560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2019-0178; FRL-7055.1-01-OAR]

RIN 2060-AW79

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reconsideration of final rule.

SUMMARY: On April 5, 2024, the U.S. Environmental Protection Agency (EPA) published the National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review (2024 Final Rule). The 2024 Final Rule revised the Commercial Sterilization Facilities NESHAP based on a residual risk and technology review (RTR) pursuant to the Clean Air Act (CAA) sections. On March 12, 2025, the EPA announced that it was reconsidering the 2024 Final Rule. Based on its reconsideration of the RTR in the 2024 Final Rule, the EPA is proposing to amend the Commercial Sterilization Facilities NESHAP. The amendments would rescind the risk based standards, revise the standard for new aeration room vents that resulted from the technology review, revise the compliance demonstration requirements, and rescind a requirement related to permanent total enclosure (PTE). This proposal also includes technical corrections and clarifications to the Commercial Sterilization Facilities NESHAP and Performance Specification 19 to address erroneous cross-references, omissions of text, and typographical errors in the regulatory text that the EPA has identified after publication of the 2024 Final Rule.

DATES: Comments must be received on or before **[INSERT DATE 45 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 a virtual public hearing on [**INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. Please refer to the **SUPPLEMENTARY INFORMATION** section for information on registering for the public hearing.

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 U.S. EPA, Attn: Brian Langloss, Mail Drop: D243-04, 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0675; and email address: *langloss.brian@epa.gov*.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. The hearing will be held via virtual platform on **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. 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*.

The EPA will begin pre-registering speakers for the hearing no later than 1 business day after a request has been received. 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 *NRDpublichearing@epa.gov*. The last day to pre-register to speak at the hearing will be **[INSERT DATE 12 CALENDAR 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 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 electronically 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 *NRDpublichearing@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 CALENDAR 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 action 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 as pdf versions that can only be accessed on the EPA computers in the docket office reading room. Certain databases and physical items cannot be downloaded from the docket but may be requested by contacting the docket office at 202-566-1744. The docket office has up to 10 business days to respond to these requests. Except for such material, publicly available docket materials are available electronically at *https://www.regulations.gov*.

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 should 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*.

Throughout this proposal, the EPA is soliciting comment on numerous aspects of the proposed rule. The EPA has indexed each comment solicitation with an identifier (*e.g.*, "Question 1, Question 2, . . .) to provide a consistent framework for effective and efficient provision of comments. Accordingly, we ask that commenters include the corresponding identifier when providing comments relevant to that comment solicitation. We ask that commenters include the identifier in either a heading, or within the text of each comment (*e.g.*, "In response to Question 1, . . .") to make clear which comment solicitation is being addressed.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/*. Clearly mark the part or all the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI, and 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 Office of Clean Air Programs (OCAP) CBI Office at the email address oaqps_cbi@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 oaqps_cbi@epa.gov to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OCAP Document Control Officer (C404-02), OCAP, 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 preamble 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:

APCD	air pollution control device
ARV	aeration room vent
ASTM	American Society for Testing and Materials
CAA	Clean Air Act

CBI	Confidential Business Information
CEMS	continuous emission monitoring system
CEV	chamber exhaust vent
CFR	Code of Federal Regulations
CMS	continuous monitoring system
EAV	equivalent annualized values
EPA	Environmental Protection Agency
EtO	ethylene oxide
FTP	File Transfer Protocol
FR	Federal Register
HAP	hazardous air pollutant
ICR	information collection request
IRIS	Integrated Risk Information System
NAICS	North American Industry Classification System
NESHAP	national emission standards for hazardous air pollutants
OCAP	Office of Clean Air Programs
OMB	Office of Management and Budget
ppm	parts per million
PRA	Paperwork Reduction Act
PTE	permanent total enclosure
PS	performance specification
PV	present values
RFA	Regulatory Flexibility Act
RGM	Research Gas Mixture
RIA	regulatory impact analysis
RTR	risk and technology review
SCV	sterilization chamber vent
SSM	startup, shutdown, and malfunction
SWEL	site wide emission limitation
TCEQ	Texas Commission on Environmental Quality
tpy	tons per year
VCS	voluntary consensus standards

Table of Contents. The information in this preamble is organized as follows:

I. General Information

A. Executive Summary

In this reconsideration action, the EPA is proposing, after consultation with U.S. Department of Health and Human Services, to rescind or revise certain amendments made to the Commercial Sterilization Facilities NESHAP in the 2024 Final Rule to adhere to the best reading of the statute. The Agency first promulgated standards for this source category in 1994. Under CAA section 112(f)(2), the EPA was required to review the standards within eight years to identify and address residual risk to human health and the environment. Under CAA section 112(d)(6), the EPA is also required to review and

revise the standards "as necessary" at least every eight years to address developments in practices, processes, and control technologies. In 2006, the Agency discharged these obligations by completing the RTR for the Commercial Sterilization Facilities source category, finding that the existing standards adequately protected public health with an ample margin of safety and, separately, concluding that no further revisions were "necessary" at that time given the minimal emission reductions and high costs associated with available control strategies.

In 2024, however, the EPA for the first time implemented an interpretation of CAA section 112(f)(2) that authorizes the Agency to conduct additional discretionary residual risk reviews (after completing the mandatory residual risk review within eight years of promulgating MACT standards) and impose risk-based standards pursuant to a second risk review. We reasoned in the 2024 Final Rule and related actions that the Agency possesses this authority because nothing in the statute expressly precludes discretionary residual risk reviews. Upon reconsideration, the EPA proposes that the interpretation as finalized in the 2024 Final Rule is inconsistent with the best reading of the statute. We "possess only the authority that Congress has provided,"[1] and statutes have a "single, best meaning" that is "'fixed at the time of enactment.'"[2] We propose that, read in context, CAA section 112(f)(2) explicitly authorizes a single residual risk review of the MACT standards within eight years, coupled with an express authority to review and revise the standards "as necessary" through a technology review at least every eight years under CAA section 112(d)(6). This interpretation better reflects the structure of CAA section 112, which Congress deliberately designed with detailed implementation timelines and requirements that cannot be squared with the assertion of authority to revisit residual risk reviews on an ad hoc, category-by-category basis. We propose to

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[1] *NFIB v. DOL*, 595 U.S. 109, 117 (2022).
[2] *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400, 411 (2024) (quoting *Wis. Cent. Ltd. v. United States*, 585 U.S. 274, 284 (2018)).

rescind the section 112(f)(2) standards imposed by the 2024 Final Rule on this basis, thereby returning the Commercial Sterilization Facilities source category to the generally applicable regulatory framework arising under section 112(d).

The EPA is also proposing relatively minor adjustments to the revised standards finalized in the 2024 Final Rule under CAA section 112(d)(6). We propose to reduce the emission standard for new ARVs at facilities with EtO use of at least 10 tpy, which would result in a single standard for both new and existing ARVs. This has the benefit of allowing facilities to share infrastructure, streamline facility operations, and reflect common practices at facilities. Finally, we are proposing several technical corrections and clarifications to the regulatory text identified after publication of the 2024 Final Rule, including erroneous cross-references, omissions, and typographical errors.

B. Does this action apply to me?

Table 1 of this preamble lists industrial categories potentially affected by this action. Table 1 is not 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 directly apply 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* and *Documentation for Developing the Initial Source Category List, Final Report*,[3] the Commercial Sterilization Facilities source category includes 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

[3] 57 FR 31576 (July 16, 1992) and EPA-450/3-91-030, July 1992, respectively

to control microorganisms. Facilities may sterilize materials produced on site, or contract sterilizers may sterilize products manufactured by other companies.

Table 1. 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 EPA website. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities*. Following publication in the *Federal Register*, the EPA will post the *Federal Register* version of the proposal and key technical documents on the same webpage.

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 proposed action?

The statutory authority for this action is provided by CAA section 112, as amended.[4] CAA section 112 establishes a multi-stage regulatory process to develop standards for emissions of HAP from stationary sources. Generally, the first stage involves establishing technology-based standards that reflect the maximum achievable control technology (MACT) or an appropriate alternative.[5] The second stage involves evaluating those standards within eight years under CAA section 112(f)(2) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions.[6] This second stage is commonly referred to as the "residual risk review." In addition to the residual risk review, CAA section 112(d)(6) also requires the EPA to review the standards every eight years and "revise as necessary," taking into account "developments in practices, processes, and control technologies."[7] This review is commonly referred to as the "technology review."

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. The requirements for major sources are the relevant requirements for the present rulemaking. "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.[8] For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of reduction in emissions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental

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[4] 42 U.S.C. 7412.
[5] 42 U.S.C. 7412(d)(1)-(3).
[6] 42 U.S.C. 7412(f)(2).
[7] 42 U.S.C. 7412(d)(6).
[8] 42 U.S.C. 7412(a)(1).

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," which is based on emission controls achieved in practice by a certain percentage of the best performing sources. The EPA also considers control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as "beyond-the-floor" standards. The next stage in standard-setting focuses on identifying and addressing any remaining (*i.e.*, "residual") risk within eight years pursuant to CAA section 112(f)(2) and concurrently conducting a technology review pursuant to CAA section 112(d)(6). This latter provision 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 eight 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.[9] The EPA considers cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).

The proposed amendments in this action result from the EPA's reconsideration of certain aspects of the 2024 Final Rule, including the interpretation of CAA section 112(f)(2) adopted in the 2024 Final Rule to justify imposing additional risk-based standards rather than solely considering whether such standards were "necessary" under CAA section 112(d)(6). Specifically, the EPA took the position in the 2024 Final Rule (and again in two additional rules finalized the following month) that the Agency may, on a discretionary basis, utilize the risk-review process in CAA section 112(f)(2) to promulgate additional risk-based standards for a source category that has already

[9] *Ass'n of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667 (D.C. Cir. 2013); *Natural Resources Def. Council (NRDC) v. EPA*, 529 F.3d 1077, 1084 (D.C. Cir. 2008).

undergone a residual risk review after promulgation of MACT standards.[10] As explained further below, the EPA now proposes to interpret CAA section 112(f)(2) as setting out a one-time authority and obligation to assess the residual risk remaining for the source category at issue within eight years of promulgating MACT standards.

Agencies have authority to reconsider prior policy and to revise, replace, or repeal prior actions to the extent permitted by the governing statute and supported by a reasoned explanation.[11] This is true when, as is the case here, an agency reconsiders a prior action after a change in administration.[12] As explained below, the EPA is proposing to repeal certain standards imposed in the 2024 Final Rule on the ground that the Agency erred in interpreting CAA section 112(f)(2) as authorizing the imposition of further rounds of risk-based standards in lieu of the ongoing authority and obligation at least every eight years to revise the standards "as necessary" under CAA section 112(d)(6). We are also proposing revisions to certain additional standards promulgated in the 2024 Final Rule under CAA section 112(d)(6). We propose that nothing in the relevant statutory language precludes or conditions the EPA's authority to repeal the CAA section 112(f)(2) standards based on new conclusions about the best reading of the statute or the EPA's authority to further revise prior standards adopted under CAA section 112(d)(6).

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[10] *See New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry*, 89 FR 42932 (May 16, 2024) (finalizing NESHAP amendments for two source categories in same *Federal Register* notice). The Agency proposed to apply this interpretation to a third source category in a December 2024 proposed rule on which we have not yet taken final action. *See Review of National Emission Standards for Hazardous Air Pollutants for Polyether Polyols Production Industry*, 89 FR 105986 (Dec. 27, 2024).

[11] *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 567 (2025); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

[12] *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038, 1043 (D.C. Cir. 2012) (explaining that an agency's "reevaluation of which policy would be better in light of the facts" is "well within" its discretion and that a change in administration is a "perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations" (internal quotation marks omitted)).

In doing so, the EPA acknowledges that this proposed action would, if finalized, change the position taken in the 2024 Final Rule with respect to CAA section 112(f)(2) and, at a more granular level, change several of the Agency's conclusions with respect to standards adopted in the 2024 Final Rule under CAA section 112(d)(6). The rationale for each of these changes is described in the relevant section of this document. We do not believe that the standards or supporting interpretations adopted in the 2024 Final Rule have generated significant and cognizable reliance interests, including because the standards have not yet gone fully into effect. With respect to questions of statutory interpretation, we do not believe any such reliance interests could support retaining an action that is inconsistent with the best reading of the statute. Nevertheless, we seek comment on whether the 2024 Final Rule and underlying interpretations have generated such reliance interests and, if so, how the EPA should consider them in any final action (Question 1).

B. What is the scope of the reconsideration proposal?

On March 12, 2025, the EPA announced that it is reconsidering the 2024 Final Rule.[13] Subsequently, in a letter dated March 21, 2025, the EPA provided further details on the reconsideration, indicating that we would reexamine our authority and decision to undertake a second residual risk review pursuant to CAA section 112(f)(2), the standards promulgated pursuant to CAA section 112(d)(6), and the requirement to demonstrate compliance using a continuous emission monitoring system (CEMS).[14] This action is consistent with Executive Order 14192 which promotes prudent financial management and alleviates unnecessary regulatory burdens.

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[13] U.S. EPA, Trump EPA Announces Reconsideration of Air Rules Regulating American Energy, Manufacturing, Chemical Sectors (NESHAPs), (March 12, 2025) [Press Release].

[14] Letter from U.S. EPA to Ethylene Oxide Sterilization Association, (March 21, 2025), https://www.epa.gov/system/files/documents/2025-03/revised-epa-response-to-meibao-zhuang-eto-sterilizers-reconsideration.pdf.

In this action, based on the EPA's reconsideration of the 2024 Final Rule, we are proposing amendments to the Commercial Sterilization Facilities NESHAP. Specifically, the EPA is proposing to rescind the standards that were established under CAA section 112(f)(2), to amend the standard promulgated under section 112(d)(6) for new aeration room vents (ARVs) where EtO use is at least 10 tons per year (tpy), to amend the compliance demonstration requirements to allow facilities to choose between annual performance testing and parametric monitoring or operation of a CEMS, and to rescind the requirement that PTE be used to ensure complete capture of EtO. This proposal also includes technical corrections and clarifications to the Commercial Sterilization Facilities NESHAP and Performance Specification 19 (PS 19). Any other issues or any other provisions of the 2024 Final Rule not specifically addressed in this proposed rulemaking are not within the scope of this proposal, and the EPA reserves the right to respond to such comments as out of scope.

C. *What is this source category and how does the current NESHAP regulate its EtO emissions?*

1. Regulatory Background

The Commercial Sterilization Facilities source category consists of major and area sources that use EtO to sterilize or fumigate materials, including medical equipment and supplies, certain spices, and other miscellaneous products and items. Generally speaking, these facilities use chambers or sealed pouches to disinfect materials through exposure to EtO gas at predetermined concentrations (including materials not amenable to other sterilization techniques, such as high temperatures), which is then evacuated from the chamber or pouch prior to retrieving the sterilized materials.[15] Sources in this category provide essential sterilization services at scale for hospitals, clinics, and other

[15] For more information, *see* 88 FR 22796-97 (Apr. 13, 2023).

medical locations that lack capacity to sterilize equipment at the volume and regularity required to maintain safe and efficient operations.

The EPA promulgated the initial Commercial Sterilization Facilities NESHAP on December 6, 1994.[16] The standards are codified at 40 CFR part 63, subpart O. The original 1994 rulemaking for this source category set standards for EtO emissions originating from three emission points: sterilization chamber vents (SCVs), ARVs, and chamber exhaust vents (CEVs). 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.

