Final Report

of the

Small Business Advocacy Review Panel on

EPA's Planned Proposed Rule

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

April 26, 2021

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1. INTRODUCTION

This report is presented by the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened to review the planned proposed rulemaking on the National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide (EtO) Commercial Sterilization and Fumigation Operations. Under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel is required to be convened prior to publication of the initial regulatory flexibility analysis (IRFA) that an agency may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel will consist of the Director of the Sector Policies and Programs Division of the EPA Office of Air Quality Planning and Standards (OAQPS), the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration.

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that may be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities; and
- A summary of the comments that have been received to date from those representatives.

Section 609(b) of the RFA directs the Panel to consult with and report on the comments of small entity representatives (SERs) and make findings on issues related to elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule;
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. This analysis shall discuss any significant alternatives such as:
    - the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
    - the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
    - the use of performance rather than design standards; and
    - an exemption from coverage of the rule, or any part thereof, for such small entities.

Once completed, the Panel Report is provided to the agency issuing the proposed rule and is included in the rulemaking record. The agency is to consider the Panel's findings when completing the draft of the proposed rule. In light of the Panel Report, and where appropriate, the agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion will be based on the information available at the time the final Panel Report is drafted. EPA will continue to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

Any options identified by the Panel for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with the Clean Air Act and its amendments.

2. BACKGROUND AND DESCRIPTION OF RULEMAKING

2.1 Regulatory History

On July 16, 1992 (57 FR 31576), the EPA published a list of major and area sources for which NESHAPs were to be promulgated (i.e., the source category list). Commercial sterilization facilities were listed as a category of major sources and area sources. On December 6, 1994 (59 FR 62585), the EPA promulgated standards for the EtO Emission Standards for Sterilization Facilities source category. This source category includes facilities that use EtO in any equipment that destroys bacteria, viruses, fungi, insects, or other unwanted microorganisms or materials when such facilities are engaged in the growth, manufacture, construction, transportation, retail or wholesale trade, or storage of commercial products, or when such facilities are engaged in the operation of museums, art galleries, arboreta, or botanical or zoological gardens or exhibits. Hospitals, doctor offices, veterinary offices, clinics and other facilities where medical services are rendered are not included in the source category.[1] If there is no active sterilization occuring at a facility, then it is not considered to be part of the source category. The rulemaking addressed EtO emissions originating from three major types of emission points: the sterilization chamber vent (SCV), the aeration room vent (ARV), and the chamber exhaust vent (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 these emissions were assumed to be negligible during development of the original NESHAP, and EPA has not set standards for those emissions. The standards for EtO emissions from sterilization activities are listed in 40 CFR Part 63, Subpart O.

Following promulgation of the rule, the EPA suspended certain compliance deadlines and ultimately removed the 1994 standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at EtO commercial sterilization facilities, and in response, the EPA suspended all rule compliance dates pending the investigation of the explosions (62 FR 64736, December 9, 1997). In 1998, the suspension of the compliance dates was extended for the ARVs and the CEVs (63 FR 66990, December 4, 1998) and the requirements for the SCVs went into effect. EPA later determined that EtO emissions from aeration rooms could be safely controlled, and the suspensions for the ARVs were not extended past December 2000 (64 FR 67789, December 3, 1999). For CEVs, EPA determined that the primary contributing issue leading to the explosions was that EtO concentrations within the exhaust streams were above the safe limit (i.e., above the lower explosive limit (LEL)), 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 requirements for CEVs were removed in 2001 (66 FR 55577, November 2, 2001) and have not been reinstated.

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

Figure 1 provides a diagram of emission sources at commercial sterilization facilities.

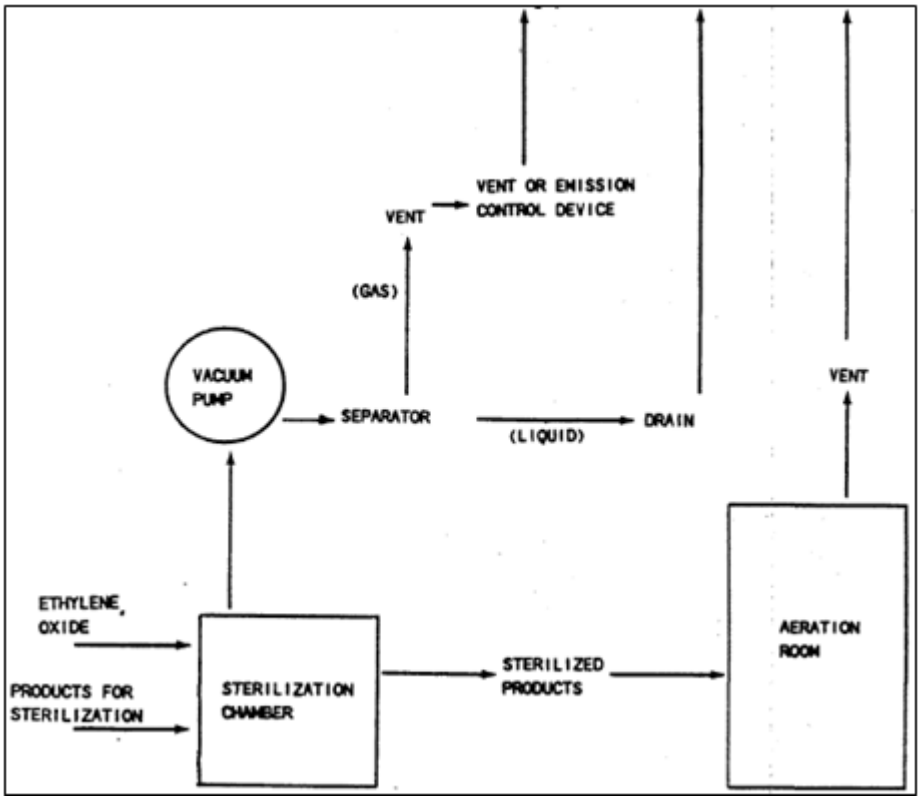

Figure 1. Emission sources at EtO commercial sterilization facilities.

In addition, in 2005 the EPA proposed a residual risk analysis and a technology review under Clean Air Act (CAA) section 112(f)(2) and CAA section 112(d)(6), respectively, and issued a final decision on the risk and technology review (67 FR 17712, April 7, 2006). No changes were made to the rule as part of that action. Section 112(d)(6) requires EPA to conduct such a technology review every 8 years so the subsequent review was due in 2014. The purpose of this Report is to inform the proposed technology review rule.

2.2 Description and Scope of Existing Rule

The emission reduction requirements in the EtO Commercial Sterilization and Fumigation Operations NESHAP apply to both major and area sources that use at least 1 ton of EtO per any consecutive 12-month period in sterilization or fumigation operations. (Sources using less than 1 ton per any consecutive 12-month period are required by current standards to keep records to document that EtO usage remains below the threshold.) The standards that currently apply to hazardous air pollutant (HAP) emissions from sterilization facilities are listed in 40 CFR part 63, subpart O and are shown in Table 1.

Table 1. Current EtO Standards for Commercial Sterilizers and Fumigation Operations

Existing and new sources subcategory[2]	Sterilization chamber vent (SCV)	Aeration room vent (ARV)	Chamber exhaust vent (CEV)[3]
Sources using 10 tons or more of EtO in any consecutive 12-month period (Major Sources)	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
Sources using 1 ton or more of EtO but less than 10 tons of EtO in any consecutive 12-month period (Area Sources)	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 (Area Sources)	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)).)

2.3 Overview of Revisions under Consideration

Stakeholders have suggested a broad range of program improvements through a variety of mechanisms including EPA's review of previous standards for CEVs, quantification and regulation of fugitive emissions, and accounting for front-end process improvements. From these suggested improvements, EPA identified those which required a regulatory change, and those which would provide the most protective impact. Sections 2.3.4, 2.3.5, and 2.3.6 contain regulatory revisions currently being considered and evaluated by EPA. The revisions considered below are not final. The control options under consideration for the upcoming proposed rule for EtO commercial sterilizers include strengthening the current rule requirements and implementing requirements for emissions sources not currently covered by the rule.

2.3.1 Obligations under Section 112

EPA is currently conducting a technology review under section 112(d)(6), where EPA reviews the standards it has set under section 112 every 8 years and revises them "as necessary (taking into account developments in practices, processes, and control technologies)."[4] Through the course of the current technology review for section 112(d)(6), EPA has discovered additional sources of EtO emissions within the source category. For those emission sources that are covered under the current rule requirements, EPA must adopt developments or improvements in the "practices, processes, and control technologies" in the source category since the last technology review.

For any additional emissions sources that have been identified, EPA is required to establish technology-based standards under section 112, and to establish maximum achievable control technology (MACT) standards for major sources under section 112(d)(2) and (3). For major and area sources, section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reduction of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). "Major sources" are defined as a stationary source, or group of stationary sources, that emit, or have the potential to emit, 10 or more tons per year (tpy) of a single HAP or 25 or more tpy of a combination of HAPs. An "area source" is any stationary source that is not a major

[2] Determined as a rolling 12-month emission rate.
[3] Control requirements were included for the CEV emission source in the original (1994) standard, but those requirements were eliminated and removed from 40 CFR part 63, subpart O in 2001.
[4] This review was required to have been completed by 2014 (i.e., 8 years after completion of the last review in 2006).

source. Section 112(d)(3) establishes the MACT floor level, specifies how to calculate the "floor" or the lowest level that may be considered the maximum achievable emission reduction, and indicates that EPA must also consider control options that are more stringent than the floor, often referred to as "beyond the floor" standards. For these "beyond the floor" standards, EPA must consider "the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements..." before it establishes a standard that is based on a "beyond the floor" level of control. For existing and new sources, section 112(d)(3) provides the standard cannot be less stringent, but may be more stringent than:

> *(A) The average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emission information), … for categories and subcategories with 30 or more sources, or*
>
> *(B) The average emission limitation achieved by the best performing 5 sources (for which the Administrator has… emission information) in the category or subcategory…with fewer than 30 sources.*

In certain instances, EPA may set work practice standards, as provided for in section 112(h), where it is not feasible to prescribe or enforce a numerical emissions standard. As stated in CAA section 112(h)(1), work practice standards or other requirements can be prescribed in lieu of a numerical emission limit if the Administrator determines that a numerical emission limit is not feasible. Section 112(h)(2) further defines the term "not feasible" in this context. For work practice standards and other requirements, section 112(h)(2) notes that "not feasible to prescribe or enforce an emission standard" means:

> *(A) a hazardous air pollutant or pollutants cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant…, or*
>
> *(B) the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations.*

In addition, for area source categories, section 112(d)(5) provides EPA with the discretion to set standards based on generally available control technologies or management practices (GACT) in lieu of MACT standards. For area source categories, section 112(d)(5) provides that in lieu of MACT standards in section 112(d)(2) and (f), the Administrator may promulgate standards or requirements that provide for the use of GACT technologies or management practices by such sources to reduce emissions of HAP.

2.3.2 Use of Risk Analysis in Rulemaking

As part of this rulemaking, EPA is conducting risk analyses to inform its decision-making. These analyses are focused on long-term risk and are not focused on short-term risk. In 2016, EPA conducted a toxicology review of EtO cancer risk and published an updated unit risk estimate (URE) as part of its Integrated Risk Information System (IRIS).[5] EPA plans to use this URE for the risk analysis associated with this rulemaking. As a complement to its regulatory program, EPA also uses non-regulatory tools, like the National Air Toxics Assessment (NATA), to manage air toxics. NATA is the EPA's nationwide air toxics screening tool, and it is designed to help the EPA and state, local, and tribal air agencies identify areas, pollutants, or types of sources that need further examination. In 2018, EPA released the latest version of NATA, based on 2014 emissions (note, we refer to this version of NATA as the 2014 NATA). The 2014 NATA revealed that EtO significantly contributes to potential elevated cancer risks in some census tracts. In some cases, this was due to EtO emissions to the outdoor air from commercial sterilization facilities. Given the 2014 NATA and the 2016 IRIS update, it is appropriate to consider risk in this rulemaking. We are modeling risk associated with EtO emissions from commercial sterilization. While

[5] https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf

the residual risk analysis for section 112(f)(2) was previously conducted in 2006, the 2016 toxicology review resulted in an updated URE. The current level of risk will be used to inform the risk impacts of the technology review and the revision of the emission standards to be promulgated. For any additional emissions sources that have been identified, EPA is required to establish technology-based standards under section 112, and to establish maximum achievable control technology (MACT) standards for major sources under section 112(d)(2) and (3). The MACT floor for the currently unregulated HAP emissions will be based on current data that reflect the present day performance of the best performing sources (i.e. this data will reflect any improvements to the HAP controls or work practices that have been implemented by sources in the category since the first Technology Review). There is no consideration of risk in the MACT floor calculation. The beyond the floor analysis for section 112(d)(2) requires EPA to consider the cost of achieving the emission reduction and any non-air quality health and environmental impacts and energy requirements. We evaluate and determine whether to select the beyond the floor option based on cost effectiveness (e.g., dollars per ton of EtO reduced, $/ton), and in conjunction with the updated URE, the increased risk will be considered as we determine the cost threshold for achieving the emission reduction, i.e., selection of increased control requirements and higher control costs as "reasonable."

The results of the preliminary risk assessment are presented in **Table 3**.

Table 3. Preliminary Results from Commercial EtO Sterilization Risk Assessment

MIR[6] per million	No. of facilities	No. of small business facilities
Greater than 100	51	12
Greater than 1,000	15	4
Greater than 10,000	1	1

2.3.3 Sources of Emissions

Commercial sterilization sources that use EtO to sterilize or fumigate products are covered under the source category. Emission sources from EtO commercial sterilization include both stack emission sources and fugitive emission sources, as indicated below:

- **Stack emission sources** include the SCV, ARV, CEV, and ethylene glycol (EG) storage tanks.
- **Fugitive emission sources** include EtO storage (both outdoor and indoor), EtO dispensing, once-through vacuum pump water, handling of sterilized products (both pre-aeration and post-aeration), and operation of air pollution control devices (APCDs) (both oxidizers and non-oxidizers).

Under the current subpart O rule requirements, the SCV and ARV are subject to emissions standards. As part of the section 112(d) technology review, additional emissions sources may become subject to control requirements or work practices. **Table 2** lists the emission sources currently covered under the subpart O rule and additional EtO emission sources that have been identified.

[6] MIR is an acronym for maximum individual risk and represents the maximum individual excess lifetime cancer risk due to HAP emissions from the source category.

