Medical Design & OUTSOURCING

Understanding the EPA's final NESHAP ruling for commercial EtO sterilizers

An FTIR gas analysis expert offers a comprehensive overview of regulatory guidelines and the monitoring solutions available for long-term resiliency.

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For years, the Environmental Protection Agency has been looking for ways to regulate the use of ethylene oxide (EtO) — a difficult-to-measure gas that is widely used to sterilize medical devices and some food products — as it's been found to have carcinogenic properties.

In March 2024, the EPA made its final amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for EtO commercial sterilizers, which will require that facilities significantly reduce emissions, employ systems for continuous monitoring, and regularly report monitoring data to the agency. The goal is to achieve over 90% reduction in EtO emissions nationwide.

To comply with the EPA's NESHAP guidelines and mitigate disruption to the medical device supply chain, it's critically important for sterilizing facilities to thoroughly understand which emissions sources are being regulated, the applicable compliance standards and parameters for the size of facility and operational use of EtO, the variables in the timeline to come into compliance, the types of continuous emissions monitoring technologies available for long term resiliency, and the performance metrics as required by the NESHAP.

Required compliance at several emissions sources

The EPA's final rule requires owners and operators to use continuous monitoring to demonstrate compliance at several emissions sources: sterilization chamber vents (SCV), aeration room vents (ARV), chamber exhaust vents (CEV) and room air emissions. The SCV evacuates EtO following sterilization, fumigation, and any subsequent gas washes before the chamber door is opened, while the ARV evacuates EtO-laden air from the aeration room or chamber that is used to facilitate off-gassing of the sterile product.

Commercial sterilization facilities *provide a vital service for the American healthcare system, ensuring that there's a safe supply of medical devices for patients and hospitals.*
Photo by Peakstock via Stock.Adobe.com

Some facilities may need to introduce monitoring technologies at emissions sources that were previously unregulated, such as building leaks or room air emissions and at CEVs. Room air emissions include emissions resulting from indoor EtO storage, dispensing, vacuum pump operation, and pre- and post-aeration handling of sterilized material. Each source will require continuous emissions monitoring and quarterly reporting, including electronic reporting and technical revisions.

Commercial sterilizing facilities will also need to ensure compliance at each source during periods of startup, shutdown, or malfunction so there is continuous protection.

As required by the final ruling, commercial sterilizers must adopt technology that allows for real-time and continuous monitoring of EtO. The EPA also set standards for compliance based on facility size and operational use of EtO. Facilities that use more than 100 pounds of EtO per year must use a continuous emissions monitoring system (CEMS) to demonstrate compliance. Facilities that use less than 100 pounds of EtO per year will have the option to use CEMS or performance testing and parametric monitoring to demonstrate compliance.

Technologies required to demonstrate compliance

While the EPA's NESHAP requires that 10 parts per billion by volume (ppbv) be consistently demonstrated and replicated across a wide range of emissions profiles, there are cutting-edge analytical technologies that allow users to achieve single-digital ppbv detection limits. Owners and operators of the facilities will need CEMS to stay compliant.

Techniques such as gas chromatography (GC) have been used historically, but GC cannot achieve the sensitivity required by the updated NESHAP, and operating GC technology can be costly and often requires experienced workers to maintain the analyzer. Today, there are optically enhanced Fourier-transform infrared (OE-FTIR) spectroscopy solutions which can be engineered to meet the standards for EtO emissions testing at ultra-low detection limits, allowing both novice and experienced operators to get fast and accurate data. For commercial sterilizers who need to comply with the EPA's NESHAP, fully automated FTIR CEMS have provide reliable continuous emissions monitoring without calibrations.

While not explicitly required by the NEHSAP, facilities are encouraged to implement redundant backup monitoring systems, which are CEMS installed to be on standby in case the primary system can't provide reliable data. A CEMS with multi-channel sampling capabilities as the redundant system can be a cost-effective way to allow for future facility expansion and prepare for potential amendments to the NESHAP's downtime requirements.

Understanding performance metrics and compliance standards based on facility size and operational output

When choosing a CEMS, facilities should consider the performance metrics for CEMS devices, including level of detection (LOD), calibration drift and measurement error (ME). The EPA chose these metrics to meet the new Performance Specification 19 (PS-19) used to evaluate the acceptability of an EtO CEMS. A source that demonstrates its CEMS meeting the criteria of PS-19 may use the system to continuously monitor EtO under any regulation or permit that requires compliance with this specification. When choosing a CEMS technology, an owner or operator should ensure that it meets PS-19.

Emission standards vary depending on the source and quantity of EtO used, but all are based on percent emission reduction by the control device rather than the mass of EtO emitted. Existing and new sterilization chamber vents using at least 30 tons of EtO per year are required to demonstrate 99.99% percent emission reduction by the pollution control device. Most facilities will need to monitor at the inlet and outlet of their pollution control device to determine percent reduction. This is an important consideration when evaluating the suitability of an EtO CEMS because inlet concentrations are significantly higher than at the outlet, so the CEMS must be capable of analyzing EtO over a wide concentration range. Monitoring technologies like OE-FTIR are cost-effective because the same analyzer can be used to measure higher concentrations of EtO at the inlet and low ppb levels at the outlet.

Breaking down the timeline for compliance

The timeline for facilities to come into initial compliance has some variation. At a high level, facilities will have two to three years to comply and produce an initial validation report, but the steps to compliance are broken down by emissions source. Facilities should work with technology vendors for retrofits to their existing control devices, implementing new controls and procuring CEMS and other equipment needed according to the NESHAP. Any new facility designs will be required to meet EPA's current emissions standards. Once the initial compliance timeframe is completed, facilities will have an additional 180 days to demonstrate compliance with a validation report.

It's important to note that the EPA issued a separate proposed interim decision to reduce sterilization worker exposure to EtO under a federal pesticide control law, which is expected to be finalized in October 2024. This ruling may also impact facility design decisions.

Solutions for long-term resiliency

The EPA is constantly reviewing the evolving needs of industry and improving technologies and applications, conducting health and risk assessments of pollutants, and making amendments to proposed regulations. As owners and operators work to bring their facilities into compliance, they should consider solutions that will provide long-term resiliency for EtO monitoring. Innovative technologies such as OE-FTIR are highly effective for demonstrating compliance with EtO emission reduction standards, and installing redundant monitoring systems can be a cost-effective solution to mitigate future downtime with expansion or new regulations.

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