B BRAUN US DEVICE MFG LLC/ALLENTOWN



COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION AIR QUALITY PROGRAM

STATE ONLY SYNTHETIC MINOR OPERATING PERMIT

Issue Date: November 13, 2024 Effective Date: January 20, 2025

Expiration Date: January 20, 2030

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: 39-00055

Synthetic Minor

Federal Tax Id - Plant Code: 99-2791944

Owner Information

Name: B BRAUN US DEVICE MFG LLC

Mailing Address: 901 MARCON BLVD

ALLENTOWN, PA 18109-9512

Plant Information

Plant: B BRAUN US DEVICE MFG LLC/ALLENTOWN

Location: 39 Lehigh County 39910 Hanover Township

SIC Code: 3841 Manufacturing - Surgical And Medical Instruments

Responsible Official

Name: MIKE BARTHOLOMEW

Title: PRESIDENT

Phone: (610) 596 - 2857 Email: mike.bartholomew@bbraunusa.com

Permit Contact Person

Name: CHRIS GREENE Title: EHS/S MANAGER

Phone: (610) 596 - 2240 Email: Chris.Greene@bbraunusa.com

[Signature]

MARK J. WEJKSZNER, NORTHEAST REGION AIR PROGRAM MANAGER





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Note: These same sub-sections are repeated for each source!

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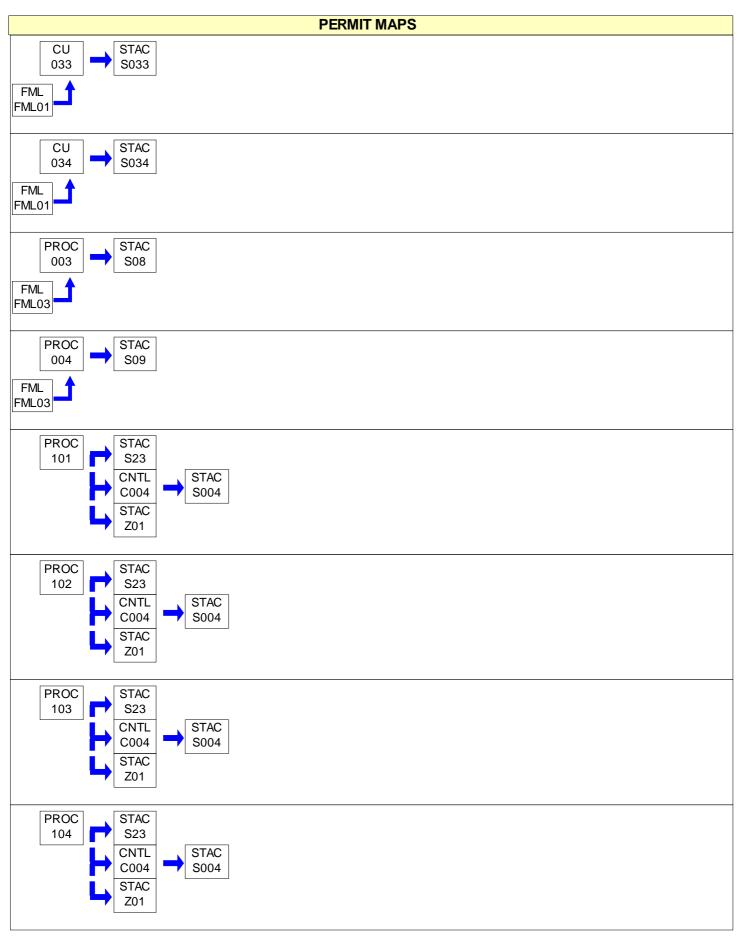
SECTION A. Site Inventory List

Source I	D Source Name	Capacity/	Throughput	Fuel/Material
033	BOILER- 21.0 MMBTU/HR	21.000	MMBTU/HR	
034	BOILER- 21.0 MMBTU/HR	21.000	MMBTU/HR	
003	EMERGENCY GENERATOR - 635HP			
004	FIRE PUMP - 149HP			
101	STERILIZER - 1000 CU FT			
102	STERILIZER - 1000 CU FT			
103	STERILIZER - 1000 CU FT			
104	STERILIZER - 1000 CU FT			
105	STERILIZER - 1200 CU FT			
106	STERILIZER - 1250 CU FT			
107	STERILIZER - 3700 CU FT			
108	STERILIZER - 130 CU FT			
110	AERATION ROOM			
111	EMERGENCY GENERATOR - 173 HP			
113	FIRE PUMP - 110 HP			
118	FIRE PUMP - 220 HP			
119	EMERGENCY GENERATOR - 750KW			
120	THREE (3) COOLING TOWERS - 2,849 GPM EACH			
124	TWO (2) OFFSET PRINTING PRESSES			
C004	CATALYTIC OXIDIZER WITH PEAK SHAVER			
FML01	NATURAL GAS			
FML03	DIESEL			
S004	CATALYTIC OXIDIZER STACK			
S033	BOILER NO. 33 STACK			
S034	BOILER NO. 34 STACK			
S04	111 GENERATOR STACK			
S05	113 FIRE PUMP STACK			
S08	003 GENERATOR STACK			
S09	004 FIRE PUMP STACK			
S23	COMMON REAR STERILIZER EXHAUST STACK			
S24	118 FIRE PUMP STACK			
S25	119 GENERATOR STACK			
S26	THREE (3) COOLING TOWER STACKS			
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Z01	FUGITIVE EMISSIONS-SOURCE ID 101 THROUGH 108			