Table 2. Emission Sources in the Commercial EtO Sterilization Source Category

Stack emission sources covered under current rule
Sterilizer chamber vent
Aeration room vent
Additional stack emission sources to be covered
Chamber exhaust vent
EG storage tanks
Fugitive emission sources to be covered
Indoor EtO storage
Outdoor EtO storage
EtO dispensing
Once-through vacuum pump water
Pre-aeration handling of sterilized product
Post-aeration handling of sterilized product
Operation of non-oxidizer APCDs
Operation of oxidizer APCDs (work practice)

Through our analysis, we have found that facilities generally fall into one of five configurations as described below:

- **Separate, CEV:** These are traditional facilities where sterilization and aeration occur in separate vessels. A CEV is activated upon opening the sterilization chamber in order to draw EtO away from workers as they unload product.
- **Separate, No CEV:** Some facilities conduct sterilization and aeration in separate vessels but do not have or need a CEV. In these situations, the EtO that would have normally been emitted through the CEV is included in the fugitive emissions from pre-aeration handling of sterilized product. If facility documents do not indicate the presence of a CEV, it is assumed that the facility does not have one.
- **Combination:** These facilities use vessels where both sterilization and aeration occur. This means that the EtO that would normally be emitted through the CEV and pre-aeration handling of sterilized product are now mitigated, and the only quantifiable sources of emissions are the SCV and post-aeration handling of sterilized product. Spice fumigators and small, specialized facilities are included here, but some large-scale medical companies also fall into this category.
- **Single-Item:** At these facilities, workers place product into a bag, and a slight vacuum is applied. EtO gas is injected into the sealed bag under specified temperature and humidity levels. The sealed bag is placed in a room, chamber, or cabinet where EtO both sterilizes and then off-gasses or aerates. The EtO slowly dissipates from the bag by diffusion. Once the product is removed from the room, chamber, or cabinet, the product is held in the warehouse for 2 days to monitor the biological indicator before shipping.
- **Non-Commercial:** These include research, government, and non-profit facilities. They are characterized by using combination sterilizers, and because sterilized products are not produced in bulk, fugitive emissions are assumed to be negligible. These sterilizers are not part of the regulated source category.

A summary of the number of facilities with each configuration is presented in **Table 4**.

Table 4. Number of facilities in each commercial EtO sterilization configuration[7]

Configuration	Major Source (EtO Usage >=10 tpy) - Number of facilities						Area Source (EtO Usage <10 tpy) - Number of facilities			
	EtO Usage >=250 tpy		EtO Usage >=30 tpy and <250 tpy		EtO Usage >=10 tpy and <30 tpy		EtO Usage >=1 tpy and <10 tpy		EtO Usage <1 tpy	
	All Facilities	*Small Businesses*	*All Facilities*	*Small Businesses*	*All Facilities*	*Small Businesses*	*All Facilities*	*Small Businesses*	*All Facilities*	*Small Businesses*
Separate, CEV	7	2	27	5	2	0	4	3	3	1
Separate, No CEV	0	0	8	3	3	2	5	0	3	1
Combination	0	0	3	1	4	2	4	1	14	8
Single-Item	0	0	0	0	0	0	8	0	3	0
Non-Commercial	0	0	0	0	0	0	0	0	4	0

Using information collected from a questionnaire that was distributed to nine EtO sterilization companies in December 2019[8], we have been able to calculate how much EtO used by each facility is ultimately emitted from the different emission sources. These nine companies cover almost half of the commercial EtO sterilization industry, but their facilities are not necessarily representative of all facilities. The emission profiles of the facilities that responded to the questionnaire vary based on facility configuration and are presented in **Table 5**. To further inform future rulemaking, EPA is developing an Information Collection Request under the Paperwork Reduction Act (PRA). The 60-day notice for the proposed collection seeking public comment, as required by the PRA, was published in the Federal Register on June 12, 2020 (85 FR 35931).

[7] The total number of facilities may not sum to 103, as some facilities with multiple buildings can have more than one configuration.

[8] See https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities (Additional Resources) for more information. The emission source data for point sources and fugitive sources in response to the questionnaire are the most up-to-date and comprehensive information EPA has available.

Table 5. EtO Emission Profiles by Sterilization Facility Configuration

Emission Source	Separate, CEV	Separate, No CEV	Combination	Single-Item	Non-Commercial
Pre-Control					
Sterilization Chamber Vent	93%	93%	98.4%	98%	100%
Aeration Room Vent	4%	4%	N/A	N/A	N/A
Chamber Exhaust Vent	1%	N/A	N/A	N/A	N/A
Pre-Aeration Handling of Sterilized Product	0.4%	1.4%	N/A	N/A	N/A
Post-Aeration Handling of Sterilized Product	0.6%	0.6%	0.6%	0.6%	N/A
Injection Room	N/A	N/A	N/A	0.4%	N/A
Post-99.9% Control for SCV and 99% Control for ARV and CEV					
Sterilization Chamber Vent	8.1%	3.0%	14.1%	98.2%	100%
Aeration Room Vent	3.5%	1.3%	N/A	N/A	N/A
Chamber Exhaust Vent	0.9%	N/A	N/A	N/A	N/A
Pre-Aeration Handling of Sterilized Product	35.0%	76.6%	N/A	N/A	N/A
Post-Aeration Handling of Sterilized Product	52.5%	19.2%	85.9%	0.6%	N/A
Injection Room	N/A	N/A	N/A	0.4%	N/A

EPA is currently only able to quantify fugitive emissions from pre-aeration and post-aeration handling of sterilized product. Based on control scenarios that are commonly observed throughout the source category (99.9% SCV control and 99% ARV and CEV control), fugitive emissions, i.e., pre-aeration handling and post-aeration handling of sterilized product, of EtO are estimated to comprise more than 80% of post-control emissions, on average, and these emissions are largely uncontrolled.

2.3.4 Potential Improvements to Current Rule Requirements

Increased removal efficiencies for SCVs and ARVs. As indicated in Table 4, the SCV and ARV are the two largest sources of pre-control EtO emissions at commercial sterilization facilities, with the portion EtO use going to these sources being 93% and 4%, respectively. While the current standards for SCV and ARV control device efficiency are 99% EtO removal (along with a 1-ppmv alternative for ARVs), EPA has either collected permit information where the required emission reductions for the SCV and ARV exceed the current standard, or has collected performance test data that demonstrate emission control exceeding the current standard, for many of the SCVs and ARVs across the source category.

Revision under Consideration -- EPA is considering increasing the removal efficiency requirements for existing SCV and ARV standards, requiring control of ARV emissions at area source facilities using 1 tpy or more of EtO, and requiring control of SCV emissions at facilities using less than 1 tpy of EtO.

The EPA is considering increasing the existing removal efficiency requirements as follows:

- For major source facilities using less than 30 tpy of EtO, EPA is considering increasing the required SCV removal efficiency from 99% to 99.9%. There are 9 facilities within this category, the SCV removal efficiencies range from 99% to 99.9976%, and 4 facilities are achieving at least 99.9% control. For facilities owned by small businesses, there are 3 major source facilities using less than 30 tpy of EtO. The SCV removal efficiencies for these facilities range from 99.7% to 99.9976%, and 1 facility is achieving at least 99.9% control.

- For major source facilities using 30 tpy or more of EtO, EPA is considering increasing the required SCV removal efficiency from 99% to 99.99%. As part of the risk assessment, EPA has determined that for some facilities in this usage range, 99.9% SCV removal efficiency will not be enough for reducing risk to 100-in-1 million or lower. There are 43 facilities within this category, the SCV removal efficiencies range from 99% to 99.999996%,[9] and 13 facilities are achieving at least 99.99% control. For facilities owned by small businesses, there are 10 major source facilities using 30 or more tpy of EtO. The SCV removal efficiencies for these facilities range from 99% to 99.92%. Therefore, none of these facilities are currently achieving at least 99.99% control.
- For all major source facilities, EPA is considering increasing the required ARV removal efficiency from 99% to 99.9%. There are 45 major source facilities that have ARVs, the removal efficiencies range from 90.01% to 99.998%, and 16 facilities are achieving at least 99.9% control.[10] For facilities owned by small businesses, there are 13 major source facilities that have ARVs. The ARV removal efficiencies for these facilities range from 90.01% to 99.9976%, and 1 facility is achieving at least 99.9% control.
- For area source facilities using 1 tpy or more of EtO, EPA is considering increasing the required SCV removal efficiency from 99% to 99.9%. Of these 21 area source facilities, 16 are controlling their SCV emissions.[11] The removal efficiencies range from 99% to 99.999%, and 9 facilities are achieving at least 99.9% SCV control. For facilities owned by small businesses, there are 2 area source facilities using 1 tpy or more of EtO, and the SCV removal efficiency for both facilities is 99.99%.

In addition to tightening control requirements for existing standards, EPA is also considering expanding SCV and ARV control requirements to include facilities that are not currently required to control these emission sources:

- For area source facilities using 1 tpy or more of EtO, EPA is considering a 99.6% control requirement for ARVs. 9 of these area source facilities have ARVs, 7 of which are controlling them.[12] The removal efficiencies for these ARVs range from 99% to 99.999%, and 5 facilities are achieving at least 99.6% control. For area source facilities using 1 tpy or more of EtO that are owned by small businesses, 2 have ARVs, both are controlled, and the removal efficiency for these ARVs at both facilities is 99.99%.
- For facilities using less than 1 tpy of EtO, EPA is considering a 99% control requirement for SCVs. There are 22 of these facilities that are controlling their SCVs, the removal efficiencies range from 99% to 99.99%, and 14 facilities are achieving at least 99% control. For facilities using less than 1 tpy of EtO that are owned by small businesses, 10 have SCVs, and 10 are controlling their SCV emissions. The removal efficiencies range from 99% to 99.99%, and all facilities are achieving at least 99% SCV control.

Typical APCDs used to control EtO emissions from SCVs and ARVs include catalytic oxidizers, dry bed scrubbers, wet acid scrubbers, and thermal oxidizers. The EtO concentrations in the ARV at the inlet to the APCD range from 3.9 to 79 parts per million by volume (ppmv). In addition to tightening control requirements for ARVs, EPA is also considering the elimination of the 1 ppm alternative for ARV control. With new air pollution control setups that have emerged, there is the potential for dilution of the ARV exhaust stream from room air capture. Dilution could render a concentration-based standard ineffective

[9] Report of Air Pollution Source Testing of an Ethylene Oxide Emission-Control System Operated by Sterigenics, Inc. in Salt Lake City, Utah on April 19, 2016. May 22, 2016
[10] In addition, there are 2 major source facilities that do not appear to control their ARVs.
[11] The uncontrolled facilities are single-item sterilizers, which EPA will clarify are subject to the rule.
[12] The remaining two facilities have plans to install controls for their ARVs.

because facilities could reduce their emitted concentration of EtO by increasing air flow but not by actually reducing the quantity of EtO emitted. In addition, EPA has identified some facilities for which a 1 ppm alternative would continue to pose an unreasonable risk to nearby communities.

Clarification that the source category includes single-item sterilizers. In single-item sterilization, the product is placed into a plastic bag and sealed, and the sealed bag is placed in a room, chamber, or cabinet where the EtO sterilizes the product and the EtO then off-gasses or aerates. Because the sterilization step and the aeration step occur within the same room, chamber, or cabinet, this equipment is a sterilization chamber. In general, single-item sterilizers tend to be facilities that do not use large quantities of EtO. The EPA has collected data indicating that EtO usage at single-item sterilizers ranges from 0.43 to 2.1 tons per year.

Revision under Consideration -- EPA is considering clarifying that single-item sterilizers are included in the source category.

The EPA intends to clarify that single-item sterilizers are part of the EtO commercial sterilization source category and are subject to the emission reduction requirements under subpart O. Sterilization sources using 1 tpy or more of EtO would be required to meet 99.9% reduction of EtO from sterilization and aeration, and those using less than 1 tpy of EtO would be required to meet 99% control from sterilization and aeration. EPA has not identified single-item sterilization facilities that are owned by small businesses.

2.3.5 Additional Emissions Sources to be Regulated

CEV controls plus safety measures. The CEV is an EtO emissions source that is present at some commercial sterilization facilities. The CEV evacuates EtO-laden air from the sterilization chamber after the chamber door is opened for product unloading (and reloading) following the completion of sterilization and associated gas washes. As previously mentioned, the EPA suspended the compliance deadlines for CEVs in 1997 due to safety concerns and later removed the requirements for CEVs in 2001 because the EPA could not conclude at the time that the CEVs could be safely controlled.

It was determined at that time that the primary contributing issue leading to the explosions was that EtO concentrations in the CEV exhaust streams were above the safe limit (i.e., the LEL). Following the removal of the CEV regulatory requirement in 2001, many EtO sterilization facilities ceased, or never implemented, controls for EtO emissions from the CEV. Since the late 1990s and early 2000s, facilities have revised their operating procedures related to the CEV, and in more recent years, facilities have begun to control their CEV emissions. Most facilities currently control emissions from this source.

EtO concentration limit in the sterilizer chamber before opening chamber door. Facilities that currently 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 to significantly less than the LEL 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 the EtO concentration is significantly less than the LEL.

As safety measures, some facilities have established an upper in-chamber EtO concentration limit prior to opening the chamber door and activating 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. A 2007 report from the National Institute for Occupational Safety and Health determined that additional air washes were essential

for mitigating any safety issues.[13] 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.[14] The LEL of EtO is 3.0 percent by volume, or 30,000 ppmv.[15] In order to ensure safe conditions when opening the sterilizer chamber at the end of the sterilization cycle, and in order to ensure limited fugitive emissions are released from opening the sterilizer chamber door, facilities reduce the EtO concentration in 70% of sterilization chambers to some value less than the LEL, often to ranges of nearly 0 to 25 percent of the LEL (i.e., 7,500 ppmv).[16]

While an in-chamber EtO concentration monitoring technique was not available when the original NESHAP was promulgated in 1994, in-chamber monitors based on the photoacoustic principle are available and currently in use at most 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.

As part of the process change, facilities have implemented 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, as discussed below, 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.

Interlock system tied to in-chamber EtO concentration limit. To further reduce 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 systems are tied to the monitoring and control equipment already operating within the 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 interlock system ensures that the CEV is not activated until the EtO concentration within the chamber is well below the LEL. The automated lock on the sterilizer chamber door does not allow the door to open until a non-explosive EtO concentration level is achieved within the chamber.

Revision under Consideration -- EPA is considering reinstating control requirements for CEVs, plus additional safety measures that reduce concentration below the LEL, measure the in-chamber concentration, and use of an interlock system.

The EPA is considering reinstating CEV control requirements at both major and area sources to vent emissions to an APCD that achieves at least 99% emission reduction.

- Of the 35 major source facilities that have CEVs, 29 are controlling them. The removal efficiencies range from 98.6% to 99.998%, and 27 facilities are achieving at least 99% control. For major source facilities that are owned by small businesses, 6 have CEVs, 3 are controlling them. 1 is achieving at least 98.7% control, and it is assumed that the other two facilities are

[13] 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/.
[14] Chemical Safety and Hazard Investigation Board, Investigation Report: Sterigenics (4 Employees Injured). March 2006. https://www.csb.gov/sterigenics-ethylene-oxide-explosion/.
[15] https://pubchem.ncbi.nlm.nih.gov/compound/Ethylene-oxide#section=Lower-Explosive-Limit-(LEL).
[16] See memorandum, Meeting Minutes for Discussion with Representative of LESNI, located at Docket ID No. EPA–HQ–OAR–2019–0178. March 7, 2019.

achieving at least 99% control based on the APCDs that they reported using (the CEVs are routed to the same control device as the SCV and ARV).
    - EPA is also considering increasing the CEV removal efficiency to 99.9% for facilities that use 250 or more tpy of EtO. Of the 7 facilities using 250 or more tpy that have CEVs, all are controlling them. The removal efficiencies range from 99% to 99.97%, and 4 facilities are achieving at least 99.9% control. For facilities using 250 or more tpy of EtO that are owned by small businesses, 2 have controlled CEVs, but it is not known whether they are achieving 99.9% removal efficiency.
- Of the 4 area source facilities using 1 tpy or more of EtO that have CEVs, 3 are controlling them. The removal efficiencies range from 99.61% to 99.99%, which means that all facilities are achieving at least 99% control. For area source facilities using 1 tpy or more of EtO that are owned by small businesses, 2 have CEVs, and 1 is controlling them.

