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National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review

March 20, 2024

Key Takeaways

On March 14, 2024, the United States Environmental Protection Agency (EPA) issued a Final Rule to revise the Commercial Sterilization Facilities National Emission Standards for Hazardous Air Pollutants (NESHAP)[1], as related to ethylene oxide (EtO). Additional information about the Final Rule, including an EPA fact sheet and video presentation is also available.

In the Final Rule, EPA amended current standards and established new standards for previously unregulated sources (e.g., room air emissions, chamber exhaust vents) within the Commercial Sterilization Facility (CSF) source category. In addition, EPA finalized both risk-based standards to protect public health and emissions standards based on the EPA's review of practices, processes, and control technologies for the CSF source category. Several changes provided in the Final Rule are based on EPA's authority under the Clean Air Act (CAA).[2]

In the Final Rule, there are several key changes from the Proposed Rule; some of which reflect Vizient's recommendations on the Proposed Rule's need to ensure medical device supply chains will not be disrupted. EPA provides that many of these modifications were provided to avoid any impact to the integrity of the medical device supply chain, while ensuring the standards reduce communities' cancer risk. EPA makes clear that it "does not anticipate that the implementation of these standards will have any adverse impacts on the medical supply chain." Additional information regarding the anticipated effects of the Final Rule are available in the Final Rule's Regulatory Impact Analysis.

While the regulations in the Final Rule are effective immediately upon publication in the Federal Register, timelines to comply generally range from two to three years and EPA has provided that CSFs will have an additional 180 days to demonstrate compliance and additional extensions may be available.[3]

Major Proposals Finalized & Key Changes from the Proposed Rule

In the Final Rule, EPA finalized as proposed a definition for "affected source" as previous regulations did not include a definition of this term. For sterilization chamber vents (SCVs), aeration room vents (ARVs), and chamber exhaust vents (CEVs), the "affected source" definition is the individual vent. For Group 1 and Group 2 room air emissions, the "affected source" definition is the collection of all room air emissions for each group at any sterilization facility.[4]

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[1] 40 CFR part 63, subpart O
[2] Section 112 of the Clean Air Act
[3] The Clean Air Act provides that under certain standards (i.e., those established under section 112(d)), facilities can apply for a 1-yr extension. The 1-year extension is not available for standards issued under section 112(f)to reduce risk. In addition, if more time is needed to comply with any standard, as noted in the CAA, then the President may exempt any source from compliance under certain circumstances (e.g., technology to implement requirements are not available and that it is in the national security interest of the United States).
[4]Group 1 room air emissions are defined as emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material. Group 2 room air emissions are defined as emissions from post-aeration handling of sterilized material.

Due to concerns regarding the medical supply chain, EPA revised the proposed standards for new and existing CEVs at major source facilities and EPA re-calculated the maximum achievable control technology (MACT) floor based on the percent emission reduction, as opposed to mass emissions rates. Table 1 of the Final Rule (pg. 15-16) includes the standards finalized based on the emission source (i.e., SCV, ARV, CEV at major source facilities, CEVs at area source facilities, Group 1 air emissions at major sources, Group 1 air emissions at area sources, Group 2 room air emissions at major sources, and Group 2 air emissions at area sources).[5]

Due to other monitoring and reporting requirements,[6] EPA did not finalize a requirement for area source facilities subject to this regulation to obtain a title V permit from the authority in which the source is located.

Other changes EPA finalized include capture requirements for CSFs to demonstrate compliance with the emissions limits and a requirement that CSFs (except small users) monitor with an EtO continuous emissions monitoring system (CEMS). Also, under the Final Rule, CSFs are subject to emission standards during periods of startup, shutdown, and malfunction. In addition, EPA finalized an alternative compliance approached for combined emissions streams to increase the ease and efficiency of complying with the Final Rule.

Compliance Timeline

EPA had initially proposed an 18-month compliance deadline for all the proposed standards for existing sources. In the Final Rule, EPA has extended this timeline and provided variable deadlines based on a CSF's EtO use. Table A provides additional information regarding compliance timelines.

