EPA UPDATES RULES FOR COMMERCIAL STERILIZERS' USE OF ETHYLENE OXIDE

The U.S. Environmental Protection Agency (EPA) recently issued two decisions regarding the use of ethylene oxide (EtO) by commercial sterilizers.

EtO has long been used to sterilize medical devices and surgical instruments, playing a critical role in preventing infections. Its effectiveness stems from its ability to penetrate packaging, allowing multiple devices to be sterilized simultaneously – an advantage over methods like radiation, which typically require time-consuming individual treatment.

Despite its utility, however, EtO poses significant health risks. Workers in commercial sterilization facilities must be protected from potential exposure, and nearby communities may face elevated risks, too.

EPA Updates

In response to these concerns, the EPA has released updated decisions aimed at improving safety and reducing EtO emissions:

Indoor Concerns

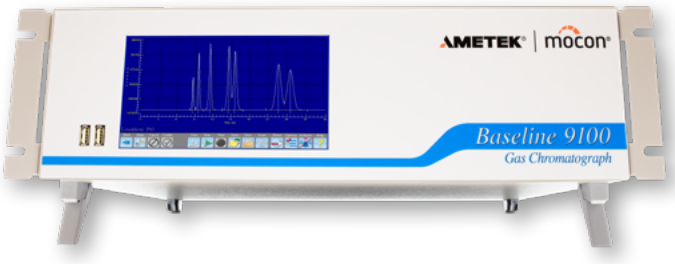
The EPA regulates the use of EtO as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, the EPA has released an interim decision that:

- ***Lowered the worker exposure limit of 0.5 parts per million (ppm) by 2028, 0.25 ppm by 2030, and 0.1 ppm (100 parts per billion) by 2035.***
- Declared that any workers who might be exposed to concentrations of EtO above those limits would need to wear additional respiratory protection.
- Established a concentration limit of 600 mg/L for new medical device sterilization cycles within the next decade.

Explore the complete list of rules and regulations.

AMETEK MOCON Solution

For decades, the AMETEK MOCON BASELINE® Model 9100 Ethylene Oxide (EtO) Gas Chromatograph (GC) (see Fig. 1) has supported commercial sterilizers in protecting their workers by accurately monitoring EtO concentrations throughout their facilities. When EtO levels exceed safe thresholds, the system triggers alarms to alert personnel. With long-term data, additional safety measures can be taken, such as implementing the use of personal protective equipment when necessary.



(Fig. 1) BASELINE® 9100 EtO Gas Chromatograph

KEEP WORKERS SAFE
THROUGHOUT THE ENTIRE FACILITY

Equipped with our unique High-Sensitivity Photoionization Detector (HS-PID), the Model 9100 offers a detection limit as low as 1-2 parts per billion (ppb) – well below the exposure levels established in the EPA's recent decisions. When integrated with the Model 9150 Multipoint Sampler, the Model 9100 EtO GC enables monitoring of multiple areas within a sterilization facility (see Fig. 2). EtO concentration data and alarm status are easily transmitted to facility monitoring systems, ensuring accurate documentation and regulatory compliance.

(Fig. 2) Sample Sterilization Facility

Outdoor Concerns

The EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) was recently updated to address EtO emissions from commercial sterilization facilities. The new ruling sets stricter limits on the total amount of EtO that can be released and recommends safe concentration levels in surrounding areas. These regulations are designed to better protect public health – particularly in communities near sterilization facilities – by reducing exposure to EtO, a known carcinogen.

This ruling includes:

- A recommendation for gas monitoring down to 10 ppb EtO, providing an alarm below this level.
- Commercial sterilizers must report EtO emissions to the EPA.

Conclusion

While the new EPA rulings specifically address commercial sterilizers, other EtO users – such as smaller sterilization operations and laboratories – may also benefit from adopting these guidelines as best practices for safety. AMETEK MOCON remains committed to supporting organizations in monitoring EtO levels and maintaining safe, compliant work environments.

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