PERMIT MAPS

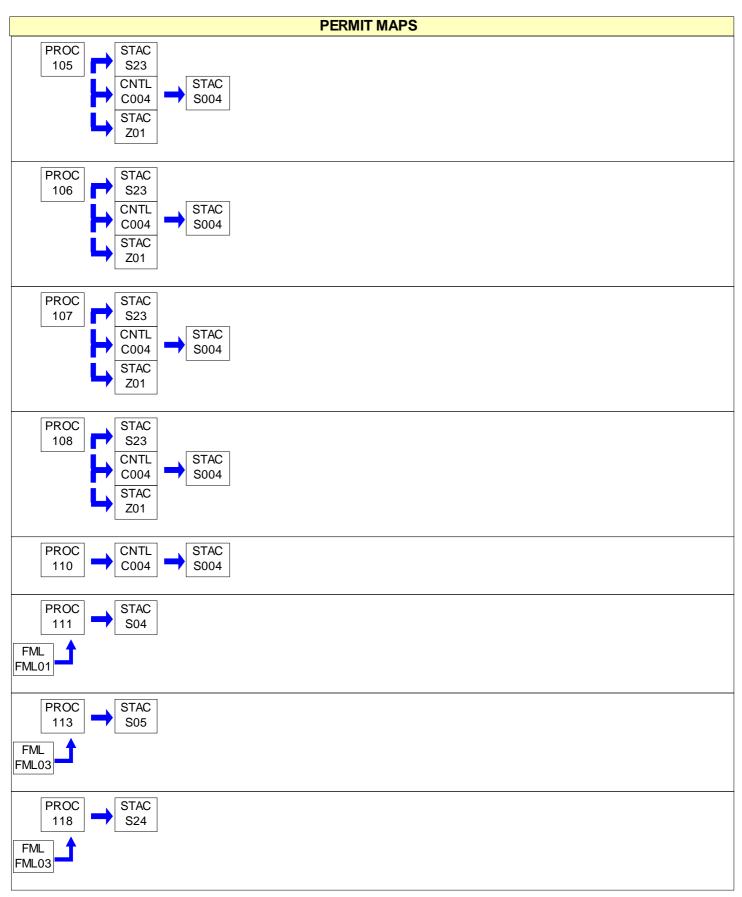






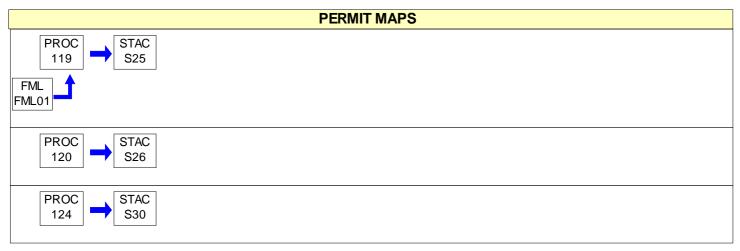












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#001 [25 Pa. Code § 121.1]

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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 I.

- (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.



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SECTION B. General State Only Requirements

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

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- (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

#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
- (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:

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SECTION B. General State Only Requirements

- (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 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.
 - (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)

#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.

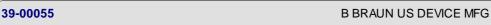
#018 [25 Pa. Code §§ 127.402(d) & 127.442]

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.

#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 §135.3]

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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.

#024 [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).

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001 [25 Pa. Code §123.1]

Prohibition of certain fugitive emissions

- (a) No person may permit the emission into the outdoor atmosphere of a 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) Sources and classes of sources other than those identified in paragraphs (1)-(6), 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.

002 [25 Pa. Code §123.2]

Fugitive particulate matter

The permittee may not permit fugitive particulate matter to be emitted into the outdoor atmosphere from a source specified in Site Level Condition #001, if such emissions are visible at the point the emissions pass outside the person's property.

003 [25 Pa. Code §123.31]

Limitations

The permittee 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.

004 [25 Pa. Code §123.41]

Limitations

The permittee 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 123.41 (relating to limitations) 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.



SECTION C. Site Level Requirements

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(3) When the emission results from sources specified in Site Level Condition #001.

006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- a) The emissions of Nitrogen Oxides (NOx) for the entire facility shall not equal or exceed 100 tons in any 12 consecutive month period. (12 month rolling sum)
- b) The emissions of Volatile Organic Compounds (VOC) for the entire facility shall not equal or exceed 50 tons in any 12 consecutive month period. (12 month rolling sum).
- c) The aggregate emissions of all hazardous air pollutants (HAPs) for the entire facility shall not equal or exceed 25 tons in any 12 consecutive month period (12 month rolling sum).
- d) The emissions of ethylene oxide or any individual hazardous air pollutant (HAP), for the entire facility shall not equal or exceed 10 tons in any 12 consecutive month period (12 month rolling sum).

II. TESTING REQUIREMENTS.

007 [25 Pa. Code §139.1]

Sampling facilities.

Upon the request of the Department, the person responsible for a source shall provide adequate sampling ports, safe sampling platforms and adequate utilities for the performance by the Department of tests on such source. The Department will set forth, in the request, the time period in which the facilities shall be provided as well as the specifications for such facilities.

008 [25 Pa. Code §139.2]

Sampling by others.

Sampling and testing done by persons other than the Department may be accepted by the Department provided that:

- (1) The Department has been given reasonable notice of the sampling and testing and has been given reasonable opportunity to observe and participate in the sampling and testing.
- (2) The sampling and testing is conducted under the direct supervision of persons qualified, by training and experience, to conduct such sampling and testing.
- (3) Procedures for the sampling and testing are in accord with the provisions of this chapter.
- (4) The reports of the sampling and testing are accurate and comprehensive.

III. MONITORING REQUIREMENTS.

009 [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.

010 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall conduct a monthly inspection during daylight hours when the plant is in production to inspect for visible,





SECTION C. **Site Level Requirements**

fugitive, and malodor emissions. If visible, fugitive or malodor emissions are detected, corrective actions shall be taken immediately to abate the emission.

RECORDKEEPING REQUIREMENTS.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

The facility- wide emissions shall be updated monthly and maintained on a 12-month rolling sum.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

All records shall be maintained for a minimum of 5 years in accordance with Section B, Condition #020.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

All monthly inspection results for visible, fugitive, or malodor emissions, shall be recorded in a logbook. The logbook shall be maintained on-site and be made available to the Department upon request. At a minimum, the permittee shall record the date, time, results of the inspection, and individual conducting the inspection.

