COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
AIR QUALITY PROGRAM

STATE ONLY NATURAL MINOR OPERATING PERMIT

Issue Date:	November 20, 2024	Effective Date:	April 17, 2026
Revision Date:	April 17, 2026	Expiration Date:	October 31, 2029
Revision Type:	Amendment		

In accordance with the provisions of the Air Pollution Control Act, the Act of January 8, 1960, P.L. 2119, as amended, and 25 Pa. Code Chapter 127, the Owner, [and Operator if noted] (hereinafter referred to as permittee) identified below is authorized by the Department of Environmental Protection (Department) to operate the air emission source(s) more fully described in this permit. This Facility is subject to all terms and conditions specified in this permit. Nothing in this permit relieves the permittee from its obligations to comply with all applicable Federal, State and Local laws and regulations.

The regulatory or statutory authority for each permit condition is set forth in brackets. All terms and conditions in this permit are federally enforceable unless otherwise designated.

State Only Permit No: 25-00918
Natural Minor
Federal Tax Id - Plant Code: 39-2186610-1

Owner Information

Name: LYNX MEDICAL PENNSYLVANIA, LLC
Mailing Address: 2205 E 33RD ST
ERIE, PA 16510-2555

Plant Information

Plant: LYNX MEDICAL PENNSYLVANIA, LLC/ERIE
Location: 25 Erie County 25001 Erie City
SIC Code: 3841 Manufacturing - Surgical And Medical Instruments

Responsible Official

Name: DEBORAH A. LENT
Title: GENERAL MANAGER
Phone: (814) 636 - 6065 Email: dlent@lynxmedical.life

Permit Contact Person

Name: DEBORAH A LENT
Title: GENERAL MANAGER
Phone: (814) 636 - 6065 Email: dlent@lynxmedical.life

[Signature] _____
LORI L. MCNABB, NORTHWEST REGION AIR PROGRAM MANAGER

SECTION A. Table of Contents

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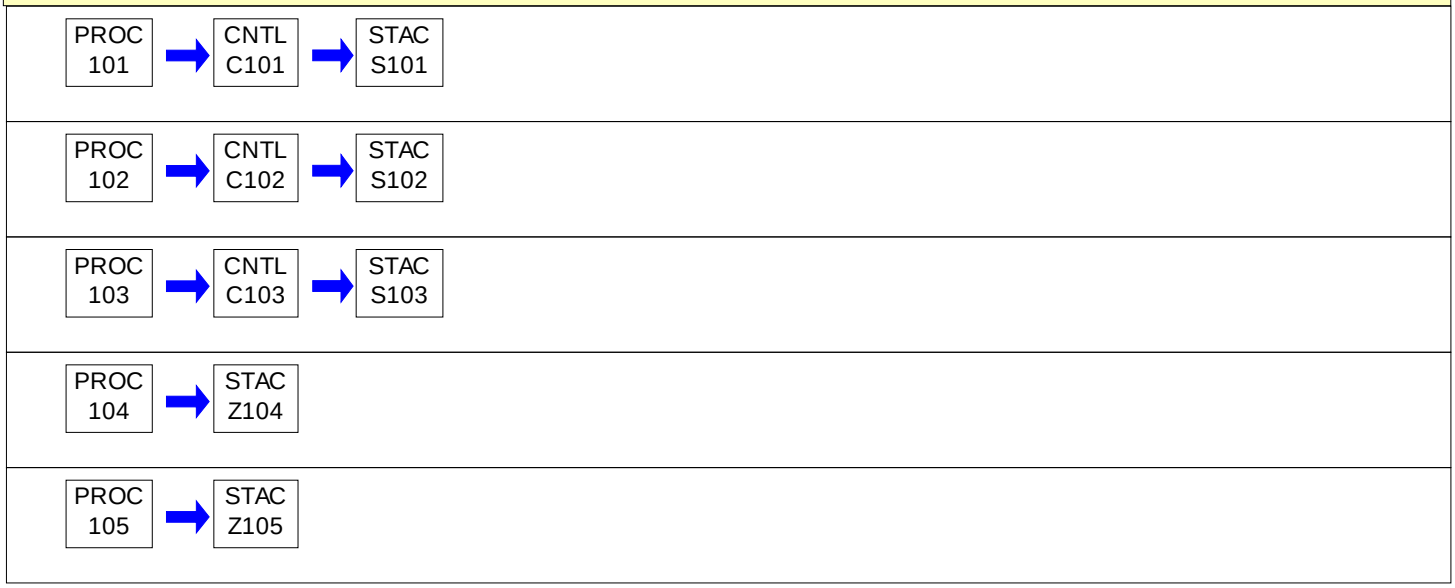
SECTION A. Site Inventory List

Source ID	Source Name	Capacity/Throughput		Fuel/Material
101	4 ETO STERILIZER CHAMBERS (SCV)	0.004	Lbs/HR	ETHYLENE OXIDE
102	2 AERATION ROOMS (ARV)	0.001	Lbs/HR	ETHYLENE OXIDE
103	ETO STERILIZATION CHAMBER EXHAUST VENTS (CEV)	1.000	Lbs/HR	ETHYLENE OXIDE
104	GROUP 1 ROOMS (ETO STORAGE&DISPENSING, VACUUM, PRE-AERATION)	1.000	Lbs/HR	ETHYLENE OXIDE
105	GROUP 2 ROOMS (EMISSIONS FROM POST-AERATION HANDLING)	1.000	Lbs/HR	ETHYLENE OXIDE
C101	ACID SCRUBBER			
C102	ETO ABSORBENT (3 UNITS)			
C103	SOURCE 103 CONTROLS- 2 DRY SORBENT BEDS			
S101	SCRUBBER STACK			
S102	ABSORBENT STACK			
S103	STACK-C103 & STERILIZER CHAMBER EXHAUST VENTS			
Z104	INDOOR FUGITIVES FROM GROUP 1 ROOM EMISSIONS			
Z105	INDOOR FUGITIVES FROM GROUP 2 ROOM EMISSIONS			

PERMIT MAPS



SECTION B. General State Only Requirements

#001 [25 Pa. Code § 121.1]

Definitions.

Words and terms that are not otherwise defined in this permit shall have the meanings set forth in Section 3 of the Air Pollution Control Act (35 P.S. § 4003) and in 25 Pa. Code § 121.1.

#002 [25 Pa. Code § 127.446]

Operating Permit Duration.

(a) This operating permit is issued for a fixed term of five (5) years and shall expire on the date specified on Page 1 of this permit.

(b) The terms and conditions of the expired permit shall automatically continue pending issuance of a new operating permit, provided the permittee has submitted a timely and complete application and paid applicable fees required under 25 Pa. Code Chapter 127, Subchapter I and the Department is unable, through no fault of the permittee, to issue or deny a new permit before the expiration of the previous permit.

#003 [25 Pa. Code §§ 127.412, 127.413, 127.414, 127.446 & 127.703(b)]

Permit Renewal.

(a) The permittee shall submit a timely and complete application for renewal of the operating permit to the appropriate Regional Air Program Manager. The application for renewal of the operating permit shall be submitted at least six (6) months and not more than 18 months before the expiration date of this permit.

(b) The application for permit renewal shall include the current permit number, a description of any permit revisions that occurred during the permit term, and any applicable requirements that were promulgated and not incorporated into the permit during the permit term. An application is complete if it contains sufficient information to begin processing the application, has the applicable sections completed and has been signed by a responsible official.

(c) The permittee shall submit with the renewal application a fee for the processing of the application as specified in 25 Pa. Code § 127.703(b). The fees shall be made payable to "The Commonwealth of Pennsylvania Clean Air Fund" and submitted with the fee form to the respective regional office.

(d) The renewal application shall also include submission of proof that the local municipality and county, in which the facility is located, have been notified in accordance with 25 Pa. Code § 127.413.

(e) The application for renewal of the operating permit shall also include submission of supplemental compliance review forms in accordance with the requirements of 25 Pa. Code § 127.412(b) and § 127.412(j).

(f) The permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall promptly submit such supplementary facts or corrected information as necessary to address any requirements that become applicable to the source after the permittee submits a complete application, but prior to the date the Department takes action on the permit application.

#004 [25 Pa. Code § 127.703]

Operating Permit Fees under Subchapter F.

(a) The permittee shall pay the annual operating permit maintenance fee according to the following fee schedule in either paragraph (1) or (2) in accordance with 25 Pa. Code § 127.703(d) on or before December 31 of each year for the next calendar year.

(1) For a synthetic minor facility, a fee equal to:

(i) Four thousand dollars ($4,000) for calendar years 2021—2025.

(ii) Five thousand dollars ($5,000) for calendar years 2026—2030.

(iii) Six thousand three hundred dollars ($6,300) for the calendar years beginning with 2031.

(2) For a facility that is not a synthetic minor, a fee equal to:

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(i) Two thousand dollars ($2,000) for calendar years 2021—2025.

(ii) Two thousand five hundred dollars ($2,500) for calendar years 2026—2030.

(iii) Three thousand one hundred dollars ($3,100) for the calendar years beginning with 2031.

(b) The applicable fees shall be made payable to "The Commonwealth of Pennsylvania Clean Air Fund" with the permit number clearly indicated and submitted to the respective regional office.

#005 [25 Pa. Code §§ 127.450 (a)(4) and 127.464]

Transfer of Operating Permits.

(a) This operating permit may not be transferred to another person, except in cases of transfer-of-ownership that are documented and approved by the Department.

(b) In accordance with 25 Pa. Code § 127.450(a)(4), a change in ownership of the source shall be treated as an administrative amendment if the Department determines that no other change in the permit is required and a written agreement has been submitted to the Department identifying the specific date of the transfer of permit responsibility, coverage and liability between the current and the new permittee and a compliance review form has been submitted to, and the permit transfer has been approved by, the Department.

(c) This operating permit is valid only for those specific sources and the specific source locations described in this permit.

#006 [25 Pa. Code § 127.441 and 35 P.S. § 4008]

Inspection and Entry.

(a) Upon presentation of credentials and other documents as may be required by law, the permittee shall allow the Department or authorized representatives of the Department to perform the following:

(1) Enter at reasonable times upon the permittee's premises where a source is located or emissions related activity is conducted, or where records are kept under the conditions of this permit;

(2) Have access to and copy, at reasonable times, any records that are kept under the conditions of this permit;

(3) Inspect at reasonable times, any facilities, equipment including monitoring and air pollution control equipment, practices, or operations regulated or required under this permit;

(4) Sample or monitor, at reasonable times, any substances or parameters, for the purpose of assuring compliance with the permit or applicable requirements as authorized by the Clean Air Act, the Air Pollution Control Act, or the regulations promulgated under the Acts.

(b) Pursuant to 35 P.S. § 4008, no person shall hinder, obstruct, prevent or interfere with the Department or its personnel in the performance of any duty authorized under the Air Pollution Control Act or regulations adopted thereunder including denying the Department access to a source at this facility. Refusal of entry or access may constitute grounds for permit revocation and assessment of criminal and/or civil penalties.

(c) Nothing in this permit condition shall limit the ability of the EPA to inspect or enter the premises of the permittee in accordance with Section 114 or other applicable provisions of the Clean Air Act.

#007 [25 Pa. Code §§ 127.441 & 127.444]

Compliance Requirements.

(a) The permittee shall comply with the conditions of this operating permit. Noncompliance with this permit constitutes a violation of the Clean Air Act and the Air Pollution Control Act and is grounds for one or more of the following:

(1) Enforcement action

SECTION B. General State Only Requirements

(2) Permit termination, revocation and reissuance or modification

(3) Denial of a permit renewal application

(b) A person may not cause or permit the operation of a source which is subject to 25 Pa. Code Article III unless the source(s) and air cleaning devices identified in the application for the plan approval and operating permit and the plan approval issued for the source is operated and maintained in accordance with specifications in the applications and the conditions in the plan approval and operating permit issued by the Department. A person may not cause or permit the operation of an air contamination source subject to 25 Pa. Code Chapter 127 in a manner inconsistent with good operating practices.

(c) For purposes of Sub-condition (b) of this permit condition, the specifications in applications for plan approvals and operating permits are the physical configurations and engineering design details which the Department determines are essential for the permittee's compliance with the applicable requirements in this State-Only permit. Nothing in this sub-condition shall be construed to create an independent affirmative duty upon the permittee to obtain a predetermination from the Department for physical configuration or engineering design detail changes made by the permittee.

#008 [25 Pa. Code § 127.441]

Need to Halt or Reduce Activity Not a Defense.

It shall not be a defense for the permittee in an enforcement action that it was necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

#009 [25 Pa. Code §§ 127.442(a) & 127.461]

Duty to Provide Information.

(a) The permittee shall submit reports to the Department containing information the Department may prescribe relative to the operation and maintenance of each source at the facility.

(b) The permittee shall furnish to the Department, in writing, information that the Department may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Department copies of records that the permittee is required to maintain in accordance with this permit.

#010 [25 Pa. Code § 127.461]

Revising an Operating Permit for Cause.

This operating permit may be terminated, modified, suspended or revoked and reissued if one or more of the following applies:

(1) The permittee constructs or operates the source subject to the operating permit so that it is in violation of the Air Pollution Control Act, the Clean Air Act, the regulations thereunder, a plan approval, a permit or in a manner that causes air pollution.

(2) The permittee fails to properly or adequately maintain or repair an air pollution control device or equipment attached to or otherwise made a part of the source.

(3) The permittee has failed to submit a report required by the operating permit or an applicable regulation.

(4) The EPA determines that the permit is not in compliance with the Clean Air Act or the regulations thereunder.

#011 [25 Pa. Code §§ 127.450, 127.462, 127.465 & 127.703]

Operating Permit Modifications

(a) The permittee is authorized to make administrative amendments, minor operating permit modifications and significant operating permit modifications, under this permit, as outlined below:

(b) Administrative Amendments. The permittee shall submit the application for administrative operating permit amendments (as defined in 25 Pa. Code § 127.450(a)), according to procedures specified in § 127.450 unless

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precluded by the Clean Air Act or its regulations.

(c) Minor Operating Permit Modifications. The permittee shall submit the application for minor operating permit modifications (as defined 25 Pa. Code § 121.1) in accordance with 25 Pa. Code § 127.462.

(d) Significant Operating Permit Modifications. The permittee shall submit the application for significant operating permit modifications in accordance with 25 Pa. Code § 127.465.

(e) The applicable fees shall be made payable to "The Commonwealth of Pennsylvania Clean Air Fund" with the permit number clearly indicated and submitted to the respective regional office.

#012 [25 Pa. Code § 127.441]

Severability Clause.

The provisions of this permit are severable, and if any provision of this permit is determined by a court of competent jurisdiction to be invalid or unenforceable, such a determination will not affect the remaining provisions of this permit.

#013 [25 Pa. Code § 127.449]

De Minimis Emission Increases.

(a) This permit authorizes de minimis emission increases in accordance with 25 Pa. Code § 127.449 so long as the permittee provides the Department with seven (7) days prior written notice before commencing any de minimis emissions increase. The written notice shall:

(1) Identify and describe the pollutants that will be emitted as a result of the de minimis emissions increase.

(2) Provide emission rates expressed in tons per year and in terms necessary to establish compliance consistent with any applicable requirement.

(b) The Department may disapprove or condition de minimis emission increases at any time.

(c) Except as provided below in (d), the permittee is authorized to make de minimis emission increases (expressed in tons per year) up to the following amounts without the need for a plan approval or prior issuance of a permit modification:

(1) Four tons of carbon monoxide from a single source during the term of the permit and 20 tons of carbon monoxide at the facility during the term of the permit.

(2) One ton of NOx from a single source during the term of the permit and 5 tons of NOx at the facility during the term of the permit.

(3) One and six-tenths tons of the oxides of sulfur from a single source during the term of the permit and 8.0 tons of oxides of sulfur at the facility during the term of the permit.

(4) Six-tenths of a ton of PM10 from a single source during the term of the permit and 3.0 tons of PM10 at the facility during the term of the permit. This shall include emissions of a pollutant regulated under Section 112 of the Clean Air Act unless precluded by the Clean Air Act, the regulations thereunder or 25 Pa. Code Article III.

(5) One ton of VOCs from a single source during the term of the permit and 5.0 tons of VOCs at the facility during the term of the permit. This shall include emissions of a pollutant regulated under Section 112 of the Clean Air Act unless precluded by the Clean Air Act, the regulations thereunder or 25 Pa. Code Article III.

(6) Other sources and classes of sources determined to be of minor significance by the Department.

(d) In accordance with § 127.14, the permittee is authorized to install the following minor sources without the need for a plan approval or permit modification:

(1) Air conditioning or ventilation systems not designed to remove pollutants generated or released from other sources.

SECTION B. General State Only Requirements

(2) Combustion units rated at 2,500,000 or less Btu per hour of heat input.

