Request for Presidential Exemption:

National Emissions 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): DeRoyal Industries, Inc., 1135 and 1211 Highway 33 South (Two Facilities), New Tazewell, TN 37825

About DeRoyal Industries, Inc.: DeRoyal is a global medical device manufacturer headquartered in Powell, Tennessee, with over 50 years of experience serving the healthcare industry. The company offers a vast portfolio of products across several distinct markets, including surgical and safety devices, orthopedic bracing and supports, custom procedure trays, wound care products, and inventory management technologies. As one of the most vertically integrated companies in medical device manufacturing, DeRoyal has sterilized products for itself and others over the last 40 years.

Emissions standards or limitations subject to the request:

National Emissions 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)

Facility(ies) and/or affected source(s):

- 1135 Highway 33 South, New Tazewell, TN 37825
- 1211 Highway 33 South, New Tazewell, TN 37825

Length of compliance period being requested:

2 years

Why the technology to implement the standard is not available:

The U.S. Environmental Protection Agency ("EPA") published final amendments to its Sterilizer Rule in March 2024. The Sterilizer Rule sets forth extensive requirements for commercial sterilizers to reduce air emissions of ethylene oxide ("EtO"), install systems for continuous monitoring of air emissions, and report monitoring data to the agency.

The Sterilizer Rule includes stricter emissions control standards for chamber sterilization vents and aeration room vents and new standards for previously unregulated emissions sources such as chamber exhaust vents and "room air emissions," also known as fugitive emissions. The strictness of the rule's emissions control standards varies based on the volume of EtO used by a facility. For large volume sterilizers, the emissions control standards changed significantly:

- Sterilization chamber vent: continuously reduce EtO emissions by 99.99% *(previously 99% except during startup, shut down and malfunction)*
- Aeration room vent: continuously reduce EtO emissions by 99.9% *(previously 99% except during startup, shut down and malfunction)*
- Chamber exhaust vent: continuously reduce EtO emissions by 99.9% *(previously unregulated)*
- Room air emissions (Group 1 and Group 2 emissions): contain all room air emissions within a permanent total enclosure (per EPA Method 204) and continuously reduce EtO emissions by 98% *(previously unregulated)*

Notably, several rule changes were made to emissions standards with the publication of the final Sterilizer Rule that were not provided in the proposed rule for public comment.[1] An important example is the change from 99.94 percent emission reduction for sterilization chamber vents for ETO use of at least 40 tpy to 99.99 percent emission reduction. It remains unclear at this time that the technology available for purchase meets the stringent requirements of the final rule regarding emission limitations. There is significant concern that the available emission control equipment will consistently achieve 99.99% destruction removal efficiency. However, it is certain that these unannounced changes made at the finish line in the rule-making process moved the target that commercial sterilizers were pushing towards in their compliance plans.

The Sterilizer Rule also makes clear that emissions standards apply during startup, shutdown, and malfunction. This is a new requirement. The particular lack of exemption for a malfunction is extremely onerous. Indeed, other NESHAPs have implemented less stringent alternative emission limits or work practice standards during startup, shutdown and malfunction periods of operation. Malfunctions are neither predictable nor routine. Due to the nature of sterilization operations and various stages of sterilization cycles, commercial sterilizers must be able to address malfunctions that could result in a potential risk to the employees and/or facility without the risk of automatically being in noncompliance.

EPA's determination of 10 ppb as the lowest level at which current technology can measure EtO is based on the potential make-up of emissions streams and the "belief" that this is the lowest level that can be demonstrated and replicated across a wide range of emission profiles.[2] Emission profiles are dependent upon inlet and outlet concentrations making it difficult to establish a 99.99% destruction removal efficiency, especially at lower concentrations. It is still undetermined whether current technologies can reliably provide continuous emissions monitoring at these varying concentrations. Without technologies with efficacy to continuously measure the emissions standards to that level for all emissions profiles, compliance cannot be demonstrated with the emission limits set forth in the Sterilizer Rule. While the EPA has stated that it expects "EtO CEMS manufacturers, measurement companies, and laboratories will continue to improve EtO detection levels,"[3] it is unknown

[1] Sterilizer Rule, 89 FR 24123, April 5, 2024.
[2] *Id.*
[3] Sterilizer Rule, 89 FR 24108, April 5, 2024.

how long it may take EtO CEMS manufacturers, measurement companies, and laboratories to make and validate improvements. However, the industry is certain that more time is needed.