014 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- a) The facility shall keep records of Nitrogen Oxides (NOx) emissions for the entire facility to verify compliance with the 100 tons in any 12 consecutive month period (12 month rolling sum) limitation.
- b) The facility shall keep records of Volatile Organic Compounds (VOC) emissions for the entire facility to verify compliance with the 50 tons in any 12 consecutive month period (12 month rolling sum) limitation.
- c) The facility shall keep records of aggregate hazardous air pollutants (HAP) emissions for the entire facility to verify compliance with the 25 tons in any 12 consecutive month period (12 month rolling sum) limitation.
- d) The facility shall keep records of ethylene oxide emissions for the entire facility to verify compliance with the 10 tons in any 12 consecutive month period (12 month rolling sum) limitation.
- e) These records shall be kept for a five (5) year period and be made available to the Department upon request.

V. REPORTING REQUIREMENTS.

015 [25 Pa. Code §127.441]

Operating permit terms and conditions.

On a quarterly basis, the permittee shall compile a report of all logged instances of exceedance of the fugitive, visible and malodor emission limitations, as required by Site Level Conditions #001, #003 and #004, that occurred during the previous three (3) months. These reports shall be submitted to the Department within thirty (30) days of the close of the calendar quarter. If no deviations were detected this report shall be retained on site and made available the Department upon request.

016 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- 1) The company, within one hour of discovery of occurrence, shall notify the Department, at 610-861-2070, of any malfunction of the source(s) or associated air cleaning device(s) which results in, or may possibly be resulting in, the emission of air contaminants in excess of the limitations specified in, or established pursuant to, any applicable rule or regulation contained in Article III of the Rules and Regulations of the Department of Environmental Protection. A written report shall be submitted to the Department within two working days following the incident describing the malfunctions and corrective actions taken.
- 2) Any changes in the location of the aforementioned source, or any changes in the process or control equipment would be consider a modification and would require the submittal of an amended application for plan approval in accordance with the provisions of 25 PA Code 127.11 and 127.12.



SECTION C. Site Level Requirements

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3) Any notification as a result of any condition herein should be directed to:

Air Quality Program Manager Department of Environmental Protection 2 Public Square Wilkes-Barre, PA 18701-1915

VI. WORK PRACTICE REQUIREMENTS.

017 [25 Pa. Code §123.1]

Prohibition of certain fugitive emissions

The permittee 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.

018 [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) Exceptions: The requirements of subsections (a) 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) A fire set in conjunction with the production of agricultural commodities in their unmanufactured state on the premises of the farm operation.
- (5) A fire set for the purpose of burning domestic refuse, when the fire is on the premises of a structure occupied solely as a dwelling by two families or less and when the refuse results from the normal occupancy of such structure.
- (6) A fire set solely for recreational or ceremonial purposes.
- (7) A fire set solely for cooking food.

VII. ADDITIONAL REQUIREMENTS.

019 [25 Pa. Code §121.7]

Prohibition of air pollution.

The permittee may not permit the presence in the outdoor atmosphere of any form of contaminant, including, but not limited to, the discharging from stacks, chimneys, openings, buildings, structures, open fires, vehicles, processes or any other source of any smoke, soot, fly ash, dust, cinders, dirt, noxious or obnoxious acids, fumes, oxides, gases, vapors, odors, toxic, hazardous or radioactive substances, waste or other matter in a place, manner or concentration inimical or which







SECTION C. **Site Level Requirements**

may be inimical to public health, safety or welfare or which is or may be injurious to human, plant or animal life or to property or which unreasonably interferes with the comfortable enjoyment of life or property.

[25 Pa. Code §127.441] # 020

Operating permit terms and conditions.

Internal combustion engines, regardless of size, shall maintain a combined NOx emissions less than 100 lbs/hr, 1000 lbs/day, 2.75 tons per ozone season and 6.6 tons per year on a 12-month rolling basis for all exempt engines at the site.

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.





Source ID: 033 Source Name: BOILER-21.0 MMBTU/HR

> Source Capacity/Throughput: 21.000 MMBTU/HR

Conditions for this source occur in the following groups: GROUP 3



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).

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).



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SECTION D. **Source Level Requirements**

Source ID: 034 Source Name: BOILER-21.0 MMBTU/HR

> Source Capacity/Throughput: 21.000 MMBTU/HR

Conditions for this source occur in the following groups: GROUP 3



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).

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).



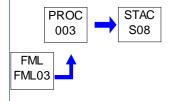




Source ID: 003 Source Name: EMERGENCY GENERATOR - 635HP

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 2



RESTRICTIONS.

Emission Restriction(s).

[40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4205] Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What emission standards must I meet for emergency engines if I am an owner or operator of a stationary CI internal co-

(b) Owners and operators of 2007 model year and later emergency stationary CI ICE with a displacement of less than 30 liters per cylinder that are not fire pump engines must comply with the emission standards for new nonroad CI engines in §60.4202, for all pollutants, for the same model year and maximum engine power for their 2007 model year and later emergency stationary CI ICE.

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).

MONITORING REQUIREMENTS. III.

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).

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).

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.

002 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4211] Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

(a) If you are an owner or operator and must comply with the emission standards specified in this subpart, you must operate and maintain the stationary CI internal combustion engine and control device according to the manufacturer's written instructions or procedures developed by the owner or operator that are approved by the engine manufacturer. In addition, owners and operators may only change those settings that are permitted by the manufacturer. You must also meet the requirements of 40 CFR parts 89, 94 and/or 1068, as they apply to you.







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).



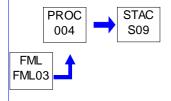




Source ID: 004 Source Name: FIRE PUMP - 149HP

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 2



I. RESTRICTIONS.

Emission Restriction(s).