In 2006, the EPA finalized the RTR for the Commercial Sterilization Facilities NESHAP under CAA section 112(f)(2) and CAA section 112(d)(6), respectively.[17] With respect to the residual risk review, we concluded that the MACT standards protected public health and the environment with an ample margin of safety by reducing maximum individual cancer risk, as well as chronic noncancer and acute risks, below the levels generally considered acceptable for purposes of CAA section 112(f)(2).[18] With respect to the technology review, we concluded that additional standards "would achieve, at best, minimal emission and risk reductions at a very high cost."[19] No changes were made in the RTR to MACT standards given these findings. In responding to comments on the residual risk review, we explained that the Agency considered a California EPA cancer risk

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[16] 59 FR 62585 (Dec. 6, 1994).
[17] 71 FR 17712 (Apr. 7, 2006).
[18] *Id.* at 17713.
[19] *Id.* at 17714.

estimate as the best available estimate, for reasons including because it built upon our own 1985 EtO health assessment. We noted that the Agency was working on an updated cancer assessment for EtO that was not yet complete.[20] Finally, we disagreed with comments arguing that the residual risk review should "account for reasonably foreseeable changes that could result in increased risk, such as new residences being built closer to the facility, or increases in actual emissions within the current permit limitations." Specifically, we stated that risk assessments need not consider such foreseeable changes because we "have the authority to revisit (and revise, if necessary) any rulemaking if there is sufficient evidence" for doing so, citing to CAA section 301.[21]

In 2022, several environmental groups filed a mandatory duty suit against the EPA under CAA section 304(a)(2).[22] The groups alleged that the EPA failed to perform its non-discretionary duty under CAA section 112(d)(6) to review, and as necessary revise, the Commercial Sterilization Facilities NESHAP every eight years. The parties resolved the lawsuit through a consent decree, which required the EPA to sign a final rule completing the CAA section 112(d)(6) review by March 1, 2024. The consent decree did not speak to or reference CAA section 112(f)(2).

2. 2024 Final Rule

In April 2023, the EPA proposed "decisions concerning" the completed RTR, including certain amendments resulting from a second residual risk review for EtO and additional amendments resulting from a technology review.[23] With respect to the second residual risk review, the Agency proposed to rely on the Integrated Risk Information System (IRIS) value for EtO issued by the EPA in December 2016[24] and, in "deciding

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[20] *Id.* at 17715-16.
[21] *Id.* (citing 42 U.S.C. 7601).
[22] *Cal. Communities Against Toxics v. Regan*, No. 1:22-cv-03724 (D.D.C).
[23] 88 FR 22790 (Apr. 13, 2023).
[24] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide,* December 2016, EPA/635/R-16/350Fc.

whether to conduct a second residual risk review," considered "the advantages of EtO reductions and the distribution of those reductions consistent with the clear goal of CAA section 112(f)(2) to protect the most exposed and susceptible populations, which in this case include communities with EJ [environmental justice] concerns."[25] We acknowledged at the time that "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." However, we asserted that the provision "does not limit the EPA's discretion or authority to conduct another risk review" and identified a "discretionary authority to conduct another CAA section 112(f)(2) analysis" at will separate and apart from the review and revision authority provided in CAA section 112(d)(6).[26]

The 2024 Final Rule amended 40 CFR part 63, subpart O pursuant to CAA sections 112(d)(2) and (3), 112(d)(5), 112(d)(6), and 112(f)(2).[27] That action established standards for unregulated sources of emissions (CEV[28], Group 1[29] and Group 2[30] room air emissions) under the authority of CAA section 112(d)(2) and (3) for major sources and CAA section 112(d)(5) for area sources. The EPA also revised the existing standards in response to a technology review under CAA section 112(d)(6). The EPA for the first time implemented an interpretation that CAA section 112(f)(2) authorizes the imposition of

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[25] *Id.* at 22793.
[26] *Id.* at 22794.
[27] 89 FR 24090 (Apr. 5, 2024).
[28] 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 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).
[29] Group 1 room air emissions mean emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material.
[30] Group 2 room air emissions mean emissions from post-aeration handling of sterilized material.

new standards based on additional discretionary residual risk reviews and finalized new risk-based standards after conducting a second risk review based largely on the 2016 EtO IRIS value. The 2024 Final Rule also finalized other changes to the NESHAP, including adding requirements and clarifications for periods of startup, shutdown, and malfunction (SSM); requiring the use of CEMS to demonstrate compliance for facilities where EtO use is at least 100 pounds per year (lb/yr); adding provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports; and other minor editorial and technical changes.

Table 2 shows a summary of the 2024 emission standards for commercial sterilizers facilities in 40 CFR part 63, subpart O. Footnote 1 of Table 2 shows the standards subject to reconsideration.

Table 2. 2024 Ethylene Oxide Standards for Commercial Sterilization Facilities

Emission Source	Existing or New	EtO Use	Standards	CAA section
SCV	Existing and new	At least 30 tpy	99.99 percent emission reduction[1]	112(f)(2)
		At least 10 tpy but less than 30 tpy	99.9 percent emission reduction[1]	112(f)(2)
		At least 10 tpy	99.9 percent emission reduction	112(d)(6)
		At least 1 but less than 10 tpy	99.8 percent emission reduction	112(f)(2) and (d)(6)
		Less than 1 tpy	99 percent emission reduction	112(d)(5)
ARV	Existing	At least 30 tpy	99.9 percent emission reduction[1]	112(f)(2)
		At least 10 tpy but less than 30 tpy	99.6 percent emission reduction[1]	112(f)(2)
		At least 10 tpy	99.6 percent emission reduction	112(d)(6)
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5)
		Less than 1 tpy	99 percent emission reduction	112(d)(5)

	New	At least 30 tpy	99.9 percent emission reduction[1]	112(f)(2)
		At least 10 tpy	99.9 percent emission reduction[1]	112(d)(6)
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5)
		Less than 1 tpy	99 percent emission reduction	112(d)(5)
CEVs at major source facilities	Existing and new	N/A	99.94 percent emission reduction	112(d)(2) and (3)
CEVs at area source facilities	Existing and new	At least 400 tpy	99.9 percent emission reduction[1]	112(f)(2)
		At least 60 but less than 400 tpy	99.9 percent emission reduction[1]	112(f)(2)
		Less than 60 tpy	99 percent emission reduction	112(d)(5)
Group 1 room air emissions at major sources	Existing and new	N/A	97 percent emission reduction and PTE[1]	112(d)(2) and (3)
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98 percent emission reduction and PTE[1]	112(f)(2)
		Less than 40 tpy	80 percent emission reduction and PTE[1]	112(d)(5)
Group 2 room air emissions at major sources	Existing and new	N/A	86 percent emission reduction and PTE[1]	112(d)(2) and (3)
Group 2 room air emissions at area sources	Existing	At least 20 tpy	98 percent emission reduction and PTE[1]	112(f)(2)
		At least 4 but less than 20 tpy	80 percent emission reduction and PTE[1]	112(f)(2)
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 part per million (ppm) before the chamber can be opened.	112(d)(5)
	New	At least 20 tpy	98 percent emission reduction and PTE[1]	112(f)(2)
		At least 4 but less than 20 tpy	80 percent emission reduction and PTE[1]	112(f)(2)
		Less than 4 tpy	80 percent emission reduction and PTE[1]	112(d)(5)

[1] Standards subject to reconsideration.

For more information on the commercial sterilization industry and the 2024 standards under 40 CFR part 63, subpart O see the 2024 Final Rule preamble.[31]

D. *What data collection activities were conducted to support this action?*

The EPA used data collected during the rulemaking for the 2024 Final Rule for this reconsideration. The EPA began with the facility list used during the 2024 Final Rule. For details on the data collected for the 2024 Final Rule, see section II.C of the 2023 proposal preamble.[32] Since the promulgation of the 2024 Final Rule, the EPA identified two facilities that have opened and one facility that has decommissioned its use of EtO, resulting in a final facility list of 89 commercial sterilization facilities. A complete list of known commercial sterilization facilities is available in the document titled *2024 Facility List,* which is available in the docket for this rulemaking.

In addition to the information obtained during the investigation for the 2024 Final Rule, the EPA held meetings with industry and trade association representatives to discuss the 2024 Final Rule and the implementation issues, unintended impacts, and challenges that have resulted from the rule. Summaries of these meetings can be found in the docket for this action (Docket ID No. EPA-HQ-OAR-2019-0178).

E. What other relevant background information is available?

On June 5, 2024, the Ethylene Oxide Sterilization Association (EOSA) and various environmental and community groups, including California Communities Against Toxics, Clean Power Lake County, Comité Diálogo Ambiental, Rio Grande International Study Center, Sierra Club, and the Union of Concerned Scientists, brought

[31] 89 FR 24090 (Apr. 5, 2024).
[32] 88 FR 22790 (Apr. 13, 2023).

separate judicial challenges to the 2024 Final Rule. The cases were consolidated and are currently being held in abeyance pending the EPA's reconsideration of the rule.

On July 17, 2025, President Trump signed the Proclamation, "Regulatory Relief for Certain Stationary Sources to Promote American Security With Respect to Sterile Medical Equipment" (90 FR 34747, July 23, 2025).[33] This Proclamation exempted certain facilities, identified in Annex 1 of the Proclamation, from compliance with the 2024 Final Rule. The Presidential exemption is for a period of 2 years beyond the 2024 Final Rule's compliance dates. During the exemption period, facilities identified in Annex 1 that were subject to the Commercial Sterilization Facilities NESHAP, 40 CFR part 63, subpart O, in effect prior to the issuance of the 2024 Final Rule must continue to comply with those standards.

III. Reconsideration and Other Issues, Proposed Changes and Rationale

The EPA is proposing amendments to the Commercial Sterilization Facilities NESHAP. Specifically, the EPA is proposing to rescind standards promulgated under CAA section 112(f)(2), to revise the standard promulgated under CAA section 112(d)(6) for new ARVs at facilities using at least 10 tpy of EtO, to amend the compliance demonstration requirements to allow facilities to choose between parametric monitoring or CEMS, and to rescind the requirement that PTE be used to ensure complete capture of EtO. The EPA is also proposing technical corrections and clarifications to the Commercial Sterilization Facilities NESHAP and PS 19. The subsequent sections of this preamble describe these changes in detail as well as provide the EPA's reasoning for the proposed changes. Table 3 summarizes the proposed changes to emission limits that would result from this reconsideration. Specifically, the table shows the proposed rescission of CAA section 112(f)(2) standards and the resulting changes in applicable

[33] A copy of the Presidential Proclamation and Annex 1 are available in the rulemaking docket (Docket ID No. EPA-HQ-OAR-2019-0178).

standards affected by this rescission. It also shows the proposed revised standard for new ARVs at facilities using at least 10 tpy of EtO (*i.e.*, 99.6 percent reduction).

Table 3. Emission Standards After Incorporating the Proposed Changes

Emission Source	Existing or New	EtO Use	2024 Final Rule Standard (% reduction)	Emission Standard (% reduction) After Proposed Amendments	CAA Section
SCV	Existing and New	At least 30 tpy	99.99	-	112(f)(2)
		At least 10 tpy but less than 30 tpy	99.9	-	112(f)(2)
		At least 10 tpy	99.9	99.9	112(d)(6)
		At least 1 but less than 10 tpy	99.8	99.8	112(d)(6)
		Less than 1 tpy	99	99	112(d)(5)
ARV	Existing	At least 30 tpy	99.9	-	112(f)(2)
		At least 10 tpy but less than 30 tpy	99.6	-	112(f)(2)
		At least 10 tpy	99.6	99.6	112(d)(6)
		At least 1 but less than 10 tpy	99	99	112(d)(5)
		Less than 1 tpy	99	99	112(d)(5)

	New	At least 30 tpy	99.9	-	112(f)(2)
		At least 10 tpy	99.9	99.6	112(d)(6)
		At least 1 but less than 10 tpy	99	99	112(d)(5)
		Less than 1 tpy	99	99	112(d)(5)
CEVs at major sources	Existing and New	N/A	99.94	99.94	112(d)(2) and (3)
CEVs at area sources	Existing and New	At least 400 tpy	99.9	-	112(f)(2)
		At least 60 but less than 400 tpy	99.9	-	112(f)(2)
		Less than 60 tpy	99	99[1]	112(d)(5)
Group 1 room air at major sources	Existing and New	N/A	97 and PTE	97	112(d)(2) and (3)
Group 1 room air at area sources	Existing and New	At least 40 tpy	98 and PTE	-	112(f)(2)
		Less than 40 tpy	80 and PTE	80[1]	112(d)(5)

Group 2 room air at major sources	Existing and New	N/A	86 and PTE	86	112(d)(2) and (3)
Group 2 room air at area sources	Existing	At least 20 tpy	98 and PTE	-	112(f)(2)
		At least 4 but less than 20 tpy	80 and PTE	-	112(f)(2)
		Less than 4 tpy	Lower EtO concentration to 1 ppm before opening chamber	Lower Concentration to 1ppm before opening chamber[1] or 80[1]	112(d)(5)
	New	At least 20 tpy	98 and PTE	-	112(f)(2)
		At least 4 but less than 20 tpy	80 and PTE	-	112(f)(2)
		Less than 4 tpy	80 and PTE	80[1]	112(d)(5)

[1] With the removal of CAA section 112(f)(2) standards, this CAA section 112(d)(5) standard would apply to all facilities regardless of the amount of EtO used.

A. What changes are we proposing for the CAA section 112(f)(2) standards, and what is the rationale for those decisions?

The EPA is proposing to rescind the risk-based standards promulgated in 2024 pursuant to CAA section 112(f)(2) for the reasons explained below.

In 2006, the EPA finalized the RTR for the Commercial Sterilization Facilities source category pursuant to CAA sections 112(f)(2) and 112(d)(6), consisting of both the eight-year residual risk review under section 112(f)(2) and the first technology review of the NESHAP for this source category pursuant to section 112(d)(6).[34] The EPA determined that the MACT standards protected public health and welfare with an ample margin of safety and that any revisions would achieve minimal emissions reductions at high cost, such that no revisions were necessary under CAA section 112(f)(2) or CAA section 112(d)(6). For purposes of the risk review, the EPA relied on evidence and assessments available at that time, including a cancer risk evaluation developed by California EPA that was informed by a prior evaluation developed by the EPA. Since the 2006 RTR, the EPA was subject to a mandatory duty suit in connection with the ongoing obligation to review the standards under CAA section 112(d)(6) but did not seek to revisit the residual risk review until the rulemaking that resulted in the 2024 Final Rule.

In the 2024 Final Rule, the EPA for the first time implemented an interpretation of CAA section 112(f)(2) that allowed the Agency to conduct another residual risk review for this source category and promulgate additional risk-based standards. In doing so, we acknowledged that "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."[35] However, we also concluded that "[CAA section 112(f)(2)] does not limit our discretion or authority to conduct another risk review should we consider that such review is warranted."[36] The EPA has since revisited the explanation for this interpretation and proposes that it is incorrect for the following reasons.[37]

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[34] 71 FR 17712 (Apr. 7, 2006).
[35] 89 FR 24090 (Apr. 5, 2024).
[36] *Id.*
[37] *See Summary of Public Comments and Responses for Risk and Technology Review for Ethylene Oxide Sterilization Facilities* (February 2024) (2024 Rule RTC) (Document ID No. EPA-HQ-OAR-2019-0178-1595), 229-33.

First, in 2024, the EPA concluded that the CAA authorizes additional, discretionary risk reviews because the statute "does not *prohibit* the EPA from revisiting standards promulgated under … CAA section 112(f)(2)."[38] However, the EPA did not consider at the time that a limitation on authority must sometimes be inferred from the structure of the provision and surrounding statutory language. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."[39] Here, Congress enacted a detailed process and timeline for developing and revising HAP emission standards under CAA section 112(d), including the general authority and obligation to promulgate regulations for each listed source category under section 112(d)(1), the development of MACT standards under section 112(d)(2)-(3), the health-threshold and area-source regulatory alternatives under section 112(d)(4) and (5), respectively, and the ongoing obligation to review and revise standards "as necessary" every eight years under section 112(d)(6). In contrast, CAA section 112(f) sets out a one-time obligation and authority to conduct a risk review for each source category within eight years of promulgating MACT standards, including a requirement to promulgate additional standards if the MACT standards-setting process did not adequately address residual risk and provide an ample margin of safety. One can infer from the explicit requirement to conduct subsequent technology reviews in CAA section 112(d)(6), and the absence of such a requirement in section 112(f)(2), that Congress did not authorize multiple risk reviews under section 112(f)(2).

