monitoring plan, you must document your approach for determining the EtO sterilization chamber concentration. If you choose a parametric approach you must meet the requirements in paragraph (h)(1) of this section and if you choose a direct measurement approach you must meet the requirements in paragraph (h)(2) of this section. Alternatively, you may petition the administrator for an alternative monitoring approach under § 63.8(f).

(1) If you choose a parametric approach for determining chamber EtO concentrations you must document parameter(s) used in the calculation to determine of EtO concentrations and the calculation(s) used to determine the chamber concentration. Any instrumentation used for parametric monitoring must also be identified in the monitoring plan and at a minimum this plan should include the following for each instrument:

(i) Parameter measured and measurement principle of the monitor.

(ii) Instrument name, model number, serial number, and range.

(iii) Manufacturer recommended operation practices, including daily operational check.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(2) If you choose a direct measurement approach for determining chamber EtO calibrations you must document the procedures used for the operation of the instruments. Any instrument used for direct measurement of EtO must be identified in the monitoring plan and at a minimum this plan must include the following information:

(i) Instrument name, model number, serial number, and range.

(ii) Description of the measurement principle and any potential interferences.

(iii) If applicable, the description of the sampling condition system.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(i) *EtO usage.* If you own or operate a sterilization facility subject to the requirements of this subpart you must monitor and record on a daily basis the daily and 30-operating day EtO usage according to the requirements of this paragraph. Additionally, you must record EtO usage for each calendar month.

(1) Monitor and record on a daily basis, the daily total mass of ethylene oxide, in pounds, used at the facility. The daily total mass must be determined using the methodology specified in § 63.365(c)(1)(i) and (ii).

(2) Determine and record daily the 30-operating day rolling ethylene oxide usage rate using equation 6 to this paragraph.

Equation 6 to paragraph (i)(2)

$$M_{Fac} = \sum_{i=1}^{30} m_{Fac,i} \qquad \text{(Eq. 6)}$$

Where:

M_{Fac} = Facility EtO use over the previous 30 operating days, in pounds.

$m_{Fac,i}$ = Daily EtO use for operating day *i,* in pounds, as determined in accordance with paragraph (i)(1) of this section

i = Operating day index.

(3) Determine and record the total mass of EtO used in each calendar month.

§ 63.365 Test methods and procedures.

(a) *General*—(1) *Performance testing for facility where EtO use is less than 100 pounds per year.* If you own or operate an affected source at a facility where EtO use is less than 100 lb/yr that is subject to an emission standard in § 63.362, you must comply with the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, using the methods in paragraph (b) or (c) of this section, following the applicable procedures for initial compliance and continuous compliance in paragraphs (d), (e), and (f) of this section.

(2) *Facilities subject to capture efficiency.* If you are subject to capture efficiency requirements in § 63.362, you must follow the applicable procedures for initial and continuous compliance in paragraph (f) of this section.

(b) *Test methods for facility where EtO use is less than 100 pounds per year.* You must use the following test methods to determine the average mass emissions of EtO in lb/hr at the inlet of a control system ($M_{APCD,\ i}$) and/or outlet of a control system or stack ($E_{APCD,\ o}$).

(1) Select the location of the sampling ports and the number of traverse points according to Method 1 of appendix A–1 to part 60 of this chapter. Alternatively, for ducts less than 0.3 meter (12 in.) in diameter, you may choose to locate sample ports according to Method 1A of appendix A–1 to part 60 of this chapter.

(2) Determine the flow rate through the control system exhaust(s) continuously during the test period according to either Methods 2, 2A, or 2C of appendix A–1 to part 60 of this chapter, as appropriate. If using Method 2, 2A, or 2C, you must complete velocity traverses immediately before and subsequently after each test run. If your test run is greater than 1 hour, you must also complete a velocity traverse at least every hour. Average the velocity collected during a test run and calculate volumetric flow as outlined in the appropriate method.

(3) Determine the oxygen and carbon dioxide concentration of the effluent according to Method 3A or 3B of appendix A–2 to part 60 of this chapter. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 63.14) may be used as an alternative to EPA Method 3B.

(4) Determine the moisture content of the stack gas according to Method 4 of appendix A–3 to part 60 of this chapter. Alternatively, you may use an on-line technique that has been validated using Method 301 of appendix A to this part.

(5) Determine the EtO concentration according to either paragraph (b)(5)(i) or (ii) of this section.

(i) Follow Method 320 of appendix A to this part and the following paragraphs (5)(i)(A) through (D).

(A) The instrumentation used for measurement must have the measurement range to properly quantify the EtO in the gas stream. Additionally, for outlet emission streams, the instrumentation must have a method detection limit an order of magnitude below concentration equivalent of the emission limit.

(B) Instrumentation used must be continuous in nature with an averaging time of one minute or less.

(C) Calibration Spectra and all other analyte spiking required in the method must use EtO gaseous cylinder standard(s) which meet the criteria found in Performance Specification 19 of appendix B to part 60 if this chapter.

(D) Other methods and materials may be used; however, these alternative test methods are subject to Administrator approval.

(ii) Alternatively, ASTM D6348–12 (Reapproved 2020), (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) The test plan preparation and implementation in the Annexes to ASTM D 6348–12 (R2020), Sections A1 through A8 are mandatory; and

(B) In ASTM D6348–12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). In order for the test data to be acceptable

for a compound, %R must be 70% ≥ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using equation 1 to this paragraph:

Equation 1 to paragraph (b)(5)(ii)

Reported Results = ((Measured Concentration in Stack))/(%R) x 100.]

(6) Calculate the mass emission of EtO by using equations 2 and 3 to this paragraph:

Equations 2 and 3 to paragraph (b)(6)

$$M_{APCD,in} = \frac{C_{Eto,i} \text{ x } Q_i \text{ x } 44.05}{385.1 \text{ x } 10^6} \quad \text{(Eq. 2)}$$

$$E_{APCD,o} = \frac{C_{EtO,o} \text{ x } Q_o \text{ x } 44.05}{385.1 \text{ x } 10^9} \quad \text{(Eq. 3)}$$

Where:

$M_{APCD, i}$ = average inlet mass rate of EtO per hour, lb/hr

$C_{EtO,i}$ = inlet EtO concentration, ppmdv.

Qi = average inlet volumetric flow per hour at standard conditions, dscf/hr

44.05 = molecular weight (MW) of EtO, lb/lb-mole

MW/385.1 × 10^6 = conversion factor, from ppmv at standard conditions to lb/cf

$E_{APCD, o}$ = average outlet mass rate of EtO per hour, lb/hr

$C_{EtO,o}$ = outlet EtO concentration, ppbdv.

Q_o = average outlet volumetric flow per hour at standard conditions, dscf/hr

MW/385.1 × 10^9 = conversion factor, from ppbv at standard conditions to lb/cf

(c) *Alternative approach for SCVs for facility where EtO use is less than 100 pounds per year.* If you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to paragraph (b) of this section to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(1) Determine the mass ($M_{SCV,n}$) of EtO used for each charge and at each sterilization chamber used during the performance tests using the procedures in either paragraph (c)(1)(i) or (ii) of this section.

(i) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 4 to this paragraph.

Equation 4 to paragraph (c)(1)(i)

$$M_{SCV,n} = M_{charge} \text{x } \%EO_w \quad \text{(Eq. 4)}$$

Where:

$M_{SCV,n}$ = Theoretical total mass of EtO vented to controls per charge, g (lb)

M_{charge} = total mass of sterilizer gas charge, g (lb)

%E.O.$_w$ = weight percent of EtO

(ii) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Q_m) and duration of each sterilizer charge. Calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 5 to this paragraph.

Equation 5 to paragraph (c)(1)(ii)

$$M_{SCV,n} = \left(Q_m \text{ x } T_n \text{ x } \%EO_v \text{ x } \frac{MW}{SV}\right) \quad \text{(Eq. 5)}$$

Where:

$M_{SCV,n}$ = Total mass of EtO sent to controls per charge

Q_m = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and

101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))
T_n = time duration of each charge, min
$_n$ = number of EtO charges
$\%E.O._v$ = volume fraction percent of EtO
MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))
SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(2) Determine the mass rate of EtO sent to controls during the performance test using equation 6 to this paragraph.

Equation 6 to paragraph (c)(2)

$$M_{SCV} = \frac{\sum_{i=1}^{n} M_{SCV,n}}{T_t} \times f \qquad \text{(Eq. 6)}$$

Where:

M_{SCV} = Total mass of EtO sent to controls per hour, g/hr (lb/hr)
$M_{SCV,n}$ = Total mass of EtO sent to controls per charge per chamber, g (lb)
T_t = Total time of the performance test, hour
n = Total number of charges during testing period
f = Portion of EtO use that is assumed to be routed to the control system (0.93 if aeration is conducted in separate vessel; 0.98 otherwise)

(d) *Compliance determination for facility where EtO use is less than 100 pounds per year.* Each compliance demonstration shall consist of three separate runs using the applicable methods in paragraph (b) or (c) of this section. To determine compliance with the relevant standard, arithmetic mean of the three runs must be used. These procedures may be performed over a run duration of 1-hour (for a total of three 1-hour runs), except for the SCV testing from this category, where each run shall consist of the entirety of the sterilizer chamber evacuation and subsequent washes. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent the entire range of normal operation, including operational conditions for maximum emissions if such emissions are not expected during maximum production. The owner or operator must also account for the control system residence time when conducting the performance test. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. The following procedures shall be used to demonstrate compliance with a removal efficiency standard. In addition to these procedures, the procedures in paragraph (e) of this section must be followed to establish the operating parameter limits for each applicable emission control(s).