Based on responses to the December 2019 questionnaire, EPA estimates that the capital cost for routing CEV emissions to an existing APCD is $17,000, which may be a reasonable approach if the current APCD has additional capacity. In addition, EPA is considering a requirement for the EtO concentration within the sterilization chamber to be reduced to 5% of the LEL (i.e., 1,500 ppmv) before the chamber door can be opened, along with an interlock system for the sterilization chamber that prevents the CEV from activating until that EtO concentration limit is met. The EtO concentration limit may be achieved by conducting an increased number of air washes. Based on responses to the December 2019 questionnaire, EPA estimates that the annual cost for increased gas washes to reduce EtO concentration is $34,000 (the annual cost includes the cost for additional air washes and does not reflect the increased time that product would be held in the sterilizer chamber or the impact to annual production rate). EPA also estimates that the capital and annual costs for installing and operating chamber interlock systems are $22,000 and $2,600, respectively.

Fugitive Emissions from Indoor EtO Storage. Indoor EtO storage areas are typically enclosed and equipped with reinforced walls, floors, and blast panels. At some facilities, indoor EtO storage is combined with other activities, including EtO dispensing and handling of sterilized product. In order to reduce fugitive emissions from indoor EtO storage, many facilities either capture the room air and vent it to a control device, or they implement an LDAR program. National Fire Protection Association (NFPA) 55 Chapter 14 places an upper limit on the amount of EtO that can be stored within a building:

> *14.3.2.1.1 The maximum quantity of ethylene oxide stored in a sterilization building shall be 10,000 lb (4536 kg).*

Revision under Consideration -- EPA is considering a requirement for capture and control of fugitive emissions from indoor EtO storage, as well as an LDAR alternative for area sources facilities using 1 tpy or more of EtO.

Of the 42 facilities that were included in the December 2019 questionnaire, only 12 responded that they did not have any indoor EtO storage. Therefore, it is assumed that facilities that were not included in the December 2019 questionnaire have indoor EtO storage. EPA has identified 41 major source facilities that have indoor EtO storage, 13 of which are owned by 10 small businesses. Seven major source facilities are implementing some sort of capture and control system for these emissions. For fugitive emissions

from indoor EtO storage, the MACT floor for existing major source facilities will be based on the top 5 performers, which are presented in **Table 6**:

Table 6. MACT Pool for Fugitive Emissions from Indoor EtO Storage

Facility	Location	Removal Efficiency[17]	Source
Medline	Waukegan, IL	99.99%	3/24/20 stack test report
STERIS AST	Temecula, CA	99.98%[1]	ANPRM comment
STERIS AST	Spartanburg, SC	99%[1]	9/18/19 meeting with STERIS
STERIS AST	San Diego, CA	98.2%	6/9/19 permit and July 2000 stack test
STERIS AST	El Paso, TX	71%	December 2019 questionnaire response[18]
	MACT Floor:	**94%**	

[1] Assumed value based on the APCD the facility reported using (EtO storage emissions are typically routed to the same control device as the SCV and ARV). For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available however EPA will collect and review the tests.

The devices that would more than likely be used to control these sources are guaranteed by the manufacturer to achieve at least 99% control efficiency. For this reason, EPA is considering going "beyond the floor" and requiring this control efficiency, as well as 100% capture, for existing major source facilities. For new major source facilities, the best performing source for fugitive emissions from indoor EtO storage has a system that is capable of 100% capture and at least 99.99% control efficiency. It is assumed that all area source facilities that use 1 tpy or more of EtO have indoor EtO storage. If these area source facilities are included in the MACT pool, then the MACT floor would be based on the top 8 performers (12 percent of 41 facilities plus 21 facilities). EPA has not identified any area source facilities using 1 tpy or more of EtO that are controlling their indoor EtO storage emissions. Therefore, the MACT floor including these area source facilities could potentially drop to 63% removal efficiency for existing facilities. The remaining facility that controls indoor EtO storage emissions (STERIS AST in Northborough, MA) only does so in emergency situations. An alternative to MACT requirements for these area source facilities could be GACT requirements in the form of an LDAR program. This program could consist of a monitoring frequency, a threshold value for required actions, and repair and resurvey timelines. Some area source facilities currently implement an LDAR program for fugitive emissions from indoor EtO storage. EPA estimates that 4 area source facilities using 1 tpy or more of EtO owned by 4 small businesses would be impacted by imposing new requirements.

Fugitive Emissions from Outdoor EtO Storage. An outdoor EtO storage area may be a partially enclosed area or room, with one or more sides open/exposed, and with a roof covering. It should be noted that NFPA 55 Chapter 14 also places a lower limit on the portion of the perimeter that must be open to the atmosphere:

> *14.3.3.2.1 Outdoor storage areas shall have a minimum of 25 percent of the perimeter open to the atmosphere.*

The "open" sides may consist of chain-link fencing or some type of lattice wall. Outdoor storage is used only for larger EtO drums (and not for smaller cylinders or cartridges). Most facilities monitor the EtO concentration in outdoor EtO storage areas. There are no combination-type rooms for outdoor EtO storage (i.e., where more than one activity occurs in the room area).

[17] Removal Efficiency = Capture Efficiency · Control Efficiency
[18] This facility is a complex of two buildings, only one of which controls indoor EtO storage (assumed to be 99%). Overall removal efficiency is calculated assuming that emissions are proportional to use.

Revision under Consideration -- EPA is considering a requirement for capture and control of fugitive emissions from outdoor EtO storage.

In the December 2019 questionnaire, outdoor EtO storage areas were reported once a building reached 30 tpy of EtO usage. EPA has not identified any outdoor EtO storage areas at existing sources that are routed to APCDs. Per NFPA 55, at least 25% of the outdoor EtO storage area perimeter must be open to the atmosphere. In addition to safety constraints, commercial EtO sterilization facilities are typically located in industrial parks where space may not be available to construct new enclosures for outdoor EtO storage that would satisfy NFPA requirements. While one might assume that these conditions would prohibit 100% capture of fugitive emissions from outdoor EtO storage, in fact these emissions can be conveyed to an APCD using a fume hood. While EPA has not identified any facilities currently using these technologies to control these emissions, the presence of effective, commercially available control technology leaves EPA unable to allow for the use of a work practice standard to reduce these emissions. The devices that would more than likely be used to control these sources are guaranteed by the manufacturer to achieve at least 99% control efficiency. A minimum flowrate through the fume hood could be required in order to ensure some level of capture.

Fugitive Emissions from EtO Dispensing. Fugitive emissions can occur from leaks and losses of EtO while it is being dispensed from a non-cartridge storage container to a sterilizer chamber. The EtO storage container is connected to the sterilizer chamber via piping and lines that feed or charge the EtO into the chamber. These piping lines and connections in EtO service and the gas dispensing area are subject to requirements in NFPA 55 Chapter 14. There are specific requirements for joining pipes, tubing, flanges, gaskets, valves, fittings, flexible connectors. Monitoring of EtO concentration in the dispensing room area is also required:

> *Section 14.4.2.2.1 Joints shall be made gastight and shall be welded, flanged, brazed, or threaded.*
>
> *Section 14.2.2.2 Joints shall be welded where located in concealed spaces within buildings.*

While facility equipment is required to meet NFPA requirements to limit leaks and maintain safe operation, EtO leaks may occur at the connection between the EtO storage container valve and the piping/lines. Facilities often conduct LDAR programs in room areas for transferring EtO to the sterilizer chamber. Facilities also routinely conduct pressure tests to confirm there are no leaks in the piping and lines to the sterilizer chamber.

Single-item sterilization facilities have an extra, but related, step to EtO dispensing which involves injecting EtO into bags. Once the bags have been injected with EtO, they may sit on a tray in a holding room until the tray is filled. At that point, the bags are transferred to the sterilizer chamber. EPA considers these activities to be part of EtO dispensing, since it is part of a mechanism to ultimately get EtO into the sterilizer chamber (via bags, in this case).

Revision under Consideration -- EPA is considering a requirement for capture and control of fugitive emissions from EtO dispensing, with an LDAR alternative for area source facilities using 1 tpy or more of EtO.

Dispensing occurs if EtO is stored in a drum, cylinder, or other non-cartridge medium that involves incorporating that medium into some sort of dispensing mechanism. Therefore, it is assumed that all 52 major source facilities have dispensing activities, 12 of which capture and control the associated emissions. Approximately 12 of the major sources are small businesses, and \1 of these sources is

controlling EtO dispensing emissions. For fugitive emissions from EtO dispensing, the MACT floor for existing major source facilities will be based on the top 7 performers, which are presented in the **Table 7**:

Table 7. MACT Pool for Fugitive Emissions from EtO Dispensing

Facility	Location	Removal Efficiency	Source
Medline	Waukegan, IL	99.99%	3/24/20 stack test report
STERIS AST	Temecula, CA	99.98%[1]	ANPRM comment
Sterigenics	Ontario, CA	99.9595%	10/25/19 stack test report
BD	Covington, GA	99%[1]	5/28/20 permit application
BD	Madison, GA	99%[1]	12/13/19 permit application
Sterigenics	Atlanta, GA	99%[1]	7/30/19 permit application
Sterigenics	Charlotte, NC	99%[1]	11/7/19 permit
Cook	Ellettsville, IN	99%[1]	3/6/20 permit
STERIS AST	Grand Prarie, TX	99%[1]	December 2019 questionnaire response
	MACT Floor:	**99%**	

[1] Assumed value based on the APCD the facility reported using (EtO Dispensing emissions are typically routed to the same control device as the SCV and ARV). For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available however EPA will collect and review the tests.

Use of EPA Method 204, *Criteria for and Verification of a Permanent or Temporary Total Enclosure,* may be required in order to demonstrate 100% capture of the emissions. EPA Method 204 provides criteria to determine whether a facility's capture efficiency is 100% (criteria include the size of natural duct openings (NDO), distance from the NDO to the emission source, flow rate through the NDO, etc.) For new major source facilities, the best performing source for fugitive emissions from EtO dispensing has a system that is capable of 100% capture and at least 99.99% control efficiency.

EPA has identified 19 area source facilities that use 1 tpy or more of EtO and have EtO dispensing activities, 4 of which are owned by 4 small businesses. If these area source facilities are included in the MACT pool, then the MACT floor would be based on the top 9 performers (12 percent of 52 major plus 19 area sources). EPA has not identified any area source facilities using 1 tpy or more of EtO that are routing fugitive emissions from EtO dispensing to an APCD. Therefore, the MACT floor including these area source facilities could potentially remain at 99% removal efficiency for existing facilities. Approximately 5 of the area sources are small businesses. Because some facilities conduct leak monitoring on EtO storage containers, an alternative to MACT requirements for these area source facilities could be GACT requirements in the form of an LDAR program. This program could consist of a monitoring frequency, a threshold value for required actions, and repair and resurvey timelines. Some area source facilities currently implement an LDAR program for fugitive emissions from EtO dispensing. In addition, for single-item sterilization facilities, EPA is considering a work practice requirement for trays with EtO-loaded bags to be moved into a sterilization chamber as soon as the trays are filled.

Once-through vacuum pump water. In both once-through vacuum pumps and recirculating vacuum pumps, the seal fluid or working fluid in the pump is combined with the EtO vent gas. In a recirculating vacuum pump, the seal fluid (and vent gas) is sent to a separation tank where the vent gas is routed to an APCD, and the seal fluid is held for recirculation back to the pump. The seal fluid is held and reused, allowing any EtO gas to off-gas from the fluid and be routed to the APCD. In a once-through vacuum pump, the seal fluid and vent are also sent to a separation tank. However, the vent gas is routed to the APCD and the seal fluid is not recycled to the vacuum pump. It is removed from the tank, and any EtO contained in the seal fluid is released to the atmosphere. The use of a recirculating vacuum pump greatly minimizes EtO emissions to the atmosphere from the seal fluid.

Revision under Consideration -- EPA is considering a requirement for use of recirculating vacuum pumps.

EPA is considering an equipment standard to require the use of recirculating vacuum pumps to remove EtO gas from sterilizer chambers. In the December 2019 questionnaire, only 5 out of the 42 facilities that were included in the December 2019 questionnaire indicated the use of once-through vacuum pumps (2 of which are owned by a small business, with a combined total of 35 once-through vacuum pumps). Therefore, it is assumed that all other facilities use recirculating vacuum pumps. The use of these pumps reduces most of the EtO-laden seal fluid from once-through vacuum pumps, and significantly reduces EtO emissions to the atmosphere.

Fugitive Emissions from Pre-Aeration Handling of Sterilized Product. At facilities where sterilization and aeration occur in separate vessels, fugitive emissions can occur when transferring sterilized product from the sterilizer chamber to an aeration vessel. The quantity of fugitive emissions varies, but it is understood to be a function of the type and quantity of materials that are being sterilized, the amount of time that it takes to transfer the sterilized product to the aeration room, and whether the facility has a CEV. This is a significant source of fugitive emissions that can be quantified. EPA estimates that the portion of EtO usage emitted from this source is 0.4% for facilities that have CEVs, and 1.4% for facilities that do not have a CEV.

Revision under Consideration -- EPA is considering a requirement for capture and control of fugitive emissions from pre-aeration handling of sterilized products, with work practice alternatives for area source facilities using 1 tpy or more of EtO.

EPA has identified 45 major source facilities that have emissions associated with pre-aeration handling of sterilized product, 12 of which are owned by 9 small businesses. Eleven major source facilities are implementing some sort of capture and control system for these emissions. Here, the MACT floor for existing major source facilities will be based on the top 6 performers. The current best performers for this emissions source are presented in **Table 8**:

Table 8. MACT Pool for Fugitive Emissions from Pre-Aeration Handling of Sterilized Product

Facility	Location	Removal Efficiency	Source
Medline	Waukegan, IL	99.99%	3/24/20 stack test report
STERIS AST	Temecula, CA	99.98%[1]	ANPRM comment
Sterigenics	Ontario, CA	99.9595%	10/25/19 stack test report
STERIS AST	Northborough, MA	99.5%	4/30/07 permit
STERIS AST	Spartanburg, SC	99.4%[1]	9/18/19 meeting with STERIS AST
BD	Covington, GA	99%[1]	5/28/20 permit application
BD	Madison, GA	99%[1]	12/13/19 permit application
Sterigenics	Atlanta, GA	99%[1]	7/30/19 permit application
Sterigenics	Charlotte, NC	99%[1]	11/7/19 permit
Cook	Ellettsville, IN	99%[1]	3/6/20 permit
	MACT Floor:	**99.6%**	

[1] Assumed value based on the APCD the facility reported using (these emissions are typically routed to the same control device as the SCV and ARV). For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available however EPA will collect and review the tests.

Use of EPA Method 204 may need to be required in order to demonstrate 100% capture of the emissions. For new major source facilities, the best performing source for fugitive emissions from pre-aeration handling of sterilized products has a system that is capable of 100% capture and at least 99.99% control efficiency. EPA has identified 9 area source facilities that use 1 tpy or more of EtO and have emissions

associated with pre-aeration handling of sterilized product, 3 of which are owned by 3 small businesses. If these area source facilities are included in the MACT pool, then the MACT floor would be based on the top 7 performers (12 percent of 45 facilities plus 9 facilities). EPA has not identified any area source facilities using 1 tpy or more of EtO that are controlling these emissions. Approximately 6 of the area sources that conduct pre-aeration handling of sterilized product are small businesses. The MACT floor including these area source facilities could potentially drop to 99.5% removal efficiency for existing facilities. An alternative to MACT requirements for these area source facilities could be GACT requirements in the form of the following work practice standards:

- Requiring EtO valves to be closed prior to opening the chamber and for as long as the chamber is open
- Prohibiting the storage of pre-aeration sterilized product in uncontrolled areas
- Prohibiting the inclusion of paper instructions in products to be sterilized
- Prohibiting the use of wooden pallets[19]

Fugitive Emissions from Post-Aeration Handling of Sterilized Product. Once sterilized products have left the aeration phase, they are moved to a shipping or warehouse room area within the facility for storage until they are ready to be distributed. While they await distribution, the EtO that is still present within the product continues to off-gas, often in large amounts due to the high volume of sterilized product that is present in these areas. This is a significant source of fugitive emissions that can be quantified, with EPA estimating that the portion of EtO usage emitted from this source is 0.6%.

