Sterigenics®

June 27, 2023

Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comments of Sterigenics U.S., LLC on NESHAP Proposed Rule, Docket ID No. EPA-HQ-OAR-2019-0178

On April 13, 2023 the U.S. Environmental Protection Agency ("EPA") posted notice of the availability of its National Emission Standards for Hazardous Air Pollutants ("NESHAP"): Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Proposed Rule (Docket ID No. EPA-HQ-OAR-2019-0178).[1]

Sterigenics U.S., LLC ("Sterigenics") is concerned with some of the scientific, technical, and legal conclusions in these documents. Sterigenics operates ethylene oxide ("EtO") processing facilities across the United States to provide contract sterilization services for critical medical products, ensuring that they are free from dangerous and potentially deadly organisms prior to patient use. EtO sterilization facilities, like those operated by Sterigenics, sterilize 50 percent of medical devices used in the United States, or 20 billion devices per year, and many of these critical medical devices can only be sterilized with EtO and would not be available for life-saving medical care without EtO.

Sterigenics respects, supports and shares EPA's commitment to ensuring worker and community safety. But Sterigenics does not believe that the proposed NESHAP uses the best available science in estimating risks. Moreover, some of the proposed emission control measures may be infeasible if not impossible to implement in many facilities, would be difficult for any facility (let alone all facilities) to complete in the proposed timeframes, and will reduce already-strained sterilization capacity, drastically reducing the supply of sterilized medical devices and unnecessarily putting lives at risk.

At a recent medical device conference, U.S. Food and Drug Administration ("FDA") Commissioner Robert Califf expressed his concern that limitations on EtO sterilization capacity will have grave effects on the American healthcare system, stating "This issue is very much on the forefront for us. We are highly aware of it and we're engaged in the discussions. I'm very worried." Numerous trade

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

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associations representing a broad range of healthcare professionals, including physicians' groups and hospitals, have echoed the FDA's concerns about the dangers to the healthcare supply chain if EPA's proposed requirements are finalized as written. Strikingly, the U.S. Small Business Administration's ("SBA") Office of Advocacy reports in comments submitted on this NESHAP proposal that "it is not unreasonable to believe that more than half of the small commercial sterilizers will exit the market if this proposal and the PID are finalized as proposed" – a prospective reduction in capacity far more extensive than the closure of one or two facilities about which the FDA has already expressed dire concerns. ***Sterigenics shares the concerns of FDA, SBA and a wide range of healthcare professionals that the proposed restrictions pose a serious risk to the health and lives of American patients.***

Sterigenics submits this additional information in the hope that its comments together with those of other domain experts will allow EPA to amend its proposed NESHAP in ways that will maintain critical medical supplies and appropriately reflect the totality of the requirements of the Clean Air Act, including a complete and more balanced cost-benefit analysis.

Thank you for reviewing these comments. Please contact us if you have any questions or require additional information.

Sincerely,

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Abbreviation	Definition
ARV	Aeration room vent
CAA	Federal Clean Air Act, 42 U.S.C. § 7401 et seq.
CDC	U.S. Centers for Disease Control
CEMS	Continuous emission monitoring systems
CEV	Chamber exhaust vent
CRDS	Cavity ringdown spectroscopy
Draft Circular A-4	OMB, Circular A-4 - DRAFT FOR PUBLIC REVIEW (Apr. 6, 2023)
Dscfm	Dry standard cubic feet per minute
EO	Executive Order
EPA or Agency	U.S. Environmental Protection Agency
EtO	Ethylene oxide
FDA	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GACT	Generally available control technology
HAI	Healthcare-associated infection
IRIS	Integrated Risk Information System
IRIS assessment or IRIS evaluation	EPA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)* (Dec. 2016)
IUR	Inhalation Unit Risk
MACT	Maximum achievable control technology
µg	Micrograms

Abbreviation	Definition
$\mu g/m^3$	Micrograms per cubic meter
MIR	Maximum individual risk
NESHAP	National Emission Standards for Hazardous Air Pollutants
NHANES	U.S. Centers for Disease Control and Prevention National Health and Nutrition Examination Survey
NIOSH	National Institute of Occupational Safety and Health
OE-FTIR	Optically-enhanced Fourier transform infrared spectroscopy
OMB	Office of Management and Budget
PHE	Public health emergency
PID	Proposed Interim Decision
PPE	Personal protective equipment
Ppb	Parts per billion
Ppbv	Parts per billion by volume
Ppmv	Parts per million by volume
Ppm	Parts per million
PTE	permanent total enclosure
Proposed NESHAP	National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 88 Fed. Reg. 22,790 (Apr. 13, 2023)
RIA	Regulatory Impact Analysis
SBA	U.S. Small Business Administration
SCV	Sterilization chamber vent
Sterigenics	Sterigenics U.S., LLC

Abbreviation	Definition
Supply Chain EO	Executive Order on a Sustainable Public Health Supply Chain, EO 14001 (Jan. 21, 2021)
Tpy	Tons per years
UA	Urbanized areas
UC	Urban clusters
URE	Unit risk estimate
WTP	Willing to pay

I. INTRODUCTION

Sterigenics U.S., LLC ("Sterigenics"), submits these comments on the U.S. Environmental Protection Agency's ("EPA") National Emission Standards for Hazardous Air Pollutants ("NESHAP"): Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Proposed Rule (Dkt. No. EPA-HQ-OAR-2019-0178).[1]

Through these comments, Sterigenics seeks to assist EPA achieve its goal of maintaining the ability for ethylene oxide ("EtO") sterilization facilities to sterilize the 50 percent of medical devices used in the United States that are made safe using EtO, many of which can only be sterilized with EtO and would not be available for life-saving medical care without it. As written, the NESHAP and EPA's companion Proposed Interim Decision ("PID") and Draft Risk Assessment Addendum for Ethylene Oxide under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")[2] would dramatically limit the United States capacity to sterilize such critical medical supplies. Because the NESHAP and its problems overlap with the PID and its problems, and because requirements from one impact the ability to comply with the other, Sterigenics attaches to this comment, as Attachment 1, its comments on the PID.

The FDA has expressed its concern that limitations on EtO sterilization capacity will have grave effects on the American healthcare system. Numerous trade associations representing a broad range of healthcare professionals, including physicians' groups and hospitals, have echoed concerns about the dangers to the healthcare supply chain if EPA's proposed requirements were finalized as written. Sterigenics shares the concern of FDA and of healthcare professionals that the proposed restrictions pose a serious risk of costing American lives and believes that reasonable changes to the NESHAP are required in order to preserve the healthcare supply chain.

Sterigenics has substantial experience with the use of EtO as a sterilizing agent for medical devices and products. We and our affiliates have and continue to operate numerous EtO facilities in the United States and abroad. For the last several years, on our own initiative we have been enhancing the emission control systems in all of our U.S. facilities. We as an organization have spent in excess of $50 million on these enhancements. Through this effort we have learned valuable lessons regarding the challenges and feasibility of retrofitting existing facilities while also maintaining operations to meet customer demand for sterilized

[1] 88 Fed. Reg. 22,790 (Apr. 13, 2023) ("proposed NESHAP").
[2] EPA, Ethylene Oxide Proposed Interim Registration Review Decision, Case Number 2275 (Mar. 28, 2023), *available at* https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf ("PID").

products. Sterigenics also is a defendant in approximately one thousand tort actions that have been premised on fundamental misunderstandings and imbalanced communications about the risks of EtO. Although Sterigenics has vigorously defended itself in these actions, which are without merit, some of our facilities periodically have been required to suspend operations and one facility has been permanently shut down because of unfounded and oftentimes political concerns about the safety of EtO sterilization. Stated differently, the prospect that further reductions in the nation's capability to ensure the safety of our medical supply chain could result from a rulemaking insufficiently grounded in sound science and analysis is not theoretical. Sterigenics is well positioned to provide constructive comments on the potential consequences of straying from the legitimate science regarding the use of EtO to preserve the health and save the lives of American patients.

Sterigenics is a leading provider of terminal sterilization for medical products in the United States. Sterigenics operates EtO and gamma processing facilities across the United States to provide contract sterilization services for critical medical products, ensuring that they are free from dangerous and potentially deadly organisms prior to patient use. As of May 31, 2023, Sterigenics employed approximately 800 individuals across 24 U.S. facilities—nine EtO facilities, 14 gamma facilities and its headquarters office.[3]

Sterigenics' facilities offer to medical device manufacturers critical services needed for healthcare in the United States. These customers range from large global medical device manufacturers and pharmaceutical companies to small niche start-up companies as well as local hospitals and medical centers. All are dependent on Sterigenics' nine EtO facilities to get their products sterilized and distributed to the ultimate end users—doctors, clinics, hospitals, and patients. Sterigenics is committed to the continued operation of these facilities and the delivery of the critical services they provide in a manner that will protect the health of its workers and the communities in which the facilities are located.

Terminal sterilization is the process of sterilizing a product in its final packaging. It is an essential, and often government-mandated, last step in the manufacturing process of healthcare products before they are shipped to end-users. These products include surgical procedure kits and trays, implants, syringes, catheters, wound care products, medical protective barriers, including personal protective equipment ("PPE"), laboratory products and pharmaceuticals,

[3] Sterigenics also holds a registration under FIFRA to produce EtO that can be used in its own or other sterilization facilities (EPA Reg. No. 89514-1), but Sterigenics has never utilized this registration.

as well as bioprocessing equipment used in the pharmaceutical industry to produce vaccines and other prescription and over the counter treatment products.

The effective sterilization of medical devices is essential to public health. In 2007, the U.S. Centers for Disease Control ("CDC") calculated that annually there are 1.7 million healthcare-associated infections ("HAIs") and 99,000 HAI-related deaths, and these unfortunate circumstances occur even when the country is doing all it can to sterilize medical devices. HAIs are a particular concern during medical procedures where our bodies can be exposed to infection from microbes, bacteria, or viruses. Approximately 53 million such outpatient surgical procedures are performed in this country every year, and each of these procedures involves direct contact between human tissue and medical devices or surgical equipment. Each such contact poses a risk of infection.

Sterigenics sterilizes millions of medical devices and products each day using EtO according to specific processes validated by the FDA. Sterilization by EtO is the "method with the broadest application available for medical products due to its effectiveness at lower temperatures and its general compatibility with a diversity of materials, resins and product types."[4] The FDA has explained that "ethylene oxide is the most common method of sterilization of medical devices in the U.S. and is a well-established and scientifically proven method of preventing harmful microorganisms from reproducing and causing infections."[5] "[M]ore than 20 billion devices sold in the United States every year are sterilized with [EtO], accounting for approximately 50 percent of devices that require sterilization."[6]

EtO sterilization is also the only viable sterilization method approved by the FDA for many delicate, complex, and sophisticated medical products. The FDA has emphasized that

> [i]t's important to note at this time there are no readily available processes or facilities that can serve as viable alternatives to those that use ethylene oxide to sterilize these devices. In short: this method is

[4] Medical Device Network, Sterigenics, Ethylene Oxide, https://www.medicaldevice-network.com/products/ethylene-oxide/ (last visited May 26, 2023).
[5] FDA, Press Announcement, Norman E. "Ned" Sharpless, MD, Acting Commissioner of Food and Drugs, Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures (Oct. 25, 2019), https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.
[6] FDA, Press Announcement, Jeffrey E. Shuren, MD, JD, Director – CDRH Offices, FDA Continues Efforts to Support Innovation in Medical Device Sterilization (Aug. 3, 2022), https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization.

critical to our health care system and to the continued availability of safe, effective, and high-quality medical devices.[7]

Sterigenics' nine EtO facilities consistently have operated in accordance with applicable air quality permits issued by the relevant State permitting agencies pursuant to delegated authority under the federal Clean Air Act, 42 U.S.C. § 7401 et seq. ("CAA"), as well as Occupational Safety and Health Administration requirements for EtO and the EPA-approved labels for EtO. Beginning in 2018, however, EPA and some State agencies, relying upon EPA's 2016 *"Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" (CASRN 75-21-8) in support of Summary Information on the Integrated Risk Information System* ("IRIS"),[8] have asserted that compliance with existing permit requirements is no longer sufficiently protective of human health. Both before and since EPA released its 2016 IRIS assessment, Sterigenics' highest priority has been to protect the health of employees, patients, and residents of the communities in which it operates. In keeping with this focus, Sterigenics voluntarily has continuously sought to improve the safety of its EtO operations and undertaken a comprehensive design, engineering, and construction program to extensively enhance the emission control systems at all its EtO facilities and its related worker protection and education programs.

As Sterigenics has implemented new technology to reduce emissions or improve worker safety, the company found that changes can often have unintended consequences for other safety metrics. For example, as Sterigenics implemented measures to reduce fugitive emissions, it found that the effect was to raise temperatures and EtO concentrations within the facility to the detriment of workers. Accordingly, Sterigenics has a keen appreciation for the importance of aligning the implementation of emission control measures with increased airflow within the facility to moderate temperature increases and avoid increasing employee exposure to EtO, a process that can require extended timelines. Sterigenics has learned from years of experience that changes to enhance employee and community protections require years-long, iterative processes to address the complexities and limitations of seemingly quick improvements. Our experience with these programs, combined with decades of experience operating EtO sterilization facilities, provides a solid foundation for these comments.

Sterigenics respects EPA's mandate to craft a regulatory approach under the CAA that allows for the continued, safe, and effective use of EtO. But it is vital to a

[7] Sharpless Statement, *supra* note 5.
[8] EPA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)* (Dec. 2016), *available at* https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730#tab-3.

sound rulemaking process that the Agency actively and appropriately consider the input of other federal agencies with equally pertinent domain expertise, such as the FDA and the National Institute of Occupational Safety and Health ("NIOSH"). Involving and reflecting the expert advice of all departments and agencies charged with protecting the public health is essential to ensure that any new EPA regulations are soundly based on the entirety of the best available science and other pertinent considerations and appropriately tailored both to preserve public health and to protect the health and safety of sterilization workers and communities surrounding EtO facilities.

It bears emphasis that Sterigenics is not submitting these comments in the hope of avoiding investments that are necessary to maintain and upgrade the safety of its EtO operations. To the contrary, Sterigenics has chosen not to wait for a new NESHAP to upgrade its facilities and the technologies deployed at these facilities. Since 2018, Sterigenics has invested over $50 million to enhance its emission controls and anticipates spending additional tens of millions of dollars over the next several years. The lessons Sterigenics has learned over the course of this process of continuous improvement can be summarized as follows:

1. **One size does not fit all.** Because the existing EtO facilities across the United States were constructed at different times by different owners, none are the same. The design, cost, and time required to install new and/or retrofit existing emission control equipment will vary greatly from facility to facility.

2. **Timely availability of equipment, materials, and contractors is not guaranteed.** Sterigenics regularly has experienced significant delays in the delivery of necessary emissions control equipment and materials and regular shortages of trained personnel to install and calibrate such equipment.

3. **Issuance of necessary State and local permits is often delayed.** Installing new emissions control equipment and modifying existing facilities often require issuance of State and/or local permit amendments and local building or occupancy permits. Sterigenics frequently has experienced delays in acquiring such permits.

4. **Validation and operation of new, untested systems and technologies require substantial time.** In many situations, the requirements mandated by the proposed NESHAP will require installation and operation of technologies that are new and untested. To ensure that these systems perform as required likely will take more time than is proposed by the NESHAP.

5. **Projected cost estimates usually fall short.** Cost estimates are just estimates and, more often than not, prove to be unduly optimistic. This proposition has held true as Sterigenics has enhanced its facilities and technologies at an overall cost that represents *only a portion* of the additional expenditures that would be required for Sterigenics to comply with the feasible aspects of the proposed NESHAP and will undoubtedly hold true if the rest of the EtO sterilization industry is required to comply with EPA's proposed new standards.

6. **Temporary closure of the facility and cessation of sterilization operations are often required in order to install new emissions control equipment.** Many EtO sterilization facilities operate at or very near full capacity. Yet, it likely will be necessary for most, if not all, of these facilities to shut down or reduce operations for some period of time—likely up to several months—to make the modifications required by the NESHAP.

It is with a view to these lessons learned that Sterigenics submits these comments on the NESHAP. Environmental responsibility, employee safety, and protection of public health are core values of Sterigenics. The company respects that its sterilization facilities must comply with stringent regulatory requirements to protect its employees and the communities in which its facilities are located. But Sterigenics also is proud of the essential mission served by its EtO facilities – to safely provide critical medical devices to patients and the healthcare industry. The purpose of these comments is to guide EPA in achieving the appropriate balance between these goals.

