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EPA–HQ–OAR–2019–0178
FRL–7055–03–OAR
Attn: Jonathan Witt, Sector Policies and Programs
Attn: Matt Woody
Office of Air Quality Planning and Standards,
U.S. Environmental Protection Agency

RE: Docket ID EPA–HQ–OAR–2019–0178; U.S. Environmental Protection Agency Proposed National Emission Standards for Hazardous Air Pollutants—Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review

Dear Mr. Witt and Mr. Woody:

The Advanced Medical Technology Association ("AdvaMed"), on behalf of itself and its membership, submits the following comments on the U.S. Environmental Protection Agency's (EPA's or Agency's) proposed revisions to the National Emission Standards for Hazardous Air Pollutants ("NESHAP") and Residual Risk and Technology Review for Ethylene Oxide published in the Federal Register on April 13, 2023 ("Proposed Rule").[1]

AdvaMed is the largest association representing companies that develop lifesaving, life-enhancing medical technology innovations for patients nationwide and around the world. We represent more than 450 companies supplying the sterile devices upon which Americans depend. Our members create and manufacture IV tubing, blood sample kits, surgical tools, heart valves, pacemakers, syringes, catheters, and much more serving patients in every healthcare setting. Many of AdvaMed members use and rely on ethylene oxide (EtO) as an essential infection prevention measure to sterilize the critical equipment they develop and manufacture used in surgeries, testing and vaccine administration, and other life-changing medical care.

[1] 88 FR 22,790 (Apr. 13, 2023).

EtO sterilized devices can be found in many healthcare procedures from a standard blood draw during an annual physical to a complex surgical procedure such as an open-heart surgery. EtO sterilization is crucial for preventing infection in patients. The process is used to sterilize half, or 20 billion, of all medical devices in the United States each year. As the EPA notes, EtO sterilizes an estimated 95 percent of all surgical kits. And it is the only effective, viable sterilization method for many medical devices.

For these sensitive and intricate devices, there is no existing alternative method for sterilization. EtO allows for the sterilization of many critical medical technologies and devices that otherwise would be destroyed or unsafe by other sterilization methods as they would not be able to ensure sterilization without affecting the integrity and function of the device. Inability to use EtO would prevent the use of many lifesaving technologies that have advanced medical care over the past 50 years.

The MedTech industry is committed to protect and improve public health. We place the highest priority on the safety of our communities, employees, and millions of patients we serve. Use of EtO for the sterilization of medical equipment has been and will continue to be safe and is subject to stringent regulations in place by an array of local, state, and federal agencies.

It is important to consider that EtO sterilization of medical devices takes many forms. In the first place, some manufacturers sterilize their own devices in-house, while others contract with commercial sterilizers or other manufacturers. The Proposed Rule therefore affects not only sterilization facilities within the source category, but medical device manufacturers who do not use EtO themselves (and thus are not directly subject to Subpart O).

In addition, not all sterilization facilities are designed and engineered in the same manner. AdvaMed member companies vary in many ways, including with respect to products and packaging, cycle design, equipment, facility design and configurations, process, and geographies.

These are not uniform operations—there is no "one-size-fits-all" approach to the medical technology industry. As a starting point then, any final determination must allow for flexibility to meet the needs of the diverse products and processes to ensure innovation and technological advancements to continue to prevent any delays in lifesaving, life-enhancing, and timely patient care.

Medical device sterilization is a tiny fraction of commercial uses of EtO, representing only half of one percent of all commercial EtO use. But the risk of a public health threat is real if we are constrained in our ability to serve patients with the safe, effective, sterile medical technology delivered on time and in the vast volume our healthcare system requires.

It is critically important that EPA recognize the importance of EtO in our healthcare system, and for individual patients. ***Amid tremendous demand in the U.S. healthcare system for sterile medical technologies, EtO sterilization is already at capacity. If the NESHAP is not reasonable and feasible (both economically and technically), it will further constrain capacity***

and jeopardize the availability of sterile medical devices and supplies (with no ability to shift that capacity across the market). Taking even a handful of facilities offline briefly would cause supply disruptions. Further, the proposal does not appropriately take into account the time and cost of cycle revalidation that would be necessitated for changes in manufacturers' FDA-regulated sterility assurance processes. Millions of products would require cycle revalidation, which includes extensive testing and change management with U.S. and worldwide regulatory submissions and approvals taking even longer. This validation work will also cut capacity sharply amidst sterilization capacity constraints and jeopardizes U.S. supply chain resiliency and overall critical sterile infrastructure. All of this in turn will likely result in a significant disruption and public healthcare crisis because AdvaMed's members will be constrained in their ability to serve patients with the timely and steady supply of safe, effective, and sterile medical technology that our healthcare system requires.

AdvaMed appreciates EPA's efforts in development of the Proposed Rule. Given the scope of the operations of AdvaMed members, the Proposed Rule would directly and significantly impact each individual member and will adversely impact the end users that our members serve.

AdvaMed has a long-standing record as a collaborative and cooperative stakeholder with EPA (and other agencies) in responding to implementation of requirements across a variety of regulations and initiatives that help supply the American people with the most innovative medical technology in the world, while protecting community members and employees. In fact, the medical technology industry has been proactive—well before the Proposed Rule publication—in researching and developing improved sterilization cycles, facility design, process optimization, plant upgrades, and emission control upgrades. This knowledge and experience are invaluable to the rulemaking process. For that reason, we welcome the opportunity to meet with you to discuss these comments and our members very real concerns about the Proposed Rule.

AdvaMed further requests EPA carefully consider the following comments, including those set out in the Appendices, in the course of this rulemaking. Our membership places the highest priority on the safety of our communities, employees, and millions of patients we serve, and we support reasonable and balanced science-based regulation.

We ask that EPA seriously consider our comments and work together with us on final regulations that ensure uninterrupted supply of vital sterile medical technologies for U.S. patients while achieving EPA's goals, which we share, of protecting community members and employees.

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Executive Summary

The Proposed Rule will profoundly impact the critical medical device supply chain. EPA acknowledges that its proposals will require facilities to shut down for an extended period of time. The Agency also knows that "EtO sterilization facilities operate continuously at near full capacity with few breaks and most manufacturers cannot use any alternative methods to substitute for EtO."[2] The Proposed Rule, however, does not adequately address capacity and supply chain impacts that will occur as a result of the Proposed Rule.

It is essential that EPA undertake **a careful account of all the costs and benefits—not just of the Proposed Rule, but also the proposed interim registration review decision announced on the same day with the same comment period regulating the same chemical and applicable to the same sources**.[3] EPA has not provided nearly enough time to assess and comment on the vast magnitude of regulatory changes the Agency is proposing.

The Proposed Rule eliminates a significant amount of flexibility that is especially critical for commercial sterilizers. Differences in products and packaging, cycle design, equipment, and facility layout make it impossible to impose a single control scheme across the industry. Not all EtO sterilization facilities are designed, constructed, and operated in the same manner. AdvaMed member companies vary in many ways, including with respect to products and packaging, cycle design, equipment, facility design and configurations, process, and geographies. There is no "one-size-fits-all" approach to the medical technology industry. As a starting point then, any final determination must allow for flexibility to meet the needs of the diverse products and processes to ensure innovation and technological advancements to continue to prevent any delays in lifesaving, life-enhancing, and timely patient care. Requiring facilities meet multiple emissions targets (Destruction Rate Efficiency and lbs/hour) rather than providing flexibility to meet the most appropriate target based on the facility design and engineering to achieve the desired result creates an impossible framework. A more overall flexible approach is needed that considers the unique anatomy of every facility and process.

In particular, AdvaMed members have actively worked with EPA in recent years to significantly reduce EtO use and emissions through process optimization, plant upgrades,

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[2] EPA, *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations* (March 2023) at 2-8 (hereinafter "RIA").

[3] When there are "two rules proposed by the same agency, at the same time, on overlapping topics," the agency *must* "consider the combined impact of these rules." *Immigrant Legal Res. Ctr. v. Wolf*, 491 F. Supp. 3d 520, 541 (N.D. Cal. 2020).

cycle optimization, and emissions control upgrades based on the unique sterilization modalities and facility layouts.

EPA's attempt to find an easy, one-size-fits-all solution is ultimately counterproductive to the goal—shared by AdvaMed and EPA—of reducing EtO emissions. Many of the proposals would have little to no impact on emissions. Indeed some of the proposals will make it more difficult to comply with the emissions limits and incentivize use of *more*, not less, EtO. Further, **requiring area sources to obtain Title V permits will only add a layer of bureaucratic expense with *no* additional benefit to pollution control or compliance**.

Further, the proposal does not appropriately take into account the time and cost of cycle revalidation that would be necessitated for changes in manufacturers' FDA-regulated sterility assurance processes. Millions of products would require cycle revalidation, which includes extensive testing and change management with U.S. and worldwide regulatory submissions and approvals taking even longer. This validation work will also cut capacity sharply amidst sterilization capacity constraints and jeopardizes U.S. supply chain resiliency and overall critical sterile infrastructure. All of this in turn will likely result in a significant disruption of supply and subsequent public healthcare crisis because AdvaMed's members will be constrained in their ability to serve patients with the timely and steady supply of safe, effective, and sterile medical technology that our healthcare system requires.

AdvaMed looks forward to continuing to work with EPA to develop workable standards to protect the environment, our workers, and our communities. We provide further additional comment in support of this objective below.

Comment

I. The Proposed Rule's implementation timeframe is impossible to meet and will exacerbate critical infrastructure shortages. [C-80]

The Proposed Rule would significantly change the regulatory scheme of subpart O and the commercial sterilization landscape. EPA is proposing sweeping revisions to many existing requirements and undertaking to regulate entirely new sources. Yet EPA proposes that "all existing affected sources must comply with all amendments no later than 18 months after the effective date of the final rule" and that "all new affected sources must comply with all amendments upon startup."[4]

[4] Proposed Rule at 22,852 .

EPA's proposed compliance timeline is not feasible and would have grave consequences for the sterilization supply chain and the critical life-saving tools AdvaMed's members provide. EPA acknowledges some of the complications that will require time before existing sources will be able to comply but trivializes the gravity of these consequences:

> We are aware that, in order to implement the capture and emission reduction systems necessary to comply with the requirements that we are proposing, facilities will need to cease operations for a certain period of time in order to implement these systems. However, an expedited compliance timeframe could result in more facilities needing to cease operations simultaneously. This means that increased coordination would be needed to ensure that the supply of medical devices is not adversely impacted.[5]

As explained throughout this comment, many of the problems the Proposed Rule would create cannot be solved by "increased coordination." And no amount of coordination would make it possible to meet EPA's proposed deadline. Further, many products are qualified at only one facility or one chamber, making it unlikely that the product could be sterilized at any other location.

Against the backdrop of these serious concerns, and for the reasons set forth more fully below, ***EPA should set the Proposed Rule's compliance deadline for existing sources at a minimum of 4 years (48 months) after the effective date, with the ability to make case-by-case exceptions in special circumstances***.

A. EPA's expedited implementation timeline is infeasible and would significantly disrupt the supply chain for critical life-saving medical tools. [C-80]

Attempting to meet EPA's proposed abbreviated compliance timeframe will require virtually every regulated source to suspend or curtail sterilization services simultaneously.

Facilities are simply incapable of complying with the Proposed Rule within 18 months. Implementing permanent total enclosure will require at least 24 months for most facilities while other requirements EPA is proposing here and in the Proposed Interim Registration Review Decision (PID or decision) would require more than four years to implement—and in some cases much longer.

Modifying sterilization equipment is no trivial matter. These complex facilities, no two of which share the same design or process, typically must go at least partially offline to make modifications to the equipment. Even routine maintenance or periodic upgrades require

[5] *Id.* at 22,853.

significant planning to minimize downtime across the monthly or annual supply cycle. Furthermore, there are a limited number of technical experts who support this industry. Facilities will not have the option of planning within these natural industry rhythms if they are forced to scramble to achieve compliance within 18 months. This will have a devastating effect on supply levels.

AdvaMed members estimate that, if a facility manages to continue operations at all during implementation, ***sterilization capacity will decrease by at least 30% while the facility is being overhauled***. As explained further in the Supply Chain and Capacity Considerations report by economists at the National Economics Research Associates (or NERA), the inelasticity of demand for medical devices "means that even modest sized shifts or disruptions in supply will cause medical device shortages that will affect patients."[6]

This would risk severe disruptions to the supply chain of life-saving medical devices that are essential across the healthcare sector and used to sterilize 95% of surgical kits.'[7] Even with perfect coordination of downtimes among competitors across the sterilization industry, critical shortages would still be unavoidable. In a panel discussion about challenges during the pandemic, the FDA Center for Devices and Radiological Health explained that a shortage arises when supply is restricted and demand remains essentially unchanged. This economic scenario can arise for various reasons, but the Proposed Rule would fall into the category of "manufacturing interruption" resulting from a "man-made disaster."[8]

Another FDA scientist brought the abstract economics down to a personal level: **"Medical device shortages can impact patient care," and "if essential, and irreplaceable devices are unavailable, physicians can't make a diagnosis or provide life-saving therapeutic interventions."**

Even with the perfect coordination of downtimes among competitors across the sterilization industry (and ignoring the obvious legal and practical obstacles), critical shortages would still be unavoidable.

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[6] *See* Appendix I (NERA Report) at 7.
[7] *See* EPA, *Ethylene Oxide: Proposed Interim Registration Review Decision*, Case Number 2275, Docket No. EPA-HQ-OPP-2013-0244 (March 2023) at 12 & nn.17–20 (hereinafter "PID").
[8] FDA, *Shortage of Ethylene Oxide Sterilized Medical Devices: CDRH's Role*.

B. EPA and other stakeholders must be able to assess the Proposed Rule in conjunction with other proposals affecting commercial sterilizers.

Eighteen months is far too short to implement the proposed NESHAP on its own, but these timeline concerns are aggravated by EPA's parallel regulations imposing separate often conflicting restrictions on EtO sterilization.

The same day the Proposed Rule was published, EPA also announced the PID. This other regulatory action proposed an entirely different set of equally, if not more, extensive changes and gives regulated entities the exact same period as the Proposed Rule in which to review and comment. The combination of these two proposed actions results in a massive and unprecedented overhaul of rules and regulations governing commercial sterilizers. "The limited [] comment period for this Rule, combined with the timing of these other rules" would "deprive the public of the opportunity to consider how these rules intersect[] . . . and also raise[s] serious questions about whether the agency 'meaningfully addressed the interaction of these rules.'"[9]

In that PID, EPA proposed to require, among other things, reduced concentrations of EtO in sterilization cycles, all-in-one sterilization and aeration, use of covered conveyors to transport sterilized products, and potential modifications to ventilation requirements. These requirements would force sterilizers to change and revalidate cycles and undertake dramatic—mostly infeasible—facility overhauls. **The closures and downtimes required to implement both this NESHAP proposal and the FIFRA proposal would be felt across the supply chain and would significantly impact the availability of safe and effective medical devices**.

EPA acknowledges that "EtO is used on approximately 50% of all sterilized medical devices, annually, including an estimated 95% of all surgical kits[,]" and that there are currently "no viable alternatives to EtO for the sterilization of certain medical devices and equipment."[10] Yet EPA is engaging in at least two separate major efforts that are certain to lead to significant medical device shortages.

EPA must carefully analyze the interplay between the Proposed Rule and its proposed interim registration review decision applicable to ethylene oxide, and AdvaMed and other citizens subject to these rules are entitled to adequate time to do the same. We are not aware of any indication that EPA has considered, in connection with either proposal, the interplay between these two major and overlapping regulations.

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[9] *Centro Legal de la Raza v. Exec. Office for Immigration Review*, 524 F. Supp. 3d 919, 962 (N.D. Cal. 2021).
[10] PID at 3

For example, there are provisions where the Proposed Rule and the interim registration review decision conflict. As outlined in AdvaMed's comments on the proposed interim registration review decision, EPA should not mandate a fixed level of ventilation (i.e., number of air exchanges per hour) for product storage and packaging areas for various technical and feasibility considerations, including that it may result in air imbalances between parts of the building and result in difficulty in complying with other requirements of the PID, NESHAP, or other regulatory requirements such as OSHA.

Similarly, the Proposed Rule has proposed control of post-sterilization product storage areas in the Group 2 air emissions category. One of the controls the NESHAP has proposed is limiting the exhaust flow rate to 2,900 CFM with a maximum concentration of 30 ppb. If the final FIFRA decision requires a minimum number of air exchanges per hour, due to the large volume of these product storage areas/warehouses, it will be impossible for the exhaust rate to be ≤ 2,900 CFM.

