The EPA Administrator, Andrew R. Wheeler, signed the following notice on 12/05/2019, and EPA is submitting it for publication in the Federal Register (FR). While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of compliance. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (https://www.govinfo.gov/app/collection/fr) and on Regulations.gov (https://www.regulations.gov) in Docket No. EPA-HQ-OAR-2019-0178. Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

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

RIN 2060-AU37

National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In this advance notice of proposed rulemaking (ANPRM), the U.S. Environmental Protection Agency (EPA) is soliciting information that will aid in potential future revisions to the Ethylene Oxide Emission Standards for Sterilization Facilities. The EPA is soliciting information and requesting comment on potential control measures for reducing ethylene oxide (EtO) emissions from commercial sterilization facilities. These control measures include controls for fugitive emissions of EtO, safety measures for the chamber exhaust vents (CEVs), process equipment improvements, and advances in add-on control technologies for point sources. In addition, the EPA is considering, and requesting comment on, how best to assess potential impacts on small businesses. The EPA is also taking comment on the available EtO usage data for individual facilities and on additional data contained in the modeling file that will be used to evaluate the impact of emissions from commercial EtO sterilizers.

DATES: *Comments*. Comments must be received on or before **[INSERT DATE 60 DAYS**

AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 action. 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 action, contact Mr. Jonathan Witt, Sector Policies and Programs Division (E143-05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-5645; email address: *witt.jon@epa.gov*.

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SUPPLEMENTARY INFORMATION:

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 Regulations.gov. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in Regulations.gov or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue, NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1742.

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

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the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets*.

The EPA is soliciting comment on numerous aspects of the action. The EPA has indexed each comment solicitation with an alpha-numeric identifier (*e.g.*, "C-1," "C-2," "C-3") to provide a consistent framework for effective and efficient provision of comments. Accordingly, the EPA asks that commenters include the corresponding identifier when providing comments relevant to that comment solicitation. The EPA asks that commenters include the identifier in either a heading, or within the text of each comment (*e.g.*, "In response to solicitation of comment C-1, …") to make clear which comment solicitation is being addressed. The EPA

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emphasizes that the Agency is not limiting comment to these identified areas and encourages provision of any other comments relevant to this action.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, clearly indicate on the outside of the digital storage media that it does not contain CBI. 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 CFR part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2019-0178.

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

ANPRM	advance notice of proposed rulemaking
APCD	air pollution control device
ARV	aeration room vent
CAA	Clean Air Act
CBI	Confidential Business Information

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CEV	chamber exhaust vent
CFR	Code of Federal Regulations
EOSA	Ethylene Oxide Sterilization Association
EPA	Environmental Protection Agency
EtO	ethylene oxide
GACT	generally available control technology
HAP	hazardous air pollutant(s)
IR	infrared
IRIS	Integrated Risk Information System
LEL	lower explosive limit
MACT	maximum achievable control technology
NAICS	North American Industry Classification System
NATA	National Air Toxics Assessment
NESHAP	national emission standards for hazardous air pollutants
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
ppmv	parts per million by volume
PRA	Paperwork Reduction Act
PTE	permanent total enclosure
SBA	Small Business Administration
SBAR	Small Business Advocacy Review
SCV	sterilization chamber vent
tpy	tons per year

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

I. General Information
A. What is the purpose of this ANPRM?
B. Does this action apply to me?
C. Where can I get a copy of this document and other related information?
II. Background
A. Statutory Background
B. Regulatory Background
C. Risks Associated with EtO Emissions
III. Small Business Considerations
IV. Request for Comment
A. Modeling File and Annual EtO Usage Data
B. Control of Fugitive Emissions
C. Chamber Exhaust Vent Control and Safety Considerations
D. Other Point Source Control Options

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E. Types of Sterilization Facilities
V. Statutory and Executive Order Reviews

I. General Information

A. What is the purpose of this ANPRM?

This ANPRM is intended to solicit information from the public in order to inform the EPA as the Agency considers proposing a future rulemaking to further address emissions of EtO from commercial sterilizers. This ANPRM focuses on considerations pertinent to potential future amendments to 40 CFR part 63, subpart O, in order to further address emissions of EtO from commercial sterilizers. Subpart O contains the emissions control standards for hazardous air pollutants (HAP) that apply to commercial EtO sterilization facilities. In this ANRPM, the EPA identifies additional control technologies and measures that may be used to reduce emissions of EtO and provides an opportunity for stakeholders to provide additional information about these technologies and measures. In addition, the EPA is seeking information about the costs associated with controlling EtO emissions from all sources and, specifically, those that qualify as small businesses. The EPA is also taking comment on facility and emissions data as part of the modeling file that will be used to evaluate the impact of emissions from commercial EtO sterilizers.

B. Does this action apply to me?

The current standards in 40 CFR part 63, subpart O, regulate emissions of EtO from existing and new commercial sterilization operations using 907 kilograms per year (1 ton per year (tpy)) of EtO or more. The EtO Commercial Sterilization and Fumigation Operations source category covers 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

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use EtO as a sterilant for heat- or moisture-sensitive materials and as a fumigant to control microorganisms or insects. Materials may be sterilized at the facility that produces or uses the product, or by contract sterilizers (*i.e.*, firms under contract to sterilize products manufactured by other companies). Table 1 of this preamble lists the entities that are regulated by the current subpart O rule.

TABLE 1. NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS ACTION

Source Category	NAICS Code[1]
Surgical and Medical Instrument Manufacturing	339112
Surgical Appliance and Supplies Manufacturing	339113
Pharmaceutical Preparation Manufacturing	325412
Spice and Extract Manufacturing	311942
Dried and Dehydrated Food Manufacturing	311423
Packaging and Labeling Services	561910

[1] North American Industry Classification System.