(3) Combustion units with a rated capacity of less than 10,000,000 Btu per hour heat input fueled by natural gas supplied by a public utility or by commercial fuel oils which are No. 2 or lighter, viscosity less than or equal to 5.82 c St, and which meet the sulfur content requirements of 25 Pa. Code §123.22 (relating to combustion units). For purposes of this permit, commercial fuel oil shall be virgin oil which has no reprocessed, recycled or waste material added.

(4) Space heaters which heat by direct heat transfer.

(5) Laboratory equipment used exclusively for chemical or physical analysis.

(6) Other sources and classes of sources determined to be of minor significance by the Department.

(e) This permit does not authorize de minimis emission increases if the emissions increase would cause one or more of the following:

(1) Increase the emissions of a pollutant regulated under Section 112 of the Clean Air Act except as authorized in Subparagraphs (c)(4) and (5) of this permit condition.

(2) Subject the facility to the prevention of significant deterioration requirements in 25 Pa. Code Chapter 127, Subchapter D and/or the new source review requirements in Subchapter E.

(3) Violate any applicable requirement of this permit, the Air Pollution Control Act, the Clean Air Act, or the regulations promulgated under either of the acts.

(f) Emissions authorized under this permit condition shall be included in the monitoring, recordkeeping and reporting requirements of this permit.

(g) Except for de minimis emission increases, installation of minor sources made pursuant to this permit condition and Plan Approval Exemptions under 25 Pa. Code § 127.14 (relating to exemptions), the permittee is prohibited from making changes or engaging in activities that are not specifically authorized under this permit without first applying for a plan approval. In accordance with § 127.14(b), a plan approval is not required for the construction, modification, reactivation, or installation of the sources creating the de minimis emissions increase.

(h) The permittee may not meet de minimis emission threshold levels by offsetting emission increases or decreases at the same source.

#014 [25 Pa. Code § 127.3]

Operational Flexibility.

The permittee is authorized to make changes within the facility in accordance with the regulatory provisions outlined in 25 Pa. Code § 127.3 (relating to operational flexibility) to implement the operational flexibility requirements provisions authorized under Section 6.1(i) of the Air Pollution Control Act and the operational flexibility terms and conditions of this permit. The provisions in 25 Pa. Code Chapter 127 which implement the operational flexibility requirements include the following:

(1) Section 127.14 (relating to exemptions)

(2) Section 127.447 (relating to alternative operating scenarios)

(3) Section 127.448 (relating to emissions trading at facilities with Federally enforceable emissions caps)

(4) Section 127.449 (relating to de minimis emission increases)

(5) Section 127.450 (relating to administrative operating permit amendments)

(6) Section 127.462 (relating to minor operating permit modifications)

(7) Subchapter H (relating to general plan approvals and general operating permits)

SECTION B. General State Only Requirements

#015 [25 Pa. Code § 127.11a]

Reactivation of Sources

(a) The permittee may not reactivate a source that has been out of operation or production for at least one year unless the reactivation is conducted in accordance with a plan approval granted by the Department or in accordance with reactivation and maintenance plans developed and approved by the Department in accordance with 25 Pa. Code § 127.11a(a).

(b) A source which has been out of operation or production for more than five (5) years but less than 10 years may be reactivated and will not be considered a new source if the permittee satisfies the conditions specified in 25 Pa. Code § 127.11a(b).

#016 [25 Pa. Code § 127.36]

Health Risk-based Emission Standards and Operating Practice Requirements.

(a) When needed to protect public health, welfare and the environment from emissions of hazardous air pollutants from new and existing sources, the permittee shall comply with the health risk-based emission standards or operating practice requirements imposed by the Department, except as precluded by §§ 6.6(d)(2) and (3) of the Air Pollution Control Act [35 P.S. § 4006.6(d)(2) and (3)].

(b) A person challenging a performance or emission standard established by the Department has the burden to demonstrate that performance or emission standard does not meet the requirements of Section 112 of the Clean Air Act.

#017 [25 Pa. Code § 121.9]

Circumvention.

No person may permit the use of a device, stack height which exceeds good engineering practice stack height, dispersion technique or other technique which, without resulting in reduction of the total amount of air contaminants emitted, conceals or dilutes an emission of air contaminants which would otherwise be in violation of 25 Pa. Code Article III, except that with prior approval of the Department, the device or technique may be used for control of malodors.

#018 [25 Pa. Code §§ 127.402(d) & 127.442]

Reporting Requirements.

(a) The permittee shall comply with the applicable reporting requirements of the Clean Air Act, the regulations thereunder, the Air Pollution Control Act and 25 Pa. Code Article III including Chapters 127, 135 and 139.

(b) The permittee shall submit reports to the Department containing information the Department may prescribe relative to the operation and maintenance of any air contamination source.

(c) Reports, test data, monitoring data, notifications and requests for renewal of the permit shall be submitted to the:

Regional Air Program Manager
PA Department of Environmental Protection
(At the address given in the permit transmittal letter, or otherwise notified)

(d) Any records or information including applications, forms, or reports submitted pursuant to this permit condition shall contain a certification by a responsible official as to truth, accuracy and completeness. The certifications submitted under this permit shall require a responsible official of the facility to certify that based on information and belief formed after reasonable inquiry, the statements and information in the documents are true, accurate and complete.

(e) Any records, reports or information submitted to the Department shall be available to the public except for such records, reports or information which meet the confidentiality requirements of § 4013.2 of the Air Pollution Control Act and §§ 112(d) and 114(c) of the Clean Air Act. The permittee may not request a claim of confidentiality for any emissions data generated for the facility.

SECTION B. General State Only Requirements

#019 [25 Pa. Code §§ 127.441(c) & 135.5]

Sampling, Testing and Monitoring Procedures.

(a) The permittee shall comply with the monitoring, recordkeeping or reporting requirements of 25 Pa. Code Chapter 139 and the other applicable requirements of 25 Pa. Code Article III and additional requirements related to monitoring, reporting and recordkeeping required by the Clean Air Act and the regulations thereunder including the Compliance Assurance Monitoring requirements of 40 CFR Part 64, where applicable.

(b) Unless alternative methodology is required by the Clean Air Act and regulations adopted thereunder, sampling, testing and monitoring required by or used by the permittee to demonstrate compliance with any applicable regulation or permit condition shall be conducted in accordance with the requirements of 25 Pa. Code Chapter 139.

#020 [25 Pa. Code §§ 127.441(c) and 135.5]

Recordkeeping.

(a) The permittee shall maintain and make available, upon request by the Department, the following records of monitored information:

(1) The date, place (as defined in the permit) and time of sampling or measurements.

(2) The dates the analyses were performed.

(3) The company or entity that performed the analyses.

(4) The analytical techniques or methods used.

(5) The results of the analyses.

(6) The operating conditions as existing at the time of sampling or measurement.

(b) The permittee shall retain records of any required monitoring data and supporting information for at least five (5) years from the date of the monitoring, sample, measurement, report or application. Supporting information includes the calibration data and maintenance records and original strip-chart recordings for continuous monitoring instrumentation, and copies of reports required by the permit.

(c) The permittee shall maintain and make available to the Department upon request, records including computerized records that may be necessary to comply with the reporting, recordkeeping and emission statement requirements in 25 Pa. Code Chapter 135 (relating to reporting of sources). In accordance with 25 Pa. Code Chapter 135, § 135.5, such records may include records of production, fuel usage, maintenance of production or pollution control equipment or other information determined by the Department to be necessary for identification and quantification of potential and actual air contaminant emissions.

#021 [25 Pa. Code § 127.441(a)]

Property Rights.

This permit does not convey any property rights of any sort, or any exclusive privileges.

#022 [25 Pa. Code § 127.447]

Alternative Operating Scenarios.

The permittee is authorized to make changes at the facility to implement alternative operating scenarios identified in this permit in accordance with 25 Pa. Code § 127.447.

#023 [25 Pa. Code § 121.7]

Prohibition of Air Pollution

No person may permit air pollution as that term is defined in the Air Pollution Control Act (35 P.S. §§ 4001-4015).

SECTION B. General State Only Requirements

#024 [25 Pa. Code §135.3]

Reporting

(a) If the facility is a Synthetic Minor Facility, the permittee shall submit by March 1 of each year an annual emissions report for the preceding calendar year. The report shall include information for all active previously reported sources, new sources which were first operated during the preceding calendar year, and sources modified during the same period which were not previously reported. All air emissions from the facility should be estimated and reported.

(b) A source owner or operator of a Synthetic Minor Facility may request an extension of time from the Department for the filing of an annual emissions report, and the Department may grant the extension for reasonable cause.

#025 [25 Pa. Code §135.4]

Report Format

If applicable, the emissions reports shall contain sufficient information to enable the Department to complete its emission inventory. Emissions reports shall be made by the source owner or operator in a format specified by the Department.

SECTION C. Site Level Requirements

I. RESTRICTIONS.

Emission Restriction(s).

 # 001 [25 Pa. Code §123.1]

Prohibition of certain fugitive emissions

(a) No person may permit the emission into the outdoor atmosphere of fugitive air contaminant from a source other than the following:

(1) Construction or demolition of buildings or structures.

(2) Grading, paving and maintenance of roads and streets.

(3) Use of roads and streets. Emissions from material in or on trucks, railroad cars and other vehicular equipment are not considered as emissions from use of roads and streets.

(4) Clearing of land.

(5) Stockpiling of materials.

(6) Open burning operations.

(7) [Not applicable]

(8) [Not applicable]

(9) Sources and classes of sources other than those identified in paragraphs (1)-(8), for which the operator has obtained a determination from the Department that fugitive emissions from the source, after appropriate control, meet the following requirements:

(i) the emissions are of minor significance with respect to causing air pollution; and

(ii) the emissions are not preventing or interfering with the attainment or maintenance of any ambient air quality standard.

(b) An application form for requesting a determination under either subsection (a)(9) or 129.15(c) is available from the Department. In reviewing these applications, the Department may require the applicant to supply information including, but not limited to, a description of proposed control measures, characteristics of emissions, quantity of emissions, and ambient air quality data and analysis showing the impact of the source on ambient air quality. The applicant shall be required to demonstrate that the requirements of subsections (a)(9) and (c) and 123.2 (relating to fugitive particulate matter) or of the requirements of 129.15(c) have been satisfied. Upon such demonstration, the Department will issue a determination, in writing, either as an operating permit condition, for those sources subject to permit requirements under the act, or as an order containing appropriate conditions and limitations.

(c) [Paragraph (c) of the regulation is printed under WORK PRACTICE REQUIREMENTS in this section of permit.]

(d) [Paragraph (d) of the regulation is not applicable to this facility.]

 # 002 [25 Pa. Code §123.2]

Fugitive particulate matter

A person may not permit fugitive particulate matter to be emitted into the outdoor atmosphere from a source specified in 25 Pa. Code § 123.1(a)(1) -- (9) (relating to prohibition of certain fugitive emissions) [Condition #002 above] if such emissions are visible at the point the emissions pass outside the person's property.

 # 003 [25 Pa. Code §123.31]

Limitations

A person may not permit the emission into the outdoor atmosphere of any malodorous air contaminants from any source in such a manner that the malodors are detectable outside the property of the person on whose land the source is being operated.

SECTION C. Site Level Requirements

 # 004 [25 Pa. Code §123.41]

Limitations

A person may not permit the emission into the outdoor atmosphere of visible air contaminants in such a manner that the opacity of the emission is either of the following:

(1) Equal to or greater than 20% for a period or periods aggregating more than three minutes in any 1 hour.

(2) Equal to or greater than 60% at any time.

 # 005 [25 Pa. Code §123.42]

Exceptions

The limitations of 25 Pa. Code § 123.41 (relating to limitations) [Condition #005 above] shall not apply to a visible emission in any of the following instances:

(1) When the presence of uncombined water is the only reason for failure of the emission to meet the limitations.

(2) When the emission results from the operation of equipment used solely to train and test persons in observing the opacity of visible emissions.

(3) When the emission results from sources specified in 25 Pa. Code § 123.1(a)(1) -- (9) (relating to prohibition of certain fugitive emissions). [123.1(a)(1) -- (9) are printed under Emission Restrictions of Condition #002 in this section of permit.]

(4) [Not applicable]

II. TESTING REQUIREMENTS.

 # 006 [25 Pa. Code §123.43]

Measuring techniques

Visible emissions may be measured using either of the following:

(1) A device approved by the Department and maintained to provide accurate opacity measurements.

(2) Observers, trained and qualified to measure plume opacity with the naked eye or with the aid of any devices approved by the Department.

III. MONITORING REQUIREMENTS.

No additional monitoring requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

IV. RECORDKEEPING REQUIREMENTS.

No additional record keeping requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

VI. WORK PRACTICE REQUIREMENTS.

 # 007 [25 Pa. Code §123.1]

Prohibition of certain fugitive emissions

(a) - (b) [Paragraphs (a) and (b) of 25 Pa. Code § 123.1 are printed under Emission Restrictions in this section of permit.]

SECTION C. Site Level Requirements

(c) A person responsible for any source specified in 25 Pa. Code § 123.1(a)(1) -- (7) or (9) [Condition 002 above] shall take all reasonable actions to prevent particulate matter from becoming airborne. These actions shall include, but not be limited to, the following:

(1) Use, where possible, of water or chemicals for control of dust in the demolition of buildings or structures, construction operations, the grading of roads, or the clearing of land.

(2) Application of asphalt, oil, water or suitable chemicals on dirt roads, material stockpiles and other surfaces which may give rise to airborne dusts.

(3) Paving and maintenance of roadways.

(4) Prompt removal of earth or other material from paved streets onto which earth or other material has been transported by trucking or earth moving equipment, erosion by water, or other means.

(d) [Paragraph (d) of the regulation is not applicable to this facility.]

 # 008 [25 Pa. Code §129.14]

Open burning operations

(a) Air basins. No person may permit the open burning of material in an air basin.

(b) [Not applicable]

(c) Exceptions: The requirements of subsections (a) and (b) do not apply where the open burning operations result from:

(1) A fire set to prevent or abate a fire hazard, when approved by the Department and set by or under the supervision of a public officer.

(2) A fire set for the purpose of instructing personnel in fire-fighting, when approved by the Department.

(3) A fire set for the prevention and control of disease or pests, when approved by the Department.

(4) [Not applicable]

(5) [Not applicable]

(6) A fire set solely for recreational or ceremonial purposes.

(7) A fire set solely for cooking food.

(d) Clearing and grubbing wastes. The following is applicable to clearing and grubbing wastes:

(1) As used in this subsection the following terms shall have the following meanings:

Air curtain destructor -- A mechanical device which forcefully projects a curtain of air across a pit in which open burning is being conducted so that combustion efficiency is increased and smoke and other particulate matter are contained.

Clearing and grubbing wastes -- Trees, shrubs, and other native vegetation which are cleared from land during or prior to the process of construction. The term does not include demolition wastes and dirt laden roots.

(2) [Not applicable]

(3) Subsection (b) notwithstanding clearing and grubbing wastes may be burned outside of an air basin, subject to the following limitations:

(i) Upon receipt of a complaint or determination by the Department that an air pollution problem exists, the

SECTION C. Site Level Requirements

Department may order that the open burning cease or comply with subsection (b) of this section.

(ii) Authorization for open burning under this paragraph does not apply to clearing and grubbing wastes transported from an air basin for disposal outside of an air basin.

(4) During an air pollution episode, open burning is limited by Chapter 137 (relating to air pollution episodes) and shall cease as specified in such chapter.

[This permit does not constitute authorization to burn solid waste pursuant to Section 610(3) of the Solid Waste Management Act, 35 P.S. Section 6018.610(3), or any other provision of the Solid Waste Management Act.]

VII. ADDITIONAL REQUIREMENTS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

VIII. COMPLIANCE CERTIFICATION.

No additional compliance certifications exist except as provided in other sections of this permit including Section B (relating to State Only General Requirements).

IX. COMPLIANCE SCHEDULE.

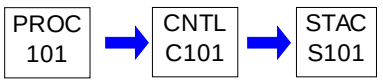
No compliance milestones exist.

SECTION D. Source Level Requirements

Source ID: 101 Source Name: 4 ETO STERILIZER CHAMBERS (SCV)

Source Capacity/Throughput: 0.004 Lbs/HR ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP



I. RESTRICTIONS.

Emission Restriction(s).

 # 001 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Total ethylene oxide emissions from the medical equipment sterilizers shall not exceed 0.1 pound per hour (one cycle average) and 0.4 tons per year.

[From plan approval 25-399-041, as amended by plan approval 25-332-001A.]

Throughput Restriction(s).

 # 002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

EtO gas usage shall be less than 30.0 tons per year.

[Compliance with this EtO throughput restriction of less than 30.0 tpy requested by Cosmed in a June 25, 2024, email assures compliance with the 82,352 pounds per year (41.176 tons per year) of EtO throughput derived from plan approval 25-399-041 and plan approval 25-332-001A as amended by the June 21, 1993, RFD approval.]

[Compliance with this usage restriction also assures that category 1.c of Table 1 to 40 CFR Part 63 Subpart O will not apply to this source.]

Control Device Efficiency Restriction(s).