The EPA further discusses in the NESHAP that to meet the 2,900 CFM limit, facilities may have to restrict the number of room air changes (RACs) per hour. That will be problematic if the FIFRA decision requires a minimum number of air changes per hour. It should also be noted that the NESHAP proposes that, as an option, facilities establish minimum volumetric exhaust flow rate for PTE areas. This would mean their exhaust flow rate for Group 2 areas would have to be ≤ 2,900 CFM and > whatever minimum they establish. It is important to recognize the measurement of exhaust flow rates can be difficult due to the amount of variances in such measurements over even short time periods. Measurements can vary 100's or 1,000's of CFM over the span of seconds depending on the system control. This is just one example and is the type of analysis that EPA must conduct regarding the interplay between the Proposed Rule and the proposed interim registration review decision.

C. Existing facilities will need at least the maximum compliance time permissible under section 112.

Many ***existing*** facilities would require significant changes to comply with the Proposed Rule, and we cannot overstate the extent of changes (and the required timeframes) that would be required to comply with the Proposed Rule.

Five examples demonstrate the period of time needed for facilities to comply with the proposed rules:

Permanent Total Enclosure. While we discuss in further detail later in our comments that room air emissions standards are highly problematic due to the difficulties in emissions capture, technological limitations and cost, we note such a newly regulated source could entail, for example, a Permanent Total Enclosure with routing to a control device. This

new approach would require significant facility alterations. In many circumstances, the area where products are packaged may be on the opposite side of a facility from the sterilization activities and existing control system. In these circumstances, the Group 2 room may need to be relocated within a facility before construction of a Permanent Total Enclosure can even begin. As another example, facilities may not be able to relocate natural draft openings (NDOs) or relocate exhaust points to comply with Method 204, as EPA proposes, and so a broad redesign of the facility would be required in many instances, which would again require well more time than 18 months.

The required steps for these types of projects would, in general, be as follows: (a) site evaluation to inform design; (b) engineering and design to plan the project; (c) state and local permitting; (d) fabrication, construction, and installation; (e) commissioning and validation; and (f) update operations and maintenance procedures. While some of these steps can be conducted in parallel, there is inherent separation between others; construction and installation must wait for design and permitting, and commissioning/validation must occur after construction.

Validation. Some facilities also serve international customers, and so validation depends not only on FDA approval but also the approval of other countries' regulatory agencies, further extending the necessary timelines. Additionally, EPA's proposal fails to consider FDA's workload, and the realistic possibility of FDA efficiently processing a flood of regulatory (or revalidation) submissions in an unreasonably short amount of time.

Equipment Lead Time. AdvaMed's members are currently experiencing *extended* equipment lead times from vendors of up to two years before the equipment is delivered—and that is before installation can even begin. One equipment vendor told the EPA more than four years ago that even installing components of that vendor's system on an existing facility would take up to a year.[11] And this is under current, relatively normal conditions—the sudden spike across the entire industry will stretch all of these timelines out considerably. Companies will be competing for new or additional control equipment, CEMS, facility-wide pressure monitoring systems, as well as the designs for this new equipment.

FIFRA Registration. EPA's Proposed FIFRA registration review will impact and complicate the design and engineering of the facilities beyond just those necessary to comply with NESHAP. Further examination of facility engineering and sterilization processes to ensure compliance with both the proposed NESHAP and FIFRA PID requires significantly more time, testing, and validation than if these facilities were to comply with just one or the other.

[11] LESNI Meeting Minutes (March 7, 2019), https://downloads.regulations.gov/EPA-HQ-OAR-2019-0178-0015/content.pdf.

Permitting Timelines. Permitting timelines can often lead to substantial delays. Even if a Title V permit is not required, the state and local permits required to even *begin* construction can also take long enough that it would occupy a significant portion of the proposed 18-month timeline. In our members' experience, permitting can often take 12 to 18 months alone, with Title V permitting well exceeding those timelines. It makes no sense to require compliance with the entire NESHAP on the same timeline that typically is required just for permitting.

AdvaMed therefore requests that EPA adjust the compliance schedule so that *existing* facilities have 4 years from the effective date of the final NESHAP Subpart O revisions before any new standards take effect, representing the Clean Air Act's default 3-year compliance schedule in addition to the statutorily permitted 1-year extension. Here, 3 years plus a 1-year blanket extension are both merited, to allow for the 4 years for compliance that is necessary (and potentially not even sufficient) for existing facilities to comply.[12]

EPA cannot rely on the Proposed Rule as providing notice of future requirements. The Proposed Rule contains significant flaws that EPA will no doubt strive to correct based on the extensive feedback the Agency has solicited. EPA is not expected to publish the final rule for about one year.[13] In any event, a federal agency cannot expect citizens to comply with potential regulations not enacted as required by the Constitution and statute.

In proposing an 18-month compliance timeline, EPA has "failed to consider" many "important aspect[s] of the problem" exemplified by the many considerations raised in this section.[14] Any final rule should allow 4 years for compliance, or in the alternative (and at minimum), EPA should set the compliance deadline at 3 years with a specified process for sources to seek a 1-year extension.

II. EPA's inadequate risk assessment would render the entire final rule arbitrary and capricious. [Proposed Rule generally; Risk Assessment and Analyses (Sections III(C)-(E) & C-36, C-37, C-38, C-39, C-40]

The Proposed Rule exaggerates EtO risk, overstates emissions reductions, and underestimates costs of implementation. If these basic underlying flaws are not

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[12] *See White Stallion Energy Center, LLC v. EPA*, 748 F.3d 1222, 1251–52 (D.C. Cir. 2014) (, contemplating that blanket extension under Section 112(i)(3)(B would be permissible).
[13] *See* EPA, *National Webinar About EPA Actions to Address EtO and Multi-Day Public Hearing on Commercial Sterilizer Proposal* (May 1, 2023).
[14] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 43 (1983) ("agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem").

corrected—and the corresponding proposed regulations adjusted, the final rule will be arbitrary and capricious.

A. EPA's Proposal relies on an exaggerated assessment of EtO risks.

Most fundamentally, EPA overly relied on an assessment of EtO inhalation risk that suffers from a variety of analytical infirmities. Because EPA overestimates the risk of EtO, its analysis considered even trivial emissions reductions to represent inflated public health benefits, which the Agency failed to quantify or even describe in any meaningful way. EPA then compared that distorted picture of the Proposed Rule's advantages to a simplistic estimate of the costs, both to critical medical device infrastructure and the industry, of implementing the proposed rule.

The Proposed Rule adopts an "adjusted EtO inhalation URE" of 5 x 10^{-3} per µg/m,^{3} which means that a continuous exposure of 0.02 µg/m^3 triggers EPA's 1-in-10,000 risk threshold. But EPA's own ambient air measurements show EtO concentrations as high as 0.297 µg/m^3 and an average of approximately 0.3 µg/m^3—nearly 1500% of the level EPA purports to use as its risk threshold.[15] EtO in much higher concentrations is produced by lawnmowers (up to 32,000 µg/m^3) and backyard barbecue grills (9,000 µg/m^3).[16]

Exposure from natural human biological processes is even higher, up to 27,000 times EPA's risk threshold. A recent study examined eight EtO-emitting facilities and found that average "concentrations were not substantially elevated above the related background mean concentrations" and exposure from the facilities "composed a small fraction of the endogenous" exposure.[17] The 2016 EtO IRIS value creates "a serious gap in confidence in interpreting the health significance of general population E[t]O exposure," in large part because it is not "consistent with clinical metrics for which the risk of disease does not increase significantly until the values are above the healthy population normal range defined by individual variability within the population."[18]

We further note EPA's method in risk modeling has included invalid and arbitrary data, such as EtO air dispersion in risk modeling performed for some individual facilities. This has included invalid incorrect inputs in air dispersion modeling (e.g., facility layout,

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[15] *See* EPA, *Ethylene Oxide Ambient Concentrations at National Air Toxics Trends Stations and Urban Air Toxics Monitoring Program October 1, 2018 – March 31, 2019*.
[16] Montrose Air Quality Services, *Emerging Technologies Test Report: Proton Transfer Reaction/Time of Flight Mass Spectrometry (PTR-TOF-MS) Measurements of "Everyday Sources" for Ethylene Oxide* (submitted Oct. 16, 2019).
[17] Patrick J. Sheehan et al., *Ethylene Oxide Exposure in U.S. Populations Residing Near Sterilization and Other Industrial Facilities: Context Based on Endogenous and Total Equivalent Concentration Exposures*, 18 INT'L J. ENVT'L RES. & PUBLIC HEALTH 607 (Jan. 12, 2021).
[18] *Id.*

locality wind direction, and speed), which has potential impacts on a facility's risk score and has been as a basis to advance the proposed regulation.

EPA's overall risk assessment arrives at an unjustifiably low IRIS value by adopting a flawed model and statistically significant over-predictions that are unsupported by epidemiological, toxicological and biological studies. Based on EPA's risk assessment, "the background levels of [EtO] in the population would be predicted to cause more lymphoid cancer than is actually observed in the general population (and ignoring any other potential cause of lymphoid cancer)."[19] In short, EPA's risk assessment is, on its face, indefensible and scientifically unsound. Our view is shared by regulatory agencies, industry experts, and the scientific community.

The Texas Commission on Environmental Quality (TCEQ) Toxicology, Risk Assessment, and Research Division identified "several substantial scientific issues with U.S. EPA's [risk] assessment," including EPA's model fit criteria calculations, visual misrepresentation of model fit, and statistically significant model over-predictions.[20] TCEQ found, inter alia, that the linear two-piece spline model used in EPA's assessment overpredicted key NIOSH data and the "consistent with the statistically significant over-predictions by USEPA's preferred model (i.e., the linear two-piece spline model) . . . for the key and supporting cohorts, the reality checks above based on endogenous/background levels of EtO alone suggest that USEPA's lymphoid cancer [unit risk factor] is scientifically unreasonable (i.e., leaving no room in the background rate for other causes of lymphoid cancer)."[21]

The TCEQ's critiques were echoed in a thorough and scholarly report prepared by eight experienced scientists. This scientific report explained that "a steep supralinear model . . . should not be used because it is not consistent with the epidemiological and biological evidence" and that "both USEPA (2005) cancer risk assessment guidelines and Crump (2005) strongly caution against the use of steep slopes because they can lead to low-dose extrapolations that distort the true exposure-response relationship."[22] The report also noted that EPA's model selection was based almost exclusively on a fundamentally flawed statistical analysis and a flawed assessment of visual fit in relation to categorical data without considering biological plausibility.[23]

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[19] Texas Commission on Environmental Quality, Ethylene Oxide Development Support Document website, https://www.tceq.texas.gov/toxicology/ethylene-oxide.
[20] Texas Commission on Environmental Quality, *Ethylene Oxide Carcinogenic Dose-Response Assessment Development Support Document* (May 15, 2020) at 135.
[21] *Id.* at 160.
[22] *Cancer Risk Estimates for Ethylene Oxide Based on Epidemiological and Biological Weight-of-Evidence*, EXPONENT (March 11, 2020) at 4.
[23] *Id.* at 6–18.

A 2019 scientific study on cancer evidence integration and dose-response implication regarding EtO concluded that the inhalation unit risk (IUR) derived by EPA using the two-piece spline model grossly overestimates risk.[18] The study states that "the IUR derived by EPA using the two-piece spline model is approximately 1000-fold more potent than the IURs derived from animal data and the TCEQ unit risk estimate based on the same epidemiological evidence."[24]

Many other parties have raised issues with both the IRIS process itself and the 2016 EtO IRIS analysis in particular,[25] including perhaps most notably repeated reports by the National Academy of the Sciences and the Government Accountability Office (which at one point added the IRIS program to its "High-Risk List" of programs vulnerable to fraud, waste, abuse, and mismanagement).

A full discussion of the problems with the 2016 EtO IRIS would take up considerably more space and potentially distract from comments on other important aspects of the Proposed Rule. To avoid that result, the attached report of toxicologist Dr. Lucy Frasier summarizes the most significant of those issues.[26]

EPA's risk-assessment "model bears no rational relationship to the characteristics of the data to which it is applied"[27] and there is no "rational connection between the factual inputs, modeling assumptions, modeling results and conclusions drawn from these results."[28] These flaws threaten to undermine EPA's entire premise for regulation and could lead to the Proposed Rule being deemed "arbitrary and capricious."[29]

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[24] Melissa J. Vincent *et al.*, *Ethylene Oxide: Cancer Evidence Integration and Dose-Response Implications*," Dose-Response (Dec. 11, 2019).

[25] The ranking member of the House Committee on Science, Space, and Technology referred to the IRIS program's "lack of transparency" and "improper scientific processes" that led to "an absurd risk value that is 19,000 lower than the levels . . . that naturally occur in the human body." Opening Statement of Ranking Member Frank Lucas at Joint Subcommittee Hearing on EPA's IRIS Program (March 27, 2019); *see also* Angela Logomasini, Ph.D., EPA's Flawed Iris Program Is Far from Gold Standard (Feb. 12, 2019) ("IRIS has a long history of sloppy research and lack of transparency that has advanced faulty and often counterproductive regulations that impose needless burdens on the public.").

[26] *See* Appendix II.

[27] *EME Homer City LLP v. EPA*, 795 F.3d 118, 137 (D.C. Cir. 2015) (quoting *Appalachian Power Co. v. EPA*, 135 F.3d 791, 802 (D.C. Cir. 1998)).

[28] *Id.*

[29] The problems with the underlying risk assessment affect many aspects of the Proposed Rule, but are most apparent in EPA's discussion of proposals intended to address perceived residual risk (see C-36 through C-40).

B. EPA overestimates the purported benefits of the Proposed Rule.

With this exaggerated view of EtO risk in hand, EPA can easily find that even the smallest reduction in emissions is worthwhile. While the costs of EPA's proposal are enormous, many aspects of the proposal would generate very limited emissions reductions and significant cost.

For example,

- Reducing concentrations of EtO used in sterilization cycles—although totally improper as explained below—will not necessarily reduce emissions *at all* because longer cycles would be required, resulting in deeper absorption in materials, additional gas make-ups to maintain process conditions, and attendant increased off-gassing.

- The proposal to require Group 2 room air emissions to be maintained under a permanent total enclosure likewise is unlikely to significantly, or even measurably, reduce the already very low emission contributions of these operations.

- The Proposed Rule's monitoring provisions such as the CEMS requirement significantly improve existing metrics with respect to the long-term exposure with which EPA is concerned.

Finally, and consistent with EPA's approach in the hexavalent chromium example, EPA should have assessed the benefits from *each* individual proposed standard—particularly here, where EtO is integral to safe, reliable, and timely patient care.[30] **This individualized analysis is especially important to assessing the cost-effectiveness of a sweeping proposed rule that jeopardizes our critical domestic sterilization infrastructure and is all but guaranteed to cause disruption to the healthcare supply chain and medical device product shortfalls.**

But EPA does not provide this information in the Proposed Rule. Although EPA provided a summary of its *total* estimated reductions of cancer risks from the entire Proposed Rule (itself plainly inflated, as explained above),[31] that approach makes it impossible to assess the potential costs and benefits of each individual proposal. Indeed, some proposals may have *no* beneficial impact yet impose significant costs.

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[30] 77 Fed. Reg. at 58,227 (discussing reductions in maximum individual cancer risk in relation to the adopted standard for small hard chromium electroplating sources).
[31] This is true for each one of the GACT analyzes EPA performed. *See id.* at 22,809–14, 22,817–18, 22,820–23.

In addition to depriving citizens of the ability to evaluate whether an *individual* cost-per-ton threshold is cost-effective, EPA's approach suggests that the Agency itself has not attempted to do so. This failure also renders the Proposed Rule arbitrary and capricious.[32]

C. EPA understates the costs of the Proposed Rule.

Because EPA has not adequately considered any aspect of the Proposed Rule's burden on the sterilization industry, the Proposed Rule fails to satisfy Section 112(d)(2)'s requirement to take "into consideration the cost of achieving [the estimated] emission reduction."[33]

1. The Proposed Rule virtually ignores the risk of reduced sterilization capacity and impacts on the national and global supply chains.

The Proposed Rule acknowledges that "[c]ommercial sterilization facilities play a vital role in maintaining an adequate supply of medical devices."[34] EPA then states that it gave "careful consideration to the important function these facilities serve, drawing from extensive engagement with industry stakeholders as well as Federal agencies with expertise in and responsibility for the medical supply chain," and that it is "proposing a set of standards that [it] believe[s] are achievable and reflect techniques and control technologies that are currently used within the industry."[35] Regarding medical device supply chain impacts, EPA "project[s] that the largest impacts are limited to a handful of companies" and that companies involved in sterilizing the most sensitive medical devices "are already in the planning stage for additional controls."[36]

EPA repeatedly appears to credit concerns about supply chain issues and availability of medical devices, but then proceeds with proposals that would cause such issues anyway.