(1) You may determine the mass rate emissions of the stream prior to the control system and at the outlet of the control system using the test methods in paragraph (b) of this section. If the vent stream is comprised only of one or more SCVs, then you may use the procedures in paragraph (c) of this section for the mass rate emissions at the inlet.

(2) Calculate the total mass of EtO per hour that is routed to the control system by summing the mass of EtO per hour from each vent.

(3) Determine percent emission reduction (%ER) using the equation 7 to this paragraph:

Equation 7 to paragraph (d)(3)

$$\%ER = \frac{M_{APCD,i} - E_{APCD,o}}{M_{APCD,i}} \times 100 \qquad \text{(Eq. 7)}$$

Where:

% ER = percent emission reduction
$M_{APCD,i}$ = total mass of EtO per hour to the control device
$E_{APCD,o}$ = total mass of EtO per hour from the control device

(4) Repeat these procedures two additional times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control system.

(e) *Determination of operating limits for control device(s).* If you are using performance testing to demonstrate compliance with removal efficiency standards, and if you are not demonstrating continual compliance with the applicable standard(s) using an EtO CEMS, you must also determine the operating limit(s) for each control device and then monitor the parameter(s) for each control device. The procedures in the following paragraphs shall be used to establish the parameter operating limits to be continually monitored in § 63.364.

(1) *Acid-water scrubbers.* The procedures in paragraph (e)(1) of this section shall be used to determine the operating limits for acid-water scrubbers.

(i) *Ethylene glycol concentration.* For determining the ethylene glycol concentration operating limit, you must establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; use the sampling and analysis procedures in ASTM D3695–88 (incorporated by reference, see § 63.14) to determine the ethylene glycol concentration.

(ii) *Scrubber liquor tank level.* During the performance test, you must monitor and record the scrubber liquor tank level to the nearest ¼ inch at the end of each of the three test runs. Use the data collected during the most recent performance test to calculate the average scrubber liquor tank level. This scrubber liquor tank level is the maximum operating limit for your scrubber liquor tank. Repeat this procedure for every scrubber liquor tank that is included in the performance test.

(iii) *Scrubber liquor pH.* During the performance test, you must monitor and record the scrubber liquor pH at least once every 15 minutes during each of the three test runs. You must use pH

monitors as described in § 63.364(b)(3). Use the data collected during the most recent performance test to calculate the average scrubber pH measured. This scrubber liquor pH is the maximum operating limit for your acid-water scrubber. Repeat this procedure for every scrubber liquor tank that is included in the performance test.

(2) *Thermal oxidizers.* The procedures in this paragraph shall be used to determine the operating limits for thermal oxidizers.

(i) During the performance test, you must monitor and record the temperature at least once every 15 minutes during each of the three test runs. You must monitor the temperature in the firebox of the thermal oxidizer or immediately downstream of the firebox. You must use temperature monitors as described in § 63.364(c)(4).

(ii) Use the data collected during the performance test to calculate and record the average temperature for each test run maintained during the performance test. The average temperature of the test runs is the minimum operating limit for your thermal oxidizer, unless it exceeds the recommended maximum oxidation temperature provided by the oxidation unit manufacturer. If this occurs, the minimum operating limit for your thermal oxidizer consists of the recommended maximum oxidation temperature provided by the oxidation unit manufacturer.

(iii) Paragraphs (e)(2)(i) and (ii) of this section must be completed for each thermal oxidizer that is involved in the performance test.

(3) *Catalytic oxidizers.* The procedures in this paragraph shall be used to determine the operating limits for catalytic oxidizers.

(i) Prior to the start of the performance test, you must check the catalyst bed for channeling, abrasion, and settling. If problems are found during the inspection, you must replace the catalyst bed or take other correction action consistent with the manufacturer's recommendations.

(ii) During the performance test, you must monitor and record the temperature at the inlet to the catalyst bed and the temperature difference across the catalyst bed at least once every 15 minutes during each of the three test runs. You must use temperature monitors as described in § 63.364(c)(4).

(iii) Use the data collected during the performance test to calculate and record the average temperature at the inlet to the catalyst bed and the average temperature difference across the catalyst bed maintained for each test run, and then calculate the arithmetic averages of the test runs. These arithmetic averages of the test runs are the minimum operating limits for your catalytic oxidizer, unless it exceeds the recommended maximum oxidation temperature provided by the oxidation unit manufacturer. If this occurs, the minimum operating limit for your catalytic oxidizer consists of the recommended maximum oxidation temperature provided by the oxidation unit manufacturer.

(iv) Paragraphs (e)(3)(i) through (iii) of this section must be completed for each catalytic oxidizer that is involved in the performance test.

(4) *Gas/solid reactors.* During the performance test, you must monitor and record the gas/solid reactor pressure drop at least once every 15 minutes during each of the three test runs. Use the data collected during the most recent performance test to calculate the gas/solid reactor pressure measured. This gas/solid reactor pressure is the maximum operating limit for your gas/solid. Repeat this procedure for every gas/solid reactor that is included in the performance test.

(5) *Other control system for facility where EtO use is less than 100 pounds per year.* If you seek to demonstrate compliance with a standard found at § 63.362 with a control device other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator the information requested under § 63.363(e). You must submit a monitoring plan that contains the following items: a description of the device; test results collected in accordance with § 63.363(e) verifying the performance of the device for controlling EtO emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored, identifying the ongoing QA procedures and performance specifications that will be conducted on the instruments; the frequency of conducting QA and performance checks; and the frequency of measuring and recording to establish continuous compliance with the standards. Your monitoring plan is subject to the Administrator's approval. Upon approval by the Administrator you must install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted in your monitoring plan. You must include in your monitoring plan proposed performance specifications and quality assurance procedures for your monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.

(f) *Determination of compliance with PTE requirement.* If you are required to operate any portion of your facility with PTE, you must demonstrate initial compliance with the requirements of this subpart by following the procedures of paragraphs (f)(1) through (3) of this section, as applicable, during the initial compliance demonstration or during the initial certification of the CEMS tests.

(1) Determine the capture efficiency by verifying the capture system meets the criteria in section 6 of Method 204 of appendix M to part 51 of this chapter and directs all the exhaust gases from the enclosure to an add-on control device.

(2) Ensure that the air passing through all NDOs flows into the enclosure continuously. If the facial velocities (FVs) are less than or equal to 9,000 meters per hour (492 feet per minute), the continuous inward flow of air shall be verified by continuous observation using smoke tubes, streamers, tracer gases, or other means approved by the Administrator over the period that the volumetric flow rate tests required to determine FVs are carried out. If the FVs are greater than 9,000 meters per hour (492 feet per minute), the direction of airflow through the NDOs shall be presumed to be inward at all times without verification.

(3) If you are demonstrating continuous compliance through monitoring the volumetric flow rate, you must monitor and record the volumetric flow rate (in cubic feet per second) from the PTE through the stack(s) at least once every 15 minutes during each of the three test runs. Use the data collected during the most recent compliance demonstration to calculate the average volumetric flow rate measured during the compliance demonstration. This volumetric flow rate is the minimum operating limit for the stack. Repeat this procedure for every stack that is included in the compliance demonstration.

§ 63.366 Reporting requirements.

(a) *General requirements.* The owner or operator of an affected source subject to the emissions standards in § 63.362 must fulfill all reporting requirements in § 63.10(a), (d), (e), and (f), according to the applicability in table 6 to this subpart. These reports will be made to the Administrator at the appropriate address identified in § 63.13 or submitted electronically.

(b) *Initial compliance report submission.* You must submit an initial compliance report that provides summary, monitoring system

performance, and deviation information to the Administrator on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for one year, whichever date is later, to the EPA via CEDRI, which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the extensible markup language (XML) schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, along with information from any calibration tests in which the monitoring equipment is not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the summary report shall include:

(1) The following information:

(i) Date that facility commenced construction or reconstruction;

(ii) Hours of commercial sterilization operation over the previous 12 months; and

(iii) Monthly EtO use, in tons, over the previous 36 months.

(iv) 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), you must report the daily EtO use from each applicable chamber for the previous 7 months.

(v) An indication if you are required to comply with one or more combined emission stream limitations. If so, indicate the affected sources that are included in each combined emission stream limitation.

(vi) An indication if you are electing to comply with a site-wide emission limit. If you are electing to comply with a site-wide emission limit, report the daily EtO use over the previous 7 months.

(2) If your sterilization facility is demonstrating continuous compliance through periodic performance testing, you must report the following:

(i) Control system ID;

(ii) Control device ID;

(iii) Control device type; and

(iv) 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;

(3) You must report the following for each sterilization chamber at your facility:

(i) The sterilization chamber ID;

(ii) The ID of the control system that the SCV was routed to, if applicable;

(iii) The portion of SCV exhaust that was routed to the control system, if applicable;

(iv) The ID of the EtO CEMS that was used to monitor SCV emissions, if applicable;

(v) The portion of SCV exhaust that was monitored with the EtO CEMS, if applicable;

(vi) The ID of the control system that the CEV was routed to, if applicable;

(vii) The portion of CEV exhaust that was routed to the control system, if applicable;

(viii) The ID of the EtO CEMS that was used to monitor CEV emissions, if applicable;

(ix) The portion of CEV exhaust that was monitored with the EtO CEMS, if applicable;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the following for each room where there is the potential for EtO emissions:

(i) Room ID;

(ii) Documentation of emissions occurring within the room, including aeration, EtO storage, EtO dispensing, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material;

(iii) The ID of the control system that the room air was routed to, if applicable;

(iv) The portion of room air that was routed to the control system, if applicable;

(v) The ID of the EtO CEMS that was used to monitor room air emissions, if applicable;

(vi) The portion of room air that was monitored with the EtO CEMS, if applicable;

(5) 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:

(i) The information specified in section 11 of appendix A to this subpart.