Sterigenics also is a member of the Ethylene Oxide Sterilization Association and the Ethylene Oxide Task Force and incorporates by reference the comments submitted on its behalf as a member of those organizations.[9]

II. EXECUTIVE SUMMARY

Sterigenics' comments on EPA's proposed NESHAP are summarized here. Detailed comments on each of these general points are found in the body of the comments below.

[9] These comments represent Sterigenics' individual positions and understanding of factual issues. In general, they align with those of EOSA and EOTF. Any differences may be due to Sterigenics' unique facilities, the fact that EPA has provided insufficient time to develop and communicate regarding comments on two, complex, and interrelated sets of requirements, or differences in viewpoints that are inherent in any multi member organization.

A. The Proposed NESHAP and PID Are Not Based on the Best Available Scientific Evidence.

In the NESHAP and the PID, EPA ignores the best available scientific evidence in favor of EPA's 2016 IRIS report: a report based on a modeling exercise that intentionally exaggerates hypothetical risks. By contrast, scientific studies of real-world data conducted over the past decades consistently have found that low levels of EtO are safe and do not increase the risk of cancer for employees who regularly work around facility levels of EtO, let alone for people who live or work in areas near EtO facilities.

EPA also has not done any meaningful review of important and highly relevant new health science developments since 2016 as part of this rulemaking. For example, since 2016, six different State environmental health departments have found no actual evidence of increased cancer in communities around EtO sterilization facilities. Moreover, monitoring by State agencies and EPA since 2016 has established that there are background levels of EtO in the ambient air unrelated to sterilization facilities or other industrial activities that are over a thousand times higher than the IRIS risk value. In addition, routine blood testing conducted by the CDC has confirmed that endogenous levels in the human body are tens of thousands of times greater than the IRIS value. The Agency's failure to address, much less reflect, the new data and studies creates significant uncertainty regarding the credibility of the IRIS risk value and raises serious questions about EPA's continued and exclusive reliance upon the IRIS risk value.

Even though the 2016 IRIS level is based on demonstrably flawed science, EPA, non-governmental organizations, and litigants continue to treat it as a de facto regulatory standard, and they persist in doing so even though entities regulated by EPA have never been afforded an opportunity as part of any rulemaking process to challenge the legitimacy of the IRIS process or conclusions.[10]

[10] We would note that utilization of the 2016 IRIS is currently being challenged in connection with EPA's use of the IRIS value for EtO in assessing cancer risk for the Miscellaneous Organic Chemical Manufacturing category, including as to whether EPA acted in an arbitrary and capricious fashion by arguing that any challenge to the scientific underpinning of the IRIS value was too late. Non-Binding Statement of Issues, American Chemistry Counsel & Louisiana Chemical Association, *Huntsman Petrochemical LLC v. EPA*, No. 23-1045 (D.C. Cir. Mar. 27, 2023), Doc. No. 1991825. EPA could be subject to similar petitions for review concerning utilization of the 2016 IRIS value, depending on the outcome of this proposed rulemaking.

B. EPA Has Failed to Properly Evaluate the Impact of the Proposed NESHAP on the Supply Chain of Sterilized Medical Devices in the United States.

The cost and time required to retrofit existing facilities to meet the NESHAP requirements, if they are in fact able to meet the requirements at all, could result in the temporary closure of many facilities in the United States and, as the U.S. Small Business Administration's ("SBA") Office of Advocacy itself has noted in comments on this rule, could result in the permanent closure of several EtO facilities. The FDA has recognized that given the lack of excess sterilization capacity in the United States, temporary and permanent closures to accommodate emissions enhancements have in the past and very well could in the future result in shortages of critically needed sterilized devices. In a media interview at a November 2019 FDA conference on medical device sterilization, Dr. Suzanne Schwartz, FDA's Director of Partnership in Technology and Innovation, stated: "We would be concerned if even one additional facility shut down. We will start to see spot shortages; there is no question about that. In terms of more catastrophic national impact, with two facility shutdowns, it is almost a certainty."[11] Although Dr. Schwartz made that statement nearly four years ago, it is even more salient today in light of FDA's concerns regarding EPA's proposed NESHAP.

Among other factors, when establishing a NESHAP, EPA is required by the CAA to consider any non-air quality health and environmental impacts of the proposal. In this regard, it is vital that the Agency actively consider the input of other federal agencies, such as the FDA and the SBA. While EPA is responsible for implementing the CAA, involving the expert advice of all departments and agencies charged with protecting the public health is essential to ensure that any new EPA regulations are fully informed and appropriately tailored to both preserve public health and to protect the health and safety of sterilization workers and surrounding communities. Despite receiving significant input from the FDA on potential medical device shortages, EPA has not adequately evaluated the non-air quality health impacts of a diminished ability to sterilize medical equipment in the United States. Nor has EPA explained how it evaluated the risks that could be created under its proposed standards.

In addition, EPA has elected to issue both the NESHAP and PID at the same time and with overlapping compliance schedules. As the 86 U.S.-based EtO medical devices sterilization facilities subject to the proposals seek to meet the very short compliance schedules, there will be unprecedented demand for

[11] David Lim, "Ethylene Oxide Plant Closures Put US on 'Cusp of a Major Medical Logistical Failure,'" MedTech Dive (Nov. 8, 2019), https://www.medtechdive.com/news/ethylene-oxide-plant-closures-place-united-states-on-cusp-major-medical-logistical-failure/566922/.

pollution control equipment and engineering and contractor resources, resulting in shortages and likely price increases of the supplies and personnel who could implement the requirements, both of which will affect the ability of the industry to meet the proposed compliance schedules. If the industry cannot meet both requirements, facilities will be required to close or risk violating one or both statutes. EPA has apparently not considered the effect of such shortages or price increases or the combined effects of the two, coordinated decisions.

C. Stringent Performance-Based Standards that Account for the Vast Differences in Sterilization Facilities and Cycles Will Achieve Appropriate Risk Reduction.

Sterigenics supports EPA's goal to further control and minimize EtO emissions from commercial medical device sterilization facilities. To accomplish that goal, the NESHAP should set standards that are clear, measurable, and achievable. Each U.S. EtO sterilization facility is unique and requires an individualized approach that accounts for differences in configuration, size and number of sterilization chambers, number and type of sterilization cycles, and amount of EtO used. The NESHAP should require compliance with stringent, realistic performance-based standards while allowing the facility operator to select the best specific actions to comply with those standards. Specifically, adopting performance-based standards that account for the vast differences in sterilization facilities and cycles would fully protect public health and the environment but avoid creating unnecessary risks of disruption of hospital and medical supply chains. Such measures could include stringent performance levels based on utilization of facility-wide negative pressure systems with permanent total enclosure, emission control systems with high pollutant destruction efficiencies, optimized discharge points, and more frequent stack testing or continuous emission monitoring systems ("CEMS").

D. Many of the Proposed NESHAP's Requirements Cannot Be Met by Existing Technologies, Are Technologically Unachievable, and/or Cannot Be Met by the Compliance Deadline.

The proposed NESHAP includes several requirements that fail to recognize the vast differences between EtO sterilization facilities, particularly differences in facility size. EPA has relied upon this "one size fits all" approach in determining what the various requirements should be as well as in assuming that all 86 EtO facilities can meet those requirements.

Several specific requirements are unachievable, impractical, add unnecessary complexity, or simply make no sense. Many of the proposed numerical standards are at odds with equipment manufacturers' performance guarantees. Technological limitations in the ability to monitor low levels of EtO

will result in substantial limits on facilities' abilities to comply with the proposed percent emission reduction standards. Proposed new testing and test methodologies are not adequately supported or developed and will create safety risks for employees. EPA has not demonstrated that current EtO measuring technology can achieve the detection level upon which the proposed new standards are premised.

In addition, even for those aspects of the proposed new standards where compliance with the requirements would be technologically achievable, doing so within the proposed timeframe would not be. EPA has proposed that all 86 EtO facilities demonstrate compliance with all of the requirements of the proposed NESHAP within 18 months of the date of final publication. This timeframe does not reflect the real-world challenges and difficulties that the sterilization industry will confront when retrofitting their facilities.

E. Certain of the Proposed NESHAP Requirements Conflict and Result in Requirements that Are Inconsistent with EPA's Companion PID.

EPA has proposed requirements in the NESHAP and PID that, at best are in conflict and at worst are irreconcilable. EPA has not analyzed nor provided any guidance on how to comply with the requirements of the NESHAP while simultaneously complying with the PID and protecting employee safety. The primary objective of the NESHAP is to address ambient air quality. It does so by requiring facilities to install negative pressure systems that will contain all traces of EtO inside the facility where the EtO will be treated by pollution control systems prior to being emitted to the outside environment through a stack. Although this is an effective means to limit the release of EtO to the environment, it *increases* the level of EtO internally within the building. This conflicts with the primary objective of the PID which is to minimize exposure of facility employees to EtO. Thus, implementation of the proposed NESHAP requirements makes protection of employees more difficult if adequate time (far beyond the timeline proposed by EPA) is not allowed to design and implement additional measures to protect employees, which in turn will vary based on the configuration of individual existing facilities. If compliance with both the NESHAP and PID as proposed is required on the timeline that EPA proposes, compliance may be impossible given the conflicting goals of the PID and NESHAP. EPA does not account for this conflict and has unlawfully ignored its duty to harmonize the two applicable statutes and their seemingly contradictory objectives when regulating pursuant to them.

F. EPA's Cost Benefit Analysis Is Insufficient under the CAA.

A huge cost of the NESHAP is the potential loss of EtO sterilization capacity in the United States. While EPA acknowledges that EtO sterilization services are critical to ensuring a stable supply of safe medical devices and that there is uncertainty regarding how the NESHAP will impact the medical device supply chain, it fails to even attempt to quantify costs associated with potential shortages. EPA also fails properly to quantify the benefits of the NESHAP. Likewise, EPA's approach is inconsistent with Office of Management and Budget ("OMB") guidance and does not follow EPA's own guidelines. Finally, EPA's estimates of costs on the sterilization industry are significantly understated and it has no basis for its assumptions that these costs can be "passed through" by the industry. Even if customer demand could support some passed-through cost increases, compliance with the requirements in the proposed NESHAP likely will result in short-term capacity disruptions leading to medical devices shortages, which, according to the Small Business Administration (SBA) are "more likely to affect disadvantaged or physically isolated communities."[12]

G. EPA's Legal Authority for the Proposed Emission Standards Is Unclear.

In the proposed NESHAP, EPA cites several different statutory provisions as the basis for its proposed standards. EPA also attempts to parse its use of each authority regarding its proposed standards for new and existing sources.[13] But EPA does not explain in sufficient detail how it analyzed and utilized its legal authority to address both existing and new facilities. With reference to standards proposed pursuant to CAA sections 112(d)(5) and (6), EPA cites only claimed emission reductions and cost-effectiveness as the basis of its decision-making.[14] For CAA sections 112(d)(2)-(3) standards, EPA's maximum achievable control technology ("MACT") floor analysis is limited and, in some cases, references only one facility.[15] For CAA 112(f)(2) standards, EPA based proposed standards on maximum individual risk ("MIR") calculations derived from the highly flawed IRIS assessment.

For a rulemaking with such significant potential effects on public health, this level of analysis does not suffice. For example, in setting standards for new

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[12] Comments of the U.S. Small Business Administration Office of Advocacy in re National Emission Standards for Hazardous Air Pollutants: Commercial Ethylene Oxide Sterilization Technology Review (Docket ID No. EPA-HQ-OAR-2019-0178) & Ethylene Oxide Proposed Interim Registration Review Decision (Docket ID No. EPA-HQ-OPP-2013-0244), at 13 (June 23, 2023) ("SBA Comments").
[13] *See, e.g.*, Proposed NESHAP, 88 Fed. Reg. at 22,831 (Table 23).
[14] *See, e.g.*, *id.* at 22,808-10 (explanations for CAA section 112(d)(5) standards), 22840-41 (CAA section 112(d)(6) standards).
[15] *Id.* at 22,819 (regarding MACT floor for existing Group 1 room air emissions).

and existing sources pursuant to CAA section 112(d)(2)-(3), EPA must evaluate numerous criteria, including all "non-air quality health" impacts, which include risks to the U.S. medical supply chain. For CAA section 112(d)(5) standards, EPA must explain on what basis it considered control technologies to be "generally available." And when addressing residual risk under CAA section 112(f)(2), EPA must consider the protection of "public health" in the world in which we live among other considerations.

EPA also has not explained how it has accounted for the substantial reductions in EtO emissions from commercial sterilizers that have been achieved over the last 30 years. Instead, EPA continues to rely on a facility's *use* of EtO when determining standards without reference to different classes or types of sources—rather than focusing on actual emissions considering the pollution controls that have been installed.

Finally, EPA has not explained how its proposed NESHAP standards *and* requirements contained in the PID are achievable by individual facilities or the commercial sterilization industry at large. EPA cannot ignore how these two proposed requirements interact, nor promulgate final standards which cannot reasonably be achieved given conflicting standards. EPA has a duty to resolve any conflicts prior to issuing final actions under the CAA and FIFRA.

H. EPA Failed to Assess Relevant Executive Orders and National Strategies Regarding the Public Health Supply Chain.

While EPA claims to understand the potential impact of the NESHAP on the medical supply chain, EPA failed to consider (let alone abide by) the requirements of President Biden's Executive Order ("EO") 14001 on a Sustainable Public Health Supply Chain and EO 14017 regarding America's Supply Chains. EPA's proposals put our nation's healthcare supply at risk without any consideration of the President's recent orders to mitigate this critical risk.

III. FUNDAMENTAL FLAWS IN EPA'S ETO RISK ANALYSIS

EPA's proposed NESHAP is based upon an inherently flawed residual risk analysis of the use of EtO in sterilization operations. EPA's calculation of cancer risk reductions relies solely on EPA's 2016 IRIS report. The Inhalation Unit Risk ("IUR") from the IRIS 2016 evaluation, in turn relies solely on the findings from a study conducted by the NIOSH, which analyzed thousands of EtO sterilization facility workers to determine whether those workers had any increased risk of cancer.

The IRIS program is designed to set preventative environmental standards for chemicals through a series of modeling assumptions that are intended and understood to overstate actual cancer risks. This program uses data to generate a predictive toxicity value for chemicals deemed to be carcinogenic to humans. For EtO the IRIS estimate is fundamentally flawed; EPA's use of data from the NIOSH study is directly at odds with the findings of the same study. The NIOSH study definitively concluded that EtO concentrations even thousands of times greater than those that EPA has modeled around certain EtO sterilization facilities would be safe.

EPA has been adamant that it will not question the validity or credibility of the IRIS assessment in the context of the NESHAP and has even advised commenters not to address the IRIS assessment in their comments.[16] Despite EPA's admonition, Sterigenics is providing the following comments on the IRIS assessment because:

(1) it presents a seriously flawed, overly conservative risk value that does not reflect real-world conditions;

(2) EPA's reliance upon it ignores the substantial new health science information regarding EtO background and endogenous levels developed since 2016; and

(3) it leads to extremely stringent emission control standards, many of which likely are unachievable.

A. EPA's IRIS Value for EtO Cannot Be Reconciled with the NIOSH Study.

The IRIS assessment analyzed epidemiologic data assembled by NIOSH from a cohort of more than 18,000 sterilization facility workers with quantitative estimates of exposure to EtO. Yet, while NIOSH concluded that there was no overall excess incidence of cancer in the 18,000 sterilization facility workers with historically high EtO exposures, the IRIS assessment reached the opposite conclusion, finding that EtO posed an excess cancer risk at exceedingly low exposure levels.

Sterigenics is very familiar with the NIOSH study, having through its predecessor companies contributed data from thousands of the workers in the cohort and having received repeated updates and worker notifications from NIOSH regarding the study findings.

[16] Statement of Jonathan Witt of EPA during Roundtable Discussion hosted by the Small Business Administration on April 25, 2023.

Given the central importance of the NIOSH study on the derivation of the IRIS IUR, it is worth reviewing what the NIOSH scientists stated about their findings in the peer review publications themselves, as well as in a contemporaneous worker notification that NIOSH sent to Sterigenics and other sterilization companies and required them to publish to their workers. Notably, rather than suggesting that EtO posed an excess cancer risk at the exceedingly low level of the IRIS IUR, NIOSH's clear and unmistakable conclusion was that EtO concentrations at historical workplace exposure levels many orders of magnitude higher than the IRIS IUR did not lead to any increase in cancer.