Revision under Consideration -- EPA is considering a requirement for capture and control of fugitive emissions from post-aeration handling of sterilized products, with work practice alternatives for area source facilities using 1 tpy or more of EtO.

All 52 major source facilities have emissions associated with post-aeration handling of sterilized product. Eleven of these facilities implement some sort of capture and control system for these emissions, some of which use the “cascading air method”, which involves moving air from one area of the facility to another area that is controlled. Approximately 12 of the major sources are small businesses, and 1 of these facilities is controlling emissions from this source. For this emission source, the MACT floor for existing major source facilities will be based on the top 7 performers. The current best performers for this emissions source are presented in **Table 9**:

Table 9. MACT Pool for Fugitive Emissions from Post-Aeration Handling of Sterilized Product

Facility	Location	Removal Efficiency	Source
Medline	Waukegan, IL	99.99%	3/24/20 stack test report
STERIS AST	Temecula, CA	99.98%[1]	ANPRM comment
Sterigenics	Ontario, CA	99.9595%	10/25/19 stack test report
Sterigenics	Los Angeles, CA	99.9549%	4/16/219 stack test report
BD	Covington, GA	99%	7/23/20 stack test report
BD	Madison, GA	99%[1]	12/13/19 permit application
Sterigenics	Atlanta, GA	99%[1]	7/30/19 permit application
Sterigenics	Charlotte, NC	99%[1]	11/7/19 permit
	MACT Floor:	**99.6%**	

[1] Assumed value based on the APCD the facility reported using (these emissions are typically routed to their own control system). For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available however EPA will collect and review the tests.

[19] A 2020 engineering study indicated that wooden pallets absorb much more EtO compared to pallets composed of other materials (e.g., polypropylene).

EPA Method 204 may need to be required in order to ensure 100% capture of the emissions. For new major source facilities, the best performing source for fugitive emissions from post-aeration handling of sterilized product has a system that is capable of 100% capture and at least 99.99% control efficiency. All 21 area source facilities that use 1 tpy or more of EtO have emissions associated with post-aeration handling of sterilized product. If these area source facilities are included in the MACT pool, then the MACT floor would be based on the top 9 performers (12 percent of 52 facilities plus 21 facilities). EPA has not identified any area source facilities using 1 tpy or more of EtO that are controlling these emissions. The MACT floor including these area source facilities could potentially drop to 88% removal efficiency for existing facilities. An alternative to MACT requirements for these area source facilities could be GACT requirements in the form of the following work practice standards:

- Prohibiting the inclusion of paper instructions in products to be sterilized
- Prohibiting the use of wooden pallets

Fugitive Emissions from Operation of APCDs. Common APCDs for this industry include wet scrubbers, catalytic oxidizers, thermal oxidizers, and dry bed scrubbers. Based on responses to the December 2019 questionnaire, the portion of EtO usage that is emitted as fugitive emissions from the operation of APCDs is relatively small. Emission reduction options are determined by whether the APCD is an oxidizer. Fugitive emissions from non-oxidizer APCDs can either be enclosed and routed to an APCD, or an LDAR program can be implemented in order to reduce those emissions. Oxidizer APCDs are only able to implement the latter option, as they cannot be enclosed due to safety concerns.

Revision under Consideration -- EPA is considering a requirement for capture and control of fugitive emissions from the operation of non-oxidizer APCDs, with an LDAR alternative for area source facilities using 1 tpy or more of EtO.

EPA has identified 41 major source facilities that have at least 1 non-oxidizer APCD. Twelve of these facilities are owned by 7 small businesses. For this emission source, the MACT floor for existing major source facilities will be based on the theoretical top 5 performers. However, only 3 facilities are implementing some sort of capture and control system for fugitive emissions from the operation of these APCDs, and they are presented in the **Table 10**:

Table 10. MACT Pool for Fugitive Emissions from Operation of Non-Oxidizer APCDs

Facility	Location	Removal Efficiency	Source
Sterigenics	Atlanta, GA	99.1%	8/18/20 stack test review
Sterigenics	Charlotte, NC	99%[20]	11/7/19 permit
Medline	Waukegan, IL	92.99%[21]	3/24/20 stack test report
	MACT Floor:	**60%**	

The devices that would more than likely be used to control these sources are guaranteed by the manufacturer to achieve at least 99% control efficiency. For this reason, EPA is considering going "beyond the floor" and requiring this control efficiency for existing major source facilities. For new major source facilities, the best performing source for operation of non-oxidizer APCDs is routing the fugitive emissions to a capture and control system that can achieve 100% capture and at least 99.1% removal

[20] Assumed value based on the APCD the facility reported using (Fugitive emissions from APCDs are routed to the same control device as the SCV and ARV). For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available however EPA will collect and review the tests.
[21] Per the company's response to the December 2019 questionnaire, only the Glygen scrubbers at this facility are enclosed. It is assumed that 93% of EtO usage goes through these APCDs.

efficiency of EtO emissions. EPA has identified 6 area source facilities that use 1 tpy or more of EtO and have at least 1 non-oxidizer APCD. Three of these facilities are owned by 3 small business. If these area source facilities are included in the MACT pool, then the MACT floor would be based on the top 6 performers. EPA has not identified any area source facilities that are capturing and controlling fugitive emissions through the operation of APCDs. The MACT floor including these area source facilities could potentially drop to 49% removal efficiency for existing facilities. An alternative to MACT requirements for these area source facilities could be GACT requirements in the form of an LDAR program. This program could consist of a monitoring frequency, a threshold value for required actions, and repair and resurvey timelines. Some area source facilities currently implement an LDAR program for fugitive emissions from the operation of non-oxidizer APCDs.

Revision under Consideration -- EPA is considering an LDAR requirement for reducing fugitive emissions from the operation of oxidizer APCDs.

EPA has identified 42 facilities using 1 tpy or more of EtO that have at least 1 oxidizer APCD. Seven of these facilities are owned by 5 small businesses. As previously mentioned, we believe that we are unable to require capture and control of these emissions due to safety concerns. However, EPA is considering implementing LDAR program that would reduce the amount of fugitive emissions from the operation of these oxidizer APCDs. An LDAR program may consist of a monitoring frequency, a threshold value for required actions, and repair and resurvey timelines.

Ethylene glycol storage tanks. Ethylene glycol (EG) storage tanks (EGSTs) are part of the wet scrubber and Glygen APCDs used at EtO commercial sterilization facilities. In these wet scrubber APCD systems, the EtO vent gas mixes with water, and EtO is absorbed into the water. The EtO-laden water reacts with sulfuric acid to generate EG, which can then be moved over into an EGST. Most EGSTs are located inside buildings, generally in the APCD room, and are maintained at a relatively constant temperature. Therefore, EG emissions are generally due to working losses and there are minimal breathing losses.

Revision under Consideration -- EPA is considering a control requirement for emissions from the EGSTs.

EPA has identified 33 major source facilities that have at least 1 EGST, 9 of which appear to be controlling the emissions from those tanks. Approximately 7 of these facilities are small businesses, and none are controlling EGST emissions. For this emission source, the MACT floor for existing major source facilities will be based on the top 4 performers. In the December 2019 questionnaire, 8 facilities indicated that they control their EGST emissions with the same wet scrubber that is generating the EG. Therefore, EPA is considering a requirement for sources to route EGST emissions to the same wet scrubber that is generating the EG or some other APCD that can achieve an equivalent EtO destruction efficiency.

Post-Facility Emissions. Once sterilized product leaves the facility, there is still residual EtO left within the product that continues to off-gas into the surrounding air. One study estimates that 1% of EtO usage remains within the sterilized product after it leaves the facility.[22] EPA believes that the work practices that have been previously suggested (increased gas washes, reduced paper packaging, and elimination of wooden pallets) should reduce these emissions.

[22] Lexamed February 17 to 20, 2014 Trip Report. Edwards Life Sciences, Añasco, Puerto Rico

2.3.6 Other Rule Revisions Under Consideration

Stack and Performance Testing. There are several elements of stack testing that are under review as part of this rulemaking:

- **Frequency**: The current rule only requires a one-time performance test for APCDs, with an annual option for catalytic oxidizers as an alternative to other work practices. This can result in some APCDs operating for a substantial amount of time with no re-testing, and no way to ensure that the device is still meeting the rule requirements.

- **SCV Methodology**: The current methodology for testing the SCV removal efficiency is laid out in 40 CFR §63.365, with paragraph (1) prescribing the following:

  First evacuation of the sterilization chamber. These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

  After the rule was last reviewed in 2006, EPA issued its national stack testing guidance in 2009.[23] It would be ideal for the testing requirements in this rule to more closely align with this guidance, particularly so that SCV testing is conducted under representative operating conditions.

- **Methods**: For measuring outlet EtO concentrations, the current rule allows for the use of either EPA Method 18 or 25A. Given that facilities will potentially be measuring very low levels of EtO in their exhaust stream(s), EPA is considering revising the approved methods in order to ensure proper measurement of EtO.

- **Oxidizer baseline temperature**: Current requirements for oxidizer baseline temperatures are set in 40 CFR §63.363(3):

  (3) For facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.

  The recommended minimum temperature from the manufacturer may not be appropriate for achieving the required EtO removal efficiency. A more appropriate baseline temperature could be established during the stack test itself, where it would be known that proper removal efficiency was being achieved at that temperature.

In addition to stack testing, performance testing will also be needed for Permanent Total Enclosures (PTEs), where required, in order to ensure 100% capture of EtO emissions. Either a routine validation procedure, or continuous monitoring system (CMS), will also be needed in order to ensure that the PTE is continuing to function properly. A corrective action plan will be needed for situations where a PTE is not functioning properly.

Revision under Consideration -- EPA is considering requiring routine stack tests, aligning stack test requirements to the 2009 guidance, revising approved methods, and including PTE testing requirements.

[23] https://www.epa.gov/sites/production/files/2013-09/documents/stacktesting_1.pdf

EPA is considering requiring annual stack tests and aligning stack test requirements with the 2009 guidance. This will ensure that SCVs are tested with the typical number of loaded chambers running simultaneously and will include sterilization phases past the initial vacuum. For methods, EPA is considering prohibiting the use of Method 25A for measuring low levels of EtO and allowing for the use of Method 320 as a replacement. EPA Method 25A determines total gaseous organic concentration, expressed as propane or in terms of carbon (essentially counts carbons), does not speciate the VOC or hydrocarbon by compound, and the detection limit is approximately 0.1 parts per million by volume (ppmv). Method 18 speciates or separates hydrocarbons, expressed as propane, and is appropriate to use when the pollutant is known. Method 320 provides lower detection limit for EtO. For oxidizers, EPA is considering a requirement for the baseline temperature to be established during the stack test, as opposed to being set to the recommended minimum temperature from the manufacturer. For PTEs, EPA is considering requiring an initial performance test to ensure that the capture system is functioning properly. EPA is also considering the following mechanisms to ensuring continuing compliance with PTE requirements:

- Annual validation test coupled with ongoing reporting of key parameter measurements to EPA
- CMS to measure air flow going into the APCD(s)

EPA is also considering prescribing a corrective action plan for situations where the PTE is not functioning properly.

Common Stack Continuous Emission Monitoring Compliance Alternative. Some facilities that have recently installed capture and control systems for their fugitive emissions have also elected to route either a portion of or all their EtO exhaust streams to a common stack. This setup presents an opportunity for streamlined compliance in the form of a facility continuously monitoring this exhaust stack in order to ensure that EtO emissions based on established operating conditions are not exceeded. If they are exceeded, then a corrective action plan would be implemented in order to bring the facility back into compliance. With this option in place, a facility has the potential to reduce costs by not having to conduct routine stack tests, though some costs would be incurred for monitoring systems and routine Relative Accuracy Test Audits (RATAs). Current estimates place the capital and annual costs for new EtO monitors at $210,000 and $53,000, respectively. EtO monitoring technology has improved greatly since the last technology review, with newer instruments achieving detection capabilities in the single parts per billion by volume (ppbv) range.

Revision under Consideration -- EPA is considering a compliance alternative for operators to route a portion of or all EtO exhaust streams to a common stack and monitor for direct EtO emissions.

The EPA is considering allowing for a facility to measure the EtO emission rate that is achieved while meeting the required removal efficiencies, and then prohibiting the facility from exceeding that value. Under this alternative, there would not be a need for routine stack tests, but EPA is considering requiring annual RATAs to ensure that the continuous emissions monitoring system (CEMS) and air flow CMS are functioning properly. EPA is also considering prescribing a corrective action plan for situations where the established threshold emission rate is exceeded.

Indoor air monitoring for area source facilities using 1 tpy or more of EtO. As previously mentioned, work practice standards such as LDAR and various operational and material changes are being considered for fugitive emissions from area source facilities, as opposed to capture and control requirements. EPA has the authority to set GACT standards in place of MACT standards for area source facilities. However, EPA recognizes that the quantity of fugitive emissions may change over time. Therefore, requirements for

continuous room air monitoring merit consideration. EPA can use this data to estimate any changes in fugitive emissions and determine whether subsequent changes to the rule are needed during the next review cycle. Approximately 25% of area source facilities conduct some type of EtO concentration monitoring, with 1 facility conducing EtO monitoring in room areas using Drager tube monitoring.

Revision under Consideration -- EPA is considering a requirement for monitoring the EtO concentration in room areas for area source facilities using 1 tpy or more of EtO.

Proximity. Many commercial EtO sterilization facilities are near residences, schools, and day cares (i.e., potentially sensitive receptors). Generally, the closer a facility is to a receptor, the higher the MIR will be, as the EtO will likely not have had enough time to adequately disperse. In 2019, Illinois put in place "setback" requirements for new sources (e.g., new sterilizers may not be constructed within a 10 – 15 miles of a park or school).[24] EPA used a similar approach in the past for area source dry cleaners that are co-located at residences (70 FR 75884). In that rule, EPA prohibited the use of perchloroethylene at new dry cleaners at a residence, and this requirement was promulgated under CAA 112(d)(6).

Revision under Consideration -- EPA is considering a requirement for new sources to be located some minimum distance away from the nearest receptor.

Based on results from EPA's preliminary risk assessment, there are no facilities with risks above 100-in-1 million where the nearest receptor is at least 1.5 miles away. Therefore, EPA is considering requiring that any new facilities be constructed at least 1.5 miles away from the nearest residence, school, or day care.

Summary of rule revisions under consideration. **Tables 11 and 12** below contain the current and potential revised standards for Major Source and Area Source EtO facilities, respectively.