(ii) The affected sources that are included in each inlet that is being monitored with EtO CEMS;

(iii) The IDs of each inlet(s) to and outlet(s) from each control system.

(iv) The daily sum of EtO for each inlet, along with 30-operating day rolling sums.

(v) The daily sum of EtO emissions from each outlet of the control system, along with 30-operating day rolling sums.

(vi) For each day, calculate and report the daily mass emission limit that the control system must achieve based on the previous 30 days of data. For control systems with multiple emission streams, and complying with a combined emission stream limitation in § 63.362(i) or a SWEL in § 63.362(j), report the daily 30-operating day mass emission limit as determined in accordance with CES in § 63.362(i)(1)(i) and (i)(2)(i) or with § 63.362(j)(1)(i) and (j)(2)(i), as applicable.

(vii) For each day, the mass of EtO emitted from the control system over the previous 30 operating days.

(6) If any portion of your facility is required to be operated with PTE, you must report the following:

(i) If you are choosing to demonstrate continuous compliance through the use of volumetric flow rate monitoring, you must report the 3-hr rolling average, rolled hourly volumetric flow from each outlet where air from the PTE is sent, in cubic feet per second.

(ii) If you are choosing to demonstrate continuous compliance through use of differential pressure monitoring, you must report the 3-hr rolling average, rolled hourly pressure differential reading, in inches water.

(7) If you are complying with the requirement to follow the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.362(h).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you must report the following for each room where there are Group 2 room air emissions:

(i) Room ID;

(ii) Number of room air changes per hour;

(iii) Room temperature, in degrees Celsius; and

(iv) EtO concentration, in ppmv dry basis (ppbvd).

(9) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and EtO use is less than 4 tpy, you are not required to report the information in paragraph (b)(8) of this section if you meet the following requirements:

(i) 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

(ii) The requirements of § 63.363 are met.

(10) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, the cause and duration of each deviation. For each deviation the report must include 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 determine the emissions.

(c) *Quarterly compliance report submission.* You must submit compliance reports that provide summary, monitoring system performance, and deviation information to the Administrator within 30 days following the end of each calendar quarter. Beginning on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for 1 year, whichever date is later, submit all subsequent reports to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the XML schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, and information from any calibration tests in which the monitoring equipment is not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the summary report shall include:

(1) The information listed in paragraphs (b)(1)(i) through (vi) of this section, with the exception that monthly EtO use, in tons, only needs reported for the previous 12 months;

(2) If your sterilization facility is demonstrating continuous compliance through periodic performance testing, you must report the ID for any control system that has not operated since the end of the period covered by the previous compliance report. If a control system has commenced operation since end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(2)(i) through (iv) of this section has changed for a control system that was included in the previous compliance report, you must report the information in paragraphs (b)(2)(i) through (iv) of this section for those control systems;

(3) You must report the ID for any sterilization chamber that has not operated since then end of the period covered by the previous compliance report. If a sterilization chamber has commenced operation since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(3)(i) through (ix) of this section has changed for a sterilization chamber that was included in the previous compliance report, you must report the information in paragraphs (b)(3)(i) through (ix) of this section for those sterilization chambers;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the ID for any room where there has not been the potential for EtO emissions since the end of the period covered by the previous compliance report. If a room has had the potential for EtO emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(4)(i) through (vi) of this section has changed for a room where there is the potential for EtO emissions that was included in the previous compliance report, you must report the information in paragraphs (b)(4)(i) through (vi) of this section for those rooms;

(5) If an EtO CEMS was used to demonstrate continuous compliance, you must report the information specified in paragraphs (b)(5)(i) through (vi) of this section.

(6) If any portion of your facility is required to be operated with PTE, you must report the information listed in paragraph (b)(6) of this section.

(7) If you are complying with the requirement to follow the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.362(h).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you must report the ID for any room where Group 2 room air emissions have ceased since end of the period covered by the previous compliance report. If a room has had Group 2 room air emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(8)(i) through (iv) of this section has changed for a room where there are Group 2 room air emissions that were included in the previous compliance report, you must report the information in paragraphs (b)(8)(i) through (iv) of this section for each room where there are Group 2 room air emissions.

(9) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you are not required to report the information in paragraph (c)(8) of this section if you meet the requirements in paragraph (b)(9) of this section.

(10) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, the cause, and duration of each deviation. For each deviation, the report must include a list of the affected sources or equipment, the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(d) *Construction and reconstruction application.* You must fulfill all requirements for construction or reconstruction of a facility in § 63.5, according to the applicability in table 6 to this subpart, and in this paragraph.

(1) *Applicability.* (i) This paragraph (d) and § 63.5 implement the preconstruction review requirements of section 112(i)(1) for facilities subject to these emissions standards. In addition, this paragraph (d) and § 63.5 include other requirements for constructed and reconstructed facilities that are or become subject to these emissions standards.

(ii) After April 5, 2024, the requirements in this section and in § 63.5 apply to owners or operators who construct a new facility or reconstruct a facility subject to these emissions standards after April 5, 2024. New or reconstructed facilities subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) and (e).

(2) *Advance approval.* After April 5, 2024, whether or not an approved permit program is effective in the jurisdictional authority in which a facility is (or would be) located, no person may construct a new facility or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and § 63.5(d)(3) and (4) and (e).

(3) *Application for approval of construction or reconstruction.* The provisions of paragraph (b)(3) of this section and § 63.5(d)(3) and (4) implement section 112(i)(1) of the Act.

(i) *General application requirements.* (A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new facility subject to these emissions standards, the reconstruction of a facility subject to these emissions standards, or the reconstruction of a facility such that the facility becomes a facility subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (e)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(*1*) The applicant's name and address.

(*2*) A notification of intention to construct a new facility subject to these emissions standards or make any physical or operational change to a facility subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2.

(*3*) The address (*i.e.,* physical location) or proposed address of the facility.

(*4*) An identification of the relevant standard that is the basis of the application.

(*5*) The expected commencement date of the construction or reconstruction.

(*6*) The expected completion date of the construction or reconstruction.

(*7*) The anticipated date of (initial) startup of the facility.

(*8*) The type and quantity of hazardous air pollutants emitted by the facility, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the facility reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.

(*9*) Other information as specified in paragraph (b)(3)(ii) of this section and § 63.5(d)(3).

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(*8*) and (b)(3)(ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) *Application for approval of construction.* Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of

operation of the facility subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) *Approval of construction or reconstruction based on prior jurisdictional authority preconstruction review.* (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) if the owner or operator of a new or reconstructed facility who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed facility subject to these emissions standards has undergone a preconstruction review and approval process in the jurisdictional authority in which the facility is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the facility will meet these emissions standards as proposed, if the facility is properly built and operated;

(B) In making its finding, the jurisdictional authority has considered factors substantially equivalent to those specified in § 63.5(e)(1).

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in § 63.5. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(e) *Notification requirements.* The owner or operator of an affected source subject to an emissions standard in § 63.362 shall fulfill all notification requirements in § 63.9, according to the applicability in table 6 to this subpart, and in this paragraph (e).

(1) *Initial notifications.* (i) If you own or operate an affected source subject to an emissions standard in § 63.362, you may use the application for approval of construction or reconstruction under paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed facility subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (d)(3) of this section and § 63.5(d)(3) and (4) shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new facility subject to these emissions standards, reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (d)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked no later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the facility, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the facility, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the jurisdictional authority in which a facility subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new facility subject to these emissions standards or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that it becomes a facility subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (d)(3) of this section and § 63.5(d)(3) and (4). For facilities subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.9.

(2) If an owner or operator of a facility subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, in place of the actual emissions data or control efficiencies required in paragraphs (d)(3)(i)(B)(*8*) and (b)(3)(ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) If you own or operate an affected source subject to an emissions standard in § 63.362, you must also include the amount of EtO used at the facility during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3). For new sterilization facilities subject to this subpart, the amount of EtO used at the facility shall be an estimate of expected use during the first consecutive 12-month period of operation.

(4) Beginning October 7, 2024, you must submit all subsequent Notification of Compliance Status reports in PDF formatto the EPA following the

procedure specified in § 63.9(k), except any medium submitted through mail must be sent to the attention of the Commercial Sterilization Sector Lead.

(f) *Performance test submission.* Beginning on June 4, 2024, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (f)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via the CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *CBI.* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (f)(1)(i) or (ii) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (f)(1)(i) and (ii) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(g) *Performance evaluation submission.* Beginning on June 4, 2024, within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (g)(1) through (3) of this section.

(1) *Performance evaluations of CEMS measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Performance evaluations of CEMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *CBI.* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (g)(1)(i) or (ii) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The CBI file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (g)(1)(i) and (ii) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(h) *Extensions for CDX/CEDRI outages.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with that reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (h)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(i) *Extensions for force majeure events.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of *force majeure* for failure to timely comply with that reporting requirement. To assert a claim of *force majeure,* you must meet the requirements outlined in paragraphs (i)(1) through (5) of this section.

(1) You may submit a claim if a *force majeure* event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a *force majeure* event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the *force majeure* event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the *force majeure* event;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of *force majeure* and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

§ 63.367 Recordkeeping requirements.

(a) If you own or operate an affected source subject to § 63.362, you must comply with the recordkeeping requirements in § 63.10(a) through (c), according to the applicability in table 6 to this subpart, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection.

(b) You must maintain the previous five years of records specified in § 63.366(b) and (c), as applicable.

