6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2019-0178; FRL-]

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: Proposed rule.

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SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Commercial Sterilization Facilities source category. The EPA is proposing decisions concerning the risk and technology review (RTR), including proposing amendments pursuant to the technology review for certain point source emissions and proposing amendments pursuant to the risk review to specifically address ethylene oxide (EtO) emissions from point source and room air emissions from all commercial sterilization facilities. The EPA is also proposing amendments to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate. Lastly, the EPA is proposing to revise monitoring and performance testing requirements and to add provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports. We estimate that, if finalized, these proposed amendments would reduce

EtO emissions from this source category by 19 tons per year (tpy) and reduce risks to public health to acceptable levels.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Public hearing: The EPA will hold virtual public hearings on **[INSERT DATES 21 AND 22 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].** See **SUPPLEMENTARY INFORMATION** for information on the public hearings.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2019-0178, by any of the following methods:

- Federal eRulemaking Portal: *https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- Email: *a-and-r-docket@epa.gov.* Include Docket ID No. EPA-HQ-OAR-2019-0178 in the subject line of the message.
- Fax: (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2019-0178.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2019-0178, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

- Hand/Courier Delivery: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. – 4:30 p.m., Monday – Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Jonathan Witt, Sector Policies and Programs Division (E143-05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5645; ~~fax number: (919) 541-0516;~~ and email address: *witt.jon@epa.gov*. For specific information regarding the risk modeling methodology, contact Matt Woody, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-1535; ~~fax number: (919) 541-0840;~~ and email address: *woody.matt@epa.gov*.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing.

The public hearings will be held via virtual platform on **[INSERT DATES 21 AND 22 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]** and will convene at 1~~0~~1:00 a.m. Eastern Time (ET) and conclude at ~~8~~7:00 p.m. ET each day. On each hearing day, the EPA may close a session 15 minutes after the last pre-registered speaker has testified if there

are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities*. If the EPA receives a high volume of registrations for the public hearing, we may continue the public hearing on **[23 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

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The EPA will begin pre-registering speakers for the hearing no later than 1 business day following the publication of this document in the *Federal Register*. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities* or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. The last day to pre-register to speak at the hearing will be **[INSERT DATE 12 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities*.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing. However, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 4 minutes to provide oral testimony. The EPA encourages commenters to submit a copy of their oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during

the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities*. While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the *Federal Register* announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by **[INSERT DATE 7 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2019-0178. All documents in the docket are listed in *https://www.regulations.gov/*. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) 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. With the exception of such material, publicly available docket materials are available electronically in Regulations.gov. All publicly available docket materials are available in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. 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.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2019-0178. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/*, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically to *https://www.regulations.gov/* any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made

available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets*.

The EPA is soliciting comment on numerous aspects of this action. The EPA has indexed each comment solicitation with an alpha-numeric identifier (*e.g.*, ''C–1,'' ''C–2,'' ''C–3'') to provide a consistent framework for effective and efficient provision of comments. Accordingly, the EPA asks that commenters include the corresponding identifier when providing comments relevant to that comment solicitation. The EPA asks that commenters include the identifier in either a heading, or within the text of each comment (*e.g.*, "In response to solicitation of comment C–1, . . .") to make clear which comment solicitation is being addressed. The EPA emphasizes that the Agency is not limiting comment to these identified areas and encourages provision of any other comments relevant to this action.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/*. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket

through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (*e.g.*, Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov* and, as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2019-0178. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this document the use of "we," "us," or "our" is intended to refer to the EPA. 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
AERMOD	air dispersion model used by the HEM model
AIHA	American Industrial Hygiene Association
APCD	air pollution control device
ARV	aeration room vent
ASME	American Society of Mechanical Engineers
ATSDR	Agency for Toxic Substances and Disease Registry
CAA	Clean Air Act
CalEPA	California EPA
CBI	Confidential Business Information
CEMS	continuous emissions 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
ERPG	emergency response planning guideline
ERT	Electronic Reporting Tool
EtO	ethylene oxide
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	*Federal Register*
FTIR	Fourier Transform Infrared Spectroscopy
GACT	generally available control technology
GC	gas chromatography
HAP	hazardous air pollutant(s)
HCl	hydrochloric acid
HEM	Human Exposure Model
HF	hydrogen fluoride
HQ	hazard quotient
ICR	Information Collection Request
IRIS	Integrated Risk Information System
ISO	International Organization for Standardization
km	kilometer
lb/hr	pounds per hour
LEL	lower explosive 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
NEI	National Emissions Inventory
NESHAP	national emission standards for hazardous air pollutants
NIST	National Institute of Standards and Technology
NTTAA	National Technology Transfer and Advancement Act
OAQPS	Office of Air Quality Planning and Standards
~~OCSPP~~	~~Office of Chemical Safety and Pollution Prevention~~
OMB	Office of Management and Budget
PB-HAP	hazardous air pollutants known to be persistent and bio-accumulative in the environment
PID	Proposed Interim Decision
ppbv	parts per billion by volume
ppm	parts per million
ppmv	parts per million by volume
PoAHSM	post-aeration handling of sterilized material
POM	polycyclic organic matter
PpO	propylene oxide
PRA	Paperwork Reduction Act
PrAHSM	pre-aeration handling of sterilized material
PS	Performance Specification
PTE	permanent total enclosure
RAC	room air change
RBLC	RACT/BACT/LAER Clearinghouse
REL	reference exposure level
RDL	Representative detection level
RFA	Regulatory Flexibility Act
RfC	reference concentration
RTR	risk and technology review
SAB	Science Advisory Board
SBAR	Small Business Advocacy Review
SCV	sterilization chamber vent
SSM	startup, shutdown, and malfunction
TOSHI	target organ-specific hazard index
tpy	tons per year
TRIM.FaTE	Total Risk Integrated Methodology, Environmental Fate, Transport, and Ecological Exposure
UF	uncertainty factor

UPL	upper prediction limit
$\mu g/m^3$	microgram per cubic meter
URE	unit risk estimate
VCS	voluntary consensus standards
WebFIRE	Web Factor and Information Retrieval

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

E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51
J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

The EPA is proposing to revise the NESHAP for Commercial Sterilization Facilities by both amending existing standards and establishing additional standards for this source category, exercising authority under multiple provisions of section 112 of the Clean Air Act (CAA). First, the EPA is proposing emission standards under CAA sections 112(d)(2)-(3) or (d)(5) for a number of currently unregulated emission sources of EtO. Second, the EPA is proposing risk-based standards under CAA section 112(f)(2) in order to protect public health with an ample margin of safety. Third, the EPA is proposing emission standards under CAA section 112(d)(6) based on the Agency's review of developments in practices, processes, and control technologies for this source category.

This proposed rulemaking reflects the EtO toxicological assessment that the EPA's Integrated Risk Information System (IRIS) Program completed in December 2016,[1] which indicated that EtO is a far more potent carcinogen than EPA had understood at the time of the previous RTR for this source category. There are 86 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. The EPA has determined that approximately 23 of these facilities pose elevated lifetime cancer risks to the surrounding communities, some of which are exceptionally high.

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

Throughout this rulemaking process, we have engaged in outreach activities to these communities, along with their state and local governments.

This important action, if finalized, will reduce EtO emissions and lifetime cancer risks in multiple communities across the country, including communities with EJ concerns, and it proposes to update our standards considering proven and cost-effective control technologies that are already in use at some facilities in this source category. Recognizing that EPA now has additional information about the health risks of EtO that was not available at the time of the last RTR, and in order to ensure that EPA's standards for this source category adequately protect public health, we have also conducted a second residual risk review under CAA section 112(f)(2), as discussed in section I.A.3 of this preamble.

In deciding whether to conduct a second residual risk review, we considered ~~Consistent with the statutory design of CAA section 112, in considering~~ the advantages of EtO reductions and ~~, we also consider~~ the distribution of those reductions ~~and~~ consistent with the ~~statute's~~ clear goal of CAA section 112(f)(2) to protect the most exposed and susceptible populations, which in this case include ~~such as~~ communities with EJ concerns. While commercial medical device sterilizers provide a critical benefit for the health of all, sparing Americans who live near commercial sterilization facilities the disproportionate risk of being significantly harmed by toxic pollution is also essential.

Commercial sterilization facilities play a vital role in maintaining an adequate supply of medical devices. 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." ~~The~~ 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

Commented [A1]: This text has been modified in response to comments from DOJ on 2/2

Commented [A2]: As an editorial note applicable here and throughout, we note our convention in policy documents to refer simply to "FDA" rather than "the FDA." We recognize that this convention may be different for EPA, but suggest the edit for consideration.

Commented [A3R2]: EPA will refer to "FDA" rather than "the FDA"

sterilization process."[2] In developing this proposed rule, EPA has given careful consideration to 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 supply chain.

In order to ensure EPA's 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 proposed rulemaking. This has enabled EPA to work from the best possible information when conducting the analyses to support this proposed 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 ~~the~~ FDA, regarding the potential impacts of this proposal on commercial sterilization facilities. These discussions have focused on identifying and addressing any potential concerns regarding the potential impact on the availability of certain medical devices that are sterilized with EtO where alternative sterilization methods are not readily available, including those that are (1) experiencing or at risk of experiencing a shortage, (2) in high demand as a result of the COVID-19 pandemic, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility.

In this rulemaking, we are proposing a set of standards that we believe are achievable and reflect techniques and control technologies that are currently used within the industry. We are

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

Commented [A4]: While we fully support EPA's goal to reduce health risks associated with EtO emissions, including for communities with EJ concerns, additional discussion of aspects of the rule is warranted to help ensure it does not inadvertently contribute to significant medical device supply chain disruptions. Our specific comments are embedded in this document and the accompanying memorandum, and we request a follow-up policy meeting with EPA to discuss them.

Commented [A5R4]: EPA appreciates these comments and met with FDA on February 14, 2023.

Commented [A6]: RE: the issue of devices that can only be sterilized by ethylene oxide. It is unclear whether this consideration is meant to be included among the considerations listed here, or if this issue is relevant in the context of this rulemaking under the Clean Air Act. Given that the OPP initiative on ethylene oxide labeling conditions are meant to be concurrent with this rulemaking, we recommend confirming that the rationales here are accurate and edited to reflect this added consideration if needed. If helpful, it may be useful to add a footnote here simply referencing this rulemaking's mention/discussion of OPP's initiatives (*e.g.*, as seen on page 71 and later referenced throughout the rule).

Commented [A7R6]: This consideration would apply more broadly to devices that are sterilized with EtO where alternative sterilization methods are not readily available. Text has been added accordingly.

References to OPP's initiative (*i.e.*, PID) are made to aid the public as they draft their comments on relevant proposed standards. Therefore, EPA prefers that references to the PID be made only when proposing those standards.

also proposing to provide sufficient time to enable these facilities to continue sterilizing essential products while installing and testing new control systems and associated equipment that will afford ample protection for nearby communities. In terms of potential impacts to the medical device supply chain, we project that the largest impacts are limited to a handful of companies, and those that are also involved in sterilizing the types of medical devices previously mentioned are already in the planning stage for additional controls.

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

The EPA is proposing 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 is also proposing 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.

For the following emission sources that are currently unregulated,[3] the EPA is proposing to set standards under CAA sections 112(d)(2)-(3) or (d)(5): sterilization chamber vent (SCV), aeration room vent (ARV), and chamber exhaust vent (CEV) at facilities where EtO use is less

[3] In 1992, pursuant to CAA section 112(c)(1), the EPA published a list of major and area sources for regulation under CAA section 112, including major and area sources of commercial sterilizers. 57 FR 31576, 31586 (July 16, 1992). Area sources of commercial sterilizers were listed for regulation under CAA section 112(c)(3) based on the EPA's finding that it presents 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.

than 1 tpy, ARV and CEV at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEV at facilities where EtO use is at least 10 tpy,[4] and room air emissions.[5]

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

- 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
- Group 2 room air emissions[6] at area source facilities where EtO use is at least 20 tpy,

Finally, under CAA section 112(d)(6), the EPA is proposing to revise standards for the following sources that are regulated in the current 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

[4] The standards for CEVs were originally promulgated on December 6, 1994. Following promulgation of the rule, the EPA 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. The EPA 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) and have not been re-instated.

[5] As discussed in section II.F.1, 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.

[6] As discussed in section III.B.8, Group 2 room air emissions cover post-aeration handling of sterilized material.

To demonstrate compliance with the emission limits, the EPA is proposing capture requirements. The EPA is also proposing that facilities either monitor with an EtO continuous emissions monitoring system (CEMS) or conduct initial and annual performance tests with continuous parameter monitoring.

3. EPA Authority

The EPA notes that it 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 the EPA's discretion or authority to conduct another risk review should the EPA consider that such review is warranted. As discussed in more detail in section III.C of this document, as our understanding of the health effects of EtO developed, the EPA conducted a second residual risk review under CAA section 112(f)(2) for commercial sterilization facilities using ethylene oxide in order to ensure that the standards provide an ample margin of safety to protect public health.

As discussed in further detail in section III.C, this second residual risk review also encompasses certain area sources for which EPA did not evaluate residual risk in its 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, the EPA 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 its discretion under CAA section 112(f)(5) to not do a CAA section 112(f)(2) analysis for those emission points for which GACT standards were established (67 FR 17715). However, as the EPA 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 unit risk estimate (URE) for EtO, which is approximately 60 times greater than the value the EPA used in its previous risk assessment, the EPA is now exercising its discretionary authority to conduct another CAA section 112(f)(2) analysis and to include in this analysis area sources of commercial sterilizers using EtO for which the EPA has promulgated, or is now proposing, GACT standards.

Section 112(d)(6) of the CAA also requires the EPA to review and revise, as necessary, standards promulgated under CAA section 112 at least every 8 years, taking into account developments in practices, processes, and control technologies. The EPA last completed this required technology review for the Ethylene Oxide Commercial Sterilization NESHAP (40 CFR 63, subpart O) in 2006. Accordingly, in this proposed action the EPA is also conducting a CAA section 112(d)(6) review for this source category.

4. Costs and Benefits

Table 1 of this preamble summarizes the costs of this proposed action for 40 CFR part 63, subpart O (Ethylene Oxide Commercial Sterilization NESHAP).

Table 1. Summary of Costs of the Proposed Standards
[2021~~19~~ Dollars]

Requirement	Total capital investment	Total annualized capital costs	Total annual operation and maintenance costs	Total annual cost
Permanent total enclosure	$~~39,571,246~~65,798,622	$~~2,574,166~~6,577,542	$~~2,020,664~~430,729	$~~4,594,831~~7,008,271
Additional gas/solid reactors	$~~73,782,396~~133,890,631	$~~3,897,790~~13,384,341	$~~11,154,740~~18,991,555	$~~15,052,530~~32,375,896
Cycle revalidations	$0	$0	$~~3,300,000~~2,490,000	$~~3,300,000~~2,490,000
Monitoring and testing	$~~18,888,558~~19,925,046	$~~2,689,722~~2,936,022	$~~7,863,576~~8,232,973	$~~10,553,298~~11,168,996
Recordkeeping and reporting	$0	$0	$~~2,401,981~~8,618,124	$~~8,575,255~~15,166,922[1]
Total	$~~132,242,199~~219,614,299	$~~9,161,678~~22,897,905	$~~26,740,961~~38,763,381	$~~42,075,913~~68,210,084

[1] This includes $~~6,173,274~~6,548,798 of one-time annual costs for reading the rule, developing record systems, and initial Title V permitting.

Consistent with the compliance deadlines proposed in this rule, EPA has assumed for purposes of this analysis that all capital costs and one-time annual costs would be incurred within 18 months of the publication of a final rule. The capital costs for permanent total enclosure (PTE) and additional gas/solid reactors were annualized to ~~3~~20 years ~~and 60 years, respectively~~. We estimate that, if finalized, these proposed amendments would reduce EtO emissions from this source category by 19 tpy. Table 2 of this preamble summarizes the cancer risk reductions that would result from the proposed amendments.

Table 2. Summary of Cancer Risk Reductions

	Current Cancer Risks	Cancer Risks If Proposed Amendments Are Finalized
Maximum Individual Risk (MIR)[1]	6,000-in-1 million	100-in-1 million
Number of People with ~~Maximum Individual~~ Cancer Risks > 100-in-1 million	18,000	0

Commented [A8]: It does not appear that the estimates for cycle revalidation considered the capital costs for sites needing to use the cycle calculation or BI indicator approach. That change is expected to necessitate the need for additional equipment since facilities typically use large chambers for mixed loads. Custom cycles for each device will likely result in the need to replace large chambers with multiple smaller chambers and this could result in significant capital investment.

In addition, if the bioburden approach is used, additional staff will need to be hired to monitor the facility's bioburden to ensure compliance. The facility may also need to invest in the equipment needed to frequently test bioburden in this way.

Commented [A9R8]: EPA was not made aware of these additional requirements and, therefore, did not consider them in the cost analysis.

Commented [A10]: Leaving aside the concern that the 60-year and 30-year timeframes for annualization of capital costs significantly

Commented [A11R10]: As stated earlier in this preamble, EPA is also conducting a risk review. Under step 1 of the risk review, EPA

Commented [A12]: We are concerned that this 18-month timeline provides insufficient time for compliance. As EPA states in this

Commented [A13R12]: EPA understands the commenter's concerns and has laid out potential reasons for why an 18-month

Commented [A14]: This time horizon is unreasonable. Even large businesses don't finance investments over a 60-year horizon.

Commented [A15R14]: EPA has updated the annualized costs to reflect a 20-year annualization for PTE and gas/solid reactors.

Commented [A16]: Suggest add a line for estimated excess cancer cases.

Commented [A17R16]: Done

Commented [A18]: Please provide better context here for what the MIR actually represents.

Commented [A19R18]: EPA has added the definition of the MIR

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Commented [A20]: Correct?

Commented [A21R20]: The maximum individual cancer risk is associated with an individual with the highest potential risk. These

Commented [A22]: Unclear why > is used for 100 in a million and >= is used for 1 in a million cancer risk. From language it seems that either both should use > or both should use >=.

Commented [A23R22]: The CAA [112(f)(2)(A)] states that the Administrator shall promulgate standards if cancer risks are not l

Commented [A24]: The maximum individual cancer risk (or MIR) represents an individual.

Number of People with ~~Maximum Individual~~ Cancer Risks ≥ 1-in-1 million	8.3 million	1.26 ~~million~~[1]million[2]
Estimated Annual Cancer Incidence (cases per year)	0.9	0.1

[1]The MIR is defined as the cancer risk associated with a lifetime of continuous exposure at the highest concentration of HAP where people are likely to live.
~~[1]As~~ [2]As discussed in section III, this value may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

As indicated in Table 2, EPA projects that the standards in the proposed rule would significantly reduce incremental lifetime cancer risks associated with emissions of EtO from this source category. Currently, EPA estimates that the maximum increase in lifetime cancer risk associated with any facility in this source category is 6,000-in-1 million, and that approximately 18,000 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 EPA's presumptive upper bound for acceptable health risks). Under the proposed rule, no individual would 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 would be reduced by approximately 85 percent.

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

B. Does this action apply to me?

The standards in 40 CFR part 63, subpart O regulate emissions of EtO from existing and new commercial sterilization operations. Table 3 of this preamble lists the NESHAP and some examples of regulated industrial categories that are the subject of this proposal. Table 3 is not

Commented [A25]: Presentation of these numbers does not convey the extent to which these are intentional overestimates of individual risks. I appreciate that these levels "correspond" to a lifetime cancer risk, rather than a statement that 18,000 people actually have a cancer risk of 10E-4, but that nuance is often lost.

Commented [A26R25]: The population represents an approximation, which is why EPA rounds it to the nearest 1,000. There are inherent uncertainties to any risk assessment, and EPA does use health protective assumptions to ensure our standards protect public health. That said, given the uncertainties in the assessment, it is still possible our estimates represent an underestimate of risks, if, for example, our emission estimates are biased low.

Commented [A27]: Table lists >=. Propose editing for consistency in different locations.

Commented [A28R27]: EPA has corrected this to be greater than or equal to

intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA-450/3-91-030, July 1992), the Commercial Sterilization Facilities source category is any facility engaged in the use of EtO as a sterilant and fumigant following the production of various products (*e.g.*, medical equipment and supplies) and in miscellaneous sterilization and fumigation operations at both major and area sources. These commercial sterilization facilities use EtO as a sterilant for heat- or moisture-sensitive materials and as a fumigant to control microorganisms. Materials may be sterilized at the facility that produces or uses the product, or by contract sterilizers (*i.e.*, firms under contract to sterilize products manufactured by other companies).

Table 3. NESHAP and Industrial Categories Affected by This Proposed Action

INDUSTRIAL CATEGORY	NESHAP	NAICS CODE[1]
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.

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 action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/ethylene-oxide-emissions-standards-sterilization-facilities*. Following publication in the *Federal Register*, the EPA will post the *Federal Register* version of the proposal and key technical documents at this same website.

A memorandum showing the rule edits that would be necessary to incorporate the changes to 40 CFR part 63, subpart O, proposed in this action is available in the docket (Docket ID No. EPA-HQ-OAR-2019-0178). Following signature by the EPA Administrator, the EPA also will post a copy of this document to *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities*.

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*.). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the "residual risk review." In addition to the residual risk review, the CAA also requires the EPA to review MACT and ~~generally available control technology (~~GACT~~)~~ standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account any "developments in practices, processes, or control technologies." This review is

commonly referred to as the "technology review." The discussion that follows identifies the most 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.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). 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 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are "area sources." For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT "floor." In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. 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 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 document, in light of the updated URE regarding EtO, the EPA is choosing to exercise that discretion.

The second stage in standard-setting 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)[7] 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.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less often than every 8 years. In conducting this review, which we call the "technology review," the EPA is not required to recalculate the MACT floors that were established in earlier rulemakings. *Natural Resources Defense Council*

[7] Although defined as "maximum individual risk," MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

(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 also 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).

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

On July 16, 1992, pursuant to CAA section 112(c)(1), the EPA listed certain major and area sources of HAP for regulation, including both major and area sources of commercial sterilization facilities. 57 FR 31576, 31592. As explained in that document, area sources of commercial sterilization facilities were listed pursuant to CAA section 112(c)(3) based on a finding of a threat of adverse effects from commercial sterilizers using EtO. Id at 31588. In 1994, the EPA promulgated the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP, 40 CFR part 63, subpart O (referred to in this proposed rulemaking as the EtO Commercial Sterilization NESHAP) (59 FR 62589), which is codified at 40 CFR part 63, subpart O. The EtO Commercial Sterilization NESHAP regulates EtO emitted from commercial sterilization facilities. The current NESHAP regulates point sources of emissions, specifically SCVs and ARVs, at facilities that use at least 1 ton of EtO in sterilization or fumigation operations in each 12-month period. In a *Federal Register* document published on July 16, 1992 (57 FR 31576), the EPA listed for regulation both major and area sources of EtO commercial sterilization and fumigation operations pursuant to CAA section 112(c)(1) and 112(c)(3) (based on a finding of a threat of adverse effects), respectively.

EtO commercial sterilization covers the sterilizer process that uses EtO to sterilize or fumigate materials (*e.g.*, medical equipment and supplies, spices, and other miscellaneous products and items). The original rulemaking addressed EtO emissions originating from three emission points: SCV, ARV, and 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 residual EtO desorbing from sterilized products within the facility, but the EtO Commercial Sterilization NESHAP does not include standards for these emissions.

In the chamber EtO sterilization process, products and 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 residual EtO 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

Commented [A29]: Flagging that, later in the document, our comments address validation approaches (e.g., cycle calculation). Those approaches are used to determine the appropriate dwell (exposure) time of the devices to EtO. They do not have any relevance to aeration or aeration rooms as indicated later in the document, where we discuss these approaches more extensively.

Commented [A30R29]: It is EPA's understanding that the sterilization process has a direct impact on downstream EtO emissions, as the combination of various parameters (*e.g.*, EtO concentration, dwell time, number of gas washes, etc.) determines how much EtO remains in the material. However, EPA plan to solicit comment on the effectiveness of changes to the sterilization process on reducing EtO emissions (new comments C-5 and C-6)

sterilization and aeration steps of the process occur within the same chamber, though this configuration may or may not have a chamber exhaust.

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.

Multiple control technologies were available for EtO commercial sterilization at the time the EtO Commercial Sterilization NESHAP was promulgated (December 1994). Control technologies for SCVs included: acid-water scrubbers; thermal oxidizer/flares; catalytic oxidizers; condensers/reclaimers; and a combination packed bed scrubber and gas-solid reactor (dry bed reactor) systems. Control technologies for CEVs included: packed bed scrubber; catalytic oxidizer; gas-solid reactor; and a combination packed bed scrubber and gas-solid reactor. Control technologies for ARVs included: acid-water scrubber, catalytic oxidizer, and gas-solid reactor.

In 2006, the EPA 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 emission standards that currently apply to sterilization facilities covered by 40 CFR part 63, subpart O are shown in Table 4:

Table 4. 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]

Commented [A31]: Would facilities set up like this only be in group 1 being the aeration room is not separate?

Commented [A32R31]: While this configuration would eliminate emissions from pre-aeration handling of sterilized material, there are other sources of group 1 room air emissions, including indoor EtO storage, EtO dispensing, and vacuum pump operation. If any of those sources are present, then group 1 room air emissions are still present at the facility. In addition, unless products are shipped directly from aeration (which EPA has only observed at one facility), group 2 room air emissions would also be present.

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 recordkeeping requirements apply (see 40 CFR 63.367(c)).)	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c)).)	No control required; minimal recordkeeping 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.

We note that hospital sterilizers are regulated under a different NESHAP (40 CFR part 63, subpart WWWWW), which is not addressed in this rulemaking.[8] 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 data collection activities were conducted to support this action?*

The EPA used several sources to develop the list of existing commercial sterilization facilities. We began with the facility list used during the previous RTR and supplemented that with facilities identified in the 2017 National Emissions Inventory (NEI), as well as facilities identified using the Office of Enforcement and Compliance Assurance's Enforcement and

[8] 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.

Compliance History Online tool (*https://echo.epa.gov*). We then reviewed available Federal, state and local data to determine whether any of these facilities had closed or ceased using EtO for sterilization purposes. We also asked our EPA regional offices to identify any commercial sterilization facilities that we missed, and when we conducted the December 2019 CAA section 114 questionnaire and September 2021 CAA section 114 Information Collection Request (ICR) (discussed below), we asked the parent companies to identify any commercial sterilization facilities they owned that we did not identify. This review and analysis produced the final facility list of 86 commercial sterilization facilities. A complete list of known commercial sterilization facilities is available in the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule*, which is available in the docket for this rulemaking.

For this RTR, the EPA investigated developments in practices, processes, and control technologies through communications and direct discussions with EPA regional offices, state and local agencies, Small Business Environmental Assistance Program personnel, industry representatives, and trade association representatives. Details of these conversations are included in the memorandum titled *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 (Technical Support Document)*, available in the docket for this action (Docket ID No. EPA-HQ-OAR-2019-0178). The EPA conducted literature reviews, operating permit reviews, Internet web searches, and site visits; published an Advanced Notice of Proposed Rulemaking (84 FR 67889, December 12, 2019); reviewed public comments received; sent requests for information to industry under the authority of CAA section 114; and searched the EPA's

Technology Transfer Network Clean Air Technology Center – RACT/BACT/LAER Clearinghouse (RBLC) database.

The RBLC provides several options for searching the permit database online to locate applicable control technologies. We queried the RBLC database for specific commercial sterilization Process Type 99.004 (Commercial Sterilization Facilities), as well as a related source category, Process Type 99.008 (Hospital Sterilization Facilities). In querying results dating back to January 1, 2006 (the date of the residual risk and initial technology review), no results were returned when searching for Process Type 99.004 and no results were returned for Process Type 99.008. None of these searches returned relevant information on developments in practices, processes, or control technologies used in EtO commercial sterilization facilities. Full details of the RBLC database search in support of this technology review are included in the *Technical Support Document*, available in the docket for this action (Docket ID No. EPA-HQ-OAR-2019-0178). Prior to this proposed rulemaking, the EPA engaged in outreach activities to communities we expect to be impacted most by the rulemaking.[9] Any information related to these outreach activities that we receive prior to the conclusion of the comment period will be considered as part of the final rulemaking, along with direct comments on this proposed rulemaking. Any updated emissions information received during the EPA's ongoing public outreach activities that may change the projected impacts for these populations will be considered as part of the final rulemaking, as well as direct comments received on this proposed rulemaking.

[9] *https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information*

The EPA issued two requests to gather information about process equipment, control technologies, and emissions from facilities in the source category. In December 2019, the EPA issued a CAA section 114 request to a small number of entities that were operating 42 facilities at the time (now 39) to gather information, including information about types of process equipment, sterilization cycles, control technologies, EtO usage and storage, room areas, movements of sterilized products, and EtO concentration data. We also included requests for facility documents (*e.g.*, process flow diagrams, air permits, air permit applications, process and instrumentation diagrams), performance test reports, parametric monitoring data, startup shutdown and malfunction plans, and EtO residual studies in products. These entities were selected because, collectively, they comprised a significant portion of the sterilization industry. All respondents completed the questionnaire and submitted responses to the EPA in February 2020. Additionally, in September 2021, the EPA issued an information collection request (ICR), pursuant to CAA section 114, to gather information from all facilities in the EtO commercial sterilization category. Additional questions in the September 2021 ICR included information on non-EtO sterilization techniques and stand-alone, non-co-located warehouses or distribution centers. The facilities not included in the December 2019 request were asked to respond to the full set of questions, and those facilities were only asked to provide responses to the additional questions. Responses to the ICR were due in November 2021.

The Agency made the data results from the two questionnaires available as part of a Freedom of Information Act request.[10] The EPA used the collected information to assist in filling

[10] Results from the December 2019 questionnaire are available at *https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2020-004133&type=Request*, and results from the September 2021 ICR are available at *https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2022-003690&type=Request*.

data gaps, establish the baseline emissions and control levels for purposes of the regulatory reviews, identify the most effective control measures, and estimate the environmental impacts associated with the regulatory options considered and reflected in this proposed action. The responses to the December 2019 and September 2021 questionnaires are listed in the memorandum titled *Documentation of Database Containing Information from Responses to the December 2019 Questionnaire and the September 2021 Section 114 for the Ethylene Oxide Commercial Sterilization NESHAP Review*, which is available in the docket for this rulemaking. The information not claimed as CBI by respondents and received in time to be included in this proposal is available in the database titled *Data Received from Information Collection Requests for the Commercial Sterilization Facilities Source Category*, which is available in the docket for this rulemaking.

D. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, "the first step judgment on acceptability cannot be reduced to any single factor" and, thus, "[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information." (54 FR 38046). Similarly, with regard to the ample margin of safety determination, "the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors." *Id.*

The Benzene NESHAP approach provides flexibility regarding the factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by emissions of HAP that are carcinogens from each source in the source category, the hazard index for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.[11] The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the explanation in the EPA's response to comments on our policy under the Benzene NESHAP:

> The policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will "protect the public health".

(54 FR 38057). Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that "an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would

[11] The MIR is defined as the cancer risk associated with a lifetime of continuous~~24-7-365~~ exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP exposure concentration to the noncancer dose-response value. The HI is the sum of HQs for HAP that affect the same target organ or organ system.

be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors." *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: "EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category." *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.*, reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health

effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.*, other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA "that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."[12]

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly

[12] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://www.epa.gov/sites/default/files/2021-02/documents/epa-sab-10-007-unsigned.pdf.*

greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

E. How does the EPA perform the technology review?

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT and GACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is "necessary" to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a "development":

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT and GACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT and GACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT and GACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT and GACT standards; and

- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT and GACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed or last reviewed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. We also review the NESHAP and the available data to determine if there are any unregulated emissions of HAP within the source category and evaluate these data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

F. How do we estimate risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB-HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the hazard index for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also

provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The eight sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document that provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule*. The methods used to assess risk (as described in the eight primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009, and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How Did We Estimate Actual Emissions And Identify The Emissions Release Characteristics?

Commercial sterilizers using EtO were listed for regulation in 1992 as described in section II.B of this preamble. The standards in the current NESHAP subpart O are based on facilities' EtO usage amount. Specifically, 40 CFR part 63, subpart O contains SCV and ARV standards for facilities where EtO use is at least 10 tpy and a separate SCV standard for facilities where EtO use is at least 1 tpy but less than 10 tpy. Currently there are 86 facilities in the source category. Based on actual EtO usage data, 47 facilities are sterilization sources where EtO use is at least 10 tpy, 20 facilities are sterilization sources where EtO use is at least 1 tpy but less than 10 tpy, and 19 facilities are sterilization sources where EtO use is less than 1 tpy. The EPA also identified, based on permits and responses to the December 2019 questionnaire and September 2021 ICR, 11 research facilities, as defined under CAA 112(c)(7), which are not part of the source category.

For these facilities, the emissions information that was derived from the 2014 NEI was, in general, found to be insufficient to set appropriate standards. Most notably, for most facilities, room air emissions were not accounted for in the NEI. In addition, 28 facilities had no Emissions Inventory System ID and, therefore, no emissions data to pull from the NEI. Therefore, the EPA generated new EtO emissions data as described below. The complete Commercial Sterilization facility list is available in Appendix 1 of the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule*, which is available in the docket for this rulemaking.

In general, emissions were estimated using a mass balance approach, beginning with annual EtO use (*i.e.*, the previous consecutive 12-month period of EtO use). Where available, the latest annual EtO usage for each facility was used. Where we lacked data, we assumed that the facility was using 50 percent of the maximum usage listed in state and local permits because this is the industry average. Then, EtO use was apportioned to the different emission process groups using emission factors. Emission sources from Commercial Sterilization Facilities include SCVs, ARVs, CEVs, and room air emission sources (Descriptions of SCV, ARV, and CEV emission sources are provided in section II.B). The room air emission sources are:

- Indoor EtO storage: EtO drums and cylinders are often stored in storage areas inside the facility, and emissions may occur from improperly sealed/leaking drums and cylinders into the storage room area.
- EtO dispensing: This includes connecting pressurized lines from the storage drum or cylinder valve to the sterilization chamber to charge EtO to the process cycle. EtO is often moved from the drum to the sterilizer chamber using nitrogen. EtO drums or cylinders may sit in a separate room for dispensing, or the drum or cylinder may be

placed near the sterilization chamber. In either scenario, emissions may occur from connectors and valves on the pressurized lines that connect the storage drum or cylinder to the chamber.