001 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4205]
Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines
What emission standards must I meet for emergency engines if I am an owner or operator of a stationary CI internal co

(c) Owners and operators of fire pump engines with a displacement of less than 30 liters per cylinder must comply with the emission standards in table 4 of 40 CFR Part 60, Subpart IIII for all pollutants.

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.

002 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4211]
Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines
What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

(a) If you are an owner or operator and must comply with the emission standards specified in this subpart, you must operate and maintain the stationary CI internal combustion engine and control device according to the manufacturer's written instructions or procedures developed by the owner or operator that are approved by the engine manufacturer. In addition, owners and operators may only change those settings that are permitted by the manufacturer. You must also meet the requirements of 40 CFR parts 89, 94 and/or 1068, as they apply to you.







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).

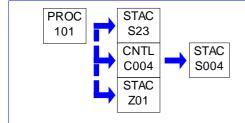




Source ID: 101 Source Name: STERILIZER - 1000 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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).

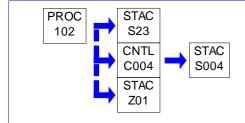




Source ID: 102 Source Name: STERILIZER - 1000 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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).

TESTING REQUIREMENTS. II.

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).

MONITORING REQUIREMENTS. III.

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).

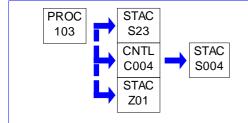




Source ID: 103 Source Name: STERILIZER - 1000 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



39-00055

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).

TESTING REQUIREMENTS. II.

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).

MONITORING REQUIREMENTS. III.

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).



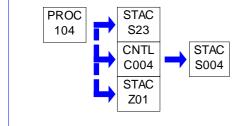




Source ID: 104 Source Name: STERILIZER - 1000 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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).

TESTING REQUIREMENTS. II.

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).

MONITORING REQUIREMENTS. III.

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).

RECORDKEEPING REQUIREMENTS. IV.

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).



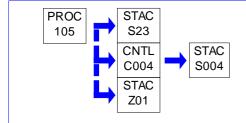




Source ID: 105 Source Name: STERILIZER - 1200 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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).

TESTING REQUIREMENTS. II.

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).

MONITORING REQUIREMENTS. III.

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).

RECORDKEEPING REQUIREMENTS. IV.

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).



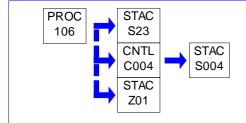




Source ID: 106 Source Name: STERILIZER - 1250 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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.

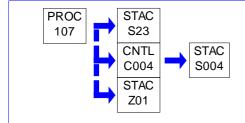
No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).



Source ID: 107 Source Name: STERILIZER - 3700 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



39-00055

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).

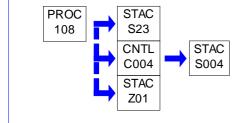




Source ID: 108 Source Name: STERILIZER - 130 CU FT

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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).





Source ID: 110 Source Name: AERATION ROOM

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 1



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).

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).

MONITORING REQUIREMENTS. III.

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).

RECORDKEEPING REQUIREMENTS. IV.

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).

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).

WORK PRACTICE REQUIREMENTS. VI.

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).

ADDITIONAL REQUIREMENTS. VII.

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).

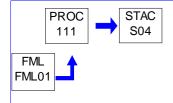




Source ID: 111 Source Name: EMERGENCY GENERATOR - 173 HP

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 2



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).



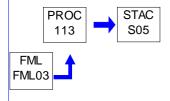


SECTION D. Source Level Requirements

Source ID: 113 Source Name: FIRE PUMP - 110 HP

Source Capacity/Throughput:

Conditions for this source occur in the following groups: GROUP 2



I. RESTRICTIONS.

Emission Restriction(s).

001 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6604]

Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

What fuel requirements must I meet if I own or operate an existing stationary CI RICE?

Beginning January 1, 2015, if you own or operate an existing emergency CI stationary RICE with a site rating of more than 100 brake HP and a displacement of less than 30 liters per cylinder that uses diesel fuel and operates for the purpose specified in § 63.6640(f)(4)(ii), you must use diesel fuel that meets the requirements in 40 CFR 1090.305 for nonroad diesel fuel, except that any existing diesel fuel purchased (or otherwise obtained) prior to January 1, 2015, may be used until depleted.

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).





SECTION D. Source Level Requirements

VII. ADDITIONAL REQUIREMENTS.

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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).



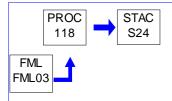


B BRAUN US DEVICE MFG LLC/ALLENTOWN

SECTION D. **Source Level Requirements**

Source ID: 118 Source Name: FIRE PUMP - 220 HP

Source Capacity/Throughput:



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RESTRICTIONS.

Emission Restriction(s).

001 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4205] Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What emission standards must I meet for emergency engines if I am an owner or operator of a stationary CI internal co-

Pursuant to the requirements of 40 CFR § 60.4205(c) and 60.4211(c), the engine-pump, Source ID 118, shall be EPA certified to meet the emissions standards that are specified in 40 CFR §§ 60.4205(c) for the same model year and maximum engine power.

Fuel Restriction(s).

002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

[Additional authority for this permit condition is also derived from the provisions of 40 CFR § 60.4207]

Pursuant to best available technology requirements of 25 Pa. Code §§ 127.1 and 127.12, the permittee shall only use diesel fuel that is classified as ULTRA-LOW SULFUR NON-HIGHWAY DIESEL FUEL (15 ppm Sulfur Maximum) pursuant to 40 CFR Part 80 Subpart I, to operate the engine-pump (Source ID 118).

Operation Hours Restriction(s).

003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to best available technology requirements of 25 Pa. Code Sections 127.1 and 127.12, the total operation of Source ID 118 shall not exceed 500 hours in any 12 consecutive month period. This limit includes 100 hours per year of testing and maintenance purposes, of which 50 hours can be utilized for non-emergency operation.