Second, the EPA's prior interpretation did not fully consider the overall statutory framework of CAA section 112. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the

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[38] *Id.* at 229.

[39] *Nken v. Holder*, 556 U.S. 418, 430 (2009) (quoting *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987)); *see also Russello v. United States*, 464 U.S. 16, 23 (1983).

overall statutory scheme."[40] Here, Congress explicitly set forth a system of recurring technology reviews every eight years under CAA section 112(d)(6) and a one-time risk review under section 112(f). In addition, Congress stated twice in section 112(f)(2) that any required standard must be promulgated within 8 years of promulgating section 112(d) standards.[41] Reading section 112(f)(2) to allow more than one residual risk review that could result in additional risk standards long after the eight-year statutory deadline, in this case twenty years after section 112(d) standards were promulgated in 1994, "would effectively gut Congress's carefully articulated existing system."[42] Moreover, Congress enacted the detailed regulatory scheme in CAA section 112 with the express goal of achieving rapid regulation of the HAP identified in CAA section 112(b) across all relevant source categories.[43] An implied authority to conduct discretionary risk reviews on an ad hoc basis disrupts the statutory scheme by eliminating the finality of residual risk reviews, undermining certainty for regulated industry and the public, and placing certain source categories on a different trajectory from the rest, all without providing a standard for the use of such implied discretion. This approach is also inconsistent with CAA section 112(f) itself, which envisions potential further action from Congress to

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[40] *West Virginia v. EPA*, 597 U.S. 697, 721 (2022) (internal quotations omitted).
[41] *See* CAA sections 112(f)(2)(A) and (C).
[42] *Loving v. I.R.S.*, 742 F.3d 1013, 1020 (D.C. Cir. 2014) (finding IRS's regulations of tax preparers to be invalid because, among other factors, the overall statutory framework did not support IRS's interpretation of the statute to encompass authority to regulate those entities); *see also Natural Resources Def. Council v. Regan*, 67 F.4th 397, 404 (D.C. Cir. 2023) (""Regardless of how serious the purported problem an administrative agency seeks to address, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law." (citation modified)).
[43] Per CAA section 112(e), Congress required the Agency to promulgate MACT standards for all listed source categories by 2000, with intervening milestones in 1992, 1994, and 1997. Initial source categories and subcategories were to be listed by 1990 under CAA section 112(c). The RTRs for those source categories were to be completed within eight years of the initial standards, meaning that by approximately 2008, all source categories would be regulated under standards that provide an ample margin of safety. The periodic, eight-year technology review under CAA section 112(d)(6) is the only ongoing review-and-revise obligation for a provision consciously designed to achieve protections for the HAPs Congress listed for regulation in the 1990 CAA Amendments.

address residual risk. CAA section 112(f)(1) required the Agency to develop a report on the calculation of residual risk, the impacts of such risk, including the costs of control, and recommendations for further legislation. CAA section 112(f)(2) required the one-time residual risk within eight years only if "Congress does not act on any recommendation submitted under paragraph (1)." In this way, CAA section 112 contemplates a one-time residual risk review, followed by ongoing reductions achieved, when "necessary," through the promulgation of additional standards under CAA section 112(d)(6).

Third, the EPA did not appropriately grapple with relevant regulatory history. The 2024 Final Rule, together with a handful of actions issued several months later, marked the first time that the Agency had completed a second, "discretionary" residual risk review and imposed corresponding standards under CAA section 112(f)(2). The novelty of this approach presents an additional reason to proceed with caution. In prior actions, including the Benzene NESHAP incorporated by reference into the statute in CAA section 112(f)(2)(B), the EPA had acknowledged that residual risk reviews entail significant uncertainty accounted for, in part, by providing an ample margin of safety, and had not taken the position that follow-on risk reviews under CAA section 112(f)(2) were the appropriate mechanism to address new information. Rather, the EPA has reviewed and revised "as necessary" under CAA section 112(d)(6), including by evaluating the cost-effectiveness of potential developments by reference to the nature of the risk posed by the particular HAP at issue (i.e., by accepting higher values for cost-per-ton of emission reduction for extremely dangerous HAP).[44] We propose that contrary statements made in the 2024 Final Rule, including the statement that "the EPA's

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[44] *See National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units: Final Repeal*, 91 FR 9088, 9099 (Feb. 24, 2026) ("2026 MATS Repeal") (explaining that "the statutory benchmarks for risk provide relevant guidance on whether additional regulation is 'necessary' under CAA section 112(d)(6)").

discretion to revise prior standards where the statute does not contain limiting language . . . has been implemented without controversy," misapprehended the nature of the cited actions and did not account for the mine run of consistent regulatory practice.[45] We further propose that the 2024 Final Rule overread the statement in the 2006 RTR that, in response to a comment suggesting residual risk reviews should account for future uncertainties, the Agency may "revisit (and revise, if necessary) any rulemaking if there is sufficient evidence" for doing so, citing to CAA section 301.[46] Read in context, this statement is better understood as a general reference to the EPA's authority to reconsider and revise under CAA section 112(d)(6), which is where the operative term "necessary" appears in the statute. In any event, that statement does not stand for the proposition that the Agency anticipated finalizing an entirely new residual risk review and associated standards nearly 20 years later based on a new record and new considerations, nor did it grapple with the text and structure of the statute as we propose to do in this action.

Lastly, the EPA cited CAA section 307(d)(1)(C) as supporting the EPA's authority to conduct a discretionary risk review. The EPA concluded that this provision "assumes the EPA might review standards set under 112(f)(2) and imposes CAA section 307(d) rulemaking processes on such revisions, when conducted."[47] Section 307(d)(1)(C), which references "the promulgation or revision of . . . any standard under section [112(f)(2)]," acknowledges that there are situations where section 112(f)(2) standards might be revised, not that the EPA has the discretion to revise such standards when it chooses. For example, the EPA might have to revise a section 112(f)(2) standard as the result of an adverse judicial decision or mandatory administrative reconsideration

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[45] 2024 Rule RTC at 229-33. For example, the EPA cited at that time a prior action to revise new locomotive and engine standards under CAA section 213(a)(5) without acknowledging the substantially different text and structure of that provision. *Id.* Similarly, the EPA cited prior actions to remove standards or revise a MACT floor that did not involve the imposition of new standards under CAA section 112(f)(2). *Id.*
[46] 71 FR 17715-16 (citing 42 U.S.C. 7601).
[47] *See id.*

under CAA section 307(d)(7)(B). Under those scenarios, the EPA would be required to reconsider a prior risk review. However, because the EPA may be required to reconsider and revise section 112(f)(2) standards in certain limited circumstances does not speak to whether the EPA may conduct a discretionary second risk review.

For these reasons, the EPA proposes to find that the CAA does not authorize the discretionary second risk review that the Agency conducted for this source category in 2024. The EPA is therefore proposing to rescind the risk standards promulgated in the 2024 rule. These standards can be seen in table 3 and are as follows:

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

After the proposed removal of these risk-based standards, affected sources would be required to comply with their section 112(d)(2) and (3) or 112(d)(5) standards; if such standards have been revised pursuant to section 112(d)(6), affected sources would

comply with their section 112(d)(6) standards. Additionally, the EPA proposes that for existing source Group 2 room air emissions, facilities may choose to comply with either the existing source standard (lower EtO concentration to 1 ppm before opening the aeration chamber) or the new source standard (80 percent reduction of EtO). The EPA is proposing this change to address concerns that the existing source standard may impact the supply chain of medical equipment. Table 3 above identifies the applicable standards for these affected sources with the removal of the section 112(f)(2) standards.

The proposed amendments would remove the EtO-usage based subcategories that resulted from the section 112(f)(2) standards, and facilities that would have been subject to those standards would instead be subject to the appropriate subcategories as promulgated by the 2024 Final Rule under section 112(d)(2), (3), (5), or (6). For instance, for both new and existing SCVs, EtO use categories for facilities where EtO use is at least 30 tpy, and for facilities where EtO use is at least 10 tpy but less than 30 tpy under CAA section 112(f)(2), would also be removed in conjunction with the proposed rescission of section 112(f)(2) standards. As a result, these facilities will all be in the subcategory of facilities where EtO use is at least 10 tpy. Similarly, for new and existing ARVs, with the removal of subcategories established under section 112(f)(2) for facilities where EtO use is at least 30 tpy and facilities where EtO use is at least 10 tpy but less than 30 tpy, these facilities would all comprise a single subcategory of facilities where EtO use is at least 10 tpy.

Additionally, area sources of CEVs, Group 1 room air emissions, existing Group 2 room air emissions, and new Group 2 room air emissions would each have a single standard rather than different risk-based standards due to subcategorization based on a facility's EtO use under section 112(f)(2). The EPA is proposing amendments to the applicable standards in tables 1 to 5 to subpart O of part 63 to address these changes. The EPA is soliciting comment on the proposed removal of the CAA section 112(f)(2)

emission standards and all related questions of statutory interpretation, including any additional regulatory history or case law bearing on the best reading of CAA section 112 and the Agency's rationale for changing the position taken in the 2024 Final Rule and related actions (Question 2).

Separate from the EPA's position on the Agency's authority to conduct a second CAA section 112(f)(2) risk review described above, we are proposing that significant uncertainties regarding the magnitude of EtO's carcinogenic potency, particularly at low concentrations, would be an additional reason for rescinding the EtO standards in the 2024 Rule and seeking detailed comment on this issue from interested stakeholders. Specifically, we propose that it would not be appropriate to rely on the 2016 EtO IRIS value in setting standards. If this position is finalized, the EPA would evaluate as necessary and appropriate in future regulatory actions other EtO risk values, ranges, or additional means to assess risk when relevant to the statutory scheme.

Because such comment submissions will be essential to informing whether this proposed rationale is an appropriate basis for taking final action, we request that interested stakeholders provide relevant data, studies, and analyses to support any claims made about the adequacy or inadequacy of the 2016 EtO IRIS value and any alternative values the commenter believes would be more appropriate and consistent with the statutory framework. If commenters believe a range or multiple potential values would be appropriate or wish to opine on the breadth of the Agency's discretion to select among values, we ask that the commenter support such assertions with appropriate citations. Although the EPA will respond to all significant comments received, we view such information as critical to ensuring that the record reflects all perspectives and relevant information given the highly technical nature of issue and the breadth of potentially relevant scientific and other literature.

The EPA previously acknowledged that uncertainties regarding the magnitude of EtO's carcinogenic potency could materially affect risk estimates, thereby substantially informing the risk evaluation as a whole and any resulting standards. As discussed in a 2019 technical memorandum,[48] the EPA identified two key sources of uncertainty in the 2016 EtO IRIS value: dose-response model selection and the use of the statistical upper confidence limit. Regarding the former, during the development of the 2016 EtO IRIS value, the EPA considered many different dose-response models to describe the available lymphoid cancer data. Several of these models, including the one the EPA ultimately selected, fit the exposure data well. However, the EPA estimated that choosing one of the alternative viable models could have resulted in an EtO IRIS value up to two times lower than the final 2016 EtO IRIS value. Regarding the latter, while the EPA chose to focus on the statistical upper confidence limit of the cancer value, the Agency later estimated that using the statistical central estimate instead could have resulted in an EtO IRIS value up to three times lower than the final value. The technical memo concluded that, if combined, these two factors could have resulted in an EtO IRIS value that was up to five times lower (i.e., EtO is five times safer than the 2016 EtO IRIS value provided). The analysis in the technical memorandum demonstrates that both model selection and the underlying cancer data (in this case epidemiological studies of cancer in humans exposed to EtO) can greatly influence the resulting risk estimate. It is important to note that the analysis in the technical memorandum relies entirely on results and equations presented in the final EtO IRIS assessment, which was peer reviewed by EPA's Science Advisory Board.

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[48] Sensitivity of Ethylene Oxide Risk Estimates to Dose-Response Model Selection. Memorandum drafted by EPA's Office of Research and Development, docketed in the Miscellaneous Organic Chemical Manufacturing NESHAP Proposed Rule, 84 FR 69182 (Dec. 17, 2019).

The EPA recognizes that the Agency defended its use of the 2016 EtO IRIS value in *Huntsman Petrochemical LLC v. EPA*.[49] In that case, industry groups challenged the EPA's 2020 Miscellaneous Organic Chemical Manufacturing NESHAP (MON) rule[50] and the EPA's 2022 reconsideration of that rule.[51] The main issues raised in industry's reconsideration petition and the resulting consolidated litigation were whether the EPA acted reasonably in using the 2016 EtO IRIS value and rejecting the Texas Commission on Environmental Quality's (TCEQ) alternative value. Industry challenged numerous technical decisions made by the EPA in the course of developing the 2016 EtO IRIS value, including but not limited to, model selection and choice of underlying epidemiological studies and exposure estimates.[52] Ultimately, the U.S. Court of Appeals for the D.C. Circuit denied the petitions for review of the 2020 MON Rule and the 2022 reconsideration, finding that Petitioners failed to show that EPA had acted arbitrarily and capriciously in using the 2016 EtO IRIS value.[53]

While the EPA defended its use of the 2016 EtO IRIS value in the 2020 MON rule and subsequent reconsideration action, the Agency acknowledged at the time it issued the rule that significant uncertainties remained regarding the magnitude of EtO's carcinogenic potency, as discussed above. It is known that EtO can be produced within the body (endogenously) via normal metabolic processes and that tobacco smoke is a source of EtO exposure. However, the EPA recognized that uncertainties remained regarding the quantity and relative contribution of endogenous, tobacco smoke, and background EtO levels from non-industrial sources. Furthermore, the EPA recognizes that new empirical data may trigger a need to reevaluate toxicity values. For example, prior to 2016, the EPA used a toxicity value derived in 1985 to estimate the cancer risk

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49 114 F.4th 727 (D.C. Cir. 2024).
50 85 FR 49,084 (Aug. 12, 2020).
51 87 FR 77,985 (Dec. 21, 2022).
52 *See Huntsman*, 114 F.4th at 737-40.
53 *Id*. at 742.

from EtO and, in rulemakings including the 2006 RTR for the Commercial Sterilization Facilities NESHAP, used assessments that were informed by and built upon that value (including an analysis issued by the California EPA). Such values reflected the best evidence available at that time, but newer epidemiological studies later prompted both the EPA and TCEQ to produce updated assessments.[54] Since the EPA defended the use of the 2016 EtO IRIS value in *Huntsman*, new scientific evidence has continued to emerge.[55,56] While it is not entirely clear how many new studies or methodological advancements have developed in recent years, given the sensitivity of EtO risk estimates at low concentrations to both model selection and the underlying cancer data, it is plausible that any new information could change the EPA's understanding of EtO's carcinogenic potency. Therefore, the EPA is proposing that the significant uncertainties in the 2016 EtO IRIS value are an additional reason to support reconsideration and repeal of the 2024 Final Rule, separate and apart from the limits on our authority to conduct a residual risk review under CAA section 112(f)(2), and seeking detailed comment on that issue as indicated throughout this section.

Specifically, the EPA is soliciting comment on any new information related to the underlying cancer data, such as epidemiological studies of cancer in humans exposed to EtO or advancements relevant to analyzing the relationship between occupational human

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[54] Both the 2016 EtO IRIS and the 2020 EtO TCEQ assessments have undergone expert peer review by authoritative bodies. *See* Science Advisory Board (SAB). 2015. *Science Advisory Board Review of the EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft - August 2014).* EPA-SAB-15-012.; and National Academies of Sciences, Engineering, and Medicine. 2025. Review of Texas Commission on Environmental Quality's Ethylene Oxide Development Support Document. Washington, DC: The National Academies Press.

[55]Kelly-Reif K, Bertke SJ, Stayner L, Steenland K. Exposure to Ethylene Oxide and Relative Rates of Female Breast Cancer Mortality: 62 Years of Follow-Up in a Large US Occupational Cohort. Environ Health Perspect. 2025 May;133(5):57013. doi: 10.1289/EHP15566. Epub 2025 May 22. PMID: 40168621; PMCID: PMC12097532.

