



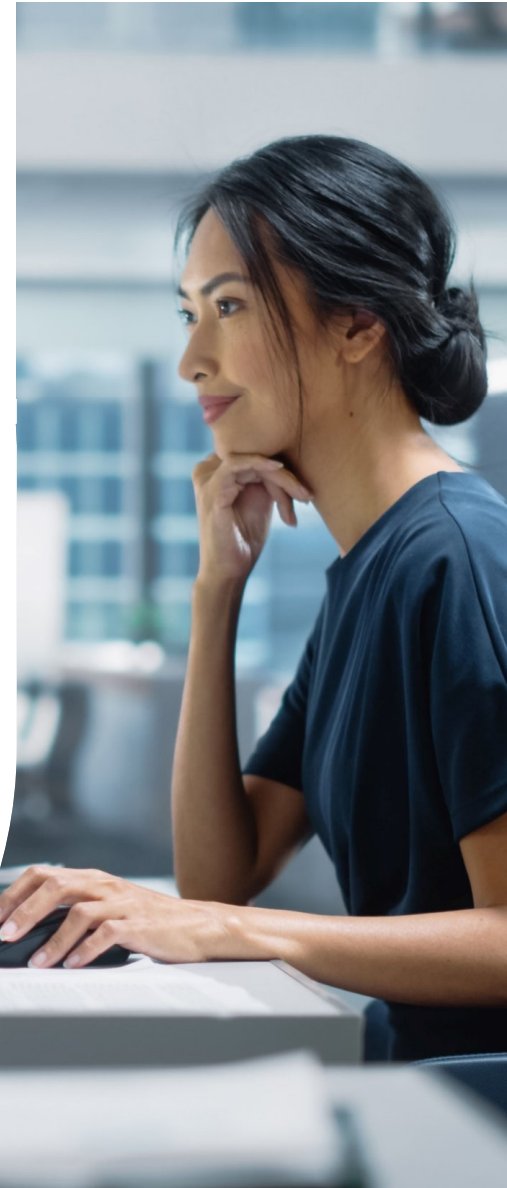
Celebrating **50** Years  
1974-2024

# Quirks of the New NESHAP Subpart O Regulations

Picarro EtO Conference

Amy Moore, Managing Consultant

October 29, 2024



# Content

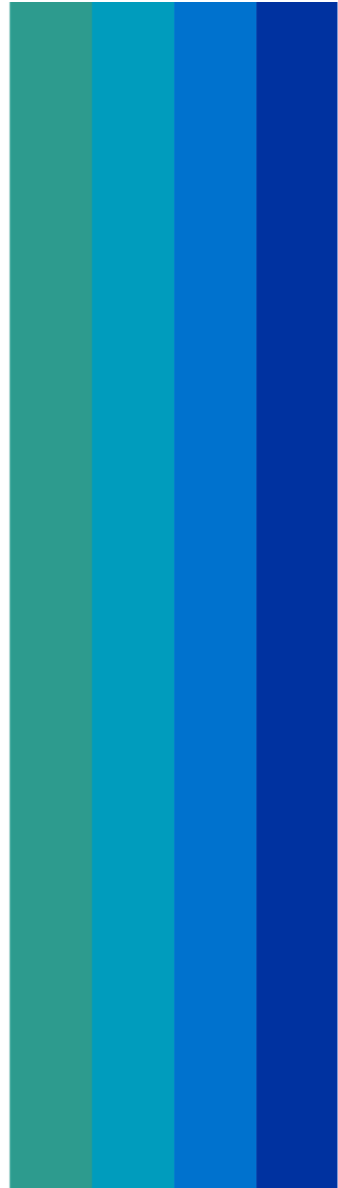
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01

# Introduction



## Panelist profile

# Amy Moore

## Managing Consultant | Trinity Consultants

Amy has a BS in Chemical Engineering from the University of Arkansas and has been with Trinity since 2014. Her focus areas include air permitting and compliance, hazardous waste compliance, oil pollution prevention planning, stormwater and wastewater permitting and compliance, and chemical reporting. She is based in Little Rock but works from the Rogers, AR satellite office. She is fond of writing, hiking, interior design, and talking about herself in the third person.



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# Trinity Consultants

## Company Information

### How We Started

Started in 1974 by **one consultant** in Dallas, Texas serving clients' **air quality** regulatory compliance needs.

### Who We Are

Today, we are **over 2,000 employees** in more than **85 locations** on **four continents**.

### What We Do

We help organizations overcome complex, mission-critical **EHS, engineering, and science** challenges through **consulting, technology, training, and staffing** support.