First, and most importantly, 18 months presents an impossible timeline for many existing sterilization facilities. EPA must recognize the extent of changes required at existing facilities under the Proposed Rule and that all existing facilities would need to make these changes simultaneously, thereby resulting in a significant shortfall of vendor capacity with ensuing disruption in the availability of sterile medical devices.

Further, sterilization facilities would need to revalidate their sterilization cycles. EPA acknowledges that "the revalidation of sterilization cycles is a time-intensive process and

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[32] *State Farm Mutual Auto Ins. Co.*, 463 U.S. at 43 (stating agency must "examine the relevant data and articulate a satisfactory explanation for its action").
[33] 42 U.S.C. § 7412(d)(2). This requirement, though appearing in § 7412(d)(2), is applicable to all of § 7412(d) because subsection (d)(2) specifies this requirement for the "subsection."
[34] Proposed Rule. at 22,973.
[35] *Id.*
[36] *Id.*

could also worsen potential bottlenecks in the medical device supply chain,"[37] and indeed that "***completing the revalidation for a single product can potentially take months***."[38] Nowhere does EPA explains why it nevertheless proposes an implausible 18-month compliance deadline or how that proposal can be squared with EPA's assertion that it is "trying to minimize disruptions to the supply of medical devices and thereby avoid creating a potential health concern."[39]

Additionally, while EPA acknowledges that the supply chain for medical devices could be impacted by the Proposed Rule, EPA does not take any steps to assess the intensity, duration, and breadth of these shortfalls. For example, EPA states that "[t]he EtO sterilization industry is an integral part of the supply chain for many medical devices and capacity constraints have been reported,"[40] and that "EPA is aware of other facilities that, according to FDA, could impact the availability of certain medical devices, including those that are (1) Experiencing or at risk of experiencing a shortage, (2) in high demand as a result of the COVID–19 pandemic, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility."[41] But then despite these concerns, EPA does not perform any in-depth analysis on the character of such impacts by assessing the costs of supply shortages.

AdvaMed members supply critical medical devices not only in the United States but also abroad. We have first-hand knowledge of the material capacity and supply chain impacts that will be experienced if the Proposed Rule is adopted as is. Forcing facilities to shut down or dramatically reduce output capacity to make extensive retrofits—and on a short compliance timeline—will not safeguard this "integral part of the supply chain for many medical devices" and does not recognize the "capacity constraints [that] have been considered."[42] As stated by the economists who examined the Proposed Rule:

> "Commercial sterilization facilities are running at a high capacity year-round because there is the need for sterilization to support the medical services needs and demonstrating the critical need for its services to the health care system. Any disruption in the operation of sterilization that is running in full capacity, in the absence of alternatives, will have supply impacts."[43]

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[37] Proposed Rule at 22,809
[38] RIA 2-7.
[39] *See* Proposed Rule. at 22,807.
[40] *Id.* at 22,854.
[41] *Id.* at 22,822–23.
[42] *Id.* at 22,854.
[43] NERA Report at 11–12.

2. EPA underestimates costs of implementation.

Aside from the supply crisis the Proposed Rule is all but sure to create (especially in conjunction with the PID), EPA's estimates for capital costs are not consistent with AdvaMed's members' expected costs.

Take just the facility redesign for enclosure and other requirements. These costs include (1) design, (2) engineering, (3) facility modifications and equipment, (4) installation, (5) implementation, (6) commissioning, (7) testing, and (8) facility down time during install. AdvaMed's members' costs would be up to *100 times greater* than EPA estimates. Given this dramatic cost differential, we encourage EPA to engage further with sterilization stakeholders to understand how its cost estimates diverge so much. Several of AdvaMed's members received quotes from qualified vendors for implementing permanent total enclosures meeting the requirements of Method 204 (Comment C-30), and these costs are summarized below[44]:

- One vendor quoted $25 million to meet the requirements of Method 204.
- Another vendor provided an estimate of at least $19 million in capital investment for high level PTE costs for Group 1 and 2. This does not include full measures to ensure Method 204 compliance at the facility.
- For certain configurations, it will cost approximately $10 million to $20 million per site to implement the proposal.
- The implementation cost for two locations of one operation is estimated at approximately $50 million.
- Another experienced enclosure vendor developed an extensive conceptual design for an existing sterilization operation. The estimate of $23 million to implement the proposal at an existing facility would work out to approximately $100,000 *per pound*, or ***$200,000,000 per ton*** of reduced emissions.

These facts imply costs far in excess of the approximately $100 million that EPA estimated for all existing Group 1 room air emissions at area source facilities to implement, and the estimated cost of $100 million is significant and remarkable on its own. EPA must also consider the costs of installation of air handling equipment/ductwork and pressure monitoring for permanent total enclosure, maintenance for permanent total enclosure equipment, abatement systems that can accommodate the required air flow for Group 1 & 2 rooms, maintenance of the abatement system, additional staffing required, and validation and regulatory submission of all changes. Additionally, these costs are not reflective of

[44] Notably, these costs do not include the cost of downtime or the cost of additional abatement systems.

the monitoring, recordkeeping, and reporting requirements contained in the Proposed Rule, especially with the addition of continuous emissions monitoring ("CEMS") (C-49).

And this is just one aspect of the Proposed Rule. Revalidating sterilization cycle for millions of products would cost upwards of $200,000 per cycle,[45] apart from the time and costs of U.S. and worldwide regulatory submissions and approvals.

EPA also appears not to have considered significant indirect economic effects, which will likely be more burdensome for underprivileged communities. As explained by several economists:

> A reduction in the supply of sterilized devices would lead to lower hospital and healthcare delivery resulting in higher costs to patients and in some instances supply shortages reduction in output value from these sectors that depend on EtO. Reduction in output from the EtO sterilization facilities and downstream sectors would result in lower labor income for employees and hence less income to spend on goods and service. Lower output also leads to lower tax collection for municipalities, state, and federal government. The interlinkage between the sectors creates economic feedback or ripple effect that permeates across the economy. The impact resulting from subsequent business spending by entities which are not directly paid by EtO sterilization facilities that will be lost if EtO using facilities operate at lesser capacity which results in a diminution of "indirect economic benefits."[46]

Other unnecessary burdens EPA failed to consider are addressed throughout this comment.

D. EPA's cost-benefit analysis is incongruous and contradicts its own assumptions.

As explained above, EPA both overstates the potential emission reductions and understates the cost required to achieve those inflated reductions. The analysis makes no sense even on its own terms. But even accepting all of these flawed numbers, EPA's cost-benefit analysis would still be inadequate. For example, EPA reviews the cost-effectiveness (in $/ton) of some of its proposed control measures for generally available control technology ("GACT") for area sources. EPA arrives at extremely high dollar values for per-ton emissions reductions. The highest estimate EPA produced was $19,420,188/ton, but virtually all estimates are uniformly high and exceed $1,000,000/ton.[47] Nevertheless, EPA

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[45] This does not include the costs of product for testing nor additional testing costs such as biocompatibility testing.
[46] NERA Report at 15–16.
[47] *See* Proposed Rule. at Table 5 ($3,678,138/ton); Table 6 ($161,105/ton); Table 7 ($2,597,271/ton); Table 8 ($336,823/ton); Table 9 ($3,094,182/ton and $17,541,860/ton); Table 10 ($2,549,177/ton and $8,005,582/ton); Table 11 ($2,315,197/ton and $10,383,471/ton); Table

concludes that such cost-per-ton numbers represent cost-effective options.[48] In past NESHAP rulemakings, EPA has determined that far lower costs were too expensive on a cost-per-ton basis.[49]

Further, even if it were reasonable for EPA to aggregate across all proposed standards for evaluating the total amount of cancer risk reduction, EPA's estimates show the proposed rule to be less cost-effective than the hexavalent chromium example it cited. In that rulemaking, EPA estimated $500,000 in annual costs to generate a 0.01 reduction of annual cancer incidence.[50] This converts to $50 million per 1 reduction of annual cancer incidence. By contrast, the Proposed Rule here would result in an estimated reduction of annual cancer incidence of 0.8 (cases per year) for an annual cost of $68 million, which converts to a cost of $85 million per 1 reduction of annual cancer incidence—a 70 percent higher cost than EPA's hexavalent chromium example with no reasoned analysis in support thereof. Further, this does not even consider and weigh for such benefit the negative impact to the medical device supply chain as a result of disruptions and shortfalls in critical medical technologies for patient care.

Because EPA's costs are underestimated, and EPA has not properly weighed its flawed cost estimates against purported benefits, EPA has arbitrarily and capriciously failed to "reasonably consider[] the relevant issues and reasonably explain[] the decision [it reaches]."[51]

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12 ($677,911/ton and $2,571,429/ton); Table 13 ($4,350,265/ton and $18,181,818/ton); Table 14 ($$2,733,571/ton and $4,445,789/ton); Table 15 ($629,830/ton and $1,000,000/ton); Table 16 ($19,420,188/ton and $16,790,792/ton); Table 17 ($8,820,981/ton and $6,562,500/ton); *see also id.* at Table 22 (estimating a cost-effectiveness of $194,111,365/ton for existing Group 2 room air emissions limit).

[48] *Id.* at 22,822 ("Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. This includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety.").

[49] *See, e.g.*, 79 Fed. Reg. 60,238, 60,264 (Oct. 6, 2014) (finding $1,700,000/ton reduced not cost effective for polycyclic aromatic hydrocarbons, which are carcinogens); 71 Fed. Reg. 34,422, 34,434 (June 14, 2006) (considering $410,000/ton too high to require additional controls) 69 Fed. Reg. 21,198, 21247–48 (Apr. 20, 2004) (Because of cost of $12,000,000/ton "of chlorine removed, we are not proposing a beyond-the-floor standard based on improved wet scrubbing control for new sources.").

[50] 77 Fed. Reg. at 58,277 tbl.5.

[51] *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

III. EPA should adjust its approach to removing current SSM exemptions. [C-47, C-48]

EPA may be correct that the Clean Air Act (CAA) prohibits exempting sources from emissions limits during periods of startup, shutdown, and malfunction (SSM). AdvaMed and its members have concerns, however, with how EPA proposes to revise existing regulations to adjust for the removal of the current SSM provision.

A. EPA should work with sources to adequately account for startup, shutdown, and malfunction contingencies. [C-47, C-48]

While EPA cannot provide a blanket exemption to emissions requirements under Section 12, the Agency should consider using other tools at its disposal to account for the reality of SSM events. For example, EPA can classify sources in SSM phases as sub-sources subject to different emissions requirements or subject to alternative work-standard requirements.

As part of these considerations, EPA should work with sources to develop potential solutions to account for SSM events. One area of concern is the ability to continue demonstrating compliance during startup and shutdown. While EPA is correct that it is common to start up air pollution control equipment prior to the sterilization process equipment, some equipment—such as a CEMS or parametric monitoring system—usually comes online before the sterilization process ramps up. The Proposed Rule offers no way for a source to remain in compliance during the inevitable and foreseeable—but not predictable—failure of monitoring equipment.

EPA should consider specific reporting and monitoring alternatives for these scenarios. One example is a requirement specific to releases from sterilizer pressure relief devices resulting from malfunctions or required during shutdown events. These requirements could be modeled after other recent pressure relief device requirements such as those in 40 C.F.R. §63.648(j).

B. EPA should remove the general duty clause from any final rule.

EPA proposes "to add general duty regulatory text at 40 C.F.R. §63.362(j) that reflects the general duty to minimize emissions while not including any reference to periods covered by an SSM exemption."[52] Specifically, EPA proposes to require sources "[a]t all times" to "operate and maintain any affected source . . . in a manner consistent with safety and good air pollution control practices for minimizing emissions."

[52] Proposed Rule. at 22,842.

EPA should not include its proposed general duty language in any final rule. In the first place, it is not clear on what basis EPA claims authority to impose a general standard of behavior on regulated sources. Section 112 grants EPA authority to set emissions limits and certain specific alternative standards—not impose a vague and subjective code of conduct requiring "safety and good air pollution control practices" from the citizenry.

Further, the "general duty" is redundant of the proposed amendment to § 63.632(b) requiring compliance "at all times." It is unclear the extent to which EPA's proposed general duty requirement, which also applies "at all times," differs from the specific proposed CAA regulations. EPA's proposed general duty provision is additionally puzzling given that EPA itself acknowledges that "[t]he general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved." If compliance with the Proposed Rule's specific requirements will satisfy the general duty, there is no need for EPA's alarming reservation of the right to sit in judgment on a source's "good air pollution control practices."[53]

EPA should remove the proposal to add the new § 63.632(j). In the alternative, it would be preferable to simply incorporate the general duty clause from Subpart A of the NESHAP, which contains language more clearly explaining the Agency's exercise of enforcement discretion during SSM periods.

IV. Requiring Title V permits would impose significant burdens with no benefit for pollution control or compliance. [C-74]

EPA should not adopt the proposed "requirement for area sources in the source category to obtain a Title V permit."

Requiring all commercial sterilizer area sources to obtain Title V permits is unnecessary, as EPA previously recognized. The Proposed Rule spends only a few lines discarding the Agency's previous well-reasoned and amply supported decision.[54] In addition to being incorrect, EPA's proposal is therefore arbitrary, capricious, and contrary to law.[55]

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[53] In addition, general duty provisions are a relic of a regulatory era in which air quality control rules lacked the specificity of monitoring, reporting, and recordkeeping such as that included in the Proposed Rule. For example, the archetypal general duty provision in EPA's new source performance standards ("NSPS") program—40 C.F.R. § 60.11(d)—dates back to 1973 and were meant to address the method for insuring compliance—discrete performance tests.

[54] Proposed Rule at 22,850.

[55] *See e.g. Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Adm'n*,, 41 F.4th 586, 595 (D.C. Cir. 2022) ("agency action must be 'reasonable and reasonably explained" to satisfy the arbitrary and capricious standard.) (quoting. *Prometheus Radio*, 141 S. Ct. at 1158); *Constellation Mystic Power, LLC v. FERC*, 45 F.4th 1028, 1056 (D.C. Cir. 2022) ("when an

For nearly two decades, EPA has exempted *commercial sterilizer area sources* from Title V permitting.[56] In its well-reasoned and thorough 2005 decision, EPA evaluated four factors in reaching its decision: "(1) [w]hether title V would result in significant improvements to the compliance requirements, including monitoring, recordkeeping, and reporting that are proposed for the area source category; (2) whether title V permitting would impose significant burdens on the area source category and whether the burdens would be aggravated by any difficulty in obtaining assistance from permitting authorities; (3) whether the costs of title V permitting for area sources would be justified taking into consideration any potential gains in compliance likely to occur for such sources; and (4) whether adequate oversight by state and local permitting authorities could achieve high compliance with the NESHAP requirements without relying on title V permitting."[57] In addition to the four factors, EPA considered whether an exemption from Title V permitting for area sources aligns with the legislative history.

EPA's analysis and conclusions in 2005 remain correct today.

A. Factor 1: Requiring Title V Would Not Result in Emissions Reductions or Compliance Improvements.

In its 2005 Decision, EPA determined that NESHAP requirements for all area sources "are substantially equivalent to Title V."[58] Relevant to this discussion, Title V permitting requires continuous monitoring methods,[59] deviation reports,[60] six-month monitoring

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agency 'fail[s] to provide an intelligible explanation' for its decision, it has 'fail[ed] to engage in reasoned decisionmaking'",) (quoting *FPL Energy Marcus Hook, L.P. v. FERC*, 430 F.3d 441, 448 (D.C. Cir. 2005));).

[56] EPA, *Exemption of Certain Area Sources From Title V Operating Permit Programs*, 70 Fed. Reg. 75,320 (Dec. 19, 2005) ("Title V Exemption")..

[57] 88 Fed. Reg. at 22,850.

[58], Title V Exemption at 75324.

[59] 42 U.S.C. § 7661c(b) (EPA "may by rule prescribe procedures and methods for determining compliance and for monitoring and analysis of pollutants regulated under this chapter, but continuous emissions monitoring need not be required if alternative methods are available that provide sufficiently reliable and timely information for determining compliance").

