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Environment, Land Use & Natural Resources ADVISORY

MARCH 21, 2024

EPA Finalizes Amendments to Air Toxics Standards for Ethylene Oxide Commercial Sterilizers

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On March 14, 2024, the U.S. Environmental Protection Agency (EPA) announced that it has finalized amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) (40 C.F.R. Part 63, Subpart O) for ethylene oxide (EtO) commercial sterilizers pursuant to Section 112 of the Clean Air Act (CAA).

Commercial sterilization facilities, or commercial sterilizers, use EtO to sterilize approximately 50% of the medical products and devices in the United States in accordance with procedures that are validated by the U.S. Food and Drug Administration. Commercial sterilizers operate under regulations and emissions standards of the EPA and state environmental agencies. Throughout the rulemaking process, the EPA highlighted the critical role that sterilizers that use EtO play in ensuring medical devices are properly sterilized across the nation, which, in turn, directly impacts community health and safety.

The EPA has been clear that the revised NESHAP is the first of several actions it plans to take concerning EtO. While this final rule does not address EtO emissions from alternate sources such as warehouses that store sterilized products, the EPA has stated that it intends to investigate emissions from such locations. The EPA has also stated its intent to address emissions from hospital sterilizers in a future rulemaking.

Emissions Control

The final EtO NESHAP amendments include 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. However, the strictness of the rule's emissions control standards varies based on the volume of EtO used by a facility. The final rule also makes clear that emissions standards apply during startup, shutdown, and malfunction.

The revised NESHAP's standards vary based on the size of the facility, the amount of EtO used, and the date of startup of the source. The least restrictive standards are for the smallest facilities that use the least EtO.

- Sterilization chamber vent: continuously reduce EtO emissions by 99–99.99%
- Aeration chamber vent: continuously reduce EtO emissions by 99–99.9%
- Chamber exhaust vent: continuously reduce EtO emissions by 99–99.9%
- Room air emissions: contain all room air emissions within a permanent total enclosure (per EPA Method 204) and continuously reduce EtO emissions by 80%–98%

Compliance

In the final rule, the EPA has estimated that the capital costs for compliance will exceed $313 million. In this final rule, the timeline for compliance runs from two years to three years (instead of the 18 months proposed in the EPA's 2023 initial proposed rule), depending on the amount of EtO used by the commercial sterilizer and depending on the specific regulatory requirement. Further, NESHAP permits any compliance deadline to be extended for one year.

The revised NESHAP also provides for alternative methods of compliance with the rule through combined emission streams. These alternative methods would allow a facility to demonstrate compliance through a mass emission limit that is determined by a standard for that component stream and the characteristics of the facility or through a sitewide emission limit. These alternative compliance methods would permit a facility to achieve compliance through a single emissions limitation instead of having to maintain compliance for each individual emission stream.

Reporting & Monitoring

The final rule has changed the way commercial sterilizers will certify their compliance with emissions control requirements. All commercial sterilizers must submit compliance reports, performance test reports, and performance evaluation reports electronically through the EPA's Central Data Exchange.

Additionally, commercial sterilizers that use 100 lbs or more of EtO per year must use continuous emission monitoring systems to demonstrate compliance with the updated emissions standards. Sterilizers that use less than 100 lbs of EtO may use either continuous emission monitoring systems or performance testing and parametric monitoring to demonstrate compliance.

One administrative relief provided by the final rule is that it does not require minor sources to become permitted under Title V.

The final rule also does not require fence line or ambient air monitoring. The EPA reasoned that this monitoring was unnecessary due to the rule's requirement that uncontrolled emissions be captured and routed through a control device, as well as the difficulty of implementing fence line and ambient monitoring technology.

Looking Forward

Compliance with the final NESHAP amendments will be a significant undertaking for commercial sterilizers. While the final rule provides a longer time than was initially proposed to comply, facilities should begin assessing their compliance obligations now. This includes determining the facility's applicable emissions limitations and options for compliance, including any available alternative compliance options. If compliance with the revised NESHAP will require technology such as a permanent total enclosure or continuous emissions monitoring, implementation of these measures will require permit amendments, facility retrofitting, and the installation and testing of new equipment.

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