004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- 1. The permittee may not permit the emission into the outdoor atmosphere of particulate matter, expressed as PM, in excess of 0.04 grain per dry standard cubic fool.
- 2. The permittee may not permit the emission into the outdoor atmosphere of sulfur oxides, expressed as SO2, in excess of 500 parts per million, dry basis.

TESTING REQUIREMENTS.

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

III. MONITORING REQUIREMENTS.

005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Source shall be equipped with a non-resettable meter for hours of operation prior to startup and the meter shall be operated



SECTION D. **Source Level Requirements**

at all times Source is in operation.

IV. RECORDKEEPING REQUIREMENTS.

006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall keep records of the fuel certification reports for each delivery of diesel fuel to verify compliance with the fuel restriction requirements.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- a. The permittee shall maintain comprehensive, accurate records which, at a minimum, shall include:
- i. The number of hours per 12 month rolling sum that fire engine or piece of equipment operated. Document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency.
- ii. The amount of fuel used per 12 month rolling sum in fire engine or piece of equipment.
- b. These records shall be retained for a minimum of five (5) years and shall be made available to the Department upon request.

008 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The owner or operator must keep records of the operation of the engine in emergency and non-emergency service that are recorded through the non-resettable hour meter. The owner must record the time of operation of the engine and the reason the engine was in operation during that time.

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.

009 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The company shall maintain and operate the fire pump engine in accordance with the manufacturer's specification and with good engineering practice.

010 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4206]

Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines How long must I meet the emission standards if I am an owner or operator of a stationary CI internal combustion engine?

The permittee shall operate and maintain the engine-pump, Source ID 118, to achieve the emission standards in this permit over the entire life of the engine.

(a) Any testing used to verify compliance with this work practice restriction shall be performed in accordance with 40 CFR Part 64 Subpart IIII, including 40 CFR § 60.4212, and test methods and procedures acceptable to the Department.

011 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4211] Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

The engine-pump, Source ID 118, shall be installed and configured according to the manufacturer's emission-related

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SECTION D. Source Level Requirements

VII. ADDITIONAL REQUIREMENTS.

012 [25 Pa. Code §127.441]

Operating permit terms and conditions.

[Compliance with this permit condition will assure compliance with the requirements of 40 CFR Part 63 Subpart ZZZZ]

The engine-pump, Source ID 118, is subject to the requirements in 40 CFR Part 60 Subpart IIII. The permittee shall comply with all applicable provisions specified 40 CFR §§ 60.4200 through 60.4219, including appendices.



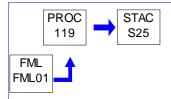




SECTION D. **Source Level Requirements**

Source ID: 119 Source Name: EMERGENCY GENERATOR - 750KW

Source Capacity/Throughput:



RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall comply with all applicable Emission Standards requirements specified in 40 CFR Part 60 Subpart JJJJ 60.4233 through 60.4234.

002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- 1. The permittee may not permit the emission into the outdoor atmosphere of particulate matter, expressed as PM, in excess of 0.04 grain per dry standard cubic fool.
- 2. The permittee may not permit the emission into the outdoor atmosphere of sulfur oxides, expressed as SO2, in excess of 500 parts per million, dry basis.

Operation Hours Restriction(s).

003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to best available technology requirements of 25 Pa. Code Sections 127.1 and 127.12, the total operation of Source ID 119 shall not exceed 500 hours in any 12 consecutive month period. This limit includes 100 hours per year of testing and maintenance purposes, of which 50 hours can be utilized for non-emergency operation.

II. TESTING REQUIREMENTS.

004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall comply with all applicable Testing requirements specified in 40 CFR Part 60 Subpart JJJJ 60.4244.

III. MONITORING REQUIREMENTS.

005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Source shall be equipped with a non-resettable meter for hours of operation prior to startup and the meter shall be operated at all times Source is in operation.

RECORDKEEPING REQUIREMENTS.

006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- a. The permittee shall maintain comprehensive, accurate records which, at a minimum, shall include:
- i. The number of hours per 12 month rolling sum that engine or piece of equipment operated. Document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency.



SECTION D. Source Level Requirements

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- ii. The amount of fuel used per 12 month rolling sum in engine or piece of equipment.
- b. These records shall be retained for a minimum of five (5) years and shall be made available to the Department upon request.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The owner or operator must keep records of the operation of the engine in emergency and non-emergency service that are recorded through the non-resettable hour meter. The owner must record the time of operation of the engine and the reason the engine was in operation during that time.

V. REPORTING REQUIREMENTS.

008 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall comply with all applicable Notification, Reporting and Records requirements specified in 40 CFR Part 60 Subpart JJJJ 60.4245.

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.

009 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The natural gas fueled engine is subject to 40 CFR, Part 60, Subpart JJJJ - Standards of Performance for Stationary Spark Ignited Internal Combustion Engines and the permittee shall comply with all applicable requirements of the subpart.

010 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall comply with all applicable Compliance requirements specified in 40 CFR Part 60 Subpart JJJJ 60.4243.

011 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The engine shall be designed to comply with the Compliance Requirements for Manufacturers specified in 40 CFR Part 60 Subpart JJJJ 60.4238 through 60.4242.

012 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall comply with all applicable Compliance requirements specified in 40 CFR Part 60 Subpart JJJJ 60.4235 through 60.4237.

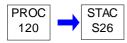




SECTION D. **Source Level Requirements**

Source ID: 120 Source Name: THREE (3) COOLING TOWERS - 2,849 GPM EACH

Source Capacity/Throughput:



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L RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to the Best Available Technology provision of 25 Pa. Code §§127.12, the PM/PM10/PM2.5 emissions shall not exceed any of the following:

These cooling towers shall be operated or equipped with high efficiency drift eliminators that reduce emissions to levels equal to or less than:

1. PWPM10/PM2.5- 0.26 lb/hr, 1.14 tons per year based on 12 month rolling total from all three towers.

The company shall use methods used in plan approval application in estimating PM, PM10 & PM2.5 emissions to show compliance with these limitations.