# Trinity Consultants

## Office Locations



### Europe

England, UK / Dublin, IE



### Asia

China / Singapore / India



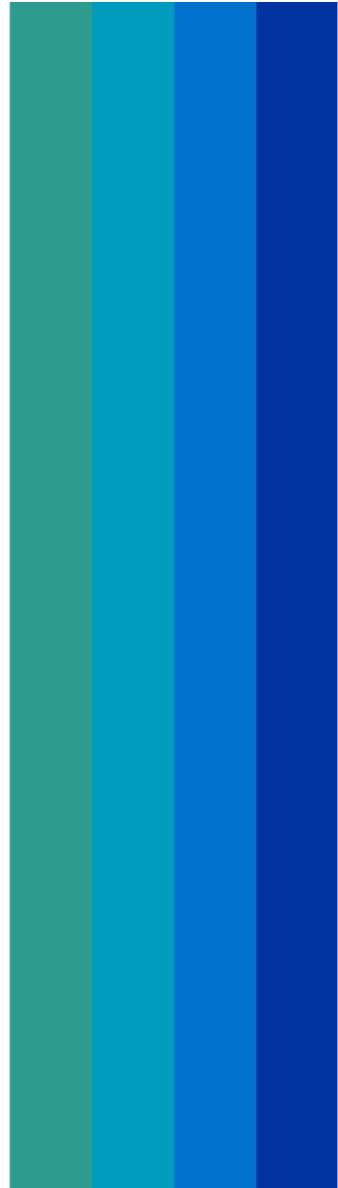
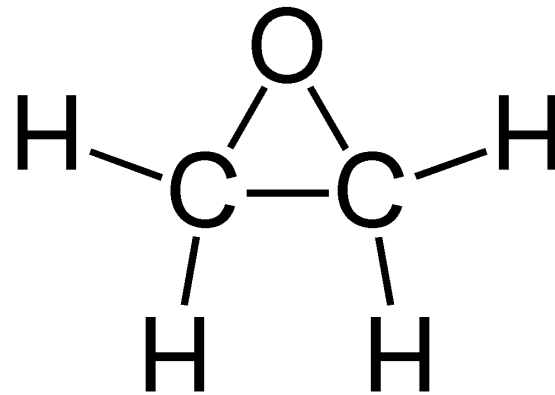
### Australia

Queensland / New South Wales



02

# Historical Subpart O





# 1994 Proposed Subpart O Rule

## Proposed Rule – 3/7/1994

The proposed rule aimed for a capital cost effectiveness of roughly \$10,000/ton to \$20,000/ton of EtO controlled.

Proposed Rules		Federal Register
		Vol. 59, No. 44
		Monday, March 7, 1994
<p>This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.</p>	<p><i>Public Hearing.</i> If anyone contacts the EPA requesting a public hearing, it will be held at the EPA Office of Administration Auditorium in Research Triangle Park, North Carolina. Persons interested in requesting a hearing, verifying that a hearing will be held, or wishing to present oral testimony should contact Ms. Lina Hanzely, Chemicals and Petroleum Branch (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5673 by the dates specified above.</p> <p><i>Background Information Document.</i> The background information document (BID) for the proposed standards may be obtained from the U.S. Department of Commerce, National Technical Information Service (NTIS), Springfield, Virginia 22161, telephone number (703) 487-4650. Please refer to "Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations—Background Information for Proposed</p>	<p>U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For information concerning the health effects of EO, contact Dr. Nancy Pate at (919) 541-5347, Pollutant Assessment Branch, Emission Standards Division (MD-13) at the above address.</p> <p><b>SUPPLEMENTARY INFORMATION:</b> The information presented in this preamble is organized as follows:</p> <ul style="list-style-type: none"><li>I. List of Categories and Subcategories.</li><li>II. Background.</li><li>III. NESHAP Decision Process.<ul style="list-style-type: none"><li>A. Source of Authority for NESHAP Development.</li><li>B. Criteria for Development of NESHAP.</li><li>C. Maximum Achievable Control Technology Floor Determination and Process of Developing Regulations for Major and Area Sources.</li></ul></li><li>IV. Summary of Proposed Standards.<ul style="list-style-type: none"><li>A. Source Categories to be Regulated.</li><li>B. Pollutant to be Regulated.</li><li>C. Affected Emission Points.</li><li>D. Format of the Standards.</li><li>E. Proposed Standards.</li></ul></li></ul>
<p><b>ENVIRONMENTAL PROTECTION AGENCY</b></p> <p>40 CFR Part 63</p> <p>[AD-FRL-4845-7]</p> <p>RIN 2060-AC28</p> <p><b>National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations</b></p> <p>AGENCY: Environmental Protection Agency (EPA).</p> <p>ACTION: Proposed rule and notice of public hearing.</p>		



# Originally Promulgated Rule Highlights

Promulgated Rule – 12/6/1994

## 01 Economic Impacts

The rule estimated nationwide annualized costs for existing commercial EO sterilization facilities of about \$6.6 million beyond baseline.

Total estimated cost to comply with the rule for a large facility was \$600,000.

