Technical note

Ethylene oxide (EtO) monitoring

What you need to know about EtO monitoring

Solutions for long-term resiliency following the EPA's final NESHAP ruling

The U.S. Environmental Protection Agency's (EPA) final National Emission Standards for Hazardous Air Pollutants (NESHAP) rule requires commercial sterilizers to demonstrate compliance by continuously monitoring their emissions at multiple emissions sources. Olivia Madamba, applications engineer, gas analysis solutions at Thermo Fisher Scientific, recently sat down with Ethan Spira, public policy and environmental science associate at AJW, Inc., to answer questions about the latest ruling and provide recommendations on what technology should be in place to achieve compliance.

Which emissions sources are regulated under the final ruling, and what are the differences between them?

Sterilization chamber vents, aeration room vents (ARV), chamber exhaust vents (CEV), and room air emissions are regulated by the final rule and must be monitored to prove compliance. It's important to note the differences between each of these sources:

- Sterilization chamber vents evacuate ethylene oxide from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes before the chamber door is opened.
- Aeration room vents evacuate ethylene oxide-laden air from the aeration room or chamber used to facilitate off-gassing of the sterile product and packaging.
- Chamber exhaust vents evacuate ethylene oxide-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes.
- Room air emissions include emissions resulting from indoor ethylene oxide storage, ethylene oxide dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material.

Some emissions sources were previously unregulated, such as room air emissions and chamber exhaust vents, so facilities will need to ensure that continuous emissions monitoring systems technology, also known as CEMS, are installed at each source point to demonstrate compliance. Facilities will also need to ensure compliance at each source during periods of startup, shutdown, or malfunction so there is continuous protection.

Are there parameters for facilities' sizes or operational use of ethylene oxide? How do I know which compliance standards are applicable to a facility?

There are parameters for compliance based on the facility's size or operational use of ethylene oxide. According to the ruling, all owners and operators of sterilization facilities must use a CEMS to demonstrate compliance, with few exceptions.

For facilities that use more than 100 pounds of ethylene oxide a year, the NESHAP ruling does not include an alternative to a CEMS for demonstrating compliance with emissions standards. However, facilities that use less than 100 pounds of ethylene oxide a year will still have the option to use CEMS or performance testing and parametric monitoring to demonstrate compliance.

The EPA outlined Level of Detection (LOD), calibration drift and Measurement Error (ME) as performance metrics—how can I evaluate the acceptability of a CEMS to demonstrate compliance?

The final NESHAP includes performance metrics for CEMS so that facility owners and operators can make an informed decision when looking to implement the new technology. These metrics include:

- Level of detection (LOD)—facilities may not use a CEMS whose LOD or standard addition detection level (SADL) is greater than 20 percent of the applicable regulatory limit or other action level for the intended use of the data.
- Calibration drift—the zero- and high-level calibration drift for the CEMS must not exceed 5.0 percent of the span value or an absolute difference of 10.0 parts per billion by volume (ppbv) for 7 consecutive operating days.
- Measurement error (ME)—the ME must be less than or equal to 5.0 percent of the span or an absolute difference of 10.0 ppbv at the low-, mid-, and high-level reference gas concentrations.

The EPA chose these metrics to meet its revised Performance Specification 19 (PS-19), which is used to evaluate the acceptability of an EtO CEMS. A source that demonstrates its CEMS can meet the criteria of PS-19 may use the system to monitor EtO under any regulation or permit that requires compliance with this specification. Additional performance metrics under PS-19 include relative accuracy, response time, interference response, and others.

How long do facilities have to meet compliance? Are there any variables or exceptions to the timeline?

According to the NESHAP, facilities have two to three years to come into initial compliance and produce a validation report, but each emissions source has a slightly different timeline. The EPA lays out a series of steps that should be completed within the initial timeframe:

Step 1

Secure vendors for retrofits, control devices, CEMS, and any other equipment and services needed to comply with the NESHAP.

Step 2

Partner with a vendor to work on:

- Any new facility or control system designs that will be required for compliance.
- A schedule to ensure timely compliance with the NESHAP.
- Purchasing the necessary equipment for each emissions source, along with a CEMS.

Step 3

Submit a permit application to the relevant permitting authority.

Step 4

Complete the necessary facility retrofits, control device installations, and CEMS installations.

Step 5

Test the control and facility air handling systems to ensure the NESHAP is being met.

After the initial compliance period, facilities will have an additional 180 days until continuous compliance is mandatory.

According to the final NESHAP, facilities need to have 99.9% destruction efficiency of ethylene oxide. What solutions are currently available to improve emissions control, abatement systems, and monitoring methods?

As required by the final ruling, commercial sterilizers must adopt technology that allows for real time and continuous monitoring of ethylene oxide. The NESHAP requires that a limit of detection of 10 ppbv be consistently demonstrated and replicated across a wide range of emissions profiles. Owners and operators need to confirm the facility's current level of emissions at each source and ensure that their emissions control and abatement systems are accurately measuring the levels of ethylene oxide in the air. Installing a CEMS can help facilities audit abatement efforts and understand what improvements are needed to comply with the NESHAP.

What types of CEMS technology can be implemented to demonstrate compliance with the emissions standards?

While techniques such as gas chromatography (GC) can be used to monitor emissions, the process—especially with the EPA's requirement of regular reporting to confirm compliance—can be time-consuming, costly, and requires specialists to acquire the data. Innovative technologies, such as optically enhanced Fourier transform infrared spectroscopy (OE-FTIR), are proven to be highly effective for monitoring both the ultra-low levels of EtO at the outlet of abatement devices and the high-level concentrations present at the inlet. The dynamic calibration range of the OE-FTIR allows these measurements to be performed sequentially without the need for dilution of the high EtO concentrations. This saves the facility both time and consumables such as ultra-high purity nitrogen. FTIR CEMS can be fully automated, allowing users of all experience levels to collect reliable data and remain in compliance.

While the EPA acknowledges that ethylene oxide CEMS is a relatively new requirement in this industry, CEMS has been accepted as a highly effective method for demonstrating compliance with emissions standards. OE-FTIR CEMS offers a ready solution to empower the users to monitor the destruction removal efficiency of EtO across an abatement device.

The EPA previously set standards for commercial sterilizers in 2006, and we know that the agency is constantly reviewing the evolving needs and impact on industry. What solutions are available to ensure long-term resiliency?

The EPA is constantly reviewing the evolving needs of industry, improving technologies and applications, health and risk assessments of air pollutants, and regulations proposed or enacted by other rulemaking bodies. Consequently, we anticipate the EPA will continue evaluating the impacts of ethylene oxide and exploring methods of measurement and monitoring to reduce ethylene oxide emissions.

To ensure long-term resiliency, facilities should consider implementing redundant backup monitoring systems, which are CEMS installed to be on standby in case the primary system is unable to provide the data required to maintain compliance. Redundant systems can be a cost-effective and future-proof solution for ensuring that facilities can remain in compliance in the event of amendments to the current guidelines or facility expansions. By implementing redundant systems during the initial retrofit, facilities will prevent downtime and lags in data.

What are the next steps I can take to ensure compliance going forward?

Facility owners and operators should connect with technology vendors as soon as possible to ensure that they are working within the allotted timeline for compliance. As a consultive partner, Thermo Fisher Scientific will work with you to find solutions that meet the current and future needs of your facility.

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