In both its 2003 publication focused on breast cancer incidence and its 2004 publication on cancer mortality more broadly, NIOSH concluded that there was no overall excess incidence of cancer in the 18,000 sterilization facility workers with historically high EtO exposures:

- "Our data do not indicate any overall excess of breast cancer incidence among the cohort as a whole compared to the U.S. population."[17]

- "In conclusion, we found no overall evidence of excess cancer mortality in this cohort, with the exception of bone cancer based on small numbers."[18]

In its IRIS assessment, EPA sought to explain away these findings by contending that they were due to the "healthy worker" effect—i.e., that the working population might have lower cancer incidences than the general population. But the scientific literature does not support any such healthy worker effect for blood cancers or breast cancers.[19] Moreover, EPA ignores the fact that NIOSH specifically considered and rejected this argument in its 2004 publication, stating that the "healthy worker effect would seem an unlikely explanation for the lack of cancer excesses in exposed versus non-exposed comparisons."[20] Indeed, the epidemiologic literature established decades ago shows that a "healthy worker effect" is predominately related to workers with shorter follow-up and non-cancer causes.[21]

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[17] K. Steenland, et al., *Ethylene oxide and breast cancer incidence in a cohort of 7567 women (United States)*, 14 Cancer Causes & Control 531, 537 (2003), https://link.springer.com/article/10.1023/A:1024891529592.
[18] K. Steenland, et al., *Mortality analyses in a cohort of 18,235 ethylene oxide exposed workers: follow up extended from 1987 to 1998*, 61 Occup. Env't Med. 2, 7 (2004), *available at* https://oem.bmj.com/content/61/1/2.short.
[19] J. Kirkeleit, et al., *The Healthy Worker Effect in Cancer Incidence Studies*, 177(11) Am. J. Epidemiology 1218 (2013), *available at* https://academic.oup.com/aje/article/177/11/1218/95903.
[20] Steenland (2004), *supra* note 18, at 6.
[21] R. Monson, *Observations on the Healthy Worker Effect*, 28(6) J. Occup. Med. 425 (1986).

NIOSH provided further reassurance in its contemporaneous worker notification of its study findings, which the CDC continues to post on the CDC website.[22] As it had in its published studies, NIOSH assured sterilization facilities and their workers that its study found "[n]o overall elevated risk for any type of cancer or other disease as compared to the general U.S. population."[23] NIOSH noted moreover that "most workers in our studies were exposed years prior to 1985 when EtO exposures were much higher than they are today," and that the average exposure level for workers in the NIOSH cohort (a group again that on average demonstrated no excess cancer risk) from 1976-1985 was 4.3 parts per million ("ppm") for sterilization workers and 2 ppm for other workers.[24] These exposure levels are many orders of magnitude higher than the IRIS IUR.

EPA did not base its IUR on any new data or scientific measurements or other developments subsequent to the completion of the NIOSH study. Rather, EPA reinterpreted the NIOSH data to reach conclusions contrary to those stated in the peer-reviewed NIOSH studies themselves. Further, EPA's reinterpretation of the NIOSH data has been anything but transparent. EPA has chosen to present only purported findings/outcomes of this reinterpretation of cancer risks from the NIOSH cohort in its IRIS documentation, without including the underlying data or modeling output in the document or an appendix.

B. EPA's Exclusive Reliance Upon the IRIS Assessment Conflicts with Several State-Sponsored Epidemiological Studies.

The disconnect between EPA's IRIS assessment and the scientific evidence has become even more stark in the years following the 2016 release of the IRIS assessment, as state health agencies across the country have conducted investigations in communities surrounding EtO sterilization and manufacturing facilities in search of the purported increases in cancers associated with historic EtO facility emissions.[25] In considering these findings, it is worth recalling that

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[22] CDC, NIOSH, Worker Health Study Summaries – Ethylene Oxide, https://www.cdc.gov/niosh/pgms/worknotify/ethyleneoxide.html (last visited June 13, 2023).
[23] *Id.*
[24] *Id.*
[25] *See also* Comments of Sterigenics U.S., LLC in re Notice of Proposed Rulemaking Title 27, California Code of Regulations – Amendment to Section 25705 Specific Regulatory Levels Posing No Significant Risk: Ethylene Oxide (June 14, 2023), *available at* https://oehha.ca.gov/media/dockets/21072/21116-sterigenics/oehha_proposed_eo_prop_65_nsrl_comments_june_14_2023_final.pdf; Comments of Sterigenics U.S., LLC in re OAL Notice File No. Z2023-0328-02 Draft Cancer Inhalation Unit Risk Factor for Ethylene Oxide and Draft Technical Support Document (June 14, 2023), *available at* https://oehha.ca.gov/media/dockets/21069/21117-sterigenics/oehha_proposed_eo_iur_comments_june_14_2023_final.pdf.

many of these facilities were in operation dating back to the early 1980s, before the existing NESHAP regulations came into effect. Given the long latency period for many cancers, emission levels during the relevant time period for potential cancer initiation in these communities were likely higher than they are today. Even with these potentially higher historic EtO emission levels though, the search for the IRIS-predicted excess cancers in these communities has come up empty:

- In Colorado, the "incidence of all cancers combined and five individual types of cancer in the community surrounding Terumo BCT were no different than expected based on cancer rates in the remainder of Colorado for the years 2000 through 2017."[26]

- In Illinois, the "two assessments [of communities surrounding ethylene oxide sterilization and manufacturing facilities] did not offer clear convergence of evidence in specific cancer elevations."[27]

- In Michigan, the "results of this analysis presented in this report do not suggest that further investigation is needed at this time."[28]

- In Pennsylvania, the "cancer analysis within a 2-mile radius of the site revealed no consistent pattern for adult lymphohematopoietic and female breast cancer rates between 1985-2017."[29]

- In Tennessee, a "cancer cluster investigation provided no evidence for the clustering of high numbers of leukemia, Non-Hodgkin Lymphoma, breast, or stomach cancer near the facility when compared to a group away from the facility in 2000-2009 or 2010-2019."[30]

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[26] Colo. Dep't of Pub. Health & Env't, *Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado* (Dec. 3, 2018), *available at* https://www.terumobct.com/Pages/Eto-FAQ.aspx.

[27] Ill. Dep't of Pub. Health, *Cancer Incidence near Two Facilities Utilizing Ethylene Oxide, Lake County, Ill. 1998-2017* (Nov. 19, 2021), *available at* https://dph.illinois.gov/data-statistics/epidemiology/cancer-registry/cancer-assessment-lake-county.html.

[28] Mich. Dep't of Health & Human Servs., *Cancer Incidence Data Review: Area Surrounding Viant Medical Inc., Grand Rapids, MI* (2019), *available at* https://www.michigan.gov/egle/about/organization/air-quality/facility-specific-info/viant-medical.

[29] Penn. Dep't of Health, *Community Cancer Incidence Data Review: B. Braun Medical Sterilization Facility, Allentown, Lehigh County, Pennsylvania* (May 2022), *available at* https://www.health.pa.gov/topics/Documents/Environmental%20Health/Community%20Cancer%20Incidence%20Data%20Review%20B.%20Braun%20Medical%20Sterilization%20Facility-Factsheet.pdf.

[30] Tenn. Dep't of Health, *Potential Cancer Cluster Investigation for Sterilization Services of Tennessee located in Memphis, TN* (Feb. 27, 2023), *available at* https://www.shelbytnhealth.com/571/Ethylene-Oxide-EtO.

- In West Virginia, the "results show no evidence that cancer incidence is related to living near these facilities."[31]

C. EPA's Exclusive Reliance Upon the IRIS Assessment Ignores Background and Endogenous Levels of EtO Unrelated to Sterilization Facilities.

EPA's proposed NESHAP also disregards newly-collected data on background levels of EtO in ambient air unrelated to sterilization facility emissions, as well as EtO levels present through endogenous production of EtO in our own bodies. These data show that the general population experiences background EtO exposure at levels thousands of times greater than the IRIS IUR.

EtO is ubiquitous because it is produced by normal biological processes in microbes and vertebrates, including mammals. It also is a byproduct of the combustion of organic materials, including petroleum derivatives, coal, and wood. Since these normally occurring sources are widespread, there are background concentrations of EtO unrelated to sterilization facilities or other industrial facilities. As California's South Coast Air Quality Management District, in comments submitted on the California Office of Environmental Health Hazard Assessment, stated: "it is currently unclear what sources are contributing to background levels of EtO – based on our monitoring data, it does not appear to be due to medical sterilizers."[32]

EPA conducts a national scale monitoring program for various compounds in air. The related Air Quality System ("AQS") database currently includes results from 71 ambient air monitoring stations around the United States.[33] Most of the EtO samples reported in this collection were collected after the EtO IRIS risk assessment was issued. All of the stations have been sampled repeatedly, and many are sampled routinely on a six-day cycle. This yields a substantial basis for evaluating variability over time.

Sterigenics queried the AQS database in May 2023 for all EtO results from 2018 to 2022 (the most recent year available). This query yielded 10,238 EtO measurements from the 71 monitoring stations, which include both urban and

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[31] W. Va. Dep't of Env't Prot., *Evaluation of Ethylene Oxide-related Cancers in Kanawha County, West Virginia* (June 9, 2022), *available at* https://oeps.wv.gov/cancer/Documents/Data/Ethylene_Oxide_in_Kanawha_County.pdf.

[32] South Coast Air Quality Management District Comments on OEHHA's Proposed Draft Cancer Potency Factor for Ethylene Oxide and Technical Support Document, at 1 (June 14, 2023), *available at* https://oehha.ca.gov/media/dockets/21069/21123-south_coast_aqmd/oehha_eto_-_south_coast_aqmd_comment_letter_6-14-23.pdf.

[33] *See* EPA, Air Quality System (AQS) API, https://aqs.epa.gov/aqsweb/documents/data_api.html (last visited June 16, 2023).

rural locations. For each station, the day-to-day variation in observed levels was represented by comparing:

- 10^{th} percentile of the results to the 90^{th} percentile (expected range), and
- 25^{th} percentile to the 75^{th} percentile (typical range).

The calculated ranges for each station were then averaged to yield the typical range of expected variability (Table 1).

Table 1 – Characterization of Normal Variability at Monitoring Stations (Results shown in µg/m³)

Stations	10^{th} Percentile	90^{th} Percentile	**"Expected" Range (90^{th}-10^{th} percentiles)**	25^{th} Percentile	75^{th} Percentile	**"Typical" Range (75^{th}-25^{th} percentiles)**
ALL	0.009	0.340	**0.331**	0.053	0.213	**0.160**
Urban	0.009	0.334	0.325	0.051	0.212	0.161
Rural	0.007	0.367	0.360	0.064	0.216	0.152

Looking at all 71 monitoring stations, the "expected range" of values spans 0.331 µg/m³ from day to day. Assuming EPA's IRIS-based risk factor is accurate (0.0002 µg/m³ = 1 in 1 million excess risk), the background risks estimated based on a given day's measurement could be expected to range between 45 and 1,700 in a million—a difference of 1,655 in a million in the risk estimate based on the day of sampling considered.

Using the middle half of the range (25^{th} to 75^{th} percentile), the "typical range" spans 0.160 µg/m³ from day to day. Again, assuming that the IRIS unit risk factor is accurate, the risks estimated based on typical inter-sample variability would be expected to range between 265 and 1,065 in a million—a difference of 800 in a million in the risk estimate based on the day of sampling considered.[34]

Most EtO sterilization facilities, and other industrial facilities that emit EtO, typically are located in urban areas rather than remote rural areas. To address

[34] More recent EtO monitoring conducted by state environmental regulators have resulted in similar findings. *See* Ga. Dep't of Nat. Res., Env't Prot. Div., Air Protection Branch, 2021 Air Quality Report (2022), https://storymaps.arcgis.com/stories/e30085ae1e5345b9bf18595ee0a713c6 (measuring background ambient concentration of 0.43 µ/m³ or 0.24 parts per billion ("ppb")). The CDC, in turn, through its NHANES program, has measured endogenous average EtO levels in our bodies (as reflected in hemoglobin adduct measurements) of 2.5 ppb.

potential feedback about monitoring stations reflecting industrial sources in addition to routine, ubiquitous background, Sterigenics also compared the overall results measured at urban versus rural locations. The monitoring locations were categorized as urban if they fell within identified urbanized areas ("UA") (>50,000 population) or urban clusters ("UC") (2500-50,000 population) as shown by the U.S. Census Bureau on its U.S. Urban Areas map, based on the 2010 U.S. Census.[35] Monitoring locations outside of U.S. Census UA and UC mapped areas were categorized as rural.

Of the total 71 monitoring stations, 58 mapped to urban locations and 13 mapped to rural locations. Standard representations of average values (mean and median) were determined for each category of monitoring station (Table 2).

Comparing the results between urban and rural monitoring stations reinforces that the EPA monitoring network is a reasonable and appropriate representation of typical background conditions. Results at the urban monitoring stations are not higher, as would be expected if sterilization facilities, or other point sources, were affecting the results at the monitoring stations. In fact, the mean results at the rural locations (0.18 µg/m^3) were slightly higher than the urban locations (0.15 µg/m^3).

Table 2. Comparison of "Average" Results at Urban and Rural Monitoring Stations 2018-2022
(Results shown in µg/m^3)

Station Type	Mean	Median	Standard Deviation
All	0.165	0.099	0.283
Urban	0.161	0.099	0.238
Rural	0.184	0.11	0.433

Furthermore, the Utah Department of Environmental Quality recently published the results from a completed study that measured EtO concentrations near two medical sterilization facilities and some background areas. They found a seasonal impact on the EtO measurements at all locations, including the background locations.

In the proposed NESHAP, EPA aims to eliminate any theoretical cancer risk above 100 in a million. Not only is this theoretical level much lower than the level that would remain due to the ubiquitous background EtO concentration, it also

[35] Data.gov, TIGER/Line Shapefile, 2019, 2010 nation, U.S., 2010 Census Urban Area National, https://catalog.data.gov/dataset/tiger-line-shapefile-2019-2010-nation-u-s-2010-census-urban-area-national/resource/0f2cbe50-85ca-4a60-af99-933119f06581.

would be lower than the natural *variation* in that background risk based on the day-to-day variability in the concentration. The result is counterintuitive, to say the least, and yet there is no indication anywhere in the NESHAP administrative record that EPA has considered its own data collected over the past four to five years in evaluating the risks actually posed (or not posed) by EtO utilized at sterilization or other industrial facilities.

There also is no indication that EPA has considered more recent analysis from the CDC. The CDC, through its National Health and Nutrition Examination Survey ("NHANES") program, has measured endogenous average EtO levels (as reflected in hemoglobin adduct measurements) corresponding to ambient concentrations of 2.5 ppb.[36] EtO exposures to the public from sterilization facilities are indistinguishable from these background and naturally occurring levels.

IV. FAILURE TO EVALUATE RISKS OF POTENTIAL MEDICAL DEVICE SHORTAGES CAUSED BY ETO CAPACITY CONSTRAINTS

A. EPA Must Consider *All* Impacts on Public Health.

EPA relies on several different authorities within CAA section 112 in proposing newly applicable standards. But in each case, EPA must consider the statutory factors that Congress has enacted in setting new standards that would apply to commercial sterilizers.

Specifically, in promulgating standards pursuant to CAA sections 112(d)(2)-(3), EPA is required to consider "the cost of achieving such emission reduction, and any *non-air quality health and environmental impacts*."[37] EPA must therefore consider the broader impact of provisions promulgated under this authority on health, including the vital role of EtO in the sterilization of medical supplies and devices. Pursuant to CAA section 112(d)(5), EPA is to promulgate "generally available control technologies or management practices." In addition, when promulgating standards pursuant to CAA section 112(f)(2), EPA is required to assess whether standards would provide "an ample margin of safety to protect public health." Citing precedent, EPA has stated that under this provision it is to

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[36] *See* CDC, National Report on Human Exposure to Environmental Chemicals, https://www.cdc.gov/exposurereport/whats_new_060622_1.html (last visited May 26, 2023); I. Rietjens, et al., *The role of endogenous versus exogenous sources in the exposome of putative genotoxins and consequences for risk assessment*, 96(5) Arch. Toxicol. 1297 (2022), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9013691/.

[37] 42 U.S.C. § 7412(d)(2) (emphasis added).