[60] *Id.* § 7661b(b)(2) ("regulations shall further require the permittee…to promptly report any deviations from permit requirements to the permitting authority").

reports,[61] and annual compliance certification reports[62] certified by a responsible official.[63] In EPA's analysis of this factor, it determined that the NESHAP requirements applicable to area sources are already subject to continuous monitoring, are required to assess, report and certify[64] compliance status on a semiannual basis, and reporting is similar to that required by Title V.[65]

Additionally, in response to a comment on its 2005 proposed rule, EPA also concluded that NESHAP provisions independently require schedules of compliance, provide inspection and entry authority are independently found within NESHAP, and establishes emissions limitations and standards that are enforceable regardless of Title V permitting; and that "in [their] experience the NESHAP are more stringent than typical [state implementation plans]."[66]

The Proposed Rule, in contrast, simply states that "the compliance benefits of Title V are greater today than in 2005." Rather than explain this statement in any meaningful way, EPA simply asserts, without analysis, that the Proposed Rule's "greater degree of complexity" means the compliance benefits of requiring Title V for area sources will be greater.[67]

This logic, however, does not stand. EPA concedes, like in 2005, that EtO sterilizers "are subject only to a single NESHAP."[68] EPA also recognizes again in the Proposed Rule, as

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[61] *Id.* § 7661c(a) ("Each permit issued…shall include…a requirement that the permittee submit to the permitting authority, no less often than every 6 months, the results of any required monitoring").
[62] *Id.*§ 7661b(b)(2) ("regulations shall further require the permittee to periodically (but no less frequently than annually) certify that the facility is in compliance with any applicable requirements of the permit").
[63] *Id.*§ 7661c€ ("Any report required to be submitted by a permit issued to a corporation under this subchapter shall be signed by a responsible corporate official, who shall certify its accuracy.").
[64] *Id.*§63.366(a)(3) ("The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report") (determined to be substantively similar to 42 U.S.C. § 7661c(c) ("Any report required to be submitted by a permit issued to a corporation under this subchapter shall be signed by a responsible corporate official, who shall certify its accuracy.")).
[65] 40 C.F.R. §63.310(e)(3) ("The owner or operator of an affected source required to install a CMS by a relevant standard shall submit an excess emissions and continuous monitoring system performance report and/or a summary report to [EPA] semiannually") (determined to be substantively similar to 42 U.S.C.A. § 7661b(b)(2) ("regulations shall further require the permittee…to promptly report any deviations from permit requirements to the permitting authority")).
[66] Title V Exemption at 75,334.
[67]Proposed Rule at 22,851.
[68] *Id.*

it did in 2005, that other area sources that are exempted from Title V are typically subject to only one NESHAP, and the benefit of requiring Title V is to roll-up into a single document "the various and sometimes complex [CAA] regulations" that apply to those area sources.[69] Thus, while EPA's Proposed Rule is certainly more *onerous*—often needlessly so, as explained elsewhere—the Proposed Rule offers no reason to believe Title V would make it easier to comply with subpart O.

B. Factor 2: Title V compliance would place significant burdens on Area Sources.

The second factor considers whether Title V permitting would be significantly burdensome for area sources and whether the burden would be exacerbated by difficulties in obtaining assistance from state agencies. For its 2005 decision, EPA gathered data on the burdens and costs of Title V, along with area source economic data. Sufficient economic data was not obtained for EtO area sources to make a determination based on empirical evidence.[70] Since these factors "assist EPA in evaluating whether the statutory criteria are satisfied,"[71] its lack of decision regarding factor two did not interfere with an overall determination: the other factors supported Title V exemption for EtO area sources.[72]

Now, however, EPA plainly states that "the costs imposed upon area source EtO commercial sterilizers . . . the burden is not insignificant."[73] Thus, Title V is even *less* appropriate now than it was in 2005. EPA's own rationale leads to the conclusion that factor two results in a finding of a significant burden.

C. Factor 3: There is no justification for imposing the burden of Title V permitting.

Factor three considers whether the cost of Title V permitting would be justified in relation to the potential gains from Title V compliance. While data available was limited, EPA nonetheless determined that since factors one and four showed that Title V permitting would be unnecessary, "it follows that the potential for gains in compliance is low. Although there may be some compliance benefits from Title V for EO sterilizers, we believe they will be small, and not justified by Title V costs and burdens for them."[74]

The Proposed Rule briefly describes estimated (not actual or reported) hours of time required to achieve compliance with Title V permitting, and the resulting costs that may be

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[69] Proposed Rule at 22,851 (emphasis added).
[70] Title V Exemption. at 75,325.
[71] *Id.* at 75,334.
[72] *Id.* at 75,325.
[73] Proposed Rule at 22,851.
[74] Title V Exemption at 75,325, 75,331.

incurred. EPA concludes that the costs would be $67,211 the first year, and $6,287 in total costs for the second and third years. EPA states that "this burden is not insignificant," but justifies the costs because it "represents a small portion of the anticipated costs related to the amendments of this proposed rule."

But the analysis on Title V applicability does not ask how the burden compares to the cost of complying some other measure. The question is whether the potential compliance benefits outweigh the steep costs, the answer to which EPA seems to concede is "No."

EPA's assertion that these costs are an overestimate is also a conclusory statement.[75] According to the Proposed Rule, EtO sources are comprised of 11 major sources and 86 area sources. The area sources by number far outweigh the major sources in numbers, which would largely correct for higher major source costs used in the estimate. EPA also could have easily separated the cost estimate for the 86 area sources in order to provide more accurate numbers. Lastly, these 2019 estimates are not accurate in light of the EPA's proposed rule changes. These new rules will require facilities to change not only their equipment, but also their calculation methods, monitoring, and testing. Those costs need to be taken into account for a Title V cost analysis.

D. Factor 4: Whether permitting authorities can effectively implement the NESHAP without Title V permitting

The fourth factor considers "whether there are implementation and enforcement programs in place that are sufficient to assure compliance with the NESHAP for area sources, without relying on Title V permits."[76] Put another way, is Title V necessary to effectively implement the NESHAP? EPA easily determined that oversight for area sources is adequate based on "statutory requirements alone."[77] This is because CAA sections 112, 113, and 114 require implementation and enforcement programs to be conducted by EPA or delegated to the proper state authority and a small business assistance program to assist area sources exempt from Title V with compliance. In addition to the statutory requirements, states and EPA routinely conduct voluntary compliance assistance outreach and education programs. EPA's review of state provided empirical data demonstrated that area sources were adequately compliant with their requirements without Title V permitting.

The Proposed Rule is silent as to whether permitting authorities can effectively implement NESHAPs without Title V. EPA alludes to its 2019 ICR, implying that the responses thereto support EPA's Title V decision, but never actually identifies that data or explains how it would support any of EPA's cursory statements.

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[75] Proposed Rule at 22,851.
[76] Title V Exemption at 75,325.
[77] *Id.* at 75326.

The only reasonable conclusion is that EPA's prior analysis remains correct. There is no more difficulty enforcing the single NESHAP for this source than there was in 2005, when EPA unequivocally determined Title V would provide no benefits to its ability to enforce CAA regulations in tandem with its state and local partners.[78] If anything, requiring Title V now would only make enforcement *more difficult*, as state agencies would be flooded with Title V applications that would require time and state funds to implement—and could potentially shift attention away from major source compliance in a way that would compromise (and not improve) implementation of any final NESHAP program.

E. CAA Legislative History

Finally, with respect to legislative history, EPA considered whether the exemption would adversely affect public health, welfare, and the environment,[79] and ultimately determined it would not. EPA's 2005 Decision used the four factors above, along with a brief assessment of the complexity of NESHAP requirements, number of NESHAP subparts the area sources in question are subject to, and potentially adverse impacts on public health resulting from the decision to require Title V permitting to determine whether area source exemption would align with the legislative intent of whether an exemption would adversely affect public health. It was determined that exempting EtO area sources from Title V permitting would not adversely impact public health, welfare, or the environment because: the four factors supported exemption by showing that Title V requirements are not necessary; a Title V exemption does not mean that area source facilities are exempt from their NESHAP requirements; the NESHAP requirements were simple and Title V would not help in navigating complexity; the area sources were not typically subject to more than one NESHAP subpart or a large number of other CAA provisions; and state agencies would be flooded with permitting applications that would require time and state approved funds to implement and could potentially shift attention away from major source compliance in a way that would adversely affect public health and the environment.[80]

EPA now suggests that area source commercial sterilizers should be subject to Title V permitting based on the legislative history. A statement inserted into the legislative history of CAA Section 502(a) asserts that "this provision of the permit title prevents EPA from exempting sources or source categories from the requirement of" Title V.[81] EPA quotes this legislator's comment then states that "[i]n 2016, the EPA released its updated IRIS value for EtO, which indicated that cancer risks from EtO emissions were significantly higher than characterized in the prior 1985 assessment."

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[78] *Id.* at 75,326; *see also id.* at 75,320, 75,337–38.
[79] EPA is referring to a quote from the Statement of Managers, which was created as both houses actively worked on and negotiated the CAA 1990 amendments.
[80] Title V Exemption at 75,326, 75,334–35, 75,338—39.
[81] Proposed Rule at 22,850.

"This non sequitur is not a meaningful answer."[82] Even accepting EPA's 2016 IRIS conclusion, the fact that a source category presents increased risks is not relevant to whether requiring Title V permits will increase compliance with the substantive technology and work practice standards contained in the NESHAP, the purpose of which is intended to address potential public health concerns. The NESHAP requirements have not been relaxed in any way since 2005, and EPA does not explain or show why its previous determination is no longer applicable. Title V permitting offers no added benefits.

Continuing the exemption from Title V permitting would not adversely affect public health, welfare, or the environment. As EPA stated in its 2005 Decision, "title V will impose some burdens regardless of the financial resources of EO sterilizers, and any burdens associate with title V compliance will be unnecessary, since title V will not provide any significant compliance benefits" beyond the existing CAA regulations, and "[t]herefore, a title V exemption is . . . consistent with the 'unnecessarily burdensome' criterion."[83] This remains true today, as it was in 2005.

V. Emission limits must be feasible and flexible to account for the wide array of facility configurations and sterilization processes.

A. It is not feasible with existing technology to achieve many of the proposed EtO emission reductions. [C-36, C-39, C-41]

Many of the source emissions standards proposed by EPA are not feasible and are not consistent with what vendors of emission control equipment will provide/guarantee. AdvaMed encourages EPA to understand the limits of each manufacturer of emission control equipment before setting any source emission standards. AdvaMed continues to work with vendors, but it has not been able to get definitive answers in the limited time allowed for comments. We look forward to further discussion on the topic with EPA prior to the finalization of the rules.

For example, EPA proposes to require facilities where EtO use is at least 10 tpy to reduce their emissions from new and existing SCVs by 99.94 percent.[84] The Agency stated that it reviewed performance tests at all facilities where EtO use is at least 10 tpy (46 total) and reported emission reductions ranged from 99.6 to 99.9999996 percent.[85]

As an initial matter, EPA arrived at the SCV emissions limit (99.94 percent) from facility stack testing performed according to *current* requirements, where an approximately 1-hour

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[82] *Casa de Maryland, Inc. v. Wolf*, 486 F. Supp. 3d 928, 966 (D. Md. 2020), *order dissolved*, No. 8:20-CV-2118-PX, 2023 WL 3547497 (D. Md. May 18, 2023).
[83] Title V Exemption at 75,331
[84] Proposed Rule at 22,839.
[85] *Id.*

stack test is performed during the initial vacuum after EtO exposure in an empty chamber and when EtO loading to the abatement system is high.[86] It is critical to note that stack test results compliant with current emissions requirements may not necessarily translate to the 24-hour stack test that EPA is proposing. This is because a 24-hour stack test will cover a variety of operating conditions, including those of low inlet concentration, which have yet to be tested. There is not proven field data on whether state-of-the-art abatement systems can meet the 99.94 percent DRE for SCVs when subjected to a 24-hour stack test. Further, many facilities do not have such equipment. Compounding both may result in medical device supply chain shortages.

Therefore, if EPA's priority is a 24-hour stack test, we urge EPA to withhold setting a DRE for SCVs until after the Agency collects data through the new 24-hour stack test. Then, EPA should only implement DRE requirements when there is high confidence that state-of-the-art abatement systems can achieve the proposed DRE over 24 hours. Additionally, in lieu of requiring 99.94 percent DRE for SCVs, which can vary with inlet loading, we propose EPA consider establishing a concentration limit in alignment with modern abatement systems can achieve.

Even beyond the change in stack test requirements, existing technology does not support a 99.94 percent DRE for SCVs.

First, existing systems would require major reconfigurations to meet the proposed standard, and such major modifications may not be possible in all circumstances. The emission flow from an SCV is episodic, occurring in short durations between 15 to 30 minutes. With the current technology, compliance with the 99.94 percent EtO emission reduction for facilities with SCVs may prove impossible given the timing difference between emissions at the source versus emissions when air flow exits the stack as sterilization in a batch process. EPA must account for variability in destruction efficiency during periods when EtO concentrations are low and include an alternative maximum concentration limit, such as Europe's 0.5 mg/m3, to ensure combined streams can demonstrate compliance.

Second, EPA is proposing to remove the portion of the stack test method that allows facilities to use an engineering estimate of EtO pounds injected into the sterilizer when calculating DRE percentages. In lieu of pounds injected to the chamber, EPA is proposing

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[86] *Id.* at 22,844 ("The EPA has determined that the current performance testing procedures in subpart O do not reflect normal operations discussed in the 2009 *Stack Testing Guidance.* A more encompassing performance test procedure for SCVs that includes normal operation of the sterilizer chamber with product present, covers all evacuations, i.e., all venting and washes, and also includes the number of sterilizer chambers (or other emission sources) that typically vent simultaneously would provide a more representative control level actually achieved by the control system.").

that facilities must measure the concentration of the inlet to the abatement system to calculate emission.[87] Concentrations in abatement system inlets can range widely and can be up to several hundred thousand ppm. This is well above the LEL (lower explosion limit) of 30,000 ppm and therefore could cause major unintended consequences such as explosion or exposure above the IDLH limit per OSHA. We strongly recommend that EPA maintain the option to utilize pounds of EtO injected to the chamber in order to ensure continued safe stack testing practices.

B. EPA should include alternative concentration maximums for each proposed emissions limit. [C-3, C-4, C-9, C-12, C-14, C-16, C-18, C-21, C-23, C-25, C-27, C-37, C-40, C-44, C-46]

EPA has requested comment as to whether each of the Proposed Rule's emissions limits should be accompanied by an alternative standard expressed in pounds-per-hour. In each instance, AdvaMed agrees that an alternative standard is appropriate, but urges EPA to adopt a concentration-based standard (in ppmv or ppbv) instead of the Proposed Rule's contemplated emission rate format (in lb/hr). As explained in more detail below, alternative concentration maximums are important to avoid creating counterproductive incentives (such as using more EtO in order to achieve better reduction percentages). Alternative concentration maximums also allow for more accurate emissions calculations.

1. EPA's proposed emission rate limit (lb/hr) alternative is not workable for this source category.

A uniform approach to emission rate limits is not appropriate for EtO sterilization facilities. As proposed, the same emissions rate cap would apply to all facilities, regardless of room size, configuration, sterilization equipment and capacity, and other notable differences, all of which affect the relationship between destruction efficiency and mass of EtO. Two facilities may both achieve the same destruction efficiency at the SCV, for example, and have vastly different emissions rates as expressed in lbs/hr. A lbs/hour could cause many facilities to limit flow or throughput in order to maintain compliance with the lb/hour limit. Additionally, sterilization is a batch process, so the inlet concentration, and subsequently DRE can vary significantly over time.

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87 *Id.* at 22,844.

Take EPA's own reported performance tests for example. Several of these tests show an identical SCV outlet percentage reduction with widely varying emission rates in lbs/hr:

	Outlet DRE	**Emission Rate (lbs/hr)**
1	99.99%	0.0253
2	99.99%	0.01609
3	99.99%	0.00178
4	99.99%	0.0666
5	99.99%	0.0008

The same data also shows higher DRE percentages resulting in higher emissions rates. For example, one test showed a DRE result of 99.9999988% with an emission rate of 0.0011 lbs/hr. Another facility reduced EtO emissions by 99.996% and emitted 0.0092 lbs/hr.[88] And sometimes a lower DRE results in lower emission rates. One facility reduced EtO at the SCV by "only" 98.54% with a resulting emission rate of 0.002109 lbs/hr—lower than most of the tests where SCV emissions were reduced by 99.99%.

The wide variance in facility and process designs is precisely why a uniform rate limit based on a calculated industry-wide average is fundamentally flawed.