The table is not meant to be exhaustive, but rather provides a guide for readers regarding the entities that are likely to be affected by future regulation for this source category. The EtO Commercial Sterilization and Fumigation Operations source category includes medical equipment suppliers; pharmaceutical suppliers; other health-related industries; spice manufacturers; and contract sterilizers (see 57 FR 31576, July 16, 1992). 40 CFR part 63, subpart O, also applies to large libraries and large museums and archives, but does not apply to hospitals, doctor offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals; beehive fumigators; and research and laboratory facilities. In addition, review and comments are welcome from manufacturers of devices capable of measuring, monitoring, reducing, abating, or destroying EtO, particularly if such devices are or will soon be available in the commercial marketplace.

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

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In addition to being available in the docket, an electronic copy of this ANPRM is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this ANPRM at the following address: *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 ANPRM and key technical documents at this same website.

II. Background

A. Statutory Background

Section 112 of the Clean Air Act (CAA) establishes the regulatory process used to develop standards for emissions of HAP from stationary sources. In the first stage of this process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. "Major sources" are those that emit or have the potential to emit 10 tpy or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are "area sources." For major sources, CAA section 112(d)(2) provides that the technology-based national emission standards for hazardous air pollutants (NESHAP) must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards that reflect the maximum degree of emission reductions of HAP are commonly referred to as maximum achievable control technology (MACT) standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT "floor."

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The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. The EPA may establish standards more stringent than the floor based on considerations of the cost of achieving the emission reductions, any non-air quality health and environmental impacts, and energy requirements. In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards where it is not feasible to prescribe or enforce a numerical emission standard. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

In the second stage, the EPA evaluates MACT standards to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the "residual risk review." In addition to the residual risk review required by CAA section 112(f)(2), CAA section 112(d)(6) requires the EPA to review standards set under CAA section 112 every 8 years. This review is commonly referred to as the "technology review" and the EPA often conducts the residual risk review simultaneously with the first required technology review in what is commonly referred to as a "risk and technology review." The methodology used by the agency to conduct risk and technology reviews is explained in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology*, in the docket for this ANPRM.

In the CAA section (d)(6) technology reviews, the EPA is to review standards set under CAA section 112 and revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less frequently than every 8 years. CAA section 112(d)(6). In conducting these reviews, the EPA is not required to recalculate the MACT floor.

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Natural Resources Defense Council (NRDC) v. EPA, 529 F.3d 1077, 1084 (D.C. Cir. 2008); *Association of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667, 673 (D.C. Cir. 2013).

B. Regulatory Background

On July 16, 1992 (57 FR 31576), the EPA published a list of major and area sources for which NESHAP were to be promulgated (*i.e.*, the source category list). Ethylene oxide commercial sterilization and fumigation operations were listed as a category of major sources and area sources.

On December 6, 1994 (59 FR 62585), the EPA promulgated MACT and GACT standards for the EtO Emission Standards for Sterilization Facilities source category. In that final rule, the EPA set MACT for major sources under CAA section 112(d)(2). For area sources, the EPA established GACT standards pursuant to CAA section 112(d)(5). This rulemaking addressed EtO emissions originating from three major types of emission points: the sterilization chamber vent (SCV), the aeration room vent (ARV), and the CEV. The SCV evacuates EtO from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes. The ARV evacuates EtO-laden air from the aeration room, which is used to facilitate off-gassing. 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. Another source of emissions within this source category are fugitive emissions, but the EPA has not set standards for those emissions.

Following promulgation of the rule, the EPA suspended certain compliance deadlines and ultimately removed the MACT and GACT standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at commercial EtO sterilization facilities. In response, the EPA suspended all rule compliance dates pending the investigation of the explosions (62 FR

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64736, December 9, 1997). In 1998, the suspension of the compliance dates was extended for the ARVs and the CEVs (63 FR 66990, December 4, 1998), although the requirements for the SCVs went into effect in 1998. It was also later determined that EtO emissions from aeration rooms could be safely controlled, and the suspensions for the ARVs were not further extended past December 2000 (64 FR 67789, December 3, 1999). For CEVs, it was determined that the primary contributing issue leading to the explosions was that EtO concentrations were above the safe limit (*i.e.*, above the lower explosive limit (LEL)), within the CEV gas streams, and the EPA extended the suspension of the rule requirements for CEVs. The EPA could not conclude at the time that the CEVs could be safely controlled, so MACT and GACT requirements for CEVs were removed in 2001 (66 FR 55577, November 2, 2001) and have not been re-instated. The EPA is soliciting comment on the impacts associated with potentially reinstating requirements for CEVs in a future rulemaking.

In addition, the EPA conducted a residual risk analysis and a technology review under CAA section 112(f)(2) and CAA section 112(d)(6), respectively, and issued a final decision on the risk and technology review (71 FR 17712, April 7, 2006). No changes were made to the requirements as part of that action.

The HAP standards that currently apply to sterilization facilities covered by 40 CFR part 63, subpart O are shown in the following table:

TABLE 2. CURRENT ETO STANDARDS FOR COMMERCIAL STERILIZERS

Existing And New Sources Subcategory [1]	Sterilization Chamber Vent (SCV)	Aeration Room Vent (ARV)	Chamber Exhaust Vent (CEV) [2]
Sources using 10 ton or more of EtO in any consecutive 12-month period	99 percent (see 40 CFR 63.362(c))	1 ppm maximum outlet concentration or 99-percent emission reduction (see 40 CFR 63.362(d))	No control

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Sources using 1 ton or more of EtO but less than 10 ton of EtO in any consecutive 12-month period	99 percent (see 40 CFR 63.362(c))	No control	No control
Sources using less than 1 ton of EtO in any consecutive 12-month period	Recordkeeping (minimal recordkeeping requirements apply (see 40 CFR 63.367(c)).)	Recordkeeping (minimal recordkeeping requirements apply (see 40 CFR 63.367(c)).)	Recordkeeping (minimal recordkeeping requirements apply (see 40 CFR 63.367(c)).)