[24] https://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=101-0022

Table 11: Potential Emission Reduction Strategies: Summary of Potential Changes for Major Source Facilities

	Potential Revised Standards		
Emissions sources	**Current Standards for Existing Facilities**	**Existing Facilities**	**New Facilities**
Sterilization chamber vent	99% control	<30 tpy: 99.9% control >30 tpy: 99.99% control	99.99% control
Aeration room vent	1 ppm maximum outlet concentration, or 99% control	99.9% control	99.9% control
Chamber exhaust vent	No control	<250 tpy: 99% control >250 tpy: 99.9% control	99.9% control
Fugitive Emissions from Indoor EtO Storage	No control	PTE and manifold to APCD capable of 90% control	PTE and manifold to APCD capable of 99.99% control
Fugitive Emissions from Outdoor EtO Storage	No control	Minimum flow rate and manifold to APCD capable of 99% control	Minimum flow rate and manifold to APCD capable of 99% control
Fugitive Emissions from EtO Dispensing	No control	PTE and manifold to APCD capable of 99% control	PTE and manifold to APCD capable of 99.99% control
Once-through Vacuum Pumps	No control	Use recirculating vacuum pump	Use recirculating vacuum pump
Fugitive Emissions from Pre-Aeration Handling of Sterilized Product	No control	PTE and manifold to APCD capable of 99.6% control	PTE and manifold to APCD capable of 99.99% control
Fugitive Emissions from Post-Aeration Handling of Sterilized Product	No control	PTE and manifold to APCD capable of 99.6% control	PTE and manifold to APCD capable of 99.99% control
Fugitive Emissions from Operation of Non-Oxidizer APCDs	No control	Manifold to APCD capable of 99% control	PTE and manifold to APCD capable of 99.1% control
Fugitive Emissions from Operation of Oxidizer APCDs	No control	LDAR program	LDAR program
Ethylene Glycol Storage Tanks	No control	Route emissions to wet scrubber or manifold to APCD capable of 99.99% control	Route emissions to wet scrubber or manifold to APCD capable of 99.99% control

Table 12: Potential Emission Reduction Strategies: Summary of Potential Changes for Area Source Facilities using 1 tpy or more

	Potential Revised Standards		
Emissions sources	**Current Standards for Existing Facilities**	**Existing Facilities**	**New Facilities**
Sterilization chamber vent	99% control	99.9% control + 99% control for facilities using less than 1 tpy	99.9% control + 99% control for facilities using less than 1 tpy
Aeration room vent	No control	99.6% control	99.6& control
Chamber exhaust vent	No control	99% control	99% control
Fugitive Emissions from Indoor EtO Storage	No control	Manifold to APCD capable of 63% control, or LDAR program	PTE and manifold to APCD capable of 99.99% control, or LDAR program
Fugitive Emissions from Outdoor EtO Storage	No control	(No facilities identified)	Minimum flow rate and manifold to APCD capable of 99% control, or LDAR program
Fugitive Emissions from EtO Dispensing	No control	PTE and manifold to APCD capable of 99% control, or LDAR program	PTE and manifold to APCD capable of 99.99% control, or LDAR program
Once-through Vacuum Pumps	No control	Use recirculating vacuum pump	Use recirculating vacuum pump
Fugitive Emissions from Pre-Aeration Handling of Sterilized Product	No control	PTE and manifold to APCD capable of 99.5% control, or operational and material changes	PTE and manifold to APCD capable of 99.99% control, or operational and material changes
Fugitive Emissions from Post-Aeration Handling of Sterilized Product	No control	PTE and manifold to APCD capable of 88% control, or material changes	PTE and manifold to APCD capable of 99.99% control, or material changes
Fugitive Emissions from Operation of Non-Oxidizer APCDs	No control	Manifold to APCD capable of 49% control, or LDAR program	PTE and manifold to APCD capable of 99.1% control, or LDAR program
Fugitive Emissions from Operation of Oxidizer APCDs	No control	LDAR program	LDAR program
Ethylene Glycol Storage Tanks	No control	Route emissions to wet scrubber	Route emissions to wet scrubber

2.4 Related Federal Rules

There are several federal rules related to commercial EtO sterilization, spanning various agencies:

- EPA, Office of Air and Radiation: 40 CFR Part 63, Subpart WWWWW
    - In addition to the commercial sterilization source category, the Hospital Sterilizers area source category also covers EtO sterilization. The NESHAP for the hospital sterilizers was developed under the Urban Air Toxics Strategy[25] and covers EtO used to sterilize medical equipment at all hospitals nationwide. The Hospital Sterilizers NESHAP was finalized in December 2007 (72 FR 22 73611). Hospital sterilizers are not covered under the commercial EtO sterilization source category (Subpart O).
- EPA, Office of Pesticide Programs: (see discussion of their EtO Draft Risk Assessment in Section 7.3)
- Food and Drug Administration (FDA)
    - FDA validates sterilization processes, based on the characteristics of a given device, in accordance with FDA-recognized standards.
    - Sterilization facilities follow FDA regulations in 21 CFR (Food and Drugs). FDA does not directly regulate EtO emissions to outdoor air.
    - FDA regulations point to voluntary consensus standards that describe how to develop the validation cycles for EtO, gamma and e-beam sterilization for medical devices. FDA defines quality management system requirements for medical devices and the acceptable EtO residual levels for sterilized products. The standards the FDA points to include ISO 11135:2014, ISO 10993-7:2008(R)2012, ISO 11137, and ISO 13485:2016.
    - For spice fumigation, requirements are prescribed within the Food Safety Modernization Act (FSMA) regulations at 21 CFR Part 117.
- Occupational Safety and Health Administration (OSHA): 29 CFR §1910.1047
    - These regulations, which were set in 1984, address permissible worker exposure limits to EtO within sterilization facilities. There are no immediate plans from OSHA to update these requirements.
- Department of Transportation: 49 CFR §173.323
    - The regulations deal with drums in which EtO is transported.

3. APPLICABLE SMALL ENTITY DEFINITIONS

The Regulatory Flexibility Act (RFA) defines small entities as including “small businesses,” “small governments,” and “small organizations” (5 USC 601). The regulatory revisions being considered by EPA for this rulemaking are expected to affect a variety of small businesses but would not affect any small governments or small organizations. The RFA references the definition of “small business” found in the Small Business Act, which authorizes the Small Business Administration to further define “small business” by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201. Of the 103 facilities that the EPA has identified within the EtO commercial sterilization source category, we have identified approximately 27 facilities owned by small businesses. At the parent company level, there are a total of 50 total parent companies, 23 of which are small parent companies.

The detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, is included in **Table 13**, below. The estimated number of small businesses within each NAICS code and the number of employees in those small businesses is shown.

[25] 64 FR 387065.

Table 13: Industry Sectors, Definitions & Number of Small Entities Potentially Affected by EPA's Upcoming Proposal

Name of Industry/Sector	2012 NAICS Code	SBA Size Standard for Small Business	Small Businesses	
			Number	Employees[26]
Men's and Boys' Cut and Sew Apparel Manufacturing	315220	750 employees	1	**30**
Printing Machinery and Equipment Manufacturing	333244	750 employees	**1**	**400**
Surgical and Medical Instrument Manufacturing	339112	1000 employees	**10**	**1,465**
Surgical Appliance and Supplies Manufacturing	339113	750 employees	**2**	**100**
Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	423450	200 employees	**3**	**198**
All Other Support Services	561990	$11 Million	**2**	**15**
HMO Medical Centers	621491	$35 Million	**1**	**265**
Medical Laboratories	621511	$32.5 Million	**1**	**13**
All Other Miscellaneous Ambulatory Health Care Services	621999	$15 Million	**2**	**141**

4. LIST OF SMALL ENTITY REPRESENTATIVES

EPA consulted with Advocacy to develop the list of small entity representatives (SERs) in **Table 14**. EPA issued a press release inviting self-nominations by affected small entities to serve as potential SERs. The press release directed interested small entities to a web page where they could indicate their interest in serving as a SER. EPA launched the website on December 6, 2019 and accepted self-nominations until December 20, 2019. In addition, EPA supplemented the self-nominations by reaching out to other small businesses to gauge interest in participating in the panel process as a SER. The small businesses represented vary in their annual usage of EtO, scale of operations, and the type of products sterilized (e.g., medical devices, spices). A few of the potential SERs also had expertise in EtO supply, international EtO sterilization standards, and emissions control technologies used within the industry. EPA sent Advocacy a Formal Notification with the suggested list of potential SERs on February 7, 2020 and Advocacy responded on March 5, 2020.

Table 14: List of Small Entity Representatives

Name	Affiliation
A.E. (Ted) May	Anderson Products (NC)
David G. Howe	Cosmed Group (RI)
Steve Walter	International Sterilization Laboratory (FL)
Karen Fitzpatrick	Midwest Sterilization Corporation (MO)
Gary Cranston	Professional Contract Sterilization, Inc. (MA)
Dennis Christensen	SVC, LLC (CA)

[26] Refers to the total number of employees across all small businesses within the commercial EtO sterilization source category for each NAICS code.

5. SUMMARY OF SMALL ENTITY OUTREACH

To identify the small entities within the source category, EPA used SBA's small business definitions to identify 27 facilities (out 103 facilities in the source category) that are owned by small businesses at the parent company level and that could be affected by this proposed rule.

Outreach to the full source category began in early 2019, when EPA met with the Ethylene Oxide Sterilization Association (EOSA), whose members include small businesses, and with whom EPA has since maintained regular contact. On March 18, 2019, EPA conducted an informational site visit to a small business facility in Virginia to learn more about the facility and its processes. Further site visits to facilities owned by small businesses were planned but not conducted due to the ongoing COVID-19 pandemic. In 2019, at least two EPA regional offices worked with facilities that are owned by small businesses to reduce their EtO emissions. In Region 2, a facility owned by a small business is re-testing one of its control systems to ensure that it is reducing EtO emissions in accordance with the current standards. In Region 7, a facility owned by a small business recently installed a wet scrubber system to control its CEV emissions. In addition, on December 9, 2019, EPA issued a Clean Air Act section 114 request that included four small businesses that own 11 EtO sterilization facilities.

EPA conducted the pre-Panel outreach meeting with the SERs via a Microsoft Teams Meeting/teleconference on June 11, 2020. To help SERs prepare for the meeting/teleconference, on May 28, 2020, EPA sent materials to each of the SERs via email. A list of the materials shared with the SERs during the pre-Panel outreach meeting is contained in Appendix A. For the June 11, 2020 pre-Panel outreach meeting with the SERs, EPA also invited representatives from the Office of Advocacy of the Small Business Administration and the Office of Information and Regulatory Affairs within the Office of Management and Budget. A total of six SERs participated in the meeting. EPA presented an overview of the SBREFA process, an explanation of the planned rulemaking, and technical background.

This pre-Panel outreach meeting was held to solicit feedback from the SERs on their suggestions for the upcoming rulemaking. EPA asked the SERs to provide written comments by June 25, 2020. Comments raised during the June 11, 2020 pre-Panel outreach meeting and written comments submitted by the SERs are summarized in section 6 of this document.

EPA conducted the Panel outreach meeting with the SERs via a Microsoft Teams Meeting/teleconference on December 10, 2020. To help SERs prepare for the meeting/teleconference, on November 25, 2020, EPA sent materials to each of the SERs via email. A list of the materials shared with the SERs during the Panel outreach meeting is contained in Appendix A. For the December 10, 2020 Panel outreach meeting with the SERs, EPA also invited representatives from the Office of Advocacy of the Small Business Administration and the Office of Information and Regulatory Affairs within the Office of Management and Budget. A total of three SERs participated in the meeting. EPA presented an overview of pertinent background information, the risk assessment, and requirements under consideration for the rulemaking.

This Panel outreach meeting was held to solicit feedback from the SERs on their suggestions for the upcoming rulemaking. EPA asked the SERs to provide written comments by December 24, 2020. Comments raised during the December 10, 2020 Panel outreach meeting and written comments submitted by the SERs are summarized in section 6 of this document.

6. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES

6.1 Summary of Oral Comments and Pre-Panel Meeting Discussions, June 11, 2020

The following is a summary of the oral comments from the Pre-Panel outreach meeting discussion from the potential SERs, made by phone.

- One SER asked about the control efficiency that EPA would require for CEV and whether EPA is considering a removal efficiency of 99.95 or 99.99%, as well as whether EPA is considering the technical feasibility of achieving such a limit.
- One SER noted that none of the control opportunities EPA mentioned in the discussion focus on the process itself. The industry and companies have announced process changes that would reduce EtO usage and that would reduce EtO emissions, and the SER asked if there a reason that those types of EtO usage and emission reductions have been excluded. One SER also expressed concern about how the proposed EtO rule might unintentionally impact process requirements.
- One SER asked whether EPA will be able to share the detailed control efficiency requirements at the next meeting (i.e., the Panel Outreach Meeting).
- One SER asked if EPA takes the control efficiency requirements into account when calculating the costs and impacts.

6.2 Summary of Written Comments Following the Pre-Panel Meeting, June 11, 2020

As part of the Pre-Panel Outreach Meeting, EPA prepared many questions to encourage feedback from the SERs. The input and feedback from SERs helped EPA to better understand the processes in the EtO commercial sterilization industry and to understand the practices of small businesses in the industry. EPA received written comments from one SER. A summary of the written comments from the SER to the questions are provided in **Table 15**. A copy of the comment submitted by the SER is included in Appendix B.

Table 15. Questions to Small Entity Representatives and Response[27]

Overarching Topics/Questions for Small Business
How do you anticipate the potential regulations would affect your business? For example, would this require the purchase of any unique equipment or the hiring of additional staff? • One SER noted this is difficult to answer without more information as to what the regulations will require. A general answer would be that we expect the regulations to have multiple effects. Increased regulations will require additional equipment, record keeping, administrative, maintenance, etc. responsibilities. All these responsibilities will add additional routine labor costs.
What rule flexibilities do you believe may reduce small entity burden? Can these flexibilities be structured in a way to better aid small entities in reducing potential burdens? Are there any flexibilities that would help your business, specifically? • One SER thought that a better question is what potential control strategies will be too taxing for small entities or for facilities of a certain size. For instance, his company a small

[27] Questions are in bold text, and SER responses are in bulleted paragraphs.