(c) You must maintain the previous five years of records for compliance tests and associated data analysis, as applicable.

(d) Any records required to be maintained by this subpart that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

(e) If you are using an EtO CEMS to demonstrate continuous compliance, you must maintain the previous five years of records for all required certification and QA tests.

(f) For each deviation from an emission limit, operating limit, or best management practice, you must keep a record of the information specified in paragraph (g)(1) through (4) of this section. The records shall be maintained as specified in § 63.10(b)(1).

(1) The occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment.

(2) 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.

(3) 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.

(4) Record actions taken to minimize emissions in accordance with § 63.362(k) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

§ 63.368 Implementation and enforcement.

(a) This subpart can be implemented and enforced by the U.S. EPA or a delegated authority such as the applicable State, local, or Tribal agency. If the U.S. EPA Administrator has delegated authority to a State, local, or Tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. Contact the applicable U.S. EPA Regional Office to find out whether implementation and enforcement of this subpart are delegated to a State, local, or Tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or Tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of U.S. EPA and cannot be transferred to the State, local, or Tribal agency.

(c) The authorities that cannot be delegated to State, local, or Tribal agencies are as specified in paragraphs (c)(1) through (5) of this section.

(1) Approval of alternatives to the requirements in §§ 63.360 and 63.362.

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f), as defined in § 63.90, and as required in this subpart.

(3) Approval of major alternatives to monitoring under § 63.8(f), as defined in § 63.90, and as required in this subpart.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f), as defined in § 63.90, and as required in this subpart.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

Table 1 to Subpart O of Part 63—Standards for SCVs

As required in § 63.362(c), for each SCV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing SCV	a. Facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99 percent [1].	Until April 6, 2026.
	b. Facility EtO use is at least 1 tpy but less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent [1].	Until April 6, 2026.
		ii. Continuously reduce EtO emissions by 99.8 percent [2 3].	No later than April 6, 2026.
	c. Facility EtO use is at least 30 tpy	i. Continuously reduce EtO emissions by 99.99 percent [2 3].	No later than April 6, 2026.
	d. Facility EtO use is at least 10 tpy but less than 30 tpy	i. Continuously reduce EtO emissions by 99.9 percent [2 3].	No later than April 6, 2026.
	e. Facility EtO use is less than 1 tpy	i. Continuously reduce EtO emissions by 99 percent [2 4].	No later than April 5, 2027.

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
2. New SCV	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 30 tpy.	i. Continuously reduce EtO emissions by 99.99 percent[2][5].	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is at least 10 tpy but less than 30 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	No later than April 5, 2024.
	c. Initial startup is on or before April 5, 2024, and facility EtO use is at least 1 tpy but less than 10 tpy.	i. Continuously reduce EtO emissions by 99.8 percent[2][5].	No later than April 5, 2024.
	d. Initial startup is on or before April 5, 2024, and facility EtO use is less than 1 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	No later than April 5, 2024.
	e. Initial startup is after April 5, 2024, and facility EtO use is at least 30 tpy.	i. Continuously reduce EtO emissions by 99.99 percent[2][5].	Upon startup of the source.
	f. Initial startup is after April 5, 2024, and facility EtO use is at least 10 tpy but less than 30 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	Upon startup of the source.
	g. Initial startup is after April 5, 2024, and facility EtO use is at least 1 tpy but less than 10 tpy.	i. Continuously reduce EtO emissions by 99.8 percent[2][5].	Upon startup of the source.
	h. Initial startup is after April 5, 2024, and facility EtO use is less than 1 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	Upon startup of the source.

[1] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.
[2] If using EtO CEMS to determine compliance, this standard is based on the previous 30 operating days of data.
[3] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[4] The standard applies if the facility has used less than 1 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[5] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[6] The standard applies if the facility is not expected to meet or exceed 1 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 1 tpy of EtO within all consecutive 12-month periods after startup.

Table 2 to Subpart O of Part 63—Standards for ARVs

As required in § 63.362(d), for each ARV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing ARV	a. Facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99 percent[1].	Until April 6, 2026.
	b. Facility EtO use is at least 30 tpy	i. Continuously reduce EtO emissions by 99.9 percent[2][3].	No later than April 6, 2026.
	c. Facility EtO use is at least 10 tpy but less than 30 tpy	i. Continuously reduce EtO emissions by 99.6 percent[2][3].	No later than April 6, 2026.
	d. Facility EtO use is less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent[2][4].	No later than April 5, 2027.
2. New ARV	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 10 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is less than 10 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 10 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	Upon startup of the source.
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 10 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	Upon startup of the source.

[1] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.
[2] If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.
[3] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[4] The standard applies if the facility has used less than 10 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[5] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[6] The standard applies if the facility is not expected to meet or exceed 10 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 10 tpy of EtO within all consecutive 12-month periods after startup.

Table 3 to Subpart O of Part 63—Standards for CEVs

As required in § 63.362(e), for each CEV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing CEV at a major source facility.	a. Not applicable	i. Continuously reduce EtO emissions by 99.94 percent[1].	No later than April 5, 2027.
2. Existing CEV at an area source facility.	a. Facility EtO use is at least 60 tpy	i. Continuously reduce EtO emissions by 99.9 percent[1][2].	No later than April 6, 2026.
	b. Facility EtO use is less than 60 tpy	i. Continuously reduce EtO emissions by 99 percent[1][3].	No later than April 5, 2027.
3. New CEV at a major source facility.	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 99.94 percent[1].	No later than April 5, 2024.

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 99.94 percent [1].	Upon startup of the source.
4. New CEV at an area source facility.	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 60 tpy.	i. Continuously reduce EtO emissions by 99.9 percent [1 4].	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, facility EtO use is less than 60 tpy.	i. Continuously reduce EtO emissions by 99 percent [1 5].	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 60 tpy.	i. Continuously reduce EtO emissions by 99.9 percent [1 4].	Upon startup of the source.
	d. Initial startup is after April 5, 2024, facility EtO use is less than 60 tpy.	i. Continuously reduce EtO emissions by 99 percent [1 5].	Upon startup of the source.

[1] If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.
[2] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[3] The standard applies if the facility has used less than 60 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[4] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[5] The standard applies if the facility is not expected to meet or exceed 60 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 60 tpy of EtO within all consecutive 12-month periods after startup.

Table 4 to Subpart O of Part 63—Standards for Group 1 Room Air Emissions

As required in § 63.362(f), for your collection of Group 1 room air emissions at each facility, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the requirement(s) . . .
1. Existing collection of Group 1 room air emissions at a major source facility.	a. Not applicable	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	No later than April 5, 2027.
		ii. Continuously reduce EtO emissions by 97 percent [1]	
2. Existing collection of Group 1 room air emissions at an area source facility.	a. Facility EtO use is at least 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[2] Also,	No later than April 6, 2026.
		ii. Continuously reduce EtO emissions by 98 percent [1 2]	
	b. Facility EtO use is less than 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	No later than April 5, 2027.
		ii. Continuously reduce EtO emissions by 80 percent [1 3]	
3. New collection of Group 1 room air emissions at a major source facility.	a. Initial startup is on or before April 5, 2024.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	No later than April 5, 2024.
		ii. Continuously reduce EtO emissions by 97 percent [1]	
	b. Initial startup is after April 5, 2024.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	Upon startup of the source.
		ii. Continuously reduce EtO emissions by 97 percent [1]	
4. New collection of Group 1 room air emissions at an area source facility.	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[4] Also,	No later than April 5, 2024.
		ii. Continuously reduce EtO emissions by 98 percent [1 4]	
	b. Initial startup is on or before April 5, 2024, and facility EtO use is less than 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also,	No later than April 5, 2024.
		ii. Continuously reduce EtO emissions by 80 percent [1 5]	
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[4] Also,	Upon startup of the source.
		ii. Continuously reduce EtO emissions by 98 percent [1 4]	
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also,	Upon startup of the source.
		ii. Continuously reduce EtO emissions by 80 percent [1 5]	

[1] If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.
[2] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[3] The standard applies if the facility has used less than 40 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[4] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[5] The standard applies if the facility is not expected to meet or exceed 40 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 40 tpy of EtO within all consecutive 12-month periods after startup.

Table 5 to Subpart O of Part 63—Standards for Group 2 Room Air Emissions

As required in § 63.362(g), for your collection of Group 2 room air emissions, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the requirement(s) . . .
1. Existing collection of Group 2 room air emissions at a major source facility.	a. Not applicable	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also, ii. Continuously reduce EtO emissions by 86 percent [1]	No later than April 5, 2027.
2. Existing collection of Group 2 room air emissions at an area source facility.	a. Facility EtO use is at least 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[2] Also,. ii. Continuously reduce EtO emissions by 98 percent [1 2]	No later than April 6, 2026.
	b. Facility EtO use is at least 4 tpy but less than 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[2] Also, ii. Continuously reduce EtO emissions by 80 percent [1 2]	No later than April 6, 2026.
	c. Facility EtO use is less than 4 tpy.	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened [3].	No later than April 5, 2027.
3. New collection of Group 2 room air emissions at a major source facility.	a. Initial startup is on or before April 5, 2024.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also, ii. Continuously reduce EtO emissions by 86 percent [1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also, ii. Continuously reduce EtO emissions by 86 percent [1]	Upon startup of the source.
4. New collection of Group 2 room air emissions at an area source facility.	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also, ii. Continuously reduce EtO emissions by 98 percent [1 5]	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is less than 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[6] Also, ii. Continuously reduce EtO emissions by 80 percent [1 6]	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also, ii. Continuously reduce EtO emissions by 98 percent [1 5]	Upon startup of the source.
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[6] Also, ii. Continuously reduce EtO emissions by 80 percent [1 6]	Upon startup of the source.