The company shall use TDS number based on facility data for the municipal water supply.

Throughput Restriction(s).

002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The combined total circulating water flow rate of 5,698 gallons per minute for all three towers shall not be exceeded at any time through the cooling towers.

TESTING REQUIREMENTS.

003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The most recent available water supply authority's TDS analysis value shall be used to calculate the monthly cooling tower emissions.

MONITORING REQUIREMENTS. Ш

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

IV. RECORDKEEPING REQUIREMENTS.

004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall keep records of the supporting calculations on a monthly basis for the PMPM10/PM2.5 emissions to verify compliance with the total PWPM10/PM2.5 emissions limitations of tons per year in any 12 consecutive month period.

005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The Permittee shall maintain records of the following information for the cooling towers:

a. A file containing:





SECTION D. Source Level Requirements

- i. The manufacturer's specifications or design data for the cooling tower, including water circulation rate (gallons/hour) and design loss rate of the drift eliminators (percent), with supporting documentation.
- b. Records for the amount of water circulated in the cooling tower, gallons/month, with supporting calculations.
- c. The following logs for the affected units:
- i. Inspection, maintenance and repair log(s).

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.

006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The Cooling Towers shall be properly operated and maintained according to manufacturer's specifications. Manufacturer's specification, if available, shall be kept on site and readily available to Department representatives.

VII. ADDITIONAL REQUIREMENTS.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Each cell of the cooling tower shall be equipped with a drift eliminator. The drift loss shall be limited to 0.005 percent, which shall be calculated as the weighted average of the drift losses for all cooling tower cells. Verification of drift loss shall be by manufacturer's guarantee. Manufacturer's drift loss guarantee shall be kept on site and readily available to Department representatives, upon request.

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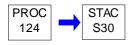




SECTION D. **Source Level Requirements**

Source ID: 124 Source Name: TWO (2) OFFSET PRINTING PRESSES

Source Capacity/Throughput:



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L RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The VOC emissions from the printing operations including cleanup solvent shall be less than 2.7 tons per year in any 12 consecutive month periods.

002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The HAPs emissions from the printing operation including cleanup solvent shall be less than 1.0 ton per year in any 12 consecutive month period.

TESTING REQUIREMENTS.

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

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.

003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall keep up-to-date records of Certified Product Data Sheets (CPDSs) or Material Safety Data Sheets (MSDSs) that identify the Volatile Organic Compound (VOC) content and Hazardous Air Pollutant (HAP) content of each VOC and/or HAP containing material used at the facility.

004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall maintain a monthly record of VOC usages at the facility. This record shall be updated on a monthly basis and shall be maintained on a 12-month rolling sum basis to demonstrate compliance with the VOC emission limitations.

REPORTING REQUIREMENTS.

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

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).







SECTION D. Source Level Requirements

VII. ADDITIONAL REQUIREMENTS.

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





Group Name: GROUP 1

Group Description: ETO STERLIZERS

Sources included in this group

ID	Name
101	STERILIZER - 1000 CU FT
102	STERILIZER - 1000 CU FT
103	STERILIZER - 1000 CU FT
104	STERILIZER - 1000 CU FT
105	STERILIZER - 1200 CU FT
106	STERILIZER - 1250 CU FT
107	STERILIZER - 3700 CU FT
108	STERILIZER - 130 CU FT
110	AERATION ROOM

I. RESTRICTIONS.

Emission Restriction(s).

001 [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) or the compliance deadline identified as part of any Department-approved extension request. For the avoidance of doubt, the Department approved a compliance extension on September 16, 2024 for this Facility until April 5, 2028, for the 99.99% destruction removal efficiency (DRE) requirement for the sterilization chamber vents (SCV), the 99.9% DRE requirement for the aeration room vent (ARV), and the 98% DRE requirement for groups 1 and 2 room air emissions and related permanent total enclosure (PTE) requirement.
- (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. 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. When streams from two or more emission sources are combined, you must demonstrate compliance by either the approach specified in paragraph (i)(1) of this section or the approach specified in paragraph (i)(2) of this section in lieu of the applicable standards in paragraphs (c) through (g) of this section for the affected source. The combined emission stream limit is based on as 30-operating day rolling sum. In order to elect to comply with a combined emission streams limit, you must use a CEMS on each exhaust stack at the facility to determine compliance.
- (1) Monitoring after emission streams are combined. You must follow requirements of paragraphs (i)(1)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine the 30-operating day rolling sum of mass inlet to the control system. Then, the emission limitation is determined by applying the most stringent emission reduction standard to the 30-operating day rolling sum of the inlet mass. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. Further suppose that the mass of uncontrolled EtO emissions from the combined stream is 5 lb during the 30-operating day period. Under this approach, the facility would need to apply an emission reduction of 99.9% to the combined stream, resulting in an emission limit of 0.005 lb for the 30-operating day period.
- (i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 1 to this paragraph.

CEScombined=M30day*(1-Max(ER)) (Eq.1)

Where:

CEScombined = The combined emission stream limit based upon monitoring after the emission streams are combined, in pounds.

M30day = The 30-operating day total mass sent to controls for the combined emission stream (i.e., monitoring data at the inlet of the control system), as calculated using equation A-3 and determined in accordance with appendix A to this subpart. The term "M30day" as used in this equation is equivalent to the term "E30day" as designated in equation A-3.

Max(ER) = The most stringent emission reduction standard specified in tables 1 through 5 of this subpart applicable to any of the constituent streams, in decimal format.

- (ii) The 30-operating day rolling sum of emissions for the combined emission stream (i.e., monitoring data at the outlet of the control system) is calculated daily using equation A-3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as ECombined. If the combined emission stream is split between two or more control systems, further sum the 30-operating day rolling sum of emissions from each control system to obtain ECombined.
- (iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that ECombined, as calculated in accordance with paragraph (i)(1)(ii) of this section, for each 30-operating day period is at or below CESCombined, as calculated in paragraph (i)(1)(i) of this section.