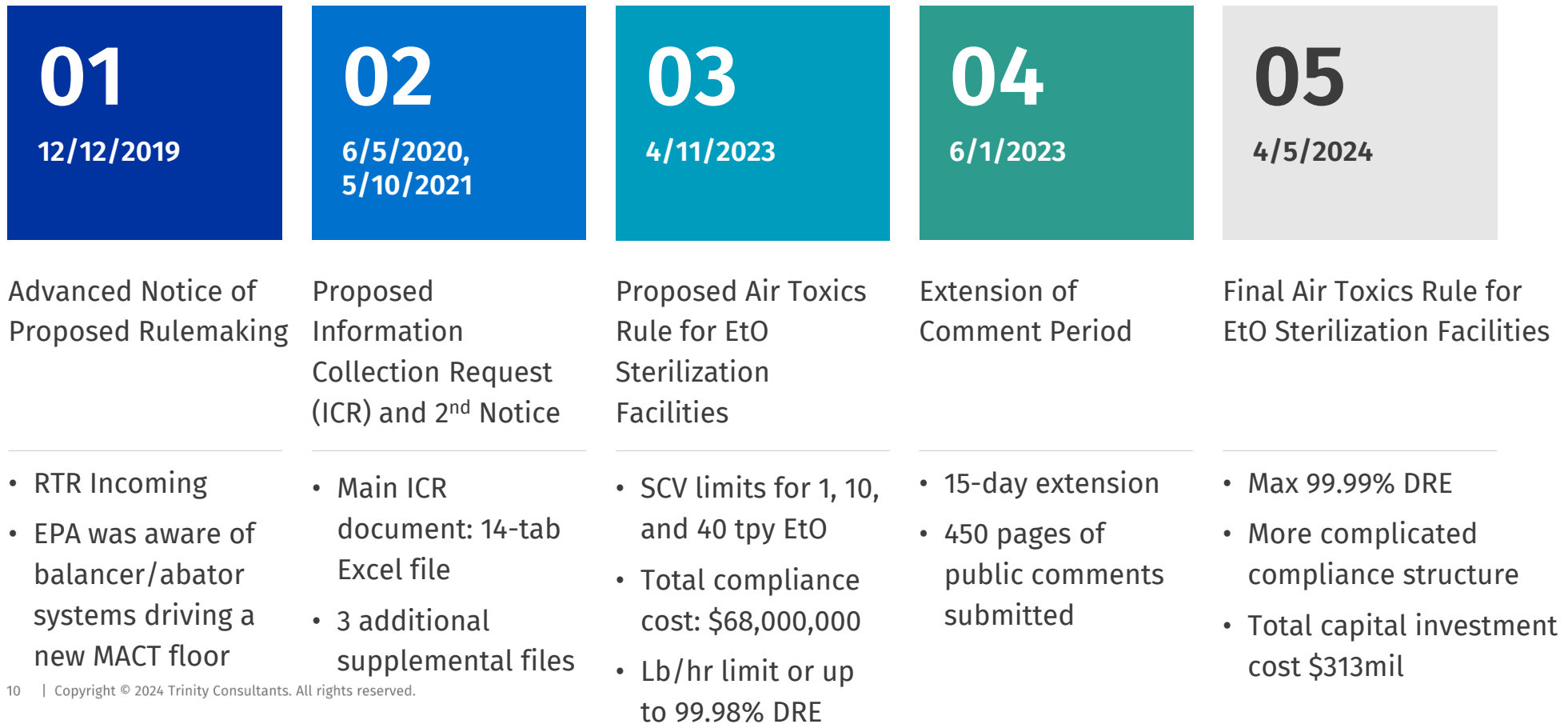
## 02 Emission Standards

< 1 ton EtO: no controls required.

1 – 10 tons EtO: 99% emissions reduction for sterilization chamber vents (SCV), no aeration room vent (ARV) controls required, 5300 ppmv max concentration for chamber exhaust vent (CEV) emissions.

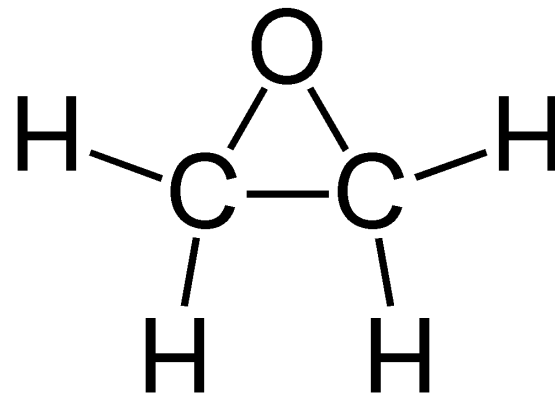
>10 tons EtO: 99% SCV emissions reduction, 99% ARV or 1 ppm outlet, 99% CEV emissions reduction.

# RTR and Rule Update Timeline



04

# Compliance Options



# Small Entity Compliance Guide

<https://www.epa.gov/system/files/documents/2024-04/secg.pdf>

Emissions reductions options based on:

## 01

### What Source

- Sterilization Chamber Vent (SCV)
- Aeration Room Vent (ARV)
- Chamber Exhaust Vent (CEV)
- Group 1 Emissions
- Group 2 Emissions

## 02

### How Much EtO Used

- SCV: 1 tpy, 10-30,  $\geq 30$
- ARV: <10 tpy, 10-30,  $\geq 30$
- CEV: <60 tpy,  $\geq 60$
- Group 1: <40 tpy,  $\geq 40$
- Group 2: <4 tpy, 4-20,  $\geq 20$

## 03

### Source Installation

- Existing Sources
- New Sources

## 04

### Source Type

- Area Source (<10 tpy single HAP, <25 tpy combination HAP)
- Major Source ( $\geq 10$  tpy single HAP,  $\geq 25$  tpy combination HAP)