[1] Determined as a rolling 12-month emission rate.
[2] The CEV emission source was included in the original standard but was later eliminated from 40 CFR part 63, subpart O, in 2001.

The NESHAP applies to both major and area sources that use at least 1 ton of EtO in sterilization or fumigation operations in each 12-month period.

C. Risks Associated with EtO Emissions

The National Air Toxics Assessment (NATA) released in August 2018 identified EtO emissions as a potential concern in several areas across the country. (NATA is the Agency's nationwide air toxics screening tool, designed to help the EPA and state, local, and tribal air agencies identify areas, pollutants, or types of sources for further examination.) The latest NATA estimates that EtO significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). These elevated risks are largely driven by an EPA risk value that was updated in December 2016.[1] The EPA conducted a previous assessment of the health effects of EtO exposure in 1985. Subsequently, EtO was designated a HAP under the 1990 CAA amid increasing concerns regarding the adverse effects of EtO exposure due to newly published human and animal studies of this chemical. Consequently, the EPA's Office of Air and Radiation expressed an interest in having the

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

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Integrated Risk Information System (IRIS) Program update the EPA's 1985 EtO assessment. In response, the IRIS Program began work on the current EtO assessment in the early 2000s and, following two external peer reviews, completed this work in December 2016.

Further investigation on NATA inputs and results led to the EPA identifying commercial sterilization using EtO as a source category contributing to some of these risks, which has led the EPA to evaluate, in greater depth, the potential health risks associated with emissions of EtO. Over the past year, the EPA has been gathering additional information to help evaluate opportunities to reduce EtO emissions through potential rule revisions and more immediate emission reduction steps. Considering these results, the EPA is seeking comment in this ANPRM on a number of potential control strategies for facilities in the EtO Emission Standards for Sterilization Facilities source category that would seek to reduce the fugitive emissions of EtO and to improve point source emission controls for commercial sterilizers.

III. Small Business Considerations

When the EPA undertakes a proposed rulemaking, it should identify any small entities within the source category and determine whether there is the potential for significant economic impacts to small businesses or other entities from any regulatory actions being considered. An entity is determined to be small based on the ultimate parent company's NAICS code and as defined by the U.S. Small Business Administration (SBA) (*https://www.sba.gov/document/support--table-size-standards*).[2] A parent company's size is defined in terms of annual revenue or number of employees; Table 3 of this preamble lists the size standards for parent companies of entities regulated by the current 40 CFR part 63, subpart

[2] SBA determines whether an entity qualifies as a small business concern by counting its receipts, employees, or other measures including those of all its domestic and foreign affiliates, regardless of whether the affiliates are organized for profit (13 CFR 121.103(a)(6)).

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O rule.

TABLE 3. SBA SIZE STANDARDS BY NAICS CODE

NAICS Code	Source Category	Size Standards (Annual Revenue - Millions)	Size Standards (Number of Employees)
339112	Surgical and Medical Instrument Manufacturing	-	1,000
339113	Surgical Appliance and Supplies Manufacturing	-	750
325412	Pharmaceutical Preparation Manufacturing	-	1,250
311942	Spice and Extract Manufacturing	-	500
311423	Dried and Dehydrated Food Manufacturing	-	750
561910	Packaging and Labeling Services	$12	-

To date, of the 108 facilities that the EPA has identified within the EtO Emission Standards for Sterilization Facilities source category, we have identified approximately 35 facilities owned by small businesses. At the parent company level, there are 59 total parent companies, 27 of which are small parent companies.

Identifying potential impacts on specific entities is challenging because of the lack of detailed facility data for this source category. Among other things, the EPA is seeking information about the costs associated with controlling EtO emissions from sources that qualify as small businesses. The EPA will use information received in response to this ANPRM to further assess the potential impacts of emission reduction strategies that may be considered. Given the potential impacts of certain emission reduction strategies on these small businesses, the EPA intends to convene a Small Business Advocacy Review (SBAR) Panel before taking any significant regulatory action. The EPA is in the process of requesting nominations for small entity representatives to serve as part of a possible SBAR Panel.

IV. Request for Comment

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The EPA is requesting comment (1) on available control technologies for reducing emissions of EtO and (2) on developments in practices, measurement, monitoring, processes, and control technologies for the control of EtO from commercial sterilization facilities. The EPA has been investigating these issues through discussions with stakeholders, reviews of operating permits, and research. As part of the information gathering to date, the EPA has consulted with the EtO sterilization industry, including companies, trade associations, and control technology vendors, to better understand the current state of controls for EtO emission sources. The EPA held teleconferences and meetings with 12 different EtO trade associations, air pollution control device (APCD) manufacturers, industry representatives, and other government agencies to better understand sterilization processes, emissions (including measurement and monitoring), current control techniques, and how widely such techniques are used, as well as how control efficiencies are determined and guaranteed by manufacturers. The discussions have focused on common operational practices, including practices used by EtO commercial sterilization facilities to determine EtO concentration at various emissions points in the process. Despite this outreach and information gathering, there are still several important information gaps that would be useful to fill prior to any future rulemaking activity.

Through information gathering and discussions with stakeholders, the EPA identified the process controls and operational practices discussed below for consideration as possible methods for reducing the amount of EtO released into the ambient air. Under section 114(a) of the CAA, the EPA may require sources to report data in a manner prescribed by the Agency. For the EtO Commercial Sterilization and Fumigation Operations source category, the EPA intends to undertake a CAA section 114 information collection to provide information to support any future rulemaking actions, such as the upcoming technology review.

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A. Modeling File and Annual EtO Usage Data

In order to ensure the accuracy of the data that could be used for any future rulemaking for this source category, the EPA is soliciting comment on available EtO usage data for individual facilities and on additional data contained in the modeling file that the EPA intends to use to evaluate the impacts of EtO emissions (Comment C-1). For the modeling file, the EPA requests that companies review the data for their facilities to ensure that the information presented is accurate and complete, including current facility and process information, emissions data[3], and release parameters. The EPA further requests that after reviewing the modeling file for this purpose, companies submit to the EPA any corrected and supplemental information as part of their comments. The modeling file is available at the following website: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities*. The current known EtO usage data is available in the docket.