 # 003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Ethylene oxide removal efficiency of the control equipment shall be at least 99%. This EtO removal efficiency shall be achieved on a weight basis over the entire evacuation cycle.

[From plan approval 25-399-041 and plan approval 25-332-001A.]

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

III. MONITORING REQUIREMENTS.

 # 004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall install and maintain equipment to monitor gas and liquid flow rates to the scrubber.

[From plan approval 25-399-041.]

SECTION D. Source Level Requirements

 # 005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The operating limit for the acid-water scrubber established during the initial performance test, as required by 40 CFR § 63.363(b)(2), is a maximum ethylene glycol concentration of 30 percent.

[This operating limit was established with the 1/28/2002 new issuance of this State Only operating permit and is based upon performance testing conducted by Microbac Laboratories on May 26, 27, 28, 1999, for which a report was submitted to the Department and for which a Source Test Review was conducted by the PA DEP Division of Source Testing on November 26, 2001.]

[Requirements for the measurement and recording of this concentration are specified in 40 CFR § 63.364(b)(1) and are printed in Section E.III of this permit.]

[A copy of § 63.364(b)(1) is also available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

IV. RECORDKEEPING REQUIREMENTS.

 # 006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) Records shall be maintained of the gas and liquid flow rates to the scrubber. The logs of gas and liquid flow rates shall include the following.

(1) The date the audit of gas and liquid flow rates was recorded;
(2) The actual gas and liquid flow rates;
(3) A comparison to the allowable ranges of the gas and liquid flow rates;
(4) The action taken if the gas or liquid flow rate is outside the allowable range; and
(5) The identifying ID or signature or initials of the employee recording the information.

(b) Records shall be maintained of the weekly analysis of the ethylene glycol concentration of the scrubber liquor as required by 40 CFR § 63.364(b)(1) printed in Section E of this permit. The records shall include, at a minimum, the following.

(1) The date the sample was taken and the analysis performed;
(2) The result of the analysis;
(3) A comparison to the maximum allowable ethylene glycol concentration of 30 percent as established during initial performance testing;
(4) The action taken if the result exceeds the allowable 30 percent maximum; and
(5) The identifying ID or signature or initials of the employee collecting the sample and performing the analysis.

(c) Records shall be maintained for at least 5 years.

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VII. ADDITIONAL REQUIREMENTS.

 # 007 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The height of the (scrubber) stack shall be at least 55 feet and the stack design shall not obstruct the proper dispersion of

SECTION D. Source Level Requirements

the air toxic substances (i.e., no rain caps, elbows, etc.).

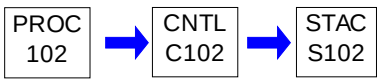
[From plan approval 25-399-041]

SECTION D. Source Level Requirements

Source ID: 102 Source Name: 2 AERATION ROOMS (ARV)

Source Capacity/Throughput: 0.001 Lbs/HR ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP



I. RESTRICTIONS.

Emission Restriction(s).

 # 001 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The emissions of ethylene oxide from the exhaust of the 3 Safe Cell Units (controlling the aeration rooms) shall not exceed 1 ppmv.

[From plan approval PA 25-918A condition # 7]

II. TESTING REQUIREMENTS.

 # 002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The facility shall perform periodic testing to determine the time to schedule reactant change-out. The testing shall be performed initially as part of the Installation Qualification, then at 6-month intervals until 0.5 ppmv is reached. The interval will then be reduced to 3 months, then monthly; and when 0.9 ppmv is reached, the reactant shall be changed out and verification testing shall be performed.

[From plan approval PA 25-918A condition # 8 and from the Aug. 2, 2000, letter of EPA approval of Alternative Control Device from US EPA Region III.]

 # 003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

[The requirement from plan approval PA 25-918A to perform the Installation Qualification using the Ethylene Oxide STEL monitor is a one-time requirement which was met on November 30, 2000. The report on the results of the testing showed compliance with the standards of 40 CFR Part 63 Subpart O and a copy of the report was submitted to the PA DEP on December 5, 2000, and is filed with plan approval PA 25-918A.]

[Derived from Plan approval PA 25-918A, condition # 10]

III. MONITORING REQUIREMENTS.

 # 004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

A magnehelic gauge or equivalent shall be permanently installed, calibrated, operated, and maintained at a conveniently readable location to indicate pressure drop across the Safe Cell Unit. The pressure drop shall be monitored to the manufacturer's specifications.

[From plan approval PA 25-918A condition # 9]

IV. RECORDKEEPING REQUIREMENTS.

 # 005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) The facility shall maintain a log of preventative maintenance inspections of the Safe Cell Units.

SECTION D. Source Level Requirements

(b) The inspection log shall, at a minimum, contain the following.
(1) dates of the inspections,
(2) any potential problems or defects encountered,
(3) the steps to correct them, and
(4) the measured pressure drop across the control device.

[From plan approval PA 25-918A condition # 13]

 # 006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) Logs shall be maintained of the periodic testing to determine the time to schedule reactant change-out. The records shall at a minimum include.

(1) The date of the testing;
(2) The ppmv result of the testing;
(3) The date that reactant was changed and verification testing was performed;
(4) The signature or initials or ID of the employee performing the testing and the reactant change.

(b) The log shall also identify the following EtO emission thresholds for comparison to the testing results of paragraph (a).
(1) The 0.5 ppmv threshold for switching from a 6-month testing interval to a 3-month testing interval;
(2) The ppmv threshold for switching from a 3-month testing interval to a 1-month testing interval;
(3) The 0.9 ppmv threshold for changing the reactant; and
(4) The 1.0 ppmv emission limit.

(c) The logs shall be maintained for a period of at least 5 years.

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

 # 007 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The facility shall maintain and operate the source and air pollution control device in accordance with the manufacturer's specifications and consistent with good air pollution control practices.

[From Plan approval PA 16-918A condition # 12]

VII. ADDITIONAL REQUIREMENTS.

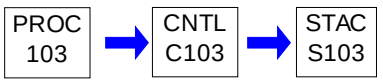
No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

SECTION D. Source Level Requirements

Source ID: 103 Source Name: ETO STERILIZATION CHAMBER EXHAUST VENTS (CEV)

Source Capacity/Throughput: 1.000 Lbs/HR ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP



I. RESTRICTIONS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

II. TESTING REQUIREMENTS.

 # 001 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) The permittee shall sample the inlet and outlet ethylene oxide (EtO) concentrations of the control devices to determine control device performance and compliance with at least 99 percent EtO emission reduction. Sampling shall occur on an approved graduated schedule that is based on the control device performance data results. Sampling may be performed by a 3rd party or by using a Department approved passive diffusion monitor or equivalent.

(b) The sampling shall be conducted at least quarterly for the first year to gather site-specific performance data. After one year of consecutive quarterly monitoring events, the permittee may petition the Department to adjust this schedule. Written approval of an adjusted schedule by the Department is required before changing the quarterly sampling schedule.

(c) All paragraphs of this operating permit testing requirement may be streamlined out of the operating permit at the compliance date (or extended compliance date) for 40 CFR Part 63 Subpart O at which time the permittee demonstrates compliance with Subpart O for the Chamber Exhaust Vents (CEV) of this source.

III. MONITORING REQUIREMENTS.

 # 002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

A magnehelic gauge or equivalent shall be permanently installed, calibrated, operated, and maintained at a conveniently readable location to indicate pressure drop across the Safe Cell Unit. The pressure drop shall be monitored to the manufacturer's specifications.

[This operating permit condition may be streamlined out of the operating permit after the 40 CFR Part 63 Subpart O compliance date or extended compliance date in favor of the monitoring requirements of Subpart O for this source.]

IV. RECORDKEEPING REQUIREMENTS.

 # 003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) The facility shall maintain a log of preventative maintenance inspections of the Safe Cell Units.

(b) The inspection log shall, at a minimum, contain the following.
(1) dates of the inspections,
(2) any potential problems or defects encountered,
(3) the steps to correct them, and
(4) the measured pressure drop across the control device.

(c) The logs shall be maintained for a period of at least 5 years.

SECTION D. Source Level Requirements

 # 004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) Logs shall be maintained of the periodic testing to determine the time to schedule reactant change-out. The records shall at a minimum include.

(1) The date of the testing;
(2) The ppmv result of the testing;
(3) The date that reactant was changed and verification testing was performed;
(4) The signature or initials or ID of the employee performing the testing and the reactant change.

(b) The log shall also identify the following EtO emission threshold for comparison to the testing results of paragraph (a).
- The 0.9 ppmv threshold for changing the reactant.

(c) The logs shall be maintained for a period of at least 5 years.

[All paragraphs of this operating permit recordkeeping condition may be streamlined out of the operating permit after the 40 CFR Part 63 Subpart O compliance date or extended compliance date in favor of the monitoring and recordkeeping requirements of Subpart O for this source.]

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

 # 005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The facility shall maintain and operate the source and air pollution control device in accordance with the manufacturer's specifications and consistent with good air pollution control practices.

[This operating permit condition may be streamlined out of the operating permit after the 40 CFR Part 63 Subpart O compliance date or extended compliance date in favor of the redundant language in the General Duty Clause in § 63.362(k) of Subpart O for this source.]

 # 006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) The Safe Cell Units of C103 shall be operated whenever the chamber exhaust vents (CEV) are open.

(b) If the Safe Cell Units of C103 are inoperable, the chambers may not be opened until the air pollution controls are back online.

VII. ADDITIONAL REQUIREMENTS.

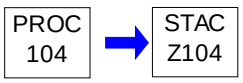
No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

SECTION D. Source Level Requirements

Source ID: 104 Source Name: GROUP 1 ROOMS (ETO STORAGE&DISPENSING, VACUUM, PRE-AERATION)

Source Capacity/Throughput: 1.000 Lbs/HR ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP



I. RESTRICTIONS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

III. MONITORING REQUIREMENTS.

No additional monitoring requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

IV. RECORDKEEPING REQUIREMENTS.

No additional record keeping requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VII. ADDITIONAL REQUIREMENTS.

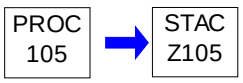
No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

SECTION D. Source Level Requirements

Source ID: 105 Source Name: GROUP 2 ROOMS (EMISSIONS FROM POST-AERATION HANDLING)

Source Capacity/Throughput: 1.000 Lbs/HR ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP



I. RESTRICTIONS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

III. MONITORING REQUIREMENTS.

No additional monitoring requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

IV. RECORDKEEPING REQUIREMENTS.

No additional record keeping requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VII. ADDITIONAL REQUIREMENTS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

SECTION E. Source Group Restrictions.

Group Name: ETO NESHAP

Group Description: 40 CFR Part 63 Subpart O, Ethylene Oxide Emission Standards for Sterilization Facilities

Sources included in this group

ID	Name
101	4 ETO STERILIZER CHAMBERS (SCV)
102	2 AERATION ROOMS (ARV)
103	ETO STERILIZATION CHAMBER EXHAUST VENTS (CEV)
104	GROUP 1 ROOMS (ETO STORAGE&DISPENSING, VACUUM, PRE-AERATION)
105	GROUP 2 ROOMS (EMISSIONS FROM POST-AERATION HANDLING)

I. RESTRICTIONS.

Emission Restriction(s).

 # 001 [25 Pa. Code §123.13]

Processes

No person may permit the emission into the outdoor atmosphere of particulate matter from this process in a manner that the concentration of particulate matter in the effluent gas exceeds 0.04 grain per dry standard cubic foot.

Control Device Efficiency Restriction(s).

 # 002 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.362]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Standards.

(a) Compliance date. If you own or operate an affected source, you must comply with the applicable requirement by the compliance date specified in § 63.360(j). The standards of this section are summarized in tables 1 through 5 to this subpart.

(b) Applicability of standards. The standards in paragraphs (c) through (k) of this section apply at all times. If using EtO CEMS to determine compliance with an applicable standard, this compliance demonstration is based on the previous 30-operating days of data. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraphs (c) through (g) and (i) of this section for each operating day, you must determine the total inlet mass to and outlet mass from the control system using the procedures laid out in § 63.364(f) and appendix A to this subpart, and you must maintain the emission limit based on the inlet mass and the applicable emission reduction standard. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraph (j) of this section, you must continuously comply with the requirements of that paragraph.

(c) SCV. You must comply with each applicable standard in table 1 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a SCV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(d) ARV. You must comply with each applicable standard in table 2 to this subpart, and you must meet each applicable requirement specified in § 63.363. If an ARV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(e) CEV. You must comply with each applicable standard in table 3 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a CEV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(f) Group 1 room air emissions. You must comply with the applicable standard in table 4 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 1 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(g) Group 2 room air emissions. You must comply with the applicable standard in table 5 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 2 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this

SECTION E. Source Group Restrictions.

section. If you are required to limit the sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must meet the monitoring requirements specified in § 63.364(h).

(h) Capture systems. Room air emissions for which numerical limits are prescribed must be captured and routed under negative pressure to a control system. You may assume the capture system efficiency is 100 percent if both conditions in paragraphs (h)(1) and (2) of this section are met:

(1) The capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and directs all the exhaust gases from the enclosure to an add-on control system.

(2) All sterilization operations creating exhaust gases for which the compliance demonstration is applicable are contained within the capture system.

(i) Requirements for combined emission streams. [Not applicable. There are no combined emission streams at this facility.]

(j) Site-wide emission limitation. You may choose to comply with a site-wide emission limitation (SWEL) specified in this paragraph (j) in lieu of the applicable standards in paragraphs (c) through (g) of this section for the facility. The SWEL, which is calculated daily, is based on the previous 30 operating days of data. In order to elect to comply with a SWEL, you must utilize an EtO CEMS on each exhaust stack at the facility to determine compliance. The owner or operator may demonstrate compliance via one of the two SWEL approaches in lieu of the applicable standard(s) in paragraphs (c) through (g) of this section for the facility. If electing to comply with a SWEL, you must comply with paragraph (j)(3) of this section.

(1) SWEL based upon facility EtO use. If you elect to comply with a SWEL based upon facility EtO use, you must follow requirements of paragraphs (j)(1)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, you first determine the 30-operating day rolling sum of EtO use. The SWEL is determined by multiplying by 0.99 and then applying the required SCV percent emission reduction standard in table 1 to this subpart to the 30-operating day rolling sum of EtO usage. Then, for each CEMS at the outlet of the control systems at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 3 to this paragraph.

(A copy of Equation 3 is available at this web address:
https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.362)

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

SWEL(Fac) = M(Fac) * 0.99 * (1 – ER(SCV)
Where:
SWELFac = SWEL based upon facility EtO use, in pounds.
MFac = Facility EtO use over the previous 30 operating days, in pounds, as determined in accordance with equation 11 of § 63.364(i)(2).
0.99 = Adjustment factor for EtO residual in sterilized product.
ERSCV = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this paragraph.

(A copy of Equation 4 is available at this web address:
https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.362)

Equation 4 to paragraph (j)(1)(ii):

E(Fac) = Summation(n, i=1) E(o,i)

SECTION E. Source Group Restrictions.

Where:

EFac = The total emissions from the facility over the previous 30-operating days, in pounds.

Eo,i = The 30-operating day rolling sum of emissions calculated at each exhaust stack, i, monitored by an EtO CEMS, as calculated using equation A-3 of appendix A to this subpart.

i = Exhaust stack index

n = Total number of exhaust stacks

(iii) Compliance with the SWEL based upon facility EtO usage shall be determined by demonstrating that EFac, as calculated in accordance with paragraph (j)(1)(ii) of this section, for each 30-operating day period is at or below the SWEL, as calculated paragraph (j)(1)(i) of this section.

(2) SWEL based upon emissions streams. If you elect to comply with a SWEL based upon emissions streams, you must follow requirements of paragraphs (j)(2)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, for each non-SCV affected source, you must determine the mass of EtO sent to controls and apply the applicable emission reduction standard. For each SCV affected source, you must determine the mass of EtO sent to controls as specified in § 63.364(f)(1)(i)(C)(1) and apply the applicable emission reduction standard. The SWEL is determined by summing across the result of this calculation for each affected source (both non-SCV and SCV). Then, for each CEMS at the outlet of the control system(s) at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 5 to this paragraph.

(A copy of Equation 5 is available at this web address:
https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.362)

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

SWELStreams = Summation(n, i=1) [M(c,i) * (1 – ER(i)] + Summation(m, j=1) [M(c,j) * (1 – ER(j)]

Where:

SWELStreams = SWEL based upon individual emissions streams, in pounds.

Mc,i = The 30-operating day total mass sent to controls (i.e., monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A-3 and determined in accordance with appendix A to this subpart. The term “Mc,i” as used in this equation is equivalent to the term “E30day” as designated in equation A-3.

ERi = The applicable emission reduction standard to each non-SCV emission stream, i, specified in tables 1 through 5 of this subpart, in decimal format.

i = Non-SCV emission streams index.

n = Total number of non-SCV emission streams.

Mc,j = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 10 in § 63.364(f)(1)(i)(C)(1).

ERj = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

j = SCV emission stream index.

m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this section.