# Small Entity Compliance Guide

<https://www.epa.gov/system/files/documents/2024-04/secg.pdf>

**Table 1. Summary of Standards for Commercial Sterilization Facilities**

Emission source	Existing or new?	EtO use	Standards
SCV	Existing and new	At least 30 tpy	99.99% emission reduction <sup>1</sup>
		At least 10 tpy but less than 30 tpy	99.9% emission reduction <sup>1</sup>
		At least 1 but less than 10 tpy	99.8% emission reduction <sup>1</sup>
		Less than 1 tpy	99% emission reduction <sup>2</sup>
ARV	Existing	At least 30 tpy	99.9% emission reduction <sup>1</sup>
		At least 10 tpy but less than 30 tpy	99.6% emission reduction <sup>1</sup>
		Less than 10 tpy	99% emission reduction <sup>2</sup>
	New	At least 10 tpy	99.9% emission reduction <sup>1</sup>
		Less than 10 tpy	99% emission reduction <sup>2</sup>
CEVs at major source facilities	Existing and new	N/A	99.94% emission reduction
CEVs at area source facilities	Existing and new	At least 60 tpy	99.9% emission reduction <sup>1</sup>
		Less than 60 tpy	99% emission reduction <sup>2</sup>
Group 1 room air emissions at major sources	Existing and new	N/A	97% emission reduction <sup>3</sup>
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98% emission reduction <sup>1,3</sup>
		Less than 40 tpy	80% emission reduction <sup>2,3</sup>

Emission source	Existing or new?	EtO use	Standards
Group 2 room air emissions at major sources	Existing and new	N/A	86% emission reduction <sup>3</sup>
Group 2 room air emissions at area sources	Existing	At least 20 tpy	98% emission reduction <sup>1,3</sup>
		At least 4 but less than 20 tpy	80% emission reduction <sup>1,3</sup>
	New	Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened <sup>2,4</sup>
		At least 20 tpy	98% emission reduction <sup>1,3</sup>
		Less than 20 tpy	80% emission reduction <sup>2,3</sup>

# Compliance Demonstration Options

40 CFR 63.362/363, Subpart O Tables 1-5

## 01

### **Emissions Reduction - Individual Streams**

Each set of SCV, ARV, CEV, Group 1 and Group 2 must be continuously monitored as an individual emissions stream using a CEMS.

## 02

### **Tiny Sources**

Performance testing on a per-year or triennial schedule for sources that use less than 100 lb/yr.

## 03

### **Combined Streams or Sitewide Limit**

Depending on the approach these are based on either EtO usage or on measured EtO inlet emissions to the control device and the most stringent applicable limit.

*Equation 1 to paragraph (i)(2)(i)*

$$CES_{Combined} = M_{30day} * (1 - Max(ER)) \quad (Eq. 1)$$

## How to Demonstrate Compliance

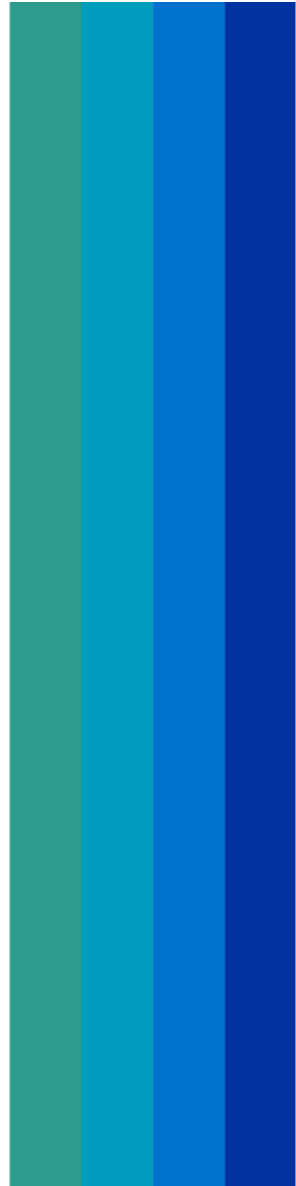
# CES-1

### Combined Emission Streams.

This option is available after all emission streams are combined prior to the control device. This option is very similar to the SWEL-1 approach.

Unlike SWEL-1, you are required to use a CEMS to measure the combined EtO inlet to the control device versus calculating the EtO usage and apply the most stringent DRE.

An example of this would be a facility with a single control device feeding all SCV, ARV, CEV, Groups 1 & 2 streams to the control.





Equation 2 to paragraph (i)(2)(i)

$$CES_{Streams} = \sum_{i=1}^n (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^m (M_{c,j} * (1 - ER_j)) \quad (\text{Eq. 2})$$

## How to Demonstrate Compliance

# CES-2

### Combined Emission Streams by Source Type.

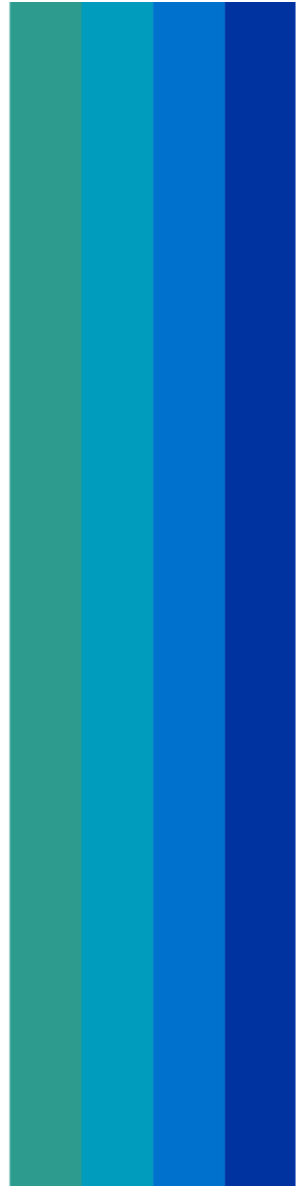
This is a refinement of the CES-1 approach by placing a CEMS monitor at the inlet of each non-SCV source type to apply lower DREs to streams.