"decide what risks are acceptable in the world in which we live" and that in setting a standard it is not required to eliminate all risk.[38] In addition, when determining an "ample margin of safety," EPA may consider costs, technological feasibility, and other relevant factors.[39]

Against this backdrop, EPA received significant input from FDA and other domain experts on potential medical device shortages. Yet, despite the prevailing legal standards, EPA failed to provide a sufficient basis within the proposed NESHAP (or with respect to technical support documents or other information placed in the docket) upon which the Agency could adequately evaluate the non-air quality health impact of a diminished ability to sterilize medical equipment in the United States. As detailed in more length below, EPA also did not provide a sufficient basis for determining when technologies and related standards were considered to be "generally available." Nor did EPA explain how it supposedly evaluated the risks that could be created under its proposed standards, including FDA's concern that "[f]or many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process."[40] EPA merely stated that it had given "careful consideration" to the important function served by sterilization facilities without any further or meaningful explication or quantification of how this consideration impacted the NESHAP requirements it proposed.[41] Without further explanation, EPA stated that it believed the largest impacts would be limited to "a handful of companies,"[42] implying that any effect on the availability of sterilized medical devices in the United States would be limited. These perfunctory dismissals of the concerns raised by FDA (and others) constitute a failure by EPA to fulfill its statutory duties under CAA section 112 when evaluating the risk associated with new and revised NESHAP.

B. FDA's Concerns About Potential Medical Device Shortages

As the United States emerges from the COVID-19 pandemic, FDA has focused its attention and resources on addressing potential shortages of medical devices

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[38] National Emission Standards for Hazardous Air Pollutants; Benzene Emissions From Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 54 Fed. Reg. 38,044, 38,049 (Sept. 14, 1989) (citing *Nat. Res. Def. Council, Inc. v. EPA*, 824 F.2d 1146, 1165 (1987)). EPA has stated it adopted the "two-step" Benzene NESHAP process for setting standards pursuant to CAA section 112's residual risk provisions.

[39] *Id.*

[40] Proposed NESHAP, 88 Fed. Reg. at 22,793.

[41] *Id.*

[42] Only with regard to exercising its authority pursuant to CAA section 112(d)(5) for existing SCVs at small sterilization facilities does EPA indicate it is addressing specific FDA concerns. *See id.* at 22,809 (discussion of Cycle Calculation Approach or the Bioburden/Biological Indicator Approach).

critical to public health and safety. In 2020, Congress gave FDA new statutory authority under the Coronavirus Aid, Relief, and Economic Security Act to help mitigate and prevent devices shortages in advance of a public health emergency ("PHE").

In a fact sheet entitled "Mitigating and Preventing Medical Device Shortages and Prioritizing Public Health," FDA highlights the fact that, during the pandemic, shortages hit hard for "critical devices as ventilators, test supplies and even some of the equipment needed to administer vaccines."[43] FDA points out that COVID-19 exposed weaknesses in the U.S. supply chain and emphasizes this country's continued dependence on supply from China and other countries.

FDA has emphasized that the sterilization of medical devices is a vital process for helping to prevent serious infections and that the use of EtO is "a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections without degrading the product, unlike some other sterilization methods."[44] FDA is keenly aware of the risk that limits on EtO capacity could have grave public health effects, stating that "[i]nadequate sterilization can lead to life-threatening infections in patients undergoing a wide range of medical procedures."[45]

Consistent with the agency's prior statements about potential medical device shortages, FDA submitted detailed comments during the interagency review process, alerting EPA to the potential that its EtO rulemakings will "inadvertently contribute to significant medical device supply chain disruptions."[46] This is exactly the type of situation FDA has been working to address; as is stated in the fact sheet, "[d]ealing with medical device supply chain disruptions requires getting ahead of problems before they become serious shortages."[47] As part of its overall work to address shortages resulting from market conditions and other facts, the FDA has been forced to sound the alarm in this rulemaking in response to proposed regulatory actions of another federal agency.

To be sure, EPA vaguely mentions in the proposed NESHAP the importance of EtO sterilization to healthcare and the growing demand for products that can

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[43] FDA Fact Sheet, Mitigating and Preventing Medical Device Shortages and Prioritizing Public Health (2022), *available at* https://www.fda.gov/media/156980/download.
[44] Shuren Press Announcement, *supra* note 6.
[45] *Id.*
[46] 12866 Interagency Review Documentation - File Set 2 of 2: "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review. Notice of Proposed Rulemaking," Att. 6 at 1 (Apr. 13, 2023), *available at* https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0489 (Margin Comment [A4], reflecting FDA input).
[47] FDA Fact Sheet, *supra* note 43.

only be sterilized with EtO. EPA also perfunctorily acknowledges that the new regulatory requirements for EtO could have a substantial impact on the operations of a large segment of America's capacity to sterilize medical devices and also may make it impracticable for the private sector to modify, reconstruct or build new facilities. But the challenges posed by the real world are starker. Six different EtO medical sterilization facilities have closed since 2016, and a few other closures are pending. No new facilities have opened since 2018, and it is unclear whether plans to construct additional facilities in the coming years will hold or be able to hold. As the SBA stated in comments on the proposed NESHAP: "Advocacy is concerned that these actions would lead to a significant number of small entities leaving the market for commercial sterilization, harming small medical device manufacturers, and causing significant supply chain disruptions and harm to patients needing sterilized medical devices."[48] Sterigenics believes this concern is not limited only to small entities. Moreover, EPA's misuse of its IRIS assessment could encourage additional litigation that could discourage needed investment and capacity growth at EtO facilities across the United States. In this regard, SBA has observed: "It also appears, from consultation with small entities, that in the current environment there is little appetite for investment in additional domestic facilities using EtO."[49]

EPA's apparent disregard of the serious public health concerns voiced by FDA during the interagency review process is inconsistent with EO 12866, which provides that a federal agency "shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies."[50] Here, although interagency review materials indicate that representatives of EPA met to address medical device supply concerns raised by FDA, the proposed NESHAP does not reflect modifications suggesting that these concerns were fully considered. In addition, the regulatory impact analysis submitted with the proposed NESHAP does not reflect the very significant public health costs associated with potential medical device shortages.[51]

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[48] SBA Comments at 14.

[49] *Id.*

[50] Executive Order 12866, § 1(b)(10) (Sept. 30, 1993).

[51] For the sake of completeness, Sterigenics also notes that the ability of medical device manufacturers to switch from EtO to alternative sterilization modalities is severely limited. As discussed previously, many medical devices and products can only be sterilized using EtO. In addition, for devices and products that could be sterilized through an alternate modality, an amendment to the existing FDA validation would be needed. Finally, the U.S. capacity for gamma radiation, the primary alternative modality to EtO sterilization, also is severely limited because of geopolitical risks related to supplies of Cobalt 60 (e.g., nuclear power plants in Russia), and EPA's EtO proposals exacerbate these geopolitical risks.

C. FDA's Ongoing Tracking of EtO Sterilization Capacity Reductions

Sterigenics' real-world experience shows that the FDA, in performing this role, correctly sees how EtO sterilization capacity reduction could lead to medical device shortages. For example, within the past two months, FDA has inquired multiple times with Sterigenics about mitigating the impact on device availability resulting from reductions in EtO medical sterilization capacity in Southern California, as the local air quality regulator has implemented new EtO emissions requirements that have resulted in curtailments of operations.

Sterigenics' experience with the permanent and temporary closure of some of its other facilities also demonstrates the validity of FDA's concerns. The closure of Sterigenics' Willowbrook, IL facility resulted in a nationwide shortage of pediatric trachea tubes. In Atlanta, after Sterigenics temporarily ceased operations in September 2019 to install emission control enhancements, the local government refused to allow the facility to restart operations due to unfounded objections by local elected officials. Among other detrimental impacts to healthcare, this action (subsequently disallowed by a court) prevented Sterigenics from sterilizing significant quantities of PPE in the early days of the COVID-19 pandemic when the entire nation was experiencing severe shortages of PPE.

D. Studies Have Documented the Link Between EtO Sterilization Capacity and Medical Device Supplies.

A study prepared for the U.S. Department of Health and Human Services by RAND Health Care entitled, "Medical Device Supply Chains: An Overview and Description of Challenges during the COVID-19 Pandemic," recognized the direct link between EtO capacity and potential medical device shortages.[52] The study noted "substantial concerns" about potential shortages of sterilized medical devices resulting from the temporary closure of contract sterilizer facilities. While this study stated that none of the specific devices that were part of the study appear to have been affected, it also stated that closures of EtO facilities had contributed to "shortages includ[ing] many vital medical devices for providing health care, including surgical kits, feeding tubes, and various types of catheters."[53]

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[52] Peggy G. Chen et al., *Medical Device Supply Chains, An Overview and Description of Challenges During the COVID-19 Pandemic* (Sept. 2021), *available at* https://aspe.hhs.gov/sites/default/files/documents/688790e106210d6434ddeed5907b0b38/pr-a328-2-devices-supply-chain.pdf.

[53] *Id.* at 30.

E. Medical Device Shortages Could Disproportionately Impact Economically Disadvantaged Communities.

Sterigenics acknowledges that the presence of EtO and other pollutants in the ambient air and in work environments can have adverse effects on economically disadvantaged communities located in or near any sources of those pollutants and that any such impacts should be addressed to protect those communities. There is, however, a risk that those same disadvantaged communities would bear the disproportionate impact of inadequacies in health care services. Basic economic market principles hold that those with the most resources likely will be able to continue to access supply of scarce goods and services and those with the least resources likely will most acutely feel an impact of the supply shortages.

One analysis of the end of the COVID PHE noted the that "potential depletion of the federally purchased supply of COVID-19 vaccines, treatments, and tests may curtail access to these supplies for some individuals, particularly those who are uninsured" and added that "[s]ince people of color and people with lower incomes are more likely to be uninsured, they may be at a disproportionate risk of facing barriers to accessing COVID-19 vaccines, tests, and treatments once the PHE ends and the federal supply is depleted."[54]

Adding to this disproportionate impact is the reality that studies have shown that socioeconomic inequality adversely affects the risk of infection.[55] One study focused on the relationship between neighborhood socioeconomic characteristics in the incidence of infection and sepsis. Sepsis is a life-threatening organ disfunction; and the number of sepsis cases in the United States resulting in hospitalization is substantial. High hospitalization rates correspond to greater demand for sterilized critical medical devices, such as ventilators, intravenous lines, urinary catheters, and many others. Thus, in considering how environmental justice concerns might be weighted in the establishment of a NESHAP for sterilization facilities, EPA should consider both the potential benefits of emissions reductions *and* the potential of establishing a standard that is likely to have negative public health effects resulting from constraints in the availability of sterilized medical equipment. Based on the information provided elsewhere in

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[54] Nambi Ndugga and Samantha Artiga, *Disparities in Health and Health Care: 5 Key Questions and Answers*, KFF (Apr. 21, 2023), https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/.

[55] Nina M. Edwards et al., *The association between socioeconomic status and the 30- and 90-day risk of infection after total hip arthroplastym*, 104-B(2) Bone & Joint J. 221 (Feb. 1, 2022), https://boneandjoint.org.uk/Article/10.1302/0301-620X.104B2.BJJ-2021-1030.R1; John P. Donnelly et al., *Association of Neighborhood Socioeconomic Status With Risk of Infection and Sepsis*, 66(12) Clinical Infectious Diseases 1940 (Feb 12, 2018), *available at* https://academic.oup.com/cid/article/66/12/1940/4850937.

these comments, we believe those health care-related disbenefits substantially outweigh any air quality-related benefits to such communities. "Although the NESHAP, RIA, and PID mention the possibility that the medical device supply chain will be disrupted, EPA does not quantify or describe qualitatively the harms that this could have on the businesses themselves or the patients they serve. EPA similarly does not acknowledge the disproportionate impacts supply chain disruptions may have on disadvantaged or physically isolated communities. EPA does not appear to seriously consider these harms in its proposals."[56]

V. COMMENTS ON SPECIFIC REQUIREMENTS IN THE PROPOSED NESHAP

A. Recommended NESHAP Approach that Accounts for the Vast Differences in Sterilization Facilities and Cycles to Achieve Appropriate Risk Reduction

Sterigenics supports EPA's goal to further control and minimize EtO emissions from commercial sterilization facilities. But the new standards must be clear, measurable, and achievable. As previously noted, over the past several years Sterigenics has gained a great deal of experience from installing emission reduction enhancements at its facilities that use EtO. The basic lesson learned is that "one size does not fit all." Each facility requires an individualized approach that accounts for the differences in configuration, size and number of sterilization chambers, number and type of sterilization cycles, and amount of EtO used. As such, this NESHAP should require compliance with stringent, realistic performance-based standards while allowing the facility operator to select the best specific actions to comply with those standards.

Sterigenics recommends that the NESHAP adopt the following general approaches.

- **Facility-wide negative pressure with permanent total enclosure ("PTE")** systems that meet EPA's Method 204 test are highly effective at containing and capturing EtO emissions inside the facilities.

- **Emission control systems with high pollutant destruction efficiencies,** including the use of state-of-the art emission controls with high destruction efficiencies or duplicative emission control systems in series. Such systems achieve the highest technologically achievable level of EtO control.

- **Optimized discharge point** with high dispersion rates which seals off the facility from the outside and creates central discharge point(s) for the

[56] SBA Comments at 14.

very small emissions that remain after treatment ensure that community exposure to EtO from the facility is minimized.

- **CEMS/Monitoring:** Sterigenics supports monitoring emissions more frequently than required in the current NESHAP. In particular, Sterigenics supports annual stack testing and the option to install CEMS in lieu of annual tests. This will allow companies to install CEMS as they become more commercially available. This more frequent and potentially continuous monitoring, along with the ubiquitous background levels of EtO, firmly supports EPA's proposals not to require fenceline or community monitoring.

Sterigenics believes that a NESHAP requiring the use of these general approaches combined with stringent performance-based emissions standards would provide the most effective method to achieve protective risk levels. Reliance upon performance-based standards will allow industry participants to employ new technologies and approaches that are tailored to the many variations in products, packaging, cycle design, equipment design, and facility design. In particular, the EtO emissions requirements should allow for any validation method using any concentration of EtO, as long as emissions are properly controlled.

B. The Multiple and Redundant Command and Control Requirements in the Proposed NESHAP Are Technologically Unachievable, Will Delay Compliance, and Are Likely to Lead to Shortages in Sterilized Medical Devices.

Sterigenics' experience also demonstrates that several specific requirements of the proposed NESHAP are unachievable, impractical, add unnecessary complexity, or simply unjustified. The following paragraphs discuss the problems with these requirements in general terms. Detailed criticism and analysis of each of the many specific requirements are contained in Attachment 2.

1. One Size Does Not Fit All.

The proposed NESHAP indicates that its requirements will be applicable to 86 existing EtO commercial sterilization facilities in the United States. None of these facilities are exactly the same. They were constructed at different times, with different materials and in different configurations. They have different numbers and sizes of sterilization chambers, implement thousands of different sterilization cycles, and sterilize millions of different products and packages. Even among Sterigenics' nine facilities, each facility is completely different. These differences require unique designs and solutions to achieve the type of emission reductions sought by the NESHAP.

As written, the proposed NESHAP includes a number of requirements that fail to respect differences among facilities, particularly differences in facility size. Most notably, the proposed NESHAP includes limits for Group 1 and Group 2 room air emissions that are stated in pounds of EtO emitted per hour. These limits were not derived from an assessment of the technology available for controlling room air emissions. Instead, EPA calculated these limits by taking the minimum EtO concentration EPA believes can be measured on a "workable-in-practice" basis (30 parts per billion by volume ("ppbv")) and multiplying that concentration by the air flows for a single sterilization facility (6,202 dry standard cubic feet per minute ("dscfm") for Group 1 room air,[57] and 13,711 dscfm for Group 2 room air[58]). Any facility that has an air flow greater than these values will be unable to demonstrate compliance with the mass-per-hour limits, because to do so, they would have to show that their EtO concentrations are lower than 30 ppbv, the minimum detection level EPA believes is workable in practice. As a result, the use of mass-per-hour emission limits functions as an implicit cap on the air flow a facility can have. In turn, when other aspects of the proposed NESHAP are considered, this cap on air flow limits the physical size of the facility.

2. The Timeframe for Compliance with the NESHAP Is Inadequate.

EPA has proposed that all 86 EtO facilities demonstrate compliance with all of the requirements of the proposed NESHAP within 18 months of the date of final publication. This timeframe does not reflect the challenges and difficulties that the sterilization industry will confront in retrofitting facilities. The availability of the equipment, materials, and contractor services necessary to modify emission control systems is severely limited. In addition, the installation of these systems is only the initial step. The systems also must be tested and calibrated to ensure that they perform as anticipated, which will require additional time. This phase of the process is made much more difficult by the need to install enhancements elsewhere in the facility to increase air flow and reduce temperatures to ensure appropriate employee protection from higher EtO levels and temperatures inside the facilities that are attributable to the installation of PTE systems. Finally, to the extent that it is necessary to validate any new sterilization cycles, even more time will be required. In Sterigenics' experience, a time-intensive iterative process is required over the course of which the PTE system and the facilities' HVAC systems can be adjusted and modified to achieve an acceptable interior temperature and EtO level.