(iii) Compliance with the SWEL based upon emission streams shall be determined by demonstrating that EFac, as calculated in accordance with paragraph (j)(2)(ii) of this section, for each 30-operating day period is at or below SWELStreams, as calculated in paragraph (j)(2)(i) of this section.

(3) Boundary. The boundary for this approach includes all affected sources at the facility.

(k) General duty. At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further

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efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

[Source: 89 FR 24172, Apr. 5, 2024]

 # 003 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR Table 1 to Subpart O of Part 63]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Standards for SCVs

Source 101:

[Applicable categories 1.a & 1.d of Table 1 are printed below. Categories 1.b, 1.e, and 2 and Notes 4, 5, and 6 do not apply and are not printed in this condition. Category 1.c does not apply because this permit contains a ETO usage restriction of less than 30 tpy in Section D for Source 101. A copy of Table 1 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%201%20to%20Subpart%20O%20of%20Part%2063]

As required in § 63.362(c), for each SCV, you must meet the applicable standard in the following table:

1.a. For each Existing SCV for which Facility EtO use is at least 10 tpy, you must continuously reduce EtO emissions by 99 percent (see note 1). You must comply with the standard until April 6, 2026.

1.d. For each Existing SCV for which Facility EtO use is at least 10 tpy but less than 30 tpy, you must continuously reduce EtO emissions by 99.9 percent (see notes 2 & 3). You must comply with the standard no later than April 6, 2026.

Note 1: The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.

Note 2: If using EtO CEMS to determine compliance, this standard is based on the previous 30 operating days of data.

Note 3: The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.

[Source: 89 FR 24172, Apr. 5, 2024]

 # 004 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR Table 2 to Subpart O of Part 63]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Standards for ARVs

Source 102:

[Applicable categories 1.a, 1.b, & 1.c of Table 2 are printed below. Categories 1.d and 2 and Notes 4, 5, and 6 do not apply and are not included in this condition. Category 1.b does not apply because this permit contains a ETO usage restriction of less than 30.0 tpy. A copy of Table 2 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%202%20to%20Subpart%20O%20of%20Part%2063]

As required in § 63.362(d), for each ARV, you must meet the applicable standard in the following table:

1.a. For each Existing ARV for which Facility EtO use is at least 10 tpy, you must continuously reduce EtO emissions by 99 percent (see note 1). You must comply with the standard until April 6, 2026.

1.c. For each Existing ARV for which Facility EtO use is at least 10 tpy but less than 30 tpy, you must continuously reduce EtO emissions by 99.6 percent (see notes 2 & 3). You must comply with the standard no later than April 6, 2026.

Note 1: The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.

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Note 2: If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.

Note 3: The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.

[Source: 89 FR 24172, Apr. 5, 2024]

 # 005 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR Table 3 to Subpart O of Part 63]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Standards for CEVs

Source 103:

[Applicable category 2.b of Table 3 is printed below. Categories 1, 2.a, 3, and 4 and Note 2 do not apply and are omitted from this condition. A copy of Table 3 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%203%20to%20Subpart%20O%20of%20Part%2063]

As required in § 63.362(e), for each CEV, you must meet the applicable standard in the following table:

2.b. For each Existing CEV at an area source facility for which Facility EtO use is less than 60 tpy, you must continuously reduce EtO emissions by 99 percent (see notes 1 and 3). You must comply with the standard no later than April 5, 2027.

Note 1: If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.

Note 3: The standard applies if the facility has used less than 60 tpy of EtO within all consecutive 12-month periods after April 6, 2026.

[Source: 89 FR 24172, Apr. 5, 2024]

 # 006 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR Table 4 to Subpart O of Part 63]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Standards for Group 1 Room Air Emissions

Source 104:

[Applicable category 2.b and Notes 1 and 3 of Table 4 are printed below. Remaining categories and remaining notes in the table do not apply and are not printed in this condition. A copy of Table 4 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%204%20to%20Subpart%20O%20of%20Part%2063]

As required in § 63.362(f), for your collection of Group 1 room air emissions at each facility, you must meet the applicable standard in the following table:

2.b. For each Existing collection of Group 1 room air emissions at an area source facility for which Facility EtO use is less than 40 tpy, you must . . .

i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,

ii. Continuously reduce EtO emissions by 80 percent. (See notes 1 and 3).

You must comply with the standard no later than April 5, 2028.

Note 1: If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.

Note 3: The standard applies if the facility has used less than 40 tpy of EtO within all consecutive 12-month periods after April 6, 2026.

[Source: 89 FR 24172, Apr. 5, 2024. The original compliance date of April 5, 2027, is extended to April 5, 2028, for Group 1

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room air emissions per the Department's August 2, 2024, letter of extension to the permittee.]

 # 007 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR Table 5 to Subpart O of Part 63]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Standards for Group 2 Room Air Emissions

Source 105:

[Applicable category 2.a of Table 5 is printed below. Remaining categories 1, 2.b, 2.c, 3, and 4 and notes 3, 4, and 5 do not apply and are not printed in this condition. A copy of Table 5 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%205%20to%20Subpart%20O%20of%20Part%2063]

As required in § 63.362(g), for your collection of Group 2 room air emissions, you must meet the applicable standard in the following table:

2.a. For each Existing collection of Group 2 room air emissions at an area source facility for which Facility EtO use is at least 20 tpy, you must . . .

i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. (See note 2.) Also,

ii. Continuously reduce EtO emissions by 98 percent. (See notes 1 and 2.)

You must comply with the standard no later than April 6, 2027.

Note 1: This standard is based on a rolling 30-operating day average.

Note 2: The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.

[Source: 89 FR 24172, Apr. 5, 2024. The original compliance date of April 6, 2026, is extended to April 6, 2027, for Group 2 room air emissions per the Department's August 2, 2024, letter of extension to the permittee.]

II. TESTING REQUIREMENTS.

 # 008 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.365]

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Test methods and procedures.

(a) General —

(1) [Not applicable]

(2) Facilities subject to capture efficiency. If you are subject to capture efficiency requirements in § 63.362, you must follow the applicable procedures for initial and continuous compliance in paragraph (f) of this section.

(b) - (e) [Not applicable]

(f) Determination of compliance with PTE requirement. If you are required to operate any portion of your facility with PTE, you must demonstrate initial compliance with the requirements of this subpart by following the procedures of paragraphs (f)(1) through (3) of this section, as applicable, during the initial compliance demonstration or during the initial certification of the CEMS tests.

(1) Determine the capture efficiency by verifying the capture system meets the criteria in section 6 of Method 204 of appendix M to part 51 of this chapter and directs all the exhaust gases from the enclosure to an add-on control device.

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(2) Ensure that the air passing through all NDOs flows into the enclosure continuously. If the facial velocities (FVs) are less than or equal to 9,000 meters per hour (492 feet per minute), the continuous inward flow of air shall be verified by continuous observation using smoke tubes, streamers, tracer gases, or other means approved by the Administrator over the period that the volumetric flow rate tests required to determine FVs are carried out. If the FVs are greater than 9,000 meters per hour (492 feet per minute), the direction of airflow through the NDOs shall be presumed to be inward at all times without verification.

(3) If you are demonstrating continuous compliance through monitoring the volumetric flow rate, you must monitor and record the volumetric flow rate (in cubic feet per second) from the PTE through the stack(s) at least once every 15 minutes during each of the three test runs. Use the data collected during the most recent compliance demonstration to calculate the average volumetric flow rate measured during the compliance demonstration. This volumetric flow rate is the minimum operating limit for the stack. Repeat this procedure for every stack that is included in the compliance demonstration.

[Source: 89 FR 24172, Apr. 5, 2024]

III. MONITORING REQUIREMENTS.

 # 009 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.363]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Compliance and performance provisions.

(a) Continuous compliance. You must demonstrate continuous compliance with the applicable emission standard(s) using an EtO CEMS, including a shared EtO CEMS, installed and operated in accordance with the requirements of Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter. [Remaining text from the regulation is omitted from this paragraph because it does not apply to facilities where EtO use is greater than 100 pounds/yr.]

[Performance Specification 19 in Appendix B is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-60/appendix-Appendix%20B%20to%20Part%2060]

[Procedure 7 in appendix F is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-60/appendix-Appendix%20F%20to%20Part%2060]

(b) Initial compliance for Facilities that use EtO CEMS. To demonstrate initial compliance with an emission standard using a CEMS that measures HAP concentrations directly (i.e., an EtO CEMS), the initial performance test must consist of the first 30 operating days after the certification of the CEMS according to Performance Specification 19 in Appendix B to part 60 of this chapter. The initial compliance demonstration period must be completed on or before the date that compliance must be demonstrated (i.e., 180 days after the applicable compliance date). You must follow the procedures in appendix A to this subpart.

[A copy of Appendix A to Subpart O is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Appendix%20A%20to%20Subpart%20O%20of%20Part%2063]

(1) The CEMS performance test must demonstrate compliance with the applicable EtO standards in tables 1 through 5 to this subpart. Alternatively, the CEMS performance test may demonstrate compliance with § 63.362(i) or (j).

(i) You may time-share your CEMS among different measurement points provided that:

(A) The measurement points are approximately equidistant from the CEMS;

(B) The sampling time at each measurement point is at least 3 times as long as the CEMS response time;

(C) The CEMS completes at least one complete cycle of operation for each shared measurement point within a 15-minute period; and

(D) The CEMS meets the other requirements of PS 19.

(2) You must collect hourly data from auxiliary monitoring systems during the performance test period, to convert the pollutant concentrations to pounds per hour.

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(c) - (e) [Not applicable]

(f) Other emission streams. If the emission stream does not consist only of an SCV(s), the procedures in paragraphs (f)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d) through (g), as applicable:

(1) You must comply with paragraph (c) of this section, as applicable.

(2) If you are complying with a percent emission reduction standard as specified in tables 1 through 5 to this subpart, you must determine compliance with § 63.362(c) through (g), as applicable, using the test methods and procedures in § 63.365(d)(1).

(3) If you are required to operate any portion of the facility under PTE, you must initially demonstrate that the PTE meets the requirements of Method 204 of 40 CFR part 51, appendix M, and that all exhaust gases from the enclosure are delivered to a control system or stack(s). You must also meet the requirements in § 63.363(f)(3)(i) and either § 63.363(f)(3)(ii) or (iii):

(i) Maintain direction of the airflow into the enclosure at all times, verifying daily using the procedures described in § 63.364(f)(5) and meet either of the requirements.

(ii) Establish as an operating limit the minimum volumetric flow rate through the affected stack(s) using the procedures described in § 63.365(f)(1); or

(iii) Install, operate, calibrate, and maintain a continuous pressure differential monitoring system using the procedures described in § 63.364(f)(4).

[Source: 89 FR 24172, Apr. 5, 2024]

 # 010 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.364]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Monitoring requirements.

(a) General requirements.

(1) If you own or operate an affected source subject to an emission standard in § 63.362, you must comply with the monitoring requirements in § 63.8, according to the applicability in table 6 to this subpart, and in this section. [A copy of regulation § 63.8 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.8]

(2) [Not applicable]

(3) If you own or operate an affected source that is subject to an emission standard in § 63.362 and that is required to monitor using EtO CEMS, you must comply with paragraphs (f), (g), and (i) of this section.

(4) If you comply with the management practice for Group 2 room air emissions at area sources, you must comply with paragraph (h) of this section.

(5) You must keep the written procedures required by § 63.8(d)(2) on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you must keep previous (i.e., superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(b) [Not applicable]

(c) [Not applicable]

(d) [Not applicable]

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(e) Performance testing, other control technology. If you are complying with § 63.363(d) or (e) using periodic performance testing and the use of a control device other than acid-water scrubbers, catalytic or thermal oxidizers, or gas/solid reactors, you must monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(e).

(f) EtO CEMS configurations. If you are using EtO CEMS to demonstrate compliance with an emission standard, you must install and operate an EtO CEMS on each outlet for the control system in accordance with the requirements of Appendix A to subpart O of this part. You must also conduct monitoring for each inlet to the control system that is used to demonstrate compliance with the emission reduction standard in accordance with the requirements of appendix A to this subpart, with the exception for SCV emission streams to the control system.

(1) EtO CEMS inlet configuration. The following caveats apply:

(i) SCVs. If you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to monitoring the inlet emission stream to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(A) Determine the mass (MSCV,n) of EtO used for each charge and at each sterilization chamber used during the previous 30 days using the procedures in either paragraph (f)(1)(i)(A)(1) or (2) of this section.

(1) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass (Mc) vented to the controls using equation 1 to this paragraph.

Equation 1 to paragraph (f)(1)(i)(A)(1)

[A copy of Equation 1 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

M(SCV,n) = M(charge) * %EO(w)

Where:

MSCV,n = Theoretical total mass of EtO vented to controls per charge, g (lb)

Mcharge = total mass of sterilizer gas charge, g (lb)

%EOw = weight percent of EtO

(2) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Qm) and duration of each sterilizer charge. Calculate the theoretical mass (MSCV,n) vented to the controls using equation 2 to this paragraph.

Equation 2 to paragraph (f)(1)(i)(A)(2)

[A copy of Equation 2 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

M(SCV,n) = (Q(m) * T(n) * %EO(v) * MW/SV)

Where:

MSCV,n = theoretical total mass of EtO sent to controls per charge

Qm = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))

Tn = time duration of each charge, min

%EOv = volume fraction percent of EtO

n = number of EtO charges

MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))

SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(B) Determine the adjustment factor (f) using equation 8 to this paragraph. Determine the mass of EtO sent to controls from all non-SCV affected sources, I, using equation 4 to this paragraph. For facilities where EtO use is less than 4 tpy, if not all Group 2 room air emissions are routed to a control device, do not include Group 2 room air emissions in I, and subtract 0.002 from this factor.

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Equation 3 to paragraph (f)(1)(i)(B)
[A copy of Equation 3 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

F = 0.99 – [1/M(fac)]
Where:
f = Adjustment factor.
I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days
MFac = Facility EtO use over the previous 30-operating days, in pounds, as determined in accordance with equation 11 of § 63.364(i)(2)

Equation 4 to paragraph (f)(1)(i)(B)
[A copy of Equation 4 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

I = Summation(i=1,n) [M(c,i)]
Where:
I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days
Mc,i = The 30-operating day total mass sent to controls (i.e., monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A-3 and determined in accordance with appendix A to this subpart. The term “Mc,i” as used in this equation is equivalent to the term “E30day” as designated in equation A-3.
i = Non-SCV emission stream index.
n = Total number of non-SCV emission streams.

(C) (1) Determine the mass rate of EtO sent to controls during the previous 30 days using equation 5 to this paragraph.
Equation 5 to paragraph (f)(1)(i)(C)(1)
[A copy of Equation 5 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

M(SCV) = f * Summation(i=1,n) [M(SCV,n)]
Where:
MSCV = Total mass of EtO sent to controls over the previous 30 operating days, g/hr (lb/hr)
f = Adjustment factor
MSCV,n = Theoretical mass of EtO sent to controls per charge per chamber, g (lb)
n = Total number of charges during the previous 30 operating days

(2) If both this approach is chosen and the SCV is (or SCVs are) combined with another emission stream, then the owner or operator cannot monitor the point after the combination occurs.

(ii) Room air emissions. If room air emissions are both subject to an emission standard and split between two or more control systems, then monitoring must be conducted for room air emissions before they are combined with other streams.

(2) EtO CEMS on exhaust configurations. Exhaust gases from the emission sources under this subpart exhaust to the atmosphere through a variety of different configurations, including but not limited to individual stacks, a common stack configuration, or a main stack plus a bypass stack. For the CEMS used to provide data under this subpart, the continuous monitoring system installation requirements for these exhaust configurations are as follows:

(i) Single unit-single stack configurations. For an emission source that exhausts to the atmosphere through a single, dedicated stack, you shall either install the required CEMS in the stack or at a location in the ductwork downstream of all emissions control devices, where the pollutant and diluents concentrations are representative of the emissions that exit to the atmosphere.

(ii) Unit utilizing common stack with other emission source(s). When an emission source utilizes a common stack with one or more other emission sources, but no emission sources not subject to this rule, you shall either:

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(A) Install the required CEMS in the duct from each emission source, leading to the common stack; or

(B) Install the required CEMS in the common stack.

(iii) Unit(s) utilizing common stack with non-commercial sterilization emission source(s).

(A) When one or more emission sources shares a common stack with one or more emission sources not subject to this rule, you shall either:

(1) Install the required CEMS in the ducts from each emission source that is subject to this rule, leading to the common stack; or

(2) Install the required CEMS described in this section in the common stack and attribute all of the emissions measured at the common stack to the emission source(s).

(B) If you choose the common stack monitoring option:

(1) For each hour in which valid data are obtained for all parameters, you must calculate the pollutant emission rate; and

(2) You must assign the calculated pollutant emission rate to each of the units subject to the rule that share the common stack.