B. Control of Fugitive Emissions

Fugitive EtO emissions at commercial sterilization facilities generally occur from (1) off-gassing associated with the handling of EtO prior to charging the sterilizer chamber; (2) off-gassing of sterilized product following product transfer from the sterilizer chamber to the aeration room; (3) off-gassing from uncontrolled and under-controlled aeration rooms; and (4) any off-gassing that may occur after product is removed from the aeration room. For the purpose of this rule, fugitive emissions are those emissions which are not routed to an existing pollution control device. The magnitude of the fugitive emissions from the industry is not well characterized, and the extent of the fugitive emissions may be dependent on building design, the building air handling system, and the capacity of the existing air pollution control system. A

[3] Primarily derived from the EPA's 2014 National Emissions Inventory, version 2.

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recent analysis of ambient air monitoring data performed in close proximity to a commercial sterilizer in Illinois[4] indicated that the previous EtO emission estimates for this facility may have been underestimated. Specifically, this analysis indicated that the fugitive component of the emissions accounted for approximately 0.5 percent of the total EtO usage at that facility, which was significantly higher than previously assumed.

The EPA is requesting comment on the use of an emission factor of 0.5 percent of EtO usage for the calculation of fugitive emissions from this source category (Comment C-2a). In addition, the EPA is requesting comment on any data that can be used to help quantify facility-wide and area/room-specific fugitive emissions from commercial EtO sterilizers (*e.g.,* internal and ambient air monitoring data), along with relevant monitoring characteristics such as monitoring collection equipment and techniques, averaging time, equipment detection limits, equipment quality assurance, and quality control procedures employed (Comment C-2b). If commenters believe that alternative fugitive EtO calculation procedures or emission factors should be considered, the EPA requests that commenters provide documentation that supports the basis or bases for why an alternative methods or factors should be considered (Comment C-2c).

1. Permanent Total Enclosure

Permanent total enclosures (PTEs) are permanently installed structures that completely surround source(s) of emissions such that all volatile organic compound emissions (*i.e.*, EtO emissions) are captured and contained for discharge to a control device(s). Specifically, PTEs could capture emissions from sterilizer chamber rooms, aeration rooms, EtO drum storage areas, shipping areas, or any facility areas through which sterilized product is moved or EtO equipment

[4] *https://www.epa.gov/il/outdoor-air-monitoring-willowbrook-community*.

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is in service. The EPA's current understanding is that the existing building, or portions of the building, in which EtO could be released could serve as the enclosure, for example, by enclosing and adapting the building or portions of the building to meet the design criteria of a PTE. EPA Method 204 (40 CFR part 51, appendix M) provides the design criteria as well as procedures for verifying the capture efficiency of the enclosure.[5] Additionally, EPA Method 204 includes requirements to route the captured and contained EtO-laden gas for delivery to an APCD. Based on recent regulations enacted in Illinois,[6] as well as increasing public awareness, multiple EtO commercial sterilization facilities have either implemented or are planning to implement PTEs to capture and control fugitive emissions from the sterilization processes.

The EPA is requesting facility-specific data items that can be used more accurately to assess the cost and emission capture/reduction of PTEs (Comment C-3). In addition, the EPA welcomes detailed facility-specific data and information regarding building and chamber design, including details on the square feet and height of the rooms where EtO is used, their temperature set point (during summer, winter, and intermediate seasons), relative humidity, air flow, number of air changes per hour, area of natural draft openings as defined in EPA Method 204, the typical EtO concentration in parts per million by volume (ppmv) within these rooms, and quantification of emissions reductions obtained via PTE, along with a description of the measurement device(s), measurement device detection limits and interferences, and measurement device quality assurance and quality control procedures and costs, the time required to implement PTE, the number of facilities currently implementing PTE or planning to do so, and the extent to which aspects of PTE might differ for small business facilities (also Comment C-3).

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[5] 40 CFR part 51, appendix M, EPA Method 204 - Criteria and Verification of a Permanent or Temporary Total Enclosure. U.S. EPA.

[6] *http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=101-0022* and *http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=101-0023*.

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2. Pollution Prevention and Other Operational Practices

Some facilities follow other operational practices to reduce fugitive emissions. These operational practices include leak detection and repair programs that encompass monitoring for fugitive leaks from drums, valves, and connection lines containing EtO; controlling air flow in the building to capture fugitive emissions (*e.g.*, sweep vents) in areas where EtO is processed and sending these emissions to existing controls; putting process controls in place to minimize storage of fumigated material in uncontrolled areas; reducing emissions from EtO-laden waste water; and reducing levels of EtO injected into the sterilization chamber.

Fugitive emissions may occur from EtO drum storage and handling. The EPA understands that personnel at commercial sterilizer facilities inspect the valves on EtO drums for leaks when delivered to their facilities and that the connectors are also checked for leaks after they are attached to a sterilizer chamber.[7] EtO drums contain approximately 400 pounds of compressed EtO liquid along with a blanket of nitrogen. The pressurized drums are commonly equipped with two valves: one for the nitrogen blanket, and the other for unloading the EtO liquid. Leak checks similar to what is required by EPA Method 21 (40 CFR part 60, appendix A) are conducted on these valves and connectors. Additionally, the drum storage room area may be enclosed and vented to either an APCD or to the atmosphere. The EPA requests comment on these and additional operational practices for monitoring leaks from EtO drums, including appropriate procedures and/or methods to use and the optimal frequency of monitoring; the emission reductions likely to be achieved by specific practices; the costs associated with specific practices; the time required to implement a leak check program for EtO drums; the number of facilities currently implementing these leak checks or plan to do so; and the extent to which

[7] National Fire Prevention Association 55 Chapter 14.