Each non-SCV emissions type must be segregated. All sources (CEV, ARV, Group 1, Group 2) would require separate CEMS monitoring systems prior to those streams combining with any other stream. If not possible, most stringent DRE for the combination would be used. For example, Group 1 with CEV would require 99.9. SCV inlet is a calculated value based on EtO feed.

You must use a CEMS to measure the inlet emissions to the control device.

Pro: allows facilities to utilize lower DREs where applicable.

Con: much higher cost in exhaust/facility design and in CEMS installation.



*Equation 3 to paragraph (j)(1)(i)*

$$SWEL_{Fac} = M_{Fac} * 0.99 * (1 - ER_{scv}) \quad (\text{Eq. 3})$$

## How to Demonstrate Compliance

# SWEL-1

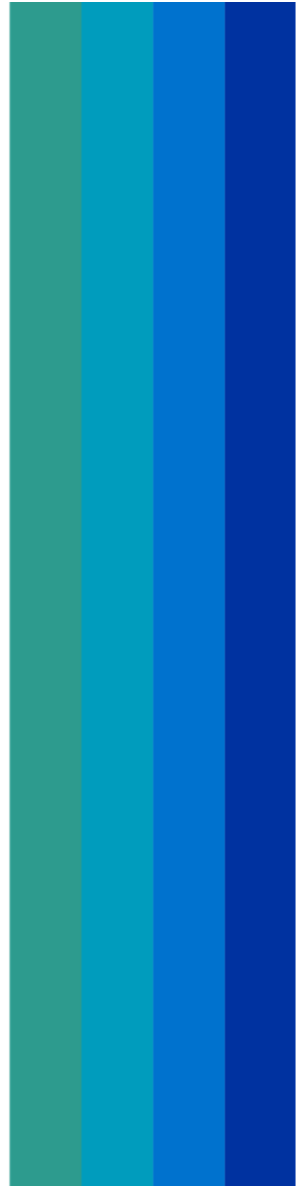
### **Sitewide Emission Limit based on total EtO usage.**

This is the simplest approach.

Emission limit = 30-day mass charge of EtO \* 0.99 (assumes 1% loss in product) \* (1-DRE) where the DRE is the most stringent (for most facilities this will be 99.99% or 0.9999.)

Measure the mass of EtO used to the nearest 0.1 lb. If your EtO from SDS, etc. is not 100%, this mass is multiplied/adjusted by the wt% EtO of the gas.

For SWEL-1, you know your EtO wt%, you know the corresponding 30-day charge and you know the DRE to use.



Equation 5 to paragraph (j)(2)(i)

$$SWEL_{Streams} = \sum_{i=1}^n (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^m (M_{c,j} * (1 - ER_j)) \quad (\text{Eq. 5})$$

## How to Demonstrate Compliance

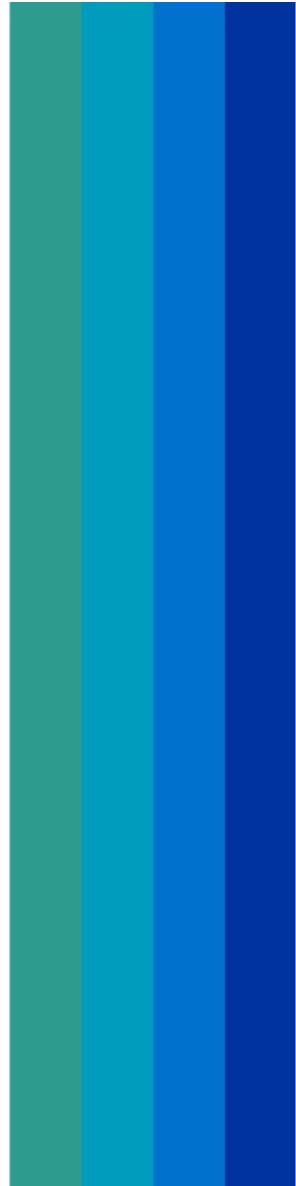
# SWEL-2

### Sitewide Emission Limit Based on Individual Streams.

This option calculates the sitewide limit based on measured SCV feed CEMS for the inlet of all non-SCV sources.

Thus, you have to have a CEMS monitor at each non-sterilization vent inlet prior to combining with any other stream (CEV, ARV, Group 1, Group 2). Otherwise, non-SCV combined stream subject to most stringent DRE of stream components.

The SCV portion is similar to SWEL-1 in that it uses a correction factor, essentially 0.99, and the mass fed to the sterilizers as discussed above.