- Vacuum pump operation: These are often used to evacuate sterilization chambers before the chamber door is opened. The vacuum pump feeds into a separation tank where the recirculating pump fluid is returned to the pump and the EtO and other gases (nitrogen and air) are vented to a control system or to the atmosphere. Emissions from leaks may occur from the vacuum pump during operation.
- Pre-aeration handling of sterilized material (PrAHSM): Following the sterilization cycle, emissions may occur from the sterilized materials when moving the material from the sterilization chamber to the aeration room or when holding the material within the facility areas. PrAHSM includes activities such as removing the sterilized materials from the sterilization chamber, transferring sterilized materials from the sterilization chamber to the aeration room, placing or holding of sterilized materials outside of process equipment for short periods of time, and, at some facilities, during aeration transfers where there are primary and secondary aeration chambers. Emissions may occur from off-gassing of residual EtO that is contained in the materials following exposure to EtO.
- Post-aeration handling of sterilized material (PoAHSM): Following the aeration step, emissions may continue to occur from the sterilized and aerated materials when moving the material and holding the material within the facility areas. PoAHSM includes activities such as removing the sterilized/aerated materials from the aeration room, transferring the sterilized/aerated materials from the aeration room to holding

areas, placing or holding of the sterilized/aerated materials in a quarantine area while awaiting confirmation of sterility, and holding of sterilized/aerated materials in shipping and warehouse areas at the facility. Emissions may occur from continued off-gassing of residual EtO that remains in the materials even after the aeration step.

- Non-oxidizer air pollution control device (APCD) area: Non-oxidizer APCDs, such as acid-water scrubbers and gas-solid reactors, are typically housed within the sterilization building. Through the responses to the section 114 requests, we learned that elevated EtO concentrations were observed in the rooms where these APCDs were located. This is likely due to equipment leaks and/or emissions not being fully captured or routed under negative pressure.

In the original rulemaking, we assumed there were no room air emissions. Using the emission source apportionment data available at that time, we assumed that 95 percent of the EtO usage was emitted through the SCV, 2 percent was emitted through the CEV, and 3 percent was emitted through the ARV.[13] The EPA now understands that in addition to emissions from point sources such as SCVs, CEVs, and ARVs, room air emissions also occur at commercial sterilization facilities. In recent years, the industry has assumed a range of room air emissions, anywhere from 0.01 to 1.5 percent of total usage. However, there is little to no documentation for these assumptions or what emission sources were included. In 2019, the EPA examined ambient air monitoring data collected around a commercial sterilization facility in Willowbrook, Illinois

[13] U.S. EPA. *Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations, Background Information for Proposed Standards*. EPA Publication No. EPA-453/D-93-016. October 1992.

and derived a room air emissions factor that equates to approximately 0.6 percent of total EtO usage.[14]

Under this rule review, the EPA reassessed the emission apportionment across the emission sources at commercial sterilization facilities. The EPA analyzed the responses from the December 2019 questionnaire and September 2021 ICR to update the fraction of EtO that is apportioned to SCV, ARV, CEV, and room air emissions.

- The data for the ARV analyses included flow rate (or room volume combined with air changeover rate), EtO concentration, and average aeration room temperature to estimate ARV emissions.
- The data for the CEV analyses included flow rate, EtO concentration, and the sterilizer chamber temperature to estimate CEV emissions.
- The data for the room area analyses included the flow rate, EtO concentration, temperature information, and annual operating hours to estimate the EtO emission for each emission source.

The estimated EtO emissions were compared to the annual actual EtO usage to develop the fraction of EtO use that goes to each emission source before controls. Under the recent emission source apportionment analysis, the EPA determined 4 percent of EtO used goes to the ARV, 1 percent goes to the CEV, 0.1 percent goes to EtO dispensing, 0.1 percent goes to vacuum pump operations, 0.2 percent goes to pre-aeration handling of sterilized material, 0.2 percent goes to post-aeration handling of sterilized material, and 0.04 percent goes to non-oxidizer APCD operation. We estimate that another 1 percent of EtO used leaves the facility still in the product.

[14] *https://www.epa.gov/sites/default/files/2019-08/documents/appendix_1_to_the_sterigenics_willowbrook_risk_assessment.pdf*, Table 1

The portion of EtO usage that is emitted from SCV is the balance of the EtO usage (*i.e.*, 93.36 percent). However, the value varies depending on the equipment configuration (traditional sterilizer chamber, combination chamber, etc.) and may range from 93.36 to 98.32 percent. The EPA was not able to quantify what percentage of EtO use is emitted from indoor EtO storage, which could result in a slight underestimation of the risk. Based on our review of the data, we do not believe that emissions from indoor EtO storage are significant. See memorandum *Development of Ethylene Oxide Usage Fractions for Ethylene Oxide Commercial Sterilization – Proposal*, which is available in the docket for this rulemaking.

Finally, the performance of the control systems used to reduce emissions, if available, was considered. Data from the CAA section 114 requests, as well as state and local permitting data, were also used to develop the other parameters needed to perform the risk modeling analysis, including the emissions release characteristics, such as stack heights, stack diameters, flow rates, temperatures, and emission release point locations.

The RTR emissions dataset developed using the data and estimates described immediately above was refined following an extensive quality assurance check of source locations, emission release point parameters, and annual emission estimates. The EPA reviewed the locations of emission release points at each facility and revised each record as needed to ensure that all release points were located correctly. If an emission release point was located outside of the facility fenceline or on an obviously incorrect location within the fenceline (*e.g.*, parking lot, lake, etc.) then the emission release point was relocated to either the true location of the equipment, if known, or the approximate center of the facility.

The emission release point parameters for stacks in the modeling input files include stack height, exit gas temperature, stack diameter, exit gas velocity, and exit gas flow rate. If emission

release point parameters were outside of typical quality assurance range checks or missing, then an investigation was done to determine whether these values were accurate. If this information could not be found, then surrogate values were assigned based on similar values observed for the control device and process group. In some cases, missing emission release point parameters were calculated using other parameters within the modeling input file. For example, missing exit gas flow rates were calculated using the reported diameter and velocity.

Additionally, the EPA compared the emission release point type (*i.e.*, fugitive, stack) to the emission unit and process descriptions for the modeling file records. In cases where information was conflicting (*i.e.*, equipment leaks being modeled as a vertical stack, or process vent emissions being modeled as a fugitive area), we updated the emission release point type to the appropriate category and supplemented the appropriate emission release parameters using either permitted values, when available, or default values.

2. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this proposal were estimated using the Human Exposure Model (HEM). The HEM performs three primary risk assessment activities: (1) conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

AERMOD, the air dispersion model used by the HEM model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities. To perform the dispersion modeling and to develop the preliminary risk estimates, HEM draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes hourly surface and upper air observations for years ranging from 2016-2019 from over 800 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk from Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each

HAP (in $\mu g/m^3$) by its URE. The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's IRIS. For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using CalEPA UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants*.

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP emitted by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ

when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (*https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary*). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) the Agency for Toxic Substances and Disease Registry (ATSDR) ~~Minimum~~ Minimal Risk Level (*https://www.atsdr.cdc.gov/minimalrisklevels/index.html*); (2) the CalEPA Chronic Reference Exposure Level (REL) (*https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0*); or (3) as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants*.

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c. Risk from Acute Exposure to HAP that May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. As part of our efforts to continually improve our methodologies to evaluate the risks that HAP emitted from categories of industrial sources pose to human health and the environment, we revised our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for Commercial Sterilization Facilities Source Category in Support of the 2022 Technology Review Proposed Rule* and in Appendix 5 of the report: Technical Support Document for Acute Risk Screening Assessment. This revised approach has been used in this proposed rule and in all other RTR rulemakings proposed on or after June 3, 2019.

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point, reasonable worst-case air dispersion conditions (*i.e.*, 99th percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure concentration by the acute dose-response

value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute reference exposure level (REL) is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration." Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours. They are guideline levels for "once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals." Id. at 21. The AEGL–1 is specifically defined as "the airborne concentration (expressed as ppm or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure." The document also notes that "Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects." *Id.* AEGL–2 are defined as "the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape." *Id.*

ERPGs are developed by the American Industrial Hygiene Association (AIHA) for emergency planning and are intended to be health-based guideline concentrations for single exposures to chemicals. The ERPG–1 is the maximum airborne concentration, established by AIHA, below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor. Similarly, the ERPG–2 is the maximum airborne concentration, established by AIHA, below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1).

For this source category, an acute emissions multiplier value of 1.2 was used because, overall, sterilization operations tend to be steady-state without much variation. A further discussion of why this factor was chosen can be found in the memorandum, *Emissions Data and Acute Risk Factor Used in Residual Risk Modeling: Commercial Sterilization Facilities*, available in the docket for this rulemaking.

In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for

these HAP. In cases where an acute HQ from the screening step is greater than 1, we assess the site-specific data to ensure that the acute HQ is at an off-site location. For this source category, all acute HQs were less than or equal to 1, and no further analysis was performed.

3. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.*, ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA's Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at *https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library*).

For the Commercial Sterilization Facilities source category, we did not identify emissions of any PB-HAP. Because we did not identify any PB-HAP emissions, no further evaluation of multipathway risk was conducted for this source category.

4. How do we assess risks considering emissions control options?

In addition to assessing baseline inhalation risks and screening for potential multipathway risks, we also estimate risks considering the potential emission reductions that would be achieved by the control options under consideration. In these cases, the expected emission reductions are applied to the specific HAP and emission points in the RTR emissions dataset to develop corresponding estimates of risk and incremental risk reductions.

5. How do we conduct the environmental risk screening assessment?

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect. Section 112(a)(7) of the CAA defines "adverse environmental effect" as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife,

aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

The EPA focuses on eight HAP, which are referred to as "environmental HAP," in its screening assessment: six PB-HAP and two acid gases. The PB-HAP included in the screening assessment are arsenic compounds, cadmium compounds, dioxins/furans, polycyclic organic matter (~~PM~~POM), mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are hydrochloric acid (HCl) and hydrogen fluoride (HF).

For the Commercial Sterilization Facilities source category, we did not identify emissions of any environmental HAP. Because we did not identify any environmental HAP emissions, no further evaluation of environmental risk was conducted for this source category.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire "facility," where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2017 NEI. The source category records of that NEI dataset were removed, evaluated, and updated as described in section II.C of this preamble: What data collection activities were conducted to support this action? Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted "facility-wide" for the populations residing within 50 km of each facility,

consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the Risk and Technology Review 2022 Proposed Rule*, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the Risk and Technology Review 2022 Proposed Rule*, which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the

uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report*.

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.*, not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.*, not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.*, meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated

by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under- nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and

others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's 2005 Guidelines for Carcinogen Risk Assessment; namely, that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective" (the EPA's 2005 Guidelines for Carcinogen Risk Assessment, page 1-7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a "plausible upper limit to the true value of a quantity" (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater. Chronic noncancer RfC and reference dose values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be "without appreciable risk," the methodology relies upon an uncertainty factor (UF) approach, which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.*, 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.*, 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health

effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.*, no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

Although we make every effort to identify appropriate human health effect dose-response values for all pollutants emitted by the sources in this risk assessment, some HAP emitted by this source category are lacking dose-response assessments. Accordingly, these pollutants cannot be included in the quantitative risk assessment, which could result in quantitative estimates understating HAP risk. To help to alleviate this potential underestimate, where we conclude similarity with a HAP for which a dose-response value is available, we use that value as a surrogate for the assessment of the HAP for which no value is available. To the extent use of surrogates indicates appreciable risk, we may identify a need to increase priority for an IRIS assessment for that substance. We additionally note that, generally speaking, HAP of greatest concern due to environmental exposures and hazard are those for which dose-response assessments have been performed, reducing the likelihood of understating risk. Further, HAP not

included in the quantitative assessment are assessed qualitatively and considered in the risk characterization that informs the risk management decisions, including consideration of HAP reductions achieved by various control options.

For a group of compounds that are unspeciated (*e.g.*, glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.*, ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (*i.e.*, 99th percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case actual exposure scenario. In most cases, it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB-HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from

multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models – TRIM.FaTE and American Meteorological Society (AMS)/Environmental Protection Agency (EPA) Regulatory Model (AERMOD) – that estimate environmental pollutant concentrations and human exposures for five PB-HAP (dioxins/furans, POM, mercury (both inorganic and methyl mercury), cadmium, and arsenic) and two acid gases (HF and HCl). For lead, the other PB-HAP, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary National Ambient Air Quality Standards standard for lead. Two important types of uncertainty associated with the use of these models in RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.

Model uncertainty concerns whether the model adequately represents the actual processes that might occur in the environment, such as the movement of a pollutant through soil or accumulation of the pollutant over time. This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTRs.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial

configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume-rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty adopts conservative assumptions that are intended to be protective of public health. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed

individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.*, screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: arsenic, cadmium, dioxins/furans, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

III. Analytical Results and Proposed Decisions

In this section, we describe the analyses performed to support the proposed decisions for establishing standards for previously unregulated processes and pollutants, the residual risk assessment, the technology review, and other issues addressed in this proposal. We also describe the proposed standards that result from this series of analyses. To develop the proposed standards, we first determined the proposed standards for previously unregulated emission sources under CAA section 112(d)(2)-(3) (MACT) or 112(d)(5) (GACT). Next, we assessed the remaining risks, taking into account the current standards and the proposed standards we developed under the first analysis for the currently unregulated sources. Based on the risk assessment, we identified additional control options to ensure that risks are acceptable and provide an ample margin of safety to protect public health. Based on those analyses, we are proposing risk-based standards for certain sources under CAA section 112(f). We also conducted a technology review, under CAA section 112(d)(6). Finally, we evaluated the startup, shutdown, and malfunction (SSM) provisions; monitoring, recordkeeping, and reporting; and performance testing requirements in the current rule, and we are proposing amendments to ensure consistency with the EPA's current approaches related to these provisions.

A. How are we proposing to define affected sources?

We are proposing to specifically define affected sources in subpart O for the reasons explained below. The current subpart O does not contain definitions for affected sources, which means the definition of an "affected source" at 40 CFR 63.2 currently applies. 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." Accordingly, an affected source under the current subpart O,

as defined under 40 CFR 63.2, includes all SCVs and ARVs at a currently regulated EtO commercial sterilization facility, and the applicable standard is based on the facility's annual EtO usage amount. It is not clear that EPA had intended to apply the "affected source" definition at 40 CFR 63.2 to subpart O as we did not find specific discussions on this topic in the prior rulemakings for subpart O. In any event, we evaluated this issue for purposes of the present rulemaking. For point source emissions (*i.e.*, SCVs, ARVs, and CEVs), we do not believe that the "affected source" definition at 40 CFR 63.2 is appropriate because a facility may not route all emissions from a particular type of point source (*e.g.*, emissions from all SCVs at a facility) to the same emission control system, thus making compliance demonstration with the standards difficult. Therefore, for point sources, we are proposing to define an affected source as each individual SCV, ARV or CEV at a facility.[15]

For room air emissions, which are currently unregulated, we are proposing to define Group 1 and Group 2 room air emissions as a collection of emissions as follows:

> ***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.

Unlike point sources, the collection of Group 1 and Group 2 emissions described above are commonly routed to the same emission control and, therefore, it seems logical to define affected sources for room air emissions by the groupings described above. Also, the equipment and processes that contribute to these emissions (*e.g.*, drums, pumps, sterilized material) are so

[15] The proposed definition, if finalized, would not apply retroactively and, therefore, would not be used to determine compliance with subpart O for periods prior to the final rule amending subpart O.

numerous that defining each of these emissions individually as an affected source would be impractical and an implementation burden.

For the reasons explained above, we are proposing to add definitions for affected sources to 40 CFR 63.360. Specifically, for SCVs, ARVs, and CEVs, we are proposing to define the affected source as the individual vent. For Group 1 and Group 2 room air emissions, we are proposing to define the affected source as the collection of all room air emissions for each group as described above at any sterilization facility. We are soliciting comment on these proposed definitions (Comment C-1).

B. What actions are we taking pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5)?

In our review of the EtO Commercial Sterilization NESHAP, we identified emission sources of EtO that are currently unregulated and developed emission standards under sections 112(d)(2)-(3) or (d)(5), as appropriate. In addition to room air emission sources, certain point source emissions are also currently unregulated, including the following: 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; and CEVs at facilities where EtO use is at least 10 tpy. Emission standards are being proposed for these sources under CAA sections 112(d)(2)-(3) or (d)(5), as appropriate. We are required under CAA section 112(d)(3) to establish MACT standards for major sources. For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best controlled similar source. For existing sources, the MACT floor cannot be less stringent than the average emission limitation achieved by the best performing 12 percent of existing sources for which data are available for source categories with 30 or more sources, or the best performing 5 sources for source categories with fewer than 30 sources. For area source facilities, CAA section 112(d)(5) gives EPA discretion to

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set standards based on GACT for those facilities in lieu of MACT standards. Unlike MACT, there is no prescription in CAA section 112(d)(5) that standards for existing sources must, at a minimum, be set at the level of emission reduction achieved by the best performing 12 percent of existing sources, or that standards for new sources be set at the level of emission reduction achieved in practice by the best controlled similar source. The legislative history suggests that standards under CAA section 112(d)(5) should "[reflect] application of generally available control technology that is, methods, practices, and techniques which are commercially available and appropriate for application by the sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems." SEN. REP. NO. 101-228, at 171 (1989). Thus, in contrast to MACT, CAA section 112(d)(5) allows us to consider various factors in determining the appropriate standard for a given area source category.

We are proposing to set EtO standards for unregulated emissions at new and existing major and area sources as authorized by the CAA.[16] In deciding how to regulate currently unregulated emissions from existing area source facilities, we are proposing that, in all cases, setting GACT standards would be appropriate because (1) a significant portion of the area source facilities are owned by small entities, (2) companies could experience significant economic burden (*i.e.*, cost-to-sales ratio exceeding 5 percent) if MACT standards are imposed, (3) we are trying to minimize disruptions to the supply of medical devices and thereby avoid creating a

[16] Some facilities also use propylene oxide (PpO) when conducting sterilization operations. The only facilities that reported PpO emissions were area source facilities. PpO is not one of the 30 urban HAP listed for regulation under CAA section 112(c)(3)/(k)(3)(B), an obligation that EPA completed in 2011 (76 FR 15308). Further, as mentioned earlier, area sources of commercial sterilizers were listed for regulation under CAA section 112(c)(3) based on a finding of threat of adverse effects from commercial sterilizers using EtO. We are therefore not proposing standards for PpO.

potential health concern, and (4) as discussed in more detail below in section III.D, we are proposing revision to the standards, including those being proposed under CAA section 112(d)(5) for certain currently unregulated emission sources, based on our assessment of the post-control risks under CAA section 112(f)(2) in this proposed rulemaking.

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 have taken a restriction so that its potential to emit is less than such amounts for major sources. For the facilities within this source category, EtO sterilization tends to be either the primary or only activity and source of HAP emissions. In addition, most of the EtO used at these facilities is released through the SCV and ARV. As discussed in more detail below, the current subpart O contains standards for certain point 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, we believe that all facilities that use more than 10 tpy are synthetic area source facilities, and all but one facility where EtO use is less than 10 tpy are true area source facilities. We have only identified one facility where EtO use is less than 10 tpy that is a major source due to other HAP emissions, which are regulated under other section 112 NESHAP.[17]

1. SCVs At Facilities Where EtO Use Is Less Than 1 Tpy

[17] This facility is also subject to 40 CFR Part 63 Subparts Q, JJJJ, and ZZZZ.

a. Existing Sources

The current subpart O does not contain emission standards for SCVs at facilities where EtO use is less than 1 tpy. There are ~~19~~20 facilities where EtO use is less than 1 tpy, all of which have SCVs. Of these ~~19~~20 facilities, 1~~9~~8 are currently controlling their SCV emissions. Fourteen of these facilities use catalytic oxidizers, five~~our~~ use gas/solid reactors, and one uses an acid-water scrubber and gas/solid reactor in series. Note that this does not sum up to 1~~9~~8 because one facility is using two different types of control systems to reduce SCV emissions. Performance tests are available for SCVs at ~~five~~three facilities where EtO use is less than 1 tpy; ~~four~~two of these facilities use catalytic oxidizers, and one uses a gas/solid reactor. We reviewed all ~~of~~ these performance tests, and the reported emission reductions range from 98.6 to 99.9~~5~~ percent.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on the SCVs, and the second option considers applying a best management practice (BMP) to reduce EtO use per sterilization cycle (*i.e.*, pollution prevention). With respect to the first option, because 1~~9~~8 out of ~~19~~20 facilities with SCVs and EtO usage less than 1 tpy are already using controls to reduce SCV emissions, we consider emission controls to be generally available ~~control technology (GACT)~~ for ~~existing~~ SCVs. We considered a standard of 99 percent emission reduction, which is the current subpart O standard for SCVs at facilities where EtO use is at least 1 tpy. We find this standard to be reasonable for existing SCVs at facilities using less than 1 tpy EtO because it is comparable to the emission reductions shown in the performance tests from facilities within this group.

The second potential GACT option we considered was a management practice that would require facilities to follow either the Cycle Calculation Approach or the Bioburden / Biological

Commented [A35]: Here, this BMP proposes the elimination of the half-cycle validation method. However, if a device manufacturer chooses to use FDA recognized consensus standards that support the half-cycle validation method, it is within FDA's regulatory authority to review that data as part of the manufacturer's premarket submission. As shared with OPP as part of their EtO registration efforts, the half-cycle approach is the most commonly used validation method by firms sterilizing medical devices. Prohibiting this method could result in significant additional time and expense for medical device firms. It's not clear that the additional validation time and resources are fully accounted for in the analysis of impacts, so we recommend further analysis or clarification. Specifically:

- This approach is well accepted and straightforward, so firms may not initially be experienced at executing the alternative methods properly. Also, firms may need to revalidate currently used sterilization processes. Validations are very time intensive and expensive so the change could cause a significant burden on firms.
- Validations are time-intensive. To the extent that contract sterilizers would spend time and capacity to revalidating cycles instead of processing medical devices for market, this could contribute to supply constraints for medical devices.
- Half-cycle validations are used as industrial sterilizers often sterilize large mixed loads with the products in that load potentially requiring varying levels of EtO to sterilize. The half cycle approach ensures each product in the load receives the amount of EO it needs to get an SAL of 10-6 while allowing the contract sterilizer to run fewer cycles because they can mix loads, thereby reducing the total amount of EtO used.
- The prohibition on the half-cycle approach as an EtO sterilization validation method could impact continued work on EtO process changes under the ongoing FDA Innovation Challenges, in which FDA is working with sterilzation exerpts, medical device manufactureres, EPA and others to advance ...

Commented [A36R35]: EPA notes that as part of this BMP, facilities could also utilize an alternative means of emission limitation (AMEL) if they can demonstrate that it achieves equivalent or better emission reductions. In addition, EPA plans to solicit comment on several aspects of this BMP, including its true effectiveness on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this BMP, and any other potential barriers to or consequences of imposing this BMP. EPA also plans to solicit comment on other potential BMPs, including a limit on EtO concentration within each sterilization chamber, as well as restrictions on packaging and pallet material (new comments C-5 through C-7)

Indicator Approach to achieve sterility assurance in accordance with International Organization for Standardization (ISO) 11135:2014 and ISO ~~14161:2009~~11138-1:2017. ISO 11135:2014 describes these two approaches ~~and cross-refences ISO 14161:2009, which provides additional guidance on the use of these approaches~~. Currently, ISO 11135:2014 is a voluntary consensus standard for EtO sterilization that is recognized by ~~the~~ FDA.[18] ~~[Insert footnote]~~ ~~These ISO standards are voluntary consensus standards for EtO sterilization that are recognized by the FDA.~~ ISO 11135:2014 "describes requirements that, if met, will provide an EtO sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity."[19] ISO ~~14161:2009~~11138-1:2017 "~~prov~~ides guidance regarding the selection, use and interpretation of results of biological indicators when used to develop, validate and monitor sterilization ~~processes~~specifies general requirements for production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes".[20] The EPA has learned, through conversations with industry stakeholders, that current EtO use is based on very conservative estimates of the amount of EtO needed to achieve sterility and that current EtO use could be reduced by as much as 50 percent while still meeting sterility standards.[21] We therefore project that this BMP, which would require facilities to follow either the Cycle

[18] FDA also recognizes ISO 11138-1:2017, which remains current per ISO. See https://www.iso.org/standard/66442.html.

[19] ISO 11135:2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices, July 2014.

[20] ISO ~~14161:2009~~11138-1:2017, Sterilization of health care products — Biological indicators — ~~Guidance for the selection, use and interpretation of results~~Part 1: General Requirements, ~~September 2009~~March 2017.

[21] See memorandum, *Meeting Minutes for Discussion with Representative of STERIS*, located at Docket ID No. EPA-HQ-OAR-2019-0178. September 18, 2019.

Commented [A37]: FDA does not currently recognize ISO 11138-1:2017 in the Agency's consensus standard database. Per ISO, 11138-1:2017 was withdrawn and revised by ISO 11138-7:2019 (https://www.iso.org/standard/43350.html). That said, FDA currently recognizes an in-effect iteration of this standard from 2017 (ISO 11138-1:2017), so we have revised the sentence for accuracy. We flag that reference to the ISO standard may need to be updated elsewhere in the document as well.

We note that the ISO standard enables the use of several validation methods, while this rulemaking proposes to limit methods to the cycle calculation or BI approach. This sets up an inconsistency between what FDA has recognized under its regulatory framework, and what EPA is proposing here.

Commented [A38R37]: All references to ISO 14161:2009 have been replaced with 11138-1:2017

Commented [A39]: We recommend adding a footnote that says FDA also recognizes ISO 11138-1:2017, which remains current per ISO. See https://www.iso.org/standard/66442.html.

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Commented [A41]: EtO can still be reduced while still using the half-cycle approach. Cycle optimization and smart packaging design can also be used.

Commented [A42R41]: EPA plans to solicit comment on limiting the EtO concentration within each sterilization chamber (new comment C-6), which we believe would lower EtO use without needing to prohibit the half-cycle approach. EPA also plans to solicit comment on limiting packaging and pallet materials (new comment C-7)

Commented [A43]: Can you explain the industry isn't attempting to use the absolutely necessary amount of EtO? One would think a reduction in EtO usage would be cost beneficial for a company. Is it just not worth their time/labor needed to adjust processes?

Commented [A44R43]: It is EPA's understanding that this is particularly an issue with contract sterilizers, as they are only responsible for following the cycle directions and do not have direct authority over its approval. They would need to go to the customer and ask them to re-validate the cycle so that it uses less EtO. Some customers have expressed hesitancy over this, as they may associate less EtO use with less sterility. In addition, it takes additional time and money to revalidate a cycle

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Calculation Approach or the Bioburden / Biological Indicator Approach to achieve sterility assurance in accordance ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, would achieve those 50 percent reductions. We consider this option to be generally available because facilities already ~~have to~~must configure sterilization cycles in accordance with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017. Option 2 would simply require that they follow either the Cycle Calculation Approach or the Bioburden / Biological Indicator Approach to meet sterility assurance according to the ISO standards. These methods can use 50 percent less EtO than the most conservative method, Half Cycle Approach, which is currently the common industry practice.

The impacts of the two potential GACT options are presented in Table 5.

Table 5. Nationwide Emissions Reductions and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for Existing SCVs at Facilities Where EtO Use Is Less Than 1 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~87,110~~92,211	$~~12,241~~21,762	3.3E-2	$~~368,192~~654,578
2	BMP (estimated 50 percent emission reduction)	$0	$870,000 (one-time annual cost)[1]	0.24	$3,678,138

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, as well as re-submitting to FDA for approval. It is expected that ~~companies~~ 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 ~~cost analyse~~analysis.

Based on the estimates above, we find both options to be cost effective. While the cost-effectiveness number for Option 2 may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness of Option 2 is within the range of the values that we have determined to be

Commented [A45]: While requiring a cycle calculation approach with the EO concentration tailored to an individual device will ensure the minimum amount of EO required is used *for that device*, this approach will necessitate that ALL devices have a custom cycle, which would likely result in more runs, less capacity/throughput, and more EO usage overall than the optimized cycles mentioned above. Currently, devices are sterilized in mixed loads from multiple vendors so that sterilization providers can sterilize multiple large pallets of devices and maximize output, minimizing the overall number of cycles that need to be run. Even in the innovation challenge discussions, these cycles are being optimized with the idea that the minimum amount of EO will be used *to achieve an SAL of 10^-6 for all types of devices placed in the chamber.* As a result, providers group devices with similar requirements together rather than sterilize each one individually. The cycle calculation approach will vastly increase the overall number of cycles that need to be run since each device now needs its own cycle.

Commented [A46R45]: EPA also notes that, as part of this BMP, facilities could apply for an AMEL if they can demonstrate that it can achieve EtO emission reductions than are at

Commented [A47]: These are large standards that present users with a variety of options and approaches for cycle design and validation. A facility being in conformance

Commented [A48R47]: EPA also notes that, as part of this BMP, facilities could apply for an alternative means of emission limitation if they can demonstrate that it can achieve EtO

Commented [A49]: So is this the capital investment to install emission controls at one facility?

Commented [A50R49]: Yes

Commented [A51]: As noted above in the comment on table 1 and elsewhere, it is unclear whether the estimates for cycle revalidation considered the capital costs for sites needi

Commented [A52R51]: EPA was not made aware of these additional requirements with cycle revalidation and, therefore, did not consider them in the cost analysis. However, EPA plan

Commented [A55]: This figure is confusing, please clarify

Commented [A56R55]: Cost effectiveness is a standard metric that EPA analyzes in its NESHAP rulemakings. It is the total annual

Commented [A53]: It's not clear to this reviewer what "one-time annual cost" means. Does that mean once a year?

Commented [A54R53]: It is a cost that we believe the companies would incur one time, but it is treated as an annual cost for the purpose of our cost analyses. This was done

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cost-effective for highly toxic HAPs. 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 both options are considered generally available under CAA section 112(d)(5), Option 1 would ensure that facilities that are currently reducing emissions from SCVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from SCVs. As mentioned earlier, ~~18~~19 out of ~~19~~20 facilities where EtO use is less than 1 tpy are currently controlling their SCV emissions. Therefore, the EtO emission reductions that occur ~~as a result~~because of Option 1 are relatively small. However, if 99 percent emission reduction were applied to uncontrolled emissions, the EtO emission reductions would be ~~6.0~~7.4 tpy. In addition, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing SCVs at facilities where EtO use is less than 1 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing SCVs by 99 percent. We solicit comment on the proposed standard (Comment C-2).

We solicit comment on whether to also adopt an alternative emission limit that reflects 99 percent emission reduction from SCVs for the following reason. There may be a point where the amount of EtO usage is so low that it may become difficult to demonstrate compliance with the proposed 99 percent emission reduction standard if available measurement instruments are not low enough to detect the resulting emissions post-control. To alleviate this problem, we considered establishing an alternative standard in a pounds per hour (lb/hr) emission rate format but recognized that the same detection issue may exist with such alternative standard for some

Commented [A57]: Facilities operate these controls without EPA requirements currently. On what basis does EPA suspect this is a reasonable course of action for any facility? Are these facilities not subject to state permits?

Commented [A58R57]: EPA does not anticipate that these facilities would remove their SCV controls, but the potential lost emission reductions (7.4 tpy) are too great to risk. 11 of these facilities are subject to state permits, and the five facilities in California are subject to local air district permits. Four facilities are not subject to any local air permits.

Commented [A59]: Does EPA know why one facility has not installed emissions controls voluntarily?

Commented [A60R59]: No

Commented [A61]: There isn't a middle ground between maintaining current practice and complete uncontrolled emission?

Commented [A62R61]: As discussed earlier in this section, we consider emission controls to be GACT. As presented in Table 5, maintaining current practice (option 1) has a very minimal impact, as only one facility would need to install controls.

Commented [A63]: Because of the issue raised here, it's not clear whether the percentage standards would result in more costs to smaller facilities due to the need to purchase more sensitive equipment and whether this was considered in the cost calculation.

Commented [A64R63]: EPA assumed $30,000 per performance test, which we believe is an appropriate assumption for these facilities. However, if more accurate information is made available between proposal and final, EPA will update cost estimates accordingly.

facilities, as explained below in section III.B.5. We solicit comment on whether to include such an alternative equivalent standard because we think sources most likely can demonstrate compliance with one or the other standard (Comment C-3). We also solicit comment on how to establish such an equivalent emission limit. We calculated the emission rate by first assuming that all of these facilities are achieving the emission reduction standard (*i.e.*, 99 percent reduction). The emission rate at each facility is dependent on EtO usage, the portion of EtO usage that is emitted from the SCVs, and the performance of the control device, if used. We then calculated the sum of SCV emissions at facilities where EtO use is less than 1 tpy by the total number of SCVs at these facilities, and rounded to two significant figures, which resulted in 2~~3~~.5~~2~~E-4 lb/hr. We solicit comment on whether 2~~3~~.5~~2~~E-4 lb/hr is equivalent to 99 percent reduction and whether the method described above used to calculate this lb/hr limit is appropriate for calculating an emission limit equivalent to a percentage emission reduction standard (Comment C-4).