(iv) Unit with multiple parallel control devices with multiple stacks. If the exhaust gases from an emission source, which is configured such that emissions are controlled with multiple parallel control devices or multiple series of control devices are discharged to the atmosphere through more than one stack, you shall install the required CEMS described in each of the multiple stacks. You shall calculate hourly, flow-weighted, average pollutant emission rates for the unit as follows:

(A) Calculate the pollutant emission rate at each stack or duct for each hour in which valid data are obtained for all parameters;

(B) Multiply each calculated hourly pollutant emission rate at each stack or duct by the corresponding hourly gas flow rate at that stack or duct;

(C) Sum the products determined under paragraph (f)(2)(iv)(B) of this section; and

(D) Divide the result obtained in paragraph (f)(2)(I(C) of this section by the total hourly gas flow rate for the unit, summed across all of the stacks or ducts.

(g) PTE monitoring. If you are required to operate all or a portion of your sterilization facility under PTE conditions, you must:

(1) Initial compliance. Demonstrate initial procedures in § 63.365(g)(1) and continued compliance with the provisions in this section. You must follow the requirements of either paragraphs (g)(2) and (3) of this section or paragraph (g)(4) of this section.

(2) Continuous compliance. If you choose to demonstrate continuous compliance through volumetric flow rate monitoring, you must monitor and record at least every 15 minutes the volumetric flow rate from each outlet where air from the PTE is sent using a flow rate monitoring system described in paragraph (g)(3) of this section. Monitoring is required when the portion of the facility covered by PTE is operated. A data acquisition system for the flow rate monitoring system shall compute and record each 3-hour average flow rate value, rolled hourly. This must be done by first averaging the flow rate readings over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even the portion of the facility covered by PTE is not operated for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average flow rate. You must maintain the 3-hour rolling average flow rate above the applicable operating limits established during the most recent compliance demonstration.

(3) Continuous flow rate monitoring system for PTE. You must install, operate, calibrate, and maintain instruments,

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according to the requirements in paragraphs (g)(3)(i) through (ix) of this section, for continuously measuring and recording the stack gas flow rate to allow determination of compliance with the minimum volumetric flow rate through the affected stack operating limit(s).

(i) You must install each sensor of the flow rate monitoring system in a location that provides representative measurement of the exhaust gas flow rate. The flow rate sensor is that portion of the system that senses the volumetric flow rate and generates an output proportional to that flow rate.

(ii) The flow rate monitoring system must be designed to measure the exhaust flow rate over a range that extends from a value of at least 20 percent less than the lowest expected exhaust flow rate to a value of at least 20 percent greater than the highest expected exhaust flow rate.

(iii) The flow rate monitoring system must be equipped with a data acquisition and recording system that is capable of recording values over the entire range specified in paragraph (g)(3)(ii) of this section.

(iv) The signal conditioner, wiring, power supply, and data acquisition and recording system for the flow rate monitoring system must be compatible with the output signal of the flow rate sensors used in the monitoring system.

(v) The flow rate monitoring system must be designed to complete a minimum of one cycle of operation for each successive 15-minute period.

(vi) The flow rate sensor must have provisions to determine the daily zero and upscale calibration drift (CD) (see sections 3.1 and 8.3 of Performance Specification 2 in appendix B to Part 60 of this chapter for a discussion of CD).

(A) Conduct the CD tests at two reference signal levels, zero (e.g., 0 to 20 percent of span) and upscale (e.g., 50 to 70 percent of span).

(B) The absolute value of the difference between the flow monitor response and the reference signal must be equal to or less than 3 percent of the flow monitor span.

(vii) You must perform an initial relative accuracy test of the flow rate monitoring system according to section 8.2 of Performance Specification 6 of appendix B to part 60 of the chapter with the exceptions in paragraphs (g)(3)(vii)(A) and (B) of this section.

(A) The relative accuracy test is to evaluate the flow rate monitoring system alone rather than a continuous emission rate monitoring system.

(B) The relative accuracy of the flow rate monitoring system shall be no greater than 10 percent of the mean value of the reference method data.

(viii) You must verify the accuracy of the flow rate monitoring system at least once per year by repeating the relative accuracy test specified in paragraph (g)(3)(vii) of this section.

(ix) You must operate the flow rate monitoring system and record data during all periods of operation of the affected facility including periods of startup, shutdown, and malfunction.

(4) Pressure differential monitor. You must instead install, operate, calibrate, and maintain a continuous pressure differential monitoring system, as follows, to verify the presence of PTE. You must operate this system whenever the facility is in operation. You must also maintain the pressure differential at or above 0.007 inches of water over a three-hour rolling average.

(i) This monitoring system must measure the pressure differential between the interior and exterior of the PTE, with at least one monitoring device located in each room that borders the PTE. These monitoring devices shall be designed to provide measurements of pressure differential to at least the nearest 0.001 inches of water and having a complete cycle time no greater than 5 minutes.

(ii) A data acquisition system for the monitoring system shall compute and record each 3-hour average pressure

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differential value, rolled hourly. This must be done by first averaging the pressure differential readings over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even in portions of the facility covered by PTE that are not operated for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average pressure differential. If data are not recorded from an alternative monitoring device, during any malfunction of the principal monitoring device(s) or the automatic recorder, you must manually record the measured data at least hourly.

(h) Sterilization chamber end-cycle EtO concentration. As part of your monitoring plan, you must document your approach for determining the EtO sterilization chamber concentration. If you choose a parametric approach you must meet the requirements in paragraph (h)(1) of this section and if you choose a direct measurement approach you must meet the requirements in paragraph (h)(2) of this section. Alternatively, you may petition the administrator for an alternative monitoring approach under § 63.8(f).

(1) If you choose a parametric approach for determining chamber EtO concentrations you must document parameter(s) used in the calculation to determine of EtO concentrations and the calculation(s) used to determine the chamber concentration. Any instrumentation used for parametric monitoring must also be identified in the monitoring plan and at a minimum this plan should include the following for each instrument:

(i) Parameter measured and measurement principle of the monitor.

(ii) Instrument name, model number, serial number, and range.

(iii) Manufacturer recommended operation practices, including daily operational check.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(2) If you choose a direct measurement approach for determining chamber EtO calibrations you must document the procedures used for the operation of the instruments. Any instrument used for direct measurement of EtO must be identified in the monitoring plan and at a minimum this plan must include the following information:

(i) Instrument name, model number, serial number, and range.

(ii) Description of the measurement principle and any potential interferences.

(iii) If applicable, the description of the sampling condition system.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(i) EtO usage. If you own or operate a sterilization facility subject to the requirements of this subpart you must monitor and record on a daily basis the daily and 30-operating day EtO usage according to the requirements of this paragraph. Additionally, you must record EtO usage for each calendar month.

(1) Monitor and record on a daily basis, the daily total mass of ethylene oxide, in pounds, used at the facility. The daily total mass must be determined using the methodology specified in § 63.365(c)(1)(i) and (ii).

(2) Determine and record daily the 30-operating day rolling ethylene oxide usage rate using equation 6 to this paragraph.

Equation 6 to paragraph (i)(2)

[A copy of Equation 6 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.364]

M(FAC) = Summation(i=1, 30) [m(Fac,i)]

Where:

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MFac = Facility EtO use over the previous 30 operating days, in pounds.
mFac,i = Daily EtO use for operating day i, in pounds, as determined in accordance with paragraph (i)(1) of this section
i = Operating day index.

(3) Determine and record the total mass of EtO used in each calendar month.

[Source: 89 FR 24172, Apr. 5, 2024]
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[Regarding compliance with § 63.364(b) above: The operating limit for the acid-water scrubber (C101) established during the initial performance test, as required by 40 CFR § 63.363(b)(2), is a maximum ethylene glycol concentration of 30 percent.]

[This operating limit was established with the 1/28/2002 new issuance of this State Only operating permit and is based upon performance testing conducted by Microbac Laboratories on May 26, 27, 28, 1999, for which a report was submitted to the Department and for which a Source Test Review was conducted by the PA DEP Division of Source Testing on November 26, 2001.]

 # 011 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.8]
Subpart A--General Provisions
Monitoring requirements.

[40 CFR § 63.8 is referenced by § 63.364(a). A copy of § 63.8 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.8]

 # 012 [40 CFR Part 63 NESHAPS for Source Categories §Appendix A to Subpart O of Part 63]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Monitoring Provisions for EtO CEMS

[Appendix A is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Appendix%20A%20to%20Subpart%20O%20of%20Part%2063]

IV. RECORDKEEPING REQUIREMENTS.

 # 013 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.10]
Subpart A--General Provisions
Recordkeeping and reporting requirements.

[A copy of § 63.10 can be viewed at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.10]

[A copy of Table 6 to 40 CFR Part 63 Subpart O can be viewed at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%206%20to%20Subpart%20O%20of%20Part%2063]

(a) Applicability and general information. [See regulation for 40 CFR §63.10(a) at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.10#p-63.10(a)]

(b) General recordkeeping requirements.

(1) The owner or operator of an affected source subject to the provisions of this part shall maintain files of all information (including all reports and notifications) required by this part recorded in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent 2 years of data shall be retained on site. The remaining 3 years of data may be retained off site. Such files may be maintained on microfilm, on a computer, on computer floppy disks, on magnetic tape disks, or on microfiche.

(2) The owner or operator of an affected source subject to the provisions of this part shall maintain relevant records for such source of—

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(i) - (ii) [Not applicable. Reference Table 6 of 40 CFR Part 63 Subpart O which references § 63.367(f)];

(iii) All required maintenance performed on the air pollution control and monitoring equipment;

(iv) - (v) [Not applicable. Reference Table 6 of 40 CFR Part 63 Subpart O];

(vi) Each period during which a CMS is malfunctioning or inoperative (including out-of-control periods);

(vii) All required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, 15-minute averages of CMS data, raw performance testing measurements, and raw performance evaluation measurements, that support data that the source is required to report);

(A) This paragraph applies to owners or operators required to install a continuous emissions monitoring system (CEMS) where the CEMS installed is automated, and where the calculated data averages do not exclude periods of CEMS breakdown or malfunction. An automated CEMS records and reduces the measured data to the form of the pollutant emission standard through the use of a computerized data acquisition system. In lieu of maintaining a file of all CEMS subhourly measurements as required under paragraph (b)(2)(vii) of this section, the owner or operator shall retain the most recent consecutive three averaging periods of subhourly measurements and a file that contains a hard copy of the data acquisition system algorithm used to reduce the measured data into the reportable form of the standard.

(B) This paragraph applies to owners or operators required to install a CEMS where the measured data is manually reduced to obtain the reportable form of the standard, and where the calculated data averages do not exclude periods of CEMS breakdown or malfunction. In lieu of maintaining a file of all CEMS subhourly measurements as required under paragraph (b)(2)(vii) of this section, the owner or operator shall retain all subhourly measurements for the most recent reporting period. The subhourly measurements shall be retained for 120 days from the date of the most recent summary or excess emission report submitted to the Administrator.

(C) The Administrator or delegated authority, upon notification to the source, may require the owner or operator to maintain all measurements as required by paragraph (b)(2)(vii), if the administrator or the delegated authority determines these records are required to more accurately assess the compliance status of the affected source.

(viii) All results of performance tests, CMS performance evaluations, and opacity and visible emission observations;

(ix) All measurements as may be necessary to determine the conditions of performance tests and performance evaluations;

(x) All CMS calibration checks;

(xi) All adjustments and maintenance performed on CMS;

(xii) Any information demonstrating whether a source is meeting the requirements for a waiver of recordkeeping or reporting requirements under this part, if the source has been granted a waiver under paragraph (f) of this section;

(xiii) All emission levels relative to the criterion for obtaining permission to use an alternative to the relative accuracy test, if the source has been granted such permission under § 63.8(f)(6); and

(xiv) All documentation supporting initial notifications and notifications of compliance status under § 63.9.

(3) Recordkeeping requirement for applicability determinations. [See regulation for 40 CFR §63.10(b)(3)]

(c) Additional recordkeeping requirements for sources with continuous monitoring systems. In addition to complying with the requirements specified in paragraphs (b)(1) and (b)(2) of this section, the owner or operator of an affected source required to install a CMS by a relevant standard shall maintain records for such source of --

(1) All required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods);

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(2) - (4) [Reserved]

(5) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks;

(6) The date and time identifying each period during which the CMS was out of control, as defined in § 63.8(c)(7);

(7) The specific identification (i.e., the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, as defined in the relevant standard(s), that occurs during startups, shutdowns, and malfunctions of the affected source;

(8) The specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances, as defined in the relevant standard(s), that occurs during periods other than startups, shutdowns, and malfunctions of the affected source;

(9) [Reserved]

(10) The nature and cause of any malfunction (if known);

(11) The corrective action taken or preventive measures adopted;

(12) The nature of the repairs or adjustments to the CMS that was inoperative or out of control;

(13) The total process operating time during the reporting period; and

(14) All procedures that are part of a quality control program developed and implemented for CMS under § 63.8(d).

(15) [Not applicable. Reference Table 6 of 40 CFR Part 63 Subpart O];

(d) - (e) [Paragraphs (d) and (e) of § 63.10 are printed in a separate condition under Reporting Requirements in this section of the permit.]

(f) Waiver of recordkeeping or reporting requirements.

(1) - (6) [Refer to regulation for 40 CFR §63.10(f)(1) - (f)(6). https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.10#p-63.10(f)]

[59 FR 12430, Mar. 16, 1994, as amended at 64 FR 7468, Feb. 12, 1999; 67 FR 16604, Apr. 5, 2002; 68 FR 32601, May 30, 2003; 69 FR 21752, Apr. 22, 2004; 71 FR 20455, Apr. 20, 2006; 85 FR 73886, Nov. 19, 2020]

 # 014 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.367]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Recordkeeping requirements.

(a) If you own or operate an affected source subject to § 63.362, you must comply with the recordkeeping requirements in § 63.10(a) through (c), according to the applicability in table 6 to this subpart, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection.

(b) You must maintain the previous five years of records specified in § 63.366(b) and (c), as applicable.

(c) You must maintain the previous five years of records for compliance tests and associated data analysis, as applicable.

(d) Any records required to be maintained by this subpart that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

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(e) If you are using an EtO CEMS to demonstrate continuous compliance, you must maintain the previous five years of records for all required certification and QA tests.

(f) For each deviation from an emission limit, operating limit, or best management practice, you must keep a record of the information specified in paragraph (g)(1) through (4) of this section. The records shall be maintained as specified in § 63.10(b)(1).

(1) The occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment.

(2) In the event that an affected unit does not meet an applicable standard, record the number of deviations. For each deviation, record the date, time, cause, and duration of each deviation.

(3) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(4) Record actions taken to minimize emissions in accordance with § 63.362(k) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

[Source: 89 FR 24172, Apr. 5, 2024]

V. REPORTING REQUIREMENTS.

 # 015 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.10]

Subpart A--General Provisions

Recordkeeping and reporting requirements.

[A copy of § 63.10 can be viewed at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.10]

[A copy of Table 6 to 40 CFR Part 63 Subpart O can be viewed at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/appendix-Table%206%20to%20Subpart%20O%20of%20Part%2063]

(a) - (c) [Paragraphs (a), (b), and (c) of § 63.10 are printed in a separate condition under Recordkeeping Requirements in this section of the permit.]

(d) General reporting requirements.

(1) Notwithstanding the requirements in this paragraph or paragraph (e) of this section, and except as provided in § 63.16, the owner or operator of an affected source subject to reporting requirements under this part shall submit reports to the Administrator in accordance with the reporting requirements in the relevant standard(s).

(2) Reporting results of performance tests. [One-time requirement which is no longer applicable.]

(3) Not applicable. [Ref. Table 1 of §40 CFR 63.360 of Subpart O]

(4) Progress reports. The owner or operator of an affected source who is required to submit progress reports as a condition of receiving an extension of compliance under § 63.6(i) shall submit such reports to the Administrator (or the State with an approved permit program) by the dates specified in the written extension of compliance.

(5) Not applicable. [Ref. Table 1 of §40 CFR 63.360 of Subpart O]

(e) Additional reporting requirements for sources with continuous monitoring systems —

(1) General. When more than one CEMS is used to measure the emissions from one affected source (e.g., multiple breechings, multiple outlets), the owner or operator shall report the results as required for each CEMS.

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(2) Reporting results of continuous monitoring system performance evaluations.

(i) The owner or operator of an affected source required to install a CMS by a relevant standard shall furnish the Administrator a copy of a written report of the results of the CMS performance evaluation, as required under § 63.8(e), simultaneously with the results of the performance test required under § 63.7, unless otherwise specified in the relevant standard.

(ii) The owner or operator of an affected source using a COMS to determine opacity compliance during any performance test required under § 63.7 and described in § 63.6(d)(6) shall furnish the Administrator two or, upon request, three copies of a written report of the results of the COMS performance evaluation conducted under § 63.8(e). The copies shall be furnished at least 15 calendar days before the performance test required under § 63.7 is conducted.

(3) Excess emissions and continuous monitoring system performance report and summary report.