[1] This standard is based on a rolling 30-operating day average.
[2] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[3] The standard applies if the facility has used less than 4 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[4] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[5] The standard applies if the facility is not expected to meet or exceed 20 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 20 tpy of EtO within all consecutive 12-month periods after startup.

Table 6 to Subpart O of Part 63—Applicability of General Provisions to This Subpart

As specified in § 63.360, the parts of the General Provisions that apply to you are shown in the following table:

Citation	Subject	Applies to subpart O
§ 63.1(a)(1)	Applicability	Yes, additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.1(a)(2)–(3)		Yes.
§ 63.1(a)(4)		Yes. Subpart O clarifies the applicability of each paragraph in subpart A to facilities subject to subpart O.
§ 63.1(a)(5)	[Reserved]	No.
§ 63.1(a)(6)–(8)		Yes.
§ 63.1(a)(9)	[Reserved].	
§ 63.1(a)(10)–(14)		Yes.
§ 63.1(b)(1)–(2)		Yes.
§ 63.1(b)(3)		No.
§ 63.1(c)(1)		No. Subpart O clarifies the applicability of each paragraph in subpart A to facilities subject to subpart O in this table.
§ 63.1(c)(2)		Yes.

Citation	Subject	Applies to subpart O
§ 63.1(c)(3)	[Reserved]	No.
§ 63.1(c)(4)		Yes.
§ 63.1(c)(5)		No. § 63.360 specifies applicability.
§ 63.1(c)(6)		Yes.
§ 63.1(d)	[Reserved]	No.
§ 63.1(e)		Yes.
§ 63.2	Definitions	Yes, additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.3	Units and abbreviations	Yes, other units used in subpart O are defined in the text of subpart O.
§ 63.4(a)(1)–(3)	Prohibited activities	Yes.
§ 63.5(a)	Construction/Reconstruction	No. § 63.366(b)(1) contains applicability requirements for constructed or reconstructed facilities.
§ 63.5(b)(1)		Yes.
§ 63.5(b)(2)	[Reserved].	
§ 63.5(b)(3)		No. See § 63.366(b)(2).
§ 63.5(b)(4)–(6)		Yes.
§ 63.5(c)	[Reserved].	
§ 63.5(d)(1)–(2)		No. See § 63.366(b)(3).
§ 63.5(d)(3)–(4)		Yes.
§ 63.5(e)		Yes.
§ 63.5(f)(1)–(2)		No. See § 63.366(b)(4).
§ 63.6(a)	Applicability	Yes.
§ 63.6(b)–(c)		No. § 63.360(j) specifies compliance dates for facilities.
§ 63.6(d)	[Reserved].	
§ 63.6(e)(1)(i)		No.
§ 63.6(e)(1)(ii)	Requirement to correct malfunctions ASAP.	No.
§ 63.6(e)(1)(iii)		Yes.
§ 63.6(e)(2)	[Reserved]	No.
§ 63.6(e)(3)	SSM Plan Requirements	No.
§ 63.6(f)(1)	SSM exemption	No.
§ 63.6(f)(2)(i)	Methods for Determining Compliance.	Yes.
§ 63.6(f)(2)(ii)		No. § 63.363 specifies parameters for determining compliance.
§ 63.6(f)(2)(iii)–(iv)		Yes.
§ 63.6(f)(2)(v)		No.
§ 63.6(f)(3)		Yes.
§ 63.6(g)	Alternative Standard	Yes.
§ 63.6(h)	Compliance with opacity and visible emission standards.	No. Subpart O does not contain any opacity or visible emission standards.
§ 63.6(i)(1)–(14), and (16)	Compliance Extension	Yes.
§ 63.6(j)	Presidential Compliance Exemption.	Yes.
§ 63.7(a)	Applicability and Performance Test Dates.	Yes.
§ 63.7(b)	Notification of Performance Test.	Yes.
§ 63.7(c)	Quality Assurance/Test Plan	Yes.
§ 63.7(d)	Testing Facilities	Yes.
§ 63.7(e)(1)	SSM exemption	No.
§ 63.7(e)(2)–(4)	Conduct of Performance Tests	Yes. § 63.365 also contains test methods specific to facilities subject to the emissions standards.
§ 63.7(f)	Alternative Test Method	Yes.
§ 63.7(g)	Performance Test Data Analysis.	Yes, except this subpart specifies how and when the performance test and performance evaluation results are reported.
§ 63.7(h)	Waiver of Tests	Yes.
§ 63.8(a)(1)	Applicability of Monitoring Requirements.	Yes.
§ 63.8(a)(2)	Performance Specifications	Yes.
§ 63.8(a)(3)	[Reserved]	No.
§ 63.8(a)(4)	Monitoring with Flares	Yes.
§ 63.8(b)(1)	Monitoring	Yes.
§ 63.8(b)(2)–(3)	Multiple Effluents and Multiple Monitoring Systems.	Yes.
§ 63.8(c)(1)(i)	General duty to minimize emissions and CMS operation.	No.
§ 63.8(c)(1)(ii)		No. A startup, shutdown, and malfunction plan is not required for these standards.
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS.	No.
§ 63.8(c)(2)–(3)		Yes.
§ 63.8(c)(4)–(5)		No. Frequency of monitoring measurements is provided in § 63.364; opacity monitors are not required for these standards.
§ 63.8(c)(6)		No. Performance specifications are contained in § 63.365.

Citation	Subject	Applies to subpart O
§ 63.8(c)(7)(i)(A)–(B)	.....	No. Performance specifications are contained in § 63.365.
§ 63.8(c)(7)(i)(C)	.....	No. Opacity monitors are not required for these standards.
§ 63.8(c)(7)(ii)	.....	No. Performance specifications are contained in § 63.365.
§ 63.8(c)(8)	.....	No.
§ 63.8(d)(1)–(2)	.....	Yes.
§ 63.8(d)(3)	Written procedures for CMS	No.
§ 63.8(e)(1)	CMS Performance Evaluation	Yes, but only applies for CEMS, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.8(e)(2)	.....	Yes.
§ 63.8(e)(3)	.....	Yes.
§ 63.8(e)(4)	.....	Yes.
§ 63.8(e)(5)(i)	.....	Yes.
§ 63.8(e)(5)(ii)	.....	No. Opacity monitors are not required for these standards.
§ 63.8(f)(1)–(5)	.....	Yes.
§ 63.8(f)(6)	.....	No.
§ 63.8(g)(1)	.....	Yes.
§ 63.8(g)(2)	.....	No.
§ 63.8(g)(3)–(5)	.....	Yes.
§ 63.9(a)	Notification requirements	Yes.
§ 63.9(b)(1)–(i)	.....	Yes.
§ 63.9(b)(1)(ii)–(iii)	Initial Notifications	No. § 63.366(c)(1)(i) contains language for facilities that increase usage such that the source becomes subject to the emissions standards.
§ 63.9(b)(2)–(3)	Initial Notifications	Yes. § 63.366(c)(3) contains additional information to be included in the initial report for existing and new facilities.
§ 63.9(b)(4)–(5)	Initial Notifications	No. § 63.366(c)(1)(ii) and (iii) contains requirements for new or reconstructed facilities subject to the emissions standards.
§ 63.9(c)	Request for Compliance Extension.	Yes.
§ 63.9(d)	Notification of Special Compliance Requirements for New Sources.	No.
§ 63.9(e)	Notification of Performance Test.	Yes.
§ 63.9(f)	Notification of VE/Opacity Test	No. Opacity monitors are not required for these standards.
§ 63.9(g)(1)	Additional Notifications When Using CMS.	Yes.
§ 63.9(g)(2)–(3)	Additional Notifications When Using CMS.	No. Opacity monitors and relative accuracy testing are not required for these standards.
§ 63.9(h)(1)–(3)	Notification of Compliance Status.	Yes, except § 63.9(h)(5) does not apply because § 63.366(c)(2) instructs facilities to submit actual data.
§ 63.9(i)	Adjustment of Submittal Deadlines.	Yes.
§ 63.9(j)	Change in previous information	Yes.
§ 63.9(k)	Electronic reporting procedures	Yes, as specified in § 63.9(j).
§ 63.10(a)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(1)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(2)(i)	Recordkeeping for startup and shutdown.	No. See 63.367(f) for recordkeeping requirements.
§ 63.10(b)(2)(ii)	Recordkeeping for SSM and failures to meet standards.	No. See 63.367(f) for recordkeeping requirements.
§ 63.10(b)(2)(iii)	Records related to maintenance of air pollution control equipment.	Yes.
§ 63.10(b)(2)(iv)–(v)	Actions taken to minimize emissions during SSM.	No.
§ 63.10(b)(2)(vi)	CMS Records	Yes.
§ 63.10(b)(2)(vii)–(ix)	Records	Yes.
§ 63.10(b)(2)(x)–(xi)	CMS Records	Yes.
§ 63.10(b)(2)(xii)	Records	Yes.
§ 63.10(b)(2)(xiii)	Records	Yes.
§ 63.10(b)(2)(xiv)	Records	Yes.
§ 63.10(b)(3)	Records	Yes.
§ 63.10(c)(1)–(14)	Records	Yes.
§ 63.10(c)(15)	Use of SSM Plan	No.
§ 63.10(d)(1)	General Reporting Requirements.	Yes.
§ 63.10(d)(2)	Report of Performance Test Results.	No. This subpart specifies how and when the performance test results are reported.
§ 63.10(d)(3)	Reporting Opacity or VE Observations.	No. Subpart O does not contain opacity or visible emissions standards.
§ 63.10(d)(4)	Progress Reports	Yes.
§ 63.10(d)(5)	SSM Reports	No. See § 63.366 for malfunction reporting requirements.
§ 63.10(e)(1)	Additional CEMS Reports	Yes.