A lbs/hour limit could cause many facilities to limit flow or throughput in order to maintain compliance with the lb/hour limit. Limiting flow could suboptimize ventilation and therefore cause safety hazards. Limiting throughput (pallets sterilized) could have a devastating impact on the medical device supply chain. We note a concentration limit, on the other hand, is independent of volumetric flow rates and therefore works better as a common approach. Any concentration limit must be in alignment with the capabilities of available abatement systems and be aligned with stacks, not individual vents.

2. EPA should not eliminate the maximum outlet concentration alternative for ARVs. [C-10, C-11, C-13, C-15, C-17, C-43 to C-46]

EPA is also proposing to remove the concentration alternative (1 ppmv under current subpart O) for ARVs at facilities that use at least 10 tpy of EtO. *See* Comment C-10. A percent-reduction standard with no concentration outlet maximum alternative is ill-suited for post-sterilization activities for several reasons.

The total amount of residual EtO making its way to the ARV is typically small, sometimes even below the detectible limit. Further, as EPA knows, industry continually strives to reduce the amount of residual EtO on products and packaging before moving them to the

[88] See Technical Support Document at 57–58 (Table 10).

aeration room. These cycle and process elements reduce the amount of EtO present at every downstream stage and at the facility overall.

This overall reduction means that only a small amount of EtO reaches the aeration vent in the first place, which makes it infeasible to comply with the proposed DRE. The following example illustrates this problem. Let's assume you have 100 ppm at the inlet. In order to achieve a 99.6 percent reduction, you would have to achieve 0.4 ppm at the outlet. If you only have 10 ppm at the inlet, you would have to achieve 0.04 ppm at the outlet. And if you have 1 ppm at the inlet, you would have 0.004 ppm at the outlet. ARV control devices lose a considerable amount of efficiency at lower concentration levels, making it increasingly difficult to achieve any percent reduction e*ven though overall emissions are lower*. In other words, it is much easier to go from 100 to 0.4 ppm than it is to go from 1 to 0.004 ppm, but assumedly, EPA would rather facilities have a lower amount than a higher amount at the inlet.

Removing the maximum outlet concentration alternative creates an incentive to ensure the residual EtO making its way to the ARV is as high as possible: the more EtO is present in the aeration room, the easier it will be to comply with the current proposal.

Further, it is difficult to obtain accurate measurements at these low concentrations. This was precisely EPA's rationale in selecting a concentration-based standard for ARVs over the past three decades:

> [B]ecause the inlet concentrations from the aeration room vents are relatively low, and the outlet concentrations of some of the controlled aeration room vents approach the levels of detection for EO, some facilities may not be able to demonstrate compliance with an "equivalent" percent reduction requirement.[89]

While detection accuracy has certainly improved over the years, the inlet/outlet concentrations typical at ARVs are often at or below the detection level of modern equipment. It remains the case now, as with the 1994 NESHAP, that "the use of the concentration limit format for these vents would provide the most accurate measurement of the performance of the control devices."[90] Indeed, in the original proposed 1994 NESHAP, the *only* ARV standard was a concentration limit.

An example proves the point. As noted, most facilities currently comply with the 1 ppmv concentration limit. If the concentration is *double* that amount, 2 ppmv, at the ARV inlet

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[89] *Proposed National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations*, 59 Fed. Reg. 10591 ,10594 (March 7, 1994).
[90] *Id.* at 10601 .

of a facility that uses at least 10 tpy, that facility would have to measure an outlet concentration of 8 ppbv to demonstrate compliance with the Proposed Rule. This is more than six times lower than EPA's own "workable-in-practice lower measurable value of 30 ppbv." The problem is even worse for new ARVs required to meet the proposed 99.9% reduction.

EPA should therefore continue "to provide owners or operators flexibility to either meet a maximum emission limit . . . or achieve a . . . reduction in ethylene oxide emissions" as it did in the 1994 NESHAP.[91]

3. The wide variance across facilities in this source category means that a flexible alternative is appropriate even for a MACT standard.

EPA's purported justification for eliminating this flexibility does not support its decision for at least two reasons.

First, EPA acknowledges that even "a MACT standard may be expressed in multiple formats so long as they are equivalent."[92] EPA then says that because the Agency thinks 1 ppmv is not in fact equivalent to 99% reduction, the rule "cannot allow compliance with a less stringent alternative standard."[93] That may be a reason to *revise* the alternative standard, but it is no explanation for *eliminating* it altogether—especially when the same difficulties that led to its promulgation still exist.

EPA did in fact calculate a revised alternative outlet concentration equivalent:

> We calculated the outlet EtO concentration that is equivalent to 99 percent removal efficiency for ARVs at facilities where EtO use is at least 10 tpy by first assuming that all of these facilities are achieving the removal efficiency standard. The outlet EtO concentration at each facility is dependent on EtO usage, the portion of EtO usage that is emitted from the ARVs, and the flowrate and temperature of the ARV. We then calculated the ARV outlet EtO concentration at each facility, calculated the average value of the ARV outlet EtO concentrations across all facilities, and rounded to one significant figure, which resulted in 0.5 ppmv.[94]

Immediately after reporting the results of its calculation, EPA simply declares "[I]n light of the above, we are proposing to remove the less stringent 1 ppmv concentration

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[91] *National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations*, 59 Fed. Reg. 62585, 62857 (Dec. 6, 1994).
[92] Propose Rule at 22,810.
[93] *Id.*
[94] Proposed Rule at 22,811.

alternative."[95] But EPA's calculated concentration limit of 0.5 ppmv provides a much more workable solution than eliminating an alternative maximum concentration altogether. EPA has not explained why it has departed from its previous determination that a concentration limit was *preferable* for ARVs.

The Proposed Rule's supporting documents provide more background, but do not fully address the discrepancies. In the Technical Support Document, EPA recites the same calculation included in the Proposed Rule leading to the 0.5ppmv result. The Agency then says: "Based on this discrepancy in the equivalence of the two formats, we are considering the removal of the alternative 1 ppmv standard."[96] Again, if the goal is equivalent formats, and EPA thinks there is a "discrepancy" in the existing rule, the natural solution is to fix the discrepancy.

EPA's logic also misapplies the concept of a MACT standard by failing to consider the substantial variability in residual EtO concentration across products and facilities. Sterilization is a batch process, and batches vary widely in size. In rare scenarios with exceptionally large batches in facilities with less robust sterilization-chamber mitigation, a percent-reduction may be both reasonably achievable and measurable.

But the converse is also true: the proposed standard is much less feasible for smaller batches in facilities that effectively prevent residual EtO from leaving the sterilization chamber. The fact that *some facilities* in *some circumstances* can achieve and measure a DRE target for *some batches* does not mean that the DRE must be the MACT floor.

EPA should therefore maintain reasonable, achievable concentration limit alternative standards for ARV outlets.

VI. EPA cannot and should not regulate sterilization or sterility assurance methods, concentration limits, or packaging. [C-2, C-5—C-8, C-11, C-13, C-15, C-17, C-20, C-22, C-24, C-26, C-30, C-31, C-34, C-35, C-82]

EPA proposes to require as a best management practice ("BMP") that existing Group 2 rooms at area sources using less than 20 tpy achieve "sterility assurance" by following either the "Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. " (Comment C-34).[97] EPA also considered, and decided against, imposing this same BMP in place of many other emissions limits in the Proposed Rule (Comments C-2, C-5, C-8, C-11, C-13, C-15, C-17, C-20, C-22, C-24, C-26, C-30, C-31, C-35). In addition, EPA

[95] *Id.*
[96] Technical Support Document at 19–20.
[97] *See generally* Proposed Rule (discussing proposed management practice of following ISO standards across a variety of emissions points).

also solicits comments on two other BMPs the Agency is also not proposing to implement now: limiting EtO concentration within each sterilization chamber (C-6) and regulating medical device packaging (C-7).

EPA does not have authority to require specific validation methods, especially when the FDA *does* have that power and actively exercises it. Irrespective of jurisdiction, it would be imprudent for the Agency to interfere with FDA's superior competency.

A. EPA does not have authority to approve or disapprove validation methods. [C-2, C-5, C-8, C-11, C-13, C-15, C-17, C-20, C-22, C-24, C-26, C-30, C-31, C-34, C-35, C-82]

In EPA's concurrent proposed registration review, the Agency acknowledged that "EPA's authority under FIFRA does not allow for OPP to prescribe on pesticide product labels FDA's process for validation assessment of sterilization modalities for medical devices."[98] EPA's authority under the CAA likewise does not allow OAR to prescribe validation methods. Section 112(d)(5)'s provision authorizing EPA to require "management practices" does not authorize EPA to dictate *how* commercial sterilizers achieve "sterility assurance." This is underscored by the fact that Congress gave FDA with the authority to ensure safe and effective medical devices. As discussed below, EPA cannot use a generalized grant of authority to require "management practices" to intrude on a core regulatory responsibility that FDA holds.

EPA's BMP in the Proposed Rule falls outside the types of practices contemplated in Section 112(d)(5). In reviewing a management practice promulgated by EPA for industrial boilers, the D.C. Circuit, in *United States Sugar Corp. v. EPA*, described the general approach such requirements should take, noting that requirements under Section 112(d)(5) "generally take the form of 'methods, practices and techniques which are commercially available and *appropriate* for application by the sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems."[99] While this quote may appear directed only at "emissions control systems," the D.C. Circuit applied it in the context of a management practice requirement.[100] Thus, as a general matter, management practice standards must be "appropriate" and take into account relevant factors. Past management practices promulgated by EPA illustrate the general contours of appropriate management practices to require.

One such requirement was at issue in *United States Sugar Corp.* and also provides a useful example of the type of management practices EPA typically requires. In that case, EPA

[98] PID at 32.
[99] 830 F.3d 579, 653–54 (D.C. Cir. 2016) (upholding a biennial tune-up requirement as a "GACT management-practice standard") (quoting S. Rep. No. 101-227, at 171 (1989)) (emphasis added).
[100] *See id.*

only required a tune-up of industrial, commercial, and institutional boilers as a management practice on a biennial basis.[101] This management practice demonstrates a light touch—EPA did not dictate how the facilities should run their day-to-day operations or how they should produce their end-products. As another relevant example, EPA's existing NESHAP for hospital EtO sterilizers provides that sterilizers "must sterilize full loads of items having a common aeration time, except under medically necessary circumstances."[102] Thus, in the EtO context, EPA limited its requirement to the number of cycles run (by ensuring full loads), but EPA *has not* specified a particular requirement for *how* any particular sterilization cycle should be run and thereby overstepped the bounds of what would be appropriate. Furthermore, it is important to note the exception EPA granted for medical necessity.[103] The two examples here (the tune-up requirement and full loads for sterilizers) illustrate that management practices under Section 112(d)(5) specify upkeep of a facility or general operating parameters of a facility, but they do not dictate precisely what methods a facility must employ. In this way, EPA's proposal to dictate how to validate their sterilization cycles—i.e., achieve "sterility assurance" by following ISO 11135:2014 or ISO 11138–1:2017—stretches past the bounds of Section 112(d)(5)'s statutory delegation.

FDA has the duty—and corresponding expertise—to "provide reasonable assurance of the safety and effectiveness of [a medical] device."[104] Pursuant to that review, FDA "weigh[s] any probable benefit to health from the use of the device against any probably risk of injury or illness from such use."[105] Importantly, in 1997 Congress passed the Food and Drug Administration Modernization Act, which further directed FDA to take the least burdensome approach to medical device premarket evaluation to eliminate unnecessary burdens and delay marketing of beneficial new products.[106] In short, Congress has tasked FDA with assuring the safety and effectiveness of medical devices—not EPA. Intending to foster innovation in medical device development, Congress directed that FDA take a

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[101] *Id.*; 40 C.F.R. Table 2 to Subpart JJJJJJ (prescribing biennial tune-up of boilers as a management practice standard).
[102] 40 C.F.R. § 63.10390.
[103] *Id.*. *see also National Emissions Standards for Hospital Ethylene Oxide Sterilizers*, Final Rule, 72 Fed. Reg. 73,611, 73,615 (Dec. 28, 2007) ("We believe that it is medically necessary to allow hospitals to sterilize medical devices that are under research and development without a full load.").
[104] 21 U.S.C. § 360c.
[105] *Id.* § 360c(a)(2)(C).
[106] *See* FDA, Guidance, *The Least Burdensome Provisions: Concept and Principles* (Feb. 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles (discussing the statute and how FDA has interpreted least burdensome).

least burdensome approach to premarket evaluation for new medical products.[107] EPA threatens to undo Congress's careful judgment here.

The Supreme Court explained in *Whitman*: "Congress . . . does not alter the fundamental details of a regulatory scheme in *vague terms* or ancillary provisions—it does not, one might say, hide elephants in mouseholes."[108] Here, however, EPA attempts just that; EPA proposes to alter the fundamental details of the regulatory scheme for assuring safety and effectiveness of medical devices across the sterilization industry by dictating the precise methods by which sterilizers will achieve sterility assurance.[109] Thus, just as in *Whitman*, EPA must point to a clear textual commitment for the authority it asserts. The authority to prescribe "management practices" falls short of this requirement, just as other vague and generalized textual authority has fallen short in other contexts.[110]

The practical problems with EPA's proposal to regulate the method of sterilization assurance also demonstrate why Congress would not have intended EPA's authority to specify "management practices" to go so far as dictating methods for validating sterilization cycles. For example, if FDA later determines that ISO 11135:2014 and ISO 11138–1:2017 no longer satisfy FDA's requirements for safety and effectiveness of the medical devices it regulates, then sterilization facilities would be caught in a "can't win" situation. Either they comply with EPA's requirements (while violating FDA's), or they comply with FDA's requirements (while violating EPA's). Similarly, for development of new sterilization cycles, FDA is expressly directed by Congress to take the least burdensome approach to medical device premarket evaluation to eliminate unnecessary burdens and delay marketing of beneficial new products, as noted above. Thus, if a sterilizer wishes to innovate new sterilization cycles, Congress has directed FDA to allow the least burdensome approach for doing so. EPA, by contrast, would forbid such innovation, undermining Congress's policy choice.

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[107] *Id.*
[108] 531 U.S. 457, 468 (2001) (emphasis added).
[109] *See* Proposed Rule at 22,808 ("The second potential GACT option we considered was a management practice that would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach *to achieve sterility assurance in accordance with International Organization for Standardization (ISO) 11135:2014 and ISO 11138–1:2017*." (emphasis added)).
[110] *See, e.g.*, *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2487–90 (2021) (authority to "prevent the introduction, transmission, or spread of communicable diseases" not enough to support an eviction ban); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 127 (2000) (authority to regulate a "drug" not clear enough textual commitment in light of backdrop of regulation and extent of authority claimed); *MCI Telecom. Corp. v. AT&T*, 512 U.S. 218, 231 (1994) (authority to "modify" is not clear enough authority for an agency to determine whether an industry will be regulated or not).

EPA also states: "In addition, we are proposing to incorporate by reference ISO 17025- - General requirements for the competence of testing and calibration laboratories (Approved November 2017). This ISO standard "contains requirements for laboratories to enable them to demonstrate they operate competently and are able to generate valid results." The ISO 17025 standard should not apply to manufacturers or internal testing laboratories. It is typically reserved for lab service providers. Internal laboratories are considered to be quality control operations and are not currently considered to be, nor should they be, in-scope of the accreditation requirements of ISO 17025. Therefore, it should not be included.

Thus, because EPA is venturing well afield of the statutory authority it has traditionally exercised and because EPA upsets Congress's allocation of authority to FDA, it is clear that Congress did not grant EPA the statutory authority it claims here.

B. EPA's proposed mandatory validation methods are not an effective way to reduce EtO emissions. [C-5, C-34]

AdvaMed shares EPA's stated goal of reducing overall EtO use to the extent possible while ensuring sensitive medical equipment is sterile. For the reasons below, AdvaMed requests EPA permit continued use of the Half Cycle Method for EtO use at facilities with SCVs.

The PID acknowledges that half cycle approach can also be used to optimize sterilization cycles.