We are aware that 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 may reduce the number of products that can be sterilized simultaneously. This may result in lower EtO emission reductions, bottlenecks in the medical device supply chain, and facilities having to invest in additional chambers and staff. In addition, the revalidation of sterilization cycles is a time-intensive process and could also worsen potential bottlenecks in the medical devices supply chain. We also understand that this requirement may interfere with the ongoing FDA Innovation Challenges, which are aimed at reducing overall EtO use in sterilization. Therefore, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and

annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C-5). We are also aware of other BMPs that may reduce EtO emissions, including a limit on EtO concentration within each sterilization chamber, as well as restrictions on packaging and pallet material. Based on responses to the December 2019 questionnaire and September 2021 ICR, we understand that the average EtO concentration within the chamber during sterilization is 600 milligrams per liter (mg/L). Considering the number of cycles that are conducted in each chamber per year, as well as the volume of the chambers themselves, we believe that limiting the EtO concentration within each sterilization chamber to 290 mg/L would reduce EtO emissions by 50 percent. We solicit comment on the effectiveness of limiting the EtO concentration within each sterilization chamber on EtO emissions, what that limit might be, the decision criteria for determining that limit, any capital and annual costs associated with that limit, the time needed to comply with that limit, and any other potential barriers to or consequences of imposing that limit (Comment C-6). Our understanding of the impact of packaging and pallet material on EtO emissions is mostly limited to one study conducted by a commercial EtO sterilizer.[22] However, the study did conclude that packaging and pallet materials do have an impact on EtO retention and, by extension, emissions. In addition, it is our understanding that reducing paper packaging (and replacing with electronic barcodes) may aid in the reduction of EtO emissions. We solicit comment on the effectiveness of limiting packaging and pallet materials on EtO emissions, what those limits might be, the decision criteria for determining those limits, any capital and annual

[22] See memorandum, *Engineering Studies Report*, located at Docket ID No. EPA-HQ-OAR-2019-0178. April 30, 2020.

costs associated with those limits, the time needed to comply with those limits, and any other potential barriers to or consequences of imposing those limits (Comment C-7).

We note that, as part of the pesticide registration review required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA~~'s Office of Chemical Safety and Pollution Prevention (OCSPP)~~ is concurrently issuing ~~proposing use rate reduction as part of the EtO~~ Proposed Interim Decision (PID) for EtO that includes use rate reduction ~~pesticide registration review required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)~~. While the proposed CAA NESHAP~~OAR~~ and ~~OCSPP proposals~~the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility. The proposed actions are also complementary in that they are intended to reduce public health risks from EtO exposure. The proposed CAA rulemaking focuses on reducing EtO emissions to outside air from commercial sterilization facilities, in order to reduce risk to people living near those facilities (called "residential bystanders" in FIFRA). The FIFRA PID would also reduce EtO risk to people outside sterilization facilities, including residential and non-residential bystanders (i.e., those who go to work or school near facilities), as well as risks to workers exposed to EtO inside sterilization facilities.

Commented [A65]: Revised to better reflect EPA's actions under the two statutory authorities.

Commented [A66]: EPA acknowledges in the NESHAP that EPA OPP will be publishing a PID and that they complement each other in their shared objective of preventing overuse of EtO in achieving sterility. It could be helpful to the reader/public to include a brief summary of differences in scope (different populations/risk groups) between this NESHAP and the PID.

Commented [A67R66]: Text added to explain the difference in scope of populations for which risk is assessed.

b. New Sources

For new SCVs at facilities where EtO use is less than 1 tpy, we considered two potential GACT options similar to those evaluated for existing SCVs at facilities where EtO use is less than 1 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described above in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. The impacts of these options, which are presented in Table 6 below, are based on a model plant for new SCVs at a facility using less than 1 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities using less than 1 tpy EtO:

- Number of SCVs: 5
- Annual EtO use: 0.3~~93~~ tpy
- Annual operating hours: ~~5~~6,000
- Portion of EtO going to SCVs: 97.4~~73~~ percent
- SCV flow rate: ~~2~~30 cubic feet per second (cfs)
- Number of unique cycles: ~~2~~1

Table 6. Model Plant Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for New SCVs at Facilities Where EtO Use Is Less Than 1 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~87,110~~92,211	$~~45,696~~60,056	0.3~~1~~7	$~~145,366~~161,105
2	BMP (estimated 50 percent emission reduction)	$0	$~~6~~30,000 (one-time annual cost)[1]	0.1~~9~~6	$~~376,939~~159,344

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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, ~~W~~we find ~~the~~both options to be cost-effective~~ness numbers to be reasonable.~~ While both options are considered generally available under CAA

Commented [A70]: Not comparable with the figure above. Same issue for every table in this section.

Commented [A71R70]: EPA disagrees with this assertion. Cost effectiveness has long been used as a metric for normalizing and comparing different emission reduction options.

Commented [A68]: Flagging relevance of earlier comments related to calculating costs.

Commented [A69R68]: EPA was not made aware of the other costs associated with cycle revalidation and, therefore, did not consider them in the cost analysis. However, EPA plans to solicit comment on any capital and annual costs that have not been accounted for (new comment C-5).

section 112(d)(5). Option 1 would achieve greater emission reductions than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish a standard for new SCVs at facilities where EtO use is less than 1 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing SCVs by 99 percent. We are soliciting comment on this proposed standard (Comment C-85). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new SCVs at facilities using less than 1 tpy and whether 2.5E-4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new SCVs at facilities using less than 1 tpy (Comment C-96).

As noted above, as part of the pesticide registration review required under the FIFRA, the EPA's ~~OCSPP~~ is concurrently ~~proposing~~ issuing an ~~use rate reduction as part of the~~ EtO PID ~~for~~ that includes use rate reduction for sterilization facilities~~pesticide registration review required under the FIFRA~~. While the ~~OAR~~ proposed CAA NESHAP and ~~OCSPP proposals~~the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

2. ARV At Facilities Where EtO Use Is At Least 10 Tpy

We first note that, unlike the other point sources discussed in this section of the preamble, ARV at facilities where EtO use is at least 10 tpy are currently regulated in subpart O. See 40 CFR 63.362(d). However, we are proposing corrections to this standard because we believe, for the following reasons, that the current standard is inconsistent with the requirements of CAA section 112. The current standard, 40 CFR 63.362(d), is a MACT standard applicable to facilities

Commented [A72]: Why is cost not considered? We don't usually just select the most emission reduction without consideration of other factors.

Commented [A73R72]: Based on the revised cost estimates, Option 1 would incur higher annual costs than Option 2

Commented [A74]: Is there a reason why EPA isn't citing the cost-effectiveness of option 1 here?

Commented [A75R74]: Text has been added stating that we consider both options to be cost effective.

Commented [A76]: Revised to align with earlier that describes EPA's proposed actions under the two statutory authorities.

where EtO use is at least 10 tpy, which include major sources of HAP (59 FR 10597). It requires these 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." While a MACT standard may be expressed in multiple formats so long as they are equivalent, the phrase "whichever is less stringent" in 40 CFR 63.362(d) suggests that these two formats are not equivalent. Further, a MACT standard cannot allow compliance with a less stringent alternative standard, which in this case is the 1 ppmv limit. As explained below, we determined that the equivalent outlet concentration to a 99 percent emission reduction is 0.45 ppmv. To determine the equivalent ARV outlet EtO concentration, the EPA reviewed all available facility information for ARVs at facilities where EtO use is at least 10 tpy. We calculated the outlet EtO concentration that is equivalent to 99 percent removal efficiency for ARVs at facilities where EtO use is at least 10 tpy by first assuming that all of these facilities are achieving the removal efficiency standard. The outlet EtO concentration at each facility is dependent on EtO usage, the portion of EtO usage that is emitted from the ARVs, and the flowrate and temperature of the ARV. We then calculated the ARV outlet EtO concentration at each facility, calculated the average value of the ARV outlet EtO concentrations across all facilities, and rounded to one significant figure, which resulted in 0.45 ppmv.

In light of the above, we are proposing to remove the less stringent 1 ppmv concentration alternative for ARVs at facilities where EtO use is at least 10 tpy. We solicit comment on removing this alternative concentration standard for ARVs at facilities where EtO use is at least 10 tpy (Comment C-107).

3. ARV At Facilities Where EtO Use Is At Least 1 Tpy But Less Than 10 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. There are ~~19~~18 facilities where EtO use is at least 1 tpy but less than 10 tpy, ~~nine~~10 of which have ARVs. Of these ~~nine~~10 facilities, ~~seven~~nine are currently controlling their ARV emissions. Fiv~~eour~~ of these facilities use ~~gas/solid reactors~~catalytic oxidizers, ~~and t~~hree~~wo~~ use ~~catalytic oxidizers~~gas/solid reactors, one uses a wet scrubber, and one uses a gas/solid reactor and catalytic oxidizer in series. Performance tests are available for ARVs at ~~two~~four facilities where EtO use is at least 1 tpy but less than 10 tpy~~,~~. ~~where both~~Two of these facilities use catalytic oxidizers, and two use gas/solid reactors. We reviewed ~~both~~all ~~of~~ these performance tests, and the reported emission reductions ~~were~~ranged from 99.~~2~~1 ~~and~~to 99.99~~8~~ percent.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on the ARVs, and the second option reflects applying a BMP to reduce EtO use per sterilization cycle (*i.e.*, pollution prevention). With respect to the first option, because ~~seven~~nine out of ~~nine~~10 facilities with ARVs and EtO usage at least 1 tpy but less than 10 tpy are already using controls to reduce ARV emissions, we consider emission controls to be generally available for existing ARVs. We considered a standard of 99 percent emission reduction, which is the current subpart O standard for ARVs at facilities where EtO use is at least 10 tpy. We find this standard to be reasonable for existing ARVs at facilities using at least 1 tpy but less than 10 tpy EtO because it is comparable to the emission reductions shown in the performance tests from facilities within this group. The second potential GACT option we considered was the same management practice discussed in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if less EtO is used during the sterilization process, this can lead to a reduction in post-sterilization EtO emissions.

The impacts of the potential GACT options are presented in Table 7.

Table 7. Nationwide Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for Existing ARVs at Facilities Where EtO Use Is at Least 1 TPY but Less Than 10 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~1,306,654~~1,290,957	$~~277,378~~327,530	0.13	$~~2,120,506~~2,597,271
2	BMP (estimated 50 percent emission reduction)	$0	$8~~7~~40,000 (one-time annual cost)[1]	7.2E-2	$~~12,072,751~~11,633,666

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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 proposing Option 1 for the

Commented [A77]: This appears to be an incorrect application of the standards to post sterilization rooms rather than the sterilization chambers themselves. Thus these standards may not have a direct reflection on aeration of devices. Off-gassing of devices are mostly based on the material characteristics.

For example, materials like metals would not off-gas much EtO because they do not absorb much EtO.

Commented [A78R77]: It is EPA's understanding that the amount of EtO used during the sterilization process has an impact on downstream EtO emissions. Therefore, EPA believes that this is an appropriate standard to consider for post-sterilization emissions. Added clarifying text

Commented [A79]: What does this translate into risk reduction? If, broadly, total 23 tpy for the whole sector translates into around 1 excess cancer case per year, a 0.5% reduction in EtO is a negligible risk reduction. Why does this GACT make sense at $2M/ton?

Commented [A80R79]: Because this standard is being proposed under CAA section 112(d), any impacts on risk were not analyzed. In addition, text has been added stating that EPA finds both options to be cost-effective

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 ensure that facilities that are currently reducing emissions from ARVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from ARVs. Third, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We solicit comment on these proposed standards (Comment C-118). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 21.14E-4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C-129).

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and

Commented [A81]: As above, why is cost not considered? Why does EPA presume that facilities that current operate these controls without an EPA requirement will disable them immediately upon promulgation of new rules?

Commented [A82R81]: Text has been added stating that EPA finds both options to be cost-effective and that option 1 would incur fewer annual costs than option 2. EPA does not anticipate that these facilities would remove their ARV emission controls, but we do not want to risk losing the emission reductions that have already occurred.

mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

b. New Sources

For new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, we considered two potential GACT options similar to those evaluated for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described above in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. The impacts of these options, which are presented in Table 8 below, are based on a model plant for new ARVs at a new facility using at least 1 tpy but less than 10 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities where both ARVs are present and EtO use is at least 1 tpy but less than 10 tpy:

- Number of ARVs: four
- Annual EtO use: ~~5~~6 tpy
- Annual operating hours: ~~7~~6,000
- Portion of EtO going to ARVs: 3.2~~4~~4 percent
- ARV flow rate: ~~72~~63 cfs
- Number of unique cycles: three

Table 8. Model Plant Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for New ARVs at Facilities Where EtO Use Is at Least 1 TPY but Less Than 10 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~261,331~~184,422	$~~64,898~~64,530	0.1~~6~~9	$~~404,319~~336,823
2	BMP (estimated 50 percent emission reduction)	$0	$90,000 (one-time annual cost)[1]	~~8~~9.7E-2	$~~1,038,097~~930,144

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We are soliciting comment on this proposed standard (Comment C-1~~3~~0). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 1.~~6~~4E-4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C-1~~4~~1).

Commented [A83]: Flagging relevance of earlier comments related to calculating costs.

Commented [A84R83]: EPA was not made aware of the other costs associated with cycle revalidation and, therefore, did not consider them in the cost analysis. However, EPA plans to solicit comment on any capital and annual costs that have not been accounted for (new comment C-5).

Commented [A85]: Again, why are no other factors considered?

Commented [A86R85]: Text has been added stating that EPA finds both options to be cost-effective and that option 1 would incur fewer annual costs than option 2

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

4. ARV At Facilities Where EtO Use Is Less Than 1 Tpy

a. Existing sources

The current subpart O does not contain emission standards for ARVs at facilities where EtO use is less than 1 tpy. There are ~~17~~20 facilities where EtO use is less than 1 tpy, ~~4~~four of which have ARVs. Of these ~~4~~four facilities, ~~2~~two are currently controlling their ARV emissions. Both of these facilities use catalytic oxidizers. There are no performance tests are available for ARVs at facilities where EtO use is less than 1 tpy.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on the ARVs, and the second option considers applying the BMP described in section III.B.1.a to reduce EtO use per sterilization cycle. With respect to the first option, because control of ARV emissions is common at facilities using 1 or more tpy of EtO as explained above, and ~~2~~two out of four~~4~~ facilities with ARVs and EtO usage less than 1 tpy are already using controls to reduce ARV emissions, we consider emission controls to be generally

available for existing ARVs at facilities with less than 1 tpy EtO usage. We don't have reason to believe that the remaining two facilities cannot use control to reduce their ARV emissions. We considered a standard of 99 percent emission reduction, which is the current subpart O standard for ARVs at facilities where EtO use is at least 10 tpy. While there are no performance test data from the ~~4~~four facilities with ARV and EtO usage less than 1 tpy, available performance data from other facilities with ARVs all indicate that controls can reduce ARV emissions by 99 percent, as described above. The second potential GACT option we considered was the management practice described in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017.

The impacts of the two options are presented in Table 9.

Table 9—Nationwide Emissions Reduction and Cost Impacts of Option Considered Under CAA Section 112(d)(5) for Existing ARVs at Facilities Where EtO Use Is Less Than 1 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~348,441~~184,422	$~~106,758~~72,633	~~3.0~~2.3E-2	$~~3,530,227~~3,094,182
2	BMP (estimated 50 percent emission reduction)	$0	$210,000 (one-time annual cost)[1]	1.~~5~~2E-2	$~~13,654,057~~17,541,860

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, as well as re-submitting to FDA for approval. It

Commented [A87]: Same question as above. 0.03tpy is negligible risk reduction if not associate with a particular facility.

Commented [A88R87]: Because the standard is being proposed under CAA section 112(d), any impacts on risk were not considered. In addition, text has been added stating that EPA finds both options to be cost-effective

Commented [A89]: Flagging relevance of earlier comments related to calculating costs.

Commented [A90R89]: EPA was not made aware of the other costs associated with cycle revalidation and, therefore, did not consider them in the cost analysis. However, EPA plans to solicit comment on any capital and annual costs that have not been accounted for (new comment C-5).

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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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 proposing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from ARVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from ARVs. Third, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing ARVs at facilities where EtO use is less than 1 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We solicit comment on these proposed standards (Comment C-152). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing ARVs at facilities where EtO use is less than 1 tpy and whether 5.61E-6 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing ARVs at facilities where EtO use is less than 1 tpy (Comment C-163).

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and~~

Commented [A91]: Same as above.

Commented [A92R91]: Text has been added stating that EPA finds both options to be cost-effective and that option 1 would incur fewer annual costs than option 2. EPA does not anticipate that these facilities would remove their ARV emission controls, but we do not want to risk losing the emission reductions that have already occurred.

~~OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

b. New Sources

For new ARVs at facilities where EtO use is less than 1 tpy, we considered two potential GACT options similar to those evaluated for existing ARVs at facilities where EtO use is less than 1 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is the BMP described in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. The impacts of these options, which are presented in Table 10 below, are based on a model plant for new ARVs at a new facility using less than 1 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities where both ARVs are present and EtO use is less than 1 tpy EtO:

- Number of ARVs: eight
- Annual EtO use: 0.34 tpy
- Annual operating hours: 6,800
- Portion of EtO going to ARVs: 4 percent

- ARV flow rate: ~~20~~4 cfs
- Number of unique cycles: two

Table 10—Model Plant Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for New ARVs at Facilities Where EtO Use Is Less Than 1 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~87,110~~92,211	$~~33,859~~37,829	1.~~5~~4E-2	$2,5~~07,423~~49,177
2	BMP (estimated 50 percent emission reduction)	$0	$60,000 (one-time annual cost)[1]	~~6.8~~7.5E-3	$8,~~797,654~~005,582

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new ARVs at facilities where EtO use is at less than 1 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We are soliciting comment on this proposed standard for new ARVs at facilities where EtO use is less

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than 1 tpy (Comment C-174). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new ARVs at facilities where EtO use is less than 1 tpy and whether 5.50E-6 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new ARVs at facilities where EtO use is less than 1 tpy (Comment C-185).

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

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5. CEV At Facilities Where EtO Use Is At Least 10 Tpy

On December 6, 1994 (59 FR 62585), we promulgated MACT standards for point sources, including CEVs, at commercial sterilization facilities where EtO use is at least 10 tpy. Emissions from CEVs occur following sterilization, as explained below. After the sterilization cycle in the sterilization chamber is completed and the chamber is vented to the SCV (*i.e.*, after most of the EtO gas is removed and after the inert nitrogen (N_2) washes and air washes are completed), the sterilized product and packaging remain in the sterilization chamber along with a small amount of EtO. CEVs evacuate 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. The CEV reduces the amount of EtO that workers are exposed to while those workers remove sterilized material from the chamber. This contributes to a facility's ability to meet U.S. Occupational Safety and Health Administration workplace exposure standards.[23] Following promulgation of the original rule, the EPA suspended certain compliance deadlines and ultimately removed the standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at commercial sterilization facilities that were initially suspected to be related to the EtO Commercial Sterilization NESHAP requirements. In response, the EPA suspended compliance with the rule for one year pending the investigation of the explosions (62 FR 64736, December 9, 1997). In 1998, the suspension of the compliance dates was extended for the ARVs and the CEVs but not for SCVs (63 FR 66990, December 4, 1998). It was also later determined that EtO emissions from aeration rooms could be safely controlled, and the suspensions for the ARVs NESHAP standards were not further extended past December 2000 (64 FR 67789, December 3, 1999). For CEVs, it was determined that the primary contributing issue leading to the explosions was that EtO concentrations were above the lower explosive limit (LEL) within the CEV gas streams, and the EPA extended the suspension of the rule requirements for CEVs. The LEL is the minimum concentration of a vapor in air below which propagation of a flame does not occur in the presence of an ignition source.[24] An explosion risk occurs if the concentration of EtO exceeds the LEL. The EPA could not conclude, at the time, that the CEVs could be safely controlled, so the standards for CEVs were removed in 2001 (66 FR 55577, November 2, 2001).

[23] 29 CFR 1910.1047.
[24] 29 CFR 1915.11.

Following the removal of the CEV regulatory requirement, many EtO sterilization facilities ceased operating controls for EtO emissions from the CEV. The safety issues that prevented earlier control techniques from being applied were linked to EtO concentrations in the sterilization chamber that exceeded the LEL for EtO. Since the late 1990s and early 2000s, however, facilities have begun revising their operating procedures related to the CEV to address the explosion issue. Specifically, facilities that control their CEV emissions have made process changes to avoid exceeding 10 to 25 percent of the LEL. Such process changes include (1) reducing the EtO concentration in the sterilization chamber before opening the chamber door and (2) using an automated lock on the sterilizer chamber door. As part of these process changes, facilities are using additional final air washes in the sterilization cycle to further reduce the EtO concentration in the sterilization chamber prior to opening the chamber door and venting the CEV to the control system. In addition, the automated lock on the sterilization chamber door prohibits the door from opening until a non-explosive EtO concentration level is achieved in the chamber. Today there are 40 facilities that have CEVs, 3~~3~~4 of which are controlling their CEV emissions. The last known explosion involving CEVs happened in 2004, and safety incidents involving CEVs have not occurred since. For these reasons, we have determined that CEVs can be safely controlled.

The previous CEV standard required facilities where EtO use is at least 10 tpy to either (1) combine their emissions from their CEVs (*i.e.*, to manifold their emissions) and send the combined emissions to a control device that was used to comply with the SCV or ARV standard or (2) achieve 99 percent emission reduction for their CEVs. At the time the rule was promulgated, there were no facilities that were controlling their CEVs with a dedicated control device. Rather, CEVs were routed to a control device used to control emissions from other vents

(59 FR 62585, 62587). Therefore, no facility was demonstrating 99 percent emission reduction for their CEVs. Today, however, multiple facilities, where EtO use is at least 10 tpy, are routing CEV emissions to dedicated control devices and demonstrating the 99 percent emission reduction. There are 34 facilities where EtO use is at least 10 tpy and that also have CEVs, and 3~~0~~1 of these facilities are controlling their CEV emissions. Of these 3~~0~~1 facilities, ~~eleven~~13 use a catalytic oxidizer, ten use a gas/solid reactor, three use an acid-water scrubber, three use an acid-water scrubber and gas/solid reactor in series, and two use a thermal oxidizer~~, and one uses an acid-water scrubber and thermal oxidizer in series~~. There are 12 facilities that have performance and engineering tests available for CEVs; six of these facilities conducted emissions testing when one CEV was venting and most of these contained a single test run for each CEV unit. Of those six facilities, two are controlling their CEV emissions using catalytic oxidizers, two are using gas/solid reactors, one is using an acid-water scrubber, and one is using an acid-water scrubber and gas/solid reactor in series.

Because facilities are currently routing CEVs to dedicated control systems and demonstrating the emission reductions achieved, we have re-calculated the MACT floors for CEVs at facilities where EtO use is at least 10 tpy. We ranked the performance of the CEVs for which data are available. The best performing 12 percent of CEVs for which data are available consists of one CEV that is being controlled by a gas/solid reactor. We then used the upper prediction limit (UPL) approach to develop the MACT floor for existing sources. As mentioned in the EPA's Response to Remand of the Record for Commercial and Industrial Solid Waste Incineration Units, available at *https://www.regulations.gov/document/EPA-HQ-OAR-2003-0119-2707*, the UPL 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. Our practice is to use the UPL's 99th percentile, or UPL 99, as that is the level of emissions 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 UPL 99 value of the existing source MACT floor is 3.2E-4 lb/hr. The UPL 99 EtO concentration that corresponds to this emission rate is 30 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 make-up 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, this 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. In the meantime, consistent with our practice regarding reducing relative measurement imprecision by applying a multiplication factor of 3 to the representative detection level (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,[25] we apply a multiplication factor of 3 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 EtO concentration, EtO emission rate, and volumetric flow rate of the exhaust stream:

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

$$EtO_C = \frac{EtO_{ER} \times 385.1 \times 10^9}{Q \times 44.05}$$

Where, EtO_C is the EtO concentration (in ppbv), EtO_{ER} is the EtO emission rate (in lb/hr), Q is the volumetric flow rate (in dry standard cubic feet per hour), 44.05 is the molecular weight of EtO, and 385.1 is the conversion factor for standard temperature and pressure. Since the MACT floor of 3.2E-4 lb/hr already represents 3 x RDL, there are no more stringent (*i.e.*, beyond-the-floor) options to consider as there would be difficulty demonstrating compliance at any such lower limit. Therefore, the proposed standard for existing CEVs at facilities using at least 10 tpy EtO is 3.2E-4 lb/hr.

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 3.2E-4 lb/hr. 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.*, beyond-the-floor) options. Therefore, the proposed standard for new CEVs at facilities using at least 10 tpy EtO is 3.2E-4 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for both new and existing CEVs at facilities where EtO use is at least 10 tpy require these facilities to limit the EtO emission rate from each new and existing CEV to 3.2E-4 lb/hr. We are soliciting comment on the proposed standards (Comment C-1~~9~~6).

6. CEV At Facilities Where EtO Use Is At Least 1 Tpy But Less Than 10 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. In the December 6, 1994 (59 FR 62585) NESHAP, we promulgated a GACT standard that required facilities, where EtO use is at least 1 tpy but less than 10 tpy, to achieve a maximum chamber EtO concentration limit of 5,300 ppm prior to activation of the chamber exhaust. Safety issues discussed above in section III.B.5 led to the removal of this CEV standard in 2001 (66 FR 55577, November 2, 2001). As explained above, the safety issues appear to have been addressed through process changes for CEV that facilities have since implemented (*i.e.*, reduce the EtO concentration in the sterilization chamber before opening the chamber door and use of an automated lock on the sterilizer chamber door). Also, as explained above, there were no dedicated controls for CEVs at the time the rule was promulgated. Today, however, facilities where EtO use is at least 1 tpy but less than 10 tpy are routing CEV emissions to control devices. Therefore, we are proposing emission CEV standards that will reflect the current status of controls.

There are ~~20~~18 facilities where EtO use is at least 1 tpy but less than 10 tpy, six~~even~~ of which have CEVs. Of these six~~even~~ facilities, ~~four~~three are currently controlling their CEV emissions. ~~Two~~All of these facilities use catalytic oxidizers~~ and two use gas/solid reactors~~. A performance test is available for CEVs at one facility where EtO use is at least 1 tpy but less than 10 tpy, where this facility uses a gas/solid reactor. We reviewed this performance test, and the reported percent reduction was 99.99 percent.

For existing sources, 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 the BMP described in section III.B.1.a, which would require facilities to configure their sterilization cycles and either the Cycle Calculation Approach or the

Bioburden / Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017. With respect to the first option, because ~~4~~3 out of 6~~7~~ facilities (~~over~~ 50 percent) with CEVs and EtO usage of at least 1 tpy but less than 10 tpy are already using controls to reduce CEV emissions, and we have no reason to believe that the other three 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 one unit in the category and the documented control efficiencies for the types of controls used on similar sources, the EPA determined that a control efficiency of 99 percent ~~represents GACT~~is generally available for existing CEVs at facilities using at least 1 tpy but less than 10 tpy of EtO.

Commented [A95]: Is there an explicit request for comment on this? This isn't particularly cost effective, especially without linking these 3 facilities to excessive risk.

Commented [A96R95]: Added to comment C-20 (previously C-17). Text is added later stating that EPA finds this option to be cost-effective

The second potential GACT option we considered was the same management practice discussed in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017.

The impacts of these two options are presented in Table 11.

Table 11—Nationwide Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for Existing CEVs at Facilities Where EtO Use Is at Least 1 TPY but Less Than 10 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~696,882~~829,901	$~~194,590~~245,764	0.11	$~~1,827,367~~2,315,197
2	BMP (estimated 50 percent emission reduction)	$0	$~~66~~570,000 (one-time annual cost)[1]	5.5E-2	$~~12,022,339~~10,383,471

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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 proposing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from CEVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from CEVs. Third, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. Specifically, we are proposing to require these facilities to continuously reduce

Commented [A97]: Same as above. Why is cost not a consideration? Why presume existing controls would be removed?

Commented [A98R97]: Text has been added stating that EPA finds both options to be cost-effective and that option 1 would incur fewer annual costs than option 2. EPA does not anticipate that these facilities would remove their CEV emission controls, but we do not want to risk losing the emission reductions that have already occurred. Because this standard is being proposed under CAA section 112(d)(5), EPA did not consider risk as part of the decision-making.

emissions from existing CEVs by 99 percent. We solicit comment on these proposed standards, including whether uncontrolled sources can use controls to reduce EtO emissions (Comment C-1720). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 9.81.6E-45 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing CEVs at facilities where EtO use is at least 1 tpy but less than 1 tpy (Comment C-2118).

As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

b. New Sources

For new CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, we considered two potential GACT options similar to those evaluated for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, for the same reasons explained above. 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 III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. The impacts of these options, which are presented in Table 12 below, are based on a model plant for new CEVs at a new facility using at least 1 tpy but less than 10 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities using at least 1 tpy but less than 10 tpy EtO:

- Number of CEVs: ~~three~~two
- Annual EtO use: 7 tpy
- Annual operating hours: 6,000
- Portion of EtO going to CEVs: 1 percent
- CEV flow rate: 20 cfs
- Number of unique cycles: three

Table 12—Model Plant Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for New CEVs at Facilities Where EtO Use Is at Least 1 TPY but Less Than 10 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$~~87,110~~92,211	$~~41,848~~46,979	6.9E-2	$6~~03,871~~77,911
2	BMP (estimated 50 percent emission reduction)	$0	$90,000 (one-time annual cost)[1]	3.5E-2	$2,571,429

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness number for Option 2 may seem high, EtO is a highly potent carcinogen, and 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 and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from new CEVs by 99 percent. We are soliciting comment on this proposed standard (Comment C-2219). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 7.81.2E-45 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new CEVs at facilities where EtO use is at least 1 tpy but less than 1 tpy (Comment C-230).

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Commented [A100R99]: Text has been added stating that EPA finds both options to be cost-effective and that option 1 would incur fewer annual costs than option 2

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the

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proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

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7. CEV At Facilities Where EtO Use Is Less Than 1 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for CEVs at facilities where EtO use is less than 1 tpy, nor did the EPA previously promulgate such standards. There are no facilities where EtO use is less than 1 tpy that have CEVs. It is possible, however, for a facility with existing CEVs to lower its EtO use to below 1 tpy as well as for newly constructed facilities to have CEVs with EtO usage below 1 tpy. Therefore, we are proposing CEV standards for facilities with EtO usage below 1 tpy.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on the CEVs, and the second option considers applying the BMP discussed in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. With respect to the first option, any existing CEV at a facility using less than 1 tpy EtO can only be from an existing facility that is currently using more than 1 tpy of EtO but in the future lowers its EtO use to below 1 tpy. As described above in section III.B.5, the proposed MACT standards for CEVs at facilities using at least 10 tpy of EtO reflect the use of emission controls. We also consider emission controls to be generally available for CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, as explained in section III.B.6. We have no reason to believe that these

facilities cannot continue to control their CEV emissions should they ever reduce their EtO usage to below 1 tpy. In light of the above, we consider emission controls to also be generally available for existing CEVs at facilities with EtO usage below 1 tpy. We considered a standard of 99 percent emission reduction, which is the same standard we are proposing for existing CEVs at facilities using at least 1 tpy but less than 10 tpy of EtO. We do not have reason to believe that a facility with existing CEVs cannot meet this standard upon reducing EtO use to less than 1 tpy. The second potential GACT option we considered was the same management practice discussed in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017.

We are proposing Option 1 for the following reasons.[26] First, Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from CEVs using emission controls would continue to do so upon lowering EtO use, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from CEVs. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing CEVs at facilities where EtO use is less than 1 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing CEVs by 99 percent. We solicit comment on these proposed standards (Comment C-2~~1~~). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing CEVs at facilities where EtO use is less than 1 tpy and whether 1~~9~~.6~~8~~E-~~5~~

Commented [A101]: Same comment.

Commented [A102R101]: As stated in the footnote, EPA is unable to perform a cost analysis for these sources because none are currently in operation

[26] Unlike the other section III subsections above, which present costs impacts of the options being considered in a table format, we cannot do the same here because there are no existing CEVs at facilities using less than 1 tpy of EtO.

lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing CEVs at facilities where EtO use is less than 1 tpy (Comment C-252).

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

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b. New Sources

For new CEVs at facilities where EtO use is less than 1 tpy, we considered two potential GACT options similar to those evaluated for existing CEVs at facilities where EtO use is less than 1 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. These assumptions are as follows:

- Number of CEVs: two~~hree~~
- Annual EtO use: 0.99 tpy
- Annual operating hours: 6,000
- Portion of EtO going to CEVs: 1 percent
- CEV flow rate: ~~8~~12 cfs
- Number of unique cycles: three

The second potential GACT option we considered is the BMP described in section III.B.1.a, which would 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 ~~14161:2009~~11138-1:2017. The impacts of these two options are presented in Table 13 below:

Table 13—Model Plant Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(5) for New CEVs at Facilities Where EtO Use Is Less Than 1 TPY

Option	Proposed Standard	~~Equivalent Standard Emission rate (lb/hr)~~	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	~~7.8E-5~~	$~~87,110~~92,211	$~~36,435~~41,502	9.~~7~~5E-3	$~~3,769,401~~4,350,265
2	BMP (estimated 50 percent emission reduction)	~~n/a~~	$0	$90,000 (one-time annual cost)[1]	5.0E-3	$18,181,818

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new CEVs at facilities where EtO

Commented [A103]: Same comment

Commented [A104R103]: Text has been added stating that EPA finds both options to be cost-effective and that option 1 would incur fewer annual costs than option 2

use is at less than 1 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from new CEVs by 99 percent. We are soliciting comment on this proposed standard (Comment C-263). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new CEVs at facilities where EtO use is less than 1 tpy and whether 7.81.2E-45 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new CEVs at facilities where EtO use is less than 1 tpy (Comment C-274).

