



Final Sterilizer Rule Overview – 2024

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RGISC's Legal Success

- EPA was required to update the sterilizer rule in 2014
 - EPA failed to meet this legal requirement
- In 2022, RGISC, along with a coalition of environmental groups, sued EPA over its failure to update the sterilizer rule.
 - In 2023, RGISC settled the case.
 - RGISC put EPA on a deadline to revise the sterilizer rule by March 1, 2024.



Old Sterilizer Regulation

- Had not been updated since 1994
- Assumed that emissions only came from three sources: Sterilization Chamber Vents, Chamber Exhaust Vents, and Aeration Room Vents
- No controls for fugitive emissions
- (See [this video](#) for industry overview of current practices at sterilizer facilities – Note lack of controls for fugitives and opening of doors to chambers)



Old Sterilizer Regulation

	Sterilization Chamber Vent (SCV)	Aeration Room Vent (ARV)	Chamber Exhaust Vent (CEV)
Facilities using 10 tons or more of EtO	99% emission reduction	1 part per million max outlet concentration or 99% emission reduction	No control
Sources using 1 ton or more of EtO, but less than 10 tons of EtO	99% emission reduction	No control	No control
Sources using less than 1 ton of EtO	No control required; minimum record keeping	No control required; minimum record keeping	No control required; minimum record keeping



New Sterilizer Regulation Sterilization Chamber Vents

Emission Source	EtO Use	Standards
Sterilization Chamber Vents	At least 30 tons per year (tpy)	99.99% emission reduction*
	At least 10 tpy but less than 30 tpy	99.9% emission reduction
	At least 10 tpy	99.9% emission reduction
	At least 1 but less than 10 tpy	99.8% emission reduction
	Less than 1 tpy	99% emission reduction

*A 100x reduction in emissions



New Sterilizer Regulation Chamber Exhaust Vents

Emission Source	EtO Use	Standards
Chamber Exhaust Vents (Area Sources)	At least 400 tpy	99.9% emission reduction
	At least 60 but less than 400 tpy	99.9% emission reduction
	Less than 60 tpy	99% emission reduction

- These emissions were previously uncontrolled



New Sterilizer Regulation

Aeration Room Vents

Emission Source	EtO Use	Standards
Aeration Room Vents	At least 30 tons per year (tpy)	99.9% emission reduction*
	At least 10 tpy but less than 30 tpy	99.6% emission reduction
	At least 10 tpy	99.6% emission reduction
	At least 1 but less than 10 tpy	99% emission reduction
	Less than 1 tpy	99% emission reduction

*A 10x reduction in EtO emissions



New Sterilizer Regulation: Fugitive Room Emissions

Emission Source	EtO Use	Standards
Group 1 room air emissions (i.e., pre-sterilization fugitives) at area sources	At least 40 tpy	98% emission reduction
	Less than 40 tpy	80% percent emission reduction
Group 2 room air emissions (i.e., post-sterilization storage) at area sources	At least 20 tpy	98% emission reduction
	At least 4 but less than 20 tpy	80% emission reduction
	Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber be opened

- These emissions were previously uncontrolled




New Sterilizer Rule: Compliance


- All facilities (except for those using less than 100 pounds of EtO) must use Continuous Emissions Monitoring Systems (CEMS)
 - Must record hourly averages of EtO concentration used
 - Must record weight differential in pounds of EtO used
 - Must provide notice to EPA directly when CEMS fails
- All facilities must install a permanent-total enclosure system to control EtO emissions



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