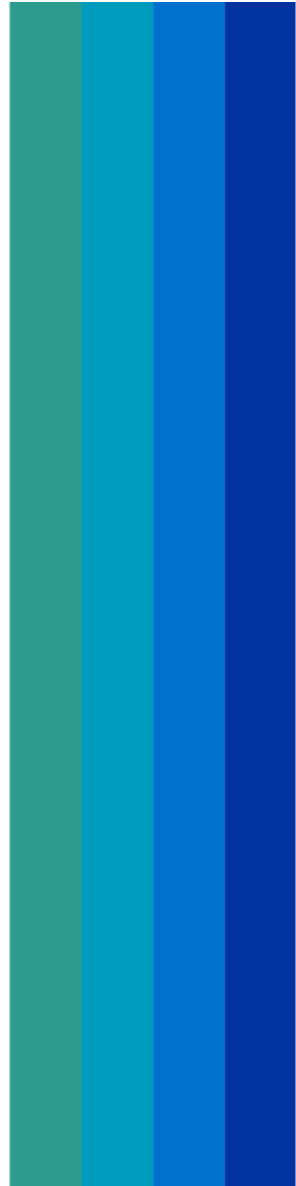
Things to Remember...

# Compliance Quirks

**The only time SCV CEMS inlet used is CES-1. All other options are based on EtO usage.**

**For CES-2, SWEL-1, SWEL-2 some form of EtO feed is used and based on 30-day usage recorded to nearest 0.1 lb.**

**CES-2 and SWEL-2 require inlet CEMS for all non-SCV streams.**



# Compliance Demonstration Timeline

40 CFR 63.360(j)

## 01

### What Source

- Sterilization Chamber Vent (SCV)
- Aeration Room Vent (ARV)
- Chamber Exhaust Vent (CEV)
- Group 1 Emissions
- Group 2 Emissions

## 02

### Facility Type

- Existing (constructed before April 13, 2023)
- New (construction commenced after April 13, 2023)

## 03

### How Much EtO Used – Existing ONLY

- SCV: <1 tpy, ≥1
- ARV: <10 tpy, ≥10
- Area Source CEV: <60 tpy, ≥60
- Area Source Group 1: <40 tpy, ≥40
- Area Source Group 2: <4 tpy, ≥4

## When to Demonstrate Compliance

Emission source	Existing or new?	EtO use	Submit Initial Notification of Applicability by...	Demonstrate Compliance with Emission Standards by...	Submit Notification of Compliance Status by...
SCV	Existing	At least 1 tpy	August 5, 2024.	October 5, 2026	December 7, 2026
		Less than 1 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A <sup>3</sup>	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
ARV	Existing	At least 10 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 10 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
CEVs at major source facilities	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
CEVs at area source facilities	Existing	At least 60 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 60 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 1 room air	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.

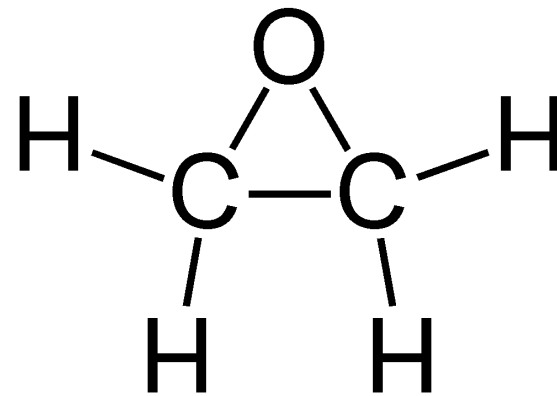
## When to Demonstrate Compliance

Emission source	Existing or new?	EtO use	Submit Initial Notification of Applicability by...	Demonstrate Compliance with Emission Standards by...	Submit Notification of Compliance Status by...
emissions at major sources	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 1 room air emissions at area sources	Existing	At least 40 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 40 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 2 room air emissions at major sources	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 2 room air emissions at area sources	Existing	At least 4 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 4 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.



05

# Regulatory Mindfulness



# Small Entity Compliance Guide

<https://www.epa.gov/system/files/documents/2024-04/secg.pdf>

**Table 1. Summary of Standards for Commercial Sterilization Facilities**

Emission source	Existing or new?	EtO use	Standards	Emission source	Existing or new?	EtO use	Standards
SCV	Existing and new	At least 30 tpy	99.99% emission reduction <sup>1</sup>	Group 2 room air emissions at major sources	Existing and new	N/A	86% emission reduction <sup>3</sup>
		At least 10 tpy but less than 30 tpy	99.9% emission reduction <sup>1</sup>			At least 20 tpy	98% emission reduction <sup>1,3</sup>
		At least 1 but less than 10 tpy	99.8% emission reduction <sup>1</sup>	Group 2 room air emissions at area sources	Existing	At least 4 but less than 20 tpy	80% emission reduction <sup>1,3</sup>
		Less than 1 tpy	99% emission reduction <sup>2</sup>			Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened <sup>2,4</sup>
ARV	Existing	At least 30 tpy	99.9% emission reduction <sup>1</sup>	New	At least 20 tpy	98% emission reduction <sup>1,3</sup>	
		At least 10 tpy but less than 30 tpy	99.6% emission reduction <sup>1</sup>		Less than 20 tpy	80% emission reduction <sup>2,3</sup>	
		Less than 10 tpy	99% emission reduction <sup>2</sup>				
	New	At least 10 tpy	99.9% emission reduction <sup>1</sup>				
		Less than 10 tpy	99% emission reduction <sup>2</sup>				
CEVs at major source facilities	Existing and new	N/A	99.94% emission reduction				
CEVs at area source facilities	Existing and new	At least 60 tpy	99.9% emission reduction <sup>1</sup>				
		Less than 60 tpy	99% emission reduction <sup>2</sup>				
Group 1 room air emissions at major sources	Existing and new	N/A	97% emission reduction <sup>3</sup>				
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98% emission reduction <sup>1,3</sup>				
		Less than 40 tpy	80% emission reduction <sup>2,3</sup>				