~~As noted above, the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

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8. Room Air Emission Sources

The current subpart O does not regulate room air emissions. In the Commercial Sterilization Facilities source category, facilities tend to group room air emission sources together to capture and route their emissions to a common control device, rather than to control each room air emission source individually. While multiple room air emission sources at a

facility are often routed to the same control system, sometimes room air emission sources are routed to different control systems, and the configurations vary from facility to facility. The configurations of room air emission sources are the following: all room air emission sources routed together; PoAHSM routed together, and all other room air emission sources routed together; and all point and room air emission sources routed together. In defining affected sources of room air emission sources for purposes of setting standards under CAA section 112, the EPA grouped room air emission sources based on process activities that occur prior to aeration and those process activities that occur after aeration of materials. This approach reflects the most common emission control configuration, which is to capture and route PoAHSM emissions to one control system and to capture and route all other room air emission sources to another control system. While room air emission sources overall tend to have higher flow rates and lower EtO concentrations compared to point sources at EtO commercial sterilization facilities, the EtO concentration and flow rate characteristics of emission streams can differ for streams prior to and after aeration. The difference in flow rates that occur for the pre- and post-aeration room air sources is important, as the post-aeration handling of sterilized material room areas (*e.g.*, quarantine, shipping, and warehouse areas) have the largest floor area and room volumes at the facility and also have the largest flow rates of any of the room air emission sources. We grouped room air emission sources into two groups. Group 1 room air emission sources include indoor EtO storage, EtO dispensing, vacuum pump operation, and pre-aeration handling of sterilized materials. Group 2 room air emission sources include post-aeration handling of sterilized material.

a. Existing Group 1 Room Air Emissions At Major Source Facilities

Commented [A105]: It is not clear how requiring the cycle calculation/bioburden approach relates to room air emissions at facilities.

Commented [A106R105]: Text has been added in sections III.B.8.c and III.B.8.g explaining how a reduction in EtO use leads a reduction in these emissions.

There are 47 facilities that use at least 10 tpy of EtO and have Group 1 room air emissions. Based on our review of available state and local permits, as well as emissions data, we believe that all of these facilities are synthetic area sources. Of these, 24 facilities are controlling all their Group 1 emissions, while 2 are partially controlling their Group 1 room air emissions. Of the 24 facilities that are controlling all their Group 1 room air emissions, 17 use gas/solid reactors, eight use catalytic oxidizers, and five use acid-water scrubbers. Note that this does not sum to 26 because some facilities use different types of control systems for reducing Group 1 room air emissions. Of the two facilities that partially control their Group 1 room air emissions, both use gas/solid reactors.

We have calculated the MACT floor for existing Group 1 room air emissions at major source facilities. CAA section 112(d)(3)(A) requires that the MACT floor be based on the best performing 12 percent of existing sources for which data are available. We ranked the performance of the facilities with Group 1 room air emissions for which data are available. There are only three performance tests that are currently available, so the best performing 12 percent of exiting sources for which data are available consists of Group 1 room air emissions at one facility that is controlling such emissions with a gas/solid reactor. That facility reported an emission rate of 4.8E-4 lb/hr. We then used the UPL to develop the MACT floor for existing sources. The UPL 99 value of the existing source MACT floor is 7.7E-4 lb/hr. The EtO concentration (UPL 99 value) that corresponds to this emission rate is 20 ppbv. Since this is below 3 x RDL, we adjusted the MACT floor by determining the emission rate using 30 ppbv and the average volumetric flow rate of the Group 1 room air emissions stream at the facility, which is 6,202 dry standard cubic feet per minute (dscfm). This results in an adjusted MACT floor of 1.3E-3 lb/hr. Since this represents 3 x RDL, there are no more stringent (*i.e.*, beyond-the-

floor) options to consider as there would be difficulty demonstrating compliance with a limit below 3 x RDL. Therefore, the proposed MACT standard for existing Group 1 room air emissions at major source facilities is 1.3E-3 lb/hr.

The proposed standards are based on complete capture of the emission from Group 1 room air emissions, which are then routed to an APCD. In recent years, state and local agencies have required EtO commercial sterilization facilities to capture room air emissions and route the emissions to an APCD. EtO commercial sterilization facilities in Illinois, Georgia, California, North Carolina, and other states have installed PTEs and add-on control systems to reduce releases of room air emissions. At most of these facilities, the PTEs meet the requirements of EPA Method 204[27], and the enclosure is monitored continuously to demonstrate capture efficiency. EPA Method 204 (40 CFR part 51, appendix M) was promulgated on June 16, 1997 (62 FR 32500) as part of a suite of methods to support State Implementation Plans for ozone for determining capture efficiency, for the purpose of reducing volatile organic compounds. Since this time, EPA Method 204 has been incorporated into a number of NESHAP (*e.g.*, Surface Coating NESHAPs) for demonstrating compliance with PTE standards. EPA Method 204 provides the design criteria for PTEs, including (1) criteria for the proximity of the emitting points to the natural draft openings (NDOs), (2) location of the exhaust hoods, (3) total area of all NDOs, (4) average facial velocity through the NDOs, (5) and requirements for access doors and windows that are not considered NDOs, to be closed. When all these criteria are met and verified, an affected source can assume 100 percent capture. Additionally, EPA Method 204 includes requirements to route the captured and contained EtO-laden gas for delivery to a control

[27] 40 CFR part 51, appendix M, EPA Method 204— Criteria and Verification of a Permanent or Temporary Total Enclosure. U.S. EPA.

system. EPA Method 204 does not include procedures for demonstrating continuous compliance, however these procedures and associated standards may be defined in the affected rule and/or state permit condition. An example of this requirement can be found in 40 CFR 63.5725(f) of the NESHAP for Boat Manufacturing (40 CFR part 63, subpart VVVV), where we require either collection of the facial velocity of air through all NDOs or the pressure drop across the enclosure. The Boat Manufacturing NESHAP also requires data on facial velocity and/or pressure drop at 3-hour block averages consistent with the requirements in Method 204. It also requires maintaining the direction of air flow into the enclosure at all times. These continuous compliance requirements are also consistent with what has been applied to many of the commercial sterilizers that have installed PTEs, through permit conditions. We are therefore proposing, as a compliance assurance measure, that each major source facility operate all areas with sources of Group 1 room air emissions in accordance with the PTE requirements of Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C-285).

b. New Group 1 Room Air Emissions At Major Source Facilities

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 1.3E-3 lb/hr. 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.*, beyond-the-floor) options. Therefore, the proposed standard for new Group 1 room air emissions at major source facilities is 1.3E-3 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for Group 1 room air emissions at major source facilities are to require these facilities to limit the Group 1 room air EtO emission rate to 1.3E-3 lb/hr. Also, for the reasons explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 1 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C-296).

c. Existing Group 1 Room Air Emissions At Area Source Facilities

A description of existing Group 1 room air emissions at synthetic area source facilities is available in section III.B.8.a of this preamble. Of these, 24 facilities are controlling all of their Group 1 room air emissions. In addition, there are 389 area source facilities where EtO use is less than 10 tpy, 27 of which have Group 1 room air emissions. Of these, three facilities are controlling all their Group 1 emissions, while ~~one is~~three are partially controlling its Group 1 room air emissions. Of the three facilities that are controlling all of their Group 1 room air emissions, two use catalytic oxidizers, and one uses a gas/solid reactor and catalytic oxidizer in series. ~~The~~Of the ~~one~~three facilities~~y~~ that partially control~~s its~~their Group 1 room air emissions, two use~~s both a~~ gas/solid reactors, one uses catalytic oxidizer, and one uses ~~as well as~~ a wet scrubber and gas/solid reactor in series. Note that this does not sum to three because one facility uses different types of control systems for reducing Group 1 room air emissions Performance tests are available for Group 1 room air emissions at three synthetic area source facilities, all of

which use gas/solid reactors. We reviewed these performance tests, and the reported emission rates ranged from 2.0E-5 lb/hr to 4.8E-4 lb/hr.[28] As explained above in section III.B.8.a, the proposed MACT standard for existing Group 1 room air emissions at major source facilities was based on the performance test of one of these three facilities as that was the only facility within "the best performing 12 percent of the existing sources (for which the Administrator has emission information)" (CAA section 112(d)(3)(A)). That facility reported an emission rate of 4.8E-4 lb/hr.

Commented [A107]: Are these performance tests possible only at PTE facilities? Given that PTE requires facility redesign, can existing facilities be subcategorized based on the ability to conduct Method 204?

Commented [A108R107]: A performance test could be possible at a non-PTE facility, but the facility would need to know what the capture efficiency is and factor that into any emission calculations. It is EPA's understanding that all facilities can conduct Method 204, so we do not see a basis for subcategorizing based on a facility's ability to conduct Method 204.

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 reflects applying a BMP to reduce EtO use per sterilization cycle (*i.e.*, pollution prevention). With respect to the first option, ~~27~~32 out of 74 area source facilities with Group 1 room air emissions are already using controls to reduce those emissions. We considered a standard of 1.3E-3 lb/hr, which is the MACT standard for Group 1 room air emissions at major source facilities. We find this standard to be reasonable for existing Group 1 room air emissions at area source facilities because it is within an order of magnitude of the Group 1 room air emission reductions shown in the 3-run performance test for an area source facility (4.8E-4 lb/hr). The second potential GACT option we considered was the same management practice discussed in section III.B.1.a, which would 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

[28] Two of these performance tests consist of one run each, and the other consists of three runs. Performance tests that consist of only one run tend to be less reliable than those with multiple runs because single run tests do not provide any information about source variability. The emission rate for the three-run test shows the reported rate that has not undergone a UPL or 3 x RDL adjustment.

~~14161:2009~~11138-1:2017. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if less EtO is used during the sterilization process, this can lead to a reduction in post-sterilization EtO emissions, including those from pre-aeration handling of sterilized material. In addition, a reduction in EtO use can result in less EtO needing to be stored at the facility, as well as less EtO throughput in dispensing equipment and vacuum pumps. This would, in turn, lead to a reduction in EtO emissions.

The impacts of these options are presented in Table 14.

Table 14. 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	Emission rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	1.3E-3	$~~91,423,827~~100,437,729	$~~11,199,301~~14,719,405	5.~~0~~4	$2,~~243,207~~733,571
2	BMP (estimated 50 percent reduction)	$0	$12,~~60~~570,000[1] (one-time annual cost	2.~~6~~8	$4,~~803,802~~445,789

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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 proposing Option 1 for the

following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from Group 1 room air emissions using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from Group 1 room air emissions. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing Group 1 room air emissions at area source facilities. Specifically, we are proposing to require these facilities to limit the Group 1 EtO emission rate to 1.3E-3 lb/hr. Also, for the reasons explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 1 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C-3027).

~~We note that the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

d. New Group 1 Room Air Emissions At Area Source Facilities.

Commented [A109]: Again, same comment. This provision drives a lot of the costs of the whole rulemaking. At ~$11M annual costs and ~$8M/annualized capital costs for a reduction of around 1/5 of total emissions, this translates into around 1 cancer case avoided every five years. This places no value on the cost to the health care system of higher medical device costs and disruption to the medical device supply chain.

Commented [A110R109]: Text has been added stating that EPA finds both options to be cost-effective. EPA does not anticipate that these facilities would remove their Group 1 room air emission controls, but we do not want to risk losing the emission reductions that have already occurred. Because this standard is being proposed under CAA section 112(d)(5), EPA did not consider risk as part of the decision-making.

For new Group 1 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 rate of 1.3E-3 lb/hr. The second potential GACT option we considered (Option 2) is a BMP that would 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 ~~14161:2009~~11138-1:2017. The impacts of these options, which are presented in Table 15 below, are based on a model plant for new Group 1 room air emissions at an area source facility with the following assumptions reflecting the average of each of the parameters at area source facilities with new Group 1 room air emissions:

- EtO use: 90 tpy
- Annual operating hours: ~~7~~8,000
- Portion of EtO going to ~~CEVs~~Group 1 room air emissions: 0.4 percent
- ~~CEV~~Group 1 room air emissions flow rate: ~~4~~300 cfs
- Number of unique cycles: six

Table 15. 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	Emission standard rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	1.3E-3	$1,~~045,323~~106,534	$~~157,279~~223,464	0.3~~56~~	$~~442,479~~629,830
2	BMP (estimated 50 percent emission reduction)	$0	$180,000[1] (one-time annual cost)	0.18	$1,000,000

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 proposing to establish standards for new Group 1 room air emissions at area source facilities. Specifically, we are proposing to require these facilities to limit the Group 1 room air EtO emission rate to 1.3E-3 lb/hr. Also, as explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 1 room air emissions in accordance with the PTE requirements of Method 204 of appendix M to 40 CFR part 51. We are soliciting comment on this proposed standard (Comment C-31~~28~~).

~~We note that the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is

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concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

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e. Existing Group 2 Room Air Emissions At Major Source Facilities

There are 479 facilities where EtO use is at least 10 tpy of EtO, all of which are both subject to subpart O and have Group 2 room air emissions. Based on our review of available state and local permits, as well as emissions data, we believe that all ~~of~~ these facilities are synthetic area sources. 254 of these facilities are controlling all their Group 2 room air emissions, and one facility is partially controlling its Group 2 room air emission. Of these 254 facilities, ~~19~~20 use gas/solid reactors, ~~four~~two use catalytic oxidizers, one uses acid-water scrubbers, and one uses a catalytic oxidizer and thermal oxidizer in series. The one facility that is partially controlling its room air emissions uses a gas/solid reactor

We have 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. There are only three performance tests that are currently available, so the best performing 12 percent of facilities for which data are available consists of one facility that is controlling its Group 2 room air emissions with a gas/solid reactor. That facility reported an emission rate of 8.3E-4 lb/hr. We then used the UPL to develop the MACT floor for existing sources. The UPL 99 value of the existing source MACT floor is 9.5E-4 lb/hr. The EtO concentration (UPL 99 value) that corresponds to this emission rate is 10 ppbv. Since this is below 3 x RDL, we adjusted the MACT floor by determining the emission rate using 30 ppbv and the average flow rate of the Group 2 room air emissions stream at the facility, which is

13,711 dscfm. This results in an adjusted MACT floor of 2.8E-3 lb/hr. Since this represents 3 x RDL, there are no more stringent (*i.e.*, beyond-the-floor) options to consider as there would be difficulty demonstrating compliance at any such lower limit. Therefore, the proposed standard for existing Group 2 room air emissions at major source facilities is 2.8E-3 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for existing Group 2 room air emissions at major source facilities are to require these facilities to limit the Group 2 room air EtO emission rate to 2.8E-3 lb/hr.[29] Also, for the reasons explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 2 room air emissions in accordance with the PTE requirements of Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C-32~~29~~).

f. New Group 2 Room Air Emissions At Major Source Facilities

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 2.8E-3 lb/hr. As explained above, because this emission limit represents the lowest level at which compliance can be demonstrated, the EPA did not consider

[29] While data from synthetic area sources are included with data from major sources in determining the MACT floor as described above, synthetic area sources, which limit their potential to emit HAP below the major source threshold, are not major sources and therefore not subject to major source standards under section 112.

more stringent (*i.e.*, beyond-the-floor) options. Therefore, the proposed standard for new Group 2 room air emissions at major source facilities is 2.8E-3 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for new Group 2 room air emissions at major source facilities are to require these facilities to limit the Group 2 room air EtO emission rate to 2.8E-3 lb/hr. as Also, as explained in III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 2 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C–3~~0~~).

g. Existing Group 2 Room Air Emissions At Area Source Facilities

A description of synthetic area sources with existing Group 2 room air emissions is available in section III.B.8.c of this preamble. Of these, 25 facilities are controlling all of their Group 1 room air emissions. In addition, there are 3~~7~~9 facilities where EtO use is less than 10 tpy that are not major sources, ~~3~~8all of which have Group 2 room air emissions. Two of these facilities are controlling all their Group 2 room air emissions, while one is partially controlling its Group 2 room air emissions. Of the 2 facilities that are controlling all of their Group 2 room air emissions, one uses a catalytic oxidizer, and one uses a gas/solid reactor. The one facility that partially controls its Group 2 room air emissions uses both a wet scrubber and gas/solid reactor in series, as well as a stand-alone gas/solid reactor. Performance tests are available for Group 2 room air emissions at three synthetic area source facilities, all of which use gas/solid reactors. We reviewed these performance tests, and the reported emission rates ranged from 5.0E-5 lb/hr

to 1.8E-2 lb/hr.[30] As explained above in section III.B.8.e, the proposed MACT standard for existing Group 2 room air emissions at major source facilities was based on the performance test of one of these three facilities as that was the only facility within "the best performing 12 percent of the existing sources (for which the Administrator has emission information" (CAA section 112(d)(3)(A)). That facility reported an emission rate of 8.3E-4 lb/hr.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on Group 2 room air emissions, and the second option that reflects applying a BMP to reduce EtO use per sterilization cycle (*i.e.*, pollution prevention). With respect to the first option, 2~~7~~8 out of 8~~4~~5 area source facilities subject to subpart O are using controls to reduce Group 2 room air emissions. We considered a standard of 2.8E-3 lb/hr (Option 1), which is the MACT standard for Group 2 room air emissions at major source facilities; as discussed above, the performance test that was used to generate the MACT floor was conducted at a synthetic area source facility This limit is within an order of magnitude of the Group 2 room air emission reductions shown in the 3-run performance test for an area source facility (8.3E-4 lb/hr). The second potential GACT option we considered (Option 2) was the same management practice discussed in section III.B.1.a, which would 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. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete.

[30] Two of these performance tests consist of one run each, and the other consists of three runs. Performance tests that consist of only one run tend to be less reliable than those with multiple runs because single run tests do not provide any information about source variability. The emission rate for the three-run test shows the reported rate that has not undergone a UPL or 3 x RDL adjustment.

Therefore, if less EtO is used during the sterilization process, this can lead to a reduction in post-sterilization EtO emissions, including Group 2 room air emissions.

The impacts of these options are presented in Table 16.

Table 16. 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	Emission standard rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	2.8E-3	$2~~05,937,778~~10,007,878	$2~~4,278,534~~7,719,141	1.4	$1~~7,924,564~~9,420,188
2	BMP	$0	$~~17,645,303~~13,050,000[1]	0.7~~84~~	$1~~7,645,303~~6,790,792

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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. 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 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 five percent.

Commented [A111]: This doesn't look like it is adjusted based on tons per year as it is the same as the number in total annual costs.

Commented [A112R111]: The annual costs were incorrect and have been updated accordingly

According to our estimates, the annual cost of the emission control option for most of the affected sources discussed above is well below five percent.[31] However, reducing existing Group 2 room air emissions at area source facilities using emission control devices (Option 1), would significantly impact ~~six~~ several companies operating 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 five percent of revenue for these companies ~~Professional Contract Sterilization, Inc., Steri-Tech, Inc. (STI), Lemco Enterprises, Inc. (Lemco), Cosmed Group, Inc. (Cosmed), Midwest Sterilization Corporation (MSC), and Andersen Scientific~~. 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, ~~STI, Lemco, Cosmed, and MSC operate~~EPA is aware of other facilities that, according to ~~the~~ FDA, could impact the availability of certain medical devices, including those that are (1) experiencing or at risk of experiencing a shortage, (2) in high demand as a result of the COVID-19 pandemic, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 2 for existing Group 2 room air emissions at area source facilities. Specifically, we are proposing to require these facilities follow either the Cycle Calculation Approach or the Bioburden / Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017. We solicit comment on these proposed standards (Comment C-3~~4~~1).

[31] 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.

Commented [A113]: See previous comment. For the same reasons noted above, we strongly advise against specifically naming these companies as it relates to their susceptibility to device shortages.

We are concerned that, as drafted, the text could be interpreted to suggest that FDA shared specific, sensitive information with EPA about these firms, which they did not. Naming facilities is not needed to make EPA's point.

Commented [A114R113]: EPA will not name companies in this preamble

Commented [A115]: This category appears to include more than the six facilities where cost to sales ratio is considered problematic by EPA and, consequently, the requirement to use the Cycle Calculation Approach seems overinclusive and could affect their competitiveness with firms that are permitted to use the manufacturer's validated approach. In addition, as noted in the comments above regarding the half cycle approach, requiring a specific approach in the rule does not allow flexibility for current and future alternatives that might achieve the same or similar results. The language in the codified appears to be inconsistent with the Table in the codified, with the former reflecting some flexibility in 63.366(b)(9).

Commented [A116R115]: This source is currently unregulated, and EPA believes that it needs to set a standard for this source. However, as noted in the text, Option 1 is projected to be more economically burdensome, so Option 2 is selected. However, EPA acknowledges the commenter's previously noted concerns about our proposed BMP, and we have included a solicitation of comment on the true impacts of the BMP, as well as other potential BMPs and their impacts (new comments C-5 thru C-7). EPA also notes that, as part of this BMP, facilities could apply for an AMEL if they can demonstrate that it can achieve EtO emission reductions than are at least equivalent to those of the BMP.

The flexibilities in new 63.366(b)(9) only apply to reporting frequency, not the standards themselves.

h. New Group 2 Room Air Emissions At Area Source Facilities.

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 2 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option we considered (Option 1) would require achieving an emission rate of 2.8E-3 lb/hr. The second potential GACT option we considered (Option 2) is a BMP that would 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 ~~14161:2009~~11138-1:2017. The impacts of these options, which are presented in Table 17 below, are based on a model plant for new Group 2 room air emissions at an area source facility with the following assumptions reflecting the average of each of the parameters at area source facilities:

- EtO use: 80 tpy
- Annual operating hours: 7,000
- Portion of EtO going to ~~CEVs~~Group 2 room air emissions: 0.2 percent
- ~~CEV~~Group 2 room air emissions flow rate: 800 cfs
- Number of unique cycles: five

Table 17. 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	Emission standard rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	2.8E-3	$2,~~003,536~~120,857	$~~267,677~~378,546	4.3E-2	$~~6,237,484~~8,820,981
2	BMP (estimated 50 percent emission reduction)	$0	$150,000[1] (one-time annual cost)	2.3E-2	$6,562,500

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, 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 these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and 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 proposing Option 1 for the following reasons. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2. Also, unlike Option 1 for existing Group 2 room air emissions at area source facilities, companies constructing new source(s) of Group 2 room air emissions in the future can plan and design operations to avoid significant impact (or choose not to build). Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new Group 2 room air emissions at area source facilities. Specifically, we are proposing to require these facilities to limit the Group 2 room air EtO emission rate to 2.8E-3 lb/hr.

Commented [A117]: Or choose to build separate facilities that are not subject to this or other NESHAPs.

Commented [A118R117]: Correct. As noted in the RIA, while the EPA is not proposing requirements for stand-alone warehouses as part of this action, we do plans to evaluate the data received and determine what requirements these facilities should be subject to, if any

~~We note that the EPA's OCSPP is concurrently proposing use rate reduction as part of the EtO PID for pesticide registration review required under the FIFRA. While the OAR and OCSPP proposals are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.~~As noted above, as part of the pesticide registration review required under the FIFRA, the EPA is concurrently issuing a PID that includes use rate reduction sterilization facilities. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility.

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As explained above in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 2 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We are soliciting comment on this proposed standard (Comment C-3~~5~~2).

9. Summary of Baseline Standards

Pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), we are proposing standards for a number of currently unregulated EtO emission sources at commercial sterilizes.[32] As mentioned earlier and described in more detail below in sections III.C and III.D, the EPA conducted a second section 112(f)(2) analysis for the source category. For that analysis, the EPA conducted a baseline risk assessment that took into account the current standards in subpart O as

[32] In addition, we are proposing a correction to the current standard under 112(d) for ARV at facilities where~~ith~~ EtO usa~~g~~e ≥is at least 10 tpy.

well as implementation of the proposed 112(d) standards for the currently unregulated emission sources discussed here in section III.B. Table 18 summarizes these standards.

Table 18. Summary of Standards After Proposed 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	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)
	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	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)
	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	
CEV	Existing	At least 10 tpy	3.2E-4 lb/hr	112(d)(2) and (3)
		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	New	At least 10 tpy	3.2E-4 lb/hr	112(d)(2) and (3)
		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)
Group 1 room air emissions at major sources	Existing and new	N/A	1.3E-3 lb/hr	112(d)(2) and (3)

Group 1 room air emissions at area sources	Existing and new	N/A	1.3E-3 lb/hr	112(d)(5)
Group 2 room air emissions at major sources	Existing and new	N/A	2.8E-3 lb/hr	112(d)(2) and (3)
Group 2 room air emissions at area sources	Existing	N/A	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 ~~14161:2009~~11138-1:2017 (~~September 15~~March~~,~~ 201~~709~~)	112(d)(5)
	New	N/A	2.8E-3 lb/hr	112(d)(5)

Commented [A119]: There does not seem to be an option here. This approach is of concern because of the reasons articulated earlier in the document.

Commented [A120R119]: As part of this BMP, facilities could apply for an AMEL if they can demonstrate that it can achieve EtO emission reductions than are at least equivalent to those of the BMP. EPA acknowledges the commenter's previously noted concerns about our proposed BMP, and we have included a solicitation of comment on the true impacts of the BMP, as well as other potential BMPs and their impacts (new comments C-5 thru C-7).

C. What are the results of the risk assessment and analyses?

We conducted a risk assessment for the Commercial Sterilization Facilities source category using the risk assessment methods described in section II.F of this preamble. We present results of the risk assessment briefly below and in more detail in the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule*, which is available in Docket ID No. EPA-HQ-OAR-2019-0178. The risk assessment was conducted on the 86 facilities in the commercial sterilization source category that are currently 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 is a lack of certainty over whether these are 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 have low risk.

All baseline risk results are developed using the best estimates of actual emissions and release parameters summarized in section II.F.1. Because allowable emissions and risks would be higher than actual emissions in this case, and in light of our finding that risks are unacceptable based on actual emissions, as discussed in section III.D.2 of this preamble, a separate assessment of allowable emissions appears unnecessary.

The results of the baseline chronic inhalation cancer risk assessment using actual emissions are shown in Table 19. The MIR is estimated to be 6,000-in-1 million, driven by EtO from Group 2 room air emissions (70 percent) and sterilization chamber vents (28 percent). The total estimated cancer incidence is 0.9 excess cancer case per year, or one cancer case every 13 months. The estimated population exposed to cancer risks between 1,000-in-1 million and the maximum risk level of 6,000-in-1 million is 900 people. The total population exposed to cancer risks greater than 100-in-1 million is 18,000 people. The population exposed to cancer risks greater than or equal to 1-in-1 million living within 50 km of a facility is approximately 8.3 million (see Table 19 of this preamble). Of the 97 facilities that were assessed, 16 facilities have an estimated maximum cancer risk greater than 100-in-1 million and six of those facilities have an estimated maximum cancer risk greater than 1,000-in-1 million. The maximum chronic noncancer TOSHI for the source category is estimated to be 0.04 (for ~~the~~ neurological ~~target organ~~effects). The acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.002 for PpO based on the REL acute health reference value. For EtO, the maximum HQ is 0.0005 based on the AEGL-2 acute health reference value.[33]

Commented [A121]: Clarification

Table 19. Sterilization Facilities Source Category Inhalation Risk Assessment Results Based on Actual Emissions

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

	Maximum Individual Cancer Risk (in 1 million)	Estimated Population at Increased Risk of Cancer > 100-in-1 Million	Estimated Population at Increased Risk of Cancer ≥ 1-in-1 Million	Estimated Annual Cancer Incidence (cases per year)	Maximum Chronic Noncancer TOSHI[1]	Maximum Screening Acute Noncancer HQ
Source Category	6,000	18,000	8,300,000	0.9	0.04 (Neurological)	0.002 (REL)

[1] The TOSHI is the sum of the chronic noncancer HQs for substances that affect the same target organ or organ system.

An assessment of facility-wide (or "whole facility") risks was performed to characterize the source category risk in the context of whole facility risks. Non-source category emissions were estimated using the EPA's 2017 NEI as described in section II.F.6. The facility-wide assessment showed that risks from non-source category emission sources were minimal. The MIR, populations above cancer risk thresholds, incidence, and maximum chronic noncancer TOSHI in the facility-wide risk assessment were the same as the source category risk assessment (Table 19). We also examined areas surrounding sterilization facilities for other significant emission sources of HAP. That analysis determined that the vast majority of sterilization facilities are not located nearby other significant sources of HAP as most are isolated or located within office parks.[34]

We then repeated our risk assessment for the Commercial Sterilization Facilities source category assuming emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as described above and summarized in Table 18, with the exception of the proposed Group 1 room air emission standards. Instead, the risk assessment was based on requiring BMP (Option 2) under section 112(d)(5) for Group 1 room air emissions, which we had initially considered proposing instead of an emission limit reflecting use of control devices (Option 1); however,

[34] EPA Air Toxics Screening Assessment (AirToxScreen). Available at: *https://www.epa.gov/AirToxScreen*.

following our risk assessment, we continued to review our regulatory options and determined that the emission limit reflecting use of control devices (Option 1) is a more appropriate option than the BMP for Group 1 room air emissions for the reason discussed in section III.B.8. We are therefore proposing such emission limit instead of the BMP under section 112(d)(5). While we have not reassessed risks based on this one change in a proposed section 112(d)(5) standard, we do not expect this change to affect the MIR for the source category in this scenario, as it was driven by Group 2 room air emissions and sterilization chamber vent emissions, although we anticipate that one or more of the other results presented in Table 20 may be lower (*e.g.*, populations at various risk thresholds and cancer incidence).

In the scenario assuming emission reductions under the proposed CAA sections 112(d)(2), 112(d)(3), and 112(d)(5),[35] the MIR is estimated to be 3,000-in-1 million driven by EtO from Group 2 room air emissions (70 percent) and sterilization chamber vents (28 percent). The total estimated cancer incidence is 0.3 excess cancer case per year, or one cancer case every 3.3 years. The estimated population exposed to cancer risks between 1,000-in-1 million and the maximum risk level of 3,000-in-1 million is 200 people, down from 900 people in the baseline scenario. The total population exposed to cancer risks greater than 100-in-1 million is 2,350 people, down from 18,000 people in the baseline scenario. The population exposed to cancer risks greater than or equal to 1-in-1 million living within 50 km of a facility is approximately 3.2 million, down from 8.3 million. Of the 97 facilities that were assessed, 13 facilities have an estimated maximum cancer risk greater than 100-in-1 million (down from 16) and two of those

35 As explained immediately above, the risk assessment assumed emission reductions from the BMP option (Option 2) for Group 1 room air emissions, and that based on further analysis following the risk assessment, we are proposing the emission limit reflecting use of control devices (Option 1) instead of the BMP option assumed in the risk assessment.

Commented [A122]: The reason discussed above was almost entirely that it reduce emissions more. That doesn't explain why it's more appropriate or what risk reduction would have been forgone.

Commented [A123R122]: In addition to higher emission reductions, EPA proposed Option 1 because it would ensure that facilities that are currently reducing emissions from Group 1 room air emissions using emission controls would continue to do so. Because the standard is being proposed under CAA section 112(d)(5), EPA did not consider risk as part of the decision-making.

Commented [A124]: Is this assessment going to be conducted?

Commented [A125R124]: Yes, EPA will conduct this assessment between proposal and promulgation of the final rule.

Commented [A126]: If it doesn't affect MIR or risks, why not adopt the cheaper option?

Commented [A127R126]: As previously stated, EPA proposed Option 1 because it would achieve higher emission reductions and because it would ensure that facilities that are currently reducing emissions from Group 1 room air emissions using emission controls would continue to do so. Because the standard is being proposed under CAA section 112(d)(5), EPA did not consider risk as part of the decision-making.

Commented [A128]: Again, marginal changes to risk do not justify such significant compliance costs.

Commented [A129R128]: In addition to higher emission reductions, EPA proposed Option 1 because it would ensure that facilities that are currently reducing emissions from Group 1 room air emissions using emission controls would continue to do so. Because the standard is being proposed under CAA section 112(d)(5), EPA did not consider risk as part of the decision-making.

facilities have an estimated maximum cancer risk greater than 1000-in-1 million (down from six). The maximum chronic noncancer TOSHI for the source category is estimated to be 0.003 for the neurological target organ. The acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.001 for propylene oxide (PpO) based on the REL acute health reference value. For EtO, the maximum HQ is 0.0003 based on the AEGL 2 acute health reference value[36].

Table 20. Sterilization Facilities Source Category Inhalation Risk Assessment Results Based on Actual Emissions After Emission Reductions Under CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5)

	Maximum Individual Cancer Risk (in 1 million)	Estimated Population at Increased Risk of Cancer > 100-in-1 Million	Estimated Population at Increased Risk of Cancer ≥ 1-in-1 Million	Estimated Annual Cancer Incidence (cases per year)	Maximum Chronic Noncancer TOSHI[1]	Maximum Screening Acute Noncancer HQ
Source Category	3,000	2,350[2]	3,200,000[2]	0.3[2]	0.003 (Neurological)	0.001 (REL)

[1] The TOSHI is the sum of the chronic noncancer HQs for substances that affect the same target organ or organ system.
[2] These values may be lower due to the proposed Group 1 room air emission standards that were not included in the risk assessment.

D. What Are Our Proposed Decisions Regarding Risk Acceptability, Ample Margin Of Safety, And Adverse Environmental Effect?

As noted in section II.A of this preamble, the EPA sets 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 limit on MIR of approximately 1-in-10 thousand" (54 FR 38045, September 14, 1989). For this proposal, the EPA estimated baseline risks based on actual

[36] RELs, ERPG-1, and AEGL-1 acute health reference values are not available for ethylene oxide.

emissions from the Commercial Sterilization Facilities source category, as well as emission reductions from the proposed standards for the currently unregulated emissions sources under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as described above and summarized in Table 18. For the purposes of risk acceptability, we considered the risks after the emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5).

1. Determination of Risk Acceptability After Emission Reductions Under CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5)

As noted in section II.D of this preamble, we weigh a wide range of health risk measures and factors in our risk acceptability determination, including the cancer MIR, the number of persons in various cancer and noncancer risk ranges, cancer incidence, the maximum noncancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and risk estimation uncertainties (54 FR 38044, September 14, 1989).

