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Small Sterilization Companies Poised To Meet EtO Emissions Goals On Time

Alternate perspectives on the EPA's rule.

by Hannah Daniel

Small sterilizers told *Medtech Insight* that they were ready for the EPA's controversial EtO emissions rule, while community advocates expressed concerns.

Small ethylene oxide sterilizers say that the supply chain concerns touted by some medtech advocates who opposed the US Environmental Protection Agency's new guidelines on use of EtO don't apply to all device sterilizers.

There are only 86 commercial facilities that sterilize medical devices in the US, and most of them are independent companies with a single facility.

Medtech Insight spoke to Brant Gard, managing member at Blue Line Sterilization Services, about his company's reaction to the rule — which was generally positive.

Blue Line Sterilization Services is the first EtO contract sterilizer in the US, Gard explained, adding that the Novato, CA-based facility provides device sterilization with quick turnarounds for small product loads.

Gard said that he "really has no concerns" about complying with the rule moving forward.

"We are well underneath the lowest tier in terms of use of ethylene oxide," he said, noting that Blue Line's bi-annual testing shows that the firm's exhaust scrubbing is 99.99% effective, a "factor of ten [times]

EPA Final Rule Limits Use Of Ethylene Oxide

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more efficient than required" for a facility of its usage.

The company was concerned about earlier provisions in the rule about EtO gas concentration limits, but those were ultimately removed from the final rule. Gard said that compliance with those provisions would have been a major disruption to the small operation, which only employs eight people.

By Elizabeth Orr

14 Mar 2024
The rule, which requires most device sterilization plants to track and report their EtO emissions, will go into effect in two years for the largest plants and three years for the smallest.

Read the full article here

Gard said that they did not get to pass on these concerns to the EPA during the comment period, because Blue Line Sterilization doesn't have the kind of "regulatory bandwidth" to do so, no matter how much it might have wanted to.

Another sterilization company, *Baxter Healthcare Corp.*, has one facility in Mountain Home, AR. In a statement, the company told *Medtech Insight* that it expects to "meet the applicable requirements and timeline" of the rule.

Baxter's work on reducing EtO emissions began before the rule, the company explained.

"Baxter is deeply committed to the health and safety of our employees, patients, and communities," the statement said.

Irvine, CA-based Applied Medical Resources Corporation, also said that complying with the new standards won't be a problem. It praised the EPA's rule in a statement to *Medtech Insight*.

"Our advanced sterilization facility is currently compliant with EPA and [South Coast Air Quality Management District]emissions standards and we have plans in place to comply with the new standards," said Zoran Falkenstein, group president for Applied Medical.

"We constructed our sterilization facility from the ground up with the most advanced technologies to support this critical process and put the well-being of our team and our communities at the forefront," Falkenstein added.

Applied Medical also does not expect any supply interruption.

All of these companies have single, one-off operations. Larger sterilization companies may have different perspectives on the regulatory burdens that come with the new rule.

For instance, Sterigenics, owned by Sotera Health, has seven facilities in the US and Puerto Rico, STERIS Isomedix Services also has seven and Becton Dickinson (BD) has three.

Sterigenics recently reached a $408m settlement with people living near its Willowbrook, IL, facility, who claim that the facility caused abnormal rates of cancer. The EPA has identified EtO as a health risk, and long-term exposure causes *higher risk of cancer*. (Also see "*Sterigenics Reaches $408m Settlement In EtO Lawsuit*" - Medtech Insight, 11 Jan, 2023.)

A full list of *commercial EtO sterilization facilities* in America can be found on the EPA's website.

Community Advocates Disappointed With Timelines

Medtech Insight spoke to Darya Minovi, a senior analyst for the Center for Science and Democracy at the Union for Concerned Scientists. UCS has been following the issue of EtO for years. In 2023, it published a report on the communities disproportionately affected by harmful EtO emissions. (Also see "*The People Living In The Shadow Of EtO Facilities*" - Medtech Insight, 1 Mar, 2023.)

She said UCS was pleased with many of the pieces of the draft rule that made it into the final, such as the requirement for continuous stack emissions monitoring, but added that from a community perspective, the delayed compliance timelines from the EPA are "disappointing."

The original proposal gave sterilizers 18 months to comply with the emission reduction requirements, which are predicted to cut emissions by over 90% and dramatically reduce the risk of cancer from EtO emissions. (Also see "*EPA Final Rule Limits Use Of Ethylene Oxide*" - Medtech Insight, 14 Mar, 2024.)

At the time of the draft, medtech advocates argued that this was not enough time to comply, and would impact the supply chain, decreasing medical device sterilization capacity by upwards of 50%. (Also see "*Harmonizing EPA And Industry Needs: EtO Emissions*" - Medtech Insight, 5 Jul, 2023.)

The final rule increased the compliance time by at least six months, giving sterilizers two to three years to comply based on EtO usage.

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> *people in hospitals," Minovi said. "It's very deeply ironic in a troubling way."*

Medical device trade groups such as AdvaMed and the Medical Device Manufacturers Association (MDMA) advocated for longer timeframes during the rule's comment periods. For example, AdvaMed explained in its comments that all sterilization facilities are different, and that a "one-size-fits-all" approach wouldn't work for the industry.

In the first few months after the rule, it's still unclear how the rule will affect the supply chain. While the industry digests the rule, AdvaMed president and CEO Scott Whitaker said that the trade group "remain[s] hopeful that these changes will not have a negative impact on the healthcare system or the patients we serve."

Minovi is skeptical about many of the supply chain arguments for delaying implementation timelines.

"Sterilization companies of course have known about the risk of ethylene oxide for many, many years. It wasn't like this is new information to them," Minovi said.

She mentioned the sterilization innovation challenges launched by the FDA, which were launched back in 2019. These challenges were meant to incentivize alternatives to EtO sterilization for medical devices. (Also see "*Got A Better Idea? US FDA Seeks Help Tackling Ethylene Oxide Troubles*" - Medtech Insight, 16 Jul, 2019.)

The FDA has also been holding sterilization town halls to promote its innovation challenges, alternate sterilization methods, and streamlined pathways for submissions for sterilization changes. (Also see "*FDA Looking To Streamline Sterilization Submissions Through Bundling, PCCPs*" - Medtech Insight, 10 Mar, 2024.)

"There are three broad areas we have emphasized throughout the rulemaking: adequate time to implement, flexibility in technologies to remove emissions, and the ability to achieve EPA targets that would not force resubmission of medical devices for FDA approval," Whitaker said in a statement.

But community advocates remain concerned.

"I understand the notion of not wanting to interrupt the entire medical supply chain, and that

these devices are lifesaving in many cases, but that also ignores the fact that this substance is putting people in hospitals," Minovi said. "It's very deeply ironic in a troubling way."