# Small Entity Compliance Guide

<https://www.epa.gov/system/files/documents/2024-04/secg.pdf>

**1 For existing sources, the standard applies if a facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025. The standard also applies if a facility with previous EtO use below the specified amount has subsequently increased its EtO use to the specified EtO use range for a consecutive 12-month period after April 7, 2025.**

**2 For existing sources, the standard applies if a facility has used less than the specified EtO use within all consecutive 12-month periods after April 7, 2026.**

**3 To ensure compliance with the emission limit, we are requiring each facility to operate sources with these emissions in accordance with the permanent total enclosure (PTE) requirements of EPA Method 204 of appendix M to 40 CFR part 51.**

**4 Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).**



# Tiny Sources

For facilities with EtO usage of less than 100 lb/yr:

## **Non-Area Sources or Area Sources without PTE**

Annual inlet/outlet performance testing  
(Method 1, 2A/2B/2C, 3A/3B, 4, 320 or  
ASTM D6348-12)

Track EtO usage

Monitor control device parameters

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## **Area Sources with Group 2 PTE**

As above, except:

Monitor differential pressure for PTE

Triennial inlet/outlet performance  
testing

# Initial Compliance Demonstration

## 01 – Compliance Demonstration Method and Deadline

Performance Specification 19 – within 180 days after the applicable compliance date

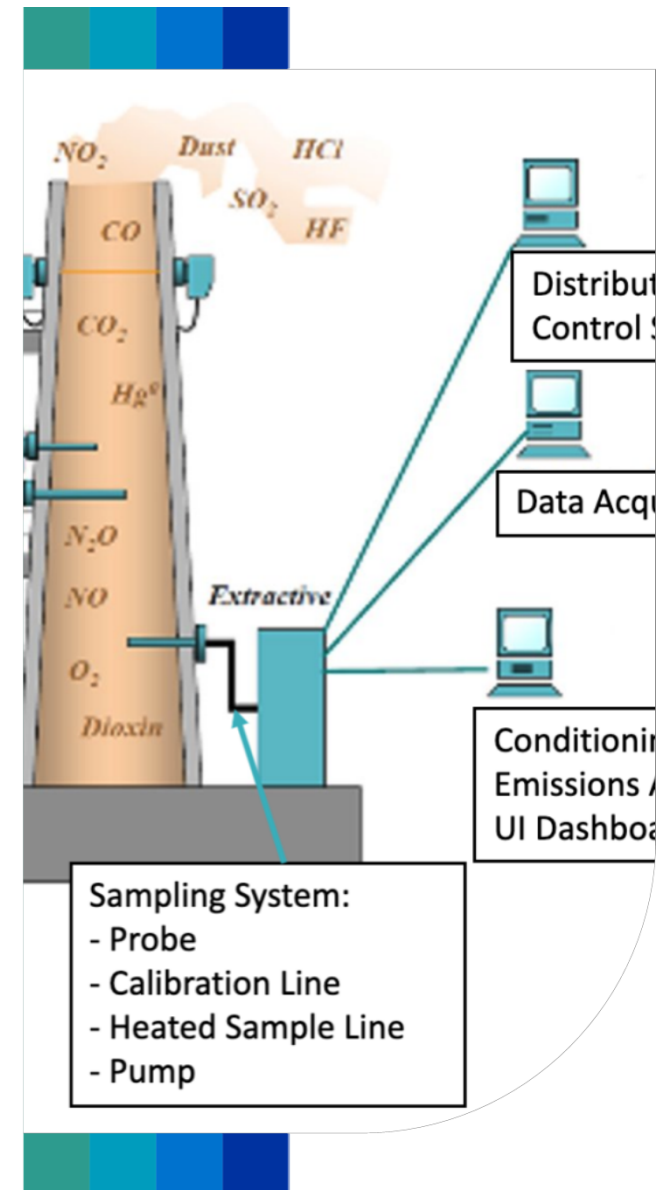
## 02 – Initial Performance Test

The first 30 operating days after the PS-19 certification per Appendix A of the subpart.

## 03 – Quirks

You are allowed to time-share the CEMS as long as:

- The CEMS is approx. equidistant from the measurement points;
- The sampling time is 3 times CEMS response time;
- The CEMS completes at least one cycle for all measurements within 15 minutes; and
- PS-19 requirements are met.



# Ongoing Compliance - CEMS

Where monitoring requirements come home to roost...

## 01

**Install and configure the unit – single-stack or common stack.**

**Remember that SCV EtO usage may be weighed on 3 of 4 compliance options.**

## 02

**Quirk: If you have control devices working in parallel with multiple stacks, you have to determine hourly flow-weighted average pollutant emission rates.**

## 03

**Quirk: If room air emissions are subject to an emissions standard and split between two or more controls, you have to monitor before the emissions are combined with other streams.**

# Ongoing Compliance - PTE

Where monitoring requirements come home to roost...