[56]Valdez-Flores C, Li AA, Bender TJ, Teta MJ. Use of updated mortality study of ethylene oxide manufacturing workers to inform cancer risk assessment. Risk Anal. 2025 Sep;45(9):2822-2837. doi: 10.1111/risa.70057. Epub 2025 Jun 3. PMID: 40458005; PMCID: PMC12474530.

exposure to EtO and the development of cancer not yet considered by the Agency (Question 3). Given the acknowledged impact of model selection, the EPA is also soliciting comment on any new or updated information relevant to dose-response model selection such as consideration of statistical analyses, visual model fit, or biological plausibility (Question 4). Further, the EPA is soliciting comment on any new or updated studies on human exposure to EtO, including information on occupational, smoking, background, or endogenous exposures not yet considered by the Agency (Question 5). The EPA anticipates that such information would be useful for updating the Agency's understanding of EtO exposure and toxicity and determining whether the 2016 EtO IRIS value remains suitable for estimating risk to inform regulatory decision-making. Finally, acknowledging that the EPA has received additional comments on the 2016 EtO IRIS value in the context of other rulemaking proposals issued after the 2024 Commercial Sterilizers final rule, the EPA is soliciting comment on the information provided in those comments; this includes information provided by commenters in the context of the more recent proposed Chemical Manufacturing Area Sources NESHAP (January 22, 2025) (see Docket ID EPA-HQ-OAR-2024-0303, comment numbers 0060, 0061, 0068, 0076, and 0079) (Question 6). As noted previously, we ask that commenters support claims with respect to the 2016 EtO IRIS value, any alternative value, or any alternative range or approach to determining risk with relevant data, studies, analyses, and other citations that the commenter believes should be considered in tandem with, or instead of, the previously recognized uncertainties in the IRIS methodology.

B. What changes are we proposing for the CAA section 112(d)(6) standards, and what is the rationale for those decisions?

The 2024 Final Rule also included a technology review pursuant to CAA section 112(d)(6) for the Commercial Sterilization Facilities source category that resulted in revisions to certain standards. Among these revisions were emission standards for both

new and existing ARVs at facilities where EtO use is at least 10 tpy. The standard for new ARVs at facilities using at least 10 tpy of EtO was 99.9 percent reduction, and the standard for existing ARVs at facilities using at least 10 tpy of EtO was 99.6 percent reduction. The EPA established the new source standard based on the conclusion that it achieved greater reduction and was more cost-effective than the two options considered (the other option being 99.6 percent reduction). The EPA set the existing source standard at a level that the Agency determined to be achievable by all sources.[57]

The EPA continues to believe that the standard for existing ARVs at facilities using at least 10 tpy of EtO is reasonable. The data provided by industry when developing the 2024 Final Rule demonstrates that 75 percent of facilities already achieve 99.6 percent reduction, and 50 percent already achieve 99.9 percent reduction of EtO from ARVs, demonstrating for purposes of relevant considerations under CAA section 112(d)(6) that the enhanced standard is reasonable and properly considered "necessary" as a revision.[58] However, for the reasons explained below, the EPA is proposing to amend the standard for new ARVs at facilities using at least 10 tpy of EtO to 99.6 percent reduction.

During the development of the 2024 Final Rule, for new ARVs at facilities where EtO use is at least 10 tpy, the EPA evaluated the cost-effectiveness of two options: 99.6 percent EtO reduction and 99.9 percent reduction.[59] When preparing cost-effectiveness calculations for new sources, the EPA based the calculations on a model plant for new ARVs reflecting the average number of ARVs, EtO use, and operating hours as an

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[57] 89 FR 24090 (Apr. 5, 2024).

[58] Although rates of achievement by individual sources are often an indicator that revisions to a standard are "necessary," that is not always the case, particularly when the costs of controls are very high and the remaining risks are very low. *See, e.g.,* 2026 MATS Repeal, 91 FR 9088 (Feb. 7, 2026).

[59] For a detailed discussion of cost-effectiveness, see section III.F.3 of the 2023 proposal preamble, 88 FR 22790 (Apr. 13, 2023).

existing facility.[60] This resulted in the following cost-effectiveness values for the two options: $2.2 million per ton at a 99.9 percent EtO reduction and $2.6 million at a 99.6 percent EtO reduction. As a result, the EPA promulgated the 99.9 percent EtO reduction standard for new ARVs at facilities where EtO use is at least 10 tpy because it would achieve greater emission reductions and be more cost-effective than a 99.6 percent reduction standard.[61] However, upon reconsideration, the EPA realizes that our cost-estimate approach did not accurately reflect the costs of new ARVs installed at existing facilities. Specifically, the EPA did not consider that, under the 99.6 percent reduction option, which would result in the same standards for both new and existing ARVs, a new ARV could share and make use of ductwork, control devices, and other existing infrastructure for the ARVs already in place at the facility; therefore, the expected capital and annual costs for the 99.6 percent reduction option would be much lower than the estimate in the 2024 Final Rule. Sharing controls would also reduce the amount of auxiliary fuel burned in combustion-type control devices. Further, it is common practice for facilities to share ductwork or control devices across multiple sources, and the 99.6 percent reduction option, which would result in a single standard for both new and existing ARVs at facilities using at least 10 tpy of EtO, has the benefit of allowing facilities to share infrastructure, streamline facility operations, and reduce costs.

For the reasons explained above, the EPA is proposing to change from 99.9 to 99.6 percent reduction for new ARVs at facilities with EtO use of at least 10 tpy, resulting in a single uniform standard for both new and existing ARVs at these facilities. This standard reflects the level already achieved by 75 percent of ARVs for which the EPA has data. The EPA is soliciting comment on this proposed emission standard, the

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[60] 88 FR 22790 (Apr. 13, 2023).
[61] 88 FR 22841 (Apr. 13, 2023).

approach by which the EPA arrived at this decision, and data regarding the costs of installing ARVs at existing facilities versus new facilities (Question 7).

Additionally, some industry representatives have suggested that the ARV standards be based on manufacturer guaranteed levels for emission reductions. This issue was also raised during the rulemaking that led up to the 2024 Final Rule.[62] At that time, industry concerns regarding this topic were focused on the requirement to use CEMS for demonstrating compliance. However, as discussed in the following section of this document, the EPA is proposing to revise the standards so that the use of CEMS is no longer mandatory. In any case, while the EPA is significantly concerned about setting standards more stringent than manufacturer certifications, the Agency does not have data on the manufacturer's guaranteed levels for reducing ARV emissions. As such, the EPA is also soliciting comment on whether there is still a concern that would necessitate considering setting ARV standards based on manufacturer guaranteed levels and, if so, what the manufacturer guaranteed level of EtO reduction is for ARVs (Question 8).

C. What changes are we proposing for initial and continual compliance with the emission reduction standards, and what is the rationale for those decisions?

The 2024 Final Rule requires compliance demonstration using EtO CEMS for all facilities except those using less than 100 lb/year "because risk remains at acceptable levels for these facilities even when considering uncontrolled emissions."[63] The 2024 Final Rule allows these facilities with "acceptable [risk] levels" the option of using either parametric monitoring and performance testing or CEMS to demonstrate compliance with the promulgated emission standards. The EPA acknowledged that "in the majority of instances, parametric monitoring is used to good effect as an ongoing means of ensuring that the control devices continue to get necessary emission reductions."[64] The EPA is

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62 88 FR 24090 (Apr. 5, 2024).
63 89 FR 24132 (Apr. 5, 2024).
64 *Id.*

proposing to provide all facilities, including those using at least 100 lb/yr of EtO, the option of using either parametric monitoring and performance testing or CEMS to demonstrate compliance for the following reason.

Under the 2024 Final Rule, whether EtO CEMS is required is based on facility risks, which were derived from a second residual risk assessment the EPA conducted for this source category under CAA section 112(f)(2). However, for the reasons explained in section III.A of this preamble, the EPA is proposing that CAA section 112(f)(2) does not authorize the EPA to conduct a second residual risk review and promulgate associated risk-based standards when the RTR has already been completed and the ongoing review-and-revise obligation and authority arises only under CAA section 112(d)(6). Because the EtO CEMS requirement was based on the results of an unauthorized second residual risk assessment and risk-based standards-setting for this source category, the EPA is proposing to amend the 2024 Final Rule to remove EtO CEMS as a requirement for facilities using at least 100 lb/yr of EtO and instead allow all facilities, regardless of the amount of EtO used, the option to choose between parametric monitoring or CEMS for demonstrating compliance. As proposed, both demonstration options would be available for all facilities. The EPA thus proposes revisions to 40 CFR 63.363(a), (b), (d), (e), and (f)(2) and to 63.365(a), (b), (c), and (d) to allow initial and continuous compliance with annual performance testing and parameter monitoring, and to allow EtO CEMS as an alternative compliance option. The EPA is soliciting comment on allowing all facilities the option to choose between parametric monitoring or CEMS for demonstrating compliance (Question 9).

In addition, the EPA is proposing amendments to the parametric monitoring provisions in the 2024 Final Rule. In reconsidering the compliance demonstration requirements in the 2024 Final Rule, the EPA noticed that the parametric monitoring provisions, which were promulgated in the original Commercial Sterilization Facilities

NESHAP in 1994, with technical corrections in the 2001 amendments, do not reflect the current understanding of air pollution control devices (APCDs) or the sterilization process(es). The EPA is thus proposing to update the monitoring parameters for APCDs in 40 CFR 63.361, 63.363(c), and 63.364(b), (c), and (d). In addition, the EPA is proposing revisions to the procedures for establishing operating parameter limits during the performance test in 40 CFR 63.365(e). The EPA is also proposing clarifying language that describes where the performance testing should be conducted in 40 CFR 63.365(b)(1), providing for the myriad of APCD configurations expected from this source category. The proposed amendments for parametric monitoring are described in the following paragraphs.

For those facilities that use acid-water scrubbers, thermal oxidizers, catalytic oxidizers, gas-solid reactors, or other control devices, the EPA is proposing they demonstrate compliance with the emission reduction standard through initial and annual performance testing and establish parametric operating limits. The EPA is also proposing to allow continuous compliance through parametric monitoring using a continuous parametric monitoring system. The EPA is proposing that facilities must determine compliance with the operating limits continuously on a 1-hour block basis instead of the current 3-hour block. Sterilization is an irregular process where the EtO emissions may fluctuate greatly with different steps in the process, some of which are less than three hours. Longer averaging times could mask how the emission controls operate and achieve the required control efficiency during operational periods immediately before or after higher EtO loading to the control devices (*e.g.*, during SCV exhaust cycles).

For facilities that use an acid-water scrubber, the current monitoring parameters are ethylene glycol concentration, scrubber liquid tank level, and scrubber liquid pH. Based on EPA's current understanding of acid-water scrubbers, the EPA believes that scrubber liquid-to-gas ratio and scrubber liquid temperature are more accurate indicators

of compliance than ethylene glycol concentration and scrubber liquor tank level. The EPA believes this because they are direct indicators that EtO will be captured in the scrubbing columns and the parameters can be monitored in real-time to ensure continuous operation. The EPA is therefore proposing to require continuous monitoring of scrubber liquid-to-gas ratio, scrubber liquid temperature, and scrubber liquid pH. The Agency is proposing that during each annual performance test, the owner or operator determines the average scrubber liquid-to-gas ratio, average inlet scrubber temperature, and average scrubber liquid pH. The EPA is proposing these parameter test averages would be the operating limit for the minimum scrubber liquid-to-gas ratio, maximum temperature of the scrubber liquid, and the maximum scrubber liquid pH.

For facilities that use thermal oxidizers, the current monitoring parameter in the rule is the temperature in or immediately downstream of the firebox. The EPA is proposing to require continuous monitoring of the combustion chamber temperature and flue gas flow rate. First, the Agency is proposing to replace the term "firebox" with "combustion chamber" as the latter is a more commonly used term in the industry. Second, the EPA is proposing monitoring the combustion chamber temperature (instead of allowing the option of monitoring immediately downstream) at a location designated by pollution control manufacturers to ensure proper control and operation. Third, the Agency is also proposing to monitor flue gas flow rate. The flue gas flow rate provides an indication of the thermal oxidizer residence time, which is a critical operating parameter because it will ensure proper flow rate through the thermal oxidizer is being maintained to ensure the continued removal efficiency of any EtO in the sample stream sent to the oxidizer. The EPA is proposing that during each annual performance test facilities determine the average combustion chamber temperature and average flue gas flow rate. The EPA is proposing these parameter test averages would be the operating limit for the minimum combustion temperature and maximum flue gas flow rate.

For facilities that use a catalytic oxidizer, the current parameters are the temperature at the inlet to the catalyst bed and the temperature difference across the catalyst bed, which requires monitoring the inlet temperature to the catalyst bed and the outlet temperature to the catalyst bed. The EPA is proposing to also require continuous monitoring of flue gas flow rate. The flue gas flow rate parameter would provide an indication of the catalytic oxidizer residence time, which is a critical operating parameter because it will ensure that proper flow rate through the catalytic oxidizer is being maintained to ensure the continued removal efficiency of any EtO in the sample stream sent to the oxidizer. Thus, the Agency is proposing to require continuous monitoring of the inlet and outlet temperatures and flue gas flow rate. The EPA is proposing that during each annual performance test, facilities determine the average inlet temperature to the catalyst bed, the average temperature difference between the inlet and the outlet of the catalyst bed, and average flue gas flow rate. The EPA is proposing these parameter test averages would be the operating limit for the minimum temperature at the inlet to the catalyst bed, the minimum temperature difference across the catalyst bed, and the maximum flue gas flow rate.

For facilities that use a gas-solid reactor, the current parameters include bed media analysis (*i.e.*, sample the bed media and analyze for activity) and the pressure drop across the media beds. In its place, the EPA is proposing that facilities must determine the average pressure drop across the reactor during each annual performance test and for this test average to be the operating limit for the maximum gas-solid reactor pressure drop. The EPA is also proposing that when a gas-solid reactor is used as the last air pollution control device prior to exhausting to the atmosphere, facilities must determine the EtO average mass emission sent to the pollution control and the outlet flow rate during the annual performance test. Using this information and the applicable emission reduction standard, facilities must calculate the upper gas-solid reactor outlet EtO

concentration operating limit. The EPA is also proposing that compliance with the outlet EtO concentration operating limit must be measured and recorded weekly. Compared to the current media analysis, this proposed parameter monitoring provides a direct assessment of ongoing performance and will ensure that the control device is optimized, and that the applicable emission reduction standard is being met by meeting the set operating limit.

To maximize flexibility in conducting parametric monitoring, the 2024 Final Rule allows facilities to apply to the EPA Administrator for approval of alternative monitoring requirements for the typical APCDs. The EPA is proposing to provide the requirements to be included in the application for alternative monitoring parameters in 40 CFR 63.365(e)(6).

For those facilities using performance testing and a control device other than acid-water scrubbers, catalytic or thermal oxidizers, or gas-solid reactors, the 2024 Final Rule requires that facilities must establish operating limits and appropriate monitoring parameters that are approved by the EPA Administrator for that specific control device. In this action, the EPA is proposing that facilities must develop a monitoring plan for their chosen continued compliance option (parametric monitoring or CEMS); see proposed rule text in 40 CFR 63.364(a)(6) and (7).

The EPA is proposing to update the reporting and recordkeeping requirements of the Commercial Sterilization Facilities NESHAP in 40 CFR 63.366 and 63.367 to reflect the revised parametric monitoring discussed above. As required by the 2024 Final Rule, if there are deviations from the established operating parameter limits, facilities must report the deviation in the quarterly compliance report. Facilities must take corrective actions to minimize emissions and return the unit to normal operations. If the established operating parameters cannot be met after the corrective action, the facility must reset the operating parameters with a performance test.

The EPA is soliciting comment on these proposed changes to the performance testing, parametric monitoring, and reporting requirements (Question 10).