Below is text from pg. 50 of the PID, from the *Cycle Design Optimization & Half Cycle Approach section:*

> There are methods to reduce the amount of EtO used during the Half Cycle Approach, and these are currently being pursued by the FDA's "Innovation Challenge 2" participants (see Section IV.B.). EPA and FDA share the same goal of reducing the overall amount of EtO used by optimizing cycle design, through the optimization of various specifications such as dwell times, pressure, and humidity, as well as the reduction in the amount of paper packaging which is known to absorb EtO. Through FDA's Innovation Challenge 2, some industry participants have already implemented their optimized cycle designs, reducing EtO use by a significant amount. Per an FDA statement, early observations suggest that some facilities have cut emissions ranging from 20-35%, with the potential to impact millions of devices. In general, manufacturers are targeting an EtO concentration that is 11-66% less than the typical concentration range.
>
> EPA proposes that sterilization facilities use the least amount of EtO needed to meet sterility assurance through cycle design optimization, taking into consideration that sterilization cycles often include mixed loads of different

> medical devices which require different levels of EtO concentrations. Industry has already demonstrated the ability to optimize dwell times, pressure, and humidity, as well as the reduction in the amount of paper packaging through FDA's Innovation Challenges.

Importantly, use of Cycle Calculation or Bioburden/BI approaches do not necessarily mean less EtO use or less EtO emissions because the amount of gas is independent of the validation method. The Cycle Calculation approach may not achieve significant reduction in EtO exposures times, especially when gas injection and after-vacuum phase are used in calculations. We predict a switch to the Cycle Calculation or Bioburden/BI approaches would significantly impact manufacturers and contract sterilizers by requiring multi-product configurations and validation of more dedicated product cycles – prolonging an already tedious process. Conducting cycle calculation studies to determine the minimum lethality concentration required for every different type of product or product categories would not be feasible with the current capacity available at contract EtO sterilizers.

In addition, shifting from the Half Cycle approach to either the Cycle Calculation or Bioburden/BI approaches will require significant effort to redesign new sterilization cycles, evaluate product and packaging performance, validate, and complete product registration. This will impact sterilization capacity as equipment is not available for production use and may cause production delays. Further, there are limited resources to support this effort and the expertise to change validation methodology on such scale is limited, placing continuity of supply, product performance, and sterility at risk. The timeline for regulatory approvals is extensive considering the global market demand. By prohibiting use of the Half Cycle approach, EPA is essentially requiring these operations to cease as suppliers await the qualification and approval processes required to adopt the new approaches.

Of note, liability for sterility of the end product lies with the business and is within the regulatory purview of FDA, not EPA. Further, significant delays in regulatory approvals are expected as FDA and notified bodies would not have sufficient resources to manage the number of regulatory submissions related to sterilization validations or product modifications. By mandating the maximum concentration of the sterilant and the validation methodology, EPA is not considering potential long-term ramifications and costs to both the end-user of the medical devices and the businesses who create and manufacture them.

Notably, revalidating existing cycles will cause significant capacity issues as production capacity is diverted to cycle validation. Sites that use more than one vendor (to avoid supply chain disruption) would have to revalidate cycles for each respective venue, making the process even more challenging. It would be impossible to achieve across the supply

chain within the unprecedented and truncated 18-month transition period without causing major production delays and impacts to patient access to necessary medical procedures.

EPA's compliance timeline does not include, among other things, administrative costs, internal research and development time, negotiations with vendors and sterilizer suppliers, or reliance on FDA's approval and requirement for cycle design validation. Thus, it is inappropriate for EPA to dictate sterilization parameters. EPA should only focus on emission control parameters and avoid issues which may conflict with FDA or impact product regulatory requirements globally. Further, while the FDA has supported a faster approval time for certain validation changes, many medical device manufacturers are global and ship products to foreign countries whose regulators may not be able or willing to expedite approval. This creates an impossible scenario for manufacturers of sterile devices. Additionally, the competing applications will undoubtedly create a bottleneck. Thus, the ramifications of prohibiting the Half Cycle Approach extend beyond regulation at the national level and will almost certainly impact the global market. Therefore, we ask EPA to consider the impact the proposed validation changes would have on the regulatory approval processes and the EtO sterilization market both domestically and globally.

In sum, the Cycle Calculation and Bioburden/BI approaches do not effectuate reduction in EtO concentration cycles as EPA intends. Reduction of exposure time can be achieved in many different ways, including the already adopted Half Cycle approach. With more dedicated product loads being required to follow these validation approaches, requiring the Cycle Calculation or Bioburden/BI approaches will have the opposite effect on overall EtO usage as more cycles would be needed routinely for different product mixes, most chambers wouldn't be able to be filled to capacity if multi-product configurations couldn't be used (thereby sterilizing air), and more cycles would be required to maintain validation. All these factors would also lead to significant increases in cost and numerous negative external harms EPA did not consider in its proposal or 18-month compliance deadline.

For these reasons, AdvaMed asks EPA to remove the cycle validation requirements from the proposal.

C. EPA should not attempt to regulate concentration limits or packaging [C-6, C-7]

For many of the same reasons described above, EPA lacks both legislative authority and the requisite expertise to regulate sterilization cycle concentration (C-6) or product packaging (C-7). Both EtO concentration and product packaging are important parameters of the sterilization process, which, as EPA knows, "is tailored to each product or group of products to consistently deliver the level of sterility needed" and requires "extensive testing to identify the correct levels of the key parameters that determine a cycle's efficacy,

including temperature, humidity, pressure, exposure time, and EtO gas concentration."[111] Furthermore, certain packaging configurations are necessary to protect the product itself to ensure the sterile barrier remains intact until use, and to prevent product damage during shipping, handling, and storage. Any change to either of these parameters requires re-evaluating the entire cycle design and validation process.

A 290 mg/L concentration maximum is not reasonable or practical. It is not possible to achieve sterility assurance for many products using the Proposed Rule's contemplated concentration maximum of 290 mg/L. This concern is especially acute for products sterilized in their final packaging, which constitutes most of the medical device supply chain, which require higher EtO concentrations to penetrate to the device itself. AAMI guidance document TIR 16 states: "Common practice is to develop and validate cycles using an EO concentration ranging from 400 to 650 milligrams per liter (mg/L), because concentrations in this range have been found to achieve microbiological lethality for most products within a reasonable and practical exposure time." For the limited number of products where it might be possible to significantly reduce gas concentration, revising the sterilization cycle, revalidating it, and obtaining the requisite FDA and international approvals would require considerable time and resources.

As noted throughout this comment, designing a cycle at this lower level requires adjusting the dwell time (and other cycle elements), which can lead to increased EtO use overall and in some cases can actually cause further EtO absorption into the product. For example, extended dwell times have a detrimental effect on combination products that have both API and medicinal components. Longer exposure times could impact biocompatibility profiles, battery life/stability, shelf-life and aging (specifically if real-time aging is required) and would require additional time to support design validation testing. Additional changes to vacuum, pressure and temperature during sterilization may also be required and result in similar challenges. As a result, the correlation between chamber concentration and emissions has been oversimplified, and the proposal will not contribute to EPA's goal to decrease EtO emissions by implementing such a requirement.

Perhaps more importantly, **longer dwell times across the industry will dramatically reduce domestic sterilization capacity** and lead to increased offshoring of sterilization business, construction of additional facilities—and therefore additional EtO emissions sources—or both. Thus, for the same reasons explained in the previous section, imposing a maximum concentration level does not necessarily reduce overall EtO use or exposure.

Further, pursuant to ISO 11135, validating a cycle with 290 mg/L requires validation parameters to show a robust and capable sterilization process at even lower levels. And, as noted throughout this comment, designing a cycle at this lower level requires adjusting

[111] RIA at 2-6.

the dwell time (and other cycle elements), which can lead to increased EtO use overall and in some cases cause further EtO absorption into the product.

For existing small capacity sterilizers with fixed chamber volumes that use 127 gram EtO cylinders, reducing the concentration level to 290 mg/L would require equipment and facility redesign.

A 290 mg/L maximum concentration would also be inconsistent with the PID's proposed 500 mg/L maximum concentration, which itself presents serious concerns. Some manufacturers have been voluntarily working on reducing concentrations below this 500 mg/L limit for the past several years for certain products, and have not been successful.

Additionally, product packaging is dictated by requirements to provide a sterile barrier for the product and to ensure the product is not damaged during processing, handling, shipment, and storage. Any proposed changes to packaging will require extensive analysis of the impact of any given change on the product, the current sterilization cycles validated and approved for that product, and the approved usage specifications of that product.

Finally and importantly, EPA's authority to update and amend the commercial sterilization NESHAP in Subpart O is broad, but limited by the Agency's statutory mandate under the CAA.[112] Put simply, while the CAA authorizes EPA to address hazardous air pollutant (HAP) emissions to ambient air that pose a threat of adverse human health effects or environmental effects, the FD&C Act authorizes the FDA to regulate the safety and effectiveness of medical device sterilization. Certain aspects of the proposal intrude into FDA's jurisdictional authority to oversee the manufacturing and sterilization of medical devices.

Ultimately, all of the BMPs contemplated are unproven concepts that would not necessarily result in lower air emissions. Importantly, there is no published evidence that products sterilized in 290 mg/ L lower fugitive emissions, which is an ultimate aim of the NESHAP. Current published data suggest that the reduction of fugitive emissions is largely material and aeration dependent. To enact such a broadly industry impacting measure on little to no data is irresponsible. The BMPs should not be placed as requirements on Group 2 room air emissions for the various reasons stated and overall negative impact to sterile device infrastructure.

VII. The NESHAP should provide necessary flexibility in controlling room air emissions [C-1, C-28 to C-35]

[112] *West Virginia v. EPA,* 142 S.Ct. 2587, 2609 (2022) ("agencies have only those powers given to them by Congress").

It is critical to build flexibility into the standard/regulation and allow equivalent alternatives for emission control using equipment and parameters that are reliable and well understood by the industry. Not all EtO sterilization facilities are designed and engineered in the same manner. Consequently, how one site achieves acceptable air emission control may not work for another site as this control of emissions will be dependent on facility design. Flexibility is critical to ensuring every facility configuration is considered. Further, there are alternative mechanisms to support more accurate options for facility control and monitoring while incorporating the necessary flexibility amidst current technical challenges with ambient testing.

While permanent total enclosure is one option offered to achieve emission control for a commercial sterilization facility, it may not work in all sterilization facilities due to size, design, multiple stacks, warehouse function, etc. These varied designs may make measuring/maintaining PTE parameters such as draft opening face velocity or pressure differential difficult if not infeasible.

Alternatives to total enclosure including cascading air flow systems or employing parametric monitoring methods for the sterilization process based on the parametric monitoring proposal AdvaMed submitted to EPA previously and attached as Appendix III should be considered. This concept provides the necessary flexibility to design controls specific for variable facility configurations and allows companies to illustrate emission control and conduct ongoing parametric monitoring to ensure operating within the set parameters.

In cases where PTEs are reasonable, Method 204 is sufficient to ensure the PTE is capturing 100% of emissions, assuming there are no changes in the operations or the PTE. The initial EPA Method 204 PTE certifications already involves verifying that the direction of air flow through all NDOs is inward. In addition to the Method 204 certification, the proposed regulation requires either 1) continuous monitoring of flow rate or 2) continuous monitoring of pressure drop. Either one of these requirements would readily detect if the PTE is no longer achieving 100% capture efficiency. Regardless of which option a facility chooses, however, EPA is proposing that facilities continuously verify the direction of air flow through daily inspections of each NDO, which may be done through a smoke test or using streamers. Daily inspections are unnecessary and do not provide meaningful additional information on the effectiveness of a PTE. Therefore, this requirement should be removed.

A. Separately regulating room air emissions will have minimal benefits and cause considerable harm.

Room air emissions have historically been unregulated no doubt in part because the EtO levels during those operations are very low and difficult to measure even with the best

current technology. Low concentrations similarly cause difficulties in channeling the chemical through the air and, especially, with meeting pollution control standards in any format.

EPA's proposed controls would have very low effectiveness in reduction of EtO emissions because they are areas of low EtO concentration. These areas already have controls and EtO monitors in place to prevent unintended releases and ensure the safety of the facility. The high cost for a facility to create a PTE and route all exhaust from Group 1 rooms (much less Group 2 areas) to an additional abatement system that could handle the required airflow would be disproportionate to the potential residual emissions that would be captured.

At the same time, EPA has underestimated the costs of implementation. EPA expects about $100M in total expenditures across 74 facilities to comply with PTE requirements for Group 1 emissions. This is a gross underestimate. The capital cost estimate reported for two locations of one operation is approximately $50 million. Another facility was quoted a high level cost estimate of about $23 million dollars after weeks of discussion and the creation of a conceptual design with a company that assists sterilization facilities with PTE installation. The latter facility calculated that the redesign would cost them around $100,000 per pound of EtO emissions reduced.

B. EPA's proposed emissions limits for room emissions are based on a limited number of data points and are not achievable generally. [C-31, C-32, C-33, C-35]

EPA's proposed standards for room air emissions (with the exception of existing group 2 area sources) are based on the Agency's calculated MACT floor for major sources in this category. The MACT floor calculation is problematic on its own because, as EPA admits, it is based on a *single* data source. Despite this standard being openly based on a single source's reported performance, the Proposed Rule greatly compounds this problem by then extending this single-source performance result to area sources as a *generally* available control technology.

EPA first claims to calculate the MACT floor for room air emission sources. For both Group 1 and Group 2 sources, EPA states that "[t]here are only three performance tests that are currently available, so the best performing 12 percent of exiting sources for which data are available consists of . . . one facility that is controlling such emissions with a gas/solid reactor."[113] Yet EPA acknowledges that at "32 facilities have controls in place for" Group 1 room air emissions and "28 facilities have controls in place: for Group 2 room air emissions.[114] EPA's proposed MACT floor is nevertheless based on *a single facility* using

[113] Proposed Rule at 22819, 22821.
[114] Technical Support Document at 28, 31

a specific control device. This facility may not be the best performing source, and certainly is not an adequate representation of the best 12% of existing sources—fully half of which do not use the same control device.[115]

As EPA acknowledges, calculating "a MACT floor emission limit based on a truncated data base (i.e., calculated using values at or near the method detection limit) may not account adequately for data measurement variability, because the measurement error associated with those values provides a large degree of uncertainty."[116] EPA should consider available information regarding control technologies in the dozens of other area sources the Agency itself acknowledges are controlling these emissions.

EPA then took the reported emissions from this one facility and "used the UPL to develop the MACT floor for existing sources." The upper prediction limit, or UPL, is designed to "address[] variability of emissions data from the best performing source or sources in setting MACT standards."[117] But EPA has repeatedly "recognize[d] that **for a sample size of fewer than three data points . . . we should not develop emissions limits using the UPL**."[118] Indeed, "if fewer than 3 data points are available for use in determining an emission limit for a particular source," EPA must "establish a different procedure for establishing the MACT floor that does not rely on the UPL." EPA also recognized in this instance that the UPL was below detection and ultimately adjusted the MACT floor using 3X the representative detection limit. However, even with this adjustment, the analysis was predicated on using the UPL from a single facility.

These flawed MACT-floor calculations are then carried over to EPA's proposed area source standards. EPA acknowledges that these area source standards for room air emissions are GACT standards, and thus are required to reflect "***generally*** available control technology . . . commercially available and appropriate for application by the sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems."[119]

The controls employed by a single source—with a specific facility design and a unique constellation of products and processes—are not "generally available" under any reasonable definition. The significant variability between *any* two facilities, described

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[115] *See Draft MACT Floor Analysis for Ethylene Oxide Commercial Sterilization – Chamber Exhaust Vents and Room Air Emission Sources – Proposal* at 5–6 (Nov. 4, 2022).
[116] *Id.* at 11.
[117] Mem. of Jonathan Witt, *Approach for Applying the Upper Prediction Limit to Limited Datasets* at 1 (Nov. 28, 2022).
[118] *Id.* at 2 (emphasis added); *see also* Mem. of Susan Fairchild, *Approach for Applying the Upper Prediction Limit to Limited Datasets* (Oct. 6, 2014).
[119] Proposed Rule at 22,807 (quoting Sen. Rep. No. 101-228, at 171 (1989) (emphasis added).

throughout this comment, raises serious concerns with EPA's attempt to impose a single standard based on data from one facility.

Equipment vendors such as Advanced Air Technologies and Lesni report that current technology cannot meet EPA's proposed Group 1 emissions standard of 1.3E-3 lb/hr and Group 2 emissions standard of 2.8E-3 lb/hr. EPA derived those standards from limited data points and did not follow its own established practice to evaluate impacts for a variety of facilities. A single snapshot of one stack test of a single facility does not reflect a reasonably obtainable expected efficiency.

These rates are orders of magnitude lower than what is achievable at many facilities. These limits are not achievable for many sources due to facility designs and the current technological limitations. Moreover, for same reasons cited above, EPA's proposal to establish an emission rate cap of 1.3E-3 lb/hr for Group 1 emissions and 2.8E-3 lb/hr for Group 2 emissions that would apply to all facilities is not workable. A large number of variables determine the efficiency level of control equipment, such as inlet concentration to the abatement system, ambient temperature, temperature within the sterilization area, humidity, altitude, air pressure, air density, etc. Two facilities achieving the same destruction efficiency or outlet concentration at a gas-solid reactor (scrubber) or other control device may have vastly different emission rates expressed in lbs/hr.