(i) Excess emissions and parameter monitoring exceedances are defined in relevant standards. The owner or operator of an affected source required to install a CMS by a relevant standard shall submit an excess emissions and continuous monitoring system performance report and/or a summary report to the Administrator semiannually, except when—

(A) More frequent reporting is specifically required by a relevant standard;

(B) The Administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the source; or

(C) [Reserved]

(D) The affected source is complying with the Performance Track Provisions of § 63.16, which allows less frequent reporting.

(ii) Request to reduce frequency of excess emissions and continuous monitoring system performance reports. Notwithstanding the frequency of reporting requirements specified in paragraph (e)(3)(i) of this section, an owner or operator who is required by a relevant standard to submit excess emissions and continuous monitoring system performance (and summary) reports on a quarterly (or more frequent) basis may reduce the frequency of reporting for that standard to semiannual if the following conditions are met:

(A) For 1 full year (e.g., 4 quarterly or 12 monthly reporting periods) the affected source's excess emissions and continuous monitoring system performance reports continually demonstrate that the source is in compliance with the relevant standard;

(B) The owner or operator continues to comply with all recordkeeping and monitoring requirements specified in this subpart and the relevant standard; and

(C) The Administrator does not object to a reduced frequency of reporting for the affected source, as provided in paragraph (e)(3)(iii) of this section.

(iii) The frequency of reporting of excess emissions and continuous monitoring system performance (and summary) reports required to comply with a relevant standard may be reduced only after the owner or operator notifies the Administrator in writing of his or her intention to make such a change and the Administrator does not object to the intended change. In deciding whether to approve a reduced frequency of reporting, the Administrator may review information concerning the source's entire previous performance history during the 5-year recordkeeping period prior to the intended change, including performance test results, monitoring data, and evaluations of an owner or operator's conformance with operation and maintenance requirements. Such information may be used by the Administrator to make a judgment about the source's potential for noncompliance in the future. If the Administrator disapproves the owner or operator's request to reduce the frequency of reporting, the Administrator will notify the owner or operator in writing within 45 days after receiving notice of the owner or operator's intention. The notification from the Administrator to the owner or operator will specify the grounds on which the disapproval is based. In the absence of a notice of disapproval within 45 days, approval is automatically granted.

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(iv) As soon as CMS data indicate that the source is not in compliance with any emission limitation or operating parameter specified in the relevant standard, the frequency of reporting shall revert to the frequency specified in the relevant standard, and the owner or operator shall submit an excess emissions and continuous monitoring system performance (and summary) report for the noncomplying emission points at the next appropriate reporting period following the noncomplying event. After demonstrating ongoing compliance with the relevant standard for another full year, the owner or operator may again request approval from the Administrator to reduce the frequency of reporting for that standard, as provided for in paragraphs (e)(3)(ii) and (e)(3)(iii) of this section.

(v) Content and submittal dates for excess emissions and monitoring system performance reports. All excess emissions and monitoring system performance reports and all summary reports, if required, shall be delivered or postmarked by the 30th day following the end of each calendar half or quarter, as appropriate. Written reports of excess emissions or exceedances of process or control system parameters shall include all the information required in paragraphs (c)(5) through (c)(13) of this section, in §§ 63.8(c)(7) and 63.8(c)(8), and in the relevant standard, and they shall contain the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no excess emissions or exceedances of a parameter have occurred, or a CMS has not been inoperative, out of control, repaired, or adjusted, such information shall be stated in the report.

(vi) Summary report. As required under paragraphs (e)(3)(vii) and (e)(3)(viii) of this section, one summary report shall be submitted for the hazardous air pollutants monitored at each affected source (unless the relevant standard specifies that more than one summary report is required, e.g., one summary report for each hazardous air pollutant monitored). The summary report shall be entitled “Summary Report -- Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance” and shall contain the following information:

(A) The company name and address of the affected source;

(B) An identification of each hazardous air pollutant monitored at the affected source;

(C) The beginning and ending dates of the reporting period;

(D) A brief description of the process units;

(E) The emission and operating parameter limitations specified in the relevant standard(s);

(F) The monitoring equipment manufacturer(s) and model number(s);

(G) The date of the latest CMS certification or audit;

(H) The total operating time of the affected source during the reporting period;

(I) An emission data summary (or similar summary if the owner or operator monitors control system parameters), including the total duration of excess emissions during the reporting period (recorded in minutes for opacity and hours for gases), the total duration of excess emissions expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control equipment problems, process problems, other known causes, and other unknown causes;

(J) A CMS performance summary (or similar summary if the owner or operator monitors control system parameters), including the total CMS downtime during the reporting period (recorded in minutes for opacity and hours for gases), the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, quality assurance/quality control calibrations, other known causes, and other unknown causes;

(K) A description of any changes in CMS, processes, or controls since the last reporting period;

(L) The name, title, and signature of the responsible official who is certifying the accuracy of the report; and

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(M) The date of the report.

(vii) If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator.

(viii) If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total CMS downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, both the summary report and the excess emissions and continuous monitoring system performance report shall be submitted.

(4) Reporting continuous opacity monitoring system data produced during a performance test. The owner or operator of an affected source required to use a COMS shall record the monitoring data produced during a performance test required under § 63.7 and shall furnish the Administrator a written report of the monitoring results. The report of COMS data shall be submitted simultaneously with the report of the performance test results required in paragraph (d)(2) of this section.

(f) [Paragraph (f) of § 63.10 is printed in a separate condition under Recordkeeping Requirements in this section of the permit.]

[59 FR 12430, Mar. 16, 1994, as amended at 64 FR 7468, Feb. 12, 1999; 67 FR 16604, Apr. 5, 2002; 68 FR 32601, May 30, 2003; 69 FR 21752, Apr. 22, 2004; 71 FR 20455, Apr. 20, 2006; 85 FR 73886, Nov. 19, 2020]

 # 016 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.366]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Reporting requirements.

(a) General requirements. The owner or operator of an affected source subject to the emissions standards in § 63.362 must fulfill all reporting requirements in § 63.10(a), (d), (e), and (f), according to the applicability in table 6 to this subpart. These reports will be made to the Administrator at the appropriate address identified in § 63.13 or submitted electronically.

(b) Initial compliance report submission. You must submit an initial compliance report that provides summary, monitoring system performance, and deviation information to the Administrator on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for one year, whichever date is later, to the EPA via CEDRI, which can be accessed through the EPA's Central Data Exchange (CDX) (https://cdx.epa.gov/). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (https://www.epa.gov/electronic-reporting-air-emissions/cedri) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the extensible markup language (XML) schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, along with information from any calibration tests in which the monitoring equipment is not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the

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summary report shall include:

(1) The following information:

(i) Date that facility commenced construction or reconstruction;

(ii) Hours of commercial sterilization operation over the previous 12 months; and

(iii) Monthly EtO use, in tons, over the previous 36 months.

(iv) If you are electing to determine the mass of EtO sent to the control device from the SCV(s) via the procedure in § 63.364(f)(1)(i), you must report the daily EtO use from each applicable chamber for the previous 7 months.

(v) An indication if you are required to comply with one or more combined emission stream limitations. If so, indicate the affected sources that are included in each combined emission stream limitation.

(vi) An indication if you are electing to comply with a site-wide emission limit. If you are electing to comply with a site-wide emission limit, report the daily EtO use over the previous 7 months.

(2) If your sterilization facility is demonstrating continuous compliance through periodic performance testing, you must report the following:

(i) Control system ID;

(ii) Control device ID;

(iii) Control device type; and

(iv) Recirculation tank ID if an acid-water scrubber is used to meet the emission standard and you elect to comply with the maximum scrubber liquor height limit;

(3) You must report the following for each sterilization chamber at your facility:

(i) The sterilization chamber ID;

(ii) The ID of the control system that the SCV was routed to, if applicable;

(iii) The portion of SCV exhaust that was routed to the control system, if applicable;

(iv) The ID of the EtO CEMS that was used to monitor SCV emissions, if applicable;

(v) The portion of SCV exhaust that was monitored with the EtO CEMS, if applicable;

(vi) The ID of the control system that the CEV was routed to, if applicable;

(vii) The portion of CEV exhaust that was routed to the control system, if applicable;

(viii) The ID of the EtO CEMS that was used to monitor CEV emissions, if applicable;

(ix) The portion of CEV exhaust that was monitored with the EtO CEMS, if applicable;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the following for each room where there is the potential for EtO emissions:

(i) Room ID;

(ii) Documentation of emissions occurring within the room, including aeration, EtO storage, EtO dispensing, pre-

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aeration handling of sterilized material, and post-aeration handling of sterilized material;

(iii) The ID of the control system that the room air was routed to, if applicable;

(iv) The portion of room air that was routed to the control system, if applicable;

(v) The ID of the EtO CEMS that was used to monitor room air emissions, if applicable;

(vi) The portion of room air that was monitored with the EtO CEMS, if applicable;

(5) If an EtO CEMS was used to demonstrate continuous compliance with an emission standard for more than 30-operating days, you must report the following:

(i) The information specified in section 11 of appendix A to this subpart.

(ii) The affected sources that are included in each inlet that is being monitored with EtO CEMS;

(iii) The IDs of each inlet(s) to and outlet(s) from each control system.

(iv) The daily sum of EtO for each inlet, along with 30-operating day rolling sums.

(v) The daily sum of EtO emissions from each outlet of the control system, along with 30-operating day rolling sums.

(vi) For each day, calculate and report the daily mass emission limit that the control system must achieve based on the previous 30 days of data. For control systems with multiple emission streams, and complying with a combined emission stream limitation in § 63.362(i) or a SWEL in § 63.362(j), report the daily 30-operating day mass emission limit as determined in accordance with CES in § 63.362(i)(1)(i) and (i)(2)(i) or with § 63.362(j)(1)(i) and (j)(2)(i), as applicable.

(vii) For each day, the mass of EtO emitted from the control system over the previous 30 operating days.

(6) If any portion of your facility is required to be operated with PTE, you must report the following:

(i) If you are choosing to demonstrate continuous compliance through the use of volumetric flow rate monitoring, you must report the 3-hr rolling average, rolled hourly volumetric flow from each outlet where air from the PTE is sent, in cubic feet per second.

(ii) If you are choosing to demonstrate continuous compliance through use of differential pressure monitoring, you must report the 3-hr rolling average, rolled hourly pressure differential reading, in inches water.

(7) If you are complying with the requirement to follow the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.362(h).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you must report the following for each room where there are Group 2 room air emissions:

(i) Room ID;

(ii) Number of room air changes per hour;

(iii) Room temperature, in degrees Celsius; and

(iv) EtO concentration, in ppmv dry basis (ppbvd).

(9) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and EtO use is less than 4 tpy, you are not required to report the information in paragraph (b)(8) of this section if you meet the following requirements:

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(i) You are complying with the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door; and

(ii) The requirements of § 63.363 are met.

(10) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, the cause and duration of each deviation. For each deviation the report must include a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(c) Quarterly compliance report submission. You must submit compliance reports that provide summary, monitoring system performance, and deviation information to the Administrator within 30 days following the end of each calendar quarter. Beginning on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for 1 year, whichever date is later, submit all subsequent reports to the EPA via CEDRI, which can be accessed through the EPA's CDX (https://cdx.epa.gov/). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (https://www.epa.gov/electronic-reporting-air-emissions/cedri) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the XML schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, and information from any calibration tests in which the monitoring equipment is not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the summary report shall include:

(1) The information listed in paragraphs (b)(1)(i) through (vi) of this section, with the exception that monthly EtO use, in tons, only needs reported for the previous 12 months;

(2) If your sterilization facility is demonstrating continuous compliance through periodic performance testing, you must report the ID for any control system that has not operated since the end of the period covered by the previous compliance report. If a control system has commenced operation since end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(2)(i) through (iv) of this section has changed for a control system that was included in the previous compliance report, you must report the information in paragraphs (b)(2)(i) through (iv) of this section for those control systems;

(3) You must report the ID for any sterilization chamber that has not operated since then end of the period covered by the previous compliance report. If a sterilization chamber has commenced operation since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(3)(i) through (ix) of this section has changed for a sterilization chamber that was included in the previous compliance report, you must report the information in paragraphs (b)(3)(i) through (ix) of this section for those sterilization chambers;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the ID for any room where there has not been the potential for EtO emissions since the end of the period covered by the previous compliance report. If a room has had the potential for EtO emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(4)(i) through (vi) of this section has changed for a room where there is

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the potential for EtO emissions that was included in the previous compliance report, you must report the information in paragraphs (b)(4)(i) through (vi) of this section for those rooms;

(5) If an EtO CEMS was used to demonstrate continuous compliance, you must report the information specified in paragraphs (b)(5)(i) through (vi) of this section.

(6) If any portion of your facility is required to be operated with PTE, you must report the information listed in paragraph (b)(6) of this section.

(7) If you are complying with the requirement to follow the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.362(h).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you must report the ID for any room where Group 2 room air emissions have ceased since end of the period covered by the previous compliance report. If a room has had Group 2 room air emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(8)(i) through (iv) of this section has changed for a room where there are Group 2 room air emissions that were included in the previous compliance report, you must report the information in paragraphs (b)(8)(i) through (iv) of this section for each room where there are Group 2 room air emissions.

(9) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you are not required to report the information in paragraph (c)(8) of this section if you meet the requirements in paragraph (b)(9) of this section.

(10) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, the cause, and duration of each deviation. For each deviation, the report must include a list of the affected sources or equipment, the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(d) Construction and reconstruction application. [Not applicable.]

(e) Notification requirements. [The requirement for initial notification was met with the plan approval application processes for these sources.]

(f) [Refer to regulation for requirements of Performance Test Submission; Section 63.366(f) is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O/section-63.366]

(g) Performance evaluation submission. Beginning on June 4, 2024, within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (g)(1) through (3) of this section.

(1) Performance evaluations of CEMS measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation. Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) Performance evaluations of CEMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation. The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) CBI. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (g)(1)(i) or (ii) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The CBI file must be generated using the EPA's ERT or an alternate electronic file consistent

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with the XML schema listed on the EPA's ERT website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (g)(1)(i) and (ii) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(h) Extensions for CDX/CEDRI outages. If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with that reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (h)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(i) Extensions for force majeure events. If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of force majeure for failure to timely comply with that reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (i)(1) through (5) of this section.

(1) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (e.g., hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (e.g., large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

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(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

[Source: 89 FR 24172, Apr. 5, 2024]

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

VII. ADDITIONAL REQUIREMENTS.

 # 017 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.2]
Subpart A - General Provisions
Definitions.

[Definitions specific to Subpart O from § 63.361 are printed in a separate condition in this section of the permit.]

[Selected definitions from 40 CFR § 63.2 are printed below. Refer to the regulation for remaining definitions. A copy of the regulation is available at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.2]

Construction means the on-site fabrication, erection, or installation of an affected source. Construction does not include the removal of all equipment comprising an affected source from an existing location and reinstallation of such equipment at a new location. The owner or operator of an existing affected source that is relocated may elect not to reinstall minor ancillary equipment including, but not limited to, piping, ductwork, and valves. However, removal and reinstallation of an affected source will be construed as reconstruction if it satisfies the criteria for reconstruction as defined in this section. The costs of replacing minor ancillary equipment must be considered in determining whether the existing affected source is reconstructed.

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable standard to be exceeded. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.

Reconstruction, unless otherwise defined in a relevant standard, means the replacement of components of an affected or a previously nonaffected source to such an extent that:

(1) The fixed capital cost of the new components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source; and

(2) It is technologically and economically feasible for the reconstructed source to meet the relevant standard(s) established by the Administrator (or a State) pursuant to section 112 of the Act. Upon reconstruction, an affected source, or a stationary source that becomes an affected source, is subject to relevant standards for new sources, including compliance dates, irrespective of any change in emissions of hazardous air pollutants from that source.

[59 FR 12430, Mar. 16, 1994, as amended at 67 FR 16596, Apr. 5, 2002; 68 FR 32600, May 30, 2003; 69 FR 21752, Apr. 22, 2004; 72 FR 27443, May 16, 2007; 85 FR 63418, Oct. 7, 2020; 85 FR 73885, Nov. 19, 2020]

 # 018 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.3]
Subpart A - General Provisions
Units and abbreviations.

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[The units and abbreviations of § 63.3 of Subpart A are available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.3]

 # 019 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.360]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Applicability.

(a) You are subject to the requirements of this subpart if you own or operate a sterilization facility that has an affected source specified in paragraph (b) of this section. Table 6 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

(b) The affected sources subject to this subpart are:

(1) Each SCV at any sterilization facility;

(2) Each ARV at any sterilization facility;

(3) Each CEV at any sterilization facility;

(4) The collection of all Group 1 room air emissions at any sterilization facility; and

(5) The collection of all Group 2 room air emissions at any sterilization facility.

(c) An existing affected source is one the construction or reconstruction of which was commenced on or before April 13, 2023.

(d) - (i) [Not applicable]

(j) You must comply with the provisions of this subpart no later than the dates specified in paragraphs (j)(1) through (17) of this section:

(1) If you own or operate an existing affected source, you must comply with the applicable provisions of this subpart no later than the dates specified in tables 1 through 5 to this subpart, as applicable.