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aspects of these leak checks might differ for small business facilities (Comment C-4).

EtO supply lines are used to connect the EtO drum to the sterilizer chamber. Prior to its use for charging EtO, the EtO line connection is often pressurized with nitrogen from the storage drum to the sterilizer chamber, to confirm that there are no leaks. The line connection is held at that pressure for a set time period, and if the line connection is able to maintain the pressure level, it is considered leak free. The EPA is seeking comment on the available operational practices for conducting regular pressure testing on the connection line between the EtO drum and sterilizer chamber. The EPA solicits comment on the feasibility of conducting the tests, the methods to be used or considered for use, the optimal frequency of such tests or methods, emission reductions likely to be achieved by specific practices, and the costs associated with specific practices, the time required to implement a leak check program for EtO supply lines, the number of facilities currently implementing these leak checks or plan to do so, and the extent to which aspects of these leak checks might differ for small business facilities (Comment C-5).

Sweep vents or floor vents are used to move and capture room air from the main room areas as operators move sterilized product from area to area at the facility. Sweep vents often maintain the sterilizer chamber room area and the aeration room area under negative pressure. Some facilities route the room air captured in sweep vents to an APCD, and other facilities vent the captured room air to the atmosphere. The floor sweeps serve to reduce the EtO in work areas to minimize occupational exposure to EtO. Facilities often measure the EtO concentration in the sterilizer chamber room area and aeration room area using a gas chromatography or infrared instrument. The EPA solicits comment on circumstances in which it would not be feasible to connect sweep vents to an APCD (including specific facility designs that may affect such feasibility); the level of capture likely be achieved for EtO fugitive emissions by specific

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practices; the costs associated with specific practices; the time required to implement sweep vents or floor vents; the number of facilities currently implementing sweep vents or floor vents; and the extent to which aspects of sweep vents or floor vents might differ for small business facilities (Comment C-6).

The EPA is aware that emissions may occur from water that comes into contact with EtO during the sterilization process. Potential emissions may come from, but are not limited to, disposal of water used in once-through liquid-ring vacuum pumps, as well as water used in recovering EtO for re-use in sterilization. The EPA solicits comment on the circumstances in which EtO may come into contact with water within commercial sterilization facilities; the frequency with which such water is or should be disposed; methods of disposal; any operational practices that are or may be used to mitigate emissions from waste water; the feasibility of implementing such operational practices; and costs associated with disposal and with specific operational practices, the time required to implement wastewater EtO emissions reductions; the number of facilities currently implementing wastewater EtO emissions reductions; and the extent to which aspects of wastewater EtO emissions reductions might differ for small business facilities (Comment C-7).

The EPA is also interested in obtaining information on other operational practices, not discussed in the preceding paragraphs, that may be available to reduce EtO emissions from commercial sterilization facilities. The EPA solicits comment on the availability, applicability, and technical feasibility of such operational practices; the emission reductions likely to be achieved by such measures; the cost of such measures; the time required to implement such measures; the number of facilities currently implementing such measures; and the extent to which aspects of such measures might differ for small business facilities (Comment C-8).

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C. Chamber Exhaust Vent Control and Safety Considerations

1. Reinstating the Chamber Exhaust Vent Control Requirement

The CEV evacuates EtO-laden air from the sterilization chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust enables facilities to meet U.S. Occupational Safety and Health Administration (OSHA) workplace exposure standards.[8] Following the removal of the CEV regulatory requirement in 2001 (66 FR 55577, November 2, 2001), many EtO sterilization facilities ceased, or never implemented, controls for EtO emissions from the CEV. In more recent years, however, facilities have begun to control EtO from the CEV, and multiple facilities currently control the CEV. The safety issues that prevented earlier control techniques from being applied were linked to EtO concentrations in the sterilizer chamber that exceeded the LEL for EtO. Since the late 1990s and early 2000s, facilities have revised their operating procedures related to the CEV.

Currently, some facilities that control EtO emissions from the CEV have made process changes to avoid exceedance of the LEL; such process changes include (1) reducing the EtO concentration in the sterilizer chamber before opening the sterilizer chamber door and venting emissions to an APCD, and (2) using an automated lock on the sterilizer chamber door that does not allow the door to open until EtO concentration is significantly less than the LEL. As part of the process change, facilities have enacted additional final air washes in the sterilization cycle to further reduce the EtO concentration in the sterilizer chamber prior to opening the sterilizer door and venting to the APCD. In addition, the automated lock on the sterilizer chamber door does not allow the door to open until a non-explosive EtO concentration level is achieved in the chamber. The MACT floor for CEVs at existing and new sources, for sources using 10 tpy or more of EtO,

[8] 29 CFR 1910.1047.

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is routing emissions from the CEV such that they are combined with a stream that is already being routed to a control device that achieves 99-percent emission reduction.[9] Typical APCDs used to control EtO emissions from CEVs include the following: catalytic oxidizers, dry bed scrubbers, wet acid scrubbers, combination wet acid scrubbers and dry bed scrubbers, and balancer/abator systems. The EPA solicits comment on implications of potentially reinstating the requirement to control the CEV and is soliciting information regarding the feasibility, emission reductions achieved, cost, the time required to reinstate the requirements; the number of facilities currently reducing their CEV emissions; the extent to which aspects of CEV emissions reductions might differ for small business facilities, and associated safety considerations (Comment C-9).