D. What changes are we proposing to PTE requirements, and what is the rationale for those actions?

The EPA is proposing to rescind the requirement to use PTE to ensure capture of EtO to comply with the emission reduction standards. In the 2024 Final Rule, the EPA finalized requirements to operate PTE in accordance with the requirements of Method 204 as a compliance assurance measure. In the proposal to the 2024 Final Rule, the EPA noted that these requirements were "consistent with what has been applied to many of the commercial sterilizers that have installed PTEs, through permit conditions."[65] In this reconsideration, we are reevaluating this approach. Based on our review of state permits for sterilization facilities, we note that some permits require PTE while others do not. We further note that configuration and design of sterilization facilities vary widely. The above observations suggest that whether PTE would be necessary to assure compliance with an emission standard could depend on a facility's design and configuration. The EPA has historically left such case-by-case reviews of facility design to the states to decide as part of their permitting process.

The EPA is proposing in the alternative to rescind the requirement for PTE on the following bases. First, we propose that the EPA did not account for the impacts of facilities shutting down due to this variation. If the facility is unable to establish a PTE and meet the other requirements, then the facility would be required to shut down thus significantly raising the costs and making it not cost-effective to establish PTE. The feasibility of PTE has been raised by stakeholders over time with respect to this NESHAP, and we seek comment on this potential alternative basis (Question 11).

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[65] *See* 88 FR 22819 (Apr. 13, 2023).

Second, the EPA is proposing in the alternative that the PTE requirement is not compelled by the D.C. Circuit's decision in *Louisiana Environmental Action Network v. Environmental Protection Agency* (*LEAN*),[66] meaning that, at minimum, the Agency has discretion whether to remove the PTE requirement as a compliance mechanism. In previous rules, the EPA has stated or suggested that *LEAN* requires the Agency, as part of the technology review process under CAA section 112(d)(6), not only to regulate previously unregulated pollutants, but also to prescribe additional standards for already regulated pollutants emitted in a manner (*i.e.,* from points or fugitive) not expressly contemplated under the existing standards. In *LEAN*, the D.C. Circuit discussed its view of the Agency's obligation to regulate previously unregulated (*i.e.*, unaddressed) pollutants when conducting a technology review and revising standards "as necessary" under CAA section 112(d)(6). In context, the court analyzed the statute with respect to, and referred specifically to, different types of air toxics (i.e., previously regulated and previously unregulated pollutants).[67] In certain actions since that decision, however, the EPA has sometimes suggested that this holding includes not only previously unregulated pollutants, but also additional emission points within an already regulated source (*e.g.*, an additional point or fugitive) that emit pollutants already captured by the NESHAP. We now propose to clarify that when conducting a CAA section 112(d)(6) review, the EPA is not obligated under the interpretation adopted in *LEAN* to prescribe particular standards for emission points with respect to pollutants already regulated under the NESHAP. If finalized, this proposed position would mean that the EPA's rationale for adopting the PTE requirement—*i.e.*, that such a requirement was necessary to assure compliance with additional standards mandated by *LEAN*—is no longer operative, and we would decline to adopt such a requirement as a discretionary matter for the reasons discussed

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[66] 955 F.3d 1088 (D.C. Cir. 2020)
[67] *See id.* at 1096.

previously. The EPA requests comments on all aspects of these alternative proposals, including with respect to the scope of the interpretation adopted by the D.C. Circuit in *LEAN* and the scope of the Agency's obligation and statutory authority to impose additional standards under the CAA section 112(d)(6) process for particular emission points not previously regulated (Question 12).

In light of the above, we propose to rescind the requirement to use PTE as a compliance assurance measure. The proposed change would not affect the permitting process for any state, which could continue to decide on a case-by-case basis, deferring to States to make the determination as States are in better positioned to determine whether PTE is required for any given sterilization facility. We solicit comment on this approach (Question 13).

E. What technical corrections and amendments to the Commercial Sterilization Facilities NESHAP are we proposing, and what is the rationale for those actions?

After the publication of the 2024 Final Rule, the EPA discovered, through internal reassessment of the regulatory text and through communications with stakeholders, erroneous cross-references and typographical errors within the regulatory text. Through those same processes, the EPA also identified erroneous language in the regulatory text (or in some cases, erroneous omissions) requiring minor wording changes to conform with the 2024 Final Rule preamble and other parts of the regulatory text. The technical corrections and amendments identified here in subsection III.E.1 of this preamble are separate from the proposed substantive changes that resulted from reconsideration; the proposed technical changes and amendments address unintended errors in the 2024 Final Rule. The EPA is proposing these corrections and clarifications to the regulatory text so that the regulated community can rely on regulatory text that is accurate and complete and avoid confusion about how to comply with the Commercial Sterilization Facilities

NESHAP. This action addresses the technical errors in the 2024 Final Rule identified to date by stakeholders and the EPA.

1. Technical Corrections to the Commercial Sterilization Facilities NESHAP

a. Cross-Reference and Typographical Errors

Following promulgation of the 2024 Final Rule, both the EPA and stakeholders identified inadvertent errors in the regulatory text of the Commercial Sterilization Facilities NESHAP, including cross-reference and typographical errors. Table 4 includes the section and paragraph of each identified error, the corrections being proposed in this action, and the reasoning for the corrections. The EPA is not soliciting comment on these corrections.

Table 4. Cross-Reference and Typographical Technical Corrections to 40 CFR part 63, subpart O

Section and paragraph	Proposed technical correction and reason for change
63.361 Continuous monitoring system (CMS)	a. Replace "samples" with "sample" to correct an inadvertent typographical error; b. Replace "evaluates" with "evaluate" to correct an inadvertent typographical error; and c. Replace "computes and records" with "compute and record" to correct an inadvertent typographical error.
63.361 Sterilization operation	a. Replace "chamber exhaust vent" with "CEV" to correct an inadvertent typographical error; and b. Replace "aeration room vent" with "ARV" to correct an inadvertent typographical error.
63.362(i) introductory text	a. Replace "affected source" with "affected sources" to correct an inadvertent typographical error; and b. Replace "as" with "a" to correct an inadvertent typographical error.
63.362(i)(1) introductory text	Replace "mass inlet" with "inlet mass" to correct an inadvertent typographical error.
63.362(i)(1), equation 1	Replace "Equation 1 to paragraph (i)(2)(i)" with "Equation 1 to paragraph (i)(1)(i)" to correct an inadvertent typographical error.
63.362(i)(2) introductory text	Add "the" between "determine" and "30-operating" to correct an inadvertent typographical error.
63.362(i)(2)(i), equation 2	a. Add ", in decimal format," between "subpart" and "to"; and b. Replace "equation 10 in § 63.364(f)(1)(i)(C)(*1*)" with "equation 7 in § 63.364(f)(1)(i)(C)(*1*)" to correct an inadvertent cross-reference error.
63.362(i)(2)(ii)	Add "in" between "calculated" and "paragraph" to correct an inadvertent typographical error.
63.362(j)(1)(i), equation 3	Replace "equation 11 of § 63.364(i)(2)" with "equation 8 of § 63.364(i)(2)" to correct an inadvertent cross-reference error.
63.362(j)(1)(ii)	Add "The term "$E_{o,i}$" as used in this equation is equivalent to the term "E_{30day}" as designated in equation A-3." After "to this subpart." to correct in inadvertent omission of text.

63.362(j)(1)(iii)	a. Add "$_{Fac}$" as a subscript to SWEL in "below the SWEL" to correct an inadvertent typographical error; and b. add "in" between "calculated" and "paragraph" to correct an inadvertent typographical error.
63.362(j)(2)(i), equation 5	a. Replace "tables 1 through 5 of this subpart" with "tables 2 through 5 of this subpart" to correct an inadvertent cross-reference error; and b. Replace "equation 10 in § 63.364(f)(1)(i)(C)(*1*)" with "equation 7 in § 63.364(f)(1)(i)(C)(*1*)" to correct an inadvertent cross-reference error.
63.363(a)	Add "(PS 19)" after "Performance Specification 19" to correct an inadvertent typographical error.
63.363(b) introductory text	a. Change paragraph designation to "63.363(e)"; and b. Replace "part 40 of this chapter" with "part 60 of this chapter" to correct an inadvertent cross-reference error.
63.363(c) introductory text	Change paragraph designation to "63.363(b)".
63.363(d)	Change paragraph designation to "63.363(c)".
63.363(d)(1)	a. Change paragraph designation to "63.363(c)(1)"; and b. Replace "§ 63.365(d)(1)" with "§ 63.365(d)" to correct an inadvertent cross-reference error.
63.363(e)	Change paragraph designation to "63.363(d)".
63.363(f)(2)	Replace "§ 63.365(d)(1)" with "§ 63.365" to correct an inadvertent cross-reference error.
63.364(f)(1)(i)(A)(*1*) introductory text	Replace "M_c" with "$M_{SCV,n}$" to correct an inadvertent typographical error.
63.364(f)(1)(i)(B) introductory text	a. Replace "f" with "f_{det}" to correct an inadvertent typographical error; and b. Replace "equation 8 to this paragraph" with "equation 3 to this paragraph" to correct an inadvertent cross-reference error.
63.364(f)(1)(i)(B), equations 3 and 4	a. Replace "f" with "f_{det}" to correct an inadvertent typographical error; and b. Replace "equation 11 of § 63.364(i)(2)" with "equation 6 of § 63.364(i)(2)" to correct an inadvertent cross-reference error.
63.364(f)(1)(i)(C)(1), equation 5	Replace "f" with "f_{det}" to correct an inadvertent typographical error.
63.364(f)(2)(iv)(D)	Replace "paragraph (f)(2)(I)(C) of this section" with "paragraph (f)(2)(iv)(C) of this section" to correct an inadvertent cross-reference error.
63.364(h) introductory paragraph	a. Replace "EtO sterilization" with "sterilization" to correct an inadvertent typographical error; and b. Add "end-cycle EtO" between "chamber" and "concentration" to correct an inadvertent typographical error.
63.364(h)(1) introductory text	Delete "of" to remove an inadvertent typographical error.
63.364(h)(2) introductory text	a. Replace "chamber" with "sterilization chamber end-cycle" to correct an inadvertent typographical error; and b. Replace "calibrations" with "concentrations" to correct an inadvertent typographical error.
63.364(i)(1)	Replace "§ 63.365(c)(1)(i) and (ii)" with "§ 63.365(c)(1)(i) or (ii)" to correct an inadvertent cross-reference error.

63.365(b)(5)(i)(C) [Previously Redesignated 63.365(b)(5)(i)(C) to 63.365(b)(6)(i)(C)]	Replace "if" with "of" to correct an inadvertent typographical error.
63.365(b)(6), equations 2 and 3 [Previously Redesignated 63.365(b)(6) to 63.365(b)(7)]	a. Replace "$M_{APCD, i}$" with "$M_{APCD,in}$" to correct an inadvertent typographical error; b. Replace "Qi" with "Q_i" to correct an inadvertent typographical error; and c. Replace "$E_{APCD, o}$" with "$E_{APCD,o}$" to correct an inadvertent typographical error.
63.365(c)(2), equation 6	Replace "f" with "$f_{default}$" to correct inadvertent typographical error.
63.365(e)(3)(i)	Replace "correction" with "corrective" to correct an inadvertent typographical error.
63.366(b)(5)(vi)	Replace "or with" with "or in accordance with SWEL in" to correct an inadvertent typographical error.
63.366(b)(7)	Replace "§ 63.362(h)" with "§ 63.364(h)" to correct an inadvertent cross-reference error.
63.366(c)(1)	Add "to be" between "needs" and "reported" to correct an inadvertent typographical error.
63.366(c)(3)	Replace "then" with "the" to correct an inadvertent typographical error.
63.366(c)(5)	Replace "paragraphs (b)(5)(i) through (vi) of this section" with "paragraphs (b)(5)(i) through (vii) of this section" to correct an inadvertent cross-reference error.
63.366(c)(7)	Replace "§ 63.362(h)" with "§ 63.364(h)" to correct an inadvertent cross-reference error.
63.366(d)(1)(ii)	Replace "paragraphs (b)(2) and (3) of this section" with "paragraphs (d)(2) and (3) of this section" to correct an inadvertent cross-reference error.
63.366(d)(2)	Replace "paragraph (b)(3) of this section" with "paragraph (d)(3) of this section" to correct an inadvertent cross-reference error.
63.366(d)(3) introductory text	Replace "paragraph (b)(3) of this section" with "paragraph (d)(3) of this section" to correct an inadvertent cross-reference error.
63.366(d)(3)(i)(A)	Replace "paragraph (b)(2) of this section" with "paragraph (d)(2) of this section" to correct an inadvertent cross-reference error.
63.366(d)(3)(i)(B)(*9*)	Replace "paragraph (b)(3)(ii) of this section" with "paragraph (d)(3)(ii) of this section" to correct an inadvertent cross-reference error.
63.366(d)(3)(i)(C)	a. Replace "paragraphs (b)(3)(i)(B)(*8*) and (b)(3)(ii) of this section" with "paragraphs (d)(3)(i)(B)(*8*) and (d)(3)(ii) of this section" to correct an inadvertent cross-reference error; and b. Replace "paragraph (c)(2) of this section" with "paragraph (e)(2) of this section" to correct an inadvertent cross-reference error.
63.366(d)(3)(ii)	a. Replace "paragraph (b)(3)(i)(B) of this section" with "paragraph (d)(3)(i)(B) of this section" to correct an inadvertent cross-reference error; b. Replace "paragraph (b)(3) of this

	section" with "paragraph (d)(3) of this section" to correct an inadvertent cross-reference error; and c. Replace "paragraph (b)(3)(i)(C) of this section" with "paragraph (d)(3)(i)(C) of this section" to correct an inadvertent cross-reference error.
63.366(d)(4)(i) introductory text	Replace "paragraphs (b)(2) and (3) of this section" with "paragraphs (d)(2) and (3) of this section" to correct an inadvertent cross-reference error.
63.366(d)(4)(ii)	Replace "paragraph (b)(3)(i) of this section" with "paragraph (d)(3)(i) of this section" to correct an inadvertent cross-reference error.
63.366(e)(2)	Replace "paragraphs (d)(3)(i)(B)(*8*) and (b)(3)(ii) of this section" with "paragraphs (d)(3)(i)(B)(*8*) and (d)(3)(ii) of this section" to correct an inadvertent cross-reference error.
63.366(e)(4)	Replace "formatto" with "format to" to correct an inadvertent typographical error.
63.366(g)(3)	a. Replace "paragraph (g)(1)(i) or (ii) of this section" with "paragraph (g)(1) or (2) of this section" to correct an inadvertent cross-reference error; and b. Replace "paragraphs (g)(1)(i) and (ii) of this section" with "paragraphs (g)(1) and (2) of this section" to correct an inadvertent cross-reference error.
63.367(f) introductory text	Replace "paragraph (g)(1) through (4) of this section" with "paragraph (f)(1) through (4) of this section" to correct an inadvertent cross-reference error.
table 2 to Subpart O, note 2	Replace "a rolling 30-operating day average" with "the previous 30 operating days of data" to correct an inadvertent typographical error.
table 3 to Subpart O, note 1	Replace "a rolling 30-operating day average" with "the previous 30 operating days of data" to correct an inadvertent typographical error.
table 4 to Subpart O, note 1	Replace "a rolling 30-operating day average" with "the previous 30 operating days of data" to correct an inadvertent typographical error.
table 5 to Subpart O, note 1	Replace "a rolling 30-operating day average" with "the previous 30 operating days of data" to correct an inadvertent typographical error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.5(a)"	Replace "§ 63.366(b)(1)" with "§ 63.366(d)(1)" to correct an inadvertent cross-reference error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.5(b)(3)"	Replace "§ 63.366(b)(2)" with "§ 63.366(d)(2)" to correct an inadvertent cross-reference error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.5(d)(1)-(2)"	Replace "§ 63.366(b)(3)." with "§ 63.366(d)(3)." to correct an inadvertent cross-reference error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.5(f)(1)-(2)"	Replace "§ 63.366(b)(4)." with "§ 63.366(d)(4)." to correct an inadvertent cross-reference error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.8(c)(4)-(5)"	Replace "§ 63.364" with "§ 63.363" to correct an inadvertent cross-reference error.