Citation	Subject	Applies to subpart O
§ 63.10(e)(2)(i)	Additional CMS Reports	Yes, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.10(e)(2)(ii)	Additional COMS Reports	No. Opacity monitors are not required for these standards.
§ 63.10(e)(3)(i)–(iv)	Reports	Yes.
§ 63.10(e)(3)(v)	Excess Emissions Reports	No. § 63.366(b) and (c) specify contents and submittal dates for excess emissions and monitoring system performance reports.
§ 63.10(e)(3)(vi)–(viii)	Excess Emissions Report and Summary Report.	Yes.
§ 63.10(e)(4)	Reporting COMS data	No. Opacity monitors are not required for these standards.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.	Yes.
§ 63.11	Control device requirements for flares and work practice requirements for equipment leaks.	Yes.
§ 63.12	Delegation	Yes.
§ 63.13	Addresses	Yes.
§ 63.14	Incorporation by Reference	Yes.
§ 63.15	Availability of Information	Yes.

Appendix A to Subpart O of Part 63—Monitoring Provisions for EtO CEMS

1. Applicability

These monitoring provisions apply to the measurement of EtO emissions from commercial sterilization facilities, using CEMS. The CEMS must be capable of measuring EtO in lb/hr.

2. Monitoring of EtO Emissions

2.1 *Monitoring System Installation Requirements.* Install EtO CEMS and any additional monitoring systems needed to convert pollutant concentrations to lb/hr in accordance with § 63.365 and Performance Specification 19 (PS 19) of appendix B to part 60 of this chapter.

2.2 *Primary and Backup Monitoring Systems.* In the electronic monitoring plan described in section 10.1.1.2.1 of this appendix, you must designate a primary EtO CEMS. The primary EtO CEMS must be used to report hourly EtO concentration values when the system is able to provide quality-assured data, *i.e.,* when the system is ''in control''. However, to increase data availability in the event of a primary monitoring system outage, you may install, operate, maintain, and calibrate backup monitoring systems, as follows:

2.2.1 *Redundant Backup Systems.* A redundant backup monitoring system is a separate EtO CEMS with its own probe, sample interface, and analyzer. A redundant backup system is one that is permanently installed at the unit or stack location and is kept on ''hot standby'' in case the primary monitoring system is unable to provide quality-assured data. A redundant backup system must be represented as a unique monitoring system in the electronic monitoring plan. Each redundant backup monitoring system must be certified according to the applicable provisions in section 3 of this appendix and must meet the applicable on-going QA requirements in section 5 of this appendix.

2.2.2 *Non-redundant Backup Monitoring Systems.* A non-redundant backup monitoring system is a separate EtO CEMS that has been certified at a particular unit or stack location but is not permanently installed at that location. Rather, the system is kept on ''cold standby'' and may be reinstalled in the event of a primary monitoring system outage. A nonredundant backup monitoring system must be represented as a unique monitoring system in the electronic monitoring plan. Non-redundant backup EtO CEMS must complete the same certification tests as the primary monitoring system, with one exception. The 7-day calibration error test is not required for a non-redundant backup EtO CEMS. Except as otherwise provided in section 2.2.4.4 of this appendix, a non-redundant backup monitoring system may only be used for 720 hours per year at a particular unit or stack location.

2.2.3 *Temporary Like-kind Replacement Analyzers.* When a primary EtO analyzer needs repair or maintenance, you may temporarily install a like-kind replacement analyzer, to minimize data loss. Except as otherwise provided in section 2.2.4.4 of this appendix, a temporary like-kind replacement analyzer may only be used for 720 hours per year at a particular unit or stack location. The analyzer must be represented as a component of the primary EtO CEMS and must be assigned a 3-character component ID number, beginning with the prefix ''LK''.

2.2.4 *Quality Assurance Requirements for Non-redundant Backup Monitoring Systems and Temporary Like-kind Replacement Analyzers.* To quality-assure the data from non-redundant backup EtO monitoring systems and temporary like-kind replacement EtO analyzers, the following provisions apply:

2.2.4.1 When a certified non-redundant backup EtO CEMS or a temporary like-kind replacement EtO analyzer is brought into service, a calibration error test and a linearity check must be performed and passed. A single point system integrity check is also required.

2.2.4.2 Each non-redundant backup EtO CEMS or temporary like-kind replacement EtO analyzer shall comply with all required daily, weekly, and quarterly quality-assurance test requirements in section 5 of this appendix, for as long as the system or analyzer remains in service.

2.2.4.3 For the routine, on-going quality-assurance of a non-redundant backup EtO monitoring system, a relative accuracy test audit (RATA) must be performed and passed at least once every 8 calendar quarters at the unit or stack location(s) where the system will be used.

2.2.4.4 To use a non-redundant backup EtO monitoring system or a temporary like-kind replacement analyzer for more than 720 hours per year at a particular unit or stack location, a RATA must first be performed and passed at that location.

2.3 *Monitoring System Equipment, Supplies, Definitions, and General Operation.*

The following provisions apply:

2.3.1 PS 19, Sections 3.0, 6.0, and 11.0 of appendix B to part 60 of this chapter.

3. Initial Certification Procedures

The initial certification procedures for the EtO CEMS used to provide data under this subpart are as follows:

3.1 Your EtO CEMS must be certified according to PS 19, section(s) 13.

3.2 Any additional stack gas flow rate monitoring system(s) needed to express pollutant concentrations in lb/hr must be certified according to part 75 of this chapter.

4. Recertification Procedures

Whenever the owner or operator makes a replacement, modification, or change to a certified CEMS that may significantly affect the ability of the system to accurately measure or record pollutant gas concentrations or stack gas flow rates, the owner or operator shall recertify the monitoring system. Furthermore, whenever the owner or operator makes a replacement, modification, or change to the flue gas handling system or the unit operation that may significantly change the concentration or flow profile, the owner or operator shall recertify the monitoring system. The same tests performed for the initial certification of the monitoring system shall be repeated for recertification, unless otherwise specified by the Administrator. Examples of changes that require recertification include: Replacement of a gas analyzer; complete monitoring

system replacement, and changing the location or orientation of the sampling probe.

5. On-Going Quality Assurance Requirements

On-going QA test requirements for EtO CEMS must be implemented as follows:

5.1 The quality assurance/quality control procedures in Procedure 7 of appendix F to part 60 of this chapter shall apply.

5.2 Stack gas flow rate, diluent gas, and moisture monitoring systems must meet the applicable ongoing QA test requirements of part 75 of this chapter.

5.2.1 *Out-of-Control Periods.* A EtO CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The EtO CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.2.2 *Grace Periods.* For the purposes of this appendix, a ''grace period'' is defined as a specified number of unit or stack operating hours after the deadline for a required quality-assurance test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.2.2.1 For the flow rate monitoring systems described in section 5.1 of this appendix, a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and a 720 unit or stack operating hour grace period is available for RATAs, as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter.

5.2.2.2 For the purposes of this appendix, if the deadline for a required gas audit or RATA of a EtO CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.2.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit; or

5.2.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.2.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.2.2.3.1 For the gas audit of an EtO CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit is required for that quarter.

5.2.2.3.2 For the RATA of an EtO CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

5.2.3 *Conditional Data Validation.* For recertification and diagnostic testing of the monitoring systems that are used to provide data under this appendix, and for the required QA tests when nonredundant backup monitoring systems or temporary like-kind replacement analyzers are brought into service, the conditional data validation provisions in §§ 75.20(b)(3)(ii) through (b)(3)(ix) of this chapter may be used to avoid or minimize data loss. The allotted window of time to complete calibration tests and RATAs shall be as specified in § 75.20(b)(3)(iv) of this chapter; the allotted window of time to complete a gas audit shall be the same as for a linearity check (*i.e.,* 168 unit or stack operating hours).

5.3 *Data Validation.*

5.3.1 *Out-of-Control Periods.* An EtO CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The EtO CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.3.2 *Grace Periods.* For the purposes of this appendix, a ''grace period'' is defined as a specified number of unit or stack operating hours after the deadline for a required quality-assurance test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.3.2.1 For the monitoring systems described in section 5.1 of this appendix, a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and a 720 unit or stack operating hour grace period is available for RATAs, as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter.

5.3.2.2 For the purposes of this appendix, if the deadline for a required gas audit/data accuracy assessment or RATA of an EtO CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.3.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit or other quarterly data accuracy assessment; or

5.3.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.3.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.3.2.3.1 For a gas audit or RATA of the monitoring systems described in sections 5.1 and 5.2 of this appendix, determine the deadline for the next gas audit or RATA (as applicable) in accordance with section 2.2.4(b) or 2.3.3(d) of appendix B to part 75 of this chapter; treat a gas audit in the same manner as a linearity check.

5.3.2.3.2 For the gas audit or other quarterly data accuracy assessment of an EtO CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit/data accuracy assessment is required for that quarter.

5.3.2.3.3 For the RATA of an EtO CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

5.3.3 *Conditional Data Validation.* For recertification and diagnostic testing of the monitoring systems that are used to provide data under this appendix, the conditional data validation provisions in § 75.20(b)(3)(ii) through (ix) of this chapter may be used to avoid or minimize data loss. The allotted window of time to complete calibration tests and RATAs shall be as specified in § 75.20(b)(3)(iv) of this chapter; the allotted window of time to complete a quarterly gas audit or data accuracy assessment shall be the same as for a linearity check (*i.e.,* 168 unit or stack operating hours).