Achieving such an emission cap would require larger facilities to reduce throughput or limit ventilation flow in Group 1 and Group 2 room areas. Limiting ventilation flow may cause safety hazards and restricting throughput would have a substantial negative impact on the medical device supply chain. On the other hand, a concentration limit is independent of flow and therefore would work better than a lb/hr cap. Any such limit, however, must be aligned with what is achievable or generally available under a MACT or GACT standard, as appropriate.

C. EPA's proposed enclosure requirements need significant revision to account for facility and process realities. [C28--C-32, C-33, C-35, C-60, C-70, C-71, C-75, C-79]

EPA's one-size-fits-all proposal needs to be revisited. The commercial sterilization industry have different warehouses and spaces for sterilization, aeration, packaging, and distribution. For example, the area where products are packaged (Group 2 emissions) may be on the opposite side of a facility from the sterilization area and control equipment. A facility like this would not only need to design and build a permanent total enclosure but would also need to relocate existing operations. The regulation of room air emissions, especially combined with the proposed permanent total enclosure requirements, would require a complete reconfiguration of many facilities and their processes. This is extraordinarily cost-prohibitive, to the point where building a new facility to accommodate

these requirements would likely be more cost-effective than renovating the existing facility layout.

Separately controlling room air emissions will require such extensive renovations that some existing sources will become "reconstructed" and therefore "subject to relevant standards for new sources."[120] This not only underscores how extensive these proposed room air emissions standards are but would also lead to additional delays in implementation of emissions standards. Facility renovation, and especially full reconstruction, will require additional permitting, time, effort, and monetary expenditure, all of which is not achievable in EPA's 18-month expedited implementation timeline.

Compliance demonstration requirements for Group 1 and Group 2 emissions are not representative of reality. In some configurations, the concentration of EtO in the Group 1, and especially Group 2 emissions, may not be correlated to emissions measured from other emission sources (e.g., SCVs) during a three-run compliance demonstration. As a result, the measured average EtO concentration for areas with potential Group 1 or 2 air emissions during the compliance demonstration at different emission sources (e.g., SCVs) may not allow for the determination of a representative maximum operation limit for the Group 1 and 2 sources. Flexibility is also needed in the determination of maximum operating limits for these sources.

D. The proposed definition of post-aeration handling is overly broad. [C-75]

EPA proposes to define post-aeration handling of sterilized material to mean:

> the storage and transportation of material that has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility. Post-aeration handling of sterilized material ***ends when that vehicle is closed for the final time before leaving the facility***.

This definition is too broad and would require not only massive facility redesign but extensive changes to sterilization processes and operations. Facility layouts are not configured and cannot easily be configured to handle all post-aeration activities within the boundaries of a permanent total enclosure. EPA cannot require emissions regulations of all post-aeration activity given the technology available to measure low amount of residual EtO left after aeration. For example, if there is also manufacturing and warehousing under the same layout as the sterilization facility, there could be thousands of square feet of clean room manufacturing, packaging and warehousing that has been set up to optimize efficiencies of the operations. We also note products could remain in warehouse areas for extended periods of time (weeks/months) before "leaving the facility." Requiring post-

[120] 40 C.F.R. §63.2.

aeration controls of all those areas is not reasonable when looking at the low residual levels of EtO. Post aeration controls should be more realistic and not require controls for personnel described in the PID, but rather consider a notification and/or signage indicating that EtO sterilized goods are stored in a particular area.

Rather than attempt to regulate every product that has come into contact with EtO at any point, the Agency should establish reasonable emissions limits as authorized by the Clean Air Act.

E. EPA should allow flexible alternatives in addition to Method 204 to demonstrate compliance. [C-28, C-29, C-30, C-31]

Method 204 is not an appropriate method to validate compliance for most commercial sterilization facilities. But Method 204 was established for volatile organic compound (VOC) capture at small point source facilities, such as paint booths. Many of the Method 204 requirements cannot be tailored to that of a larger sterilization or manufacturing facility. For example, the distance from each VOC emitting point in Method 204 must be at least four equivalent diameters of the natural draft opening (NDO) (overhead room door). This is not reasonable as a method in manufacturing plants with pallet size or even "cart sized" EtO sterilizers and aeration rooms. It will be impossible for many facilities to remain in strict compliance with this standard that was developed for a different application. In another example, product staged for shipping would not be able to be staged 4 equivalent diameters from the door.

There are more feasible ways to demonstrate that facilities are capturing emissions. Instead of strict compliance with Method 204, EPA should allow for equivalent methods to document airflow and pressure requirements. For example, capture could be demonstrated through pressure differential measurements, or smoke tests demonstrating that air does not leave the facility when a door is opened. Method 204 should still be retained as an option. The more flexibility given to facilities to tailor methods, calculations, and testing to their facility needs, the better.

PTE installation is a site-specific exercise dependent on a number of variables. For example, the EtO drum storage room is required to be located along an exterior wall and naturally must have a door for loading and removing drums. There is no practical way for most facilities to relocate the EtO drums 4 equivalent diameters away from the door (or NDO).

It is also important to note that the NESHAP proposal requiring PTE would also conflict with the PID's proposal to specify that commercial sterilization facilities ventilate spaces (at a to-be-determined rate) where EtO-sterilized products are stored. This is because

specifying a certain ventilation in storage areas rate may result in airflow imbalances between different parts of sterilization facilities.

The aeration process and residual EtO limits are already regulated in accordance with ISO/AAMI 10993. Any EPA regulations of product aeration and post-aeration activities should mirror and properly incorporate FDA and ISO/AAMI regulations and guidelines.

VIII. Combined Emission Stream Standards

A. The "Standards for Combined Emission Streams" are unworkable as written and need clarification (C-78)

AdvaMed appreciates EPA's acknowledgment of the difficulty in demonstrating compliance proposed by combined emission streams. EPA accurately summarizes this issue:

> The EPA's understanding of control configurations at commercial sterilization facilities has changed since the rule was promulgated in 1994. In recent years, companies have implemented a wide variety of combinations when controlling emission streams at these facilities. As a result, it can be difficult to determine whether one vent type is in compliance with the rule when it is being combined with other vent types. Therefore, the EPA is proposing to structure the rule requirements so that facilities can combine emission streams based on the best approach for their facilities.[121]

While we appreciate this acknowledgement, significant confusion remains on how to implement the proposed changes, and AdvaMed and its members request that EPA clarify the requirements before finalizing the rules.

Generally, EPA requires facilities to meet the more stringent requirement applicable to the individual sources within the combined stream:

- If the mixed emission sources are required to meet reduction standards: the facility must comply with the removal efficiency standard for the emission source in the composite stream that has the most stringent removal efficiency.[122]

- If the mixed emission sources are required to meet emission rate standards: the facility must comply with an emission rate standard that is equal to the

[121] Proposed Rule at 22,852.
[122] *Id.*

> sum of the emission rate standards for each emission source type in the composite stream.[123]

The proposed revision to § 63.362 suggests that these combined emissions streams would have to meet *both* the emission reduction and emission rate standards.

AdvaMed requests clarity as to what they need to do when the combined air streams have emission sources with both reduction standards and emission rate standards. It is unclear if sources will need to keep track of two separate standards, one reduction standard and one emission rate standard, within the same stream and have expressed concern regarding how they would go about doing so.

If EPA intends for facilities to convert reduction standards to emission rate standards and vice versa, members have expressed concern with the applicable conversions. The conversion of one standard to the other is no small task and will add considerable difficulty in demonstrating compliance. EPA provides an example of converting the ARV reduction standard of 99%[124] to an emission rate standard of 7.0E-3 lb/hr, but, as explained above, that conversion is inconsistent with actual industry experience.

The use of an emission rate standard is untenable given that the conversion depends on facility- and cycle-specific factors. EPA acknowledges that "[t]he emission rate at each facility is dependent on EtO usage, the portion of EtO usage that is emitted from the [vent], and the performance of the control device, if used."[125] For its own calculation of the SCV emission standard conversion of 99% to 2.5E-5 lb/hr, EPA assumed that: facilities had similar EtO usage amounts and that all SCVs had the same amount of emissions route through them.[126] Applying these conversions would require each facility to dedicate a substantial amount of time, effort, and money to calculating an emission rate standard for the emission sources in its mixed streams. This may lead to each individual facility using a different compliance standard for the same emissions source due to the use of facility specific factors in its calculations.

These proposed guidelines for combined emission streams also do not account for or provide guidance for facilities that use technologies such as peak shavers, catalyst beds, or incinerator flames. This control equipment combines and utilizes multiple air streams to control the EtO concentration before it reaches the equipment that actually destroys EtO. This allows facilities to boost EtO destruction rates and utilize their control equipment as efficiently as possible. Multiple air streams are first routed to the equipment that regulates EtO air concentrations to optimize system performance. This equipment then releases or

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[123] *Id.*
[124] *Id.* at 22,831.
[125] *Id.*
[126] *Id.*

retains EtO as needed for its proper regulation. The EtO that is collected or released cannot be traced back to a specific emission source. This severs any direct tie between an emission source and control device. The use of such equipment not only leads to mixed emissions sources, but its ability to absorb or retain EtO as needed means that the resulting emission standard cannot be tied to the timing of point source use. Facilities with this technology cannot track the emission sources in their mixed emission streams.

The timing issue with technologies such as peak shavers is an example of an overall issue with timing and keeping track of emission sources. Facilities will need to keep a detailed record of their emission streams. Though "it is important for facilities to understand how their emission streams are configured and what the ultimate emissions from these streams are," the additional time and monetary expenditure of recognizing and then reconfiguring compliance for the day is excessive, especially if CEMS and room air emissions regulations are enacted.

EPA has not explained how this level of detailed recordkeeping and constant recalculation would lead to increased compliance or decreased emissions. Neither has a cost analysis been conducted for the additional cost, time, and labor that may be needed by facilities to properly track their emission sources and mixed streams.

B. Negative-pressure requirements are not feasible. (C-78)

EPA is "proposing to require that emissions from SCVs and CEVs be routed under negative pressure when ducted to a control system." For SCVs, it is unlikely the emission control unit is at a higher static pressure than the vacuum pump discharge when the pump is in operation. Additionally, a CEV may require a booster fan to achieve require flow rate or static pressure to adequately capture EtO at the chamber.

C. It is imperative that EPA clarify standards for facilities that combine room air emissions.

Many facilities mix Group 1 emissions with other point source emissions before the air reaches emission control devices or route room air emissions to a control device, such as a peak shaver, that captures and releases EtO as needed to regulate EtO concentrations in air streams sent to destruction devices. Facilities that already have difficulties tracking mixed air streams with point sources will now have to track two additional air streams. Additionally, this would impact Group 2 emissions if a site uses cascading air flows to maintain flowrate limitations. If EPA moves forward with its room-air emissions standards, it must provide clear, flexible, and practicable standards for these facilities.

By way of further example, the combined emission stream requirements are not reasonable or practical as stated. Take an existing area source sterilizer facility (1< 10 tpy EtO use) combining all captured control streams (combination sterilizer vents plus Group 1 room air

emissions) through a peak shaver/catalytic oxidizer. Table 1 requires SCV control of 99.8% with no emission rate limit. Table 3 requires CEV control at 99% with no emission rate limit. Table 4 requires Group 1 room) area capture (no emission reduction standard) and an emission rate standard of 1.3E-3 lb/hr EtO. The facility is penalized with an emission rate limit of 1.3E-4 lb/hr EtO from what is likely the smallest affected source at the facility, compounded by the use of a Peak Shaver making the compliance demonstration of the emission rate compliance for Table 4 Group 1 sources unclear and difficult to demonstrate.

IX. EPA's compliance proposals need to be flexibly adapted to realities of equipment and sterilization processes [C-49 to C-60]

As an initial matter, EPA's compliance proposals must account for control equipment other than the equipment that destroys EtO. For example, certain control equipment systems employ an acid scrubber, water scrubber, peak shaver, or balancer to regulate the EtO concentration sent through to a catalytic oxidizer. EPA needs to specify that such equipment is not control equipment or an emission source and therefore not subject to any of the corresponding standards and regulations, like the ones proposed for C-55 & C-56. This is critical for AdvaMed members because though this equipment uses the same technology as the control equipment that destroys the EtO, it is used in an alternative manner for a different purpose.

EPA should have a flexible approach for monitoring and testing requirements. Facilities of all sizes and capacities should be able to implement monitoring and methods that conform to the unique aspects of their sterilization facility and process. This approach should also be cost effective by looking to see whether increased monitoring or compliance requirements will make an impact in terms of accuracy, compliance, and/or safety.

A. EPA should not replace the current requirement for demonstrating compliance with a requirement for either an annual compliance demonstration and operating limits or by using EtO CEMS. [C-49]

AdvaMed supports the continued availability of the current compliance demonstration requirements, which include an initial performance test, continuous parametric monitoring, and work practice standards. A flexible approach to compliance demonstration is especially important for small businesses, which EPA acknowledges "could incur total annual costs associated with the proposal that ***are at least three percent of their annual revenue.***"[127]

As a threshold matter, the Proposed Rule does not attempt to explain why there is any need to change these well-established requirements at all, let alone attempt to justify EPA's

[127] Proposed Rule. at 22845 (emphasis added).

proposed shift to either an annual compliance demonstration and operating limits or EtO CEMS.

Agencies can "change their existing policies" only when "they provide a reasoned explanation for the change."[128] But the Proposed Rule simply declares that EPA does not "believe that [current compliance requirements] are sufficient to ensure continuous compliance with the emissions limitations."

In addition, a cost/benefit analysis (which EPA does not undertake) would not support the proposed change. **AdvaMed members estimate approximately $75,000 in recurring annual costs.** Moreover, some or all of a facility's sterilization operations will need to be suspended to run the test cycles. And there is no perceptible benefit associated with these changes; indeed, EPA's concern over chronic EtO exposure suggests there are no benefits at all. Continuous, instantaneous monitoring may be useful to address acute exposure concerns, but not for potential harms caused by chronic exposure.

While AdvaMed members of all sizes have expressed concern over these proposed compliance requirements, flexibility is especially important for smaller facilities. EPA should thus consider adding even more options for facilities using less than 10 tpy or less than 1 tpy.

Further, continuous EtO monitoring not practical or reflective of industry processes. EtO is not emitted at a constant rate over a 24-hour period due to the batch nature of the process of sterilization. Three one-hour tests over a 24-hour period would be more in line with sterilization operations and properly demonstrate compliance for smaller facilities. Any potential annual compliance testing should be flexible enough to allow for such testing.

B. EPA should not shorten the time allowed for demonstrating compliance. [C-50]

EPA should not shorten the time allotted for compliance; the 180-day time frame for compliance is already difficult to meet due to the extensive process and limited third party emissions testers.

Initial performance testing requires:

- preparing test locations (ports, accessibility platforms, scaffolding, etc.)
- safety planning (completing a Job Safety Analysis (JSA) or equivalent)
- assessing the appropriate methodology and establishing a representative cycle based on the conditions and locations (including allowing time for approval of any alternatives per the General Provisions)

[128] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016).

- drafting a test plan
- internal resource planning
- identifying and contracting with a qualified stack testing company
- coordinating with and obtaining approval of the test plan from federal, state and local regulatory agencies
- implementing the test
- generating the test report
- sending the final report for approval from the local environmental authority
- receiving said approval from the local environmental authority

This is an inherently time-consuming process. As it stands, the two tasks of determining a representative cycle and obtaining approval from the state and EPA on an intent to test protocol alone can take up to 180 days. Even if the process were simpler, the timeframe for initial performance testing is largely dependent on the availability of third-party vendors who can conduct and certify such testing. Testing must be booked months in advance.

EPA's proposed changes to standards and compliance testing would further strain an already tenuous timeframe. Facilities would need to reassess their methodology, representative cycle, and test plan. Additional time will be needed due to the increased complexity of the new standards and testing requirements. Many facilities will need to obtain additional testing or monitoring equipment, which is in limited supply. Shortening the timeframe to fewer than 180 days is not doable.

C. EPA should retain flexibility in approved test methods to demonstrate compliance. [C-51, C-52]

EPA should provide maximum flexibility in the methods made available in subpart O for sterilization facilities. Nixing available methods will cause facilities using those methods considerable time and effort to shift to a different method in order to demonstrate compliance.

