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February 21, 2025

VIA U.S. MAIL

Hon. Lee Zeldin
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Relief for Medical Device Manufacturers under Revised Commercial Sterilizer Ethylene Oxide NESHAP (40 CFR part 63, subpart O)

Dear Administrator Zeldin:

I am writing on behalf of a medical manufacturing device facility with an onsite sterilizer subject to the revised National Emission Standards for Hazardous Air Pollutants (NESHAP) for Commercial Sterilizers (40 CFR Part 63, Subpart O) published in the Federal Register on April 5, 2024. As described in more detail below, we respectfully petition the EPA to exercise its authority under the Clean Air Act to minimize the burden on manufacturing facilities covered by the rule and ensure the availability of sterilized medical devices necessary for patient care across the United States.

As you know, the revised Air Toxics Standards for Ethylene Oxide Commercial Sterilizers strengthened current standards and established new standards for previously unregulated emissions. Importantly, this rule requires the implementation of a permanent total enclosure (PTE) to capture all fugitive emissions, no matter how minimal, from handling sterilized material. As EPA acknowledged in its rulemaking, most facilities were not initially designed to implement PTE, which "will likely require redesign of a portion if not all" of these facilities to comply. Inevitably, many facilities will either need to cease or reduce operations to implement these upgrades.[1] These challenges are exacerbated for manufacturing facilities whose operations include sterilization because they have been set up to optimize efficient product flow.[2] While we fully support the goal of protecting public health and the environment, the current implementation timeline and lack of clarity around the exemption request process are causing a significant concern.

While certain requirements do not take effect until 2027, most existing facilities must comply by April 6, 2026, and demonstrate compliance one hundred and eighty days thereafter. Many impacted facilities, including those manufacturing medical devices, previously told EPA that this was insufficient time. Indeed, EPA's final rulemaking said that they "believe" facilities will be able to comply without "substantial" interruption if they commenced work *immediately* after the rule

[1] Proposed Rule at 22,853.
[2] Summary of EPA Response 4-48 to Comments.

became effective. For those working to implement this rule, it has become clear that EPA underestimated the potential disruption.

Knowing that the two-year implementation period may be insufficient, impacted facilities awaited further details referenced in the final rule regarding potential compliance exemptions. However, those details were not announced until January 2025 and only provided for a burdensome process that did not allow facilities to request an exemption until twelve months before their compliance deadline, which is likely too late. Although we are unaware of any official announcements regarding this memorandum, we assume it has either been rescinded or is no longer operative. To adequately plan their operations in the future, including whether onsite sterilization operations will need to cease or be relocated, clarification is required for applying for an exemption, the criteria for approval, and how long it will take to receive a decision.

Given the urgency, we respectfully ask the EPA to consider the following to ensure timely decisions to prevent any potential supply chain disruptions of sterilized medical products that could compromise patient care:

1. **Guidance for Non-Routine Sterilized Material Handling:** To reduce the burden on facilities covered by the rule whose primary purpose is to manufacture medical devices, issue interpretative guidance that handling of individual sterilized products outside the normal flow of material between sterilization and shipment for which representative area sampling is non-detect are presumed not to have fugitive emissions and therefore are not within the scope of the definition of Group 1 and Group 2 Air Emissions. This would eliminate the need to implement costly enclosures for areas of the facility, such as R&D or QA/QC, that do not handle sterilized materials in bulk and with no discernable reduction in emissions.
2. **Demonstration of Compliance**: Clarify that no facility will be held responsible for any aspect of the rule, even those for PTE, until after the 180-day relevant compliance period to demonstrate compliance under 40 CFR 63.7(a)(2).
3. **Alignment of Compliance Deadlines:** To avoid conflicting compliance deadlines, the EPA should interpret the revised NESHAP to allow facilities to comply with whichever applicable deadline is the longest. For instance, facilities using less than 10 tons per year of EtO should have an extra year to meet Group 2 and SCV requirements, aligning with the April 5, 2027, ARV, CEV, and Group 1 Air Emissions deadline.
4. **Temporary Pause on Implementation**: Issue a temporary pause on the implementation of the NESHAP (and commencement of the 180-day period to demonstrate compliance) until the exemption process is fully established and communicated to all affected facilities. EPA should also encourage delegated states to use their authority to extend compliance for one year to allow the EPA to develop a process for requesting and obtaining a compliance exemption under the Clean Air Act.
5. **Establishment of a Streamlined Compliance Exemption Process**: Provide detailed guidance as soon as possible for how facilities can apply for an exemption under the Clean Air Act, including the specific criteria for consideration and the timeline for decision-making. Given that the EPA already has voluminous information from most sterilization facilities through Section 114 Information Requests (and has toured many of them), EPA should be able to commit to notifying applicants of any exemption determinations within 30 days.
6. **Enforcement Discretion**: Use EPA's enforcement discretion to toll the compliance period while any exemption application is pending and not include any such period in the 180-day computation to demonstrate compliance. Any approvals should be retroactive to the

beginning of the compliance period, and enforcement discretion should be used for any facilities that may have applied for an exemption and were denied.

7. **Special Consideration for Low-Risk Operations:** In issuing guidance and implementing the process for obtaining exemptions, EPA should give special consideration to facilities with low or minimal EtO emissions, including those that use less than 10 TPY and have *de minimis* fugitive emissions.

These steps are necessary to balance reducing EtO emissions with maintaining the availability of life-saving medical devices. We look forward to your prompt attention and request a meeting at your earliest convenience to discuss a workable path forward.[3]

Sincerely,

H. Max Kelln

HK/

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[3] Alternatively, if the EPA interprets its inherent authority under the Clean Air Act to grant discretionary exemptions on a case-by-case basis without formally issuing any updated guidance, we can discuss the appropriate next steps for our clients that have expressed interest.

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