2. Implementing an In-Chamber Concentration Limit

To further reduce EtO emissions from the SCV, some facilities set an upper in-chamber concentration limit on the EtO in the sterilization chamber prior to opening the chamber door and engaging the CEV. Increased air washes to remove EtO from the sterilizer chamber have been implemented over time to accommodate control of the CEV. To safely control the CEV, the concentration must be significantly below the LEL of EtO. The reduction of the in-chamber concentration at the end of the sterilization cycle is directly linked to venting of the CEV to an APCD and has enabled control of the CEV. A 2007 report from the National Institute for Occupational Safety and Health determined that additional air washes were essential for

[9] D. Hearne and K. Schmidtke, MRI, to D. Markwordt, U.S. EPA. October 24, 1994. *Revised Calculation of MACT Floors for Major Source Chamber Exhaust Vents at Ethylene Oxide Commercial Sterilization and Fumigation Operations; National Emissions Standards for Hazardous Air Pollutants (NESHAP)* (Legacy Docket ID No. A-88-03, Docket Entry IV-B-02).

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mitigating any safety issues.[10] A report by the Chemical Safety and Hazard Investigation Board on an explosion that occurred at a commercial EtO sterilization facility in 2004 arrived at the same conclusion.[11]

While an in-chamber, EtO concentration monitoring technique was not available when the original NESHAP was promulgated in 1994, in-chamber monitors are available today. Monitors based on the photoacoustic principle are available and currently in use at sterilization facilities. These monitors are used to measure the in-chamber concentration of EtO to confirm that the chamber concentration is well below the LEL of EtO. The LEL of EtO is 3.0 percent by volume, or 30,000 ppmv.[12] To ensure safe conditions when opening the sterilizer chamber at the end of the sterilization cycle and to ensure limited fugitive emissions released from the open sterilizer chamber door, facilities reduce the EtO concentration to significantly less than the LEL, often to ranges of 10 to 25 percent of the LEL (*i.e.*, 3,000 to 7,500 ppmv). (LESNI 2019)[13]

The reduction of the in-chamber concentration is achieved through additional air washes in the sterilizer chamber. The number of additional air washes required to reach a concentration below the LEL is dependent on the parameters in the individual validated sterilization cycle. Some cycles that operate under shallow vacuum conditions, or need higher EtO concentration levels to reach sterility, may require additional air washes to lower the in-chamber concentration to this level.

The addition of air washes may increase the costs to operate the sterilizer chamber

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[10] National Institute for Occupational Safety and Health, *Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities (Revised Edition)*. August 2007. https://www.cdc.gov/niosh/docs/2007-164/.

[11] Chemical Safety and Hazard Investigation Board, *Investigation Report: Sterigenics (4 Employees Injured)*. March 2006. *https://www.csb.gov/sterigenics-ethylene-oxide-explosion/*

[12] *https://pubchem.ncbi.nlm.nih.gov/compound/Ethylene-oxide#section=Lower-Explosive-Limit-(LEL)*.

[13] See memorandum, *Meeting Minutes for Discussion with Representative of LESNI,* located at Docket ID No. EPA–HQ–OAR–2019–0178. March 7, 2019.

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vacuum pump, as well as the costs to operate the APCD used to control emissions from the SCV. In addition, the overall facility sterilization capacity may be reduced due to the increased length of time required to complete the sterilization cycle. The EPA solicits comment on (1) the feasibility of using additional air washes in the sterilization chamber to further decrease in-chamber EtO concentration; (2) the emission reductions likely to be achieved by additional air washes; (3) associated costs; (4) the EtO concentration that should be typically reached before allowing activation of the CEV; (5) the time required to implement an EtO concentration reduction program; (6) the number of facilities currently reducing EtO concentration before activating the CEV; and (7) the extent to which EtO concentration reduction efforts might differ for small business facilities (Comment C-10).

3. Interlock System Tied to In-Chamber Concentration Limit

To further reduce fugitive emissions of EtO from leaving the sterilizer chamber and risking the immediate health and safety of facility operators, most facilities have installed door interlock systems on their sterilizer chambers. These door interlock systems are tied to the monitoring and control equipment already operating within the sterilizer chamber. The interlock system ensures that the sterilizer chamber doors are unable to be opened by facility personnel prior to achieving the prescribed in-chamber concentration of EtO, *i.e.*, below the LEL. By preventing premature opening of the sterilizer chamber door prior to reaching a non-explosive EtO concentration, the door interlock system accomplishes two things: (1) it ensures that gas from the sterilizer chamber is prevented from being directed to the CEV until the EtO concentration within the chamber is well below the LEL, and (2) it greatly reduces the amount of fugitive EtO that operators will be exposed to over the course of the work day. Industry trade associations have indicated that environmental health and safety issues surrounding worker

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exposure have been a major focus of EtO sterilization-centered working groups over recent years (AdvaMed 2019).[14]

The combination of an in-chamber EtO concentration limit and an interlock system tied to that limit enables facilities to continue to meet OSHA workplace exposure standards with respect to emissions from the sterilizer chamber.

The EPA is soliciting comment on cost, the time required to implement an interlock system, the number of facilities currently utilizing interlock systems, and the extent to which aspects interlock systems might differ for small business facilities, and safety considerations for an interlock system on the sterilizer chamber door that is linked to the in-chamber concentration (Comment C-11).

D. Other Point Source Control Options

1. Balancer/Abator System

Add-on control devices such as wet acid scrubbers, catalytic oxidizers, and dry bed scrubbers are commonly used to control the emissions of EtO from the commercial sterilization source category. Generally, the add-on APCD is designed based on the maximum flow rates and EtO concentrations from the emission sources vented to the device. An APCD used for reducing the EtO emissions from the Commercial Sterilization and Fumigation Operations source category that was developed since the initial NESHAP is a combination water balancer and catalytic oxidizer, also referred to as the balancer/abator system. This system vents EtO to the water balancer, where a significant portion of the EtO is stored within the water, so that a flow of air at a constant EtO concentration can be fed to the catalytic oxidizer. The SCVs are first vented to the water balancer, and the stream from the balancer is then to the catalytic oxidizer. The

[14] See memorandum, *Meeting Minutes for Discussion with Representatives of AdvaMed*, located at Docket ID No. EPA–HQ–OAR–2019–0178. July 2, 2019.