- (2) Monitoring before emission streams are combined. You must follow requirements of paragraphs (i)(2)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine 30-operating day rolling sum of inlet mass to the control system for each component stream. Then, the emission limitation is determined by applying the applicable emission reduction standards to the 30-operating day rolling sum of each component stream and summing across the components. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. Further suppose that during a 30-operating day period the mass of uncontrolled EtO emissions from the ARVs is 4 lb and the mass of uncontrolled EtO emissions from the CEVs is 1 lb. Under this approach, the facility would need to apply an emission reduction of 99.9% to the ARV stream and an emission reduction of 99% to the CEV stream, resulting in an emission limit of 0.014 lb for the 30-operating day period.
- (i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 2 to this paragraph. See equation 2 in paragraph (i)(2)(i).
- (ii) The 30-operating day rolling sum emissions for the combined emission stream (i.e., monitoring data at the outlet of the control system) is calculated daily using equation A-3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as ECombined. If the combined emission stream is split between two or more control systems, then further sum the 30-operating day rolling sum emissions from each control system to obtain ECombined.
- (iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that ECombined, as calculated in accordance with paragraph (i)(2)(ii) of this section, for each 30-operating day period is at or below CESStreams, as calculated paragraph (i)(2)(i) of this section.
- (3) If room air emissions are both subject to an emission standard and split between two or more control systems, then these control systems must be treated as part of the same control system.
- (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.

SWELfac=Mfac*0.99*(1-ERscv) (Eq.3)

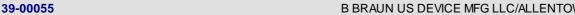
Where:

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. See equation 4 in paragraph (j)(1)(ii).
- (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. See equation 5 in paragraph (j)(2)(i).
- (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 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.

Throughput Restriction(s).

002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall not exceed usage of 393,470 pounds of ethylene oxide at the sterilization chambers for any consecutive twelve (12) month period.

II. TESTING REQUIREMENTS.

[40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.365] Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities Test methods and procedures.

- (a) General —
- (1) Performance testing for facility where EtO use is less than 100 pounds per year. If you own or operate an affected source at a facility where EtO use is less than 100 lb/yr that is subject to an emission standard in § 63.362, you must comply with the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, using the methods in paragraph (b) or (c) of this section, following the applicable procedures for initial compliance and continuous compliance in paragraphs (d), (e), and (f) of this section.
- (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) Test methods for facility where EtO use is less than 100 pounds per year. You must use the following test methods to determine the average mass emissions of EtO in lb/hr at the inlet of a control system (MAPCD, i) and/or outlet of a control system or stack (EAPCD, o).
- (1) Select the location of the sampling ports and the number of traverse points according to Method 1 of appendix A-1 to part 60 of this chapter. Alternatively, for ducts less than 0.3 meter (12 in.) in diameter, you may choose to locate sample ports according to Method 1A of appendix A-1 to part 60 of this chapter.
- (2) Determine the flow rate through the control system exhaust(s) continuously during the test period according to either Methods 2, 2A, or 2C of appendix A-1 to part 60 of this chapter, as appropriate. If using Method 2, 2A, or 2C, you must complete velocity traverses immediately before and subsequently after each test run. If your test run is greater than 1 hour, you must also complete a velocity traverse at least every hour. Average the velocity collected during a test run and calculate volumetric flow as outlined in the appropriate method.
- (3) Determine the oxygen and carbon dioxide concentration of the effluent according to Method 3A or 3B of appendix A-2 to part 60 of this chapter. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10-1981 (incorporated by reference, see § 63.14) may be used as an alternative to EPA Method 3B.
- (4) Determine the moisture content of the stack gas according to Method 4 of appendix A-3 to part 60 of this chapter. Alternatively, you may use an on-line technique that has been validated using Method 301 of appendix A to this part.
- (5) Determine the EtO concentration according to either paragraph (b)(5)(i) or (ii) of this section.
- (i) Follow Method 320 of appendix A to this part and the following paragraphs (5)(i)(A) through (D).
- (A) The instrumentation used for measurement must have the measurement range to properly quantify the EtO in the gas stream. Additionally, for outlet emission streams, the instrumentation must have a method detection limit an order of magnitude below concentration equivalent of the emission limit.
 - (B) Instrumentation used must be continuous in nature with an averaging time of one minute or less.
- (C) Calibration Spectra and all other analyte spiking required in the method must use EtO gaseous cylinder standard(s) which meet the criteria found in Performance Specification 19 of appendix B to part 60 if this chapter.
- (D) Other methods and materials may be used; however, these alternative test methods are subject to Administrator approval.
- (ii) Alternatively, ASTM D6348-12 (Reapproved 2020), (incorporated by reference, see § 63.14) may be used with the following conditions:
- (A) The test plan preparation and implementation in the Annexes to ASTM D 6348-12 (R2020), Sections A1 through A8 are mandatory; and
- (B) In ASTM D6348-12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). In order for the test data to be acceptable for a compound, %R must be 70% = R = 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (i.e., the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using equation 1 to this paragraph:

Reported Results = ((Measured Concentration in Stack))/(%R)*100 (Eq. 1)

(6) Calculate the mass emission of EtO by using equations 2 and 3 to this paragraph:

Mapcd,in = $(Ceto,i*Qi*44.05)/(385.1*10^{6})$ (Eq. 2)

Eapcd,o = $(Ceto,o*Qo*44.05)/(385.1*10^9)$ (Eq. 3)



39-00055

SECTION E. **Source Group Restrictions.**

Where:

MAPCD, i = average inlet mass rate of EtO per hour, lb/hr

CEtO,i = inlet EtO concentration, ppmdv.

Qi = average inlet volumetric flow per hour at standard conditions, dscf/hr

44.05 = molecular weight (MW) of EtO, lb/lb-mole

MW/385.1 \times 106 = conversion factor, from ppmv at standard conditions to lb/cf

EAPCD, o = average outlet mass rate of EtO per hour, lb/hr

CEtO,o = outlet EtO concentration, ppbdv.

