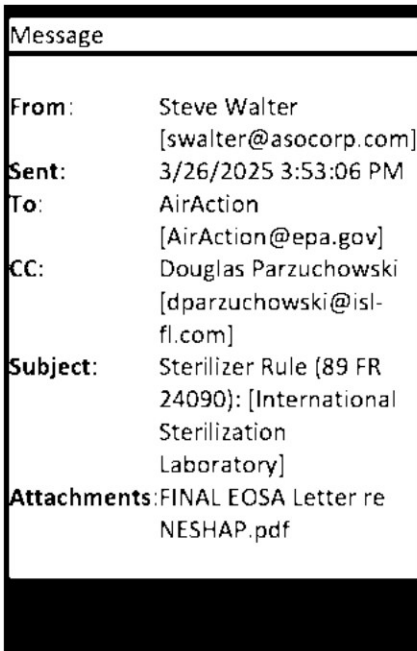




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To: airaction@epa.gov

Re: Sterilizer Rule (89 FR 24090): International Sterilization Laboratory

I write on behalf of [International Sterilization Laboratory] to request that the President issue a two-year exemption pursuant to his authority under CAA Section 112(i)(4) for all emission standards and associated requirements set or revised in EPA's April 4, 2024 *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 FR 24090 (April 5, 2024) (Sterilizer Rule).

International Sterilization Laboratory requests that the Presidential Exemption apply to the following facilities regulated by the Sterilizer Rule and all sources therein:

- International Sterilization Laboratory, 217 Sampey Road, Groveland, Florida, 34736

International Sterilization Laboratory requests that the President issue a two-year exemption as quickly as possible, but designate it as taking effect on the compliance deadlines for the standards in the Sterilizer Rule. Specifically:

- For standards set or revised under CAA Section 112(f) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 6, 2026 (the compliance deadline for those standards);
- For standards set or revised under CAA Section 112(d) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 5, 2027 (the compliance deadlines for those standards).

As explained further in the attached letter submitted to EPA on March 17 on behalf of the Ethylene Oxide Sterilization Association (EOSA), the technology necessary to implement the standards is not available because manufacturers cannot guarantee that existing emissions control equipment will enable sources to meet the new standards; there is not a sufficient supply of the necessary technology; and there are not enough experienced installation professional and technical experts to install and test that equipment within the current compliance timeframes.

As also explained further in EOSA's March 17 letter, it is in the national security interests of the United States to issue the requested exemption because if some facilities choose to cease operations rather than attempt compliance (which is likely), that will disrupt the supply of sterilized medical devices, raise the cost of those devices, and/or force medical suppliers or providers to source sterilized medical devices from abroad.

Please don't hesitate to let me know if any additional information is needed. [International Sterilization Laboratory] appreciates EPA's attention to this important matter and urges EPA to recommend that the President issue the requested exemption as quickly as possible.

Sincerely,

Steve Walter
Vice President
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International Sterilization Laboratory
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Email: swalter@ISL-FL.com

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