Ex. 4 CBI

DeRoyal appreciates that EPA changed the 18-month compliance period to 2 years in recognition of supply chain issues related to technology needs. Ex. 4 CBI

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Finally, it is this company's belief that all commercial sterilizers have undergone some element of redesign. This redesign (and any new design) has prolonged the supply chain backlog considering that there is one experienced engineering firm and one vendor for necessary control equipment.

Why an extension is in the national security interests of the United States:

Ethylene oxide sterilization is a method of sterilization that manufacturers widely use to keep medical devices safe. For many medical devices, sterilization with ethylene oxide is the only method that effectively sterilizes and does not damage the device during the sterilization process. Medical devices made from certain polymers (plastic or resin), metals, or glass, or that have multiple layers of packaging or hard-to-reach places are likely sterilized with ethylene oxide. Literature shows that about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide.[4]

[4] U.S. Food and Drug Administration, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#FC, accessed March 27, 2025.

According to the U.S. Cybersecurity & Infrastructure Security Agency ("CISA"), a program under the U.S. Department of Homeland Security, the national security of healthcare and public health serves to protect all critical infrastructure sectors of the U.S. economy from hazards such as terrorism, infectious disease outbreak and national disasters by providing continuity of operations and service delivery.[5] In other words, the healthcare and public health sector's ability to manage risk and respond to emergencies safely and effectively (whether at a national or everyday American level) is paramount to the security and well-being of this country.

As an illustration of the importance of sterilization to healthcare, the types of devices that are sterilized with ethylene oxide range from devices used in general health care practices (for example, wound dressings) to more specialized devices used to treat specific areas of the body (for example, stents) to personal protective equipment necessary for infection control (for example, surgical gloves and gowns). Without resilient supply of these types of sterile devices, safe and effective healthcare cannot be provided.

Turning to the Sterilizer Rule, EPA's last-minute rule changes to and short implementation of its Sterilizer Rule, combined with the technology concerns outlined above, places America's security and well-being in jeopardy by challenging the resiliency of the healthcare supply chain. As a result, commercial sterilizers, their equipment manufacturers and environmental engineers require more time to determine a path to compliance.

As discussed above, several rule changes were made to emission standards with the publication of the final rule that were not provided in the proposed rule for public comment. These changes made at the finish line in the rule-making process moved the target that commercial sterilizers were pushing towards in their compliance plans.

After moving compliance targets, and being well-informed during the comment period of the supply-chain concerns for engineering services and technology,[6] EPA issued a compliance period of only 2-years from publication of the final rule.

In addition, smaller commercial sterilizers are electing to close due to the requirements of the final rule. Further, any company that is unable to meet the compliance deadline will not be able to supply sterile medical devices from that date forward. Thus, when either of these situations occur, the capacity of commercial sterilization services in the U.S. is limited. This company is not aware of any additional sterilization capacity available to address these situations within the U.S. at this time. **If sterilization capacity is not available in the U.S., it will be unavoidable to obtain foreign-based services to maintain continuity of healthcare operations and services.**

[5] U.S. Cybersecurity & Infrastructure Security Agency, https://www.cisa.gov/topics/critical-infrastructure-security-and-resilience/critical-infrastructure-sectors/healthcare-and-public-health-sector, accessed March 27, 2025.
[6] Environmental Protection Agency, Summary of Public Comments and Response for Risk and Technology Review for Ethylene Oxide Commercial Sterilization Facilities, pp.334-359, February 2024.

Finally, the provision of additional time ties directly to national security concerns within the country's critical infrastructure related to healthcare safety and the availability of domestic manufacturing and processing of critical medical supplies.

In closing:

To make the emission standard changes as late as the publication of the final rule and to maintain a short compliance period has been detrimental to many commercial sterilizers.

Ex. 4 CBI

These elements of the Sterilizer Rule immediately placed commercial sterilizers behind pace and put the domestic supply chain of necessary sterile medical devices in jeopardy.

Respectfully Submitted,

Brian C. DeBusk
CEO & President
DeRoyal Industries, Inc.