table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.9(b)(1)(ii)-(iii)"	Replace "§ 63.366(c)(1)(i)" with "§ 63.366(e)(1)(i)" to correct an inadvertent cross-reference error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.9(b)(2)-(3)"	a. Replace "§ 63.366(c)(3)" with "§ 63.366(e)(3)" to correct an inadvertent cross-reference error; and b. Replace "report" with "notification" to correct an inadvertent typographical error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.9(b)(4)-(5)"	Replace "§ 63.366(c)(1)(ii) and (iii)" with "§ 63.366(e)(1)(ii) and (iii)" to correct an inadvertent cross-reference error.
table 6 to Subpart O, Applies to Subpart O Entry for "§ 63.9(h)(1)-(3)"	Replace "§ 63.366(c)(2)" with "§ 63.366(e)(2)" to correct an inadvertent cross-reference error.
Appendix A to Subpart O, 10.1	Replace "paragraphs 10.1.1 through 10.1.8 of this section" with "sections 10.1.1 through 10.1.5" to correct an inadvertent cross-reference error.
Appendix A to Subpart O, 10.1.3.2	Replace "part 75 of this chapter" with "§ 63.364(g)(2) and (3)" to correct an inadvertent cross-reference error.
Appendix A to Subpart O, 10.1.5.1.2	Replace "or" with "For" to correct an inadvertent typographical error.
Appendix A to Subpart O, 11.1.1 through 11.1.4, and 11.3.2	First a. Replace "section" to "appendix"; and then b. Replace "paragraph" to "section".
Appendix A to Subpart O, 11.4.3	Replace "measurement error (ME)" with "ME".
11.4.5.9	Replace "measurement error (ME)" with "ME".
11.4.5.14	Replace "measurement error (ME)" with "ME".
11.4.8	Replace "measurement error (ME)" with "ME".
Appendix A to Subpart O, 11.4.10	Replace "section 10.1.8.2 of this appendix" with "section 10.1.5.2 of this appendix" to correct an inadvertent cross-reference error.
Appendix A to Subpart O, 11.5.3.4	Replace "section 10.1.8.1.1 of this appendix" with "section 10.1.5.1.1 of this appendix" to correct an inadvertent cross-reference error.

b. Clarifying Technical Corrections

This action proposes technical corrections to clarify language in the regulatory text of the Commercial Sterilization Facilities NESHAP that was erroneously included (or in some cases, erroneously omitted) in the 2024 Final Rule. Table 5 includes the sections and paragraphs of the identified errors, the corrections being proposed, and the reasoning for the corrections.

Table 5. Clarifying Technical Corrections to 40 CFR part 63, subpart O

Section and paragraph	Proposed technical correction and reason for change
63.361 Acid-water scrubber	Replace "liquor" with "liquid" to streamline term use across rule.

63.361 Maximum scrubber liquor pH	Replace “liquor” with “liquid” to streamline term use across rule.
63.361 Minimum stack volumetric flow rate	Delete “corrected” between “flow rate” and “established” and add “, corrected to 20°C and 101.325 kilopascals,” after “demonstration” to clarify requirements.
63.363(b)(1)(i)(A) [Previously Redesignated 63.363(b) to 63.363(e) under Reconsideration in Table 4.]	a. Add “and/or the response times are approximately the same” after “CEMS” to clarify requirements; b. Incorporate text of 363(b)(1)(i) as part of redesignated 363(e)(1); and c. Redesignate 363(b)(1)(i)(A) through (D) as 363(e)(1)(i) through (iv).
63.363(f)(2)	a. Add “and are demonstrating continuous compliance through annual performance testing, ” between “subpart, ” and “you”; and b. Replace “§ 63.365(d)(1)” with “§ 64.365” to correct an inadvertent cross-reference error.
63.366(b)(7)	Replace “§ 63.362(h).” with “and “§ 63.364(h).” to clarify requirements.
63.366(c)(7)	Replace “§ 63.362(h).” with “and “§ 63.364(h).” to clarify requirements.
63.366(d)	Replace “facility” with “major source facility” to clarify that this paragraph, including all its subordinate paragraphs, apply only to major source facilities. 40 CFR 63.366(d)(1)(i) Final Rule regulatory language states that “This paragraph (d) and § 63.5 implement the preconstruction review requirements of section 112(i)(1) for facilities subject to these emissions standards.” (89 FR 24189). In the general provisions, 40 CFR 63.5(a)(1) similarly states that “This section implements the preconstruction review requirements of section 112(i)(1).” CAA section 112(i) states that: “After the effective date of any emission standard, limitation, or regulation under subsection (d), (f) or (h), no person may construct any new major source or reconstruct any existing major source subject to such emission standard, regulation or limitation unless the Administrator (or a State with a permit program approved under subchapter V) determines that such source, if properly constructed, reconstructed and operated, will comply with the standard, regulation or limitation.” Finally, 40 CFR 63.5(b)(3) clarifies that the approval requirement is for construction/reconstruction of a “major-emitting” affected source.
63.366(d)(2)	a. Delete “whether or not an approved permit program is effective in the jurisdictional authority in which a facility is (or would be) located, ”; and b. Replace “Administrator” with “jurisdictional authority”. Approval of a preconstruction permit does not need to come from the EPA. In section II.B.1 of a 2002 final rule amending the NESHAP general provisions (67 FR 16585, April 5, 2002), the EPA stated that “We agree that a State or local agency that has taken delegation of part 63 standards has already demonstrated that their preconstruction review process is substantially equivalent to the Federal requirements. When a State is the delegated authority, the State implements 40 CFR 63.5; we do not require two preconstruction review processes.” The purpose of 40 CFR 63.366(d)(2) is to implement CAA

	section 112(i), which states that "After the effective date of any emission standard, limitation, or regulation under subsection (d), (f) or (h), no person may construct any new major source or reconstruct any existing major source subject to such emission standard, regulation or limitation unless the Administrator (or a State with a permit program approved under subchapter V) determines that such source, if properly constructed, reconstructed and operated, will comply with the standard, regulation or limitation". Therefore, CAA section 112(i) authority is not limited to just the EPA Administrator. Under subpart E of 40 CFR part 63, which specifies the subparts (or specific sections) that the EPA has delegated to jurisdictions, the Agency occasionally delegate the entire NESHAP general provisions to a jurisdiction. If the EPA wishes to preserve a specific section, the Agency specifies that section. The Agency did not do so with the relevant § 63.5 subsections here.
63.366(e)(1)(ii)	Replace "facility" with "major source facility" to clarify that this paragraph, including all its subordinate paragraphs, apply only to major source facilities. See reasons discussed above.
63.366(e)(1)(iii)	a. Replace each instance of "facility" with "major source facility" to indicate that this paragraph only applies to major source facilities; b. Delete "whether or not an approved permit program is effective in the jurisdictional authority in which a facility subject to these emissions standards is (or would be) located"; and c. Replace "Administrator" with "jurisdictional". See reasons discussed above.
Appendix A to Subpart O, 8.2.3	To clarify the process operating time requirement and periods of data unavailability, add new section 8.2.3 which will read "EtO emissions data must be collected over at least 90 percent of the process operating time. Periods associated with normal quality assurance activities, such as daily calibrations, do not count as periods of data unavailability. Periods of out-of-control monitor operation or when the EtO CEMS is unable to provide quality-assured data, such as those periods associated with monitor or data acquisition and handling system failure, are periods of data unavailability."

[1] *See* Document ID No. EPA-HQ-OAR-2019-0178-0486.

A redline strike-out version of the proposed corrected regulatory language for the Commercial Sterilization Facilities NESHAP is available in Docket ID No. EPA-HQ-OAR-2019-0178.

2. Proposed Amendments to the Commercial Sterilization Facilities NESHAP

In addition to the technical corrections discussed above, the EPA is proposing additional amendments to the Commercial Sterilization Facilities NESHAP that are more substantive in nature.

a. Definition of Operating Day

Currently, 40 CFR 63.361 defines an "*Operating day"* as "any day that a facility is engaged in a sterilization operation." The EPA is proposing to define an "operating day" as "any day that an affected source is engaged in a sterilization operation" for the following reason. "*Sterilization operation"* is defined in 40 CFR 63.361 as "any time when EtO is removed from the sterilization chamber through the SCV or the CEV, when EtO is removed from the aeration room through the aeration room vent, when EtO is stored within the building, when EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration." The EPA's intent with this definition was to make sure no EtO emissions from sterilization and related processes go unchecked; however, one company has indicated that the operating day definition may inadvertently include facility operation emission streams from a non-operating vent in the compliance determination because the definition implies that if any affected source at a facility is engaged in a sterilization operation then all affected sources are engaged in a sterilization operation, regardless of whether or not they are actually in use. As an example, suppose a facility is engaged in a sterilization operation, but the aeration room does not contain any sterilized material. Because the operating day is currently defined by the facility itself being engaged in operation (as opposed to the affected source), the ARV (and its control device) would need to be included in the compliance analysis even when no aeration is occurring. If this example site was using CEMS for compliance, the site would be forced to report EtO mass emissions for this ARV, which result from the minimal background values from the CEMS, which do not reflect EtO use, and the flowrate from the aeration room vent.

The EPA is proposing to modify the definition of operating day so that it applies to when an affected source is engaged in a sterilization operation, as opposed to the entire facility, and the EPA solicits comment on this proposed modification to the

definition (Question 14).

b. Definitions of Single-item sterilization and Sterilization operation

The EPA reviewed the use of the terms "container," "EtO non-cartridge storage media," and "pouch" within five definitions in 40 CFR 63.361 and is proposing to modify two of the definitions for consistency.

The definition of "Sterilization operation" uses the term "container" to refer to EtO storage vessels. However, in other definitions, the different term "non-cartridge storage media (*e.g.*, drums, cylinders)" is used to refer to EtO storage vessels. For example, "non-cartridge storage media (*e.g.*, drums, cylinders)" is used in the definition of "EtO dispensing". In order to be consistent in referring to EtO storage vessels, the EPA is proposing to change the definition of "Sterilization operation" by replacing the term "container" with "non-cartridge storage media" to read as "any time when EtO is removed from the sterilization chamber through the SCV or the CEV, when EtO is removed from the aeration room through the ARV, when EtO is stored within the building, when EtO is dispensed from a non-cartridge storage media (*e.g.*, drums, cylinders) to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration."

The definition for "Single-item sterilization" uses the term "pouch" to refer to the containers used to hold the single items to be sterilized; however, other definitions use the different term "container (*e.g.*, bags, pouches)" to refer to a container to hold single items. For example, "container (*e.g.*, bags, pouches)" is used in the definitions of "Injection room" and "Post-injection handling of containers." For consistency, the EPA is proposing to change the definition for "Single-item sterilization" by replacing the term "pouch" with "container" to read as "a process in which one or more items are placed in a container (*e.g.*, bags, pouches), EtO is injected into the container, and the sealed container is placed in a vessel to allow sterilization to occur." The EPA solicits

comment on the proposed modifications to these definitions (Question 15).

c. Definition of Indoor EtO Storage

In the 2024 Final Rule, Group 1 room air emissions, which include indoor EtO storage, are subject to either 112(f)(2) or section 112(d) standards, both of which require operation in accordance with PTE requirements to assure compliance.[34] 40 CFR 63.361 states, "*Indoor EtO storage* means the storage of EtO within non-cartridge media (*e.g.*, drums, cylinders) inside a sterilization building." However, this definition does not distinguish between EtO calibration gas cylinders that are only being used to evaluate the performance of EtO CEMS and are not used for sterilization and the EtO used for sterilization. Since promulgation of the 2024 Final Rule, the EPA has been asked to clarify whether the definition of indoor EtO storage includes those EtO calibration gas cylinders that are being used to evaluate the performance of EtO CEMS. The EPA had not intended to include in the definition of "indoor EtO storage" EtO gas calibrations cylinders, which are used for verifying EtO CEMS performance, because properly stored and handled cylinders should not leak, and even if the cylinders were to leak, the EPA expects any EtO released would be negligible in light of the very small amount kept in these cylinders for EtO CEMS performance evaluation only. As such, the EPA is proposing to modify the definition of "indoor EtO storage" to exclude the EtO calibration gas cylinders stored or used only to verify the performance of EtO CEMS. The EPA proposes to modify the definition of indoor EtO storage to state "*Indoor EtO storage* means the storage of EtO within non-cartridge media (*e.g.*, drums, cylinders) inside a sterilization building to be used in the sterilization process (excluding EtO storage media of calibration gas cylinders that is only used to verify the performance of EtO CEMS)." The EPA solicits comment on this proposed modification to the definition (Question 16)

d. EtO CEMS Inlet Time-Sharing

40 CFR 63.363(e)(1) states that facilities may time-share their EtO CEMS provided that, among other things, the measurement points are equidistant. Some facilities have provided input that this requirement is impractical for systems with many measurement points (particularly inlet measurement systems). Similarly, facilities have noted that it may be impractical to retrofit these systems to comply with the equidistance requirement at 40 CFR 63.363(e)(1)(A). This requirement ensured similar response times between sources sharing the CEMS; however, the EPA has learned that CEMS manufacturers have developed systems that are able to maintain similar response times despite different distances in sampling lines, rendering the equidistance requirement unnecessary when such systems are used.[68] The EPA therefore proposes to revise the regulatory text in 40 CFR 63.363(b)(1)(i)(A)[69] to read "The measurement points are approximately equidistant from the CEMS or the response times are approximately the same under the system design" to account for those systems designed to ensure similar response times between shared systems.[70] The EPA solicits comment on this proposed change (Question 17).

e. Requirements for Flow Rate Monitors in EtO CEMS Applications

The 2024 Final Rule requires the use of a flow rate monitor to demonstrate compliance with the use of EtO CEMS. Flow rate monitoring is an essential component of EtO CEMS. However, in the 2024 Final Rule, the EPA incorporated two different sets of requirements for flow rate monitors as an oversight. At 40 CFR 63.364(g)(3), the EPA provided the requirements for flow rate monitors that are used to verify the performance of PTEs; these requirements are the correct requirements. Appendix A to

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[68] 89 FR 24090 (Apr. 5, 2024).

[69] Redesignated to 40 CFR 63.353(e)(1)(i) in this reconsideration. See the redline strikeout of the regulatory text in the docket for this rule.

[70] *See* PS-19 in Appendix B to 40 CFR part 60 for response time testing requirements.

subpart O provides a different and incorrect set of flow rate monitoring requirements. The requirements included in Appendix A to subpart O were modelled after and referenced those found in Appendix B to 40 CFR part 63, subpart UUUUU, which includes requirements relating to the monitoring of hydrochloric acid. Sterilization facilities do not use hydrochloric acid and as such, these requirements are not applicable to the subpart O NESHAP. Because the EPA is proposing to rescind the PTE requirements, we propose to update 40 CFR 63.364(g) to remove references to PTE while retaining the appropriate flow rate monitoring requirements, which would be needed should a facility choose to utilize CEMS. Additionally, the EPA is proposing revisions to Appendix A to replace any reference to the incorrect flow rate requirements with references to the updated 40 CFR 63.364(g)(2) to ensure that the flow rate monitoring requirements in Appendix A to subpart O are appropriate for sterilization facilities. The EPA is also proposing to remove additional unnecessary references found in Appendix A as a result of this oversight.

In conjunction with this proposed change, there are several sections of the regulatory text within Appendix A to the Commercial Sterilization Facilities NESHAP that would change because they would become irrelevant. Table 6 includes the sections of each correction, the correction that would need to be made should the change discussed above be finalized, and the reasoning for the corrections.

Table 6. Proposed Flow Rate Monitoring Corrections for Appendix A to the Commercial Sterilization Facilities NESHAP

Section	Proposed correction and reason for change
3.2	Replace "part 75 of this chapter" with "§ 63.364(g)(2) of this chapter" to correct an inadvertent cross-reference error.
5.2	For the reason specified above, revise entire section to state: Diluent gas and moisture monitoring systems must meet the applicable ongoing QA test requirements of part 75 of this chapter. Stack gas flow rate must meet the QA requirements in § 63.364(g)(2) of this chapter.
5.2.2.1	Given the correction to 5.2 above, text on linearity checks and part 75 is no longer necessary. Delete "a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and" and ", as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter."