Finally, modification of these facilities will require acquisition of building and/or occupancy permits from local governments as well as amendments to existing State air permits. Prompt consideration of and decisions on these permits

[57] Proposed NESHAP, 88 Fed. Reg. at 22,819.
[58] *Id.* at 22,821.

is not guaranteed, particularly in locales where EPA's imbalanced communications of risk from EtO facilities have created unwarranted fears and concerns.

In the CAA, the Congress allowed existing sources three (3) years to comply with NESHAP requirements with the potential for additional two (2) year extensions.[59] EPA has not provided any rationale for proposing a compliance deadline that is one half of the period specified by the Congress. Sterigenics recommends that, at a minimum, EPA allow the full statutory timeframe of three years to comply with the proposed NESHAP requirements and indicate that additional extensions will be granted when warranted by the particular circumstances associated with a particular facility.

3. Compliance with Both the NESHAP and the PID Involves Conflicting Approaches.

EPA's proposed approach to establishing both a NESHAP and a PID runs afoul of a core principle of statutory construction—namely, that the government should avoid interpreting statutory provisions in such a way that they conflict with other statutes enacted by the Congress.[60] The primary objective of the NESHAP is to address ambient air quality; thus, the proposed requirements seek to retain and treat as much EtO as possible inside the sterilization facility. This approach directly conflicts with the primary objective of the PID, which is to minimize exposure of facility employees to EtO. EPA has not analyzed nor provided any guidance on how to comply with the requirements of the NESHAP while simultaneously complying with the PID.

EPA is proposing to lower the employee exposure limit through the PID and to require employees to use respirators if the proposed exposure limit is exceeded. One solution to lowering indoor concentrations is to increase exhaust which will increase the volumetric flow rate of different emissions sources inside the facility. As discussed above, however, the NESHAP proposes to limit volumetric flow rates. At this point, it is unclear how facilities can comply with the NESHAP's negative pressure and room area concentration levels and still maintain EtO levels below the proposed PID exposure rate. EPA has a duty under the canons of statutory construction to harmonize these statutes and adopt interpretations of them that avoid creating such absurd results.

Similar contradictions exist even within the proposed NESHAP itself. As described above, the proposed NESHAP's mass-per hour limits for Group 1 and

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[59] CAA § 112(i)(3), (4), 42 U.S.C. § 7412(i)(3), (4).

[60] *See, e.g.*, *Lindh v. Murphy*, 521 U.S. 320, 336 (1997) (favoring reading of statutory provision that "accords more coherence" to disputed statutory provisions.); *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1619 (2018) ("[T]his Court's duty [is] to interpret Congress's statutes as a harmonious whole rather than at war with one another.").

Group 2 room air emissions implicitly limit on the air flow a facility can have to 6,202 dscfm of Group 1 air and 13,711 dscfm of Group 2 air. At the same time, the proposed NESHAP would require facilities to meet the Method 204 requirements for PTE. Method 204 requires an increase in air flow to ensure that air flows inward into the PTE. In particular, to avoid the need to demonstrate compliance through laborious means such as smoke tubes, streamers, or tracer gases, Method 204 requires that the air velocity across the face of the PTE boundary be at least 9,000 meters per hour.[61] It will be difficult for most facilities to provide enough air velocity into the PTE while also keeping air flow *out* of the PTE below 6,202 dscfm or 13,711 dscfm, as the case may be.

Sterigenics is firmly committed to emission reduction and employee protection and has proven that both can be achieved over time at EtO facilities. The emission reductions proposals that Sterigenics sets forth above, in Section V.A. of these comments, together with the proposals for continued and enhanced employee protection, as outlined in Sterigenics comments on the PID, over a reasonable implementation timeline of a minimum of three (3) years for NESHAP requirements, with a possibility of appropriate extensions, will allow Sterigenics to enhance protections for both communities and employees at its EtO facilities while serving critical healthcare needs.

4. The NESHAP Proposes Numerical Standards at Odds with Equipment Manufacturers' Performance Guarantees.

The CAA requires EPA to set emission standards based on the degree of emission reduction that is "achievable," "achieved in practice," or represents "generally available control technologies."[62] While the proposed NESHAP uses information from the industry to determine technologies that are used by the industry, the final numerical standards that EPA proposes cannot be squared with the performance that air pollution control device manufacturers are willing to guarantee their equipment will meet. The proposed NESHAP deviates from the performance that device manufacturers can guarantee in three ways.

First, some of the proposed standards are stated in terms of a certain "percent emissions reduction." Although pollution control device manufacturers frequently state their devices' performance in these terms, EPA did not use manufacturer guarantees to derive the particular numerical standards in the proposed NESHAP. Instead, EPA set the standards to match the average results of

[61] *See* EPA, Redline/Strikeout for proposed amendments to 40 CFR 63 Subpart O: Ethylene Oxide Emissions Standards for Sterilization Facilities, at 44-45 (Nov. 30, 2022), *available at* https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0486 (proposed section 63.365(g)(2)).
[62] 42 U.S.C. § 7412(d)(2), (3), and (5).

stack tests that industry had provided in response to EPA's section 114 information requests. Yet pollution control devices will vary in their performance from facility to facility and test to test. A regulatory standard set at the average of a set of stack tests (and without adequately considering differences in the class, type, and size of sources or considering what technology is generally available) will cause about half of the facilities to fall short of the standard (assuming the distribution of stack tests is not skewed). The facilities that fall short of the standard, through this random variation, will have no way of improving their performance, since they are already using the best technology available.

Second, EPA's use of average stack test results to set the numerical standards is particularly problematic because EPA concludes, in the proposed NESHAP, that the current methods for performing these stack tests need to be updated to be more representative of actual or normal operations.[63] Sterigenics does not agree with much of EPA's criticism of the industry's current methods for conducting stack tests. Regardless, the immediate point for now is that EPA cannot simultaneously argue that these stack tests are not accurate and then use those same stack tests as the basis for a regulatory standard.

Third, while many of the proposed standards are based on percent emissions reductions, the proposed standards for Group 1 and Group 2 room air emissions and chamber exhaust vents ("CEVs") (for facilities with EtO usage of at least 10 tons per year ("tpy")) are not. These standards are based on a permitted mass of EtO per hour. Mass-per-hour limits are two steps away from the percent reduction basis that air pollution control device manufacturers generally guarantee. A mass-per-hour limit depends on two variables: (1) the outlet concentration from the control device; and (2) air flow. In turn, the outlet concentration from the control device depends on: (1) the inlet concentration; and (2) the control efficiency of the device. An air pollution control device manufacturer can only control and will only guarantee the control efficiency of the device. The inlet concentration depends on the sterilization cycle being used, and it is the FDA—not EPA—that has the experience and jurisdiction to regulate the sterilization cycle. The air flow is largely a function of the size of the facility, and to avoid disruptions in the supply of medical products, EPA should be careful not to adopt standards that can only be met through operational curtailments.

Sterigenics, in principle and practice, has supported the use of the best and most advanced control technologies. Sterigenics has been an industry leader in identifying these technologies and putting them to use in its facilities. In the context of this rulemaking, Sterigenics continues to support standards that will be fully protective of our workforce and the communities surrounding our facilities

[63] *See* Proposed NESHAP, 88 Fed. Reg. at 22,844.

and that will result in verifiable reductions in EtO emissions and exposure. In our discussions with control device manufacturers, we believe that the best and most advanced technologies will be guaranteed to meet the following performance for SCVs:

- a 99.9 percent emission reduction, or
- an outlet concentration of 0.3 ppmv.

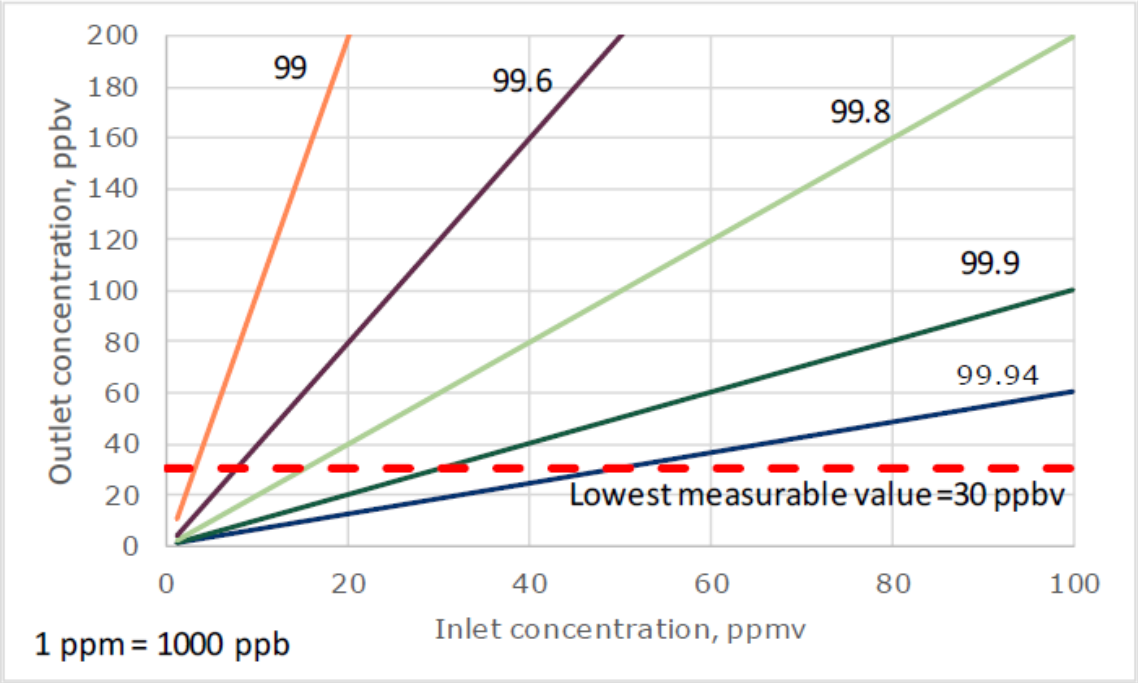
The control efficiency and outlet concentration standards for aeration room vents ("ARVs"), CEVs, and Group 1 and Group 2 room emissions are based on different subsections of CAA section 112, but EPA must consider what are real and concrete limitations regarding measurement and control technologies when determining final standards.

5. Limitations in the Ability to Monitor Low Levels of EtO Would Impose Substantial Limits on a Facility's Ability to Comply with the Percent Emission Reduction Standards in the Proposed NESHAP.

Technological limitations in the ability to monitor low levels of EtO pose significant barriers to a facility's ability to comply with the increased percent emission reduction standards in the proposed NESHAP. One key barrier is that the 30 ppbv "workable in practice" detection level that EPA discusses is not low enough to allow facilities to demonstrate compliance with the percent emission reduction standards unless those facilities have sufficiently high pre-control EtO concentrations.

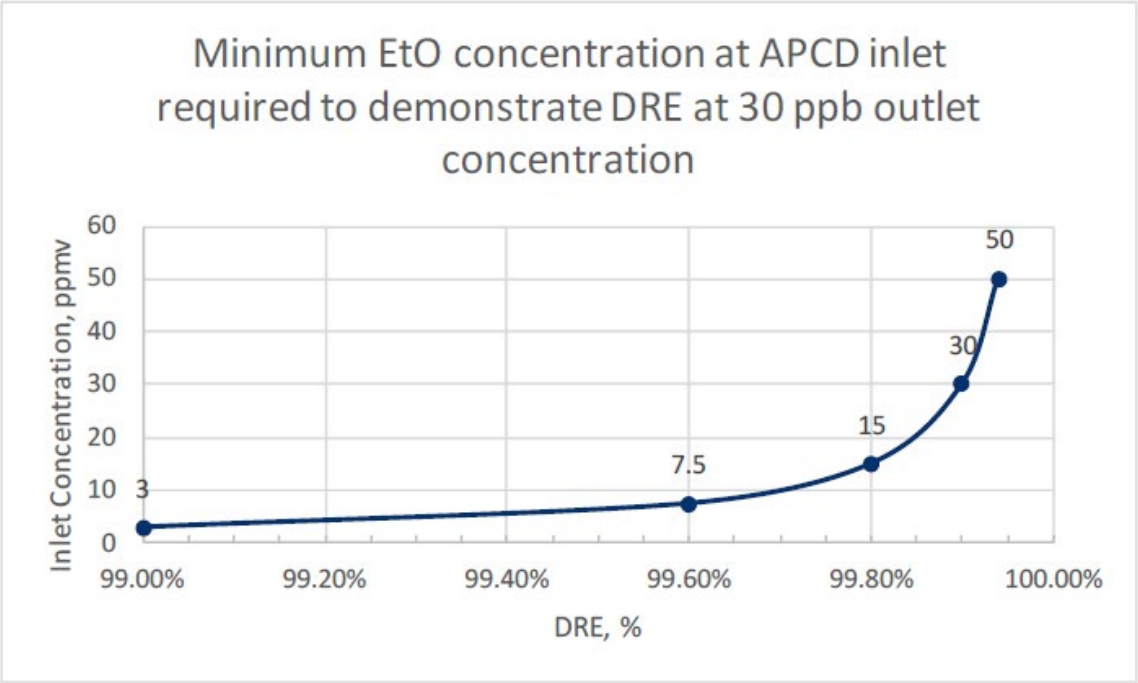
In a performance test, the percent of emission reduction is calculated as the percent reduction in mass of EtO, comparing the pre-control mass to the post-control mass. Assuming the airflow is the same at the control device input and output, the percent emission reduction is also equal to the percent reduction in concentration of EtO.

Figure 1 shows the relationship between the inlet and outlet concentration for each of the proposed percent emission reduction standards contained in the proposed NESHAP:



As the figure shows, at any given percent reduction, the lower the inlet concentration to a control device, the lower the outlet concentration will be. But if the lowest practicably measured concentration is 30 ppbv, then a facility with an *inlet* concentration that is too low will be unable to show the required percent reduction, even if the control device is providing that level of reduction, because the monitoring approach will be unable to distinguish the true outlet concentration from 30 ppbv.

Figure 2 organizes the same information to show the minimum inlet concentration required to be able to show EPA's various percent emission reduction requirements:

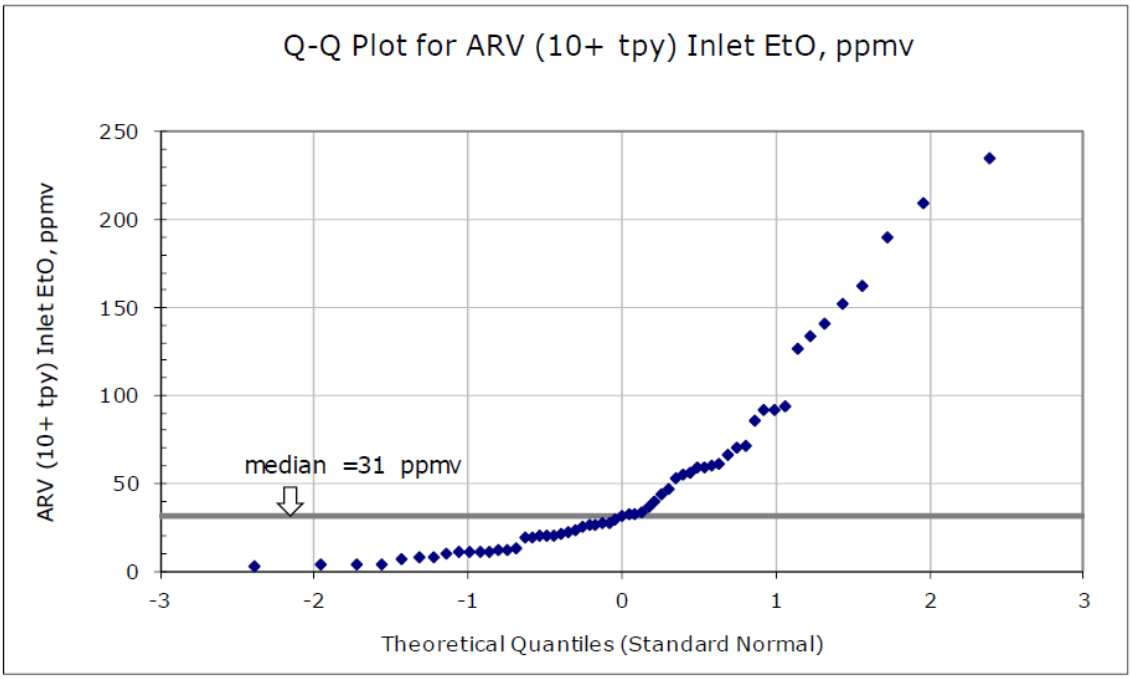


This figure shows that, to demonstrate a percent emission reduction of 99.6 percent, a facility must have an inlet concentration of at least 7.5 ppmv. To demonstrate a percent emission reduction of 99.94 percent, a facility must have an inlet concentration of at least 50 ppm.