Table A. Summary of Compliance Timeframes Based on Facility EtO Use

Facility EtO Use	Compliance Timeframe*	Number of Facilities
Over 60 tons per year	2 years	28
1-60 tons per year	2-3 years	39
Less than 1 ton per year	3 years	21

* Facilities will have an additional 180 days to demonstrate compliance. Also, the Clean Air Act provides that under certain standards (i.e., those established under section 112(d)), facilities can apply for a 1-yr extension. The 1- year extension is not available for standards issued under section 112(f)to reduce risk
Source: https://www.epa.gov/system/files/documents/2024-03/factsheet_etosterilizers_final_3-14-24.pdf

In addition, EPA reiterates a provision from the CAA, which indicates that if more time is needed to comply with any standard in the Final Rule, then "[t]he President may exempt any stationary source from compliance with any standard or limitation under this section for a period of not more than 2 years if the President determines that the technology to implement such standard is not available and that it is in the national security interests of the United States to do so. An exemption under this paragraph may be extended for 1 or more additional periods, each period not to exceed 2 years. The President shall report to Congress with respect to each exemption (or extension thereof) made under this paragraph." Also, the Final Rule notes that in states with delegated authority to implement and enforce the CSF NESHAP may grant an existing source an additional year to comply with certain CAA standards,[7] if such additional period is necessary for the installation of controls.

[5] Information regarding proposed emission standards is available in the Final Rule (pgs. 53-54)
[6] In the final rule, to demonstrate compliance EPA promulgated the following requirements: Quarterly reporting of EtO CEMS data; Minimum data availability of 90 percent for EtO CEMS; and Use of either outlet volumetric flow rate monitors or differential pressure monitors to demonstrate continuous compliance with EPA Method 204/
[7] CAA Section 112(d) standards

Regulatory Impact

In the Final Rule and in a separate Regulatory Impact Analysis (RIA), EPA provides additional information regarding the anticipated impact of the Final Rule. Table B summarizes costs associated with the Final Rule. Table 3-4 of the RIA (pg. 47) provides more detailed, additional information regarding engineering costs and the number of facilities affected by emissions point or cost component across regulatory options. In the RIA, EPA indicates that "sterilization is generally a small input when considering the total costs of making and providing medical devices and healthcare services." Additional information regarding the Market Impacts of the Final Rule is available in the RIA (pg. 80).

Table B. Total Capital Investment and Total Annual Cost (2021$)

Requirement	Number of facilities with costs associated with new requirements	Total Capital Investment	Total Annual Cost
Permanent Total Enclosure	28	$77,500,000	$8,280,000
Additional Control Devices	83	$187,000,000	$43,000,000
Monitoring and Testing	89	$48,100,000	$19,400,000
Recordkeeping and Reporting	90*	--	$2,600,0002^
Total	90*	$313,000,000	$74,000,000

Source: Final Rule (pg. 18)
*This includes the 88 facilities that are currently operating, as well as two planned facilities that are expected to start operating within the next few years.
^This includes $763,000 of one-time annual costs for reading the rule and developing record systems.

Also, regarding potential supply disruptions, EPA provides, "[w]hile higher costs of sterilization may not present significant problems for medical device manufacturers, limited capacity in the EtO sterilization industry could still potentially disrupt the medical device supply chain if there are not enough sterilization providers available to accommodate the quantity of devices that need to be sterilized with EtO." Also, while comments made in response to the proposed rule indicated that individual facilities may need to reduce capacity in the short run to install controls or adjust their operations to the requirements, EPA indicates the additional flexibilities in the Final Rule are intended to minimize the potential for impacts on the availability of medical devices. For example, the elongated compliance deadlines, according to EPA, will provide affected facilities the opportunity to stagger timing of their upgrades to reduce potential for medical device shortage.

What's Next?

While the Final Rule will be effective once published in the Federal Register, CSFs have variable compliance dates and there are opportunities for additional flexibilities regarding compliance to be provided. Affected CSFs will need to determine their compliance options. Hospital sterilizers are regulated under a different NESHAP, which is not addressed in the Final Rule, however, EPA has indicated it will address hospital sterilizers in future rulemaking. Also, later this year, EPA is expected to finalize and interim decision for registration of EtO as a pesticide which could impact other measures needed to protect workers and neighboring communities from the risks of EtO exposure.

Please reach out to Jenna Stern, Associate Vice President, Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.