## 01

**Initial compliance: Method 204**

## 02

**Continuous Compliance –  
Pressure Differential  
Monitoring**

- Install, operate, calibrate, maintain
- Operate whenever the facility is operating
- 0.007 in wc over a 3-hour rolling average

## 03

**Quirks:**

**All data collected during an operating hour must be used, even in portions of the facility covered by the PTE that are not operated for a complete hour.**

**You must record manually at least hourly if your automatic device is malfunctioning!**

**Monitor siting is important!**



# Ongoing Compliance - PTE

Where monitoring requirements come home to roost...

## 01

**Initial compliance: Method 204**

## 02

**Continuous Compliance – Flow Rate Monitoring System**

- Install, operate, calibrate, maintain
- Operate whenever the facility is operating
- Record every 15 minutes, 3-hour rolling average

## 03

**Quirks: This system is subject to many of the same calibration requirements as a CEMS, i.e., daily zero and upscale calibration drift testing to 3% of span, initial and annual relative accuracy testing!**

# Site-Specific CEMS Monitoring Plan

- **Hardcopy and electronic portions required**
- **Electronic:**
  - Submit plan to EPA via CEDRI;
  - The unit or stack ID number(s);
  - Monitoring location(s);
  - The EtO monitoring methodology used (i.e., CEMS);
  - EtO monitoring system information, including, but not limited to unique system and component ID numbers;
  - The make, model, and serial number of the monitoring equipment;
  - The sample acquisition method;
  - Formulas used to calculate emissions;
  - Monitor span and range information (if applicable).

# Site-Specific CEMS Monitoring Plan

- **Hardcopy and electronic required**
- **Hardcopy:**
  - Schematics and/or blueprints showing the location of the monitoring system(s) and test ports;
  - Data flow diagrams;
  - Test protocols;
  - Monitor span and range calculations (if applicable);
  - Miscellaneous technical justifications.
- **Quirk: the requirements for the plan under 40 CFR 75.53(g) are incredibly comprehensive, advise you check compliance line-by-line!**

Overarching Plan requirement...

# Site-Specific Monitoring Plan

**Quirk: alternative monitoring must be approved by EPA!**

Required under the General Provisions (see 40 CFR 63.8)

Covers operation and maintenance of all continuous monitoring

Your CEMS Monitoring Plan is a part of this

Also includes QA/QC procedures to assure data quality

PTE monitoring requirements and data assurance is also a part of this plan

Any alternative monitoring options are included here

# Site-Specific Test Plan

- **Required under the General Provisions (see 40 CFR 63.7)**
- **Must be submitted to EPA or delegated authority**
- **The test plan shall include:**
  - A test program summary;
  - The test schedule;
  - Data quality objectives
  - Internal and external quality assurance (QA) program.
  
- **Plan or any future changes must be approved within 30 days of receipt by Administrator**
- **Alternative methods must be approved by Administrator!**
- **Waiver requests must be made at least 60 days before testing is required**

# Recordkeeping

- **Initial Notification**
- **Notification of Compliance Status**
- **All EtO documentation and monitoring records**
- **All PTE monitoring records**
- **Site-Specific Monitoring Plan**
- **Test Plans and Protocols, test results**
- **Deviation information**
  
- **Five years for monitoring data**
  
- **Quirks:**
  - **Lifetime of the unit for CEMS monitoring plans and details (or until no longer subject)**
  - **Electronic recordkeeping allowed if records submitted via CEDRI**

# Reporting

- **Submit to EPA and delegated authority (if applicable)**
  - **Initial Notification**
  - **Notification of Compliance Status**
  - **Initial Compliance Report**
  - **Quarterly Compliance Reports**
  - **Construction and Reconstruction Information**
  - **Performance Tests and CEMS Performance Demonstrations**
- 
- **NOTE: The compliance reports in particular are BEASTS, read the requirements VERY CAREFULLY to make sure you are including all required information!**

Other things to keep in mind...

# Subpart O has a significant number of quirks to be aware of.

How are you limited if your streams are combined? Is CES or SWEL the way to go if you have combined streams? What to do with product that is going to be re-sterilized? Where are PTEs required?

## Combined Streams

If you have any combined emissions streams, you cannot demonstrate compliance against the individual stream limits!

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## CES vs. SWEL

Which option to use is going to be based on how many CEMS you want to install and which control efficiency you want to try to meet (remember that most restrictive DRE applies).

## Permanent Total Enclosure

PTEs are REQUIRED for Group 1 and Group 2 emissions!

PTEs require an initial compliance demonstration and ongoing monitoring!

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## Rework or Reprocessing

Product that is being held for reprocessing is offgassing and is therefore part of the Group 2 emissions. If you are showing compliance via monitoring of individual streams it must be stored in a Group 2 area!



Other things to keep in mind...

## Subpart O has a significant number of quirks to be aware of.

Can you trust the reg as it is written? If you operate an existing facility are you required to submit an IN or NoCS? How much data is required for a combined-streams approach? What performance specifications are you required to follow?

### Reporting Obligations

Even if you are an existing source, this regulation requires you to submit a fresh Initial Notification and Notification of Compliance Status!

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### Typos

Be aware that there are typos within the rule! Initial compliance procedures are located at 63.365(f), NOT (g)!

### Combined Streams

All combined-streams approaches are based upon a rolling 30 days of operating data!

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### Performance Specification 19

PS-19 is EtO-specific, vs. the prior performance specifications for FTIR CEMS (PS-15) or VOC (PS-8). Part of your initial compliance demonstration will be a PS-19 certification!

# Thank you

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