6. Missing Data Requirements

For the purposes of this appendix, the owner or operator of an affected unit shall not substitute for missing data from EtO CEMS. Any process operating hour for which quality-assured EtO concentration data are not obtained is counted as an hour of monitoring system downtime.

7. Bias Adjustment

Bias adjustment of hourly emissions data from an EtO CEMS is not required.

8. QA/QC Program Requirements

The owner or operator shall develop and implement a quality assurance/quality control (QA/QC) program for the EtO CEMS that are used to provide data under this subpart. At a minimum, the program shall include a written plan that describes in detail (or that refers to separate documents containing) complete, step-by-step procedures and operations for the most important QA/QC activities. Electronic storage of the QA/QC plan is permissible, provided that the information can be made available in hard copy to auditors and inspectors. The QA/QC program requirements for the other monitoring systems described in section 5.2 of this appendix are specified in section 1 of appendix B to part 75 of this chapter.

8.1 *General Requirements for EtO CEMS.*

8.1.1 *Preventive Maintenance.* Keep a written record of procedures needed to maintain the EtO CEMS in proper operating condition and a schedule for those procedures. This shall, at a minimum, include procedures specified by the manufacturers of the equipment and, if applicable, additional or alternate procedures developed for the equipment.

8.1.2 *Recordkeeping and Reporting.* Keep a written record describing procedures that will be used to implement the recordkeeping and reporting requirements of this appendix.

8.1.3 *Maintenance Records.* Keep a record of all testing, maintenance, or repair activities performed on any EtO CEMS in a location and format suitable for inspection. A maintenance log may be used for this purpose. The following records should be maintained: Date, time, and description of any testing, adjustment, repair, replacement, or preventive maintenance action performed on any monitoring system and records of any corrective actions associated with a monitor outage period. Additionally, any adjustment that may significantly affect a system's ability to accurately measure emissions data must be recorded and a written explanation of the

procedures used to make the adjustment(s) shall be kept.

8.2 *Specific Requirements for EtO CEMS.* The following requirements are specific to EtO CEMS:

8.2.1 Keep a written record of the procedures used for each type of QA test required for each EtO CEMS. Explain how the results of each type of QA test are calculated and evaluated.

8.2.2 Explain how each component of the EtO CEMS will be adjusted to provide correct responses to calibration gases after routine maintenance, repairs, or corrective actions.

9. Data Reduction and Calculations

9.1 Design and operate the EtO CEMS to complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute period.

9.2 Reduce the EtO concentration data to hourly averages in accordance with § 60.13(h)(2) of this chapter.

9.3 Convert each hourly average EtO concentration to an EtO mass emission rate (lb/hr) using an equation that has the general form of equation A–1 of this appendix:

$$E_{ho} = KC_hQ_h \qquad \text{(Eq. A-1)}$$

Where:

E_{ho} = EtO mass emission rate for the hour, lb/hr

K = Units conversion constant, 1.144E–10 lb/scf-ppbv,

Ch = Hourly average EtO concentration, ppbv,

Q_h = Stack gas volumetric flow rate for the hour, scfh.

(**Note:** Use unadjusted flow rate values; bias adjustment is not required.)

9.4 Use equation A–2 of this appendix to calculate the daily total EtO emissions. Report each daily total to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and ARV subject to 99.99% and 99.9% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation.

$$E_{day} = \sum_{h=1}^{24} (E_{ho} * 1\ hr) \qquad \text{Equation A-2}$$

Where:

E_{day} = Total daily EtO emissions, lb.

E_{ho} = Hourly EtO emission rate for unit or stack sampling hour ''h'' in the averaging period, from equation A–1 of this appendix, lb/hr.

9.5 Use equation A–3 of this appendix to calculate the 30-operating day rolling total EtO emissions. Report each 30-operating day rolling total to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and ARV subject to 99.99% and 99.9% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation.

$$E_{30day} = \sum_{i=1}^{30} E_{day,i} \qquad \text{Equation A-3}$$

Where:

E_{30day} = Total EtO emissions during the 30-operating day, lb.

$E_{day,i}$ = Total daily EtO emissions, in lbs, for each operating day *i* from equation A–2 of this appendix, lb.

$_i$ = Operating day index.

10. Recordkeeping Requirements

10.1 For each EtO CEMS installed at an affected source, and for any other monitoring system(s) needed to convert pollutant concentrations to units of the applicable emissions limit, the owner or operator must maintain a file of all measurements, data, reports, and other information required by this appendix in a form suitable for inspection, for 5 years from the date of each record, in accordance with § 63.367. The file shall contain the information in paragraphs 10.1.1 through 10.1.8 of this section.

10.1.1 *Monitoring Plan Records.* For each affected source or group of sources monitored at a common stack, the owner or operator shall prepare and maintain a monitoring plan for the EtO CEMS and any other monitoring system(s) (*i.e.,* flow rate, diluent gas, or moisture systems) needed to convert pollutant concentrations to units of the applicable emission standard. The monitoring plan shall contain essential information on the continuous monitoring systems and shall explain how the data derived from these systems ensure that all EtO emissions from the unit or stack are monitored and reported.

10.1.1.1 *Updates.* Whenever the owner or operator makes a replacement, modification, or change in a certified continuous EtO monitoring system that is used to provide data under this subpart (including a change in the automated data acquisition and handling system or the flue gas handling system) which affects information reported in the monitoring plan (*e.g.,* a change to a serial number for a component of a monitoring system), the owner or operator shall update the monitoring plan.

10.1.1.2 *Contents of the Monitoring Plan.* For EtO CEMS, the monitoring plan shall contain the applicable electronic and hard copy information in sections 10.1.1.2.1 and 10.1.1.2.2 of this appendix. For stack gas flow rate, diluent gas, and moisture monitoring systems, the monitoring plan shall include the electronic and hard copy information required for those systems under § 75.53(g) of this chapter. The electronic monitoring plan shall be evaluated using CEDRI.

10.1.1.2.1 *Electronic.* Record the unit or stack ID number(s); monitoring location(s); the EtO monitoring methodology used (*i.e.,* CEMS); EtO monitoring system information, including, but not limited to: unique system and component ID numbers; the make, model, and serial number of the monitoring equipment; the sample acquisition method; formulas used to calculate emissions; monitor span and range information (if applicable).

10.1.1.2.2 *Hard Copy.* Keep records of the following: schematics and/or blueprints showing the location of the monitoring system(s) and test ports; data flow diagrams; test protocols; monitor span and range calculations (if applicable); miscellaneous technical justifications.

10.1.2 *EtO Emissions Records.* For EtO CEMS, the owner or operator must record the following information for each unit or stack operating hour:

10.1.2.1 The date and hour;

10.1.2.2 Monitoring system and component identification codes, as provided in the electronic monitoring plan, for each hour in which the CEMS provides a quality-assured value of EtO concentration (as applicable);

10.1.2.3 The pollutant concentration, for each hour in which a quality-assured value is obtained. Record the data in parts per billion by volume (ppbv), with one leading non-zero digit and one decimal place, expressed in scientific notation. Use the following rounding convention: If the digit immediately following the first decimal place

is 5 or greater, round the first decimal place upward (increase it by one); if the digit immediately following the first decimal place is 4 or less, leave the first decimal place unchanged.

10.1.2.4 A special code, indicating whether or not a quality-assured EtO concentration value is obtained for the hour. This code may be entered manually when a temporary like-kind replacement EtO analyzer is used for reporting; and

10.1.2.5 Monitor data availability, as a percentage of unit or stack operating hours, calculated according to § 75.32 of this chapter.

10.1.3 *Stack Gas Volumetric Flow Rate Records.*

10.1.3.1 Hourly measurements of stack gas volumetric flow rate during unit operation are required to demonstrate compliance with EtO emission standards.

10.1.3.2 Use a flow rate monitor that meets the requirements of part 75 of this chapter to record the required data. You must keep hourly flow rate records, as specified in § 75.57(c)(2) of this chapter.

10.1.4 *EtO Emission Rate Records.* Record the following information for each affected unit or common stack:

10.1.4.1 The date and hour;

10.1.4.2 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. Report each emission rate to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and ARV subject to 99.99% and 99.9% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation. Use the following rounding convention: If the digit immediately following the first decimal place is 5 or greater, round the first decimal place upward (increase it by one); if the digit immediately following the first decimal place is 4 or less, leave the first decimal place unchanged;

10.1.4.4 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.

10.1.5 *Certification and Quality Assurance Test Records.* For the EtO CEMS used to provide data under this subpart at each affected unit (or group of units monitored at a common stack), record the following information for all required certification, recertification, diagnostic, and quality-assurance tests:

10.1.5.1 EtO CEMS.

10.1.5.1.1 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.

10.1.5.1.2 or each required 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.

10.1.5.1.3 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.

10.1.5.1.4 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.

10.1.5.1.5 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.

10.1.5.1.6 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.

10.1.5.1.7 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.

10.1.5.1.8 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.

10.1.5.1.9 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.

10.1.5.2 *Additional Monitoring Systems.* For the stack gas flow rate monitoring systems described in section 3.2 of this appendix, you must keep records of all certification, recertification, diagnostic, and on-going quality-assurance tests of these systems, as specified in § 75.59(a) of this chapter.