(2) - (3) [Not applicable]

(4) If existing SCV, ARV, or CEV or parts of an existing collection of Group 1 or Group 2 room air emissions are replaced such that the replacement meets the definition of reconstruction in § 63.2 and the reconstruction commenced after April 13, 2023, then the existing affected source becomes a new affected source. The reconstructed source must comply with the requirements for a new affected source upon initial startup of the reconstructed source or by April 5, 2024, whichever is later.

(5) All existing SCVs at facilities that meet or exceed 1 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(6) - (7) [Not applicable]

(8) All existing ARVs at facilities that meet or exceed 10 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(9) - (12) [Not applicable]

(13) All existing collections of Group 1 room air emissions at facilities that do not exceed 40 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the collection of Group 1 room air emissions becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

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(14) - (15) [Not applicable]

(16) All existing collections of Group 2 room air emissions at facilities that do not exceed 4 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the collection of Group 2 room air emissions becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(17) [Not applicable]

[Source: 89 FR 24172, Apr. 5, 2024; https://www.govinfo.gov/content/pkg/FR-2024-04-05/pdf/2024-05905.pdf]

 # 020 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.361]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Definitions.

[The definitions of Subpart O are printed below. Additional definitions from Subpart A also apply. Those definitions from § 63.2 of Subpart A are available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.2]

[The units and abbreviations of § 63.3 of Subpart A are available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.3]

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§ 63.2 and 63.3, or in this section. For the purposes of this subpart, if the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section.

Acid-water scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to absorb and neutralize acid gases.

Aeration means, for the purposes of this rule, exposing sterilized material at elevated temperatures to drive EtO out of the material.

Aeration room means any vessel or room that is used to facilitate off-gassing of EtO at a sterilization facility. If a facility uses only combination sterilization units, for the purposes of this rule, there are no aeration rooms at the facility.

Aeration room vent (ARV) means the point(s) through which the evacuation of EtO-laden air from an aeration room occurs. For combination sterilization units, there is no ARV.

Catalytic oxidizer means a combustion device that uses a solid-phase catalyst to lower the temperature required to promote the oxidization and achieve adequate reduction of volatile organic compounds, as well as volatile hazardous air pollutants.

Chamber exhaust vent (CEV) means the point(s) through which EtO-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes. This may also be referred to as a “backvent” (or “back vent”). For combination sterilization units, there is no CEV.

Combination sterilization unit means any enclosed vessel in which both sterilization and aeration of the same product occur within the same vessel, i.e., the vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by aeration of ethylene oxide.

Combined emission stream means when the emissions from more than one emission source are routed together using common ductwork prior to the control system.

Continuous monitoring system (CMS) means, for the purposes of this rule, the equipment necessary to continuously samples the regulated parameter specified in § 63.364 or § 63.365 of this subpart without interruption, evaluates the detector response at least once every 15 seconds, and computes and records the average value at least every 60 seconds, except during allowable periods of calibration and except as defined otherwise by the continuous emission monitoring system (CEMS) performance specifications (PS) in appendix B to part 60 of this chapter.

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Control System Residence Time means the time elapsed from entrance of flow into the control system until gaseous materials exit the control system. For control systems with multiple exhaust streams whereby the residence time may vary for the streams, the residence time for purposes of complying with this subpart means the longest residence time for any exhaust stream in use. If a peak shaver is used, it is part of the control system, and its residence time must be considered.

Deviation means any instance in which an owner or operator of an affected source, subject to this subpart:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation, parameter value, or best management practice; or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart or that is included in the operating permit for any facility required to obtain such a permit.

EtO dispensing means charging a sterilization chamber or chambers with EtO from non-cartridge storage media (e.g., drums, cylinders) via the use of piping, lines, and other equipment. This includes injection rooms and post-injection handling of containers.

Gas/solid reactor means an add-on air pollution control device that uses a dry, solid-phase system to chemically convert EtO so that it becomes bound to the solid packing. This may also be referred to as a “dry bed reactor” or a “dry bed scrubber.”

Group 1 room air emissions mean emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material.

Group 2 room air emissions mean emissions from post-aeration handling of sterilized material.

Indoor EtO storage means the storage of EtO within non-cartridge media (e.g., drums, cylinders) inside a sterilization building.

Initial startup means the moment when an affected source subject to an emissions standard in § 63.362 first begins operation.

Injection room means any room where EtO is injected into containers (e.g., bags, pouches) that are filled with product to be sterilized.

Maximum ethylene glycol concentration means the concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum gas/solid reactor pressure drop means the pressure drop of the gas/solid reactor established during a performance test when the gas/solid reactor achieves the appropriate control of EtO emissions.

Maximum liquor tank level means the level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum scrubber liquor pH means the pH of the acid-water scrubber liquor established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Minimum stack volumetric flow rate means the stack volumetric flow rate corrected established during a compliance demonstration when permanent total enclosure (PTE) requirements are met.

Minimum temperature at the inlet to the catalyst bed means the temperature at the inlet to the catalyst bed established during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum temperature difference across the catalyst bed means the temperature difference across the catalyst bed established during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

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Minimum temperature in or immediately downstream of the firebox means the temperature in or immediately downstream of the firebox established during a performance test when the thermal oxidizer achieves the appropriate control of EtO emissions.

Natural draft opening (NDO) means any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct in which a fan is installed.

Operating day means any day that a facility is engaged in a sterilization operation.

Peak shaver means a device that is used to reduce high EtO concentrations within an exhaust stream such that the downstream control device is not overwhelmed.

Permanent total enclosure (PTE) means a permanently installed enclosure that meets the criteria of Method 204 of appendix M, 40 CFR part 51 for a PTE. A PTE completely surrounds a source of emissions such that all EtO emissions are captured, contained, and directed to a control system or to an outlet(s).

Post-aeration handling of sterilized material means the storage and transportation of material that has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility. Post-aeration handling of sterilized material ends when that vehicle is closed for the final time before leaving the facility. This definition does not include handling of material that has been both previously sterilized and not removed from aeration following re-sterilization.

Post-injection handling of containers means the storage and transportation of containers (e.g., bags, pouches) that have been injected with EtO but have not been placed in a sterilization chamber.

Pre-aeration handling of sterilized material means the storage and transportation of material that has been removed from a sterilization chamber but has not been placed in an aeration room. If only combination sterilization units are used, and if material is not moved out of the vessel between sterilization and aeration, then emissions from this source do not exist. This does not include post-injection handling of containers.

Rolling sum means the weighted sum of all data, meeting QA/QC requirements or otherwise normalized, collected during the applicable rolling time period. The period of a rolling sum stipulates the frequency of data collection, summing, and reporting. As an example, to demonstrate compliance with a rolling 30-operating day sum emission reduction standard determined from hourly data, you must

(1) determine the total mass of ethylene oxide prior to control and following control for each operating day;

(2) then sum the current daily total mass prior to control with the previous 29 operating day total mass values and repeat the same process for the current daily total mass following control; and

(3) then divide the 30-operating day total mass emissions following control by the 30-operating day total mass prior to control and subtract the resulting value from one to obtain the 30-operating day emission reduction achieved.

Single-item sterilization means a process in which one or more items are placed in a pouch, EtO is injected into the pouch, and the sealed pouch is placed in a vessel to allow sterilization to occur.

Sterilization chamber means any enclosed vessel or room that is filled with EtO gas, or an EtO/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility. This does not include injection rooms.

Sterilization chamber vent (SCV) means the point (prior to the vacuum pump) through which the evacuation of EtO from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where EtO is used in the sterilization or fumigation of materials, including but not limited to facilities that engage in single-item sterilization.

Sterilization operation means any time when EtO is removed from the sterilization chamber through the SCV or the chamber exhaust vent, when EtO is removed from the aeration room through the aeration room vent, when EtO is stored within the building, when EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or

SECTION E. Source Group Restrictions.

when materials are handled post-aeration.

Thermal oxidizer means all combustion devices except flares.

Vacuum pump operation means the operation of vacuum pumps, excluding dry seal vacuum pumps, for the purpose of removing EtO from a sterilization chamber.

[Source: 89 FR 24172, Apr. 5, 2024]

 # 021 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.368]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Implementation and enforcement.

(a) This subpart can be implemented and enforced by the U.S. EPA or a delegated authority such as the applicable State, local, or Tribal agency. If the U.S. EPA Administrator has delegated authority to a State, local, or Tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. Contact the applicable U.S. EPA Regional Office to find out whether implementation and enforcement of this subpart are delegated to a State, local, or Tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or Tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of U.S. EPA and cannot be transferred to the State, local, or Tribal agency.

(c) The authorities that cannot be delegated to State, local, or Tribal agencies are as specified in paragraphs (c)(1) through (5) of this section.

(1) Approval of alternatives to the requirements in §§ 63.360 and 63.362.

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f), as defined in § 63.90, and as required in this subpart.

(3) Approval of major alternatives to monitoring under § 63.8(f), as defined in § 63.90, and as required in this subpart.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f), as defined in § 63.90, and as required in this subpart.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

[Source: 89 FR 24172, Apr. 5, 2024]

 # 022 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6]

Subpart A--General Provisions

Compliance with standards and maintenance requirements.

[From § 63.6(i). Refer to Table 6 of 40 CFR Part 63 Subpart O and refer to regulation 40 CFR § 63.6 for remaining applicable text from § 63.6. A copy of § 63.6 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.6]

(i) Extension of compliance with emission standards.

(1) Until an extension of compliance has been granted by the Administrator (or a State with an approved permit program) under this paragraph, the owner or operator of an affected source subject to the requirements of this section shall comply with all applicable requirements of this part.

(2) Extension of compliance for early reductions and other reductions —

(i) Early reductions. Pursuant to section 112(i)(5) of the Act, if the owner or operator of an existing source demonstrates that the source has achieved a reduction in emissions of hazardous air pollutants in accordance with the provisions of subpart D of this part, the Administrator (or the State with an approved permit program) will grant the owner or operator an extension of compliance with specific requirements of this part, as specified in subpart D.

(ii) Other reductions. Pursuant to section 112(i)(6) of the Act, if the owner or operator of an existing source has installed best available control technology (BACT) (as defined in section 169(3) of the Act) or technology required to meet a

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lowest achievable emission rate (LAER) (as defined in section 171 of the Act) prior to the promulgation of an emission standard in this part applicable to such source and the same pollutant (or stream of pollutants) controlled pursuant to the BACT or LAER installation, the Administrator will grant the owner or operator an extension of compliance with such emission standard that will apply until the date 5 years after the date on which such installation was achieved, as determined by the Administrator.

(3) Request for extension of compliance. Paragraphs (i)(4) through (i)(7) of this section concern requests for an extension of compliance with a relevant standard under this part (except requests for an extension of compliance under paragraph (i)(2)(i) of this section will be handled through procedures specified in subpart D of this part).

(4)

(i)

(A) The owner or operator of an existing source who is unable to comply with a relevant standard established under this part pursuant to section 112(d) of the Act may request that the Administrator (or a State, when the State has an approved part 70 permit program and the source is required to obtain a part 70 permit under that program, or a State, when the State has been delegated the authority to implement and enforce the emission standard for that source) grant an extension allowing the source up to 1 additional year to comply with the standard, if such additional period is necessary for the installation of controls. An additional extension of up to 3 years may be added for mining waste operations, if the 1-year extension of compliance is insufficient to dry and cover mining waste in order to reduce emissions of any hazardous air pollutant. The owner or operator of an affected source who has requested an extension of compliance under this paragraph and who is otherwise required to obtain a title V permit shall apply for such permit or apply to have the source's title V permit revised to incorporate the conditions of the extension of compliance. The conditions of an extension of compliance granted under this paragraph will be incorporated into the affected source's title V permit according to the provisions of part 70 or Federal title V regulations in this chapter (42 U.S.C. 7661), whichever are applicable.

(B) Any request under this paragraph for an extension of compliance with a relevant standard must be submitted in writing to the appropriate authority no later than 120 days prior to the affected source's compliance date (as specified in paragraphs (b) and (c) of this section), except as provided for in paragraph (i)(4)(i)(C) of this section. Nonfrivolous requests submitted under this paragraph will stay the applicability of the rule as to the emission points in question until such time as the request is granted or denied. A denial will be effective as of the date of denial. Emission standards established under this part may specify alternative dates for the submittal of requests for an extension of compliance if alternatives are appropriate for the source categories affected by those standards.

(C) An owner or operator may submit a compliance extension request after the date specified in paragraph (i)(4)(i)(B) of this section provided the need for the compliance extension arose after that date, and before the otherwise applicable compliance date and the need arose due to circumstances beyond reasonable control of the owner or operator. This request must include, in addition to the information required in paragraph (i)(6)(i) of this section, a statement of the reasons additional time is needed and the date when the owner or operator first learned of the problems. Nonfrivolous requests submitted under this paragraph will stay the applicability of the rule as to the emission points in question until such time as the request is granted or denied. A denial will be effective as of the original compliance date.

(ii) The owner or operator of an existing source unable to comply with a relevant standard established under this part pursuant to section 112(f) of the Act may request that the Administrator grant an extension allowing the source up to 2 years after the standard's effective date to comply with the standard. The Administrator may grant such an extension if he/she finds that such additional period is necessary for the installation of controls and that steps will be taken during the period of the extension to assure that the health of persons will be protected from imminent endangerment. Any request for an extension of compliance with a relevant standard under this paragraph must be submitted in writing to the Administrator not later than 90 calendar days after the effective date of the relevant standard.

(5) The owner or operator of an existing source that has installed BACT or technology required to meet LAER [as specified in paragraph (i)(2)(ii) of this section] prior to the promulgation of a relevant emission standard in this part may request that the Administrator grant an extension allowing the source 5 years from the date on which such installation was achieved, as determined by the Administrator, to comply with the standard. Any request for an extension of compliance with a relevant standard under this paragraph shall be submitted in writing to the Administrator not later than 120 days after the promulgation date of the standard. The Administrator may grant such an extension if he or she finds that the installation of BACT or technology to meet LAER controls the same pollutant (or stream of pollutants) that would be controlled at that source by the relevant emission standard.

(6)

(i) The request for a compliance extension under paragraph (i)(4) of this section shall include the following information:

(A) A description of the controls to be installed to comply with the standard;

(B) A compliance schedule, including the date by which each step toward compliance will be reached. At a minimum, the list of dates shall include:

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(1) The date by which on-site construction, installation of emission control equipment, or a process change is planned to be initiated; and

(2) The date by which final compliance is to be achieved.

(3) The date by which on-site construction, installation of emission control equipment, or a process change is to be completed; and

(4) The date by which final compliance is to be achieved;

(C)-(D) [Paragraphs (C)-(D) of § 63.6(i)(6)(i) are blank in the eCFR.]

(ii) The request for a compliance extension under paragraph (i)(5) of this section shall include all information needed to demonstrate to the Administrator's satisfaction that the installation of BACT or technology to meet LAER controls the same pollutant (or stream of pollutants) that would be controlled at that source by the relevant emission standard.

(7) Advice on requesting an extension of compliance may be obtained from the Administrator (or the State with an approved permit program).

(8) Approval of request for extension of compliance. Paragraphs (i)(9) through (i)(14) of this section concern approval of an extension of compliance requested under paragraphs (i)(4) through (i)(6) of this section.

(9) Based on the information provided in any request made under paragraphs (i)(4) through (i)(6) of this section, or other information, the Administrator (or the State with an approved permit program) may grant an extension of compliance with an emission standard, as specified in paragraphs (i)(4) and (i)(5) of this section.

(10) The extension will be in writing and will --

(i) Identify each affected source covered by the extension;

(ii) Specify the termination date of the extension;

(iii) Specify the dates by which steps toward compliance are to be taken, if appropriate;

(iv) Specify other applicable requirements to which the compliance extension applies (e.g., performance tests); and

(v)

(A) Under paragraph (i)(4), specify any additional conditions that the Administrator (or the State) deems necessary to assure installation of the necessary controls and protection of the health of persons during the extension period; or

(B) Under paragraph (i)(5), specify any additional conditions that the Administrator deems necessary to assure the proper operation and maintenance of the installed controls during the extension period.

(11) The owner or operator of an existing source that has been granted an extension of compliance under paragraph (i)(10) of this section may be required to submit to the Administrator (or the State with an approved permit program) progress reports indicating whether the steps toward compliance outlined in the compliance schedule have been reached. The contents of the progress reports and the dates by which they shall be submitted will be specified in the written extension of compliance granted under paragraph (i)(10) of this section.

(12)

(i) The Administrator (or the State with an approved permit program) will notify the owner or operator in writing of approval or intention to deny approval of a request for an extension of compliance within 30 calendar days after receipt of sufficient information to evaluate a request submitted under paragraph (i)(4)(i) or (i)(5) of this section. The Administrator (or the State) will notify the owner or operator in writing of the status of his/her application, that is, whether the application contains sufficient information to make a determination, within 30 calendar days after receipt of the original application and within 30 calendar days after receipt of any supplementary information that is submitted. The 30-day approval or denial period will begin after the owner or operator has been notified in writing that his/her application is complete.

