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Accelerating Science: Identifying Threats blog

Meeting New Regulations for EtO Emissions: A Comprehensive Trace Gas Monitoring Solution

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[Ethylene oxide](#) (EtO) is a colorless, odorless compound commonly used to sterilize medical products, or as a reaction intermediate in the production of ethylene glycol. While EtO is essential to produce medical devices ranging from catheters to artificial heart valves, studies show that it also has carcinogenic and mutagenic properties, which could pose long-term health risks to people working in sterilization facilities, as well as surrounding communities. In fact, the Environmental Protection Agency (EPA) has proposed new, more rigorous regulations to reduce exposure to EtO, following the recent publication of the agency's IRIS assessment – entitled [Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide](#) – and recent investigations of current sterilization procedures. If finalized, these policies will require commercial sterilizers to implement real-time continuous emissions monitoring methods to confirm that their pollution controls are working. But what are the implications of these regulations for the sterilization industry?

Delving into the details of the proposed air emissions standards

The proposed new emissions standards will affect the 86 commercial sterilizers operating in the USA currently – in addition to any new start-up companies that rely on EtO – by enforcing the installation of new pollution controls and technologies. The aim of the regulations is to decrease the release of EtO from these facilities by about 80 percent, in turn reducing exposure risks for nearby communities to levels below the [Clean Air Act](#) benchmark for elevated cancer risk. Sterilization companies will also be

required to carry out real-time monitoring of EtO, using advanced technologies that can accurately measure concentrations at or below 10 parts per billion (ppb). Data will need to be collected and reported to the EPA twice per year, enabling the agency to regularly assess the effectiveness of the proposed mitigation measures. In facilities with EtO levels surpassing 10 ppb, additional safety measures will need to be put in place to enhance staff safety levels, such as enforcing personal protective equipment (PPE) use.

The public comment period for the proposed standards recently closed, and further steps will be required before they are finalized, but the proposal specifies that commercial sterilization facilities will only have 18 months to comply with the new requirements once they are established. It is therefore important for companies to understand how best to fulfil these regulations, so that they are prepared for any potential changes they will need to make.

The difficulty of monitoring ultra-low EtO levels

[Emissions monitoring](#) is not a new concept; EtO source measurements gained a lot of interest after the results of a 2014 National Air Toxics Assessment (NATA) were published by the EPA in 2018. Historically, examining EtO levels required the collection of a sample in the field, followed by off-line analysis in a laboratory. However, detection of EtO has proved challenging for a number of reasons:

- EtO is difficult to trap and concentrate due to its low boiling point;
- the compound is highly reactive, posing a challenge for sample collection and transport;
- low levels of EtO are difficult to detect using techniques like mass spectrometry and gas chromatography, as interfering species with identical molecular weights – such as CO₂, propane and acetaldehyde – may appear in the sample matrix;
- scrubber systems at sterilization facilities may use aqueous acids to convert EtO to ethylene glycol, a less volatile compound. However, any residual acid mists present in a sample can interfere with analysis.

As a result, meeting the new requirements for real-time EtO monitoring can seem like a daunting task, and requires an analytical technology optimized for real-time, direct EtO measurements.

Meeting the challenge of compliance with OE-FTIR

Fortunately, analytical techniques used to detect hazardous air pollutants are evolving to become increasingly sensitive, cost-effective and easy to use. New technologies based on optically enhanced [Fourier transform infrared \(OE-FTIR\) spectroscopy](#) allow precise detection of EtO at very low concentrations to meet the detection limits in the EPA's proposed rules. There are also [Continuous Emissions Monitoring Systems](#) (CEMS) and [Ambient Air Monitoring Systems](#) that can identify and quantify low-level EtO leaks with a detection limit of 1 ppb, exceeding US EPA standards.

Navigating government regulations with confidence

Meeting changing EtO regulations may seem like an impossible task but, with the right tools and support, the transition becomes manageable. State-of-the-art solutions that can detect gaseous EtO with precision -- and technologies that aid sterilization companies in compliance navigation can help to ensure continued smooth operations for the medical sterilization industry, while offering long-term protection for workers and communities alike.

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