For the Commercial Sterilization Facilities source category, the risk results indicate that the cancer risks to the individual most exposed are well above 100-in-1 million, which is the presumptive upper end of the range of acceptability. The estimated inhalation cancer risk to the individual most exposed to emissions from the source category is 3,000-in-1 million after emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). The estimated incidence of cancer due to inhalation exposures is 0.3 excess cancer case per year. The population estimated to be exposed to cancer risks greater than 100-in-1 million is approximately 2,350, and the population estimated to be exposed to cancer risks greater than or equal to 1-in-1 million is approximately 3.2 million. The estimated maximum chronic noncancer TOSHI from inhalation exposure for this source category is 0.003 (for ~~the~~ neurological ~~target organ~~effects), indicating low likelihood of adverse noncancer effects from long-term inhalation exposures. The

acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.001. Therefore, we conclude that adverse effects from acute exposure to emissions from this category are not anticipated.

Considering the health risk information and factors discussed above, particularly the high MIR for the source category, we propose to find that the risks from the Commercial Sterilization Facilities source category, taking into account emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as described above and summarized in Table 18, are unacceptable. As noted in section II.A of this preamble, when risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. Therefore, pursuant to CAA section 112(f)(2), we are proposing certain standards that are more protective than those shown in Table 18 based on our proposed finding that risks from this source category remain unacceptable even after the application of revised standards under section 112(d).

a. Available Controls to Address Risks

We evaluated several control options for reducing risks. Based on the results of the risk assessment, we have identified SCVs and Group 2 room air emissions as the primary contributors to risks. Therefore, we focused our analysis of control options on SCVs and Group 2 room air emissions to reduce risk.

As mentioned above, the MIR for the source category is estimated to be 3,000-in-1 million, driven by EtO from one facility. Results from our risk assessment indicate that, for that facility with the source category MIR of 3,000-in-1 million, 28 percent of the risk is from SCVs. The remaining risk is mostly from Group 2 room air emissions (70 percent).

This facility is the only one within the source category where the emissions from SCVs contribute to the facility's MIR exceeding 100-in-1 million, and this facility currently uses 44 tpy of EtO. The current subpart O requires 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 proposed standard under CAA section 112(d)(5) for the currently unregulated SCVs, which are those facilities where EtO use is less than 1 tpy (see section III.B.1.a).

Our data do not identify any add-on controls beyond those we have already considered when promulgating the SCV standards in subpart O or proposing the standards for the currently unregulated SCV standards in section II.B.1. However, our evaluation of the performance data shows that these controls can achieve greater than 99 percent reduction. We therefore considered a more stringent SCV standard for facilities where EtO use is at least 40 tpy, which would include the one and only facility where the emissions from SCVs contribute to the facility's MIR exceeding 100-in-1 million. The emission limit that we evaluated is 99.94 percent reduction, which would reduce this facility's SCV emissions such that they no longer contribute to this facility's MIR exceeding 100-in-a-million.[37] We have determined that this is feasible because our evaluation of performance tests indicates that 27~~6~~ out of 36 facilities with SCVs and using at least 40 tpy of EtO are already exceeding this emission reduction from their SCVs. Of those 27~~6~~ facilities, 1~~3~~4 use wet scrubbers, six use catalytic oxidizers, four use a wet scrubber and gas/solid reactor in series, two use thermal oxidizers, and one uses a wet scrubber and catalytic oxidizer in series.

Commented [A130]: Consider revising/clarifying. As drafted, it is not clear whether this text is saying that the additional reduction in SCVs to 99.4% for facilities that use at least 40 tpy is being driven by a single facility.

Commented [A131R130]: EPA does not agree with this characterization and believes that the text is sufficient as written

Commented [A132]: If EPA adopted only the BMP option everywhere else and imposed these requirements on this one facility, what would be the resulting risk? Why can't the analysis start with looking at where the risks are presented?

Commented [A133R132]: As indicated in the text, EPA begins its analysis by determining what sources are contributing to over 100-in-1 million MIR, and then standards to reduce the MIR so that it does not exceed 100-in-1 million are analyzed and proposed.

[37] As mentioned above, the remaining risks from this facility are from Group 2 room air emissions, which we will address immediately below in the next subsection.

As mentioned above, results from our risk assessment indicate that, for the facility with the source category MIR of 3,000-in-1 million, 70 percent of the risk is from Group 2 room air emissions. In addition to this facility, which is an area source, there are two other facilities, also area sources, where Group 2 room air emissions contribute to the facilities' MIRs exceeding 100-in-1 million.[38] Because Group 2 room air emissions are one of the two principal contributors 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 III.B.8.g of this preamble, we are proposing a GACT standard for currently unregulated Group 2 room air emissions at existing area source facilities. Specifically, we are proposing under CAA section 112(d)(5) that facilities follow either the Cycle Calculation Approach or the Bioburden / Biological Indicator Approach to achieve sterility in accordance with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017 is not exceeded.[39]

In proposing this standard, we also considered an emission rate of 2.8E-3 lb/hr that reflects the use of control devices (Option 1)~~,~~ but did not propose that option based on our analysis of relevant factors under section 112(d)(5). However, having proposed to determine under CAA section 112(f)(2) that the risk for the source category is unacceptable, we must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. Therefore, we are considering under section 112(f)(2) this emission rate of 2.8E-3 lb/hr for reducing risks from existing area source facilities where EtO use is at least 20

Commented [A134]: It is unclear if any of the six facilities where the cost to sales ratio of a 2.8E-3 /b/hr would exceed 5% are now captured by this residual risk standard for facilities using 20+ tpy and what the consequence of this would be.

Commented [A135R134]: As stated in the text, EPA cannot consider cost when analyzing potential standards under risk acceptability. However, the overall costs and impacts of the rule are presented in section IV and the RIA

[38] 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.

[39] As discussed in section III.B.8 of this preamble, we are proposing an emission rate of 2.8E-3 lb/hr for all new area source facilities, regardless of EtO use, under CAA section 112(d)(5).

tpy, which would include all three facilities where the Group 2 room air emissions contribute to these facilities' MIRs exceeding 100-in-1 million.[40]

Another option for reducing Group 2 room air emissions is setting a work practice standard to limit both the maximum volumetric flow rate and maximum EtO concentration of the exhaust streams that contain these emissions. Based on our estimate, this work practice standard would reduce emissions below the 2.8E-3 lb/hr limit. We note that if both the volumetric flow rate and EtO concentration are restricted, there are at least two potential outcomes. One outcome is that a facility could keep the volume of the enclosure constant but restrict the number of room air changes (RACs) per hour. This could potentially result in an increase in EtO concentration within the enclosure. In order to maintain personnel safety, significant upgrades and changes may need to be made, which could require significant costs. Another outcome is that the facility could keep the number of RACs per hour constant but restrict the volume of the enclosure. Both of these outcomes could result in a reduced capacity to sterilize medical products, which is an important consideration in light of the role that sterilization facilities play in the medical supply chain.

b. Regulatory Options

We considered more stringent SCV and Group 2 room air emission standards to reduce risk from the source category to an acceptable level. To that end, we identified the following two options. Control Option 1 would require that (1) facilities where EtO use is at least 40 tpy reduce emissions from individual SCVs by 99.94 percent; and (2) area source facilities where EtO use is at least 20 tpy limit the Group 2 room air EtO emission rate to 2.8E-3 lb/hr. Control Option 2 would have the same two requirements as Option 1, except that the 2.8E-3 lb/hr limit would not

[40] The EtO usage at these three facilities range from 22 to 77 tpy.

apply to facilities with MIR remaining greater than 100-in-1 million even after the imposition of the requirements under Control Option 1, as determined by this risk assessment ~~(*i.e.*, STI and BD Medical)~~, and detailed in Appendix 10 of the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule*, which is available in the docket for this rulemaking. For these two facilities ~~(STI and BD Medical)~~,[41] Option 2 would require work practice standards that would reduce Group 2 room air emissions at these two facilities to a level that would lower their MIR to 100-in-1-million, based on our estimates. Under this work practice standard, Group 2 room air emissions would be limited to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv.

In considering the work practice standards described above, it is important to understand the uncertainties related to the modeled EtO emissions for the two area source facilities that would be subject to these standards. For ~~STI~~one facility, we did not receive any room area or EtO monitoring data as part of the September 2021 ICR that could have been used to quantify Group 2 room air emissions. Therefore, we modeled emissions using our default assumption that 0.2 percent of EtO used is emitted as part of Group 2 room air emissions. In addition, we did not receive any information on how the air for areas where there are Group 2 room air emissions is leaving the facility (*i.e.*, the height, temperature, diameter, velocity, and flow rate of each release point for these areas). Therefore, Group 2 room air emissions were modeled as an area source. These factors increase the uncertainty of the MIR for this facility. For ~~BD Medical~~the other

[41] As explained below in section III.D.1.c, following our risk modeling, which showed 3 facilities in this group, we conducted additional analysis that resulted in stricter proposed standards under section 112(d)(5) for Group 1 room air emissions, which in turn changed the number of facilities (from three to two) that, after taking into account emission reduction from Option 1, would still have an MIR > 100-in-a-million due to group 2 room air emissions.

Commented [A136]: If it is permissible to set standards on a facility-by-facility basis based on the results of the risk assessment, can EPA adopt BMPs instead of emission standards for facilities for which MIR is less than 10E-4 or 10E-5?

Commented [A137R136]: It is not the preference of EPA to propose facility-specific standards, but EPA is not currently aware of alternatives to reduce the MIR to 100-in-1 million. However, EPA is taking comment on our proposed option. EPA will also work with regional and local offices where these facilities are located to gather as much useful information as possible so that the analysis for the final rule will be as accurate as possible. In addition, EPA is soliciting comment on whether 400-in-1 million is acceptable.

Commented [A138]: We are concerned about naming specific sites with additional requirements. By specifically naming sites, there may be additional activism that impacts site operations in the near and long term. Also, since the sites would have to do more to come into compliance this could lead to greater disruptions in the supply chain.

Commented [A139R138]: EPA will not name companies in this preamble

Commented [A140]: EPA appears to indicate in the paragraph immediately above that these restrictions could result in a reduced capacity to sterilize medical products. Would this be a permanent reduction going forward?

Commented [A141R140]: Not necessarily. EPA is required to review standards no less than every eight years as part of a technology review, and the standard may be updated if sufficient improvements to detection technologies are made by that time. In addition, as noted above, the facilities may implement improved worker safety measures so that sterilization capacity is not permanently reduced.

facility, we understand that a new approval order has recently been issued for this facility that includes limits on Group 2 room air emissions.[42] However, we do not know how the dispersion characteristics for these emissions will change upon the installation of additional controls. This increases the uncertainty of the MIR for this facility.

Commented [A142]: Because of the subsequent activism that can result for naming facilities, seems like it would be best to have data from the facility before naming them.

Commented [A143R142]: EPA will not name companies in this preamble and will work with local air agencies to gather data from these facilities between proposal and final.

c. Determination of Risk Acceptability After Emission Reductions Under CAA Section 112(f)(2)

As discussed above, we consider two options for reducing risks. Control Option 1 would require (1) 99.94 percent emission reduction for each SCV at facilities using at least 40 tpy EtO and (2) 2.8E-3 lb/hr emission limit for Group 2 room air emissions at area source facilities using at least 20 tpy. Control Option 2 would require (1) 99.94 percent emission reduction for each SCV at facilities using at least 40 tpy EtO; (2) 2.8E-3 lb/hr emission limit for Group 2 room air emissions at area source facilities using at least 20 tpy, except for 2 facilities with MIR > 100-in-1-million after imposition of the requirements under Control Option 1; and (3) for these two facilities, work practice standards that would bring their MIR to 100-in-1-million.

In Table 21, we present the risks after the implementation of Control Options 1 and 2 based on our risk assessment. The risk metrics shown in the table include the cancer MIR, population exposed to cancer risks greater than 100-in-1 million, population exposed to cancer risks greater than or equal to 1-in-1 million, and the cancer incidence.

Table 21. Post-Control Risk Assessment Results for the Commercial Sterilization Facilities Source Category

Control Option Scenario	Maximum Individual Cancer Risk (in-1-million)	Estimated Population at Increased Risk of Cancer > 100-in-1 Million	Estimated Population at Increased Risk of Cancer ≥ 1-in-1 Million	Estimated Annual Cancer Incidence (cases per year)

[42] *https://eqedocs.utah.gov/TempEDocsFiles/142039467_142039467_AgencyInterest_10301-10400_10377%20-%20BD%20Medical-%20Medical%20Device%20Manufacturing%20Plant_New%20Source%20Review_2022_DAQ-2022-008635.pdf.*

Option 1	400	~33	1,290,000[1]	0.2[1]
Option 2	100	0	1,260,000[1]	0.1[1]

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

Control Option 1 reduces the MIR from 3,000-in-1 million to 400-in-1-million. The total number of facilities posing cancer risks greater than 100-in-1 million would drop from 13 facilities at baseline after emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) to 3 facilities (two in Puerto Rico and one in Utah). We note that 1 of those 3 facilities would be subject to the proposed Group 1 room air emission standards that were not included in the risk assessment and its risks would be below 100-in-1 million (but it would not impact the source category MIR). Additionally, the baseline population exposed to risk levels greater than 100-in-1 million would be reduced from 2,350 people to approximately 33 people. The total population exposed to risk levels greater than or equal to 1-in-1 million living within 50 km of a facility would be reduced from 3.2 million people to 1.29 million people. The total estimated cancer incidence of 0.9 drops to 0.2 excess cancer cases per year in Control Option 1. We note that the populations at risk levels greater than or equal to 1-in-1 million and the cancer incidence may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment. Control Option 2 further reduces the MIR to 100-in-1million, with no facilities or populations at risk levels greater than 100-in-1 million. The total population exposed to risk levels greater than or equal to 1-in-1 million living with 50 km of a facility would be further reduced to 1.26 million people. Finally, in Control Option 2, the total estimated cancer incidence would be further reduced to 0.1 excess cancer cases per year. Again, the populations at risk levels greater than or equal to 1-in-1 million and the cancer incidence may

be lower because the risk assessment did not account for the proposed Group 1 room air emission standards.

In summary, both Control Options 1 and 2 would provide significant health benefits by reducing the cancer MIR from 3,000-in-1 million in the baseline after emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) to 400-in-1 million in Control Option 1 and to 100-in-1 million in Control Option 2. That said, as noted earlier in this section, the EPA considers an MIR of "approximately 1-in-10 thousand" to be the presumptive limit of acceptability (54 FR 38045, September 14, 1989). Therefore, because Control Option 2 provides an MIR at the presumptive limit of 1-in-10 thousand (or 100-in-1 million), we are proposing that Control Option 2 reduces risks to an acceptable level. We expect that 405 facilities will be affected by the proposed standards of Control Option 2, 386 of these 405 facilities will be subject to the SCV provisions, and 43all of these 405 facilities are expected to be subject to the provisions for Group 2 room air emissions. We solicit comment on the proposed requirements for SCVs and Group 2 room air emissions, including whether we should apply the limits on volumetric flow rate and EtO concentration at ~~STI and BD Medical~~facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1 to all Group 2 room air emissions at facilities where EtO use is at least 20 tpy (Comment C-363). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.94 percent emission reduction for SCVs at facilities where EtO use is at least 40 tpy and whether 3.1E-3 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 40 tpy (Comment C-374). We also solicit comment on whether we should determine that

Control Option 1 would reduce risks to an acceptable level, because, while the MIR is 400-in-1 million, the population exposed to risk levels above 100-in-1 million is low (~33 people) and the population exposed to risks ≥1-in-1 million is similar to Control Option 2 (1,290,000 people in Control Option 1 and 1,260,000 people in Control Option 2) (Comment C-385).

2. Ample Margin of Safety

The second step in the residual risk decision framework is determination of whether the emission standards proposed to achieve an acceptable risk level would protect public health with an ample margin of safety, or whether more stringent emission standards would be required. In making this determination, we considered the estimate of health risk and other health information, along with additional factors relating to the appropriate level of control, including costs and economic impacts of controls, technological feasibility, uncertainties, and other relevant factors, consistent with the approach of the 1989 Benzene NESHAP.

As discussed in the previous section, SCVs and Group 2 room air emissions are the primary contributors to risks. At step 1 of our review of residual risks under section 112(f), we determined that more stringent standards for SCVs at 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 20 tpy are necessary to reduce risks to an acceptable level. For step 2 of our review of residual risks, which requires EPA to evaluate whether more stringent standards are necessary to provide an ample margin of safety to protect public health, we considered additional options to further reduce emissions from SCVs and Group 2 room air emissions.

Table 22 of this preamble presents the summary of costs and EtO emission reductions we estimated for the control options we considered, which are described immediately following the table. For details on the assumptions and methodologies used in the costs and impacts analyses,

see the technical memorandum titled *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*, which is available in the docket for this rulemaking.

Table 22. Nationwide Emission Reductions and Cost Impacts of Control Options Considered for Commercial Sterilization Facilities in the Ample Margin of Safety Analysis

Control option	Total capital investment ($)	Total annualized costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
A—99.94 percent emission reduction requirement for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy	$~~871,103~~737,689	$~~287,787~~266,687	0.1~~8~~7	$~~1,631,673~~1,531,726
B—99.6 percent emission reduction requirement for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy (prevent backsliding)	$0	$0	0	N/A
C—99.8 percent emission reduction requirement for SCVs at	$~~174,221~~92,211	$~~27,050~~34,939	~~8.9~~1.8E-~~23~~	$~~3,040,190~~1,947,753

Commented [A144]: Time horizon? Is this the same 30- and 60-year annualization?

Commented [A145R144]: Costs have been updated to reflect 20-year annualization for PTE and gas/solid reactors

facilities where EtO use is at least 1 tpy but less than 10 tpy				
D—99.2 percent emission reduction requirement for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (prevent backsliding)	$0	$0	0	N/A
E—99.3 percent emission reduction requirement for SCVs at facilities where EtO use is less than 1 tpy	$~~609,772~~368,845	$~~120,996~~92,295	~~0.16~~3.4E-2	$~~738,019~~2,724,634
F—Limit Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv[1]	$2~~7,655,344~~8,542,825	$~~2,171,832~~2,861,119	1.52~~4~~	$~~1,498,428~~1,883,935
G—Existing Group 2 room air emission limit of 2.8E-	$~~103,503,407~~98,400,887	$~~11,582,833~~10,648,525	5.5~~0~~E-2	$~~233,741,434~~194,111,365

3 lb/hr at area source facilities where EtO use is less than 20 tpy				

[1] As discussed later in this section, these costs only include PTE and do not include the costs of upgrades and changes needed to maintain personnel safety or potential revenue losses from a reduced capacity to sterilize product.

As mentioned earlier, available performance data show controls for reducing SCV emissions have much improved. We therefore consider potential options to further reduce SCV emissions. We considered two options for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy (Control Options A and B). Under Control Option A, we considered 99.94 percent emission reduction for SCVs at facilities where EtO use is at least than 10 tpy but less than 40 tpy. This is the same limit as that we are proposing for all facilities where EtO use is at least 40 tpy in order to bring the source category risk to an acceptable level. Under Control Option B, we considered the maximum SCV emission reduction that all facilities where EtO use is at least 10 tpy but less than 40 tpy are currently meeting. This emission reduction is 99.6 percent. We also considered two options for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Control Options C and D). Under Control Option C, we considered the maximum SCV emission reduction with which compliance can be demonstrated[43] at all facilities where EtO use is at least 1 tpy but less than 10 tpy considering current emission profiles. This emission reduction is 99.8 percent. Under Control Option D, we considered the maximum SCV emission reduction that all facilities where EtO use is at least 1 tpy but less than 10 tpy are currently meeting. This emission reduction is 99.2 percent. We identified one option for SCVs at

[43] 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 (3 x RDL).

facilities where EtO use is less than 1 tpy. Specifically, under Control Option E, we considered the maximum SCV emission reduction for which compliance can be demonstrated at all facilities where EtO use is less than 1 tpy considering current emission profiles. This emission reduction is 99.3 percent. The ample margin of safety analysis for these options is discussed below.

As mentioned above, Control Options A and B address SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy. For Control Option A, which would require 99.94 percent emission reduction for SCVs at all facilities where EtO use is at least 10 tpy but less than 40 tpy, we found a total capital cost of $~~871,103~~737,689 and a total annualized cost of $~~287,787~~266,687. The estimated EtO emissions reductions are 0.1~~8~~ tpy with a cost effectiveness of $1,~~631,673~~531,726 per ton of EtO. While we do not know what the full extent of risk reductions would be, we expect that some risk reduction would occur as a result of reduced EtO emissions.

Control Option B would require 99.6 percent emission reduction (reflecting the maximum reduction that all facilities within this EtO usage amount are meeting). While there would be no costs, there would also be no further reductions in emissions and in turn no further reductions in risks; at best Option B would simply prevent backsliding in the performance of current SCV emission controls at these facilities. In light of the above, we believe that Option A would be a better choice than Option B for further reducing emissions from SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy.

Control Options C and D address SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. For Control Option C, which would require 99.8 percent emission reduction (reflecting the maximum reduction with which compliance can be demonstrated at all facilities where EtO use is at least 1 tpy but less than 10 tpy), we determined a total capital cost of

$~~174,221~~92,211 and a total annualized cost of $~~27,050~~34,939. The estimated EtO emissions reductions are ~~8.9~~1.8E-~~3~~2 tpy with a cost effectiveness of $~~3,040,190~~1,947,753 per ton of EtO. While we do not know what the full extent of risk reductions would be, we expect that some risk reduction would occur as a result of reduced EtO emissions.

Control Option D would require 99.2 percent emission reduction (reflecting the maximum reduction that all facilities within this EtO usage amount are meeting). While there would be no costs, there would also be no reductions in emissions and in turn no reductions in risks; at best Option D would simply prevent backsliding in the performance of current SCV emission controls at these facilities. In light of the above, we believe that Option C would be a better choice than Option D for further reducing emissions from SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy.

Control Option E addresses SCVs at facilities where EtO use is less than 1 tpy. Specifically, Control Option E would require that these facilities reduce emissions from each SCV by 99.3 percent (the maximum emission reduction with which compliance can be demonstrated at all facilities using less than 1 tpy). We expect that some risk reduction would occur as a result of reduced EtO emissions but do not know what the full extent of risk reductions would be. The costs were found to be a $~~609,772~~368,845 total capital investment and a $~~120,996~~92,295 total annualized cost. The estimated EtO emissions reductions are ~~0.16~~3.4E-2 tpy with a cost effectiveness of $~~738,019~~2,724,634 per ton of EtO. 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 five percent. Considering Control Option E, along with the standards that we have proposed up to this point, the cost to sales ratio for one company operating a facility where EtO use is less than 1 tpy would be 11 percent, far exceeding

our estimated five percent at which point the potential for adverse economic impacts begins. Based on the available economic information, assuming market conditions remain approximately the same, we are concerned that this company would not be able to sustain the costs associated with any additional control requirements.

We consider two potential options to further reduce Group 2 room air emissions (Control Options F and G). Under Control Option F, Group 2 room air emissions would be limited to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv at all facilities. These are the same limits as that we are proposing for ~~STI and BD Medical~~facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1 in order to bring the source category risk to an acceptable level.[44] Under Control Option G, existing Group 2 room air emissions would be limited to 2.8E-3 lb/hr at area source facilities where EtO use is less than 20 tpy. This is the same limit as that we are proposing for all facilities where EtO use is at least 20 tpy (except for ~~STI and BD Medical~~facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1) ~~in order~~ to bring the source category risk to an acceptable level. The ample margin of safety analysis for these options is discussed below.

Under Control Option F, which would require that Group 2 room air emissions be limited to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv at all facilities, we were unable to fully estimate costs because it is unknown how this would affect operations. As discussed in section III.C.1.a, if both the volumetric flow rate and EtO concentration are restricted, there are at least two potential outcomes. One outcome is that a facility could keep the volume of the enclosure constant but restrict the number of RACs per

[44] As explained in section III.C.1, reducing the source category risk to an acceptable level would require a separate and more stringent standard for these two facilities.

hour. This could potentially result in an increase in EtO concentration within the enclosure. In order to maintain personnel safety, significant upgrades and changes may need to be made, which could require significant costs. Another outcome is that the facility could keep the number of RACs per hour constant but restrict the volume of the enclosure. While both outcomes could result in potential costs savings from reduced air handling, this may be offset by a loss a revenue from a reduced capacity to sterilize product. This could also impact the supply of medical devices. We did not consider this a viable option in light of the potentially adverse safety, production capacity, and cost implications of this option as described above.

Under Control Option G, which would limit Group 2 room air emission to 2.8E-3 lb/hr at area source facilities where EtO use is less than 20 tpy[45] costs were found to be a $~~103,503,407~~98,400,887 total capital investment and a $1~~1,582,833~~0,648,525 total annualized cost. The estimated EtO emissions reductions are 5.~~5~~0E-2 tpy with a cost effectiveness of $~~233,741,434~~194,111,365 per ton of EtO. While we do not know what the full extent of risk reductions would be, we expect that some risk reduction would occur as a result of reduced EtO emissions. However, the cost to sales ratio for ~~two~~three companies operating ~~two~~three facilities where EtO use is less than 20 tpy would range from ~~23~~17 to ~~45~~56 percent, far exceeding our estimated five percent at which point the potential for adverse economic impacts begins. 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 any additional control requirements.

[45] This is the proposed MACT standard for Group 2 room air emissions at major sources; it is also our proposed standard for Group 2 room air emissions at area source facilities where EtO usage is at least 20 tpy.

Based on our ample margin of safety analysis, including all health information and the associated cost and feasibility as discussed above, we propose that requiring the standards that based on our analysis would bring risks to an acceptable level, along with Control Options A and C here in the present analysis, would provide an ample margin of safety to protect public health. These standards, which we are proposing under the AMOS analysis, consist of 99.94 percent reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy, as well as 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. We are soliciting comment on our proposed determination, including whether Control Options B, D, E, F, or G would provide an ample margin of safety to protect public health. (Comment C-396). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.94 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy, and whether 1.32E-3 lb/hr for existing sources and 1.0E-3 lb/hr for new sources, which we calculated using the method described in section III.B.1.a, are appropriate alternative standards that are equivalent to the proposed 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy. Similarly, we solicit comment on whether to include alternative lb/hr limits that are equivalent to 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and whether 5.57.2E-4 lb/hr for existing sources and 5.51E-4 lb/hr for new sources, which we calculated using the method described in section III.B.1.a, are appropriate alternative standards that are equivalent to the proposed 99.8 percent emission reduction standard for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C-4037).

3. Environmental Effects

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 and we are proposing that 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.

4. Summary of Proposed Standards

Pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), we are proposing standards for a number of currently unregulated EtO emission sources at commercial sterilizers.[46] The EPA also conducted a section 112(f)(2) analysis. For that analysis, the EPA conducted a baseline risk assessment that took into account the implementation of the current standards in subpart O as well as the proposed 112(d) standards for the currently unregulated emission sources discussed here in section III.B. Having proposed to determine that the risk is unacceptable for the source category, the EPA is proposing under section 112(f)(2) standards, including tightening certain proposed section 112(d) standards, to bring the risk from this source category to an acceptable level and provide ample margin of safety to protect public health. Table 23 summarizes the proposed section 112(d) and 112(f)(2) standards.

Table 23. Summary of Standards After Taking Actions Pursuant to CAA Sections 112(d)(2), 112(d)(3), 112(d)(5), and 112(f)(2)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing	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)

Commented [A146]: Suggest including mention of PTE or Method 204 in this column where appropriate.

Commented [A147R146]: Footnotes have been added where appropriate

[46] In addition, we are proposing a correction to the current standard under 112(d) for ARV at facilities with EtO usage ≥ 10 tpy.

		At least 1 but less than 10 tpy	99.8 percent emission reduction	112(f)(2)
		Less than 1 tpy	99 percent emission reduction	112(d)(5)
	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 1 but less than 10 tpy	99.8 percent emission reduction	112(f)(2)
		Less than 1 tpy	99 percent emission reduction	112(d)(5)
ARV	Existing	At least 10 tpy	99 percent emission reduction	112(f)(2)
		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 percent emission reduction	112(f)(2)
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5)
		Less than 1 tpy	99 percent emission reduction	
CEV	Existing	At least 10 tpy	3.2E-4 lb/hr	112(d)(2) and (3)
		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	3.2E-4 lb/hr	112(d)(2) and (3)
		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)
Group 1 room air emissions at major sources	Existing and new	N/A	1.3E-3 lb/hr[1]	112(d)(2) and (3)
Group 1 room air emissions at area sources	Existing and new	N/A	1.3E-3 lb/hr[1]	112(d)(5)
Group 2 room air emissions at major sources	Existing and new	N/A	2.8E-3 lb/hr[1]	112(d)(2) and (3)
	Existing	At least 20 tpy	2.8E-3 lb/hr[1,2]	112(f)(2)

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Group 2 room air emissions at area sources		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 ~~14161:2009~~11138-1:2017 (~~September 15,~~March 201~~709~~)	112(d)(5)
	New	N/A	2.8E-3 lb/hr[1]	112(d)(5)

[1] We are also proposing to require 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.

[1] ~~STI and BD Medical~~Facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1 must instead limit the total volumetric flow rate of exhaust streams that contain Group 2 room air emissions to a maximum of 2,900 dscfm at each facility, and the EtO concentration of these streams must not exceed 30 ppbv.

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E. What environmental justice analysis did we conduct?

Consistent with the EPA's commitment to integrating EJ in the Agency's actions, and following the directives set forth in multiple Executive Orders, the Agency has carefully considered the impacts of this action on communities with EJ concerns. Overall, the results of the proximity demographic analysis (see first three columns of Table 24) indicate that the percent of the population living within 10 km of the 97 facilities that is Hispanic or Latino is substantially higher than the national average (34 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 24 to 26), which focuses on those specific locations 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 African Americans are disproportionally represented at the higher risk levels. The post-control risk-based demographic analysis focuses on how the options

considered in this proposed regulatory action would affect the distribution of risks within the population identified in the baseline. The CAA section 112(d)(2), (3), and (5) post-control scenario is shown in Tables 24 to 26 and the residual risk post-control options are shown in Tables 27 to 29. 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. EPA projects that a majority of the individuals that would remain at risk after implementation of the proposed standards is 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 benefits these proposed standards would have in reducing EtO emissions and associated health risks in communities with EJ concerns. For more details see the remainder of this section.

Executive Order 12898 directs EPA to identify the populations of concern who are most likely to experience unequal burdens from environmental harms, which are specifically minority populations (people of color), low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 is intended to advance racial equity and support underserved communities through Federal government actions (86 FR 7009, January 20, 2021). The EPA defines EJ as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies."[47] The EPA further defines fair treatment to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative

[47] *https://www.epa.gov/environmentaljustice*

environmental consequences of industrial, governmental, and commercial operations or programs and policies." In recognizing that people of color and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution. For purposes of analyzing regulatory impacts, the EPA relies upon its June 2016 "Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,"[48] which provides recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time, resource constraints, and analytical challenges will vary by media and circumstance. The Technical Guidance states that a regulatory action may involve potential EJ concerns if it could: (1) create new disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; (2) exacerbate existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; or (3) present opportunities to address existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples through this action under development.

For this proposal, the EPA examined the potential for the 97 facilities that were assessed to pose concerns to EJ communities both in the baseline and under the control options considered in this proposal. Specifically, the EPA analyzed how demographics and risk are distributed both pre- and post-control, enabling us to address the core questions that are posed in the EPA's 2016 Technical Guidance for Assessing Environmental Justice in Regulatory Analysis. In conducting this analysis, we considered key variables highlighted in the guidance including "minority

[48] See *https://www.epa.gov/environmentaljustice/technical-guidance-assessing-environmental-justice-regulatory-analysis.*

populations (people of color and Hispanic or Latino), low-income populations, and/or indigenous peoples". 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.

To examine the potential for EJ concerns in the pre-control baseline, the EPA 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 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 proposed rule.

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 proposed by this action ("baseline"). Again, in this preamble, we focus on 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 proposed rule.

1. Demographics

The first three columns of Tables 24, 25 and 26 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 19.4 million people live within 10 km of the 97 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 (34 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 baseline proximity analysis indicates that the proportion of other demographic groups living within 10 km of commercial sterilizers is similar to the national average, although some differences do exist.~~ The percent of the population that is "Other and multiracial" (13 percent) is higher than the national average (8 percent). The percentages of the population that are African American (13 percent) or Native American (0.3 percent) are similar to or less than the national averages (12 percent and 0.7 percent, respectively). The percent of people living below the poverty level (14 percent) and those over the age of 25 without a high school diploma (15 percent) are higher than the national averages (13 percent and 12 percent, respectively). The percent of people living in linguistic isolation is double the national average (10 percent versus 5 percent).[49]However, 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.

Commented [A148]: Doe EPA have an example?

Commented [A149R148]: This sentence is not necessary as we provide detailed examples for each of the other demographics in the subsequent sentences.

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

[49] 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 speak English less than "very well" (have difficulty with English)."

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.

Commented [A150]: Can this analysis carry through the special case of Puerto Rico in the tables?

Commented [A151R150]: EPA has added more detail in the text for the 7 PR facilities.

2. Baseline Risk-Based Demographics

The baseline risk-based demographic analysis results are shown in the "baseline" column of Tables 24, 25, and 26. This analysis focused on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 24), greater than or equal to 50-in-1 million (Table 25), and greater than 100-in-1 million (Table 26). The risk analysis indicated that emissions from the source category, prior to the reductions we are proposing, expose a total of 5.3 million people to a cancer risk greater than or equal to 1-in-1 million around 78 facilities, 119,000 people to a cancer risk greater than or equal to 50-in-1 million around 42 facilities, and 18,000 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 significantly above 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). In contrast, the smaller populations with baseline cancer risk greater than or equal to 50-in-1 million (119,000 people) and > 100-in-1 million (18,000 people) are predominantly made up of African Americans (45 and 34 percent versus 12 percent nationally), have a higher percentage of the population below the poverty level (22 and 23 percent versus 13 percent nationally), the percent over 25 without a

high school diploma is above the national average (17 and 16 percent versus 12 percent) and linguistic isolation is above the national average (7 and 10 percent versus 5 percent). This shows that risks tend to be higher 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 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 (18 and 19 percent) than the total population living within 10 km (34 percent Hispanic or Latino) and is near the national average (19 percent).