This is particularly problematic for ARVs. EPA has proposed that ARVs demonstrate 99.9 percent emission reduction for new facilities using at least 10 tpy of EtO and 99.6 percent reduction for existing facilities of that size. As Figure 2 shows, new facilities would have to have pre-control aeration room concentrations of at least 30 ppmv to make this demonstration, and existing facilities would have to have pre-control concentrations of 7.5 ppmv or greater.

Figure 3 shows inlet concentrations for ARVs of this size class listed in EPA's compilation of test data,[64] presented as a normal quantiles plot. (One high outlier value of 794 ppmv is not shown for clarity.) This type of plot represents the distribution of the data: the median value occurs at a value of zero on the x-axis, with lower values to the left of that point and higher values to the right.

[64] EPA, Memorandum – Test Data for Aeration Room Vents and Chamber Exhaust Vents, Proposal, Att. 1 - Table A.1. Full List of Facilities with ARV, at Facilities where EtO Use is at least 10 tpy (Nov. 22, 2022), *available at* https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0488.



The median value occurs at 31 ppmv, which is barely sufficient to demonstrate the proposed percent emission reduction for a new facility. Nearly half (47 percent) of the aeration room inlet concentrations that EPA compiled are less than 30 ppmv, so for those facilities, it would not be possible to demonstrate compliance with this standard, even if the actual percent emission reduction were sufficient.

6. EPA Lacks Sufficient Data to Conclude that Instruments Can Achieve the Detection Level It Relies on for the Proposed NESHAP.

Another critical technological problem is that the data are insufficient to allow EPA to conclude that the instrumentation technologies it has specified as being capable of achieving a 10 ppbv minimum detection level—and, thus, the 30 ppbv "workable in practice" level—can actually do so. EPA relies on two technologies that it says can meet this level: optically-enhanced Fourier transform infrared spectroscopy ("OE-FTIR") and cavity ringdown spectroscopy ("CRDS").

OE-FTIR

In its memorandum to the docket regarding OE-FTIR,[65] EPA concludes that the "reliable detection limit" for EtO using OR-FTIR is approximately 10 ppb and:

[65] EPA, Memorandum – In-stack Method Detection Limits of Optically Enhanced FTIR, at 2 (Jan. 3, 2023), *available at* https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0421.

> While this technology may achieve lower detection limits under some circumstances, it is unknown if it will offer this level of sensitivity at all commercial sterilizers. For that reason, we are applying a margin of safety of 1.7 to 3.3 for this detection limit.

This caveat is certainly relevant since EPA has established standards assuming a 10 ppb detection limit is achievable for all commercial sterilizers. If the detection limit achievable is 1.7 to 3.3 times 10 ppbv, then the "workable in practice" value would range from 50 ppbv to 99 ppbv.[66] Therefore, EPA should revise the proposed standards to reflect a detection limit that is achievable for all sources subject to the rule.

EPA cites data from a single test report in the docket indicating detection levels as low as 6 ppb using OE-FTIR. In that report,[67] the authors make no claim regarding detection limits achieved during the tests and offer only a general statement about low detection levels in the description of the apparatus. Although EPA cites its own internal research lab evaluations, none of those data are provided to substantiate EPA's conclusions. EPA should show how it drew its conclusions from the cited test report and assess if their conclusions are sufficiently robust for standard-setting.

Although OE-FTIR technology is expected to reduce water vapor and other interferences compared with regular FTIR technologies, at low ppb measurement levels this remains a source of potential interference that must be specifically evaluated. The source that was tested had a low stack gas water vapor concentration (approximately 1 percent by volume). Other EtO control devices and other facilities are expected to have water vapor concentrations considerably higher than 1 percent (for example, thermal oxidizers which also have combustion products including water vapor in the exhaust stream). EPA provided no information on the performance of OE-FTIR for sources with water vapor levels greater than approximately 1 percent .

While Sterigenics agrees that OE-FTIR technology is promising and ultimately may be capable of achieving detection limits on the order of 10 ppb and lower at least for some sources, more data are needed (including more challenging applications) to establish whether this level of performance is achievable, repeatable, and reproducible for all sterilizers subject to the proposed rule.

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[66] 10*1.7*3=50 ppbv to 10*3.3*3=99 ppbv.

[67] EPA January 2023 Memorandum, *supra* note 65, Att. 2 - Compliance Test Report (10/31 - 11/4/2022) for the Baxter Healthcare facility in Mountain Home, AR.

CRDS

EPA assessed detection limits for CRDS analyzers.[68] Relying on two test reports, EPA concludes:

> Based upon the data reviewed, EPA considers the reliable in-stack detection limit of CRDS to be approximately 8 - 10 ppbv. While this technology may achieve lower detection limits under some circumstances, it is unknown if it will offer this level of sensitivity at all commercial sterilizers. For that reason, we are applying a margin of safety of 2 to 2.5 times the SADL for this detection limit.

As noted above for OE-FTIR, this caveat is very relevant. If the achievable detection limit is 1.7 to 3.3 times 10 ppb, then the "workable in practice" value would range from 48 ppbv to 75 ppbv.[69] Therefore, EPA should revise the proposed standards to reflect a detection limit that is achievable for all sources subject to the rule.

EPA supports its conclusion with citations to a single manufacturer's literature, one stack test method comparison study and one stack test. Unfortunately, the report on which EPA relies is not posted to the regulations.gov docket because the authors claim copyright protection. This strongly implies that there are proprietary aspects of the test equipment, procedures and/or practices necessary to achieve such performance that may not be reproducible by others. While the report could be viewed in the docket room in Washington, D.C., we were unable to do so before the public comment deadline. Therefore, we were not able to judge whether this level of measurement performance is achievable, repeatable, and reproducible for all sources subject to the rule.

7. The NESHAP Proposes New Testing and Test Methodologies that Create Safety Risks and Are Not Adequately Supported or Developed.

EPA is proposing significant changes to the requirements for performance tests run for facilities that use more than 10 tpy of EtO. The stated purpose of this change is to better reflect normal operating conditions of the facilities. However, these changes pose safety risks and lengthen the time needed for performance testing to the point that the availability of testing companies to meet the proposed requirement will be strained.

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[68] EPA, Memorandum - In-stack Method Detection Limits of Ethylene Oxide for Cavity Ringdown Spectroscopy Instrument (11/7/2023), at 2, *available at* https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0473.

[69] 8*2*3=48 ppbv to 10*2.5*3=75 ppbv.

The primary safety risk in EPA's proposed changes comes from EPA's proposal to require that a flammable and combustible chemical be sampled from the process air stream that travels from the sterilization chamber vent ("SCV") to the inlet of the control device. Out of concern for safety, current performance testing rules avoid sampling in this location (i.e., the scrubber inlet) by requiring that testing be done on an empty chamber and by allowing the tester to calculate the EtO present in the uncontrolled SCV air stream, rather than measuring it directly. Direct measurement requires a breach in the ductwork, allowing an uncontrolled, high-concentration and highly-flammable air stream to travel through a sample port in an environment in which it is difficult to guarantee that no spark or ignition source is present. Since EtO is explosive, such a sample port could result in a profoundly serious safety incident. It is also a leak source for high concentration EtO exhaust fugitive emissions within the workplace.

In addition, EPA has chosen an arbitrary test duration of 24 hours, rather than a test duration that matches normal operations. Sterilization chambers are batch cycles and typically run from 6 to 12 hours. The SCVs to emission controls only during part of this cycle. If a cycle lasts 6 hours there is no need to test for 24 hours to capture normal operations. Moreover, at facilities with multiple chambers, a time frame shorter than the 6-12 hour average cycle duration would be sufficient to capture normal operations of SCVs. CEVs run for an even shorter time than SCVs, so a long test duration is not necessary to capture normal operation of those vents, either. And aeration rooms operate more closely to a continuous process than a batch process, so there is no need for a 24-hour test duration for ARVs or for Group 1 and Group 2 room air emissions.

Requiring an overly long test duration, particularly if multiple test runs are required, would greatly increase the cost of performance testing, to more than $100,000 per performance test. Perhaps more importantly, the proposed testing duration, if multiple test runs are required, would require a stack tester to spend more than a week at an individual facility for an individual test. When combined with the significant proposed changes in testing methodology, this would place a strain on the availability of testing companies.

VI. INSUFFICIENT COST/BENEFIT ANALYSIS

A. Most Significant Impacts (and Associated Costs) Have Been Ignored.

EPA fails to consider the most significant costs of its proposals. These include the infections and deaths likely to result from the reduction of EtO sterilization capacity in the United States if EPA's proposals are implemented.

In its proposed EtO NESHAP, EPA has taken an exceedingly narrow approach to cost/benefit analysis that threatens to undermine the CAA's public health mandate, with potentially catastrophic consequences. Congress has required EPA to conduct scientifically reviewed studies on the impact of the CAA on the public health, economy, and environment of the United States and EPA has claimed that the benefits of CAA regulations have significantly exceeded costs. In emphasizing the stated goal of the CAA "to cut pollution and protect the health of American families and workers," EPA emphasizes that "[f]ewer premature deaths and illnesses means Americans experience longer lives, better quality of life, lower medical expenses, fewer school absences, and better working productivity."[70]

In its Regulatory Impact Analysis ("RIA"), EPA admits that "EtO sterilization services are a critical input in the provision of safe medical devices and there is uncertainty in how the proposal could potentially affect the medical device supply chain."[71] It would be difficult to overstate the potential significance of this "uncertainty." These "potential" impacts on the medical device supply chain, and resulting negative economic and health effects (including illness and deaths from doctors and patients unable to access safe medical devices and supplies), should be clearly understood to be part of the resulting costs of EPA's proposed rule and evaluated accordingly. EPA needs to thoroughly assess such costs, taking into account relevant EOs and the broader purposes of the CAA. In the interagency review process, FDA echoed these concerns, stating that, "EPA needs to do a complete consideration of the capacity reductions required to implement this rule on their timeline, and, as recognized elsewhere, the costs of facilities that will be unable to operate if they are unable to complete the compliance investments on time."[72]

Provisions contained in the proposed NESHAP include technical requirements that are infeasible and timelines for implementation that are unrealistic. EPA therefore must further analyze such requirements and implementation timelines before taking final action on the proposed rule. Moreover, EPA should recognize that its proposed standards are driven by a risk analysis that is inconsistent with real-world data and substantially overstates

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[70] EPA, Clean Air Act Overview, The Clean Air Act and the Economy, https://www.epa.gov/clean-air-act-overview/clean-air-act-and-economy (last visited June 15, 2023).

[71] EPA, *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, at 1-13, EPA-452/R-23-007 (Mar. 2023), *available at* https://www.epa.gov/system/files/documents/2023-04/RIA_EtO_Commercial_Sterilizers_NESHAP_Proposal.pdf ("RIA").

[72] 12866 Interagency Review Documentation - File Set 1 of 2: "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review." Notice of Proposed Rulemaking, Att. 36 at 2-8 (Margin Comment [A8]).

actual human risk. This results in a significant overstatement of the benefits of the rulemaking.

Therefore, when combined with the requirements in the proposed PID (issued the same day), there is a very real risk that EPA's proposed rules will result in shortages of medical devices and create a lack of sterilization capacity within the United States. Such shortages and the risks inherent in depending on foreign supply would have both an immediate and long-term negative impact on public health. Indeed, one need look no further than the recent COVID-19 pandemic for examples of significant onset of disease and, ultimately, thousands of lives lost in the United States because of the inability of the medical supply chain to meet public health requirements.

B. EPA Makes No Attempt to Quantify the Proposed NESHAP Benefits.

EPA does not offer any attempt to quantify the benefits of the revised EtO emissions standards and other requirements in the proposed NESHAP. EPA simply asserts that "[w]hile we expect that these avoided emissions will result in reductions in adverse human health effects, we have determined that the quantification of those benefits cannot be accomplished for this proposed rule."[73] And, as noted above, in making this conclusory statement about "reductions in adverse human health effects," EPA does not consider—nor ask for comments or data relevant to—the potential health effects of medical device shortages.

This problem is exacerbated by the misuse of the NIOSH data in the IRIS risk calculation for EtO; flawed data leads to an assumed level risk that is purportedly reduced by the proposed rule. Put more simply, EPA offers no data or specific information to explain the benefits of undertaking this rulemaking.

EPA does attempt to calculate the level of cancer risk reduction that results from the proposed NESHAP requirements. EPA estimates that the proposed rule will result in a reduction of annual cancer incidence (cancer cases per year; not deaths) from 0.9 to 0.1. In the interagency review process, reviewers estimated that the costs of the proposed NESHAP requirement ranged from $52.5 million to $110 million per theoretical cancer case avoided.[74] One agency commenter stated that "this is an unreasonable cost, and given the concerns about the medical supply chain, hard to justify against likely unintended consequences."[75]

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[73] *Id.* at 1-15, 6-1.

[74] *See* 12866 Interagency Review Documentation - File Set 2 of 2, *supra* note 46, Att. 7 at 6; *id.*, Att. 2 at 2.

[75] *Id.*, Att. 2 at 1.

C. EPA's Approach Is Inconsistent with OMB Guidance.

OMB issues guidance to agencies to assist them in developing well-reasoned regulations. One such publication, Circular A-4,[76] specifically addresses benefits or costs that are difficult to quantify or monetize because of difficulty in collecting data, or constraints in current analytical methods. In such cases, OMB advises that agencies should:

> present any relevant quantitative information along with a description of the unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. You should provide a discussion of the strengths and limitations of the qualitative information. This should include information on the key reason(s) why they cannot be quantified.
>
> ...
>
> For cases in which the unquantified benefits or costs affect a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs.[77]

EPA appears to have ignored OMB's guidance, offering only the conclusory statement that "[w]hile we expect that these avoided emissions will result in reductions in adverse human health effects, we have determined that the quantification of those benefits cannot be accomplished for this proposed rule."[78] EPA is undoubtedly making a policy choice about the appropriate regulation of EtO based on these unquantified asserted benefits, yet wholly absent from EPA's analysis is any discussion of the "nature, timing, likelihood, location, and distribution" of these purported benefits. What is particularly striking is that, even though EPA was faced with dire predictions about the potential medical supply chain effects of the proposed rule, the agency offers no additional information about what data might inform a quantitative analysis of the claimed

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[76] OMB, Circular A-4 (Sept. 17, 2003), *available at* https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf. In April 2023, OMB released a proposed revision to this circular, which provided updated guidance on cost/benefit analysis. OMB, Circular A-4 - DRAFT FOR PUBLIC REVIEW (Apr. 6, 2023), *available at* https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf ("Draft Circular A-4"). This proposal retains the section on addressing costs and benefits that are difficult to quantify, and makes some revisions that do not alter the analysis above. If anything, the retention of this section in the revision reinforces how important it is to OMB that agencies include this analysis.

[77] *Id.* at 27.

[78] RIA at 1-15, 6-1.

"reduction in adverse human health effects." Nor does EPA discuss the qualitative information it was relying upon to make the above-quoted statement.

D. EPA Did Not Follow Its Own Suggested Approach.

EPA's approach on analyzing claimed benefits of the NESHAP is not consistent with its own recent guidance. In a presentation made just three months ago entitled "Towards More Complete Benefits Assessments," EPA economists outlined the agency's evolving approach to expanding its methodologies to allow for more robust analysis of rulemaking benefits.[79]

According to EPA, a common approach is to assess benefits by estimating what individuals would be willing to pay ("WTP") for environmental improvements resulting from the regulation (including reduced exposure to potential hazards). The current practice is to quantify endpoints deemed "causal" or "likely causal," but not to quantify "suggestive endpoints" (based on causality determinations in the National Ambient Air Quality Standards Integrated Science Assessments).

EPA economists stated the importance of including in an assessment potential effects for which the casual relationship may be less certain, but the impact would be substantial. EPA acknowledges that the current literature could support quantification of additional benefits, including labor productivity; cognitive impacts; respiratory disease burden; and altruism related to disproportionate exposures.