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ARVs and CEVs are sources of more dilute EtO-laden streams and, therefore, are not vented to the water balancer—they are vented directly to the catalytic oxidizer. Emissions from the ARVs and CEVs are first mixed with the stripped EtO stream from the SCV and then emissions from all three vents are routed to the catalytic oxidizer. The water balancer does not convert the EtO into ethylene glycol, as the scrubbing water is not acidic enough to drive the conversion (*i.e.*, addition of sulfuric acid would drive the conversion to ethylene glycol).

One advantage of this APCD is related to the intermittent venting of high EtO concentration streams from the sterilizer chamber. The concentration of EtO within an SCV stream can vary depending on how much EtO is used for sterilizing a product, as well as what sterilization phase the chamber is in at the time of exhaust (*e.g.*, dwell period, gas washing, etc.). The number of chambers venting to one balancer also has an impact on overall concentration. The water balancer essentially "stores" the EtO peaks from the SCV in the water, and the catalytic oxidizer is designed based on a relatively constant flowrate and EtO concentration from the combination of the stream from the balancer and the ARV and CEV emission streams, rather than based on the peak flowrates and EtO concentrations from the SCV.

The balancer/abator system design was introduced in the U.S. in 2006, and there are at least four facilities currently using this APCD in four states and territories. The balancer/abator system achieves 99.9-percent reduction of EtO emissions and EtO concentrations of 0.5 milligrams per normal cubic meter (roughly equivalent to 0.27 ppmv) (LESNI 2019).[15] The ARV and CEV concentrations are characterized as dilute concentrations in a high-volume air flowrate. The balancer/abator system helps normalize both the flowrate and the EtO concentration fluctuations. The EPA is soliciting comment on use of the balancer/abator system,

[15] See memorandum, *Meeting Minutes for Discussion with Representative of LESNI*, located at Docket ID No. EPA–HQ–OAR–2019–0178. March 7, 2019.

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the emission reductions likely to be achieved from such use, the associated costs, the time required to implement a balancer/abator system, the number of facilities currently using balancer/abator systems, and the extent to which aspects of a balancer/abator system might differ for small business facilities (Comment C-12).

2. Improvements to Existing Point Source Controls

While the current standard for control device efficiency requires 99-percent removal (along with a 1-ppmv alternative for ARVs), the EPA is aware of many situations in which testing has revealed emission control performance that is significantly superior to the current standard. The EPA is soliciting comment on potential improvements to control device efficiencies and observed removal efficiencies or outlet concentrations, along with any costs potential implementation issues associated with achieving those higher control efficiencies, the time required to improve existing point source controls, the number of facilities that have made improvements to their existing point source controls, and the extent to which improvements to existing point source controls might differ for small business facilities (Comment C-13).

3. Improved Monitoring Instruments for Ethylene Oxide

Since the regulations at 40 CFR part 63, subpart O, were finalized in 2001, there have been significant improvements in monitoring equipment, including new continuous monitoring instruments that are considerably more sensitive than previous monitoring technology. In the past, there have been concerns over detecting low concentrations of EtO, but instrumentation is now available with a detection capability in the single parts per billion by volume within the exhaust stack for the APCD. Instrument manufacturers have developed innovative techniques which use optical spectroscopy that allow for greater sensitivity and better time-resolution than the current monitoring techniques specified in the rule. The EPA is requesting comment on the

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feasibility of using continuous monitoring systems and is soliciting comment on the cost considerations for installing and operating the monitoring units, particularly for control devices. The EPA is also soliciting comment on the number of facilities currently using improved monitoring instruments (Comment C-14).

4. Accelerated Aerator Design and Aeration Cells

One process equipment improvement available is the use of accelerated aeration cells. The use of focused aeration was discussed in the 1992 EtO Sterilization Background Information Document,[16] including use of both smaller, heated aeration chambers (43 degrees Celsius (ºC)) and vacuum cycles on the small aeration cells. The use of aeration cells rather than aeration rooms significantly reduces the volume of air vented to the APCD. The EPA does not have information on the total number of facilities that are using aeration cells.

A large aeration room requires large volumetric flowrates to move the EtO out of the room. Such rooms have low EtO concentrations and large volumes of gas and entail many air changeovers (*e.g.*, 20 air changes per hour). It may take 5 to 10 days to complete the aeration cycle for such a room. Replacing the large aeration room with an aeration cell reduces the volumetric flowrate from the emission source. Use of smaller aeration cells may reduce the amount of aeration time needed, remove the EtO more efficiently, and reduce the residual EtO in the final product.

Combining heated aeration cells with high-turbulence air flow or with vacuum cycles is a newer approach to aeration for commercial sterilization, sometimes referred to as acceleration aeration. Heated chambers are typically in the range of 40ºC to 60ºC. Inlet air is introduced at

[16] U. S. EPA, Office of Air Quality Planning and Standards, Emission Standards Division. *Ethylene Oxide Emissions for Commercial Sterilization Fumigation Operations Background Information for Proposed Standards*. October 1992 (Legacy Docket A-88-03, Docket Entry II-A-022).

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multiple inlet ports along the side of the aeration cell and removed at multiple outlet points along the top of the cell to provide even distribution of air throughout the cell. Combining aeration cells with high-turbulence air movement throughout the cell can accelerate the aeration process by reducing the number of air changeovers needed to remove the EtO from the product. One manufacturer noted that shallow vacuum intervals vary between 50 and 700 millibars, and that the use of shallow vacuum is expected to reduce the aeration time by 65 percent or more compared with traditional aeration procedures. Based on discussions with one trade organization, at least one company is currently modifying a facility so that it will incorporate the new accelerated aerator design (EOSA 2019).[17]

The EPA is soliciting comment on the use of accelerated aeration design and aeration cells; the emission reductions likely to be achieved by such changes; the feasibility of implementation of such changes; associated costs; the time required to implement accelerated aeration design or aeration cells; the number of facilities currently using accelerated aeration design or aeration cells; and the extent to which aspects accelerated aeration or aeration cells might differ for small business facilities (Comment C-15).