Overarching Topics/Questions for Small Business
entity, however, it can operate large scale facilities. Specifically controlling fugitive emissions from large warehouse style facilities can be unfeasible from a technical standpoint as well as an economic standpoint.
Do you anticipate any significant issues or circumstances not addressed in the materials provided? • Yes, the control of fugitive air from large sterilizers is something that is not always feasible from a technical standpoint and even less feasible from an economic standpoint.
If you serve a niche market or are in a unique geographical location, do you anticipate any specific burdens and/or issues resulting from the potential rulemaking? • [No SERs provided input.]
Do your answers to any of the above questions differ depending on the start date or stringency level of the standards? • One SER indicated that the start date will not change his answers, however, the stringency level will. We are not provided with enough information here for us to provide a more detailed answer. For example, increasing control efficiencies from 99% to 99.9% may seem like a small increase, however, can be a very complex process; increases in control efficiencies almost always require additional equipment and sometimes require you to replace the existing equipment all together. Certain performance efficiencies may also exceed certain technical and economical limits.
Do you believe that additional lead time would be necessary for you to comply with new standards? • Yes, once new regulations are written there will be an increased demand for the equipment, consultants, engineers, and everything else necessary to meet the new requirements. Companies with larger pocketbooks will be able to pay higher expedite fees for their orders causing the orders for smaller companies to get delayed and pushed back
Are there any sector-unique business or competitive issues that [EPA] should understand? Are there any business or competitive issues associated with your business, specifically? • Need more specific information or provide an example.
Are there any subcategories that you would recommend for your industry (e.g., product type, sterilizer size, EtO usage, etc.)? If so, please identify them and document the basis for your recommendation. • [No SERs provided input.]
Do you anticipate any unique legal, administrative, or record-keeping burdens associated with your compliance? • Yes, any additional equipment upgrades to meet new regulations will require maintenance, administrative, and record keeping increases which will all come with increased operating costs. Increased record keeping requirements alone will come with additional operating costs.
Number of employees (at each of your facilities and/or business wide)? • Approximately 75 employees at one facility and approximately 170 employees at another facility with approximately 50 of those employees working through a placement agency.
What is the relative capital and labor intensity of production at small facilities, e.g., are production costs primarily labor or capital? • Costs are a mix with the primary being capital for our facilities.
Profit or sales information, if you are willing to share (these data may be claimed as CBI). • [No SERs provided input.]
What are your business' plans? Include expansions, new facilities, expansion into new sterilization or fumigation methods, etc.? • Expansion plans are very difficult to determine without knowing what future regulations will require. However, one company currently has had difficulty meeting customer capacity requirements and has had to turn away many customers recently, potentially causing shortages of medical equipment. Some customers have even reported going out of business. So, if feasible, the company is willing to install additional sterilizers and or open future

Overarching Topics/Questions for Small Business
facilities to prevent medical device shortages. The SERs noted they must know what the new regulations will require so we know if it is feasible to continue expanding our operations.
Would the potential control strategies increase your labor costs? • Yes, any potential control strategies will require additional preventative maintenance, record keeping, and administrative costs which will increase our labor costs. It is not possible to give specific details until more details about the regulations are released, however, we estimate the control of fugitive emissions to pose the most significant labor and material costs potentially to a point where they are not economically feasible.
Are the potential control strategies technically feasible for your facilities? Are they economically feasible for small businesses in this industry? Might they impose more of a disadvantage to small businesses than larger ones? If so, what type of control options might be feasible for small businesses? • One SER noted that this question cannot be completely answered until they are given more information, such as the emissions control efficiency of each potential control strategy, etc. A lot of the Potential Control Strategies are still vague. For example, with "Reinstating CEV Control Requirement" you mention several options; the first one – venting emissions to an APCD – does not give an efficiency rating for the APCD. Implementing a CEV control requirement of 99% may be feasible, however, a control efficiency of 99.9% or more may become very challenging and may not be technically and economically feasible for our facilities. The next option of implementing a limit on the EtO concentration in the sterilizer before opening the chamber door does not define what that limit is. Certain limits may be economically and technically feasible and some may not. The third option of using interlocks on chambers not allowing them to open until a certain concentration is met does not define what this limit is. Certain limits may be economically and technically feasible and some may not. • So, it is difficult to say what exactly is technically and economically feasible for most of these options, including the option of "Increasing control device efficiencies and removal efficiencies" since we do not know the specifics of these efficiencies. The control strategy posing the most potential impacts is the control of fugitive emissions. Pollution control equipment is sized off of many factors, however, one primary factor is airflow ratings. If you are trying to send all the air in a facility to a piece of control equipment the size of this piece of equipment will have to be very substantial. Our facilities exhaust hundreds of thousands of cfm of air. The size of the pollution control equipment to handle this much air is not something that is technically or economically feasible for our facilities. Another factor to consider is the current control technology is not designed to handle such low concentrations of EtO as you would find in a warehouse. So, trying to capture this air with a piece of pollution control equipment would only yield minor results, if any. Some small businesses may not be able to weather the economic impacts of installing additional control equipment.
Would the potential control strategies interrupt operations at your facilities and/or reduce sales revenue? For example, would you have to shut down a facility to add controls or add time/steps to your process? • Yes, anytime a piece of emissions control equipment is added or modified the facility will have to shut down. This is because emissions streams would have to be turned off (meaning sterilization chambers/aeration rooms/etc. must finish processing and then be shut down) to connect these streams to the pieces of control equipment. The system must then be started back up and brought up to certain operating conditions, this process will vary depending on the type of equipment and the size of the equipment. Once the system is operating it will have to be validated to ensure all components are operating sufficiently and any issues are corrected. Once the system is operating sufficiently the emissions streams will have to be reactivated so the equipment performance can be determined. This entire process may take up to a few weeks. Our facilities operate 24 hours a day, 7 days a week, 365 days a year so any shut down in operations effects the number of medical products we can process each year.

Overarching Topics/Questions for Small Business
Do you currently conduct any work or operating practices (other than the use of an air pollution control device) that would have an impact on EtO emitted from your facilities? If yes, please explain. • Yes, we develop sterilization cycles to remove as much EtO as possible out of the products prior to ending the sterilization cycle.
Are there other regulations that have been issued since your business started that imposed impacts on your operations (e.g., OSHA rules, rules from other agencies that regulate chemicals like DHS, etc.)? How have small businesses dealt with past regulatory impacts? • OSHA has standards to what levels of EtO employees can be exposed to which have been modified since we have been in business. We have modified warehouse procedures, cycles, air flow, etc. to meet these standards.
Are there other potential control strategies that you are aware of that should be considered in a proposed rulemaking? • [No SERs provided input.]
Technical Topics/Questions for Small Business
ETO Drum Storage
Is there a standard size drum or cylinder that is typically used for commercial sterilization or fumigation at small businesses? • One SER stated that they use two types of drums, drums which sit on the scale (operating cylinders) and drums which the EtO ships in (shipping containers). The size of operating cylinders can vary; however, shipping containers are consistently 400 pounds for us and from what we have seen for other companies with multiple pallet sterilizers. Some much smaller sterilizers (room or table-top size) may use smaller sizes, however, we are not familiar with them.
What is the range of annual EtO usage at small businesses? • A SER stated small businesses can see a range of usage just as large businesses can. The EtO usage depends on the number of sterilizers and what types of sterilizer chambers used. Our facilities use more EtO than a lot of the facilities operated by larger businesses because we operate larger sterilization facilities.
Do your facilities typically conduct leak monitoring? What leak monitoring is conducted on drums and cylinders? What leak monitoring is conducted on lines and connections to the sterilizer/fumigation chamber? • Yes, at our facilities vacuum leak tests are performed back to the EtO storage room during routine production cycles. Vacuum leak tests are also performed anytime maintenance is performed on a piece of chamber equipment which could cause a leak. Extended vacuum leak tests are also performed quarterly in every chamber. Lines which are not included during these leak tests are visually inspected for leaks
Are there dedicated rooms for the storage of the drums/cylinders? • There are dedicated rooms at our facilities for EtO storage and distribution
Sterilizer Chamber
Are there any differences in the sterilizer chamber equipment in use at small businesses versus other companies? • There are different types of sterilizers, however, this is not business size dependent. Small and large sterilizers may use the same types of equipment, typically just different amounts of equipment and amounts of locations. Some small businesses have large scale facilities, just not very many employees or very many locations like the larger businesses.
Can you describe the vacuum cycles that are used at your facilities, including physical equipment utilized for the vacuum cycle? • Our facilities use liquid ring vacuum pumps as primary pumps and rotary positive displacement blowers for booster pumps. Our facilities use a large variety of cycles with vacuums levels from anywhere between slightly below atmospheric and 1.0 in. HgA. All cycles operate below atmospheric pressure.

Overarching Topics/Questions for Small Business
How many chambers are in EtO service at any given time? • One SERS asked what EPA is referring to as EtO service? At our facilities all our chambers can be running at any given time, however, they will be in various stages of the cycle. Some may be just starting a cycle, with others in a dwell period, other in wash phases, and others being unloaded.
Do any companies pressure test their sterilization chambers for leaks, and how often does this occur? Are any other leak tests performed? • Yes, at our facilities vacuum leak tests are performed back to the EtO storage room during routine production cycles. Vacuum and pressure leak tests are also performed anytime maintenance is performed on a piece of chamber equipment which could cause a leak. Extended vacuum and pressure leak tests are also performed quarterly in every chamber. Lines which are not included during these leak tests are visually inspected for leaks.
Aeration Room
Are there differences in the aeration equipment used at small business facilities? What type of aeration unit is most used, e.g., aeration room, aeration cell, aeration chamber? • Small businesses can see a range of anything that large businesses can. The usage depends on the number of sterilizers and what types of sterilization chambers they are using. As well as what type of aeration they were originally set up using as switching to a new form of aeration will have extensive technical impacts which may not be feasible because of their current building design and may not be economically feasible because they would have to shut down operations to modify the aeration cells.
Are there any instances where products are not immediately moved to aeration after sterilization? If so, please elaborate. • [No SERs provided input.]
Is the aeration unit monitored for pressure drop (or facial velocity) to verify the inflow of air? • Yes, the exhaust velocity of the aeration rooms is measured at our facilities
Do any small business use "accelerated degassing cells" for aeration? If so, please elaborate on how and why they are used. • One SERs asked for more information on EPA's definition of accelerated degassing cells.
Chamber Exhaust
Are chamber exhaust vents typically sent to a control device at small businesses, or is it more typical to vent to atmosphere? • This is independent of business size, and simply depends on the equipment the business uses, if it is feasible, and their preference. Our chamber exhaust goes to a control device at each of our facilities.
Is that control device also used to control other emission sources at the facility (e.g., sterilizer chamber vents or aeration room vents), or is the control device dedicated to the chamber exhaust? • At one facility it is and at another facility it isn't currently. We are working to install new equipment and then each facility will have the chamber exhaust going to a wet scrubber which also acts as a polishing system for already treated SCV emissions.
Warehouse Storage
Have small businesses typically conducted measurements on the residual EtO remaining in the sterilized product following aeration? • Medical device manufactures are responsible for following FDA guidelines and ensuring that products meet certain EtO residual limits before they reach the patient. Contract sterilizers cannot send product to laboratories for EtO residual analysis since they do not own the product. So, if a small business is the manufacturer of the product they are sterilizing then they may have, however, this is not a requirement since sterilizers do not always own the products and this is a responsibility of the manufacturers of the products.

Overarching Topics/Questions for Small Business

Work Area Air

Is the room air from the areas listed below at the facility sent to a control device?

- **Room air surrounding the ETO tanks:** No
- **Room air surrounding the sterilizer chambers:** No
- **If Aeration cells or Aeration chambers are used, room air surrounding these aeration units:** [No SERs provided input.]
- **Warehouse area:** Not at our facilities except that makeup air for aeration rooms comes from the warehouse and that air goes through the aeration room control device.
- **Other:** Only SCV, CEV, ARVs (including the air mentioned above) are currently sent to control devices at our facilities

During the unloading of material from the sterilization chambers, what is the typical concentration of EtO observed within the in work/room areas?

- [No SERs provided input.]

Do any companies have facilities with requirements to control these room air emissions?

- [No SERs provided input.]

What mechanisms are in place at your facilities to ensure that the areas in EtO service are under negative pressure, if applicable?

- [No SERs provided input.]

Control Equipment

Capital and annual costs for range of sizes, flowrates, and EtO concentrations.
Typical engineering and installation costs.
Parametric monitoring of controls and Parameter set points (pH, liquor level, temperature, pressure drop, etc.)

- There is not enough information listed here to provide adequate cost information. Costs for all of the listed equipment/services will vary greatly with different projects. The SERs noted they have many questions about and potentially think the cost information listed in Appendix D. Preliminary Draft Cost Estimates for Potential Control Strategies is fairly misleading. For example, you list various types of control equipment pricing without even stating all process specifications, loading rates, and performance efficiencies. You also do not provide a list of supporting equipment, preventative maintenance, recordkeeping, administration, installation, and other associated tasks/costs. These can range drastically and can sometimes cost more than the control devices themselves. For example, we recently installed a wet scrubber system at one facility. This wet scrubber controls a combined emissions stream coming from our other wet scrubber system and our chamber exhaust vent system. The cost for just this scrubbing equipment from the manufacturer was a certain amount, however, this was not the cost to make this system functional. The total cost of the system was approximately three times the cost of the scrubber alone. So just because a piece of control equipment costs a certain amount does not mean that is the total amount for the system to be completed.

Performance Testing and Monitoring

Is in-plant EtO concentration monitoring for room areas conducted, and what measurement techniques are used, e.g., gas chromatography (GC), lower explosive limit (LEL) monitors, etc.?

- **Is the air within the EtO storage area monitored for EtO concentration?**
  - Yes, gas chromatography, oxygen monitoring, and LEL monitoring are performed at our facilities
- **Is the room air surrounding the sterilizer chambers monitored for EtO concentration?**
  - Yes, gas chromatography and LEL monitoring are performed at our facilities
- **If Aeration cells or Aeration chambers are used, is the room air surrounding these aeration units monitored for EtO concentration?**
  - [No SERs provided input.]

Overarching Topics/Questions for Small Business
• **Are warehouse areas at small businesses typically monitored for EtO concentration?** o One SER stated that gas chromatography is performed at their facilities, however, they did not know if this is a standard practice for small businesses. • **Has any performance testing been conducted outside of Subpart O? (State, Local, CD, Vendor Guarantee)** o [No SERs provided input.]
Post-control EtO monitoring (measurement of stack EtO concentration using CEMs), what is the detection limit of the monitor, and capital and annual cost? • One SER noted they do not have one of these systems in place, however, they have been quoted approximately $150,000 for a CEMS system. This does not include labor, installation pieces, maintenance, sampling lines, and anything else necessary to make this system operational.

One SER submitted as an attachment to their comment a letter that focused on uncertainty in EtO science and risk assessment methods, which is summarized below.

Scientific Evidence on EtO Carcinogenicity

One SER stated that EPA should not use risk assessment results to develop regulations for the purpose of protecting public health without considering the strengths and weaknesses of the evidence implicating a pollutant as a risk driver.

The SER noted that the 2014 NATA concluded that EtO emissions from sterilization and chemical plants may cause elevated cancer risks in surrounding communities. These elevated cancer risks were the direct result of a 30-fold increase in EPA's modeled hypothetical cancer potency factor (published in 2016), which was used to estimate risk in the NATA, not any evidence of increased emissions or new scientific data showing EtO to be a more potent carcinogen. The SER noted that according to the 2014 National Emissions Inventory technical support document, emissions of EtO are down substantially from 2011. Moreover, the SER claimed that EPA's 2016 cancer potency estimate is based on the same worker studies, involving exposures spanning the period from 1938 to 1986, used to support previous, less stringent EtO cancer potency factors.

The SER claimed that, although the 2016 cancer potency factor for EtO is one of the highest inhalation unit risk factors published, EPA concluded that the human evidence of EtO carcinogenicity was strong but inconclusive, while the International Agency for Research on Cancer determined that the human evidence was limited.

Additionally, the SER noted that the Texas Commission on Environmental Quality (TCEQ) derived a cancer potency factor that was a small fraction of EPA's (i.e., 0.00046 or <0.05%). The TCEQ's cancer potency factor equates to an acceptable ambient EtO concentration of 0.043 µg/m^3 vs EPA's acceptable concentration of 0.0002 µg/m^3, which is 100-times more stringent (i.e., lower). The SER stated that the reason for this difference is that EPA only included one study conducted by the National Institute for Occupational Health and Safety (NIOSH) in their model. This study had a positive cancer risk, leading to an overstated cancer risk when compared to the TCEQ assessment that included two studies. According to research noted by the SER, by not including the second study, EPA underestimated EtO exposure concentrations for all years prior to 1978 (by a factor of more than 10-fold), which had the effect of overestimating EtO cancer potency. The SER recommended that EPA's exclusive reliance on the NIOSH cohort to estimate EtO cancer potency and risk be re-examined.