5.3.2.1	For the reason specified above, revise entire section to state: "For stack gas flow rate monitoring systems, a 720 unit or stack operating hour grace period is available for RATAs. For diluent gas and moisture monitoring systems, a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and a 720 unit or stack operating hour grace period is available for RATAs, as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter."
8 introductory text	Replace last sentence with "The QA/QC program requirements for stack gas flow rate monitoring systems are specified in § 63.364(g)(2) of this chapter. The QA/QC program requirements for diluent gas and moisture monitoring systems are specified in section 1 of appendix B to part 75 of this chapter."
10.1.1.2	a. 40 CFR 63.364(g)(2) does not contain monitoring plan requirements, therefore Delete "stack gas flow rate, " and the comma proceeding "diluent gas"; and b. Replace "evaluated" with "submitted".
10.1.3.2	a. Replace "part 75 of this chapter" with "§§ 63.364(g)(1) and (2) of this chapter" to correct an inadvertent cross-reference error; and b. Delete ", as specified in § 75.57(c)(2) of this chapter."
10.1.4.4	a. Redesignate 10.1.4.4 as 10.1.4.3; and b. Delete "required under part 75 of this chapter."
10.1.5.2	Replace "§ 75.59(a) of this chapter" with "§ 63.364(g)(2) of this chapter" to correct an inadvertent cross-reference error.
11.3.1	Replace 75.53(g) with "§63.364(a)(6) of this chapter" to correct an inadvertent cross-reference error.
11.5.3.5	Interference checks are not required under 40 CFR 63.364(g)(2). Remove entire section.

The EPA solicits comment on the proposal to remove all references to 40 CFR part 75 for flow rate monitors within Appendix A to the Commercial Sterilization Facilities NESHAP, with references to 40 CFR 63.364(g)(2), as well as the corrections described in table 6 that would result from this change (Question 18).

f. Other Proposed Corrections

In addition to the proposed amendments described above, the EPA is also proposing, and solicits comment on, the following correction to add text regarding the timing requirements for RATA testing consistent with other performance specifications that was inadvertently omitted from the 2024 Final Rule:

- In section 2.2.4.3 of Appendix A to subpart O, add "RATA test runs must be at least 21 minutes in length" at the end (Question 19).

A redline strike-out version of the proposed regulatory language for the Commercial Sterilization Facilities NESHAP is available in Docket ID No. EPA-HQ-

OAR-2019-0178.

F. What technical corrections and amendments to Performance Specification 19 are we proposing, and what is the rationale for those actions?

The 2024 Final Rule introduced a new performance specification for EtO CEMS (PS 19) and an associated quality assurance procedure that are applicable not just to Commercial Sterilization Facilities but for any facility that chooses to continuously monitor its EtO emissions. After the publication of the 2024 Final Rule, the EPA discovered, through its own internal reassessment of the regulatory text as well as through communications with stakeholders, erroneous cross-references and typographical errors within PS 19. This action addresses the technical errors in PS 19 identified to date by stakeholders and the EPA.

1. Technical Corrections for PS 19

The EPA has identified inadvertent errors in the regulatory text of PS 19, including cross-reference and typographical errors. Table 7 includes the sections of each identified error, the corrections being made by this action, and the reasoning for the corrections.

Table 7. Cross-Reference and Typographical Technical Corrections to PS 19 of 40 CFR part 60, Appendix B

Section	Technical correction and reason for change
1.1	Delete "," after "lbs/hr" to correct an inadvertent punctuation error.
3.13	Add "material" after "zero air" to correct language to be consistent with the term defined in 40 CFR 72.2.
3.17	Add "indicate" between "and" and "the" to correct an inadvertent typographical error.
7.1	Add "material" after "zero air" to correct language to be consistent with the term defined in 40 CFR 72.2.
11.3.1	Delete " a change" to remove an inadvertent typographical error.
11.5.3	Replace "section 11.7 of this PS" with "section 11.4 of this PS" to correct an inadvertent cross-reference error.
11.6.7	Replace "equations 9 through 14 in section 12.6" with "equations 6 through 11 in section 12.6" to correct an inadvertent cross-reference error and inadvertent typographical errors.
13.1	Delete " as required in section 11.7" to correct an inadvertent cross-reference error.
13.4.1	Replace "equation 14" with "equation 11" to correct an inadvertent cross-reference error.

13.4.2	Replace “equation 14” with “equation 11” to correct an inadvertent cross-reference error.
table 1	Replace both instances of “H_2 O” with “H_2O” to correct inadvertent typographical errors.

This action proposes technical corrections to clarify language in the regulatory text that was erroneously included (or in some cases, erroneously omitted). First, in section 3.1, the EPA is proposing to revise the definition of “Calibration drift” to delete everything from “Calibration Span” to the end of section 3.1. Then, the Agency is proposing to add section 3.2 to define “Calibration Span”, which includes all the text that was deleted from section 3.1. Second, in section 3.18, the EPA is proposing to revise the definition of “Standard addition” by adding “to the actual measurement path or” between “dynamically)” and “measured” to clarify that the term applies to both the measurement path and the measured sample gas stream. Also, through this correction, the definition of “Standard addition” will be consistent with how that term is defined in PS 18, which was the model for PS 19. A redline strike-out version of the proposed corrected regulatory language for PS 19 is available in Docket ID No. EPA-HQ-OAR-2019-0178.

2. Technical Corrections for PS 19 Appendix A

Following signature of the 2024 Final Rule, the EPA identified inadvertent errors in the regulatory text of PS 19 Appendix A, including cross-reference and table designation errors. In section 8.1.4, the Agency is proposing to replace “section 8.2 or 8.3” with “section 8.2” to correct an inadvertent cross-reference error. In section 13.0, the Agency is proposing to redesignate “Table A13—1” to “Table A1”. A redline strike-out version of the proposed corrected regulatory language for PS 19 Appendix A is available in Docket ID No. EPA-HQ-OAR-2019-0178.

3. Technical Corrections for PS 19 Appendix B

Following signature of the 2024 Final Rule, the EPA identified inadvertent errors in the regulatory text of PS 19 Appendix B, including cross-reference and typographical

errors. Table 8 includes the sections of each identified error, the proposed corrections being made by this action, and the reasoning for the proposed corrections.

Table 8. Cross-Reference and Typographical Technical Corrections to PS 19 Appendix B of 40 CFR part 60, Appendix B

Section	Proposed technical correction and reason for change
3.5	Replace "document The protocol" with "protocol that" to correct an inadvertent typographical error
3.13	a. Replace "*Materials*" with "*Material"* to correct an inadvertent typographical error; and b. Add "that " between "composition" and "is" to correct an inadvertent typographical error.
3.15	a. Replace "*RGMs*" with "*RGM"* to correct an inadvertent typographical error; and b. Delete ", are called Research Gas Mixtures (RGMs)" to correct an inadvertent typographical error.
8.1(b)	Add "*Gravimetric*" between "*GMPS*" and "*Cylinder*" for consistency with section 8.1.2.
8.1(e)	Add "*Testing*" after "*Stability*" for consistency with section 8.1.5.
8.1.3	a. Add "*Cylinder*" between "*GMPS*" and "*Independent*" for consistency with 8.1(c); and b. Replace "com" with "component" to correct an inadvertent typographical error.
8.1.4	Add "*Cylinder*" between "*GMPS*" and "*Certification*" for consistency with 8.1(d).
8.1.4.1	Replace "equation B-1" with "equation B1" to correct an inadvertent cross-reference error.
8.1.4.2	Replace "equation B-2" with "equation B2" to correct an inadvertent cross-reference error.
8.1.4.3	a. Replace "section 8.1.5.3" with "section 8.1.4.1" to correct an inadvertent cross-reference error; and b. Replace "section 8.1.5.4" with "section 8.1.4.2" to correct an inadvertent cross-reference error.
8.1.4.4	a. Replace "SGMs" with "SGM" to correct an inadvertent typographical error; and b. Replace "section 8.1.5.1 or 8.1.5.2" with "section 8.1.4.1 or 8.1.4.2" to correct an inadvertent cross-reference error.
8.1.5	Add "*Cylinder*" between "*GMPS*" and "*Stability*" for consistency with 8.1(e).
8.1.5.2	Replace "section 8.1.4" with "section 8.1.3" to correct an inadvertent cross-reference error.
8.1.6	Add "Cylinder" between "GMPS" and "Expiration" for consistency with 8.1(f).
8.1.7	a. Replace "is" with "in" to correct an inadvertent typographical error; b. Replace "section 8.1.8.1 and 8.1.8.2" with "section 8.1.7.1 and 8.1.7.2" to correct an inadvertent cross-reference error; and c. Replace "section 8.1.8.3" with "section 8.1.7.3" to correct an inadvertent cross-reference error.
8.2.1	Replace "section 8.1.8.1" with "section 8.1.7.1" to correct an inadvertent cross-reference error.
8.2.2	a. Replace "section 8.1.5.3" with "section 8.1.4.1" to correct an inadvertent cross-reference error; and b. Replace "section 8.1.5.4" with "section 8.1.4.2" to correct an inadvertent cross-reference error.
8.2.3	Replace "section 8.1.6" with "section 8.1.5" to correct an inadvertent cross-reference error.
8.2.5	Replace "section 8.1.8" with "section 8.1.7" to correct an inadvertent cross-reference error.

8.2.6(k)	Replace “section 14 of this appendix” with “section 16 of this appendix” to correct an inadvertent cross-reference error.
10.0	Delete “ and develop” to correct an inadvertent typographical error.

A redline strike-out version of the proposed corrected regulatory language for PS 19 Appendix B is available in Docket ID No. EPA-HQ-OAR-2019-0178.

4. Technical Corrections for Procedure 7 of 40 CFR 60 Appendix F

Following signature of the 2024 Final Rule, the EPA identified inadvertent errors in the regulatory text of Procedure 7 of 40 CFR 60 Appendix F, including cross-reference, section designation, and typographical errors. Table 9 includes the section of each identified error, the corrections being proposed in this action, and the reasoning for the corrections.

Table 9. Cross-Reference, Section Designation, and Typographical Technical Corrections to Procedure 7 of 40 CFR part 60, Appendix F

Section	Proposed technical correction and reason for change
Heading	Replace “Exide” with “Oxide” to correct an inadvertent typographical error.
3.2	Replace “section 5.4” with “section 5.3” to correct an inadvertent cross-reference error.
4.1.1	Replace “section 11.3 of PS-19 in appendix B to this part” with “section 11.5 of PS-19 in appendix B to this part” to correct an inadvertent cross-reference error.
5.1.1	Replace “sections 5.1.5 or 5.5 of this procedure” with “sections 5.1.5 or 5.4 of this procedure” to correct an inadvertent cross-reference error.
5.1.4.1	Replace “section 11.8 of PS-19 in appendix B of this part” with “section 11.5 of PS-19 in appendix B of this part” to correct an inadvertent cross-reference error.
5.2.4.3	Replace “RMavg” with “RM_{avg}” to correct an inadvertent typographical error.
5.5.1	Change section designation to “5.4.1”.
5.5.2	Change section designation to “5.4.2”.
5.5.3	Change section designation to “5.4.3”.
Newly designated 5.4.3	Replace “section 5.5” with “section 5.4” to conform cross-reference with corrected section designation (see above).
6.1	Replace “equations 9 through 14 in section 12 of PS-19 in appendix B to this part” with “equations 6 through 11 in section 12 of PS-19 in appendix B to this part” to correct an inadvertent cross-reference error.

This action also proposes technical corrections to clarify language in the regulatory text that was erroneously included. First, in section 5.1.3.2, the EPA is proposing to delete "5.2.3.3 Calculate results as described in section 6.3." and add a new section 5.1.3.3 which will read "Calculate results as described in section 6.3". This language was clearly meant to be its own section, but due to an inadvertent typographical error, it was made part of section 5.1.3.2. Second, in section 7.1.1, the EPA is proposing to delete " 7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.", as this language is already present in section 7.1.2.

A redline strike-out version of the proposed corrected regulatory language for Procedure 7 is available in Docket ID No. EPA-HQ-OAR-2019-0178.

G. What compliance dates are we proposing, and what is the rationale for the proposed compliance dates?

The 2024 Final Rule includes standards promulgated under CAA section 112(d)(2) and (3), (d)(5), and (d)(6), and existing sources must comply within three years, the maximum time allowed under CAA section 112(i)(3)(A).[71] In addition, the 2024 Final Rule includes more stringent risk-based standards for some affected sources pursuant to CAA section 112(f)(2), and existing sources must comply within two years, as required by CAA section 112(f)(4).[72] Accordingly, under the 2024 Final Rule, the compliance deadlines for existing sources are April 6, 2026, for the section 112(f)(2) standards, and April 5, 2027, for the section 112(d) standards. For all standards, new sources must comply by the effective date of the 2024 Final Rule (*i.e.*, April 5, 2024) or

[71] 89 FR 24090 (Apr. 5, 2024).
[72] *Id.*

upon startup, whichever is later. See 40 CFR 63.360(j) and tables 1 through 5 to subpart O of part 63; see also CAA sections 112(i)(3)(A) and 112(f)(4).

As discussed in section III.A of this document, the EPA is proposing to remove the CAA section 112(f)(2) standards. As a result, existing sources that currently are subject to both section 112(d) standards and section 112(f)(2) standards promulgated in the 2024 Final Rule would only be subject to the applicable section 112(d) standards. As mentioned above, the compliance deadline for section 112(d) standards for existing sources is April 5, 2027.[73] For new sources (as defined under the 2024 Final Rule) subject to section 112(f)(2) standards that have already started up, because the section 112(f)(2) standards in the 2024 Final Rule are more stringent than section 112(d) standards (with several that are the same as section 112(d)(6) standards), compliance with section 112(f)(2) standards would also mean compliance with section 112(d) standards. For the reasons stated above, the EPA believes that sources can still meet the current compliance deadlines with the removal of the section 112(f)(2) standards.

In addition to proposing removal of the CAA section 112(f)(2) standards, the EPA is proposing to amend the section 112(d)(6) standard for new ARVs at facilities where EtO usage is at least 10 tpy. For the reasons explained in section III.B, the EPA is proposing to change this standard from 99.9 percent reduction to 99.6 percent reduction. Because new ARVs (as defined in the 2024 Final Rule) that already started up are currently operating under the more stringent 99.9 percent reduction standard in the 2024 Final Rule, they are already meeting the less stringent proposed standard of 99.6 percent reduction. The EPA does not foresee problems with new ARVs (as defined by the 2024 Final Rule) at facilities where EtO usage is at least 10 tpy complying with the proposed

[73] As discussed in section II.D of this preamble, this compliance deadline is now extended to April 5, 2029, for facilities granted a two-year waiver via Presidential Proclamation, "Regulatory Relief for Certain Stationary Sources to Promote American Security With Respect to Sterile Medical Equipment," 90 FR 34747 (July 23, 2025).

revised standard by the current deadlines in the 2024 Final Rule (i.e., upon startup or by April 5, 2024, whichever is later).[74]

The EPA considered whether the proposed changes to the methods for demonstrating compliance could impact facilities' ability to demonstrate compliance with existing source standards under the current deadline. This reconsideration proposes to remove the requirement that CEMS be used for demonstrating compliance; thus, industry will not need time to comply with this requirement. However, this change represents a return to the compliance demonstration practice currently used by industry. While the EPA is proposing to amend the specific requirements and details of the parametric monitoring and performance testing approach, these changes do not represent a substantial change in methods and should not present a substantial burden to industry. As such, the EPA does not anticipate these changes to need more time than provided by the compliance deadline already in place.

For these reasons, the EPA is proposing to retain the compliance dates for existing and new sources in 40 CFR 63.360 and in tables 1 to 5 to subpart O of part 63. The EPA is soliciting comment on compliance deadlines (Question 20).