In summary, the baseline risk-based demographic analysis, which focuses on those specific locations that are expected to have higher cancer risks, suggests that African Americans are the one demographic group 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 significantly higher proportion of African Americans (34 percent) than the national average (12 percent).

3. Risk-Based Demographics Considering Standards Under CAA Sections 112(d)(2), (3), and (5)

This analysis focused on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 24), greater than or equal to 50-in-1 million (Table 25), and greater than 100-in-1 million (Table 26) after implementation of

standards that we are proposing 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 24, 25, and 26 titled "Baseline and CAA Section 112(d)(2), (3), and (5)." In this analysis we evaluated how the proposed CAA sections 112(d)(2), (3), and (5)emission reductions in this proposed regulatory action affect the distribution of risks identified in the baseline. This enables us to characterize the post-control risks and to evaluate whether the proposed action creates or mitigates potential EJ concerns as compared to the baseline. Note that as described in section III.C, the risk results in this scenario were based on requiring BMP (Option 2) under section 112(d)(5) for Group 1 room air emissions, instead of the proposed emission limit reflecting use of control devices (Option 1). Therefore, the populations at the various risk levels may be lower than reported here (and the demographics slightly different).

Commented [A152]: Will this analysis be updated?

Commented [A153R152]: Yes, EPA will update this analysis between proposal and promulgation of the final rule.

The risk analysis indicated that the emissions from the source category, after implementation of the emissions reductions we are proposing under CAA section 112(d), 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 78 facilities to 2.6 million people around 73 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 119,000 people around 42 facilities to 19,000 people around 20 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 18,000 people around 16 facilities to 2,350 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 proposing under CAA section 112(d) 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 significantly above the national average (32 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 (16 percent versus 12 percent), and the percent linguistic isolation is two times the national average (10 percent versus 5 percent).

After implementation of the standards we are proposing under CAA section 112(d), the percentage and number of African Americans at cancer risks greater than 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 34 percent or 6,000 people in the baseline to 11 percent or 300 people after implementation of the proposed technology review emissions reductions. It should be noted that, the percentage of the population that is Hispanic or Latino exposed to risks greater than 100-in-1 million went up from 18 percent in the baseline to 51 percent after the proposed technology review emissions reductions. However, the number of Hispanic or Latino people with risks greater than 100-in-1 million was reduced from 3,000 to 1,200 people. Similarly, the percentage of the population that are below the poverty level or are linguistically isolated with a cancer risk greater than 100-in-1 million went up from the baseline, but the number of people in these demographics decreased significantly. 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 (34 percent versus 23 percent), but the number of people was reduced from 4,000 people to 800 people.

In summary, the proposed CAA section 112(d) standards significantly reduced 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 about 40 percent in the baseline to about 15 percent after the technology review 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 24. Comparison of Baseline and CAA Section 112(d)(2), (3), and (5) Post-Control 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	19.4M	5.3M	2.6M[1]
Number of Facilities	-	97	78	73[1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	40 percent [7.7M]	40 percent [2.1M]	43 percent [1M][1]
African American	12 percent [40M]	13 percent [2.5M]	15 percent [780K]	19 percent [480K][1]
Native American	0.7 percent [2M]	0.3 percent [56K]	0.3 percent [16K]	0.3 percent [7K][1]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	34 percent [6.5M]	38 percent [2M]	32 percent [840K][1]
Other and Multiracial	8 percent [27M]	13 percent [2.6M]	7 percent [360K]	6 percent [150K][1]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	14 percent [2.8M]	16 percent [800K]	16 percent [400K][1]
Above Poverty Level	87 percent [284M]	86 percent [16.6M]	84 percent [4.5M]	84 percent [2.2M][1]
Education by Percent [Number of People]				

Over 25 and without a High School Diploma	12 percent [40M]	15 percent [3M]	18 percent [900K]	16 percent [400K][1]
Over 25 and with a High School Diploma	88 percent [288M]	85 percent [16.4M]	82 percent [4.4M]	84 percent [2.2M][1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [2M]	11 percent [600K]	10 percent [300K][1]

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

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 25. Comparison of Baseline and CAA Section 112(d)(2), (3), and (5) Post-Control 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	19.4M	119,000	19,000[1]
Number of Facilities	-	97	42	20[1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	40 percent [7.7M]	33 percent [39K]	54 percent [10K][1]
African American	12 percent [40M]	13 percent [2.5M]	45 percent [54K]	19 percent [4K][1]
Native American	0.7 percent [2M]	0.3 percent [56K]	0.1 percent [200]	0.1 percent [<100][1]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	34 percent [6.5M]	19 percent [23K]	25 percent [5K][1]
Other and Multiracial	8 percent [27M]	13 percent [2.6M]	3 percent [4K]	2 percent [400][1]

Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	14 percent [2.8M]	22 percent [26K]	23 percent [4K][1]
Above Poverty Level	87 percent [284M]	86 percent [16.6M]	78 percent [93K]	77 percent [15K][1]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	15 percent [3M]	17 percent [8K]	15 percent [2K][1]
Over 25 and with a High School Diploma	88 percent [288M]	85 percent [16.4M]	83 percent [111K]	85 percent [17K][1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [2M]	7 percent [54K]	13 percent [4K][1]

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

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 26. Comparison of Baseline and CAA Section 112(d)(2), (3), and (5) Post-Control 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	19.4M	18,000	2,350[1]
Number of Facilities	-	97	16	13[1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	40 percent [7.7M]	45 percent [8K]	37 percent [900][1]
African American	12 percent [40M]	13 percent [2.5M]	34 percent [6K]	11 percent [300][1]
Native American	0.7 percent [2M]	0.3 percent [56K]	0.1 percent [<100]	0 percent [0]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	34 percent [6.5M]	18 percent [3K]	51 percent [1.2K][1]
Other and Multiracial	8 percent [27M]	13 percent [2.6M]	3 percent [500]	1 percent [<100][1]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	14 percent [2.8M]	23 percent [4K]	34 percent [800][1]
Above Poverty Level	87 percent [284M]	86 percent [16.6M]	77 percent [14K]	66 percent [1.55K][1]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	15 percent [3M]	16 percent [2K]	17 percent [700][1]
Over 25 and with a High School Diploma	88 percent [288M]	85 percent [16.4M]	84 percent [15K]	83 percent 1.65K][1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [2M]	10 percent [6K]	31 percent [300][1]

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

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. Residual Risk Post-Control Risk-Based Demographics

This analysis focused on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 27), greater than or equal to 50-in-1 million (Table 28), and greater than 100-in-1 million (Table 29) after implementation of the control options investigated under the residual risks analysis as described in section III.D of this preamble. The demographic results for the control options are in the columns titled "Control Option 1" and "Control Option 2." One of these control options would be implemented in addition to the CAA section 112(d)(2), (3), and (5) post-control emissions reductions. Therefore, in this analysis, we evaluated how all of the proposed controls and emission reductions described in this action affect the distribution of risks. This enables us to characterize the post-control risks and to evaluate whether the proposed action creates or mitigates potential EJ concerns as compared to the baseline. Again, as described in section III.C, the risk results in this scenario were based on requiring BMP (Option 2) under section 112(d)(5) for Group 1 room air emissions, instead of the proposed emission limit reflecting use of control devices (Option 1). Therefore, the populations at the various risk levels may be lower than reported here (and the demographics slightly different).

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 27) is reduced from 2.6 million people after implementation of the CAA section 112(d)(2), (3), and (5) controls to approximately 1.15

million people after implementation of one of the residual risk control options. This represents a significant reduction (about 60 percent reduction) in the size of the populations at risk for each of the three residual risk control options investigated when compared to the populations after implementation of the technology review controls. The populations with a cancer risk greater than or equal to 1-in-1 million are located around 73 facilities for both post-control options.

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 for control options 1 and 2 (Table 27) 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 significantly above the national average (37 percent versus 19 percent), the percent below poverty is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (16 percent versus 12 percent), and the percent linguistic isolation is almost two times the national average (9 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 28) is reduced from 19,000 people after implementation of the CAA section 112(d)(2), (3), and (5) controls to 1,400 to 2,000 people after implementation of one of the residual risk control options. This represents a 90 percent reduction in the size of the populations at risk for each of the three residual risk control options investigated when compared to the populations after implementation of the CAA section 112(d)(2), (3), and (5) controls. The populations living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million are located around 11 facilities for both post-control options.

The demographics of the 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 control options 1 and 2 (Table 28) are significantly different from the population after implementation of the CAA section 112(d)(2), (3), and (5) controls. Specifically, the percent of the population that is Hispanic or Latino is significantly higher at 79 percent and 72 percent for control options 1 and 2, respectively. This higher percentage is driven by three facilities in Puerto Rico and one in Texas, for which the population is over 95 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 80 percent from 5,000 people to 1,600 and 1,000 people for Option 1 and 2, respectively. 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 these demographics decreased significantly.

The risk analysis indicated that the number of people living with 10 km of a facility and exposed to risks greater than 100-in-1 million (Table 29) is reduced from 2,350 people after implementation of the CAA section 112(d)(2), (3), and (5) controls to 33 people for Option 1 and to zero people for Option 2. For control Option 1, there are three facilities with risks greater than 100-in-1 million. Two of these facilities are located in Puerto Rico and one is in Utah.[50] The demographics in Table 29 are for one of the facilities in Puerto Rico. For the other two facilities, the MIR was located at individual residences closest to the facilities and not at a census block centroid. Therefore, we were unable to estimate the risk-based population and risk-based demographics for those facilities. However, the proximity analysis indicated that the

[50]As described in section III.D.1.c, we expect the risks at one of the facilities in Puerto Rico to be below 100-in-1 million after accounting for the proposed Group 1 room air emission reductions.

demographics for all people living within 10 km of the other Puerto Rico facility are almost identical to the one shown in Table 29. The proximity analysis shows that the population of all people living within 10 km of the Utah facility is 80 percent white with the percent Hispanic or Latino, African American, below the poverty level, over 25 without a high school education, and linguistic isolation all below the national average.

For control Option 2, there are no facilities or people with risks greater than 100-in-1 million. Therefore, there are no greater than 100-in-1 million demographics to discuss.

In summary, as shown in the residual risk post-control risk-based demographic analysis, the options under consideration in this proposal would 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 Option 1, the percentage of population that is Hispanic or Latino, below the poverty level, over 25 without a high school diploma, and in linguistic isolation increases as the cancer risk increases. This trend is driven largely by the higher risk facilities in Puerto Rico. Under Option 1, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 1-in-1 million is reduced by 50 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 70 percent, and the number of Hispanic or Latino people that are exposed to risks greater than 100-in-1 million is reduced by 97 percent. The three facilities remaining above 100-in-1 million for Option 1 are located in Puerto Rico (two facilities) and Utah. The two facilities in Puerto Rico have Hispanic or Latino populations of greater than 99 percent and the population around the facility in Utah is 80 percent white.

Under Option 2, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 1-in-1 million is reduced by 50 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 80 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, and 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 Option 2, there are no facilities or people with risks greater than 100-in-1 million.

Table 27. Comparison of Post-Control Demographics for Populations with Cancer Risk Greater than or Equal to 1-in-1 Million Living Within 10 km of Sterilizer Facilities for Various Control Options

Demographic Group	Nationwide	Cancer Risk ≥1-in-1 million		
		Post-Control CAA section 112(d)(2), (3), and (5)	Control Option 1	Control Option 2
Total Population	328M	2.6M[1]	1.2M[1]	1.1M[1]
Number of Facilities with Pop. Above Cancer Level	-	73[1]	73[1]	73[1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	43 percent [1M][1]	38 percent [447K][1]	38 percent [429K][1]
African American	12 percent [40M]	19 percent [480K][1]	18 percent [209K][1]	18 percent [208K][1]
Native American	0.7 percent [2M]	0.3 percent [7K][1]	0.4 percent [5K][1]	0.4 percent [4.5K][1]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	32 percent [840K][1]	37 percent [431K][1]	37 percent [419K][1]
Other and Multiracial	8 percent [27M]	6 percent [150K][1]	7 percent [76K][1]	7 percent [74K][1]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	16 percent [400K][1]	16 percent [182K][1]	16 percent [177K][1]
Above Poverty Level	87 percent [284M]	84 percent [2.2M][1]	84 percent [1M][1]	84 percent [900K][1]
Education by Percent [Number of People]				
> 25 w/o a HS Diploma	12 percent [40M]	16 percent [400K][1]	16 percent [186K][1]	16 percent [181K][1]

> 25 w/ HS Diploma	88 percent [288M]	84 percent [2.2M][1]	84 percent [1M][1]	84 percent [900K][1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [300K][1]	9 percent [105K][1]	9 percent [100K][1]

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

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 28. Comparison of Post-Control Demographics for Populations with Cancer Risk Greater than or Equal to 50-in-1 Million Living Within 10 km of Sterilizer Facilities for Various Control Options

Demographic Group	Nationwide	Cancer Risk ≥ 50-in-1 million		
		CAA section 112(d)(2), (3), and (5) Post-Control	Control Option 1	Control Option 2
Total Population	328M	19,000[1]	1,985[1]	1,368[1]
Number of Facilities with Pop. Above Cancer Level	-	20[1]	11[1]	11[1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	54 percent [10K][1]	12 percent [200][1]	15 percent [200][1]
African American	12 percent [40M]	19 percent [4K][1]	7 percent [100][1]	10 percent [100][1]
Native American	0.7 percent [2M]	0.1 percent [<100][1]	0.2 percent [<100][1]	0.3 percent [<100][1]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	25 percent [5K][1]	79 percent [1,600][1]	72 percent [1000][1]
Other and Multiracial	8 percent [27M]	2 percent [400][1]	2 percent [<100][1]	3 percent [<100][1]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	23 percent [4K][1]	35 percent [700][1]	26 percent [400][1]
Above Poverty Level	87 percent [284M]	77 percent [15K][1]	65 percent [1,300][1]	74 percent [1K][1]
Education by Percent [Number of People]				
> 25 w/o a HS Diploma	12 percent [40M]	15 percent [2K][1]	20 percent [400][1]	20 percent [300][1]
> 25 w/ HS Diploma	88 percent [288M]	85 percent [17K][1]	80 percent [1,600][1]	80 percent [1K][1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	13 percent [4K][1]	34 percent [700][1]	21 percent [300][1]

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

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 29. Comparison of Post-Control Demographics for Populations with Cancer Risk Greater than 100-in-1 Million Living Within 10 km of Sterilizer Facilities for Various Control Options

Demographic Group	Nationwide	Cancer Risk >100-in-1 million		
		CAA section 112(d)(2), (3), and (5) Post-Control	Control Option 1	Control Option 2
Total Population	328M	2,350[1]	33	0
Number of Facilities with Pop. Above Cancer Level	-	13[1]	3[1]	0
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	37 percent [900] [1]	0.9 percent [0]	-
African American	12 percent [40M]	11 percent [300] [1]	0.1 percent [0]	-
Native American	0.7 percent [2M]	0 percent [0]	0 percent [0]	-
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	51 percent [1.2K] [1]	99 percent [<100]	-
Other and Multiracial	8 percent [27M]	1 percent [<100] [1]	0.1 percent [0]	-
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	34 percent [800] [1]	61 percent [<100]	-
Above Poverty Level	87 percent [284M]	66 percent [1.55K] [1]	39 percent [<100]	-
Education by Percent [Number of People]				
> 25 w/o a HS Diploma	12 percent [40M]	17 percent [700] [1]	27 percent [<100]	-
> 25 w/ HS Diploma	88 percent [288M]	83 percent [1.65K] [1]	73 percent [<100]	-
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	31 percent [300] [1]	84 percent [<100]	-

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

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".

F. What are the results and proposed decisions based on our technology review, and what is the rationale for those decisions?

1. SCV At Facilities Where EtO Use Is At Least 10 Tpy

The current subpart O contains emission standards for SCVs at facilities where EtO use is at least 10 tpy. There are 47 facilities where EtO use is at least 10 tpy, all of which have SCVs. Of these facilities, 26 currently use wet scrubbers to control their SCV emissions, 11 use catalytic oxidizers, and six use a wet scrubber and gas/solid reactor in series, four use thermal oxidizers, and one uses a wet scrubber and catalytic oxidizer in series. Performance tests are available for SCVs at all facilities where EtO use is at least 10 tpy. We reviewed these performance tests, and the reported emission reductions ranged from 99.6 percent to 99.999965 percent.

We considered two potential options as part of the technology review. The first option we considered (Option 1) is 99.94 percent emission reduction. The second option we considered (Option 2) is the maximum SCV emission reduction that all facilities where EtO use is at least 10 tpy are currently meeting, which is 99.6 percent. We considered these standards as part of the analysis pursuant to CAA section 112(f)(2) as discussed in section III.C. Under Option 1, costs were found to be $3,658,631596,236 total capital investment and a $1,099,844178,927 total annualized cost. The estimated EtO emissions reductions are 1.5 tpy with a cost effectiveness of $713,38083,816 per ton of EtO. There are no cost or emission impacts for Option 2.

As discussed in section III.C.2, 99.94 percent emission reduction (Option 1) reflects the current developments in processes and technology by this industry (*i.e.*, well performing air pollution control). While Option 2 would prevent backsliding, it does not achieve additional emission reduction. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for SCVs at facilities where EtO use is at least 10 tpy. Specifically, we are proposing to require facilities where EtO use is at least 10 tpy to reduce their emissions from new and existing SCVs by 99.94 percent. This is the same standard that was proposed pursuant to CAA section 112(f)(2) as discussed in section III.C. We solicit comment on this proposed standard (Comment C-41~~38~~).

2. SCV At Facilities Where EtO Use Is At Least 1 Tpy But Less Than 10 Tpy

The current subpart O contains emission standards for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. There are 1~~8~~9 facilities where EtO use is at least 1 tpy but less than 10 tpy, all of which have SCVs. Of these facilities, ~~eight~~10 currently use catalytic oxidizers to control their SCV emissions, ~~five~~three use gas/solid reactors, ~~four~~three use wet scrubbers, one uses a wet scrubber and catalytic oxidizer in series, and one uses a wet scrubber and gas/solid reactor in series. Performance tests are available for SCVs at 1~~8~~0 facilities where EtO use is at least 1 tpy but less than 10 tpy; ~~eight~~seven of these facilities use catalytic oxidizers, ~~four use gas/solid reactors,~~ and ~~four~~three use wet scrubbers~~, one uses a wet scrubber and catalytic oxidizer in series, and one uses a wet scrubber and gas/solid reactor in series~~. We reviewed these performance tests, and the reported emission reductions ranged from 99.2 percent to 99.99~~98~~9 percent.

We considered two potential options as part of the technology review. The first option we considered (Option 1) is maximum SCV emission 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. This emission reduction is 99.8 percent. The second option we considered (Option 2) is the maximum SCV emission reduction that all facilities where EtO use is at least 1 tpy but less than 10 tpy are currently meeting, which is 99.2 percent. These standards were considered as part of the analysis pursuant CAA section 112(f)(2) as discussed in section III.C.2. The impacts of Option 1 are presented in Table 22 as Control Option C. There are no cost or emission impacts for Option 2.

As discussed in section III.C.2, the emission reduction requirements under Option 1 reflect the current developments in processes and technology by this industry (*i.e.*, well performing air pollution control). While Option 2 would prevent backsliding, it does not achieve additional emission reduction. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for new and existing SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. Specifically, we are proposing to require facilities where EtO use is at least 1 tpy but less than 10 tpy to reduce their SCV emissions by 99.8 percent. This is the same standard that was proposed pursuant to CAA section 112(f)(2) as discussed in section III.C. We solicit comment on these proposed standards (Comment C-42~~39~~).

3. ARV At Facilities Where EtO Use Is At Least 10 Tpy

a. Existing sources

The current subpart O contains emission standards for ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. As discussed in section III.B.2 of this preamble, we are proposing to remove the 1 ppmv alternative for ARVs at facilities where EtO use is at least 10 tpy. There are 47 facilities where EtO use is at least 10 tpy, 41~~0~~ of which have ARVs. Of these facilities, ~~19~~22 currently use catalytic oxidizers, ~~six~~seven use ~~wet scrubbers~~gas/solid reactors,

four~~ive~~ use ~~gas/solid reactors~~wet scrubbers, three use thermal oxidizers, three use a wet scrubber and gas/solid reactor in series, two use a catalytic oxidizer and gas/solid reactor in series, and one uses a catalytic oxidizer and thermal oxidizer in series. Performance tests are available for 3~~4~~2 ARVs at all facilities where EtO use is at least 10 tpy; 1~~8~~9 currently use catalytic oxidizers, ~~eight use wet scrubbers,~~ four use gas/solid reactors, two use wet scrubbers, ~~three~~two use a wet scrubber and gas/solid reactor in series, ~~two~~four use thermal oxidizers, and ~~two~~one use~~s~~ a catalytic oxidizer and gas/solid reactor in series~~, and one uses a catalytic oxidizer and thermal oxidizer in series~~. We reviewed these performance tests, and the reported emission reductions ranged from 95.~~2~~7 percent to 99.998 percent.

For existing ARVs at facilities where EtO use is at least 10 tpy, we considered two potential options as part of the technology review. The first option we considered (Option 1) is the emission reduction that has been demonstrated in 75 percent of all available performance tests, which is 99.6 percent. The second option we considered (Option 2) is the emission reduction that has been demonstrated in 50 percent of all available performance tests, which is 99.9 percent.

The impacts of these options are presented in Table 30:

Table 30—Nationwide Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(6) for Existing ARVs at Facilities Where EtO Use Is at Least 10 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.6 percent emission reduction	$~~4,965,285~~5,348,248	$1,~~045,614~~389,805	~~2.13~~1.89	$~~490,266~~734,581
2	99.9 percent emission reduction	$~~18,380,266~~20,563,093	$~~3,265,882~~4,504,268	~~3.32~~2.96	$~~983,458~~1,521,440

We are proposing Option 1 because Option 1 would be more cost-effective. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for existing ARVs at facilities where EtO use is at least 10 tpy under CAA section 112(d)(6). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99.6 percent. We are soliciting comment on our proposed revision to this standard (Comment C-4~~30~~). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.6 percent emission reduction for existing ARVs at facilities where EtO use is at least 10 tpy and whether 9.~~89~~E-4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99.6 percent emission reduction standard for existing ARVs at facilities where EtO use is at least 10 tpy (Comment C-4~~41~~).

b. New sources

The current subpart O contains emission standards for new ARVs at facilities where EtO use is at least 10 tpy. As discussed in section III.B.2 of this preamble, we are proposing to remove the 1 ppmv alternative for ARVs at facilities where EtO use is at least 10 tpy. For new

ARVs at facilities where EtO use is at least 10 tpy, we considered the same two potential options as those evaluated for existing ARVs at facilities where EtO use is at least 10 tpy for the same reasons explained above. The first potential option (Option 1) would require achieving 99.6 percent emission reduction, and the second potential option (Option 2) would require achieving 99.9 percent emission reduction. The impacts of these options, which are presented in Table 31 below, are based on a model plant for new ARVs at a facility using at least 10 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities at least 10 tpy EtO:

- Number of ARVs: 6~~5~~
- Annual EtO use: 150 tpy
- Annual operating hours: 8,400
- Portion of EtO going to ~~SC~~ARVs: 3.~~94~~90 percent
- ~~SC~~ARV flow rate: 300 cfs

Table 31. Model Plant Emissions Reduction and Cost Impacts of Options Considered Under CAA Section 112(d)(6) for New ARVs at Facilities Where EtO Use Is at Least 10 TPY

Option	Proposed Standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.6 percent emission reduction	$272,825~~7~~	$~~78,134~~90,990	3.5E-2	$2,~~204,435~~592,644
2	99.9 percent emission reduction	$400,076~~9~~	$~~97,121~~115,974	5.3E-2	$~~1,826,734~~2,203,031

We are proposing Option 2 because Option 2 would achieve greater emission reductions than Option 1, and Option 2 would be more cost-effective. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for new ARVs at facilities where EtO use is at

least 10 tpy under CAA section 112(d)(6). Specifically, we are proposing to require these facilities to continuously reduce emissions from new ARVs by 99.9 percent. We are soliciting comment on our proposed revision to this standard (Comment C-452). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.9 percent emission reduction for new ARVs at facilities where EtO use is at least 10 tpy and whether 2.3E-4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99.9 percent emission reduction standard for new ARVs at facilities where EtO use is at least 10 tpy (Comment C-463).

G. What other actions are we proposing, and what is the rationale for those actions?

In addition to the proposed actions described above, we are proposing additional revisions to the NESHAP. We are proposing revisions to the SSM provisions of the NESHAP in order to ensure that they are consistent with the decision in *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. We also are proposing revisions to performance test procedures and methods; revisions to monitoring, recordkeeping, and reporting requirements, including requirements for electronic reporting of emissions test results and reports; and making clarifications related to single-item sterilization processes. Our analyses and proposed changes related to these issues are discussed below.

1. SSM Requirements

In its 2008 decision in *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), the court vacated portions of two provisions in the EPA's 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 CAA section 112 standards apply continuously.

We are proposing the elimination of the SSM exemption in this rule that appears at 40 CFR 63.363(f). We are also proposing to eliminate the malfunction exemption in this rule that appears at 40 CFR 63.362(b) and instead require compliance with the standards at all times. Consistent with *Sierra Club v. EPA*, we are proposing standards in this rule that apply at all times. We are also proposing several revisions to Table 7 (the General Provisions Applicability Table) as explained in more detail below. For example, we are proposing to eliminate and revise certain recordkeeping requirements related to the SSM exemption as further described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully done so (Comment C-47~~4~~).

In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods. Emission reductions for SCV, ARV, CEV, and room air emission sources are typically achieved by routing vapors to an APCD such as a wet scrubber, catalytic oxidizer, and dry bed scrubber. It is common practice in this source category to start an APCD prior to startup of the emissions source it is controlling, so the APCD would be operating before emissions are routed to it. We expect APCDs would be operating during startup and shutdown events in a manner consistent with normal operating periods, and that these APCDs will be operated to

maintain and meet the monitoring parameter operating limits set during the performance test. We have no reason to believe that emissions are different during startup and shutdown. Therefore, we are proposing that emissions from startup and shutdown activities be included when determining if all the standards are being attained. As currently proposed in 40 CFR 63.362(b), compliance with the emission limitations (including operating limits) in this subpart is required "at all times." We solicit comment on whether facilities in the Commercial Sterilization Facilities source category will be able to comply with the standards during these times (Comment C-485).

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

a. 40 CFR 63.362(j) General Duty

We are proposing to add general duty regulatory text at 40 CFR 63.362(j) that reflects the general duty to minimize emissions while not including any reference to periods covered by an SSM exemption. In the absence of the SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty.

b. Compliance with Standards

We are proposing to revise 40 CFR 63.632 to reflect the court order and correct the CFR to remove any exemptions from compliance during an SSM event. Revisions will clarify and remove any language that is premised on the existence of an exemption and is inappropriate in

the absence of the exemption. Thus, we require compliance with standards at all times through additions to the regulatory text at 40 CFR 63.362(j).

c. 40 CFR 63.365 Performance Testing

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.7(e) by adding separate rows for 40 CFR 63.7(e)(1) through (4) and by changing the "yes" for 40 CFR 63.7(e)(1) to a "no." Section 63.7(e)(1) describes performance testing requirements. The EPA is instead proposing to modify the performance testing requirements at 40 CFR 63.365(d). The performance testing requirements that we are proposing to modify differ from the General Provisions performance testing provisions in several respects. The regulatory text does not include the language in 40 CFR 63.7(e)(1) that restated the SSM exemption and language that precluded startup and shutdown periods from being considered "representative" for purposes of performance testing. The proposed performance testing provisions will exclude periods of startup or shutdown as representative conditions for conducting performance testing. As in 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during malfunctions because conditions during malfunctions are often not representative of normal operating conditions. The EPA is proposing to add language that requires the facility to 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 normal operation. Section 63.7(e) requires that the facility make available to the Administrator upon request such records "as may be necessary to determine the condition of the performance test," but does not specifically require the information to be recorded. The regulatory text the EPA is proposing to add to this provision builds on that requirement and makes explicit the requirement to record the information.

d. Monitoring

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.8(c)(1)(iii) by changing the "yes" to a "no." The cross-references to the SSM plan requirements in that subparagraph are not necessary in light of other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.8(d) by adding separate rows for 40 CFR 63.8(d)(1) through (3) and changing the "yes" to a "no" for 40 CFR 63.8(d)(3). The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions' SSM plan requirement which is no longer applicable. The EPA is proposing to add to the rule at 40 CFR 63.367 text that is identical to 40 CFR 63.8(d)(3) except that the final sentence is replaced with the following sentence: "The program of corrective action should be included in the plan required under 40 CFR 63.8(d)(2)."

e. 40 CFR 63.367 SSM-related Recordkeeping

40 CFR 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. It will continue to be important to know when such startup and shutdown periods begin and end in order to determine compliance with the appropriate standard for normal operations or any separate standard for startup and shutdown. We are proposing to add recordkeeping requirements to 40 CFR 63.367 that require recordkeeping of startup, shutdown events and require reporting related to all exceedances.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(b)(2)(ii) by changing the "yes" to a "no." Section 63.10(b)(2)(ii) describes the recordkeeping requirements for malfunction. We are instead proposing to add recordkeeping

requirements that require reporting of malfunction events and require reporting related to all exceedances. The EPA is proposing that this requirement apply to all malfunction events requiring that the source record the date, time, cause, and duration of the malfunction and report any failure to meet the standard. The EPA is also proposing to add to 40 CFR 63.367 a requirement that sources keep records that includes the affected source or equipment, whether the failure occurred during a period of startup, shutdown or malfunction, actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing to require that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

f. 40 CFR 63.366 SSM-Related Reporting

When applicable, 40 CFR 63.10(b)(2)(iv)(B) requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required. The requirement under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now applicable by reference to 40 CFR 63.367(g).

We are proposing to add reporting requirements to 40 CFR 63.366 that would require sources that fail to meet an applicable standard at any time to report the information concerning

such events in the compliance report that we are also co-proposing in this action. We are proposing that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source 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.

Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

2. Monitoring, Recordkeeping, Reporting and Testing Requirements

a. Monitoring And Testing

Currently, the rule requires that compliance be demonstrated though an initial performance test and continuous parametric monitoring, with additional work practice standards for catalytic oxidizers. We do not believe that this is sufficient to ensure continuous compliance with the emissions limitations. We are proposing to instead require facilities to demonstrate continuous compliance through either an annual compliance demonstration and operating limits or by using EtO CEMS. We solicit comment on this proposed change (Comment C-4~~9~~6).

The rule currently requires facilities to conduct initial performance testing within 180 days of the compliance date for an emission source. We are considering reducing the amount of time allowed between the compliance date and when the initial performance test is required in order to provide more timely assurance to affected communities that emission limits are being

met. We solicit comment on what might be a more appropriate timeframe for requiring the initial performance test (Comment C-5047).

Due to the increasingly complex nature of control systems, we are also proposing to significantly revise the test methods and procedures requirements (40 CFR 63.365). The revised structure would be laid out as follows:

- Paragraph (b), currently the efficiency at the SCV, would be dedicated to the approved test methods used to determine the mass of EtO entering and exiting a control system or stack,
- Paragraph (c), currently the concentration determination, would provide an alternative method for determining the mass of EtO entering a control system if demonstrating compliance with a removal efficiency standard for a stream that only includes sterilization chamber vents,
- Paragraph (d), currently the efficiency determination at the aeration room vent (not manifolded), would lay out the procedures for determining either the removal efficiency of a control system or the emission rate,
- Paragraph (e), currently the determination of baseline parameters for acid-water scrubbers, would lay out the procedures for establishing the operating limit(s) for parameter monitoring for control devices that are used to comply with an emission limit,
- Paragraph (f) would lay out the procedures for establishing operating limit(s) for a process parameter where a control system is not used to comply with an emission limit, and
- Paragraph (g) would lay out the procedures for demonstrating compliance with EPA Method 204 and establishing an operating limit for PTE.

We are proposing to remove EPA Test Methods 2D, 18, and 25A, as well as CARB Method 431, from the list of approved methods within the rule. For EPA Method 2D, we are unaware of any facilities currently using Roots type meters to determine flow rate. EPA Methods 18 and 25A, as well as CARB Method 431, are currently required for SCV in the subpart O rule. EPA Method 25A uses an FID or PID to count carbon atoms, and EPA Method 18 uses an FID with a column that separates the hydrocarbons to speciate the compounds. CARB Method 431 has a lower detection limit of roughly 0.2 ppmv, and EPA Method 18 also uses techniques that allow detection of EtO concentrations to 0.2 ppmv (or 200 ppbv). Based on our proposed changes to the emissions standard, facilities will likely have to achieve much lower EtO concentration levels from commercial sterilization processes and control systems, and a more robust measurement technology is needed. Some states already require EtO emissions to be reduced to lower levels at 99.9 percent or greater or 0.2 ppmv (IL 2019). If the outlet from the control system is, for example 30 ppbv, the current test methods included in subpart O, such as Method 18, may not reliably detect this level of concentration. There are many performance tests in this source category conducted with M18, CARB Method 431, and M25A that report outlet concentrations as non-detect (and provide the detection level value as the lowest possible concentration detected). With non-detect concentrations at the outlet, facilities may not be able to demonstrate compliance with the removal efficiency standard or the emission rate standards. We solicit comment on the removal of these approved test methods (Comment C-5148).

We are also proposing to add EPA Test Methods 1[51] and 320[52] to the list of approved methods within the rule. Method 1 would be used for determining the location of sampling ports. EPA Method 320 for Fourier Transform Infrared Spectroscopy (FTIR) uses the absorption of the infrared (IR) spectrum to identify compounds, where each compound produces a unique absorption pattern or spectrum. The sensitivity of this approach is often reliant on the complexity of the emission stream and the presence of potential spectral interferences. For EtO commercial sterilization, the emission streams are not very complex and the primary spectral interferences (*i.e.*, water and carbon dioxide) are minimal. Furthermore, EPA Method 320 using an optically enhanced FTIR is capable of measuring in-stack EtO concentration to approximately 10 ppbv which is consistent with the proposal emission standards. We solicit comment on the addition of these test methods as well as solicit comment on other techniques or methods with detection levels in the range of EPA Method 320 (Comment C-52~~49~~).