The SER noted that one justification frequently used as a reason for excluding the results of other studies in estimating the cancer potency of EtO was small cohort size. However, instead of excluding small studies from consideration, the SER claimed that meta-analysis could have been used to critically evaluate and statistically combine the results of both positive and negative results from large and small

studies. The SER claimed that this would have increased the numbers of observations, boosted statistical power, and improved the estimates of the effect size. The SER also claimed that one meta-analysis of studies of lymphohematopoietic and breast cancer risk in workers exposed to EtO demonstrated that studies published after the year 2000 reported lower relative risks for lymphohematopoietic cancer than those published in the 1980s and 1990s.

Impracticality of Using the 2016 EtO Cancer Potency Factor to Identify Unsafe Levels in Air

The SER stated that regulation of EtO emissions needs to consider the context of the world in which we live. Given that EtO is emitted from a wide variety of sources other than sterilization plants, the SER claimed that further regulation of emissions from sterilization facilities is unlikely to substantially affect existing background EtO concentrations that are already higher than EPA-sanctioned "acceptable" levels in areas distant from the sterilization facilities. Therefore, the SER claimed that it is not possible to set standards for EtO emissions from sterilization plants that will reduce ambient concentrations to the levels dictated by the 2016 cancer potency factor. Even if such a standard could be set, the SER claimed that it would be impossible to confirm that risks had been reduced to an acceptable level because there are not currently available EtO analytical methods capable of measuring levels ranging from 0.0002 to 0.02 µg/m^3.

6.3 Summary of Oral Comments and Panel Meeting Discussion, December 10, 2020

The following is a summary of the oral comments from the Panel Meeting discussion from the SERs.

- One SER expressed concern regarding EPA's plan to remove the 1 ppmv EtO alternative standard for ARVs. The SER asked if EPA was considering use of a maximum outlet EtO concentration in the rule in addition to the percent reduction as a potential reduction strategy.
- One SER asked for additional clarification on how EPA is defining PTE (i.e., is the PTE definition being considered related to specific criteria in EPA Method 204), and also questioned whether the facilities in EPA's analysis had fully implemented the PTE. The SER further noted that the PTE capture and control efficiencies may be theoretical if not successfully demonstrated. One SER noted that several of the top performers for PTE that EPA used as the basis for their MACT floor have not yet implemented, or have just begun implementing, PTE technology at their plants. The SER further stated that performance of this technology in EtO removal is theoretical and should not be used when determining the MACT floor.
- One SER requested clarification for the ethylene glycol storage tank requirement, specifically whether EPA is referring to the wet scrubber reactor tanks or whether it is meant for ethylene glycol storage tanks.
- SERs asked if EPA may consider the size of the company in terms of number of employees and revenue as a basis for determining which facilities qualify as a [major] source. The SER noted that while their facility does emit a significant amount of EtO, because the small business company only has a few employees and not much revenue compared to other major sources at large companies, it would be difficult for the small business facility to comply with the major source regulations that EPA is considering.
- Multiple SERs noted that the timeframe for compliance with the rule is an issue for small businesses. They noted that the lead time for a new APCD is 1 year, completing the contract and installing is 2 years, and takes the entire 3-year compliance time. SERs asked if they could be granted an extension to comply with these regulations since it would take them longer than the normal 3 years to implement the new technology and methods required by the rulemaking, and if so, could this extension request be submitted in advance. SERs stated that EPA should make allowances for small business on the compliance date and grant an extra year.
- SERs stated that EPA costs are underestimated, as feasibility quotes are generally low. The cost to implement this rule could have a significant impact on small businesses.
- One SER noted that the definition of "post-aeration product" is unclear and noted concerns for control of fugitive emissions for post-aeration product handling. At some facilities, product moves

from the aeration room and is directly shipped to an offsite distribution center (i.e., an offsite warehouse storage center). At some facilities, the warehouse storage and distribution center is onsite and is part of the facility. Because their facility has an onsite warehouse storage and distribution center, the product in their warehouse would be classified as post-aeration and therefore be subject to the rule, as opposed to other facilities that send their products to an offsite warehouse for storage that would not fall under the rule. The SER believed that this discrepancy puts them at a disadvantage to other facilities that do not do their own onsite warehouse storage and distribution. The SER further stated that the total enclosure of the warehouse area is very expensive and questioned whether EPA would include an approach where a facility could demonstrate that the EtO concentration is not significant, through testing, monitoring, or other approach.
    - The SER stated that they currently use a gas chromatograph to monitor the EtO concentration in their holding room before it is moved to their warehouse for storage.
- One SER asked whether EPA considers the economic impacts of the rule. SERs reiterated that the top performer facilities used for the MACT floor analysis are very large companies/businesses, have very different revenues (i.e., billions of dollars in revenue) compared to small businesses, and operate in a completely different manner than small businesses.

6.4 Summary of Written Comments following the Panel Meeting, December 10, 2020

EPA received a written comment from one SER following the Panel Meeting. The following is a summary of the written comments submitted by the SER. A copy of the comments submitted is included in Appendix B.

- **The current emissions standard for Aeration Room Vents requires a 99% reduction OR a maximum outlet concentration of 1 ppm. EPA is considering increasing the required ARV removal efficiency from 99% to 99.9% and removing the existing 1 ppmv maximum outlet concentration.**
    - The SER expressed concern about removing the optional outlet EtO concentration. Currently the SER, and presumably other sterilizers, are working to reduce the amount of EtO remaining in pallets/products as much as technically feasible before these pallets enter the aeration rooms. This is being done by revalidating sterilization cycles and removing as much EtO as possible from [product and] pallets while they are still inside the sterilization chambers. The SER noted that these modifications can take a significant amount of time to complete considering all of the FDA regulations that must be met. These cycle changes reduce the overall emissions being released from [products and] pallets while they are being transferred from the sterilization chambers to the aeration rooms and, in turn, the amount of EtO left in the [product and] pallets once the aeration phase is complete, which reduces the overall facility emissions. These new sterilization cycles will cause lower concentrations of EtO to be released during the aeration cycles and sent through the Aeration Room Vents to APCDs. The APCDs available for EtO lose a considerable amount of efficiency as the amount of EtO being sent through them is lowered. So, new cycles with reduced overall facility emissions will also reduce the emissions reduction efficiency achieved by the APCDs controlling the exhaust streams coming from the Aeration Room Vents, even though overall emissions are less. Therefore, the SER stated, the implementation of a more stringent control efficiency requirement with the loss of an optional maximum outlet concentration may have a counter effect since this would be more challenging to comply with without leaving more EtO in the [product and] pallets after the sterilization cycle is complete.
- **Process and cycle changes**
    - The SER noted that they and other sterilizers are working to revalidate sterilization cycles to remove as much EtO as feasible from the pallets [and products] prior to the aeration

phase. Revalidation takes a significant amount of time; however, it is a very effective way of reducing fugitive emissions in many areas of sterilization facilities. If more time were allotted before releasing regulations targeting fugitives, the SER believed the EPA would be able to better understand how these efforts are already reducing fugitive emissions and to what extent any further emissions reduction strategies are necessary.

- **Potential emission reduction strategies for different areas within a facility where there is a potential for fugitive emissions to occur**
    - The SER noted that while looking at control strategies for fugitive emissions, the EPA is using the current "Best Performers" to calculate what removal efficiency should be considered for any upcoming regulations. However, the SER further stated that most of these facilities are not currently meeting these requirements and that many of the facilities listed as the best or top performers have only submitted permit applications and have not successfully implemented these fugitive control strategies or PTEs for the referenced areas. The SER is concerned as it is still unknown if these facilities will be successful with implementing these control solutions. The SER stated that the new rule limits need to be achievable. The SER also noted the economic impact of implementing PTEs must be considered, as the top performers are all larger medical device companies with revenue streams significantly higher than that of small businesses, and if these larger companies have not successfully implemented these solutions then it may be something unfeasible for smaller businesses to implement.
- **Fugitive emissions of EtO from Shipping and Warehouse areas for post-aeration products**
    - The SER stated that some sterilization facilities ship products to distribution centers [for storage] immediately after aeration while other facilities act as distribution centers themselves [with onsite product storage and warehouse areas]. The concern was that facilities acting as distribution centers [with onsite storage and warehouse areas] will have larger post-aeration warehouse areas, which will make it more technically and economically challenging to implement PTEs, especially if these facilities are small businesses. The SER suggested putting these facilities into another subcategory with regards to post-aeration emissions. Otherwise, sterilizers with distribution centers [and onsite storage and warehouse areas] will in effect be held to higher standards than those who only hold pallets [and products] for a short period of time and send them to distribution [and storage] centers elsewhere.
- **The timeline of the rulemaking on post-aeration fugitive emissions**
    - The commenter recommended that the EPA postpone implementing emissions reductions strategies around post-aeration fugitive emissions and PTEs until these emissions can be further quantified, the feasibility of these strategies can be further defined, and other emission reduction strategies can be implemented and considered.

7. PANEL FINDINGS AND DISCUSSIONS

7.1 Number and Types of Entities Affected

For a complete description of the small entities to which the proposed rule may apply, see Sections 4 and 5 of this document.

7.2 Potential Reporting, Recordkeeping, and Compliance Requirements

The reporting, recordkeeping, and compliance requirements that are under consideration are described in section 2.3.6 of this document.

7.3 Related Federal Rules

See Section 2.4 of this document for more discussion of related federal rules. On December 7, 2020, EPA's Office of Pesticide Programs (OPP) provided a plain language briefing on their EtO Draft Risk Assessment (DRA) to SBA's Office of Advocacy, OMB/OIRA, and the SERs to explain the scope of the DRA, the issues the DRA covers, and the scope of OPP's authority to manage identified risks. The purpose of the meeting was to promote understanding of EPA's position on the division/cooperation between NESHAP rules for ambient air and the Federal Insecticide Fungicide, and Rodenticide Act rules for ambient air relating to occupational exposure. The main area where there could be potential overlap between OAQPS and OPP activities related to EtO is where tolerances are set for residual EtO on food products, which may impact the emissions profile of spice sterilizers. However, EPA has not identified any spice sterilizers that are owned or operated by small businesses. Other OPP activities, including EtO product labeling which includes worker protection measures, are separate and distinct from OAQPS activities. Approval of EtO for use on specific medical devices is under FDA jurisdiction. As OAQPS and OPP work on their respective projects, they will coordinate their requirements so that the industry is not subject to duplicative standards.

EPA has met with the U.S. Food and Drug Administration on a regular basis since the beginning of the EtO commercial sterilization technology review project. FDA regulations establish the procedures that facilities must use to verify each sterilization cycle/process. The FDA regulations point to multiple voluntary consensus standards that describe how facilities are to develop validation cycles for EtO sterilization for medical devices, the quality management system requirements for medical devices, and set acceptable EtO residuals for a sterilized product. The FDA standards related to EtO commercial sterilization are as follows:

- ISO 11135:2014, *ANSI/AAMI/ISO 11135:2014, Sterilization of Healthcare Products - Ethylene Oxide —Requirements for the development, validation and routine control of a sterilization process for medical devices*.
- ISO 13485:2016, *ANSI/AAMI/ISO 13485:2016, Medical Devices – Quality Management Systems – Requirements for regulatory purposes.*
- ISO 10993:2008(R)2012, *ANSI/AAMI/ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals*.

Medical product facilities develop and validate their sterilization cycles using these ISO methods. The validation cycle is set based on the vacuum, temperature, and pressure of the cycle, and changing these requires the medical product manufacturer to redo the cycle validation. Validating and revalidating a sterilization cycle may take several months. There are efforts at FDA and in the industry to reduce the quantity of EtO used in sterilization cycles. The FDA launched a program to encourage innovation and development of novel sterilization methods, including identifying new sterilization methods and technologies that do not use EtO, and reducing EtO emissions. The FDA also launched the Ethylene Oxide Sterilization Master File Pilot Program.

Reducing the initial charge of EtO to the sterilizer chambers also reduces EtO emitted to the atmosphere, the amount of residual EtO that remains in the sterilized product and reduces the operator exposure to EtO at the facility. Use of less EtO charged to the sterilizer chambers may also reduce the needed aeration time and fugitive emissions released from the sterilized product post-aeration. Making changes to a validated sterilization cycle must involve both the medical product owner and the contract commercial sterilizer. (A contract sterilizer typically conducts sterilization for manufacturers of medical products. Contract sterilizers do not control the sterilization cycle, or validation cycle, as the product manufacturer

sets the validation cycle, the contract sterilizer simply implements and follows the medical product customer's validation cycles.) To make changes to sterilization cycles, the manufacturer or the contract sterilizer must revalidate the sterilization cycle and file with the FDA.

7.4 Regulatory Flexibility Alternatives

The Panel recommends the additional activities listed below to determine if they are appropriate to provide flexibility to lessen impacts to small entities. Some of the recommended flexibilities may lessen impacts to all entities, not just small entities.

Regulatory Options

Increased removal efficiencies for SCVs and ARVs. EPA is considering increasing the removal efficiency requirements for existing SCV and ARV standards, removing the 1 ppmv alternative standard for ARV control, requiring control of ARV emissions at area source facilities using 1 tpy or more of EtO, and requiring control of SCV emissions at facilities using less than 1 tpy of EtO.

SER comment: See sections 6.2 and 6.4

Based upon SER comments related to increased removal efficiencies, the Panel recommends that EPA review the technical and economic feasibility of the efficiencies under consideration. One SER stated that increasing control efficiencies from 99% to 99.9% may seem like a small increase, however, it can be a very complex process. Increases in control efficiencies almost always require additional equipment and sometimes require facilities to replace the existing equipment all together. The SER also stated that certain performance efficiencies may also exceed certain technical and economical limits.

Based upon SER comments related to removal of the 1 ppmv alternative standard for ARV, the Panel recommends that EPA should consider an outlet EtO concentration that correlates with the increased removal efficiency standards. This would likely include requirements to ensure that the volumetric flow rate does not exceed that which was established during the stack test. EPA recognizes that a removal efficiency standard is more difficult to achieve when starting from a lower EtO concentration. Furthermore, the EPA does not wish to disincentivize process changes that would result in lower EtO use and lower EtO concentrations being observed downstream.

The Panel recommends that EPA take comment on SCV and ARV control and removal efficiencies. The EPA should also request comments on what specific pieces of information EPA would need to set and justify concentration compliance alternatives. For example, if EPA offers a concentration compliance alternative to a subcategory of facilities, it may need facility-specific information on EtO concentration and flowrate from performance test data, along with ongoing EtO concentration and flowrate measurements. The Panel also recommends that EPA explore regulatory alternatives that will incentivize lower EtO usage, as well as potential subcategories that would minimize cost burden to small businesses while also minimizing risk to nearby populations as appropriate.

Control requirements for fugitive emissions. EPA is considering a requirement for capture and control of fugitive emissions from several emission sources, work practice alternatives, and/or monitoring, as follows:

- Indoor EtO storage capture and control, as well as an LDAR alternative for area sources facilities using 1 tpy or more of EtO.
- Outdoor EtO storage, partial capture and control.

- EtO dispensing capture and control, with an LDAR alternative for area source facilities using 1 tpy or more of EtO.
- Pre-aeration handling of sterilized products capture and control, with work practice alternatives for area source facilities using 1 tpy or more of EtO.
- Post-aeration handling of sterilized products capture and control, with work practice alternatives for area source facilities using 1 tpy or more of EtO.
- Operation of non-oxidizer APCDs capture and control, with an LDAR alternative for area source facilities using 1 tpy or more of EtO.
- Operation of oxidizer APCDs, with an LDAR requirement.
- Room area monitoring for EtO concentration, for area source facilities using 1 tpy or more of EtO.