11. Reporting Requirements

11.1 *General Reporting Provisions.* The owner or operator shall comply with the following requirements for reporting EtO emissions from each affected unit (or group of units monitored at a common stack):

11.1.1 Notifications, in accordance with paragraph 11.2 of this section;

11.1.2 Monitoring plan reporting, in accordance with paragraph 11.3 of this section;

11.1.3 Certification, recertification, and QA test submittals, in accordance with paragraph 11.4 of this section; and

11.1.4 Electronic quarterly report submittals, in accordance with paragraph 11.5 of this section.

11.2 *Notifications.* The owner or operator shall provide notifications for each affected unit (or group of units monitored at a common stack) in accordance with § 63.366.

11.3 *Monitoring Plan Reporting.* For each affected unit (or group of units monitored at a common stack) using EtO CEMS, the owner or operator shall make electronic and hard copy monitoring plan submittals as follows:

11.3.1 For a sterilization facility that begins reporting hourly EtO concentrations with a previously certified CEMS, submit the monitoring plan information in section 10.1.1.2 of this appendix prior to or concurrent with the first required quarterly emissions report. For a new sterilization facility, submit the information in section 10.1.1.2 of this appendix at least 21 days prior to the start of initial certification testing of the CEMS. Also submit the monitoring plan information in § 75.53(g) of this chapter pertaining to any required flow rate monitoring systems within the applicable timeframe specified in this section, if the required records are not already in place.

11.3.2 Update the monitoring plan when required, as provided in paragraph 10.1.1.1 of this appendix. 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.

11.3.3 All electronic monitoring plan submittals and updates shall be made to the Administrator using CEDRI. Hard copy portions of the monitoring plan shall be kept on record according to section 10.1 of this appendix.

11.4 *Certification, Recertification, and Quality-Assurance Test Reporting Requirements.* Use CEDRI to submit the results of all required certification, recertification, quality-assurance, and diagnostic tests of the monitoring systems required under this appendix electronically. Submit the test results concurrent with the quarterly electronic emissions report. However, for RATAs of the EtO monitor, if this is not possible, you have up to 60 days after the test completion date to submit the 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.

11.4.1 For each daily CD (or calibration error) assessment (including daily calibration transfer standard tests), and for each seven-day calibration drift (CD) test of an EtO monitor, report:

11.4.1.1 Facility ID information;

11.4.1.2 The monitoring component ID;

11.4.1.3 The instrument span and span scale;

11.4.1.4 For each gas injection, the date and time, the calibration gas level (zero or high-level), the reference gas value (ppbv), and the monitor response (ppbv);

11.4.1.5 A flag to indicate whether dynamic spiking was used for the high-level value;

11.4.1.6 Calibration drift (percent of span or reference gas, as applicable);

11.4.1.7 When using the dynamic spiking option, the measured concentration of native EtO before and after each mid-level spike and the spiked gas dilution factor; and

11.4.1.8 Reason for test.

11.4.2 For each RATA of an EtO CEMS, report:

11.4.2.1 Facility ID information;

11.4.2.2 Monitoring system ID number;

11.4.2.3 Type of test (*i.e.,* initial or annual RATA);

11.4.2.4 Reason for test;

11.4.2.5 The reference method used;

11.4.2.6 Starting and ending date and time for each test run;

11.4.2.7 Units of measure;

11.4.2.8 The measured reference method and CEMS values for each test run, on a consistent moisture basis, in appropriate units of measure;

11.4.2.9 Flags to indicate which test runs were used in the calculations;

11.4.2.10 Arithmetic mean of the CEMS values, of the reference method values, and of their differences;

11.4.2.11 Standard deviation, using equation 7 in section 12.6 of PS 19 in appendix B to part 60 of this chapter;

11.4.2.12 Confidence coefficient, using equation 8 in section 12.6 of PS 19 in appendix B to part 60 of this chapter;

11.4.2.13 t-value; and

11.4.2.14 Relative accuracy calculated using equation 11 in section 12.6 of PS 19 in appendix B to part 60 of this chapter.

11.4.3 For each measurement error (ME) test of an EtO monitor, report:

11.4.3.1 Facility ID information;

11.4.3.2 Monitoring component ID;

11.4.3.3 Instrument span and span scale;

11.4.3.4 For each gas injection, the date and time, the calibration gas level (zero, low, mid, or high), the reference gas value in ppbv and the monitor response.

11.4.3.5 For extractive CEMS, the mean reference value and mean of measured values at each reference gas level (ppbv).

11.4.3.6 ME at each reference gas level; and

11.4.3.7 Reason for test.

11.4.4 For each interference test of an EtO monitoring system, report:

11.4.4.1 Facility ID information;

11.4.4.2 Date of test;

11.4.4.3 Monitoring system ID;

11.4.4.4 Results of the test (pass or fail);

11.4.4.5 Reason for test; and

11.4.4.6 A flag to indicate whether the test was performed: On this particular monitoring system; on one of multiple systems of the same type; or by the manufacturer on a system with components of the same make and model(s) as this system.

11.4.5 For each LOD test of an EtO monitor, report:

11.4.5.1 Facility ID information;

11.4.5.2 Date of test;

11.4.5.3 Reason for test;

11.4.5.4 Monitoring system ID;

11.4.5.5 A code to indicate whether the test was done in a controlled environment or in the field;

11.4.5.6 EtO reference gas concentration;

11.4.5.7 EtO responses with interference gas (seven repetitions);

11.4.5.8 Standard deviation of EtO responses;

11.4.5.9 Effective spike addition gas concentrations;

11.4.5.10 EtO concentration measured without spike;

11.4.5.11 EtO concentration measured with spike;

11.4.5.12 Dilution factor for spike;

11.4.5.13 The controlled environment LOD value (ppbv or ppbv-meters);

11.4.5.14 The field determined standard addition detection level (SADL in ppbv or ppbv-meters); and

11.4.5.15 Result of LOD/SADL test (pass/fail).

11.4.6 For each ME or LOD response time test of an EtO monitor, report:

11.4.6.1 Facility ID information;

11.4.6.2 Date of test;

11.4.6.3 Monitoring component ID;

11.4.6.4 The higher of the upscale or downscale tests, in minutes; and

11.4.6.5 Reason for test.

11.4.7 For each quarterly RAA of an EtO monitor, report:

11.4.7.1 Facility ID information;

11.4.7.2 Monitoring system ID;

11.4.7.3 Begin and end time of each test run;

11.4.7.4 The reference method used;

11.4.7.5 The reference method and CEMS values for each test run, including the units of measure;

11.4.7.6 The mean reference method and CEMS values for the three test runs;

11.4.7.7 The calculated relative accuracy, percent; and

11.4.7.8 Reason for test.

11.4.8 For each quarterly cylinder gas audit of an EtO monitor, report:

11.4.8.1 Facility ID information;

11.4.8.2 Monitoring component ID;

11.4.8.3 Instrument span and span scale;

11.4.8.4 For each gas injection, the date and time, the reference gas level (zero, mid, or high), the reference gas value in ppbv, and the monitor response.

11.4.8.5 For extractive CEMS, the mean reference gas value and mean monitor response at each reference gas level (ppbv).

11.4.8.6 ME at each reference gas level; and

11.4.8.7 Reason for test.

11.4.9 For each quarterly DSA of an EtO monitor, report:

11.4.9.1 Facility ID information;

11.4.9.2 Monitoring component ID;

11.4.9.3 Instrument span and span scale;

11.4.9.4 For the zero gas injection, the date and time, and the monitor response (Note: The zero gas injection from a calibration drift check performed on the same day as the upscale spikes may be used for this purpose.);

11.4.9.5 Zero spike error;

11.4.9.6 For the upscale gas spiking, the date and time of each spike, the reference gas level (mid- or high-), the reference gas value (ppbv), the dilution factor, the native EtO concentrations before and after each spike, and the monitor response for each gas spike;

11.4.9.7 Upscale spike error;

11.4.9.8 DSA at the zero level and at each upscale gas level; and

11.4.9.9 Reason for test.

11.4.10 *Reporting Requirements for Diluent Gas, Flow Rate, and Moisture Monitoring Systems.* For the certification, recertification, diagnostic, and QA tests of stack gas flow rate, moisture, and diluent gas monitoring systems that are certified and quality-assured according to part 75 of this chapter, report the information in section 10.1.8.2 of this appendix.

11.5 *Quarterly Reports.*

11.5.1 The owner or operator of any affected unit shall use CEDRI to submit electronic quarterly reports to the Administrator in an XML format specified by the Administrator, for each affected unit (or group of units monitored at a common stack). If the certified EtO CEMS is used for the initial compliance demonstration, EtO emissions reporting shall begin with the first operating hour of the 30-operating day compliance demonstration period. Otherwise, EtO emissions reporting shall begin with the first operating hour after successfully completing all required certification tests of the CEMS.

11.5.2 The electronic reports must be submitted within 30 days following the end

of each calendar quarter, except for units that have been placed in long-term cold storage.

11.5.3 Each electronic quarterly report shall include the following information:

11.5.3.1 The date of report generation;

11.5.3.2 Facility identification information;

11.5.3.3 The information in sections 10.1.2 through 10.1.4 of this appendix, as applicable to the type(s) of monitoring system(s) used to measure the pollutant concentrations and other necessary parameters.

11.5.3.4 The results of all daily calibrations (including calibration transfer standard tests) of the EtO monitor as described in section 10.1.8.1.1 of this appendix; and

11.5.3.5 If applicable, the results of all daily flow monitor interference checks, in accordance with section 10.1.8.2 of this appendix.

11.5.4 *Compliance Certification.* Based on reasonable inquiry of those persons with primary responsibility for ensuring that all EtO emissions from the affected unit(s) have been correctly and fully monitored, the owner or operator shall submit a compliance certification in support of each electronic quarterly emissions monitoring report. The compliance certification shall include a 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.

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