Currently, the performance test that is required to be conducted to determine the control efficiency for the SCV is conducted on a single chamber that contains no product, and it is only conducted on the first evacuation of the sterilization chamber. In addition, facilities are required to perform three 1-hour test runs. In assessing the performance testing procedures for the source category, the EPA followed the *Clean Air Act National Stack Testing Guidance* issued in 2009. The intent of the 2009 stack testing guidance was to improve uniformity on how stack tests are conducted to demonstrate compliance for NESHAP (40 CFR parts 61 and 63)) programs (and

[51] See Sample/Velocity Traverses, available at *https://www.epa.gov/emc/method-1-samplevelocity-traverses*.
[52] Measurement of Vapor Phase Organic and Inorganic Emissions by Extractive Fourier Transform Infrared Spectroscopy.

also New Source Performance Standards in 40 CFR part 60).[53] In the *Stack Testing Guidance* document, the EPA recommends that performance tests be performed under representative (normal) conditions that:

- represent the range of combined process and control measure conditions under which the facility expects to operate (regardless of the frequency of the conditions); and
- are likely to most challenge the emissions control measures of the facility with regard to meeting the applicable emission standards, but without creating an unsafe condition. (EPA 2009)

Concerns with the current testing procedures in subpart O include that testing is conducted on a single sterilizer chamber while no product is present, and testing is conducted for the first evacuation only, neither of which may be representative of actual nor normal operations. Each sterilization cycle is conducted on product and packaging in the sterilizer chamber, with a set charge of EtO and a defined number of nitrogen and air washes. To incorporate the 2009 stack testing guidance, the performance testing should be conducted during normal sterilizer chamber conditions. This change to the performance testing procedure would provide an emission reduction percentage from the performance test that more closely reflects the emission reduction achieved during normal operation. To address both the maximum capacity and the low emissions loading criteria in the 2009 *Stack Testing Guidance*, the full series of nitrogen and air washes of the sterilization cycle could be included in the performance test period. For the first

[53] The 2009 *Clean Air Act National Stack Testing Guidance* document, available at *https://www.epa.gov/sites/default/files/2013-09/documents/stacktesting_1.pdf*, addresses the timeframe for conducting stack tests (*i.e.*, granting an extension), stack test waivers, stack notifications to the delegated agency, observation of stack tests by the delegated agency, representative testing conditions, stopping a stack test once started, postponement of a stack test, and information to include in the test report.

nitrogen wash, the maximum capacity of the EtO concentration would be addressed, and with each additional nitrogen wash and air wash of the sterilization cycle, the EtO concentration inlet to the control system will decline and further challenge the emission removal efficiency of the control system. Because multiple emission sources may be vented to the APCD at one time, the performance testing procedure should also include the normal, simultaneous routing of emissions sources to an APCD typically seen during operation.

The EPA has determined that the current performance testing procedures in subpart O do not reflect normal operations as discussed in the 2009 *Stack Testing Guidance*. A more encompassing performance test procedure for SCVs that includes normal operation of the sterilizer chamber with product present, covers all evacuations, *i.e.*, all venting and washes, and also includes the number of sterilizer chambers (or other emission sources) that typically vent simultaneously would provide a more representative control level actually achieved by the control system. A longer test run period would provide a better indication of the emission reduction achieved by the APCD over time with multiple normal processes routing to the device. For CEV and ARV emission sources, a longer test run period would provide the time-averaged emission reduction achieved by the APCD with multiple, normally operating processes routing to the device.

The EPA is proposing a 24-hour test run across all emission source types, SCV, CEV, ARV, and room air for facilities where EtO use is at least 10 tpy. We are proposing that the performance testing be conducted under normal operating conditions and each test run be conducted for 24 hours. For facilities where EtO use is less than 10 tpy, the EPA is proposing that each test run within the test may instead be conducted for a 1-hour period.

When determining the volumetric flow rate during performance testing, we currently require that “the flowrate must be constant during time (t).” We are unsure of whether this is feasible or necessary, and we request comment on whether this language should be modified and, if so, how (Comment C-53~~0~~).

In addition, we believe that the current language surrounding standard volume is unclear, and we are proposing to revise our description of standard volume to read as follows: “24.05 liters per gram-mole (L/g-mole) at 20°C and 101.325 kilopascals (kPa) (385.1 standard cubic feet (scf) per pound-mole (scf/lb-mole) at 68°F and 1 atmosphere). We solicit comment on our proposed revisions to language regarding standard volume (Comment C-54~~1~~).

The APCD and process parameters that are selected for monitoring should be key indicators that confirm the control system or process is operating properly and that the emission limit(s) is being met. The operating limits that are set for these parameters are important as they help to ensure that conditions are similar to those that occurred during the most recent compliance demonstration with the emissions standards. Monitoring these APCD and process parameters ensures that ongoing operations are within the range of values that occurred during the compliance demonstration. Maintaining the APCD and process parameters within the operating limits established during the performance test helps ensure the emission standard is being met. Note that APCD and process operating parameters need to be collected during each periodic performance test and perhaps revised because of the performance test. Moreover, when substantial process changes occur or control devices change, performance testing along with concurrent parameter data collection must occur, and the operating limit for the parameter be adjusted or reaffirmed, as required.

During the initial and annual performance testing, the operating limits for APCD and process parameters are determined. For the most part, the APCD parameters required in the EtO Commercial Sterilization NESHAP are appropriate and will continue to be monitored, however more explicit procedures for establishing the operating limits are needed in the rule. The current procedure for determining operating limits typically includes measuring and recording the parameter value every 15 minutes over three test runs and calculating the average parameter value for each test run. The average value from the test runs will be the minimum or maximum operating limit, depending on the parameter, for the APCD.

We are proposing several changes to how operating limits are established during and monitored between compliance demonstrations. The parameters selected for ongoing monitoring of control devices are generally related to the key operating principles for the type of control device.

For acid-water scrubbers, the current operating limits that are allowed in the rule include the maximum ethylene glycol (EG) concentration in the scrubber liquor and the maximum height of scrubber liquor in the recirculation tank(s). We are not proposing any changes to how the maximum EG concentration is established. We are, however, proposing to add requirements regarding how the maximum scrubber liquor tank level is established. Currently, the rule states that “For determining the scrubber liquor tank level, the sterilization facility shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.” We believe that a single measurement at an unspecified time during the performance test will not provide a representative operating limit that would ensure compliance with the emission limit between performance tests. We are proposing to instead require facilities that chose to establish a maximum scrubber liquor tank level(s) as their operating limit for acid-water

scrubbers to monitor and record the maximum scrubber liquor tank level once during each of the three test runs. We would further require them to use the data collected during the most recent performance test to calculate the average scrubber liquor tank level measured during the performance test. This scrubber liquor tank level would be the maximum operating limit for the scrubber liquor tank. This procedure would be conducted for every scrubber liquor tank that is included in the performance test. We are soliciting comment on these proposed changes to how the maximum scrubber liquor tank level is established (Comment C-5~~2~~).

We are also proposing to allow facilities with acid-water scrubbers to establish a maximum scrubber liquor pH as an alternative to a maximum EG concentration or scrubber liquor tank level. The pH of the scrubber liquor is a good indicator of performance and has been implemented in other rules that we have promulgated (*e.g.*, the New Source Performance Standards for Commercial and Industrial Solid Waste Incineration Units at 40 CFR Part 60 Subpart CCCC). In addition, based on responses to our data collection efforts, at least 12 facilities are already monitoring this parameter in addition to what we currently require. This limit would be established in a similar manner to our proposed changes for establishing the scrubber liquor tank level in that facilities would be required to monitor and record the scrubber liquor pH at least once every 15 minutes during each of the three test runs. They would then use the data collected during the most recent performance test to calculate the average scrubber liquor pH measured during the performance test. This scrubber liquor pH would be the maximum operating limit for the acid-water scrubber, and these procedures would be conducted for every acid-water scrubber that is included in the performance test. We would also require that the instrumentation used for monitoring the scrubber liquor pH meet the following requirements

- The pH sensor must be installed in a position that provides a representative measurement of scrubber liquor pH;
- The facility must ensure the sample is properly mixed and representative of the fluid to be measured;
- A performance evaluation of the pH monitoring system must be conducted in accordance with the facility's monitoring plan at least once each process operating day; and
- The facility must conduct 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 in accordance with the facility's monitoring plan at the time of each performance test but no less frequently than quarterly.

We solicit comment on allowing facilities with acid-water scrubbers to establish a maximum scrubber liquor pH and our proposed requirements for instrumentation and establishing the operating limit (Comment C-5~~6~~3).

In 1994, we promulgated requirements for facilities to establish a minimum operating temperature for their catalytic or thermal oxidation units during the performance test if they were used to comply with an emission limitation. In 2001, this requirement was removed, and the operating limit consisted of the manufacturer's recommended minimum operating temperature. This change was made under the old testing paradigm of the rule where, for SCVs, the performance test was only conducted for one empty chamber during one phase of the cycle (evacuation). Control systems are much more complex, with multiple sterilizer chambers at different phases exhausting to the same control system simultaneously, often with other emission source types. Therefore, establishing a minimum operating temperature during the performance test is appropriate. Temperature as the operating parameter for thermal oxidizers will be

maintained in the rule. We are proposing that the current use of manufacturer recommended minimum oxidation temperatures for catalytic and thermal oxidizers be replaced with site-specific temperatures determined during the performance test.

For thermal oxidizers, we are proposing that facilities would measure and record the temperature every 15 minutes over three test runs, calculate the average temperature for each test run, and the average of the three test runs would be calculated and would be the minimum operating limit. For catalytic oxidizers, the average of the three test runs would be calculated for both the inlet temperature to the catalyst bed and the temperature difference across the catalyst bed, where these values would be the minimum operating limits. For temperature measurement, we are proposing that the facility 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. We are also proposing that the accuracy of the temperature monitor be verified twice each calendar year 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). We are soliciting comment on the changes to establishing the operating limits for temperature and verifying the instrument two times per year (Comment C-574).

Gas-solid reactors (*i.e.*, dry bed scrubbers) are now commonly used at commercial sterilization facilities. We are aware of certain operating parameters for this type of control device, including pressure drop and temperature across the dry bed packing. However, we

believe that these are not viable parameters to monitor as indicators of EtO removal because neither indicate that the reaction is occurring on the media bed nor the remaining activity of the dry bed media, and that the only way to ensure continuous compliance is using an EtO CEMS. Therefore, we are proposing that, for control systems where a gas-solid reactor is present, facilities must demonstrate continuous compliance with the appropriate emission rate standard using an EtO CEMS. We solicit comment on (1) the viability of pressure drop and temperature across the solid packing for parametric monitoring as indicators of EtO removal or EtO concentration level, along with data demonstrating the viability for continuous compliance purposes, (2) other parameters for which an operating limit could be established, along with data demonstrating the viability of such parameters for continuous compliance purposes, and (3) requiring the use of an EtO CEMS for control systems where a gas-solid reactor is present (Comment C-585).

It is possible to demonstrate compliance with an emission rate standard without the use of a control system. However, operating limits must still be established and monitored to confirm that operation of the process stays within the range(s) established during the most recent compliance demonstration. Typical process parameters for EtO commercial sterilization could include the mass of EtO charged to the sterilizer chamber cycle and the EtO concentration of the room or vent. We are proposing that if any portion of the SCV(s) at a facility is neither routed to a control system nor monitored using an EtO CEMS, the facility must establish as an operating limit and monitor the maximum daily amount of EtO charged to the sterilization chamber(s). We are also proposing that if the ARV(s), Group 1 room air emissions, or Group 2 room air emissions at a facility are subject to an emissions limitation and if the emissions are neither routed to a control system nor monitored using an EtO CEMS, the facility must establish as an

operating limit the maximum EtO concentration for each aeration room and area where there are Group 1 or Group 2 room air emissions, as applicable. We are further proposing that the facility monitor and record every 15 minutes the EtO concentration within each of these areas and compute three-hour rolling averages that must be maintained below the appropriate operating limits. We are also proposing that an affected facility must develop a site-specific monitoring plan for the operation of the measurement systems used to monitor room air EtO concentration, and we are also proposing a set of requirements for these monitoring plans in 40 CFR 63.364(c)(5) of the proposed rule. We are soliciting comment on these proposed changes for process parameter monitoring when no control system or EtO CEMS is present (Comment C-596).

For facilities where a PTE is required (as discussed in sections III.B.8 and III.D.1 of this preamble), we are proposing to give facilities the option to either establish a minimum volumetric flow rate through the exhaust duct(s) or stack(s) or install, operate, calibrate, and maintain a continuous pressure differential monitoring system to verify the presence of PTE. If a facility chooses to use a continuous differential pressure monitoring system, a monitor must be installed within each room that is included in the PTE, and the pressure differential must be maintained above 0.007 inches of water. Regardless of whether a facility chooses to establish a minimum volumetric flow rate(s) or monitor pressure differential, we are also proposing that facilities continuously verify the direction of air flow through daily inspections of each natural draft opening (NDO), which may be done through a smoke test or using streamers. We are soliciting comment on the continuous compliance requirements for facilities implementing a PTE (Comment C-5760).

b. EtO CEMS

The use of CEMS is an option in the current rule for the measurement of EtO from the exhaust of catalytic or thermal oxidation controls for the purpose of parametric monitoring of those control options. The current rule includes two options for CEMS, one reliant on gas chromatography (GC) systems for the direct measurements of EtO (Performance Specification 9 of 40 CFR part 60, appendix B) and another which uses an appropriate detector to determine a surrogate, volatile organic compound value as EtO (Performance Specification 8 of 40 CFR part 60, appendix B). The current rule requires these systems to be capable of measuring and recording once per hour and that the facility record a 24-hour average of the EtO measurements. These recordkeeping requirements are unique to subpart O but are inconsistent with the requirements in the general provisions 40 CFR 63.8(c)(4)(ii) which require systems to be capable of measuring once each 15-minutes. While the current requirements in the rule may be appropriate for parametric monitoring, the use of speciated EtO CEMS for compliance purposes is warranted and therefore we are proposing 1) to remove Performance Specification 8 as an option for continuous monitoring because it is not selective to EtO and 2) that systems be capable of completing a collection, transport, and analysis cycle at least once each 15-minutes to be consistent with the General Provisions. Note that source facilities may choose to time-share their CEMS among different measuring points, provided that the measurement points are approximately equidistant from the CEMS, the sampling time at each measurement point is at least 3 times as long as the response time for that point, and that each measurement point has at least one complete cycle within 15 minutes. Of course, we propose that a complete description of the time-shared CEMS must be provided in the facility's monitoring plan. As an example, consider an EtO CEMS with a response time of 60 seconds and a cycling time of 75 seconds. Could it be used for time-sharing purposes, and if so, how many points could be sampled? Three

times the response time would be 180 seconds, which when added to twice the response time (from the CEMS to the measurement point and back), or 120 seconds, would be 300 seconds, so the EtO CEMS could be used. Fifteen minutes divided by 300 seconds would yield three measurement points, so a facility could sample from up to three points for this case. Note that daily calibration checks would need to be provided for each measurement point and that a facility may choose to provide fewer than the maximum number of measurement points on an EtO CEMS in order to have more data from which to calculate an hourly average. Also, a fewer number of measurement points per EtO CEMS could mean fewer numbers of excess emissions, for should the CEMS malfunction or become out-of-control, each shared measurement point would also be subject to a malfunction or would be out-of-control until corrections were made. We are soliciting comment on the removal of PS 8, the requirement to monitor every 15 minutes, and allowing time-share use of an EtO CEMS (Comment C-~~58~~61).

The techniques for measuring EtO in stationary sources have significantly improved since the risk and technology review (71 FR 17712, April 7, 2006), and to account for these changes the EPA is proposing a new set of standards for the operation of these measurement techniques as CEMS. EPA is aware of at least two optical based technologies (*e.g.*, FTIR and Cavity Ringdown Spectroscopy) being applied to continuous measurements of EtO in commercial sterilizer sector. In order to provide a pathway for these technology in the rule, EPA is also proposing a new Performance Specification (PS) 19 in 40 CFR part 60, appendix B to allow for the use of these and other EtO CEMS sampling and analytical technologies as long as the required performance criteria set out in the performance specification are met. Initial minimum requirements for instruments are contained in the PS, while ongoing quality assurance (QA) and quality control procedures are found in QA Procedures. To that end, we are also

proposing QA Procedure 7 in 40 CFR part 60, appendix F to establish consistent requirements for ensuring and assessing the quality of data measured by a EtO CEMS on an ongoing basis. These requirements will ensure that the EtO CEMS have the ability to make appropriate measurements and continue to make these measurements appropriately, as well as to demonstrate compliance with the emission limits. These proposed procedures are based on techniques found in the recently promulgated Performance Specification 18 (PS-18) in CFR part 60, appendix B and QA Procedure 6 in CFR part 60, appendix F, relying on a performance-based approach used for HCl CEMS in PS-18 and on adherence to the continual QA Procedure for their operation. However, the PS and QA Procedures proposed in this rule contain criteria specifically devised for operation at EtO commercial sterilizers. We believe performance-based techniques, along with their associated QA procedures, offer a viable path for introducing and using new measurement approaches quickly. We solicit comment on the use of performance-based approaches and on the proposed PS and QA Procedures (Comment C-6259). In addition, we are proposing that CEMS data be reported daily so that results can be shared with the public on a daily basis. We are soliciting comment on the frequency of CEMS data reporting, as well as the period that the reported CEMS data are to be shared with the public (Comment C-630).

This proposed PS-19 and associated QA procedures represent a significant adjustment in how the Agency uses CEMS for organic HAPS, specifically the application of CEMS for sub ppmv-level measurements. With these levels of measurements, there is a need to be more prescriptive as to the data quality objectives in the PS, specifically as to how the systems are initially certified and continually quality assured. For those reasons we are proposing to remove PS-9 as an option for continuous monitoring from the rule because 1) the data quality objectives of this PS are not equivalent with what is found in proposed PS-19 and 2) the underlying

technology in PS-9 (GC) would fit within the performance-based structure in proposed PS-19. We solicit comment on the removal of PS-9 as an option from the rule for continuous monitoring and on whether there were any concerns that a GC based system could meet the requirements of proposed PS-19 (Comment C-641). Also, we are aware there are currently EtO CEMS in place that use FTIR technology at commercial sterilizers that have been successfully certified according to Performance Specification 15 (PS-15) of 40 CFR part 60, appendix B as part of existing state rules, and therefore we have considered its use in the proposed rule. However, we consider the proposed PS-19 is more appropriate for low-level standards and the underlying technology fits within the performance-based structure in proposed PS-19. We are soliciting comment on whether PS-15 should be an option from the rule for continuous monitoring, and if so, how could the lower-level measurements be addressed (Comment C-652).

In addition, if a facility chooses to demonstrate continuous compliance with an emission rate standard using an EtO CEMS, we are proposing that the facility may comply with the applicable emission rate standard on a 30-day rolling average basis, where each valid hourly average is determined from the EtO CEMS; the sum of those valid hourly averages is determined for each day; and the 30-day rolling average is determined from the sum of that day's average plus the previous 29 daily averages divided by 30. We are soliciting comment on allowing facilities to comply with a 30-day rolling average emission rate if an EtO CEMS is used to demonstrate continuous compliance, as well as the 30-day rolling average calculation procedure (Comment C-663).

In the absence of NIST traceable reference gases for EtO and in an effort to improve the accuracy and reliability of continuous measurements, both for performance testing and CEMS application, in PS-19 we are also proposing to include an Appendix B for the preparation of

certification of EtO Cylinder Gas Standards consistent with the procedures used in Broadly Applicable Approved Alternative Methods (Alt) 114[54] for HCl standards and Alt 118[55] for mercury standards. We are soliciting comment on PS-19 appendix B for preparation of gas standards (Comment-C-52). Finally, we are soliciting comment on whether certain facilities or groups of facilities should be required to use CEMS to comply (Comment C-674).

c. Fenceline monitoring

The EPA has previously employed fenceline monitoring (for benzene as a surrogate for HAP emissions from fugitive sources) as part of a work practice standard for petroleum refineries, promulgated as part of the technology review for the source category (40 CFR part 63, subpart CC), to monitor and manage fugitive emissions as well as aiding in the monitoring of the sector's ground-level emission points (*e.g.*, storage tanks, wastewater collection systems, equipment leaks, etc.). This type of monitoring is performed at multiple points located at the edge of a facility's property line, commonly known as the "fenceline," and the results of this monitoring are used to calculate a long-term average (*e.g.*, annual rolling average) of a pollutant concentration at the boundary. If this long-term average exceeds an "action-level," then a facility is required to conduct the associated work practices (*i.e.*, root cause and corrective action) to identify and mitigate the source of the excess emissions. The "action-level" was set at a level reflecting full compliance with the emissions standards for the emission points described above and at a concentration in which there was a robust measurement method (*i.e.*, EPA Method 325B) for measuring benzene at and well below the action-level. This level was based on the

[54] See *https://www.epa.gov/sites/default/files/2020-08/documents/alt114.pdf*
[55] See *https://www.epa.gov/sites/default/files/2020-08/documents/alt118.pdf*

highest modeled impact from the refinery sector at the fenceline using the emission inventories and dispersion modeling.

EPA gave close consideration to the feasibility and utility of adopting a similar fenceline monitoring requirement as part of this proposed rule, in response to a substantial number of comments from front-line communities supporting the use of fenceline measurements to address potential room air emissions from Commercial Sterilization Facilities. EPA notes that room air release points from this source category differ from fugitive emission at refineries in important respects. First, the boundaries for a commercial sterilization facility are often the building itself or very small easements, making boundary line measurements problematic because these locations are unlikely to be representative of emissions from the release points. Typically for this type of monitoring, we require the fenceline monitor to be at least 50 meters from the source of emissions to the property boundary[56] to allow for some dispersion. Second, in contrast to the large number of dispersed and difficult-to-monitor emission points at a refinery, 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. Moreover, the proposed PTE design criteria, proposed room air emission standards, and associated parametric monitoring discussed in section III.B.8 will effectively and continuously ensure these previously uncontrolled emissions are captured and routed to exhaust points that are subject to removal or emission rate standards. ~~I~~As a result, EPA does not believe that a fenceline monitor would measure a significant quantity of residual EtO emissions, or identify a compliance issue that has not already been detected through the continuous monitoring requirements

[56] EPA Method 325A, section 8.2.1.1

included in this proposal~~].~~ ~~s coupled with continuous compliance demonstration to front-line communities and the public~~.

Given the feasibility to capture room air emissions from this sector through the requirements to install PTEs and continuous parametric monitoring of these capture systems, as well as control systems being proposed, we consider fenceline monitoring and the associated work practice requirements to be unnecessary. In addition, as described above, we believe fenceline monitoring could be technically challenging to implement for this source category given the physical configurations of these facilities. We solicit comment on (1) whether fenceline monitoring should be required regardless of the proposed PTE design criteria, proposed room air emission standards, and 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 (Comment C-6~~85~~).

The EPA is also considering the application of beyond the fenceline measurements (*i.e.*, ambient monitoring) as part of a work practice standard where the proposed standards in this action are in such format, or as an additional measure to assure additional compliance assurance where the proposed standards are numeric. The EPA is interested in and is therefore soliciting comment on how ambient monitoring could be used to screen for elevated concentrations of ethylene oxide 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 this commercial sterilization proposed rule. We also solicit 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

Commented [A154]: Could fenceline monitoring be an alternative to PTE?

Commented [A155R154]: No. The emissions standards (and associated post-control risk assessments) are based on capture and control of **all** emissions of the facility. PTEs are the only known effective strategy to minimize fugitive emissions form the facility as described above in the preamble.

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 (Comment C-6~~9~~6).

d. Initial Summary Report

We are proposing that facilities record and report the following information in the initial summary report to aid us in determining compliance with the proposed requirements:

- EtO use and operating hours of the facility over the previous 12 months

If a sterilization facility is demonstrating continuous compliance through periodic performance testing, the EPA is proposing that the following information be included in the initial summary report:

- Control system ID[57];
- Control device ID;
- Control device type; and
- Recirculation tank ID if an acid-water scrubber is used to meet the emission limitation and if an election is made to comply with the maximum scrubber liquor height limit.

The EPA is proposing that the following information be included in the initial summary report for each sterilization chamber at the facility:

- The sterilization chamber ID;
- The ID of the control system that the SCV was routed to, if applicable;
- The portion of SCV exhaust that was routed to the control system, if applicable;
- The ID of the control system that the CEV was routed to, if applicable; and

[57] IDs that are referenced in all reports would be generated by the owner or operator of the facility.

- The portion of CEV exhaust that was routed to the control system, if applicable.

If emissions from any room in the facility are subject to an emission limitation (*e.g.*, aeration room or rooms where Group 1 or Group 2 room air emissions are present), the EPA is proposing that the following information be included in the initial summary report for each room where there are EtO emissions:

- Room ID;
- The ID of the control system that the room air was routed to, if applicable;
- The portion of room air that was routed to the control system, if applicable; and
- Documentation of emissions occurring within the room, including aeration, EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material.

If any portion of the facility is required to be operated with PTE, the EPA is proposing that for each NDO inspection, facilities must report the same information that we are proposing to require as part of semi-annual summary reports, as discussed later in this section. If a facility is complying with the requirement 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 ~~14161:2009~~11138-1:2017, we are proposing that the facility must provide the approach that was used for each unique cycle.

We are soliciting comment on the content required for the initial summary report (Comment C-70~~67~~).

e. Semi-Annual Summary Reports

For subsequent semi-annual summary reports, we are proposing that facilities record and report the following information:

- EtO use and operating hours of the facility over the previous 12 months;
- If the facility is demonstrating continuous compliance through periodic performance testing, any changes to the corresponding information provided in the previous summary report
- Any changes related to the sterilization chambers;
- If emissions from any room in the facility are subject to an emission limitation, any changes related to the individual rooms;
- If any portion of the facility is required to be operated with PTE, the EPA is proposing that for each NDO inspection, facilities must report the inspection ID, the room ID, the NDO ID, the date and time that the inspection started, the duration of the inspection, the method of inspection (smoke test or streamers), and the direction of air flow through the NDO (into the facility or out of the facility); and
- If a facility is complying with the requirement to follow either the Cycle Calculation Approach or the Bioburden / Biological Indicator Approach to achieve sterility assurance to achieve sterility assurance in accordance with ISO 11135:2014 and ISO ~~14161:2009~~11138-1:2017, we are proposing that the facility must provide the approach that was used for each unique cycle.

We are soliciting comment on the content required for the subsequent semi-annual summary reports (Comment C-71~~68~~).

f. Quarterly Summary Reports

We are proposing different reporting requirements for facilities where EtO use is less than 20 tpy. Specifically, we are proposing that these facilities submit summary reports on a

quarterly basis and include in these reports the following additional information for each room whether there is the potential for EtO emissions:

- Number of RACs per hour;
- Average hourly temperature; and
- Average hourly EtO concentration.

We are also proposing that these facilities may instead submit summary reports once every three years if they meet the following requirements:

- 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 or through a stack(s),
- Limit Group 2 room air emissions of EtO to 2.8E-3 lb/hr (facilities where EtO use is less than 20 tpy), and
- Meet the requirements of 40 CFR 63.363.

These emission rates are the most stringent limits for which all facilities within these groups can demonstrate compliance using currently available technology. We solicit comment on different requirements for these facilities (Comment C-72~~69~~).

g. Electronic Reporting

The EPA is proposing that owners and operators of commercial sterilization facilities submit electronic copies of required compliance reports, performance test reports, and performance evaluation reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous*

Air Pollutants (NESHAP) Rules, available in the docket for this action. Following a processing period in CEDRI, each report will be sent to the EPA's Web Factor and Information Retrieval (WebFIRE) database, where it is publicly accessible. The standard processing period is 60 days for performance test reports and performance evaluation reports and 30 days for all other report submissions. Agency reviewers may extend the processing period for individual reports by up to 60 days for performance test reports and performance evaluation reports and up to 30 days for all other report submissions. The proposed 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[58] at the time of the test are submitted in the format generated through the use of the ERT or an electronic file consistent with the XML schema on the ERT website, and other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, performance evaluation results of continuous emissions monitoring systems (CEMS) measuring relative accuracy test audit (RATA) 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 or an electronic file consistent with the XML schema on the ERT website, and other performance evaluation results be submitted in PDF using the attachment module of the ERT. The proposed rule requires that Notification of Compliance Status (NOCS) reports be submitted as a PDF upload in CEDRI. For compliance reports, both initial and ongoing, the proposed rule requires that facilities use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the proposed template for these reports is included in

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

the docket for this rulemaking.[59] The EPA specifically requests comment on the content, layout, and overall design of the template.

While the ERT does not directly support submittal for EPA Reference Method 320 or ASTM D6384–12e1, a facility may complete the WebFIRE template with the performance test data and submit to the ERT as an attachment, along with a PDF version of the full performance test report. The WebFIRE template is included in the docket for this action. The EPA specifically requests comment on the content, layout, and overall design of the template(s) for use with EPA Method 320 and ASTM D6348–12e1 (Comment C–73~~0~~).

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. These circumstances are (1) outages of the EPA's CDX or CEDRI that preclude an owner or operator from accessing the system and submitting required reports and (2) *force majeure* events, which are defined as events that will be or have been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevent an owner or operator from complying with the requirement to submit a report electronically. Examples of *force majeure* events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible.

[59] See *EtO Compliance Report Draft Template.xlsx*, available at Docket ID. No. EPA-HQ-OAR-2019-0178.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan[60] to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy[61] developed in response to the White House's Digital Government Strategy.[62] For more information on the benefits 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*, referenced earlier in this section.

3. Other Changes

a. Single-Item Sterilizers

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[60] The EPA's Final Plan for Periodic Retrospective Reviews, August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154*.

[61] E-Reporting Policy Statement for EPA Regulations, September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf*.

[62] Digital Government: Building a 21st Century Platform to Better Serve the American People, May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html*.

The EPA has identified nine commercial sterilization facilities that use single-item sterilizer processes, where all of these facilities have APCDs in place to reduce EtO emissions. While a traditional sterilization chamber tends to be a larger vessel that accommodates pallets containing diverse products, a single-item sterilizer is generally smaller and may use much less EtO to sterilize products. In the single-item sterilization process, operators place the product into a plastic pouch, a slight vacuum is applied, and EtO gas is injected into the pouch and sealed. Sealed pouches with product and EtO are placed in bins and then loaded into a cabinet or chamber under specific temperature and humidity conditions where EtO both sterilizes the product and off-gasses or aerates from the pouch. The EtO slowly dissipates from the pouch or bag by diffusion. Once the pouch and product are removed from the cabinet or chamber, the product is held in the shipping/warehouse area before being sent offsite. EtO is stored in a pressurized cylinder at single-item sterilization facilities, and these cylinders are smaller than EtO storage drums used at traditional sterilization facilities. Some single-item sterilizers may use EtO ampules, and place the ampule in the pouch, seal the pouch, then break the ampule prior to placement in the cabinet or chamber.

In this proposal, the EPA is clarifying that the cabinet or chambers where sterilization and aeration occur at single-item sterilizer facilities are subject to the SCV emission standards under subpart O. The process activities, including the dwell period to expose the product to EtO and ensure sterile product, as well as aeration of the product to remove residual EtO, occur at single-item sterilization facilities in the same way as at other EtO commercial sterilization facilities. The cabinet or chamber includes air flow that is routed to a vent to an APCD or to the atmosphere. There is no technical or process difference between single-item sterilization and those at other traditional sterilizer chamber and aeration room operations that impact adopting

measures to reduce EtO emissions. The cabinet or chamber where pouches are placed should be referred to as combination sterilizer chambers, *i.e.*, where both sterilization and aeration occur in the same chamber. EtO usage at single-item sterilizer facilities range from 0.43 to 2.5 tpy. There are five single-item sterilizer facilities where EtO use is at least 1 tpy but less than 10 tpy, and these facilities are subject to the SCV emission standard for sources using 1 to 10 tons of EtO per year. There are four facilities that are using less than 1 ton, and these facilities are subject to the SCV emission standard for sources using less than 1 ton. These sources were included in the ample margin of safety analysis for SCV at sources using 1 to 10 tons (see section III.D.3) and for the proposed SCV standards at facilities using less than 1 ton (see section III.B.1). In addition, the facilities would be subject to the proposed emission standards for Group 1 room air emissions, specifically for EtO injection room air emissions, and for Group 2 room air emissions (for shipping/warehouse rooms).

b. Title V

Section 502(a) of the Clean Air Act establishes the list of sources required to obtain operating permits under title V. This list of sources includes "any other source (including an area source) subject to standards or regulations under section 111 or 112 [NESHAP]." See 40 CFR 70.3(a) and 71.3(a). Section 502(a) provides that, "The Administrator may, in the Administrator's discretion and consistent with the applicable provisions of this Act, promulgate regulations to exempt one or more source categories (in whole or in part) from the requirements of this subsection if the Administrator finds that compliance with such requirements is impracticable, infeasible, or unnecessarily burdensome on such categories, except that the Administrator may not exempt any major source from such requirements." Pursuant to this authority, the EPA

published a final rule on December 19, 2005 (70 FR 57320) that exempted area source EtO commercial sterilizers from title V permitting.

In the December 2005 final rule, the EPA articulated a four-factor balancing test to evaluate whether title V permitting requirements would be "unnecessarily burdensome" for an area source category. The four factors evaluated by the EPA were: (1) 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; (2) 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; (3) 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; and (4) whether adequate oversight by state and local permitting authorities could achieve high compliance with the NESHAP requirements without relying on title V permitting. In addition, the EPA stated that "…the legislative history of Section 502(a) suggests that EPA should not grant exemptions where doing so would adversely affect public health, welfare, or the environment. See Chafee-Baucus Statement of Senate Managers, Environment and Natural Resources Policy Division 1990 CAA Leg. Hist. 905, Compiled November 1993 (in that '[t]he Act requires EPA to protect the public health, welfare and the environment, … this provision of the permits title prevents EPA from exempting sources or source categories from the requirements of the permit program if such exemptions would adversely affect public health, welfare, or the environment')."