In the NESHAP RIA, however, EPA does none of these things. As noted above, EPA does not attempt to quantify any type of benefit. Instead, the agency simply states that the non-monetized benefits exist. EPA states that it did not have estimates for WTP for avoided cancer cases, but "continues to work on developing such values and welcomes comments on potential methods that should be considered."[80]

Sterigenics respectfully suggests that EPA must adopt some method, based upon actual scientific studies, market data, and other sources to attempt to quantify the benefits associated with any marginal EtO emissions reductions associated with the new requirements. Such a quantification must also account for

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[79] Al McGartland, EPA, "Towards More Complete Benefits Assessments," Presentation from CARB Public Meeting of the Science Advisors (Mar. 22, 2023), *available at* https://ww2.arb.ca.gov/sites/default/files/2023-04/CARB%20Slides%20for%20Public%20Meeting%20of%20Science%20Health%20Experts%20-%20for%20Website.pdf.

[80] RIA at 4-1.

the presence throughout the country of background EtO unassociated with EtO or other industrial facilities.

E. EPA's Cost Estimates Are Significantly Understated.

EPA's assessment of costs, by contrast, is vastly understated. There are significant categories of costs associated with the proposed NESHAP that EPA ignores in its estimates. In addition to the potential loss of lives associated with a shortage of critical medical devices, such a shortage may also cause risk of increased sickness and accompanying U.S. work force impacts. Other costs ignored by EPA include costs related to changed validation processes (e.g., elimination of half-cycle validation, difficulties with tailored cycle calculations); costs related to production shutdowns; and market impacts on the demand for sterilization services in the United States.

Moreover, where EPA does attempt to estimate the capital investment required to make all EtO facilities compliant with the new requirements, it misses the mark by a significant amount. EPA estimates that the present value of the estimated compliance costs from 2023 to 2042 for the proposed option is $640 million in 2021 dollars (discounted at a 7 percent rate). The estimated equivalent annualized value of the costs for the proposed rule is $74 million (using a 7 percent discount rate).[81] EPA's estimates appear to be based upon assumptions that there are: 26 facilities that will require "permanent total enclosure" capital investments of a total of $65.8 million and 57 facilities that will require "gas/solid reactors" capital investments of a total of $133.9 million.[82]

EPA's assumptions on costs are inconsistent with Sterigenics' real-world experiences in modifying its own facilities. Since 2018, Sterigenics has invested over $50 million to install state-of-the-art emissions controls and technologies to capture and control all process and fugitive EtO emissions at its U.S. facilities. These controls include ventilation systems that capture all internal air and routes it to a new emissions control system; central discharge points that further control the exceedingly small levels of emissions that remain after treatment through the emissions control systems; and often a "double scrub" process that captures EtO and sends it through a secondary emission control system.

Sterigenics' experience teaches at least two fundamental conclusions about facility modifications: (1) each facility requires different engineering solutions and has its own set of engineering and other costs. These highly variable costs can also be increased by scarcity of the supplies and services required for design, construction, and validation; and (2) timelines required for significant emission

[81] Proposed NESHAP, 88 Fed. Reg. at 22,853.
[82] RIA at 3-8.

control modifications are usually longer than expected. On the first point, while Sterigenics will have prepared detailed projections of the costs required to modify its existing facilities if EPA's proposal is adopted as proposed, the company fully expects these costs will amount to multiples of the $50 million already invested for Sterigenics' facilities alone. This does not include the additional costs and complexities introduced by the proposed PID.[83] On the second point, it is simply not feasible to make all of our facilities fully compliant with what EPA proposes in 18 months. As noted elsewhere, it likely will take three years for implementation, with the possibility of extensions to deal with unanticipated developments.

These real-world timelines may be even longer if additional challenges are encountered, including: (1) limited availability of new equipment, technology, and contractor services; (2) complications arising out of installation, validation, and operation of new or unproven technology; and (3) unanticipated delays due to complex state and local permitting requirements. These categories of additional costs do not appear to be included in EPA's cost estimates.

Sterigenics has been an industry leader in the design and implementation of facility changes to minimize emissions and to protect employees. The company has consistently demonstrated that it is willing to make significant capital investments in safety and environmental protection and will continue to do so. It is not as clear that other sterilization service providers will be as able and/or as willing to make the types of investments required to meet the standards set forth in the proposed NESHAP. If Sterigenics' competitors, both outsourced sterilization providers and in-house sterilizers, are unwilling and/or unable to make these investments, EtO capacity will be further constrained and the risks of medical device shortages may significantly increase.

Sterigenics believes that EPA's EtO rulemakings should consider the company's real-world experience in engineering, designing, and implementing the types of facility modifications that would be required if the proposed NESHAP is finalized without modification. The company's experience shows that the per-facility modification costs will likely be significantly higher than EPA's estimates. If EPA were to estimate compliance costs in a manner that reflected industry experience, the total estimated costs of compliance would be significantly higher and would further highlight the flaws in the agency's overall cost/benefit analysis.

[83] Detailed projections of anticipated engineering costs at each facility are confidential and proprietary information that Sterigenics seeks to protect from disclosure. Sterigenics is willing to share cost data with EPA, upon request, provided that such information is provided all protections available under law to prevent disclosure.

F. Flawed Assumptions about "Pass-Through" of Increased Sterilization Costs

In its RIA, EPA states that it "was not able to model potential market impacts for this proposal" and recognizes that "EtO sterilization services are a critical input in the provision of safe medical devices and there is uncertainty in how the proposal could potentially affect the medical device supply chain."[84] Nevertheless, citing "qualitative information gathered on the industry," EPA projects that demand for EtO services will remain "fairly inelastic, meaning demand may be insensitive to price changes . . . ."[85] This assumption leads EPA to conclude that, "[i]f the costs of this proposed rule are spread out among several sectors in the medical device supply chain, overall impacts could be minimal given the size of the medical device supply industry in the U.S."[86]

Perhaps recognizing the number of assumptions made to get to this conclusion, EPA then acknowledges that the proposed rule may disrupt the medical device supply chain if demand cannot be met. EPA then states, without any supporting information, that capacity could be limited "in the short run as firm adjust operations to comply with the proposed requirements."[87]

EPA offers no studies, data, or documents to support these crucial economic assumptions. There is no quantitative or qualitative evidence presented to support the statement about inelastic demand for EtO sterilization services. While it is true that there are limited sterilization options in the United States, there is no evidence that price increases resulting from rule-based cost increases will not result in some sterilization services moving to non-U.S. markets. In fact, the SBA has indicated that potential cost increases in EtO sterilization may drive customers to non-U.S. markets, stating that "highly inelastic markets are rarely inelastic permanently, and medical device manufacturers will have options to lower their costs by seeking alternative suppliers, most likely overseas given the lack of spare domestic capacity."[88]

Similarly, the assumption that any disruption in capacity would be limited to the "short run" is without support and is inconsistent with recent industry trend towards closing facilities and/or abandoning new-build plans in the face of regulatory and legal uncertainties. Significantly, EPA abruptly ends this section of the RIA by acknowledging the potential increased risk of shortages of some

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[84] RIA at 1-13 to 1-14.
[85] *Id.* at 1-13.
[86] *Id.* at 1-14.
[87] *Id.*
[88] 12866 Interagency Review Documentation - File Set 2 of 2, *supra* note 46, Att. 12 at 2-11 (Margin Comment [A9R8]).

devices but assumes that this would be temporary or short-term. EPA neither explains this assumption nor attempts to quantify any effects of any short-term shortages.

VII. EPA'S LEGAL AUTHORITY FOR PROPOSED EMISSIONS STANDARDS IS UNCLEAR.

In the proposed NESHAP, EPA did not explain the basis for its conclusions regarding the authority it claims under the CAA: (a) to set MACT standards for new sources as well as existing sources already subject to CAA standards; (b) to set generally available control technology ("GACT") standards for new and existing sources; and (c) to consider whether new standards are needed pursuant to residual risk provisions.

For a rulemaking with such significant potential effects on public health, vague references to various sections of the CAA as a basis for rigorous proposed emissions standards should not suffice. In addition, as noted above, EPA claims that its discretion and authority flow from the inherently flawed updated unit risk estimate ("URE") for EtO contained in the 2016 IRIS.

A. EPA's Regulation of Commercial Sterilizers under the CAA

To understand the fundamental legal flaws in EPA's approach, it is useful to review the history of EPA's treatment of commercial sterilizers under Section 112 of the CAA.

1. 1994 Rule

In 1994, EPA promulgated standards for EtO commercial sterilization and fumigation operations that it predicted would reduce nationwide emissions of EtO by 96 percent, lowering emissions from 950 to 48 tpy.[89] This rule determined a MACT floor for CEVs and applied this MACT floor level to major sources that contained CEVs.[90] The rule also addressed emissions from SCVs and ARVs.

The 1994 rule divided sources into three different size categories: sources using 1 or less tpy of EtO, sources using between 1 and 10 tpy of EtO and sources using 10 tons or more tpy of EO. In the rule, EPA focused on the *amount of EtO used by facilities*—rather than *EtO emitted* from the facilities—based on the presumption that "[b]ecause all of the [EtO] used for sterilization and fumigation is emitted following the sterilization process, the uncontrolled [EtO] emissions

[89] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 62,585, 62,586 (Dec. 6, 1994).
[90] 40 C.F.R. § 63.362(e)(1).

from a facility are equal to the amount of [EtO] used by the facility."[91] EPA used this presumption for all sources affected by the rule even while it noted that larger facilities already controlled some emissions.[92]

For sources using between 1 and 10 tpy of EtO and sources using more than 10 tpy of EtO, the final rule established requirements to control 99 percent of emissions from SCVs. For sources using over 10 tpy of EtO, the final rule also imposed a 1 ppm maximum outlet concentration or 99 percent emission reduction for ARVs. And for sources using more than 1 and less than 10 tpy of EtO, a concentration limit of 5,300 ppm was applied to CEVs. Sources using more than 10 tpy of EtO were required to use a manifold to a control device or comply with a 99 percent emission reduction for CEVs.

In this same rule, EPA also utilized what it termed a MACT/GACT approach for facilities that were area sources, i.e., sources that do not emit or have the potential to emit more than 10 tpy of EtO.[93] Referencing the Agency's authority in CAA section 112(d)(5), EPA: (1) did not impose *any* controls on area sources using below 1 tpy of EtO, (2) did not require controls for ARVs for sources using between 1 and 10 tpy of EtO; and (3) differentiated controls for CEVs for sources using between 1 and 10 tpy from the standards that applied to major sources over 10 tpy.[94]

All of the standards imposed by the 1994 rule applied to both new and existing sources. Existing sources, however, were allowed three years to come into compliance. The 1994 rule also specified that it did *not apply* to other new or existing sources of EtO, specifically beehive fumigators, research of laboratory facilities, or sterilization operations in hospitals, doctor's offices, clinics, or other

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[91] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 10,591, 10,592 (Mar. 7, 1994). EPA made this presumption while noting in the proposed rule that "[a]pproximately 21 facilities use 9,070 kg/yr (10 ton/yr) or more of EO, but control the majority of EO emissions, emissions from the sterilization chamber vent, and would not be required to install additional controls on this emissions point."

[92] *Id.* ("Approximately 21 facilities use 9,070 kg/yr (10 ton/yr) or more of EO, but control the majority of EO emissions, emissions from the sterilization chamber vent, and would not be required to install additional controls on this emissions point.")

[93] 59 Fed. Reg. at 62,586. CAA § 112(a)(1); 42 U.S.C. §7412(a)(1) defines a "major source" as meaning "any stationary source or group of stationary sources located within a contiguous area and under comment control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant." An "area source" is "any stationary source of hazardous air pollutant that is not a major source." 42 U.S.C. § 7412(a)(2).

[94] 59 Fed. Reg. at 62,593; 40 C.F.R. § 63.362, Table 1.

facilities "whose primary purpose is to provide medical services to humans or animals."[95]

2. 2001 Repeal of CEV Standards

The 1994 emission limits for CEVs that applied to sources using between 1 and 10 tpy of EtO and sources using more than 10 tpy were later eliminated in a 2001 rule due to safety concerns.[96] In doing so, however, EPA also agreed with a commenter who argued that the 5,300 ppmv concentration limit based on the EPA's 1994 application of MACT was actually "based on 'Agency modeling, *not actual operating conditions*.'"[97]

In eliminating the CEV regulations, EPA also agreed with commenters that "there is no proven instrumentation which could be employed to comply with the proposed requirement to determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust."[98] And EPA additionally conceded that when the concentration limit was finalized in 1994, the "limit was added to the rule as a precautionary measure; the Agency did not know of any plant operators by-passing main sterilization vent control devices."[99]

Finally, EPA declined to promulgate alternative limits for CEVs based on the existence of Occupational Health and Safety and FDA regulatory requirements. EPA stated "[t]he Agency sees no practical benefit to adding additional requirements to accomplish the same thing."[100] EPA also stated that "because the concentration cannot be measured and there is now little or no value to the requirement, we are not promulgating the [CEV] concentration limit for large facilities and are withdrawing the requirement for small facilities."[101]

3. 2006 Residual Risk Determination

In 2005, EPA published a proposed rule utilizing a combined residual risk and technology review of the 1994 final standards. This rule rested on EPA's

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[95] 59 Fed. Reg. at 62,592; 40 C.F.R. § 63.360(c)-(e). EPA did not provide any explanation for excluding other users of EtO from the regulation, nor characterize any difference in risk as between commercial sterilizers and these other users.
[96] Ethylene Oxide Emissions Standards for Sterilization Facilities, 66 Fed. Reg. 55,577 (Nov. 2, 2001). The 1994 was previously suspended in 1998 after reports of explosions at several EtO sterilization facilities. *Id.* at 55,578.
[97] *Id.* at 55,579 (emphasis added).
[98] *Id.* EPA also added that "the concentration limit approach is not feasible because there is no known way to safely measure concentration." *Id.*
[99] *Id.*
[100] *Id.* at 55,580.
[101] *Id.*

authority as contained in CAA sections 112(f) and (d)(6).[102] In the proposed rule, EPA noted that "[s]ection 112(f)(5) expressly provides . . . that EPA is not required to conduct any review under section 112(f) or promulgate any emissions limitations under that subsection for any area sources listed pursuant to section 112(c)(3) for which EPA has issued GACT standards."[103] EPA also stated that "although EPA has discretion to conduct a residual risk review under section 112(f) for areas sources for which it has established GACT, it is not required to do so."[104]

In support of the proposed rule, EPA prepared a risk assessment that found approximately 250,000 people lived in areas where individual lifetime cancer risks from EtO exceeded 1-in-1,000,000; 7,300 people lived in areas where individual lifetime cancer risks exceed 10-in-1,000,000 and that the highest calculated individual lifetime cancer risk was 90-in-1,000,000.[105] EPA stated that, based on these risk levels, there was not the need for "more stringent controls."[106] With respect to its separate technology review pursuant to CAA section 112(d)(6), EPA indicated that "we did not find any new technology or alternative controls for any of the vents—chamber, sterilizer or aeration room vents. We also found no data to support the addition of downstream control devices to existing control measures as a way of further reducing emissions . . . ."[107] EPA concluded that any additional controls "would achieve at best, minimal emission and risk reductions at very high costs."[108]

In the 2006 final rule, EPA did not change any of its proposed findings and determined to not revise the 1994 or 2001 EtO standards.[109] In EPA's response to comments, however, the Agency advanced additional interpretations of its CAA section 112 authority. First, EPA agreed with comments that EPA should not "include the risk from area sources in determining whether risks from the major source category exceeds the one-in-a-million risk trigger under section 112(f)(2) or in making judgments of acceptable risk and ample margins of safety for major sources."[110] EPA also stated that "a separate determination of acceptable risk and ample margin of safety should be made for each source category under section 112(f) of the CAA."[111] EPA additionally agreed with comments that where the

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[102] Ethylene Oxide Emissions Standards for Sterilization Facilities, 70 Fed. Reg. 61,404 (Oct. 24, 2005).
[103] *Id.* at 61,406.
[104] *Id.*
[105] *Id.*
[106] *Id*, at 61,407.
[107] *Id.*
[108] *Id.* at 61,409.
[109] Ethylene Oxide Emissions Standards for Sterilization Facilities, 71 Fed. Reg. 17,712 (Apr. 7, 2006).
[110] *Id.* at 17,714.
[111] *Id.*

Agency conducts a combined residual risk and technology review, "a revision is not necessarily required under section 112(d)(6) even if cancer risks are greater to or equal to 1 in 1 million."[112]

B. EPA's Proposed Interpretation of Legal Authority

1. Emission Standards

EPA is proposing to utilize several different sections of CAA section 112 as legal authority for its proposed emission standards for EtO. EPA is first proposing to utilize CAA sections 112(d)(2), (3), and (5) as the basis for MACT standards and GACT standards for facilities where EtO use is less than 1 tpy.[113] These standards would not apply facility-wide, but to certain emission points within the facility (i.e., CEVs, ARVs, and SVCs as well as previously unregulated room emissions).