SER comment: See section 6.4

The Panel appreciates the SER concern that some facilities may not have yet demonstrated compliance with the emission standards in their permits or permit applications. Based on current information and data, only the BD facilities in Georgia are still in the permit application phase, with the Covington facility demonstrating success in capturing emissions from post-aeration handling of sterilized material. All other facilities have either reported room air capture or have it listed in their permit. If it is reported that a facility is routing the air from a room area to an APCD, or if that air is cascaded to some other room where the air is routed to an APCD, then it is included as part of the MACT floor calculations. For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available, however EPA continues to collect and review performance test data that demonstrate the control efficiencies achieved. If the capture efficiency is not explicitly stated, then EPA assumes it to be 100%, unless there is information to suggest otherwise. This assumption is a placeholder, and EPA will work to confirm capture efficiencies. At this time, EPA Method 204 is the only method that ensures 100% capture efficiency. There are at least two facilities similar in size to the SER's major source facilities, including Medline (Waukegan, IL) and Sterigenics (Atlanta, GA), that retrofit capture at their facility and have successfully demonstrated compliance with Method 204. However, the Panel recommends that EPA continue to observe those facilities that have either implemented or are in the process of implementing Method 204 to identify any potential issues with compliance, as well as potential remedies. The Panel recommends that EPA confirm the status of facilities with respect to whether they have implemented or are implementing capture and control for fugitive emissions from room areas.

Based upon SER comments related to sterilization cycle changes, the Panel recommends the EPA consider regulatory alternatives based on process changes that lower EtO concentration in downstream, post-sterilization and post-aeration areas. Based on CAA section 112(d), the EPA can sub-categorize based on class, size, or type. Changing certain factors during the sterilization process (e.g., EtO dose, number of gas washes, aeration time, etc.) can impact downstream air EtO concentrations. Given the wide range of possible combinations of these elements, however, we have yet to identify a clear basis to sub-categorize based on class or type. One approach for determining whether a facility is in a certain class or type of sterilization could be to look at the downstream room air EtO concentration. Therefore, the Panel recommends EPA investigate whether subcategories based on class, size, or type could be developed based on observed differences in downstream room air concentration. There may be potential issues due to a lack of corrective actions available (the process parameters mentioned are dictated by FDA-validated cycles), and safeguards would need to be put in place to ensure that a facility does not artificially dilute the air to meet the standard if it is determined to be a viable option.

Based upon SER comments, the Panel recommends that EPA review the post-aeration fugitive areas for shipping and warehouse and clearly define the activities, per the EPA's obligation to set standards for

unregulated emissions at major sources. *LEAN v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020). EPA should also clearly explain future intended actions related to reduction of EtO fugitive emissions at offsite shipping and warehouse facilities. Based on section 112(d)(3), the EPA can sub-categorize based on class, size, or type. The EPA notes that with the way the source category is currently defined, if there is no active EtO sterilization taking place at a facility, then it is not part of the source category. The EPA does recognize, however, that this could create a potential gap in EtO regulations. For example, a shipping and warehouse or distribution center in Covington, GA was recently estimated to have EtO emissions of 5,600 lb per year[28]. Currently, EPA does not have enough information to justify expanding the source category to include these offsite distribution centers not located at a sterilization facility. The EPA also notes that as part of an upcoming information collection request, sterilization facilities will be asked to report where their sterilized product is being sent and how long it stays at those facilities. The Panel also recommends that EPA explore regulatory alternatives that will incentivize lower EtO usage, as well as potential subcategories that would minimize cost burden to small businesses while also minimizing risk to nearby populations as appropriate.

The Panel also recommends that EPA take comment on GACT standards for area sources and that EPA consider GACT standards for area sources to the maximum extent possible.

Once-through vacuum pump water. EPA is considering a requirement for use of recirculating vacuum pumps.

SER comment: No comments were received.

Ethylene glycol ST. EPA is considering a control requirement for emissions from the EG STs.

SER comment: No comments were received.

Stack testing and PTE requirements. EPA is considering requiring routine stack tests, aligning stack test requirements to the 2009 guidance, revising approved methods, and including PTE testing requirements.

SER comment: No comments were received.

Common Stack Continuous Monitoring Compliance Alternative. EPA is considering a compliance alternative for operators to route a portion of or all EtO exhaust streams to a common stack and monitor for direct EtO emissions.

SER comment: No comments were received.

The Panel recommends proposing this compliance alternative, with specific EtO emission concentration limits. The Panel further recommends EPA specifically solicit comments on what provisions of the current rule and proposed rule should be covered by this alternative and how reporting and recordkeeping can be streamlined. EPA should solicit comment on the appropriate way to set an EtO emission concentration

[28] For context, controls are required for sterilizers once they start using more than 1 tpy of EtO.

limit, and whether the concentration limit should be set as a site-specific limit based on the particular circumstances of a facility. EPA should also solicit comments on the technical and economic factors for a firm adopting this alternative.

Proximity. EPA is considering a requirement for new sources to be located some minimum distance (e.g., at least 1.5 miles) away from the nearest receptor.

SER comment: No comments were received.

The Panel recommends that EPA take comment on proximity requirements for new sources as described in this report. The Panel also recommends that EPA request comment on whether a proximity restriction could or should substitute or supplement emission control requirements for new or existing sources elsewhere in the proposal.

Other Agency Rules

OSHA standards.

SER comments: See section 6.2 of this document. OSHA has standards as to what levels of EtO employees can be exposed to, which have been modified since the SER has been in business. The SER stated that they have modified warehouse procedures, cycles, air flow, and other parameters in order to meet these standards.

Based upon SER comments, the Panel recommends that EPA should consider changes that a facility has made to comply with OSHA standards when proposing updates to the rule. EPA is not currently considering any changes made to OSHA requirements. In general, to comply with OSHA standards to reduce employee exposures to pollutants, facility efforts may impact the quantity of air flow and the pollutant concentration. To comply with OSHA requirements, air flow to and from a room area is typically increased to dilute the pollutant concentration within the room area and to remove the pollutant from the area. With any facility modifications taken to comply with OSHA requirements, facilities may have increased the volume of air flow from a room area while at the same time decreased the pollutant concentration. Larger air volumes with low pollutant concentrations tend to be more expensive/complicated to control, because the design flowrate for an add-on APCD may be larger, potentially increasing the capital cost, and it can be more difficult to reduce pollutants with low concentration.

Compliance Timeframe

Compliance timeframe.

SER comments: See section 6.2 of this document. SERs noted that once updated regulations are final, there will be an increased demand for the equipment, consultants, engineers, and everything else necessary to meet the new requirements. Companies with larger revenue streams will be able to pay higher expedited fees for their orders, causing the orders for smaller companies to get delayed and pushed back. Advocacy notes that this concern is similar to SER concerns expressed in previous SBAR panels.

The maximum compliance timeline is dictated by statute under section 112(i)(3) of the CAA, which requires existing sources to comply as expeditiously as practicable but no later than 3 years after the effective date (i.e., after the promulgation date). In addition, section 112(i)(3) allows EPA or a delegated State to issue a permit that grants an extension for existing sources up to 1 additional year to comply if needed to install controls. The Panel recommends that EPA highlight the availability of a 1-year extension of the compliance date if the source demonstrates to the state permitting authority or EPA that an extension is necessary for the installation of controls (section 112(i)(3)(B) of the CAA). The Panel recommends that, should a 1-year extension under 112(i)(3) be granted, EPA also take comment on how to implement other available statutory compliance flexibilities that may be necessary to maintain adequate sterilization capacity to protect public health.

Cost Information and Impacts to the Facility Operation to Implement the Updated Rule

Cost analysis and impacts to facility operation.

SER comments: See section 6.2, p. 29-31 of this document. The SERs noted that increased regulations will require additional equipment, recordkeeping, administrative requirements, maintenance, and other responsibilities, which will increase operating and labor costs (see section 6.2, p. 29 and 30 of this document). It is not possible to give specific details until more information about the regulations is released; however, one SER estimates the control of fugitive emissions to pose the most significant labor and material costs potentially to a point where they are not economically feasible (see section 6.2, p. 30 of this document).

The SER also specifically noted that controlling fugitive emissions from large warehouse style facilities can be unfeasible from a technical standpoint as well as an economic standpoint (see section 6.2, p. 29 of this document). Pollution control equipment is sized off many factors; however, one primary factor is airflow ratings. If one attempts to send all the air in a facility to a piece of control equipment, the size of this piece of control equipment will have to be very substantial. The SER stated that their facilities exhaust hundreds of thousands of cubic feet per minute of air and that the size of the pollution control equipment to handle this much air is not something that is technically or economically feasible for their facilities. They also stated that another factor to consider is that the current control technology is not designed to handle such low concentrations of ethylene oxide as found in a warehouse and that trying to capture this air with a piece of pollution control equipment would only yield minor results, if any. Some small businesses may not be able to weather the economic impacts of installing additional control equipment. (see section 6.2, p. 31 of this document)

The SER noted that anytime a piece of emissions control equipment is added or modified, the facility will have to shut down. This is because emissions streams would have to be turned off (meaning sterilization chambers, aeration rooms, etc. must finish processing and then be shut down) to connect these streams to the pieces of control equipment. The system must then be started back up and brought up to certain operating conditions. This process will vary depending on the type of equipment and the size of the equipment. Once the system is operating, it will have to be validated to ensure all components are operating sufficiently and any issues are corrected. Once the system is operating sufficiently, the emissions streams will have to be reactivated so the equipment performance can be determined. This entire process may take up to a few weeks. Some facilities operate 24 hours a day, 7 days a week, 365 days a year so any shut down in operations affects the number of medical products those facilities can process (see section 6.2, p. 31 of this document).

The Panel recommends EPA consult with FDA to understand the impact to the supply of medical equipment that could occur if all EtO sterilization facilities are concurrently making significant upgrades to their air pollution control techniques and will potentially have simultaneous periods of shutdown.

7.5 Summary of Panel Recommendations

1. The Panel recommends that EPA review the technical and economic feasibility of the increased removal efficiencies under consideration.

2. The Panel recommends that EPA should consider an outlet EtO concentration that correlates with the increased removal efficiency standards.

3. The Panel recommends that EPA take comment on SCV and ARV control and removal efficiencies.

4. The Panel recommends that EPA take comment on what specific pieces of information EPA would need to set and justify concentration compliance alternatives.

5. The Panel recommends that EPA explore regulatory alternatives that will incentivize lower EtO usage, as well as potential subcategories that would minimize cost burden to small businesses while also minimizing risk to nearby populations as appropriate.

6. The Panel recommends that EPA continue to observe those facilities that have either implemented or are in the process of implementing Method 204 to identify any potential issues with compliance, as well as potential remedies.

7. The Panel recommends that EPA confirm the status of facilities with respect to whether they have implemented or are implementing capture and control for fugitive emissions from room areas.

8. The Panel recommends the EPA consider regulatory alternatives based on process changes that lower EtO concentration in downstream, post-sterilization and post-aeration areas.

9. The Panel recommends EPA investigate whether subcategories based on class, size, or type could be developed based on observed differences in downstream room air concentration.

10. The Panel recommends that EPA review the post-aeration fugitive areas for shipping and warehouse and clearly define the activities, per the EPA's obligation to set standards for unregulated emissions at major sources. *LEAN v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020).

11. The Panel recommends that EPA clearly explain future intended actions related to reduction of EtO fugitive emissions at offsite shipping and warehouse facilities.

12. The Panel recommends that EPA take comment on GACT standards for area sources and that EPA consider GACT standards for area sources to the maximum extent possible.

13. The Panel recommends EPA propose a compliance alternative for operators to route a portion of or all EtO exhaust streams to a common stack and monitor for direct EtO emissions, with specific EtO emission concentration limits. The Panel further recommends:

    a. EPA specifically solicit comments on what provisions of the current rule and proposed rule should be covered by this alternative and how reporting and recordkeeping can be streamlined.

b. EPA should solicit comment on the appropriate way to set an EtO emission concentration limit, and whether the concentration limit should be set as a site-specific limit based on the particular circumstances of a facility.

c. EPA should also solicit comments on the technical and economic factors for a firm adopting this alternative.

14. The Panel recommends that EPA take comment on proximity requirements for new sources as described in this report.

15. The Panel recommends that EPA request comment on whether a proximity restriction could or should substitute or supplement emission control requirements for new or existing sources elsewhere in the proposal.

16. The Panel recommends that EPA should consider changes that a facility has made to comply with OSHA standards when proposing updates to the rule.

17. The Panel recommends that EPA highlight the availability of a 1 year extension of the compliance date if the source demonstrates to the state permitting authority or EPA that an extension is necessary for the installation of controls (section 112(i)(3)(B) of the CAA).

18. The Panel recommends that, should a 1-year extension under 112(i)(3) be granted, EPA also take comment on how to implement other available statutory compliance flexibilities that may be necessary to maintain adequate sterilization capacity to protect public health.

19. The Panel recommends EPA consult with FDA to understand the impact to the supply of medical equipment that could occur if all EtO sterilization facilities are concurrently making significant upgrades to their air pollution control techniques and will potentially have simultaneous periods of shutdown.

APPENDIX A: Materials EPA shared with Small Entity Representatives

Appendix A1. Materials EPA shared with potential SERs before the Pre-Panel Meeting, June 11, 2020

- Agenda for Pre-Panel Outreach Meeting, June 11, 2020
- Power Point Presentation: An Overview of the Small Business Advocacy Review Panel Process
- Power Point Presentation: Rulemaking for Ethylene Oxide Commercial Sterilization Small Business Advocacy (SBA) Review Panel
- SBAR Pre-Panel Appendices including Objectives and Topics/Questions for Small Business, Summary of the Current NESHAP, Fact Sheets, and Preliminary Draft Cost Estimates for Potential Control Strategies

Appendix A2. Materials EPA shared with SERs before the Panel Meeting, December 10, 2020

- Agenda for Panel Outreach Meeting, December 10, 2020
- Power Point Presentation: Rulemaking for Ethylene Oxide Commercial Sterilization Small Business Advocacy (SBA) Review Panel
- SBAR Panel Appendices including Food and Drug Administration, and Preliminary demographic indices of census block groups within 5 kilometers of an ethylene oxide facility and cancer risks greater than 100-in-1-million
- Midwest Sterilization Corporation Prepared Written Comments from the Pre-Panel Meeting

APPENDIX B: Written Comments Submitted by Small Entity Representatives

Appendix B1. Written Comments from potential SERs following the June 11, 2020 Pre-Panel Outreach Meeting

After the June 11, 2020 Pre-Panel Outreach Meeting, potential SERs submitted two sets of written comments, which are provided in this Appendix:

1. Midwest Sterilization Corporation from Jackson, MO – Responses to EPA Pre-Panel Questionnaire
2. Midwest Sterilization Corporation from Jackson, MO – Memorandum of Comments Regarding Uncertainty in Ethylene Oxide (EtO) Science and Risk Assessment Methods

Appendix B2. Written Comments from potential SERs following the December 10, 2020 Panel Outreach Meeting

After the December 10, 2020 Panel Outreach Meeting, SERs submitted one set of written comments, which is provided in this Appendix:

1. Midwest Sterilization Corporation from Jackson, MO