(ii) When notifying the owner or operator that his/her application is not complete, the Administrator will specify the information needed to complete the application and provide notice of opportunity for the applicant to present, in writing, within 30 calendar days after he/she is notified of the incomplete application, additional information or arguments to the Administrator to enable further action on the application.

(iii) Before denying any request for an extension of compliance, the Administrator (or the State with an approved permit program) will notify the owner or operator in writing of the Administrator's (or the State's) intention to issue the denial, together with—

(A) Notice of the information and findings on which the intended denial is based; and

(B) Notice of opportunity for the owner or operator to present in writing, within 15 calendar days after he/she is notified of the intended denial, additional information or arguments to the Administrator (or the State) before further action on the request.

(iv) The Administrator's final determination to deny any request for an extension will be in writing and will set forth the specific grounds on which the denial is based. The final determination will be made within 30 calendar days after presentation of additional information or argument (if the application is complete), or within 30 calendar days after the final date specified for the presentation if no presentation is made.

(13)

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(i) The Administrator will notify the owner or operator in writing of approval or intention to deny approval of a request for an extension of compliance within 30 calendar days after receipt of sufficient information to evaluate a request submitted under paragraph (i)(4)(ii) of this section. The 30-day approval or denial period will begin after the owner or operator has been notified in writing that his/her application is complete. The Administrator (or the State) will notify the owner or operator in writing of the status of his/her application, that is, whether the application contains sufficient information to make a determination, within 15 calendar days after receipt of the original application and within 15 calendar days after receipt of any supplementary information that is submitted.

(ii) When notifying the owner or operator that his/her application is not complete, the Administrator will specify the information needed to complete the application and provide notice of opportunity for the applicant to present, in writing, within 15 calendar days after he/she is notified of the incomplete application, additional information or arguments to the Administrator to enable further action on the application.

(iii) Before denying any request for an extension of compliance, the Administrator will notify the owner or operator in writing of the Administrator's intention to issue the denial, together with—

(A) Notice of the information and findings on which the intended denial is based; and

(B) Notice of opportunity for the owner or operator to present in writing, within 15 calendar days after he/she is notified of the intended denial, additional information or arguments to the Administrator before further action on the request.

(iv) A final determination to deny any request for an extension will be in writing and will set forth the specific grounds on which the denial is based. The final determination will be made within 30 calendar days after presentation of additional information or argument (if the application is complete), or within 30 calendar days after the final date specified for the presentation if no presentation is made.

(14) The Administrator (or the State with an approved permit program) may terminate an extension of compliance at an earlier date than specified if any specification under paragraph (i)(10)(iii) or (iv) of this section is not met. Upon a determination to terminate, the Administrator will notify, in writing, the owner or operator of the Administrator's determination to terminate, together with:

(i) Notice of the reason for termination; and

(ii) Notice of opportunity for the owner or operator to present in writing, within 15 calendar days after he/she is notified of the determination to terminate, additional information or arguments to the Administrator before further action on the termination.

(iii) A final determination to terminate an extension of compliance will be in writing and will set forth the specific grounds on which the termination is based. The final determination will be made within 30 calendar days after presentation of additional information or arguments, or within 30 calendar days after the final date specified for the presentation if no presentation is made.

(15) [Reserved]

(16) The granting of an extension under this section shall not abrogate the Administrator's authority under section 114 of the Act.

[59 FR 12430, Mar. 16, 1994, as amended at 67 FR 16599, Apr. 5, 2002; 68 FR 32600, May 30, 2003; 71 FR 20454, Apr. 20, 2006; 85 FR 73885, Nov. 19, 2020; 86 FR 13821, Mar. 11, 2021]

 # 023 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.9]

Subpart A--General Provisions

Notification requirements.

[From 40 CFR 63.9(c). Refer to Table 6 of 40 CFR Part 63 Subpart O and to regulation § 63.9 for remaining applicable provisions of 40 CFR § 63.9. A copy of § 63.9 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-A/section-63.9]

(c) Request for extension of compliance. If the owner or operator of an affected source cannot comply with a relevant standard by the applicable compliance date for that source, or if the owner or operator has installed BACT or technology to meet LAER consistent with § 63.6(i)(5) of this subpart, he/she may submit to the Administrator (or the State with an approved permit program) a request for an extension of compliance as specified in § 63.6(i)(4) through § 63.6(i)(6).

[59 FR 12430, Mar. 16, 1994, as amended at 64 FR 7468, Feb. 12, 1999; 67 FR 16604, Apr. 5, 2002; 68 FR 32601, May 30, 2003; 85 FR 73885, Nov. 19, 2020]

 # 024 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR Table 6 to Subpart O of Part 63]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities

Applicability of General Provisions to This Subpart

[Table 6 is available at this web address: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-

SECTION E. Source Group Restrictions.

O/appendix-Table%206%20to%20Subpart%20O%20of%20Part%2063]

As specified in § 63.360, the parts of the General Provisions that apply to you are shown in Table 6.

SECTION F. Alternative Operation Requirements.

No Alternative Operations exist for this State Only facility.

SECTION G. Emission Restriction Summary.

Source Id	Source Description
101	4 ETO STERILIZER CHAMBERS (SCV)

Emission Limit			Pollutant
0.100	Lbs/Hr	[From plan approval 25-332-001A]	Ethylene Oxide
0.400	Tons/Yr	[From plan approval 25-332-001A]	Ethylene Oxide
0.040	gr/DRY FT3	[25 Pa Code 123.13]	TSP

Source Id	Source Description
102	2 AERATION ROOMS (ARV)

Emission Limit			Pollutant
1.000	PPMV	[From plan approval PA 25-918A]	Ethylene Oxide
0.040	gr/DRY FT3	[25 Pa Code 123.13]	TSP

Source Id	Source Description
103	ETO STERILIZATION CHAMBER EXHAUST VENTS (CEV)

Emission Limit			Pollutant
0.040	gr/DRY FT3	[25 Pa Code 123.13]	TSP

Source Id	Source Description
104	GROUP 1 ROOMS (ETO STORAGE&DISPENSING, VACUUM, PRE-AERATION)

Emission Limit			Pollutant
0.040	gr/DRY FT3	[25 Pa Code 123.13]	TSP

Source Id	Source Description
105	GROUP 2 ROOMS (EMISSIONS FROM POST-AERATION HANDLING)

Emission Limit			Pollutant
0.040	gr/DRY FT3	[25 Pa Code 123.13]	TSP

Site Emission Restriction Summary

Emission Limit	Pollutant

SECTION H. Miscellaneous.

I. GENERAL INFORMATION

(a) This facility is located at 2205 East 33rd Street, Erie, PA, 16510.

This facility is a NATURAL MINOR with respect to Potential Emissions of regulated air pollutants.

The following eFACTS ID's are assigned to this facility for this permit issuance:
Permit number: 25-00918
eFACTS Site Name: Lynx Med Pennsylvania, LLC
APS ID: 1160563
Master Auth ID: 355670
Client ID: 399322
Site ID: 482989
Primary Facility (PF) ID: 522825

(b) The Capacity/Throughput numbers listed in Section A, the Site Inventory List, and provided in Section D of this permit for individual sources are for informational purposes only and are not to be considered enforceable limits. The actual enforceable emission and operating limits for each source, with the correct number of significant digits, are listed in Sections C, D, and E of this permit. The Emission Restriction Summary in Section G of this permit is for information purposes only and is not to be used to establish enforceable limits.

(c) Abbreviations used in this permit:

Schematics:
FML: Fuel material location
CU: Combustion Unit
PROC: Process
CNTL: Control device
STAC: Stack. The stack can represent either the emission point or fugitive emissions in a permit map.

Pollutants:
CO: Carbon Monoxide
NOx: Nitrogen Oxides
SOx: Sulfur Oxides
TSP: Total Suspended Particulate (includes both filterable and condensable)
PM10: Particulate Matter less than 10 microns
PM2.5: Particulate Matter less than 2.5 microns
VOC: Volatile Organic Compounds
HAP: Hazardous Air Pollutant
EtO: Ethylene Oxide, a HAP, also abbreviated as EO.

Source ID: Department assigned ID number for the source
Source Name: Department assigned name for the source
Capacity/Throughput: The maximum rated capacity or throughput for the source. The maximum rated capacity or throughput is not considered an enforceable limit. Enforceable limits are contained within the conditions of the permit.
Fuel/Material: The fuel/material assigned to SCC for the source

AIMS: Air Information Management System -- the DEP electronic database for permitting and emission reports
ARV: Aeration room vent
CEMS: Continuous emissions monitoring system
CEV: Chamber exhaust vent
CFR: Code of Federal Regulations
CMS: Continuous Monitoring System
Department: Pennsylvania Department of Environmental Protection (the DEP)
eFacts: Environmental Facility Application Compliance Tracking System -- the DEP electronic database for inspection reports
EtO: Ethylene Oxide.
NESHAP: National Emission Standards for Hazardous Air Pollutants (40 CFR Part 63)
NSPS: New Source Performance Standards (40 CFR Part 60)
NWRO: Northwest Regional Office of PA DEP
PTE: Permanent Total Enclosure

SECTION H. Miscellaneous.

RFD: Request for Determination of Changes of Minor Significance & Exemption from plan approval.
RICE: Reciprocating Internal Combustion Engine
SCC: Source Classification Code as defined by EPA
SCV: Sterilizer chamber vent
Source: An air contamination source (25 Pa. Code § 121.1).

STEL: Short Term Exposure; the personal monitoring system for Ethylene Oxide used to demonstrate compliance with OSHA standards. [A copy of the Ethylene Oxide STEL Personal Monitoring System is on file with the PA DEP NWRO. File: Cosmed / AQ / Plan Approval / 25-918A / Facility 522825.]

(d) All reports, submittals, and other communications required by this permit shall be submitted electronically to the PA DEP Northwest Regional office located at the following address. Web addresses for electronic submittals to this office are below.

Bureau of Air Quality
Department of Environmental Protection
230 Chestnut Street
Meadville, PA 16335
814-332-6940 (phone)
814-332-6121 (fax)
Office Hours 8 a.m. - 4 p.m.
800-541-2050 (after hours)

(i) Spills and other emergencies should be reported immediately to DEP by telephone at 800-541-2050.

(ii) Submittals of Asbestos Abatements and Demolition/Renovation Notification Forms should be made via the Online Asbestos Notification System. Information and links are located at this web address:

https://www.dep.pa.gov/Business/Air/BAQ/BusinessTopics/Pages/Asbestos.aspx

(iii) Submittals of Annual emissions inventory, if required, must be made via the DEP's AES*Online secure website. Information and links are located at this web address:

https://www.dep.pa.gov/Business/Air/BAQ/BusinessTopics/Emission/Pages/default.aspx

(iv) Submittals pertaining to emissions testing, specifically test protocols and test reports, shall be made by emailing electronic copies submissions to both PSIMS Administration in Central Office and to Regional Office AQ Program at the following e-mail addresses:

CENTRAL OFFICE:
RA-EPstacktesting@pa.gov

NORTHWEST REGIONAL OFFICE:
RA-EPNWstacktesting@pa.gov

(v) The 15-day advance notifications of emissions testing dates and supplemental testing information shall be submitted directly to:

(1) the DEP's OnBase electronic upload website where it will be forwarded to the Northwest Regional Office Air Quality Inspector. Upload the written notification at this web address:
https://www.dep.pa.gov/DataandTools/Pages/Application-Form-Upload.aspx

(2) IF the Protocol Reviewer at Central Office Division of Source Testing requested a copy of the notification, then submit a copy to the email address provided by the protocol reviewer.

(vi) Submittals of RFD's shall be made via the DEP's Greenport website at https://greenport.pa.gov

(vii) All other submittals to this office should be made via the DEP's OnBase electronic upload website at this web address:

https://www.dep.pa.gov/DataandTools/Pages/Application-Form-Upload.aspx

(e) Submittals to the EPA are made to the EPA Region III office.

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(1) The regional EPA address is:

Section Chief
U.S. Environmental Protection Agency Region III
Enforcement and Compliance Assurance Division
Air Section (3ED21)
Four Penn Center
1600 John F. Kennedy Boulevard
Philadelphia, Pennsylvania 19103-2852

(2) Electronic compliance certifications should be sent to the EPA at the following email address. Include the following in the email subject line: name of facility, state, and Title V operating permit number.

R3_APD_Permits@epa.gov

II. INFORMATION SPECIFIC TO THIS PERMIT

(f) Regulation 40 CFR Part 63 Subpart O defines 5 affected sources in §§ 63.360 and 63.361. The definitions are as follows.

Chamber exhaust vent (CEV) means the point(s) through which EtO-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes. This may also be referred to as a "backvent" (or "back vent"). For combination sterilization units, there is no CEV. (Source 101)

Aeration room vent (ARV) means the point(s) through which the evacuation of EtO-laden air from an aeration room occurs. For combination sterilization units, there is no ARV. (Source 102)

Sterilization chamber vent (SCV) means the point (prior to the vacuum pump) through which the evacuation of EtO from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes. (Source 103)

Group 1 room air emissions mean emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material. (Source 104)

Group 2 room air emissions mean emissions from post-aeration handling of sterilized material. (Source 105)

(g) This facility is an Area source exempt from the obligation to submit a Title V operating permit application under 40 CFR §63.360(f).

(h) Approvals included in this operating permit.

(1) Source 101 was authorized with the Oct. 7, 1988 issuance of plan Approval # 25-399-041 and was modified by the Jan. 16, 1991 issuance of plan approval # 25-332-001A. A modification to the gas mixture to allow the use of 100% EtO gas was RFD approved on July 8, 1993. The change in gas mixture does not increase emissions and the emission limits remain unchanged.

(2) Source 102 was authorized with the Aug. 28, 2000, issuance of plan approval PA-25-918A.

(3) Control device C103, which controls the existing chamber vents of Source 101 and is identified as Source 103, was installed on Aug. 9, 2022. A plan approval was not required for this control device because at the time of installation, there was no regulatory obligation to install the control device. In agreement with the Department, the permittee subsequently submitted an application for plan approval in order to establish terms and conditions for the proper operation of C103 to protect public health and the environment. The information in the plan approval application was reviewed and it was agreed that the plan approval application would be subsequently withdrawn and that conditions for the the source be included in the operating permit renewal.

(i) This facility has two (2) Cleaver-Brooks natural gas fired boilers rated at 1.674 MBTU. They were installed in 1988 (Model #CB-200-40, Serial #L-85189. They are used to produce steam for the sterilizers, heat for aeration and comfort heating during winter months. They were not included as sources because of the BTU rating.

(j) Incorporated into this permit is an August 2, 2000, letter from the EPA which is referenced in this permit in Section E under MONITORING REQUIREMENTS for 40 CFR §63.364(d) and under TESTING REQUIREMENTS for 40 CFR §63.365(g). The letter, dated Aug. 2, 2000, was sent from the EPA to Medical Manufacturing Corporation (MMC), the former owner of this facility. In the letter, the US EPA approved the use of an alternative control device to control EtO emissions from the Areation Room Vent to comply with 40 CFR Part 63 Subpart O, NESHAP for EtO emissions from Sterilization Facilities

(k) PERMITTING HISTORY:

(1) This permit was originally issued on January 28, 2002, and renewed on September 6, 2007.

(2) This permit was administratively amended on June 25, 2010 to incorporate the change of responsible official from Thomas

SECTION H. Miscellaneous.

Bienias to Michael Henderson - Director, Operations.

(3) This permit renewal effective May 8, 2013, is issued on May 8, 2013.

(4) This permit was amended on February 10, 2014 to change the responsible official to Jennifer Walters, Corporate Controller.

(5) This permit was amended on May 22, 2014 to change the permit contact from Paul Niemet to Nancy Rakiewicz - Site Manager.

(6) This permit was amended on July 1, 2015 to change the ownership from MMC Sterilization to Iuvo BioScience Operations, LLC. The responsible official changed to Benjamin Burton - CEO, President. The new Tax ID is 47-3409419-1.

(7) This permit was amended on February 9, 2017 to change the ownership from Iuvo BioScience Operations to Cosmed Group, Inc. The responsible official changed to David G. Howe - Chief Operating Officer. The permit contact changed to Christine Render - Director of Corporate QA and RA. The new Tax ID is 51-1598781-1.

(8) This permit renewal, effective July 16, 2018, is issued on July 16, 2018.

(9) This permit renewal, effective November 20, 2024, is issued on November 20, 2024. The renewal incorporates the April 5, 2024, amended promulgation of 40 CFR Part 63 Subpart O and incorporates an August 2, 2024, Department approval of a 1-year extension to the compliance dates for Group 1 room air emissions and Group 2 room air emissions.

(10) The permit was adminstratively amended on April 17, 2026 to incorporate the change of ownership from Cosmed to Lynx Medical Pennsylvania, LLC.

****** End of Report ******