Second, EPA is proposing standards for "ARV[s] and CEV[s] at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEV[s] at facilities where EtO use is at least 10 tpy, and room air emissions."[114] EPA specified that these "room air emissions": include "emissions resulting from indoor EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material."[115]

Third, while EPA completed a residual risk review for the entire commercial sterilization source category in 2006, EPA proposes to again utilize CAA section 112(f)(2) to set standards for SCVs in three EtO use categories (i.e., 1 tpy to 10 tpy, 10 tpy to 40 tpy, and 40 tpy or more). In addition, EPA proposes to use CAA 112(f)(2) residual risk authority to set standards for *previously unregulated* "Group 2 air emissions" or "post-aeration handling of sterilized material."[116]

Finally, EPA is proposing to use its recurring authority under CAA section 112(d)(6) to take into account developments in practices, processes, and control technologies to revise emission standards for SCVs in two EtO use categories (facilities that use at least 1 tpy but less than 10 tpy of EtO and facilities where EtO use is at least 10 tpy).[117] These CAA section 112(d)(6) standards would also apply to ARVs where EtO use was at least 10 tpy.[118]

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[112] *Id.* at 17,718.
[113] Proposed NESHAP, 88 Fed. Reg. at 22,792.
[114] *Id.* at 22,793.
[115] *Id.* at 22,793 n.5.
[116] *Id.* at 22,793.
[117] *Id.* at 22,793, 22,840-41.
[118] *Id.*

In general, EPA gives short shrift to its explanation of its legal authority as a basis for the proposed rule.[119] The agency does not detail at any length how it determined to apply these authorities: (a) to set MACT standards for new sources, as well as existing sources already subject to CAA standards; (b) to set GACT standards for new and existing sources; and (c) to consider whether new standards are needed pursuant to residual risk provisions. But EPA appears to interpret the statute to allow the Agency to:

- Conduct an additional residual risk review pursuant to CAA section 112(f)(2) where this provision indicates that EPA shall promulgate such standards within eight years of promulgating CAA section 112(d) standards, in this case, 2002, and where EPA completed such a review in 2006.

- Use "discretion" to conduct a residual risk review, even while CAA section 112(f)(2)(A) requires EPA to promulgate standards only once. But even if EPA has discretion, which is not conceded, the agency must exercise its authority in a reasonable matter as well as consider resulting costs and the impact of any standards on the public health, including the medical supply chain.

- Conduct a residual risk review of GACT standards promulgated pursuant to CAA section 112(d)(5) wherein that section states that GACT standards are promulgated "in lieu of the authorities provided in [CAA sections 112(d) and (f)]" and section 112(f) states that EPA "shall not be required" to conduct such a review.

- Conduct a residual risk review of emission points that have not previously been subject to CAA section 112 standards.

As noted above, EPA largely relies on claimed "discretion" under the statute rather than explain how it is interpreting its black letter statutory authority. But Congress wrote CAA section 112 in a deliberate manner to require achievable technology standards first, followed by a singular review of risk, a step-wise process from which EPA deviates. In addition, at least in part, EPA relies on the updated URE for EtO as contained in the 2016 IRIS assessment as rationale for the exercise of its claimed discretion.[120]

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[119] EPA does insert a "generic" explanation of its interpretation of CAA section 112 in Section II.B. of the preamble, but this "boilerplate" explanation does not specifically address the standards the Agency is proposing for commercial sterilizers. In this section of the preamble, EPA also cites CAA section 301 but again does not explain its use of this general authority in the context of the proposed rule.

[120] Proposed NESHAP, 88 Fed. Reg. at 22,796, 22,807.

2. Form and Applicability of Standards

EPA entirely fails to justify the "form" of its proposed emission limitations which are based solely on a facility's *use* of EtO. Pursuant to CAA section 112(d)(2), emission standards promulgated under subsection (d) shall require the "maximum degree of reduction *in emissions*."[121] EPA, however, proposes to retain the same form of the standards, first promulgated in 1994, based a facility's *use* of EtO.

This form of the standard is apparently based on EPA's original rulemaking proposal that theorized "[b]ecause all of the EO used for sterilization and fumigation is emitted following the sterilization process, the uncontrolled EO emissions from a facility are equal to the amount of EO used by that facility."[122] But if this was indeed the case in 1994, it is certainly and clearly no longer the case today, in 2023, nearly 30 years after EPA made its original assessment.[123] Yet EPA's exertion of its CAA section 112 authority and the gradation in the standards between lower-use and higher use facilities is based entirely on this original and outdated assessment.

EPA makes no apparent attempt in the proposed rule to reassess the form of the standard and whether, in light of three subsequent decades of installing and refining control technologies, such categorization of the resulting emission limits still remains relevant. In this regard, EPA should be reminded that pursuant to CAA section 112(a) major and area sources are distinguished according to whether "any stationary source or group of stationary sources within a contiguous area and under common control emits or has the potential to emit *considering controls*, in the aggregate, 10 tons per year of more of any hazardous air pollutant."[124] Because area sources are defined solely with respect to not constituting a major source,[125] this same consideration of a facility's emissions, considering controls, also applies to that category of sources.

As noted above, in this rulemaking EPA is proposing MACT standards for certain emission points. These include MACT standards for previously uncontrolled emission points, but also include other emission points that have been subject to CAA section 112 standards. For example, EPA has "re-calculated MACT floors for CEVs at facilities where EtO use is at least 10 tpy."[126] But while a 10 tpy level of *emissions* is above the "major source" threshold used in the NESHAP program, EPA makes no attempt to correlate use levels with such

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[121] CAA § 112(d)(2), 42 U.S.C. § 7412(d)(2) (emphasis added).
[122] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 10,591, 10,591 (Mar. 7, 1994).
[123] Consider inserting supporting technical information.
[124] CAA § 112(a)(1), 42 U.S.C. § 7412(a)(1) (emphasis added).
[125] CAA § 112(a)(2), 42 U.S.C. § 7412(a)(2).
[126] Proposed NESHAP, 88 Fed. Reg. at 22,814.

emissions to apply the statute in accordance with its written terms. EPA also applies MACT standard-setting methodology to entirely new facilities based on use of EtO, apparently without consideration of the actual or potential emissions from such a facility.[127]

In general, EPA provides no indication that the Agency considered, in any form, the actual or potential for such sources to emit EtO even while admitting that "all facilities that use more than 10 tpy are synthetic area source facilities."[128] EPA maintained its regulation of source based on use even while noting that CAA section 112(d)(3) requires MACT standards for major source, but does not require such standards for area sources.[129] And, as noted above, EPA applies this form of the standard to entirely new emission points (Group 1 and Group 2 emissions) that it seeks to newly regulate under CAA section 112. In all cases, EPA calculates a MACT floor level without considering whether these emission points fall below the major source threshold.

3. Consideration of Non-Air Quality Health and Environmental Impacts

In promulgating standards pursuant to CAA sections 112(d)(2)-(3), EPA is required to consider "the cost of achieving such emission reduction, and any non-air quality health and environmental impacts." While the proposed rule references, in two short mentions only, consideration of the "medical supply chain" beyond these brief statements there is no further examination of these extraordinarily critical impacts other than the statement that EPA has "given careful consideration to the important function [commercial sterilization] facilities serve."[130] There is also no technical support document contained in the docket for this rulemaking addressing either this statutory requirement or the vital "non-air quality health" impact posed by a diminished ability to sterilize medical equipment in the United States.

EPA indicates that with regard to unregulated emissions at new and existing major and area sources, the Agency is proposing to promulgate GACT standards on the basis of several considerations, including that a significant portion of the sources are small entities, companies could experience a significant economic burden, EPA is trying to "minimize disruption to the supply of medical devices and thereby avoid creating a potential health concern" and because of other revisions

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[127] While EPA noted that the previous CEV standard required a reduction of 99% in emissions and, while later rescinded, "[t]oday . . . multiple facilities, where EtO use is at least 10 tpy, are routing CEV emissions to dedicated control devices and demonstrating the 99 percent emission reduction," *id.*, EPA re-calculated MACT floors for these facilities.

[128] *Id.* at 22,808.

[129] *Id.* at 22,807.

[130] *Id.* at 22,793.

based on residual risk.[131] Again, however, neither the proposed rule nor the administrative record provide any detail or quantification regarding how this consideration was balanced as against the other statutory criteria contained within CAA section 112(d)(2).

C. EPA Residual Risk Calculations Rest on Layers of Uncertain Emission Estimates.

EPA utilizes the 2016 IRIS assessment as a basis for the calculation of its proposed CAA section 112(f)(2) standards. All estimates of residual risk are based on the 2016 IRIS assessment, as expressed in EPA's calculations of inhalation risk contained on Table 20.[132]

Our criticisms regarding the IRIS assessment are detailed at length elsewhere these comments. In making calculations to derive its proposed CAA section 112(f)(2) standards, however, it can also be noted that EPA admits the MIR it determined (3,000 in 1 million) was "driven by EtO from one facility."[133] On this basis, EPA proposes to set a CAA section 112(f)(2) standard for SCVs that would apply to 36 facilities with SCVs using at least 40 tpy of EtO.[134]

EPA additionally proposes emission limits for Group 2 room air emissions from existing area sources where EtO use is at least 20 tpy, based on three facilities exceeding calculated MIRs exceeding 100-in-1 million.[135] Altogether, EPA estimates that 40 facilities will be subject to Group 2 requirements. Finally, EPA is proposing Control Options A and C for facilities that use at least 10 tpy but less than 40 tpy of EtO and at least 1 tpy but less than 40 tpy, again based on limited information.[136] Starkly, with reference to Option A, EPA states that "we do not know what the full extent of risk reductions would be" but that the Agency expects "some risk reduction."[137]

The limited and anecdotal information that EPA presents as justification for these standards is insufficient to underpin EPA's exertion of CAA section 112(f)(2) authority. EPA does not attempt to explain whether it views the levels of risk as "acceptable" or "not acceptable" given the levels of population (approximately 33 people) it calculates face a 400-in-1,000,000 MIR cancer risk while it solicits

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[131] *Id.* at 22,807. EPA does note that one facility with less than 10 tpy EtO use is a major source due to the emission of other hazardous air pollutants. *Id.* at 22,808 n.18.
[132] *Id.* at 22,826.
[133] *Id.*
[134] *Id.* at 22,827.
[135] *Id.*
[136] *Id.* at 22,829.
[137] *Id.*

comment on this issue.[138] While EPA considers 100-in-1,000,000 a presumptive risk level, EPA must articulate a rational basis to explain how the limited information analyzed and the calculated risks from 1 facility can be reliably utilized to promulgate standards for 35 to 39 other facilities. Apart from the flaws noted with regard to IRIS, this provides an additional reason that EPA should not finalize these standards as proposed.

D. EPA Should Not Require Title V Permits.

EPA is proposing to reverse the determination it made in 2005 that exempted area source EtO commercial sterilizers from title V permitting.[139] In justifying its change in position on this issue, EPA states that the average burden associated with title V ($67,211 for the first year, as calculated in 2019) "likely overstate[s] the costs imposed on area source EtO commercial sterilizers."[140] And EPA claims that title V permitting costs for commercial sterilizer area sources are less than those for complex major sources associated with its 2019 cost-estimate.

EPA, however, provides no supporting data for its conclusion that the costs imposed on area sources will be minimal. And the Agency's determination is also difficult to square with EPA's argument that—as opposed to considerations in 2005 for not extending title V to area sources on the basis that NESHAP requirements were relatively simple—"the rule amendments proposed provide for a *greater degree of complexity and requirements* to achieve and demonstrate compliance for area sources."[141] Simply put, EPA cannot have it both ways. The Agency should not add to the burdens for area sources given that the Agency has already underestimated the cost of compliance for all sources subject to this rulemaking.

Finally, in seeking additional support for its changed position, EPA cites "legislative history" regarding the enactment of title V in 1990 to argue that this action supports the broader purposes of the CAA.[142] The Congressional statements that EPA references, however, do not reflect the views of the House-Senate Conference Committee regarding the 1990 Clean Air Act Amendments (in which title V was included). Nor, as the authors of the referenced statement admitted, was the legislative history otherwise "reviewed or approved by all of the conferees."[143] Thus, it is questionable what weight should be given to this

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[138] *Id*. at 22,828, Table 21, and Comment C-38.
[139] *Id* at 22,850.
[140] *Id*. at 22,851.
[141] *Id*.
[142] *Id*. (citing the Chafee-Baucus Statement of Senate Managers, Environment and Natural Resources Policy Division 1990 CAA Leg. Hist. 905, Compiled November 1993).
[143] Environment and Natural Resources Policy Division of the Congressional Research Service of the Libra. *Legislative History of the Clean Air Act Amendments of 1990*, at 880 (1998).

document in interpreting how to apply the requirements of title V to area sources affected by EPA's proposed rule.

VIII. EPA FAILED TO ASSESS RELEVANT EXECUTIVE ORDERS AND NATIONAL STRATEGIES REGARDING THE PUBLIC HEALTH SUPPLY CHAIN.

The CAA requires that EPA consider the "non-air quality health . . . impacts" of emission standards promulgated under section 112.[144] The potential for an increase in infection and the resulting cascade of negative health impacts from inadequate quantities of sterilized equipment in the medical supply chain is undoubtedly a non-air quality health impact; EPA thus undoubtedly has a duty to evaluate it. And yet, in proposing new MACT and GACT requirements for commercial sterilization facilities that will apply to all facilities within the United States, EPA only briefly mentioned that the Agency had considered potential impacts on the medical supply chain.

It is intrinsic to a unified Executive Branch that EPA promulgate rules that advance or, at the very least, not hamper, an administration's overall policy priorities. These priorities are often articulated via executive order, and the Administration's core policy of shoring up the U.S. medical supply chain is no exception. The Executive Order on a Sustainable Public Health Supply Chain ("Supply Chain EO"),[145] for example, elucidates a range of actions agencies are to undertake to fortify that system.

Apart from the immediate actions that the Supply Chain EO required to address the coronavirus pandemic in 2021, this EO directed the creation of a strategy to provide for supply chain resilience.[146] Among other requirements, the analysis was designed to "ensure necessary redundancies" in the supply chain and required "contingency planning to ensure adequate preparedness for future pandemics and public health emergencies."[147] There is no evidence within the proposed rule or the administrative record that EPA has examined these issues either with respect to the form and stringency of the proposed standards nor with regard to the proposed timeframe in which new standards will apply to newly constructed and existing facilities.

[144] 42 U.S.C. § 7412(d)(2).
[145] EO 14001 (Jan. 21, 2021).
[146] *Id.* § 4.
[147] *Id.*

EPA additionally does not cite any evidence (and there is no evidence) that the Agency considered EO 14017 regarding America's Supply Chains.[148] This order required a comprehensive review of America's supply chains, including those related to "public health."[149] The Administration has stated in no uncertain terms that the supply chain and public health are inextricably intertwined; EPA thus has a duty to give particular consideration to this non-air quality health impact.

Finally, the National Strategy for a Resilient Public Health Supply Chain,[150] issued in accordance with EO 14001, noted that "[f]or many critical medical supplies, suppliers compete based on low costs and economies of scale—resulting in overseas production and foreign dependence for both raw materials and inputs . . . [including] PPE and drugs."[151] Among the goals included in the strategy are to "[b]uild a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability for future pandemics."[152] The report also emphasized that "[s]ourcing critical materials from just one location or supplier increases supply chain vulnerability should that supplier be impacted by an unforeseen emergency."[153] Again, there is no indication that EPA, as a federal agency tasked with the protection of public health, has either reviewed these assessments nor taken such considerations into account in proposing rules that will affect a critical link in the domestic medical supply system.

IX. CONCLUSION

Sterigenics has attempted, in the limited time allowed and considering the two overlapping but different rules, to provide complete comments. Sterigenics could have provided more fulsome comments if its request for an extension had been granted in full. We hope that these comments will serve as the basis for a fruitful discussion within the EPA and allow for the necessary adjustments identified above.

Sterigenics stands ready to answer any questions about these comments and to provide any additional information that may prove helpful to EPA and other federal agencies as they consider the proposed NESHAP.

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[148] EO 14017 (Feb. 24, 2021).
[149] *Id.* § 4.
[150] Dep't of Health & Human Servs., Admin. for Strategic Preparedness & Response, National Strategy for a Resilient Public Health Supply Chain (July 2021), *available at* https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.
[151] *Id.* at 25.
[152] *Id.* at 30.
[153] *Id.* at 31.