At the time of the December 2005 final rule, the EPA's analyses of the four-factor balancing test and consideration of the legislative history of section 502(a) weighed in favor of

exempting area source EtO commercial sterilizers from title V permitting. Since that time, the EPA has gained a better understanding of the risks associated with EtO emissions. In 2016, the EPA released its updated IRIS value for EtO, which indicated that cancer risks from EtO emissions were significantly higher than characterized in the prior 1985 assessment. Subsequently, the 2014 National Air Toxics Assessment released in August 2018 identified EtO emissions as an important risk driver in several areas across the country. Following this, the EPA has engaged in assessments of community census tracts that potentially have elevated cancer risks from exposure to EtO in ambient air. Related to these risk findings, there has been significant public interest in the Commercial Sterilization Facilities source category, including robust participation in public hearings and public comment on permitting actions.

In addition to an improved understanding of the risks and ambient concentrations of EtO, the EPA has more information available to support this proposal's evaluation than was available during the 2005 rulemaking. The EPA conducted its December 2019 questionnaire and September 2021 ICR as part of this rulemaking, which included gathering data from area source EtO sterilizers related to EtO usage and emissions, parent company ownership, and revenue generation related to sterilization services. In contrast, the 2005 rulemaking was in part based upon the absence of information available to the EPA at the time.[63]

In a 2019 ICR renewal for the part 70 state operating permits program, the EPA estimated the burden for title V permitting. At the time, the EPA estimated the average burden for all affected sources at $19,031 per year (in year 2018 dollars). This burden value was calculated based upon estimates of the labor hours required for title V permitting related activities,

[63] See 70 FR 75325, December 19, 2005: "For EO sterilizers, as in the proposal, the EPA has no reliable information on the economic resources of area sources but, as described below, believes that a number of area sources are small businesses with limited economic resources."

including application preparation, monitoring development and operation, and reporting. See *2nd Notice Supporting Statement for ICR No. 1587.14 OMB No. 2060-0243*, February 2019, available in the 40 CFR Part 70 State Operating Permit Regulations, EPA Renewal ICR docket (Docket ID No. EPA-HQ-OAR-2004-0015). The EPA utilized the activity labor hour estimates from the 2019 ICR to develop a tailored estimate for this rulemaking of the labor hour and cost burden for area source EtO commercial sterilizers to comply with title V permitting requirements. The EPA estimates this burden at 391 labor hours and $67,211 in total cost (inclusive of labor and operating permit fees) for the first year of compliance, and 43 labor hours and $6,287 in total cost for the second and third years of compliance. Note that the activity labor hour estimates used in this burden estimate are based upon the average for all sources subject to the title V program, including both area sources and complex major sources. Compared to area sources, major sources experience greater burden from title V associated activities, particularly in application preparation, and are associated with increased delegated authority burden which, by law, is required to be passed onto sources in the form of permit fees. As a result, the average burden estimate is likely to overstate the costs imposed upon area source EtO commercial sterilizers. While this burden is not insignificant, it represents a small portion of the anticipated costs related to the amendments of this proposed rule. Further, we have determined that this burden is not significant and is justified when considering the anticipated benefits from requiring title V permitting for area source EtO commercial sterilizers.

In the March 2005 proposed rule to exempt area source EtO commercial sterilizers from title V permitting, the EPA evaluated the relationship to the legislative history of section 502(a) as follows: "The EPA believes the vast majority of area sources proposed today for exemption from title V permitting in this notice are typically subject to not more than one NESHAP, and

Commented [A156]: Did EPA estimate the time it takes from initiation to the permit process to permit issuance? How does the need to obtain a Title V permit impact purchase and installation of emissions control equipment?

Commented [A157R156]: EPA did not estimate the time it takes from initiation to the permit process to permit issuance. However, CAA section 503(c) says:

"Any person required to have a permit shall, not later than 12 months after the date on which the source becomes subject to a permit program approved or promulgated under this subchapter, or such earlier date as the permitting authority may establish, submit to the permitting authority a compliance plan and an application for a permit signed by a responsible official, who shall certify the accuracy of the information submitted. The permitting authority shall approve or disapprove a completed application (consistent with the procedures established under this subchapter for consideration of such applications), and shall issue or deny the permit, within 18 months after the date of receipt thereof…"

In addition, sources must comply with the standards regardless of whether a title V permit is in place. Also, CAA section 504 provides that a source that submits a timely and complete title V permit application cannot be found to be in violation of title V by operating without a permit if the permitting authority has not issued the permit to the source.

few other requirements under the Act, and that these NESHAP are relatively simple in how they apply to these sources. One of the primary purposes of the title V program is to clarify, in a single document, the various and sometimes complex regulations that apply to sources in order to improve understanding of these requirements and to help sources to achieve compliance with the requirements." (See 70 FR 15254) In contrast to the subpart O rule requirements as they existed at that time, the rule amendments proposed in this rule provide for a greater degree of complexity and requirements to achieve and demonstrate compliance for area sources. While the EPA maintains the understanding that the majority of area source EtO sterilizers are subject only to a single NESHAP, the compliance benefits of title V are greater today than in 2005.

For the reasons articulated above, the EPA has determined that it is not appropriate to exempt area source EtO commercial sterilizers from the requirement to obtain a title V permit under section 502(a). Based upon this determination, we are proposing to require that any sterilization facility subject to subpart O obtain a title V permit from the delegated authority in which the source is located. Corresponding revision is proposed to the General Provisions table entry for 40 CFR 63.1(c)(2) to remove the comment discussing the exemption of area sources from the obligation to obtain a title V operating permit. The additional public participation and compliance benefits of additional informational, monitoring, reporting, certification, and enforcement requirements that exist in title V should be required for these sources. These additional requirements are important to ensure that these sources are maintaining compliance with the requirements of this rule. While there is additional burden associated with title V permitting on the affected facilities, this burden is not significant compared to the expected benefits to public health and compliance. We estimate that approximately 86 affected area

Commented [A158]: How much time is afforded the public to provide input on new permits? Given EPA's outreach to communities, should facilities expect significant opposition to their continued operation, regardless of this rule? Is 18 months enough time to obtain what we should expect to e a permit that encounters significant local opposition?

Commented [A159R158]: Given that local permitting authorities may have different requirements regarding this matter, EPA does not have an estimate on timing for public input. However, EPA will continue to work with communities and local governments to address any concerns and so that any potential disruption to the supply of medical devices is minimized.

In addition, sources must comply with the standards regardless of whether a title V permit is in place. Also, CAA section 504 provides that a source that submits a timely and complete title V permit application cannot be found to be in violation of title V by operating without a permit if the permitting authority has not issued the permit to the source.

Commented [A160]: What the benefits to public health of a Title V permit?

Commented [A161R160]: EPA believes that more involvement from local permitting authorities and the public will result in requirements that properly address the health needs and concerns of individual communities. A benefit in a title V permit is increased transparency and public participation, so that members of affected communities can know where sources are, what they are emitting, and the standards they are subject to, as well as having an opportunity to participate in the process. Title V permits also generally include specific monitoring, recordkeeping, and reporting requirements that allow for greater transparency and assurance of sources' compliance with standards.

sources will be required to obtain title V permits. The EPA solicits comment on the requirement for area sources in the source category to obtain a title V permit (Comment C-741).

c. Definitions

We are proposing the addition, revision, and deletion of numerous terms in the regulatory text, which is provided as part of this rulemaking. Specifically, we are proposing to add terms for:

- Emission process units and sources (combination sterilizer, EtO dispensing, Group 1 room air emission, Group 2 room air emissions, indoor EtO storage, pre-aeration handling of sterilized material, post-aeration handling of sterilized material, vacuum pump operation),
- Emissions capture (natural draft opening, PTE),
- APCDs and related terminology (acid-water scrubber, catalytic oxidizer, gas/solid reactor, peak shaver, residence time),
- Monitoring (continuous monitor, maximum daily mass of EtO charged to the sterilization chamber(s), maximum scrubber liquor pH, minimum room air EtO concentration, minimum temperature at the inlet to the catalyst bed, minimum temperature difference across the catalyst bed, minimum temperature in or immediately downstream of the firebox, minimum stack volumetric flow rate, rolling average), and
- Others (aeration, single-item sterilization).

It should be noted that while aeration is a defined process, there is still off-gassing of EtO from sterilized product that occurs after aeration (and before if a combination sterilizer is not used). We solicit comment on these new definitions (Comment C-752). We are also proposing to revise existing definitions in the regulatory text.

- Adding acronyms and alternative terms to the definitions for aeration room vent, chamber exhaust vent, and sterilization chamber vent,
- Replacing “at least 99-percent control of ethylene oxide emissions” with “the appropriate control of EtO emissions” in the definitions for maximum ethylene glycol concentration and maximum liquor tank level,
- Clarifying the definition for aeration room to indicate that if a facility uses only combination sterilizers, there are no aeration rooms at the facility,
- Revising the definition for sterilization facility to clarify that facilities that engage in single-item sterilization are included in this definition, and
- Broadening the definition for sterilization operation to include times when EtO is stored within the building, EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration.

We solicit comment on these revised definitions (Comment C-76~~3~~). Finally, we are proposing to delete the following definitions from the regulatory text:

- Baseline temperature
- Compliance date
- Effective date
- Manifolding emissions
- Source(s) using less than 1 ton
- Source(s) using 1 ton
- Source(s) using 1 to 10 tons
- Source(s) using less than 10 tons
- Source(s) using 10 tons

We are proposing to remove the definition for baseline temperature because the proposed operating limits for oxidizers depend on the type of oxidizer being used, and we believe it is best to provide definitions for individual operating limits, like what is done for acid-water scrubbers. We are also proposing to remove the definitions for compliance date and effective date because the definitions are already provided in the General Provisions. Because we are proposing detailed requirements for combined emissions streams, we are proposing to remove the definition for manifolding emissions. Finally, we are proposing to remove the definitions for source(s) using less than 1 ton, source(s) using 1 ton, source(s) using 1 to 10 tons, source(s) using less than 10 tons, and source(s) using 10 tons because these terms are not descriptive enough (*i.e.*, they do not specify the duration of use). We solicit comment on the removal of these definitions (Comment C-774).

d. Standards For Combined Emissions Streams

The EPA's understanding of control configurations at commercial sterilization facilities has changed since the rule was promulgated in 1994. In recent years, companies have implemented a wide variety of combinations when controlling emission streams at these facilities. As a result, it can be difficult to determine whether one vent type is in compliance with the rule when it is being combined with other vent types. Therefore, the EPA is proposing to structure the rule requirements so that facilities can combine emission streams based on the best approach for their facilities. The EPA is proposing different emission limitations based on the format of the standard (*i.e.*, removal efficiency or emission rate) with which the facility is complying. If complying with a removal efficiency standard, the EPA is proposing that the facility must comply with the removal efficiency standard for the emission source in the composite stream that has the most stringent removal efficiency. For example, at a facility where

EtO use is at least 10 tpy, a combined stream that consists of emissions from ARVs subject to a removal efficiency of 99.5 percent and CEVs subject to a removal of 96 percent would be subject to a removal efficiency standard of 99.5 percent removal efficiency for the combined emission stream. If complying with an emission rate standard, the EPA is proposing that the facility must comply with an emission rate standard that is equal to the sum of the emission rate standards for each emission source type in the composite stream. For example, at a facility where EtO use is at least 10 tpy, a combined stream that consists of emissions from ARVs subject to an EtO emission rate of 7.0E-3 lb/hr and CEVs subject to an EtO emission rate of 3.4E-3 lb/hr must comply with an EtO emission rate standard of less than 1.0E-2 lb/hr from the combined emission stream. This approach is necessary because of the multiple configurations of emissions streams, and results in standards that are equivalent and equally protective compared to the standards for individual emissions streams. When determining compliance, it is important for facilities to understand how their emission streams are configured and what the ultimate emissions from these streams are. The EPA solicits comment on the proposed standards for combined emissions streams (Comment C-785).

e. Negative Pressure For SCVs And CEVs

The current subpart O rule does not include capture requirements for emissions. For ARVs and room air emissions, we are proposing PTE requirements to ensure complete capture of EtO from these sources. It is also important to ensure that emissions from other sources such as SCV and CEV are completely captured and routed to control systems. The EPA is proposing to require that emissions from SCVs and CEVs be routed under negative pressure when ducted to a control system. The EPA solicits comment on this proposed requirement (Comment C-796).

H. What Compliance Dates Are We Proposing, And What Is The Rationale For The Proposed Compliance Dates?

Amendments to the subpart O NESHAP proposed in this rulemaking for adoption under CAA sections 112(d)(2), (3), (5), and (6), as well as CAA section 112(f)(2), are subject to the compliance deadlines outlined in the CAA under section 112(i).

For the requirements we are proposing under CAA sections 112(d)(2)-(3), (d)(5), and (d)(6), we are proposing all existing affected sources must comply with all amendments no later than 18 months after the effective date of the final rule. In addition, we are proposing all new affected sources must comply with all amendments upon startup. For existing sources, CAA section 112(i) provides that the compliance date shall be as expeditious as practicable, but no later than 3 years after the effective date of the standard. ("Section 112(i)(3)'s three-year maximum compliance period applies generally to any emission standard . . . promulgated under [section 112]." *Association of Battery Recyclers v. EPA*, 716 F.3d 667, 672 (D.C. Cir. 2013)). In determining what compliance period is as expeditious as practicable, we consider the amount of time needed to plan and construct projects and change operating procedures. As provided in CAA section 112(i), all new affected sources would be required to comply with these requirements by the effective date of the final amendments to the subpart O standards or startup, whichever is later.

We are proposing updated operating and monitoring requirements for capture and control systems. We anticipate that these requirements would require the installation of monitoring equipment, and we project most commercial sterilization facilities would install additional or replacement systems to monitor and adjust process variables that impact the parameters being monitored. Like the addition of control equipment, these monitoring requirements for capture and control systems would require engineering evaluations, solicitation and review of vendor quotes, contracting and installation of the equipment, and operator training. Installation of

Commented [A162]: Can existing facilities operate if they have not obtained a Title V permit? How much time is typically necessary to obtain a Title V permit? Do facilities invest in compliance control equipment and begin installation before the permit issued or do they generally wait until the permit is finalized to begin installation? Has EPA included the new requirement for a Title V permit in its consideration of the 18 month compliance date?

Commented [A163R162]: CAA section 503(c) lays out the requirements for obtaining a title V permit, along with the appropriate deadlines:

"Any person required to have a permit shall, not later than 12 months after the date on which the source becomes subject to a permit program approved or promulgated under this subchapter, or such earlier date as the permitting authority may establish, submit to the permitting authority a compliance plan and an application for a permit signed by a responsible official, who shall certify the accuracy of the information submitted. The permitting authority shall approve or disapprove a completed application (consistent with the procedures established under this subchapter for consideration of such applications), and shall issue or deny the permit, within 18 months after the date of receipt thereof…"

If the requirements are followed, facilities may continue to operate. EPA does not have an estimate on the typical time required to obtain a title V permit. Sources must comply with the standards regardless of whether a title V permit is in place.

additional or replacement systems to monitor and adjust process variables may require the capture and control system(s) to be taken out of service and may also require a significant portion of the commercial sterilization facility to be shutdown. Therefore, ~~for certain groups of facilities,~~ we are proposing that it is necessary to provide 18 months after the effective date of the final rule (or upon startup, whichever is later) for facilities to comply with the updated operating and monitoring requirements for capture and control systems.

Additionally, as previously discussed in this preamble, we are proposing under CAA section 112(f), provisions for SCVs, ARVs, CEVs, and room air emissions at certain groups of facilities. The proposed provisions may require additional time to plan, purchase, and install equipment for capture and control. For example, for SCVs at facilities where EtO use is at least 40 tpy, if the affected source cannot demonstrate 99.94 percent control of EtO emissions, then a new control system will need to be installed. Therefore, ~~for certain groups of facilities,~~ we are proposing a compliance date of 18 months after the effective date of the final rule. For all new affected sources that commenced construction or reconstruction after [**INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER**], we are proposing facilities comply with the requirements that are being proposed upon startup.

Finally, we are proposing to change the requirements for SSM by removing the exemption from the requirements to meet the standards during SSM periods. We are also proposing electronic reporting requirements. We are positing that facilities would need some time to successfully accomplish these revisions, including time to read and understand the amended rule requirements, to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown, as defined in the rule, and make any necessary adjustments, including making adjustments to standard operating procedures, and to convert

Commented [A164]: It's not clear from this write-up which groups of existing facilities have more or less than 18 months.

Commented [A165R164]: All existing facilities have 18 months. Text has been removed

Commented [A166]: Same comment as above.

Commented [A167R166]: All existing facilities have 18 months. Text has been removed

reporting mechanisms to install necessary hardware and software. The EPA recognizes the confusion that multiple different compliance dates for individual requirements would create and the additional burden such an assortment of dates would impose. From our assessment of the timeframe needed for compliance with the entirety of the proposed revisions to SSM requirements as well as the new proposed electronic reporting requirements for compliance reports and performance evaluation reports, the EPA considers a period of 18 months after the effective date of the final rule to be the most expeditious compliance period practicable and, thus, is proposing that all affected sources be in compliance with these revised SSM and electronic reporting requirements upon initial startup or within 18 months of the effective date of the final rule, whichever is later. However, we are proposing to provide 60 days after the effective date of the final rule (or upon startup, whichever is later) for facilities to comply with the requirement to report performance test and evaluation results, notices of compliance status, and initial and ongoing compliance reports electronically. There are several factors that either support or undermine the justification for an expedited compliance timeframe for existing sources. We are aware that, in order to implement the capture and emission reduction systems necessary to comply with the requirements that we are proposing, facilities will need to cease operations for a certain period of time in order to implement these systems. However, an expedited compliance timeframe could result in more facilities needing to cease operations simultaneously. This means that increased coordination would be needed ~~in order~~ to ensure that the supply of medical devices is not adversely impacted. ~~In addition, we anticipate that a number of facilities will need to install gas/solid reactors in order to meet the emission standards that we are proposing. There are currently only two known manufacturers of this type of control device, which poses a potential supply issue if too many facilities are in demand for this product.~~ We

Commented [A168]: Does EPA expect these shutdowns to be a week, several weeks or months? Is the business disruption included in the cost estimates?

Commented [A169R168]: EPA believes that these shutdowns typically last at least a week but may be longer if more work is needed. EPA does not have methods to estimate how long facilities might close or what the lost revenues might be. As such these costs are not included in the cost estimates

Commented [A170]: Who does EPA anticipate would provide this coordination? What mechanisms for this coordination currently exist? Will these mechanisms provide equal access for small businesses?

Commented [A171R170]: EPA believes that a wider response from the Federal government is needed to ensure an adequate supply of medical devices. It is unknown what mechanisms for this coordinated currently exist, but it is our anticipation that much of this coordination would be led by FDA, as EPA has worked to inform them of facility closures over the past few years to ensure that the supply of medical devices is not adversely impacted. EPA believes that this coordination would provide equal access for small businesses

Commented [A172]: How many facilities will need this control device and what is capacity of these manufacturers? EPA should not be speculating on what appears to be a clear bottleneck that would jeopardize the ability of sterilizers to operate.

Commented [A173R172]: EPA anticipates that 57 facilities will need this control device. One manufacturer has noted that they can work on up to eight gas/solid reactor systems at once. This text has been deleted

also recognize the health risks that this source category currently poses and that the risks of EtO exposure have been made known to the public for some time. In addition, a significant portion of the industry is already operating the types of capture and control systems that we anticipate will be needed to comply with the proposed standards. We solicit comment on the appropriate compliance timeframe for existing sources (Comment C-8077).

IV. Summary of Cost, Environmental, and Economic Impacts

A. What Are The Affected Sources?

There are 86 facilities in the Commercial Sterilization Facilities source category that are currently operating.[64] A complete list of facilities that are currently subject to the NESHAP is available in Appendix 1 of the *Risk and Technology Review* memorandum, which is available in the docket for this rulemaking. We anticipate that an additional 23 facilities will commence operation and become subject to the rule in the next 3 years.

B. What Are The Air Quality Impacts?

For the standards that we are proposing, we estimated an EtO emissions reduction of 19 tpy for the total source category reductions from sterilizer chambers, aeration rooms, chamber exhaust, and room air emission sources. See the *Technology Review* memorandum.

C. What Are The Cost Impacts?

The nationwide costs of the proposed amendments are presented in Table 1 of this preamble. As described in this preamble, we are proposing to reduce EtO emissions from SCV, CEV, ARV, Group 1 room air, and Group 2 room air emission sources. The capital costs, for

[64] As discussed in section III.C.1, the risk assessment was conducted on these 86 facilities, as well as 11 research and development facilities, for a total of 97 facilities. To exercise caution, we included research facilities in our assessment because there is a lack of certainty over whether these are true research facilities, for which CAA section 112(c)(7) requires that a separate category be established.

facilities with controls already in place, include addition of add-on dry scrubber controls to meet the emission reduction determined under the technology review; ductwork; an interlock system, damper, and in-chamber EtO concentration monitor for the CEV; and performance testing. The capital costs also include a PTE, an add-on dry scrubber control device, pressure monitoring device, and performance testing for room air emission sources. Annual costs include annualized capital costs, media replacement cost, operating and maintenance labor, recordkeeping and reporting, electricity, and taxes and insurance. The total annual costs of the proposed rule are estimated to be $68 million in 2021 dollars.

D. What Are The Economic Impacts?

The present value (PV) of the estimated compliance costs from 2023 to 2042 for the proposed option is $640 million in 2021 dollars~~$407 million in 2019 dollars~~, discounted at a 7 percent rate. The equivalent annualized value (EAV) of the costs for the proposed rule is $747~~47~~ million, using a 7 percent discount rate. Using a 3 percent discount rate, the PV and EAV of the cost impacts are estimated to be $784~~501~~ million and $53~~34~~ million, respectively.

The EPA conducted economic impact analyses for this proposal, as detailed in the document, *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, which is available in the docket for this action. For the proposed amendments, the EPA performed a screening analysis which compared facility-level annualized compliance costs to annual revenues of the ultimate owner of the facility (or facilities), known as the ultimate parent company. These cost-to sales ratios underpin the ‘‘sales test’’ methodology the EPA uses to assess small business impacts for a rulemaking.

Commented [A174]: EPA updated the engineering costs in the following ways:
- Incorporated changes to proposed standards that were not accounted for in the first round
- Working in 2021 dollars rather than 2019
- Increased interest rate to 7.75% for calculating capital recovery
- Equipment lifetime for PTE and dry bed scrubbers has been reduced to 20 years
- Fixed minor errors such as making sure reporting and recordkeeping costs were assigned to 2 facilities which previously had them missing

There are 88 facilities affected by the proposed amendments and they are owned by 48~~7~~ ultimate parent companies.[65] Of these 88 facilities, 24 facilities, or 27 percent, are owned by 20 small entities at the ultimate parent company level. We calculated the cost-to-sales ratios for all the affected parent companies to assess the magnitude of the costs of the proposed amendments and determine whether there is potential for significant impacts on small entities. For all firms, the average cost-to-sales ratio is approximately 7.9~~5.3~~ percent; the median cost-to-sales ratio is approximately 0.3~~1~~ percent; and the maximum cost-to-sales ratio is approximately ~~57.5~~68 percent. For large firms, the average cost-to-sales ratio is approximately 0.3~~2~~ percent; the median cost to-sales ratio is approximately 0.03~~2~~ percent; and the maximum cost-to-sales ratio is approximately 3.9~~1.7~~ percent. For small entities, the average cost-to-sales ratio is approximately 19~~2.1~~ percent; the median cost to-sales ratio is approximately 7.3~~4.4~~ percent; and the maximum cost-to-sales ratio is approximately 68~~57.5~~ percent. Large firms incur most of the total costs estimated for the proposed rule and they incur higher total annual costs per firm on average than small firms. However, when estimated costs are examined relative to revenues, l~~L~~arge firms are much less affected by the proposed rule than small firms~~, and we believe that they account for a large percentage of the output of this industry~~.

Under the proposed amendments, 17~~2~~ out of 20 (85~~60~~ percent) parent companies identified as small entities are estimated to incur ~~annualized compliance~~total annual costs greater than 1 percent of annual revenues. Additionally, 12 out of 20 small entities (60 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. The 12 small entities with cost-to-sales ratios of 3 percent or greater collectively own 16 facilities.

[65] This includes the 86 facilities thar are currently operating, as well as two planned facilities that are expected to start operating before the proposed compliance deadline.

The EtO sterilization industry is an integral part of the supply chain for many medical devices and capacity constraints have been reported. As described in section I.A.1 of this preamble, we have been engaged with ~~the~~ FDA regarding the potential impacts of this proposal on commercial sterilization facilities that play a key role in the availability of certain medical devices. We project that the largest impacts are limited to a handful of companies, and ~~those that are involved in sterilizing these medical devices~~many of them are already in the planning stage for additional controls. We believe large firms account for a large percentage of the output of this industry, and they appear much less affected by the proposed rule than small firms when examining costs relative to revenues. ~~The EtO sterilization industry is an integral part of the supply chain for many medical devices and capacity constraints have been reported.~~ 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.

E. What Are The Benefits?

The EPA did not monetize the benefits from the estimated emission reductions of HAP associated with this proposed action. This does not imply that there are no benefits associated with the EtO emission reductions estimated for this proposed rule. W~~However, w~~e expect this proposed action would provide ~~significant~~ benefits associated with ~~HAP emission reductions and~~ lower risk of adverse health effects (e.g., cancer incidence) in communities near facilities subject to the NESHAP.

V. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the analyses. We are

Commented [A175]: EPA should describe the benefits it has quantified, even if they are not monetized.

Commented [A176R175]: Text has been modified accordingly

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specifically interested in receiving any information regarding developments in practices, processes, and control technologies that reduce EtO emissions.

VI. Incorporation by Reference (IBR)

We are proposing to incorporate by reference ISO 11135—Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (Approved July 25, 2014), as part of a GACT management practice standard for existing Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy (proposed to be IBR approved for Table 5 to 40 CFR part 63, subpart O). This ISO standard "describes requirements that, if met, will provide an EtO sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity". We are also proposing to incorporate by reference ISO 14161—Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results (Approved September 15, 2009), as part of a GACT management practice standard for existing Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy (proposed to be IBR approved for Table 5 to 40 CFR part 63, subpart O). This ISO standard "provides guidance regarding the selection, use and interpretation of results of biological indicators when used to develop, validate and monitor sterilization processes". Compliance with the requirements ensures that validations conducted following this International Standard will provide products that meet the defined requirements for sterile products with a high degree of confidence. We are proposing to require certain 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 ~~14161:2009~~11138-1:2017, which will result in lower EtO emissions throughout the facility. In addition, we are proposing to incorporate by reference

ISO 17025—General requirements for the competence of testing and calibration laboratories (Approved November 2017). The ISO standards are available from the International Organization for Standardization, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland. See *https://www.iso.org*.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

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

This action is an economically significant regulatory action that was submitted to OMB for review because it may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or ~~S~~state, local, or tribal governments. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an analysis of the potential economic impacts and benefits associated with this action. This analysis, *Economic Impact and Small Business Screening Assessments for Proposed Amendments to the National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization Source Category*, is available in the docket for this rulemaking.

Commented [A177]: Can EPA expand on how they made this determination? Annualized costs in the accompanying RIA seems to be below the $100 mil threshold

Commented [A178R177]: Clarifying text has been added

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to 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 proposing amendments that change the reporting and recordkeeping requirements for several emission sources at commercial sterilization facilities (*e.g.*, SCV, ARV, CEV, and room air emissions). The proposed amendments also require electronic reporting, removes the SSM exemption, and imposes other revisions that affect reporting and recordkeeping. This information would 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: 86 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.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive

comments no later than ~~XXXX XX, 2022~~**[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize the impact. The complete IRFA is available in Section 5.2 of the RIA in the docket and is summarized here.

As discussed in section II.A., the statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 et seq.). The EPA is proposing to revise the NESHAP for Commercial Sterilization Facilities by both amending existing standards and establishing additional standards for this source category, exercising authority under multiple provisions of section 112 of the CAA.

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 proposed rule contains provisions that would affect approximately 20 small entities. These small entities are involved in sterilizing various types of medical devices and spices. In addition, at least eight of these small entities are involved in sterilizing the types of medical devices discussed in section I.A.1 of this preamble. Under the proposed rule requirements, small entities would be required to comply with various emission standards, which may require the use of a

new control device. Some small entities would also be required to comply with a BMP, which would require them to re-validate some or all of their sterilization cycles if they are not already in compliance. Small entities would also need to demonstrate compliance with the emission standards through periodic performance testing and parametric monitoring or through the use of an EtO CEMS. This proposed rule includes reporting, recordkeeping, and other administrative requirements. Under the proposed rule, EPA estimates that approximately 12 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, EPA determined that there is potential for the proposed requirements to have a 'Significant Impact on a Substantial Number of Small Entities' (SISNOSE). See Section 5.2 of the RIA for more information on the characterization of the impacts under the proposed rule.

As required by section 609(b) of the RFA, 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 December 10, 2020, EPA's Small Business Advocacy Chairperson convened the Panel, which consisted of the Chairperson, the Director of the Sector Policies and Programs Division within 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 Small Business Administration (SBA).

Prior to convening the Panel, 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/SBREFA and developed the findings and discussion summarized in the SBAR report. 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. EPA is including some of these flexibilities as a part of the proposed rule requirements and soliciting comment on others that may be considered for the final rule. 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.

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 action are owned or operated by tribal governments or located within tribal lands. Thus, Executive Order 13175 does not apply to this action.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs ~~F~~federal agencies ~~that Federal health and safety standards must~~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 an economically significant regulatory action as defined by Executive Order 12866, and the EPA ~~anticipates~~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[66] 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 follow its guidelines[67] and applied age-dependent adjustment factors (ADAFs) for childhood 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 x 10-3 per µg/m^3. It should be noted that, because EtO is mutagenic, emission reductions proposed in this preamble will be particularly beneficial to children.

[66] Children's Health Policy Available at: *https://www.epa.gov/children/childrens-health-policy-and-plan*

[67] U.S. EPA. 2005. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. U.S. Environmental Protection Agency, Washington, DC, EPA/630/R-03/003F. https://www.epa.gov/sites/default/files/2013-09/documents/childrens_supplement_final.pdf

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 proposed 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.E and G and sections III.C and D of this preamble and further documented in the risk report, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed 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 proposed rule should be minimal for commercial sterilization facilities and their parent companies.

Commented [A179]: This reviewer recommends that EPA consider whether energy usage could potentially increase if devices must be transported to other facilities or even countries for EtO sterilization.

Commented [A180R179]: EPA was not able to quantify the degree to which manufacturers would need to switch sites, so we cannot estimate potential transportation cost impacts

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

This action involves technical standards. Therefore, the EPA conducted searches for the EtO Commercial Sterilization NESHAP through the Enhanced National Standards Systems Network (NSSN) 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 204 of 40 CFR part 51, appendix M; EPA Methods 1, 1, 2, 2A, 2C, and 3B of 40 CFR part 60, appendix A; and EPA Method 320 of 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 considered it as a potential equivalent method. We reviewed all

potential standards to determine the practicality of the VCS for this rule. The EPA may reconsider determinations of impracticality when additional information is available for particular VCS.

No applicable VCS were identified for EPA Methods 204, 1, 1, 2, 2A, and 2C. The following VCS were identified as acceptable alternatives to the EPA test methods for the purpose of this rule.

The EPA proposes to use the VCS ANSI/ASME PTC 19.10–1981 Part 10 (2010), "Flue and Exhaust Gas Analyses," as an acceptable alternative to EPA Method 3B 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. The EPA is not proposing to incorporate this VCS by reference. This method is available both in the docket for this rulemaking and 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*.

In addition, the EPA proposes to use the VCS ASTM D6348-12e1, "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 D6348-12e1 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. The EPA is not proposing to incorporate this VCS by reference. We are proposing the test plan

preparation and implementation in the Annexes to ASTM D 6348-03, Sections Al through A8 are mandatory; and in ASTM D6348-03 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). We are proposing 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 are 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). We are proposing that the %R value for each compound be reported in the test report, and all field measurements be corrected with the calculated %R value for that compound by using the following equation:

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

The ASTM D6348-12e1 method is available both in the docket for this rulemaking and at ASTM International, 1850 M Street NW, Suite 1030, Washington, DC 20036. See *https://www.astm.org/*.

In this rule, the EPA is proposing regulatory text for Tables 1 through 5 to 40 CFR part 63, subpart O that includes IBR in accordance with requirements of 1 CFR 51.5. Specifically, the EPA is incorporating by reference ISO 11135:2014. The ISO standards are available from the International Organization for Standardization, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland. See *https://www.iso.org*.

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable VCS, and to explain why the EPA should use such standards in this regulation (Comment C-81~~78~~).

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

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 people of color, low-income populations and/or indigenous peoples. A total of 19.4 million people live within 10 km of the 97 facilities that were assessed. The percent of the population that is Hispanic or Latino is substantially higher than the national average (34 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 this proposed regulation, cancer risks were above acceptable levels for several areas in which these demographic groups live. See section III.E for an analysis that characterizes populations living in proximity of facilities and risks prior to the proposed regulation.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This action proposed to establish 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. In addition, it

proposes to tighten 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 proposes 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 proposed changes, we expect zero people to be exposed to risk levels above 100-in-1 million. See sections III.B and III.D 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.[68] The EPA is also proposing that owners and operators of commercial sterilization facilities submit electronic copies of required compliance reports, performance test reports, and performance evaluation reports, which will provide greater access to information for impacted communities.

The information supporting this Executive Order review is contained in section III.E 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.

List of Subjects in 40 CFR Part 63

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

[68] *https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information*

Michael S. Regan,

Administrator.