5. Cascading Air Method

Some facilities use cascading air to reduce the overall volume of air use for sterilization processes. A facility using a cascading technique does not use fresh air as feed air but rather reuses air from a low-concentration fugitive area as the feed air to another area. For example, reuse of the fugitive air from the warehouse can be used as intake air to the aeration room or aeration cell. Use of cascading air reduces the amount of air that needs to be processed by the

[17] See memorandum, *Meeting Minutes for Discussion with Representatives of the Ethylene Oxide Sterilization Association (EOSA)*, located at Docket ID No. EPA–HQ–OAR–2019–0178. March 18, 2019.

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APCD. In this example, rather than using a larger APCD to handle and control the volume of air from the ARV plus the warehouse room area, the facility routes the warehouse air to the aeration room, and the ARV emissions are then routed to a smaller APCD.

The EPA solicits comment of the feasibility of the cascading air technique; the emissions reductions that are likely to be achieved; the feasibility of implementation; associated costs; the time required to implement the cascading air method; the number of facilities currently using the cascading air method; and the extent to which aspects of the cascading air method might differ for small business facilities (Comment C-16).

E. Types of Sterilization Facilities

1. Single-Item Sterilizer Facilities

The EPA has identified 27 commercial EtO sterilization facilities that use a single-item sterilizer model. While a traditional sterilization chamber tends to be a larger vessel that accommodates pallets containing diverse products, a single-item sterilizer is generally smaller and may use much less EtO to sterilize products (*e.g.*, approximately 10 percent of the EtO that a traditional sterilization chamber would use). In the single-item sterilization process, workers place the product into a plastic pouch, a slight vacuum is applied, EtO gas is injected into the pouch and sealed, and the sealed pouch is placed in a room, chamber, or cabinet under specific temperature and humidity where EtO both sterilizes and then off-gasses or aerates. The EtO slowly dissipates from the pouch or bag by diffusion. Once the product is removed from the room, chamber, or cabinet, the product is held in the warehouse for 2 days before shipping. Just as is the case with traditional sterilizer chambers, EtO is stored in a pressurized drum when the single-item sterilization approach is used, although the cylinder tends to be smaller than EtO storage drums used at traditional sterilization facilities. EtO usage in a single-item sterilizer

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facility is often much less than in traditional sterilizer chambers.

Facilities using the single-item sterilizer process were previously thought to typically use much less than 1 ton of EtO per year,[18] and under 40 CFR part 63, subpart O, processes that use less than 1 ton of EtO are only subject to the recordkeeping requirements. Processes that use over 1 ton of EtO per year are subject to additional requirements. A recent review of single-item sterilizers found the EtO usage for at least four of these facilities to be in excess of 1 ton.[19] The EPA is requesting comment on (1) specific emissions controls that are used or could be used at single-item sterilizers in EtO commercial sterilization, and (2) whether there are any technical or process differences between single-item sterilization and traditional sterilizer chambers that should be considered when adopting measures to reduce emissions. The EPA is seeking additional information on costs associated with single-item sterilization use (including costs related to machine purchase and maintenance, design considerations, and implementation) and on costs associated with compliance with the NESHAP's emissions limits under the current subpart O regulations. The EPA also solicits comment on the number of facilities that are single-item sterilization facilities (Comment C-17).

2. Combination Sterilizer Facilities

The EPA is aware of another technology, a combination sterilizer, that is used in the EtO commercial sterilization industry. In combination sterilizers, the sterilization step and aeration step occur in sequence in the same chamber. The chamber is evacuated and EtO gas is injected into the chamber. After the sterilization process is completed, air washes are used to remove most of the EtO from the product. The exhausted EtO may be vented to the atmosphere or to a

[18] *Ethylene Oxide Commercial Sterilization and Fumigation Operations NESHAP Implementation Document*, EPA-456/R-97-004, March 2004.

[19] See annual EtO usage data provided in Docket ID No. EPA–HQ–OAR–2019–0178.

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carbon canister, with charcoal adsorbent, to control the EtO. One advantage of this sterilization approach is a reduction of EtO fugitive emissions due to the elimination of the step in which product is moved from the sterilization chamber to the aeration equipment.

The EPA is seeking information and comment on the viability of replacing traditional EtO sterilization operations with combination sterilizers. The EPA is also seeking information on the emissions associated with combination sterilizers relative to traditional sterilizers; the control devices typically used for these types of chambers; costs associated with operating emissions controls for combination EtO sterilizers; and the number of facilities currently using combination sterilizers (Comment C-18).

3. Sterilization Facilities Owned by Small Businesses

As discussed in section III of this ANPRM, small businesses make up a significant portion of the EtO Commercial Sterilization and Fumigation Operations source category. Given their prevalence within this industry, it is important that the EPA understand any technical or process differences between facilities owned by small businesses and facilities in the rest of the source category. Specifically, the EPA requests comment on the extent to which facilities owned by small businesses may differ operationally from facilities operated by larger businesses, including whether the emissions profiles differ consistently. The EPA also solicits comment on whether small businesses tend to own small facilities, and whether small businesses tend to use processes that have higher or lower emissions (Comment C-19).

4. Other Distinctions Among Sterilization Facilities

While the EPA has noted differences between the types of sterilization facilities mentioned above, the EPA is also soliciting comment on whether there are other types of sterilization facilities that are markedly different in terms of processes, operations, costs, or

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environmental impact when compared with traditional sterilization facilities (Comment C-20).

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V. Statutory and Executive Order Reviews

Additional information about statutes and relevant Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

Under Executive Order 12866, *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. This action does not propose or impose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule. Should the EPA subsequently determine to pursue a rulemaking, the EPA will address relevant statutes and Executive Orders as applicable to that rulemaking.

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Dated:

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Andrew R. Wheeler,

Administrator.