IV. Severability

This proposed rule contains several discrete components, which the EPA views as severable as a practical matter—i.e., they are functionally independent and operate in practice independently of the other components. These discrete components are generally delineated by the section headings and subheadings of this preamble. For example, the proposed rescission of the risk-based standards based on the best reading of CAA section 112(f)(2) is severable from the proposed revision to the new source standard for ARV at facilities using at least 10 tpy based on EPA's reconsideration of this standard under

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[74] *Supra* n.10.

section 112(d)(6). The final rule also includes other revisions to the Sterilization Facilities NESHAP that generally function independently of one another (e.g., revisions to the compliance demonstration requirements to allow facilities to choose between parametric monitoring or using CEMS, rescission of the requirement to use PTE to ensure complete capture of EtO).

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

There are 89 facilities in the Commercial Sterilization Facilities source category that are currently operating. A complete list of facilities that are currently subject to the NESHAP is available in the document "2024 Facility List," which is available in the docket for this rulemaking.

B. What are the air quality impacts?

For the standards that the EPA is proposing, there is an estimated EtO emissions increase of 7.8 tpy for the total source category because of the removal of CAA section 112(f)(2) standards and revision of the section 112(d)(6) standards for new ARVs at facilities where EtO use is at least 10 tpy. See the memorandum titled *Regulatory Impact Analysis for the Proposed Reconsideration of the 2024 National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, which is available in the docket for this rulemaking.

C. What are the cost impacts?

The nationwide costs of the proposed amendments are presented in table 10 of this preamble. As described in this preamble, the EPA is removing the CAA section 112(f)(2) standards and revising the section 112(d)(6) standards for new ARVs at facilities where EtO use is at least 10 tpy. As a result, industry will see overall cost savings in comparison to the 2024 Final Rule. The total savings for capital investment for the proposal is estimated to be about $280 million in 2024 dollars. The Agency estimates

the total annual compliance cost savings of the proposal, compared to the estimated costs associated with the 2024 Final Rule, to be approximately $50 million.

Table 10. Total Capital Investment Cost Savings and Total Annual Compliance Cost Savings (millions of 2024$)

Requirement	Number of Impacted Facilities	Total Capital Investment Cost Savings	Total Annual Cost Savings
PTE	28	$88.1	$9.4
Additional Control Technologies	82	$130.4	$29.1
Monitoring and Testing	88	$58.1	$18.1
Recordkeeping and Reporting	89		-$0.2
Cycle Revalidations	86		-$6.3
Total	**89**	**$276.6**	**$50.1**

Note: Total annualized compliance costs include annualized capital costs, annual operating and maintenance costs, and one-time costs. Dollar values are presented to one decimal place.

D. What are the economic impacts?

The present value (PV) of the estimated compliance cost savings from 2026 to 2045 for the proposed reconsideration is $630 million in 2024 dollars, discounted at a 3 percent rate. The equivalent annualized value (EAV) of the estimated cost savings is $43 million, using a 3 percent discount rate. Using a 7 percent discount rate, the PV and EAV of the cost savings are estimated to be $510 million and $48 million, respectively. This proposed reconsideration is estimated to result in net compliance cost savings for the impacted source category.

The EPA conducted economic impact analyses for this proposal, as detailed in the memorandum titled *Regulatory Impact Analysis for the Proposed Reconsideration of the 2024 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 reconsideration, 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 (CSRs) underpin the "sales test" methodology the EPA uses to assess small business impacts for a rulemaking.

There are 89 facilities, owned by 49 ultimate parent companies, affected by the proposed amendments. Of these 89 facilities, 23 facilities (26 percent), are owned by a total 19 ultimate parent companies that are small entities. The Agency calculated the CSRs for all 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. As shown in table 10, this proposed reconsideration does incur cost increases related to one-time costs for cycle revalidations and recordkeeping and reporting costs. However, these cost increases are less than the net cost savings for 16 of the affected 19 small entities. The 16 small entities estimated to experience net cost savings under this proposed reconsideration are expected to have lower CSRs relative to the 2024 Final Rule. Of the 3 small entities projected to incur additional requirement costs relative to 2024 Final Rule, one has an estimated CSR above 3 percent. The average annualized cost savings for small entities is about $0.68 million and about $0.35 million for the remaining entities. The average annual sales for the 19 small entities is $38 million, while the remaining 30 entities have average annual sales of $15 billion. Relative to the 2024 Final Rule, the average CSR for all firms decreased by 4.3 percent, down to approximately 3.8 percent. Similarly, the CSRs for large and small firms decreased by 0.26 percent (down to approximately 0.11 percent) and by 10.6 percent (down to approximately 10 percent), respectively. 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, large firms are less affected by the proposed rule than small firms.

EtO sterilization services are a critical input in the provision of safe medical devices. According to the U.S. Food and Drug Administration (FDA), more than 20

billion medical devices used in the U.S. every year are sterilized with EtO, accounting for approximately 50 percent of medical devices that require sterilization. In the 2024 Final Rule regulatory impact analysis (RIA), the industry profile in section 2 discusses the role of EtO in providing a significant number of healthcare products to the public and why it is often the only sterilization method that can be used for a wide variety of common medical devices.[75] The EPA was not able to quantitatively assess potential market impacts for this proposed rule. However, it is likely that this proposed reconsideration would reduce the risk of capacity constraints in the sterilization sector. In the 2024 Final Rule RIA, the EPA examined a scenario where the 2024 Final Rule requirements lead to facilities needing to temporarily reduce their capacity and thus lose revenue during that time. The EPA requests comment on whether the proposed standards would result in a similar risk of capacity constraints in the sterilization sector (Question 21). To the extent that this proposed reconsideration avoids the need for facilities to reduce capacity, the cost savings of this action are estimated to be higher than the estimates of the examined scenario in the 2024 Final Rule RIA.

E. What are the benefits?

Being unable to adequately supply sterilized medical equipment to our medical personnel to safely treat patients in hospitals, operating rooms, and other medical facilities would undermine our national security. This rule, if finalized, would help ensure a secure medical supply chain as it would decrease the probability of commercial sterilizers shuttering and the United States having to rely on other countries to sterilize medical devices. While the EPA acknowledges significant national security benefits if this rule is finalized, the Agency is unable to monetize these national security benefits

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[75] U.S. EPA. (2024). *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-1557*.

Consistent with longstanding practice, the EPA did not monetize the foregone benefits from the estimated emission changes in HAP associated with this proposed reconsideration. The EPA currently does not have sufficient methods to monetize benefits associated with HAP. This does not imply that there are no impacts associated with the EtO emission increases estimated for this proposed rule. Non-monetized health disbenefits are expected under this proposed reconsideration from estimated increases of 7.8 tons of EtO annually relative to the 2024 Final Rule. A qualitative discussion of the health effects associated with EtO exposure is provided in the memorandum titled *Regulatory Impact Analysis for the Proposed Reconsideration of the 2024 National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, which is available in the docket for this rulemaking.

VI. Request for Comments

We solicit comment on all aspects of this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the analyses.

Throughout this proposal, the EPA is soliciting comment on numerous aspects of the proposed rule. The EPA has indexed each comment solicitation with an identifier (*e.g.*, "Question 1, Question 2, . . .) to provide a consistent framework for effective and efficient provision of comments. Accordingly, we ask that commenters include the corresponding identifier when providing comments relevant to that comment solicitation. We ask that commenters include the identifier in either a heading, or within the text of each comment (e.g., "In response to Question 1, . . ."") to make clear which comment solicitation is being addressed. Below, we list the questions for which the EPA invites comment.

Question #1: Has the 2024 Final Rule and underlying interpretations generated reliance interests and, if so, how should the EPA consider them in any final action?

Question #2: Should the EPA rescind the standards set under CAA section 112(f)(2) in the 2024 Final Rule, as proposed, based on the proposed finding that the discretionary second risk review conducted as part of the 2024 Final Rule was not authorized under the CAA?

Question #3: Is there new information that could be used in dose-response modeling, such as epidemiological studies of cancer in humans exposed to EtO?

Question #4: Is there any new information relevant to dose-response model selection such as consideration of statistical analyses, visual model fit, or biological plausibility?

Question # 5: Is there new information related to human exposure to EtO, including information on occupational, smoking, background or endogenous exposures that may be relevant to estimating the dose-response relationship of EtO carcinogenicity?

Question #6: Is there additional information on the comments of the 2016 IRIS value provided by commenters in the context of the more recent proposed CMAS NESHAP (January 22, 2025) (see Docket ID EPA-HQ-OAR-2024-0303, comment numbers 0060, 0061, 0068, 0076, and 0079)?

Question #7: Should the EPA modify the emission reductions levels for new ARVs at facilities where EtO use is at least 10 tpy from 99.9 to 99.6 percent reduction, as proposed?

Question #8: Should the EPA consider manufacturer guarantee levels of EtO reduction for ARVs, and if so, what are these levels?

Question #9: Should facilities have the option of using either parametric monitoring and performance testing or CEMS to demonstrate initial and continuous compliance with the Commercial Sterilization Facilities NESHAP, as proposed?

Question #10: Should the EPA finalize the proposed changes to performance testing, parametric monitoring, and reporting requirements as proposed?

Question #11: Is PTE cost effective and feasible?

Question #12: Should the EPA not be allowed to treat unregulated sources of regulated pollutants the same as unregulated pollutants?

Question #13: Should the EPA remove PTE requirements?

Question #14: Should the EPA modify the definition of "Operating day" so that it applies to when an affected source is engaged in a sterilization operation, as opposed to the entire facility, as proposed?

Question #15: Should the EPA modify the definitions of "Sterilization operation" and "Single-item sterilization" be modified as proposed?

Question #16: Should the EPA modify the definition of "Indoor EtO storage" to clarify that EtO storage media of calibration gas cylinders that is only used to verify the performance of EtO CEMS is excluded, as proposed?

Question #17: Should the EPA modify 40 CFR 63.363(b)(1) to indicate that CEMS measurement points do not need to be equidistant so long as the response times are similar, as proposed?

Question #18: Should the EPA remove all references to 40 CFR part 75 for flow rate monitors within Appendix A to the Commercial Sterilization Facilities NESHAP and should we make the corrections described in table 6 be made, as proposed?

Question #19: Should the EPA add the phrase "RATA test runs must be at least 21 minutes in length" to the end of section 2.2.4.3 of Appendix A to subpart O, as proposed?

Question #20: Should the EPA retain the compliance deadlines promulgated in the 2024 Final Rule for the section 112(d) standards as proposed?

Question #21: Would the proposed standards result in a similar risk of capacity constraints as the 2024 Final Rule in the sterilization sector?

VII. Statutory and Executive Order Reviews

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

This action is a significant regulatory action and therefore, the EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Any changes made in response to E.O 12866 review have been documented in the docket. The EPA has prepared an analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for the Proposed Reconsideration of the 2024 National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, is available in the docket. A summary of the costs and economic impacts is included in section IV of this preamble.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is expected to be an Executive Order 14192 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the EPA's analysis of the potential costs and benefits associated with this action.

C. 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.

The EPA is 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). 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: 89 facilities.

Frequency of response: Quarterly, or annual. Responses include monitoring plan, notification of compliance status reports, performance test reports and quarterly compliance reports.

Total estimated burden: 24,077 hours (per year) for the responding facilities and 2,541 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $6,883,047 (per year), which includes $4,529,143 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. The EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *www.reginfo.gov/public/do/PRAMain*. Find this information collection by selecting "Currently under Review – Open for Public Comments" or by using the search function. OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

D. Regulatory Flexibility Act (RFA)

The EPA certifies that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the EPA concludes that the impact of concern for this rule is any adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden on

the small entities subject to the rule. This proposed action would lead to reduction in EAV of costs over the 2026 to 2046 timeframe of about $43 and $48 million per year at discount rates of 3 percent and 7 percent, respectively. The average annualized cost savings for small entities is about $0.68 million and about $0.35 million for the remaining entities. For a more detailed analysis, please see the document *Regulatory Impact Analysis for the Proposed Reconsideration of the 2024 National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations* available in the docket for this rule.

E. 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 government.

F. 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.

G. 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.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to Executive Order 13045 because it is a significant regulatory

action under section 3(f)(1) of Executive Order 12866, and the EPA believes that the environmental health and safety risk addressed by this action may have a disproportionate effect on children. The environmental health and safety risks addressed by this action present a disproportionate risk to children due to EtO being mutagenic (*i.e.*, it can damage DNA).

The EPA did not conduct a new analysis of children's environmental health for this action. For details on children's health and the impact of the CAA section 112(d) standards, please see the Executive Order 13045 discussion and tables 17 and 18 in the 2024 Final Rule (89 FR 24090).

This action is preferred over other regulatory options analyzed because, while it removes the CAA 112(f)(2) standards to better comply with the text and structure of the applicable statutory language (see section III.A), it retains the first-time standards promulgated in the 2024 Final Rule under CAA sections 112(d)(2), (3) and (5) for emission sources that were unregulated prior to the 2024 Final Rule. These standards will continue to apply and protect children's health.

Furthermore, the EPA's *Policy on Children's Health* applies to this action. For details on children's health and the impact of the CAA section 112(d) standards, please see the discussion in the 2024 Final Rule (89 FR 24090).

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

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The overall energy impact of this rule should be minimal for commercial sterilization facilities and their parent companies.

J. National Technology Transfer and Advancement Act (NTTAA)

The NTTAA requires the EPA to use voluntary consensus standards (VCS) in addition to EPA methods in regulatory activities unless doing so would be inconsistent with applicable law or otherwise impracticable. VCS are technical documents, such as test methods, that are developed or adopted by VCS bodies using procedures that ensure that the standards

development process is open to all interested parties. VCS bodies are generally private sector, not-for-profit entities such as the American Society for Testing and Materials (ASTM).

The EPA searched the Enhanced NSSN Database managed by the American National Standards Institute (ANSI) for VCS that could be used in the National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emissions Standards for Sterilization Facilities. The EPA also contacted VCS organizations and accessed and searched their databases. While the EPA has made a reasonable effort to identify and evaluate potentially practical VCS, the findings do not necessarily represent all potential alternative standards which may exist.

Searches were conducted for: EPA Methods 204 and 205 of 40 CFR part 51, Appendix M; EPA Methods 1, 1A, 2, 2A, 2B, 2C, 2D, 3A, 3B, and 4 of 40 CFR part 60, Appendix A; and, EPA Methods 301 and 320 of 40 CFR part 63, Appendix A. The EPA found no VCS are acceptable alternatives for EPA Methods 1, 1A, 2, 2A, 2B, 2C, 2D, 3A, 4, 204, 205, and 301. The EPA found no acceptable alternative VCS for EPA Methods 1, 1A, 2, 2A, 2B, 2C, 2D, 3A, 4, 204, 205, and 301.

The proposed rule continues to include one VCS as an alternative to EPA Method 3B for the purposes of this rule. The manual methods in ANSI/ASME PTC 19-10-1981 Part 10, “Flue and Exhaust Gas Analyses” (2010 version) are acceptable alternatives to EPA Method 3B to analyze oxygen and carbon dioxide concentrations in the stack gas. The instrumental methods in the voluntary consensus standard ANSI/ASME PTC 19-10-1981 Part 10, “Flue and Exhaust Gas Analyses” (2010 version) are not acceptable alternatives to EPA Method 3B.

The proposed rule continues to include one VCS as an alternative to EPA Method 320 for the purposes of this rule. The VCS ASTM D6348-12 (2020), “Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy” is an acceptable alternative to EPA Method 320 with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348-12(2020), the following conditions must be met:

(1) The test plan preparation and implementation in the Annexes to ASTM D 6348-12 (R2020), sections A1 through A8 are mandatory; and

(2) In ASTM D6348-12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). For the test data to be acceptable for a compound, %R must be 70% ≤ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.*, the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using equation 1 to this paragraph:

(eq. 1) Reported Results = ((Measured Concentration in Stack))/(%R) x 100

According to 40 CFR 63.7(f) and 40 CFR 63.8(f) of subpart A of the general provisions, a source may apply to the EPA to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications or procedures in the final rule or any amendments. 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 such standards should be used in this regulation.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Lee Zeldin,

Administrator.

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