As many methods as possible, including Other Test Method 47 Measurement of Ethylene Oxide Emissions from Stationary Sources by Cavity Ring-Down Spectroscopy, should be approved as optional test methods under subpart O. This will decrease the likelihood of facilities needing to apply for separate equivalency approval; this in turn would alleviate some of the burdens on facilities as they rush to implement the myriad of other emissions requirements being proposed.

The proposed removal of certain test methods is also unnecessary. Some facilities have used Method 18 for their stack performance tests successfully for some time. Removing

that test method would require re-designing and implementing a new method to replace a method that is working perfectly fine for those facilities at present.

In addition, as EPA acknowledges, the Proposed Rule would set emissions standards at or very near the lower limit of detection. Detecting these low levels with any method is dependent on the ideal factors and circumstances involving humidity, ambient temperature, air density, altitude, and other factors. It is not clear that EPA fully appreciates the technological limitations at these levels. For example, EPA proposes to add Method 320 to the approved list, but that method does not consistently achieve the 10 ppb lower limit of detection and faces issues with accuracy and resolution as it relates to the proposed emissions limits and ability to duplicate test results.

Facilities will have difficulty complying with both destruction efficiency standards and emission standards at such low levels. EPA should thus provide a flexible range of approved test methods.

D. EPA should not mandate the use of CEMS for gas-solid reactors. [C-58]

Gas-solid reactors do not require EtO CEMS to demonstrate compliance. A number of viable alternatives are readily available. Visual confirmation of negative pressure is a low-tech approach that is simple and reliable. This can be done by streamer flags or observation of air curtains, or automatically via a control system. Most systems come with pressure indicators at each bed, which can be monitored visually or automatically via a control system. Media can be tested for efficacy at the supplier's laboratory and/or composite air samples can be taken from the outlet of the system and tested to ensure system efficacy.

EPA does not explain why it believes parametric indicators of gas-solid reactors are inadequate to determine the functionality. Given the EPA's silence on this subject, EPA should allow parametric monitoring to continue.

The scenarios in which EPA is proposing EtO CEMS would require real time inlet and outlet monitoring/calculation of emission reduction to demonstrate compliance. This could also prove difficult to the point of unworkable.

E. A constant flowrate during performance testing is not reasonable or necessary. [C-53]

AdvaMed members uniformly agree that a constant flowrate is not feasible. Requiring a constant flowrate for performance testing would also undermine or eliminate altogether EPA's impetus for these proposed testing performance changes: facilities cannot maintain "normal operating conditions" while conducting a 24-hour performance test where the flowrate must be kept at a constant. EPA should not require a constant flowrate for performance testing.

A constant flowrate for performance testing is not possible because:

- Flowrate changes as the chamber pressure decreases. These pressure changes are part and parcel for "normal" facility operations. Maintaining a constant air pressure in the sterilization chamber is not physically possible, compromises facility safety, and would frustrate the EPA's objective of having performance testing reflective of normal operations.
- Uncontrollable variables can cause fluctuations in flowrates. These fluctuations are caused by changes in temperature, barometric pressure, wind direction, windspeed, downdrafts / updrafts, etc.
- Fluctuations in flowrates can also be caused by compliance standards and requirements such as the use of control sequences to maintain adequate ventilation.
- A constant flowrate would also be impossible for facilities with PTEs and/or those demonstrating compliance with Method 204. For example, some facilities maintain the proper building pressure by installing control systems that increase or decrease the air flow in order to maintain the required static pressure.
- To further illustrate concerns, any requirement to keep flow from SCVs or CEVs, for example, constant during performance test period would not only not reflect normal operating conditions, but it could create unsafe conditions.
- We request EPA should remove the proposed requirement to hold flow steady during performance testing.

F. EPA should not require a minimum operating temperature for catalytic or thermal oxidation units based upon the unit's average temperature during performance test. [C-57]

EPA should not require a minimum operating temperature for catalytic or thermal oxidation units based upon the unit's average temperature during performance testing.

Manufacturers specify the minimum and maximum operating temperatures for oxidation systems based upon the design and intended loading of the system. Increasing the minimum temperature limit beyond that manufacturer's recommendation may produce excessive emissions of NOX, SOX, CO2 during periods of lower inlet concentrations. It could also cause a fully-loaded unit to exceed its maximum operating temperature. This would in turn lead to an adverse event, which could include unintended shutdown, system failure, explosion, or fire or explosion.

EPA also proposed that when the temperature is below the operating limit, the media in the catalyst bed must be replaced within 7 days.[129] Catalyst temperature is dependent on many air parameters, such as air flow, inlet airflow concentration, and inlet flow of EtO—not just the condition of the catalyst. Requiring the replacement of the catalyst is not necessarily the appropriate action and flexibility is needed in the Proposed Rule to consider other physical inputs other than the catalyst condition, like inlet flow, moisture condition, and burner firing rate, and take the appropriate action.

G. A 30-day rolling average for CEMS is reasonable. [C-66]

The proposed 30-day rolling average for demonstrating CEMS compliance is reasonable. EPA, however, should clarify that the average is based on calendar days rather than "operating" days. Not all facilities operate every day, and some operations (e.g., aeration) may fall partially over two days. Trying to separate out whether a day is a considered an "operating" day would add unnecessary complexity to the calculations. Using a calendar day metric to calculate emissions would be much simpler for facilities to implement. The important data is the facility's 30-day average; how those averages compare to the facility's operations is not important.

H. Semi-Annual reporting will be of greater utility than daily reporting. [C-63]

While we believe that providing accurate and timely information on EtO emissions to the public is important, we are concerned that daily reporting of CEMS data will not serve the public and in fact will cause confusion. Indeed, due to EPA's deeply flawed risk assessment and resulting inhalation URE, CEMS reporting could result in misunderstanding and widespread confusion.

EPA's risk analysis results in a finding that continuous exposure to 0.011 ppb of EtO every hour of every day for 70 years is an "unacceptable risk." Putting aside the obvious issues with EPA's derivation of this IUR value and that the air everywhere in the United States has been measured to contain EtO in higher concentrations, it is critical that information provided is accurate and meaningfully understandable to the public. We believe there will be significant confusion about what this value even represents.

Daily reporting would require significant additional public engagement by EPA and industry to mitigate resulting foreseeable confusion. Semi-annual reporting, in contrast, provides timely data that is actionable by companies and regulators, and useful as an ongoing and meaningful metric for communities.

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[129] 40 C.F.R. §63.364(c)(5) (Proposes "[f]or catalytic oxidizers, if the monitor indicates that the temperature is below the operating limit, the media in the catalyst bed must be replaced within 7 calendar days.").

I. A 15-minute sample interval is not necessary. [C-59, C-61]

During the development phase of the Proposed Rule, EPA was provided with the relative standard deviation on a demonstration of CEMS monitoring data using a cavity ring down. The monitoring was done on three banks of dry bed scrubbers. The relative percent of standard deviation at 15 minutes was 3.2% and 6.2% for one hour. Since the inlet and outlet concentrations for a Group 2 emission are very low, using a one-hour sampling interval as currently required in the NESHAP would have very little impact to estimating exposure risk.

For example, one of the hourly averages was 11.59 ppb. During the same period the highest 15-minute average of 12.40 ppb and the lowest was 10.14 ppb. Applying the 3.2% and 6.2% standard deviations to these concentrations yields 12.31 ppb for the one-hour average and 10.46 ppb and12.79 ppb as the worst-case difference in readings. Therefore, using a one-hour sampling interval would provide a range from 1.85 ppb to 0.48 ppb in potential differences in the 15-minute and one-hour reading. These variances are not sufficient to justify the testing intervals.

Further, the existing testing interval allows for the possibility of power outages or other shutdown events during which no data would be available.

Time-sharing of CEMS devices will be necessary to allow measurement of individual stacks at different intervals.

X. Ambient monitoring, including at the fenceline, is unnecessary and ineffective for identifying emission sources or evaluating compliance apart from significant technical challenges. [C-68, C-69]

Fenceline or other ambient EtO monitoring is neither feasible nor useful in controlling emissions or assuring compliance. Attempting to tie any part of the NESHAP to these unreliable measurements risks facility shutdowns due to false reports of non-compliance.

A. Ambient air monitoring is ineffective for identifying the origin of EtO present in the air all around us. [C-68, C-69]

Ambient air monitoring is problematic for many reasons, several of which EPA identifies in the Proposed Rule. Perhaps most importantly, "ethylene oxide [has] detection limits that are above health-relevant levels.[130] Indeed, as explained elsewhere, EPA's risk modeling is addressed to mitigating purported risks at concentrations some *900 times below the limit of detection.*

[130] GAO, *Air Quality Information: Need Remains for Plan to Modernize Air Monitoring*, GAO-22-106136 (July 13, 2022).

This difficulty is compounded by the presence of EtO in the environment from many sources other than sterilization. For example, fossil fuel combustion, organic matter decomposition, and natural plant respiration emit EtO. Even an employee or third party smoking a cigarette or the presence of a highway near an ambient monitor would materially alter results. Further, results will naturally vary significantly due to wind patterns, weather events, and other geographic conditions. For this reason, results often may not reflect plant operations, nor would it be possible to set an industry-wide action threshold.

Recent studies also demonstrate that ambient monitoring is inaccurate and unhelpful for monitoring EtO emissions. The considerable fluctuation in background readings and the still emerging research into other sources of EtO, coupled with variability even among co-located canisters has resulted in inconsistent and problematic interpretation at the state and local levels.

For example, a three-year study in Georgia found little to no difference in ambient air near a sterilization facility and background sites.[131] This finding was primarily due to EtO occurring naturally across the United States, even in rural areas near no known sources of EtO. Further, in EPA and other state regulatory ambient air studies, researchers found EtO in levels exceeding the IRIS-designated threshold in the middle of national and state parks where there was no known EtO source. These rigorously conducted studies demonstrate numerous known and unknown sources of EtO in the environment well beyond commercial sterilization facilities.

Technology innovations may be able to overcome some of these shortcomings, but capabilities of existing technology are insufficient and incapable of overcoming the current technological hurdles for meaningful ambient air monitoring of EtO.

B. EPA is correct that fenceline monitoring is both unnecessary and technically challenging to implement for this source category. [C-68 and C-69]

EPA correctly assesses the efficacy and feasibility of fenceline monitoring for EtO emissions from commercial sterilization facilities. In the Proposed Rule, EPA concluded that it "does not believe that a fenceline monitor would measure a significant quantity of residual EtO emissions" and would be "unnecessary" in light of the requirements proposed in section III.B.8.

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[131] Ramboll Report, *Ethylene Oxide Ambient Air Testing Samples Locations, Laboratory Analysis and Quality Control Documentation: Covington, Georgia Area,* Robert Demott (October 21, 2022).

The Proposed Rule recognizes EPA's prior application of fenceline monitoring as part of a work practice standard for petroleum refineries. [132] The "action-level" reflected full compliance with emission standards for each measurement point along the boundary at a concentration for which a robust measurement method existed.

As EPA acknowledges, EtO emissions from commercial sterilizers fundamentally differ from fugitive emissions at refineries in several respects that make "fenceline monitoring . . . technically challenging to implement for this source category."[133]

First, the detection-limit problems that plague any ambient EtO monitoring apply with equal force to fenceline monitoring. Unlike with benzene, there is no "robust measurement method . . . for measuring [EtO] at and well below" and useful "action-level."[134] The action-level for benzene was 9 $\mu g/m^3$ at the fenceline,[135] while ambient-air concentrations in the United States are often measured well below 1 $\mu g/m^3$.[136]

And unlike with benzene, the sources of ambient EtO and true baseline atmospheric levels of EtO are very poorly understood. It is not possible with current, or even developing, technology to identify the source of measured EtO, making it impossible to differentiate sterilizer emissions and other sources.

Further, the accepted methods for fenceline monitoring are not suitable for use with EtO. Among other problems, the relative distance between the emission points and boundary lines for commercial sterilization facilities is unsuitable for EPA's typical requirements for fenceline monitoring. The EPA Method 325 requires a fenceline monitor to be at least 50 meters from the source of emissions to the property boundary to allow for dispersion.[137] Meanwhile, the boundaries for commercial sterilization facilities are often the building itself or small easements. Due to the physical configurations of these facilities, the monitoring points would often be clustered together and are unlikely to be representative of emissions from the release points making ambient air monitoring problematic and not meaningful for implementation.

The nature of emissions points from commercial sterilization facilities renders fenceline monitoring futile. As EPA recognizes, current room air releases at these facilities are typically at the ground level and consist of uncontrolled building emissions through

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[132] 40 C.F.R. § 63.658.
[133] Proposed Rule at 22,848.
[134] Proposed Rule at 22,847.
[135] 63.658(f)(3).
[136] *See, e.g.*, Yanbo Pang et al., *Trends in selected ambient volatile organic compound (VOC) concentrations and a comparison to mobile source emission trends in California's South Coast Air Basin*, ATMOS. ENV'T, 2015;122:686–695 (mean benzene concentration found to be 0.4 $\mu g/m^3$ background in south coast air basin of California).
[137] EPA Method 325A § 8.2.1.

doorways, loading points, and ventilation exhausts. This differs significantly from the numerous dispersed and difficult to monitor benzene emission points at a refinery. Existing and proposed emission control requirements and associated parametric monitoring can—and do—adequately capture and monitor emissions. Fenceline monitoring will not improve these measures.

We note fenceline monitoring would also impose significant burdens on medical device manufacturers and sterilizers. Depending on the technology, the number of sampling locations, the size of the facility, and labor, the annual cost of fenceline monitoring is estimated between $1-2 million. When EPA added EtO to the list of air toxics monitored at NATTS sites, the cost of adding EtO to existing laboratory reports was more than $20,000 per year.[138] The cost would undoubtedly be higher to develop and validate completely new laboratory services. Fenceline and beyond-the-fenceline monitoring is also subject to regular interference and theft, requiring additional security and replacement allocations.

In conclusion, fenceline monitoring would be unreliable, technically challenging, and unnecessary to monitor EtO emissions for commercial sterilization facilities without commensurate impacts—if any impact at all—on emissions or compliance.

Until EPA can adequately characterize background EtO concentrations in all environments, and until technology allows measurement the levels EPA deems health-relevant, imposing any form of ambient monitoring—at the fenceline or beyond—to control EtO or measure compliance is inappropriate.

XI. Reporting [C-70 to C-73]

AdvaMed recommends EPA adopt a flexible approach that is cost-effective while retaining high quality monitoring and reporting. Content should contain similar data as is currently reported and specific to EPA's jurisdiction and purview. For example, the requirement to report the cycle calculation approach or the bioburden approach used for each cycle run is excessive and should be within the purview of FDA.

EPA should also confer with EtO control equipment manufacturers and EtO emissions testing vendors to get their input on the reporting requirements and technological limitations. AAT and Lesni have both expressed that their control equipment cannot meet the strict mass limits given current technological advancements. Any and all reporting requirements and emissions standards must be repeatedly achievable; standards cannot be based on a one-time, fluke occurrence or in perfect testing conditions.

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[138] GAO, *Air Pollution: Opportunities to Better Sustain and Modernize the National Air Quality Monitoring System*, GAO-21-38 (Nov. 2020).

XII. Conclusion

AdvaMed is committed to continuing to work with EPA, community members, other industry stakeholders, and other regulatory agencies to further reduce EtO use and emissions without unnecessarily precipitating a severe shortfall of critical medical device infrastructure—a result that is unfortunately all but assured if the Proposed Rule is not significantly revised. We are confident that a cooperative approach will allow for progress in reducing EtO exposure through flexible standards adapted to the unique technical challenges for this source category. The standards in any final rule must be achievable with existing technology across the many different facility and cycle configurations employed by nearly 100 commercial sterilizers subject to subpart O. AdvaMed and its members look forward to further productive dialogue to achieve these shared goals.

Sincerely,

Khatereh Calleja

Khatereh Calleja
Vice President
Technology and Regulatory Affairs

(Enclosures)

Attachment I: NERA Economic Consulting, *Supply Chain, Capacity Considerations and Other Key Issues: "Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants (NESHAP)" and "Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide"* (June 26, 2023)

Attachment II: Dr. Lucy Frasier, Ph.D., DABT, Comments on the U.S. Environmental Protection Agency's Clean Air Act Rulemaking for the Commercial Sterilizer Source Category and Proposed Interim Registration Review Decision for Ethylene Oxide (June 26, 2023)

Attachment III (AdvaMed Proposal, Parametric Controls—Flexible Option to Support Facility Emissions Control (January 20, 2022).