Qo = average outlet volumetric flow per hour at standard conditions, dscf/hr

MW/385.1 \times 109 = conversion factor, from ppbv at standard conditions to lb/cf

- (c) Alternative approach for SCVs for facility where EtO use is less than 100 pounds per year. 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 paragraph (b) of this section to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.
- (1) Determine the mass (MSCV,n) of EtO used for each charge and at each sterilization chamber used during the performance tests using the procedures in either paragraph (c)(1)(i) or (ii) of this section.
- (i) 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 (MSCV,n) vented to the controls using equation 4 to this paragraph.

Mscv,n = Mcharge*%EOw (Eq.4)

Where:

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

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

%E.O.w = weight percent of EtO

(ii) 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 5 to this paragraph.

Mscv,n = (Qm*Tn*%EOv*(MW)/SV)

Where:

MSCV,n = 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

n = number of EtO charges

%E.O.v = volume fraction percent of EtO

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/lbmole) at 68 °F and 1 atm).

- (2) Determine the mass rate of EtO sent to controls during the performance test using equation 6 to this paragraph. See equation 6 in paragraph (c)(2).
- (d) Compliance determination for facility where EtO use is less than 100 pounds per year. Each compliance demonstration shall consist of three separate runs using the applicable methods in paragraph (b) or (c) of this section. To determine compliance with the relevant standard, arithmetic mean of the three runs must be used. These procedures may be performed over a run duration of 1-hour (for a total of three 1-hour runs), except for the SCV testing from this category, where each run shall consist of the entirety of the sterilizer chamber evacuation and subsequent washes. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process





information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent the entire range of normal operation, including operational conditions for maximum emissions if such emissions are not expected during maximum production. The owner or operator must also account for the control system residence time when conducting the performance test. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. The following procedures shall be used to demonstrate compliance with a removal efficiency standard. In addition to these procedures, the procedures in paragraph (e) of this section must be followed to establish the operating parameter limits for each applicable emission control(s).

- (1) You may determine the mass rate emissions of the stream prior to the control system and at the outlet of the control system using the test methods in paragraph (b) of this section. If the vent stream is comprised only of one or more SCVs, then you may use the procedures in paragraph (c) of this section for the mass rate emissions at the inlet.
- (2) Calculate the total mass of EtO per hour that is routed to the control system by summing the mass of EtO per hour from each vent.
- (3) Determine percent emission reduction (%ER) using the equation 7 to this paragraph:

%ER = ((Mapcd,i-Eapcd,o)/Mapcd,i)*100 (Eq. 7)

Where:

% ER = percent emission reduction MAPCD,i = total mass of EtO per hour to the control device EAPCD,o = total mass of EtO per hour from the control device

- (4) Repeat these procedures two additional times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control system.
- (e) Determination of operating limits for control device(s). If you are using performance testing to demonstrate compliance with removal efficiency standards, and if you are not demonstrating continual compliance with the applicable standard(s) using an EtO CEMS, you must also determine the operating limit(s) for each control device and then monitor the parameter(s) for each control device. The procedures in the following paragraphs shall be used to establish the parameter operating limits to be continually monitored in § 63.364.
- (1) Acid-water scrubbers. The procedures in paragraph (e)(1) of this section shall be used to determine the operating limits for acid-water scrubbers.
- (i) Ethylene glycol concentration. For determining the ethylene glycol concentration operating limit, you must establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; use the sampling and analysis procedures in ASTM D3695-88 (incorporated by reference, see § 63.14) to determine the ethylene glycol concentration.
- (ii) Scrubber liquor tank level. During the performance test, you must monitor and record the scrubber liquor tank level to the nearest 1/4 inch at the end of each of the three test runs. Use the data collected during the most recent performance test to calculate the average scrubber liquor tank level. This scrubber liquor tank level is the maximum operating limit for your scrubber liquor tank. Repeat this procedure for every scrubber liquor tank that is included in the performance test.
- (iii) Scrubber liquor pH. During the performance test, you must monitor and record the scrubber liquor pH at least once every 15 minutes during each of the three test runs. You must use pH monitors as described in § 63.364(b)(3). Use the data collected during the most recent performance test to calculate the average scrubber pH measured. This scrubber liquor pH is the maximum operating limit for your acid-water scrubber. Repeat this procedure for every scrubber liquor tank that is included in the performance test.
- (2) Thermal oxidizers. The procedures in this paragraph shall be used to determine the operating limits for thermal oxidizers.



- (i) During the performance test, you must monitor and record the temperature at least once every 15 minutes during each of the three test runs. You must monitor the temperature in the firebox of the thermal oxidizer or immediately downstream of the firebox. You must use temperature monitors as described in § 63.364(c)(4).
- (ii) Use the data collected during the performance test to calculate and record the average temperature for each test run maintained during the performance test. The average temperature of the test runs is the minimum operating limit for your thermal oxidizer, unless it exceeds the recommended maximum oxidation temperature provided by the oxidation unit manufacturer. If this occurs, the minimum operating limit for your thermal oxidizer consists of the recommended maximum oxidation temperature provided by the oxidation unit manufacturer.
- (iii) Paragraphs (e)(2)(i) and (ii) of this section must be completed for each thermal oxidizer that is involved in the performance test.
- (3) Catalytic oxidizers. The procedures in this paragraph shall be used to determine the operating limits for catalytic oxidizers.
- (i) Prior to the start of the performance test, you must check the catalyst bed for channeling, abrasion, and settling. If problems are found during the inspection, you must replace the catalyst bed or take other correction action consistent with the manufacturer's recommendations.
- (ii) During the performance test, you must monitor and record the temperature at the inlet to the catalyst bed and the temperature difference across the catalyst bed at least once every 15 minutes during each of the three test runs. You must use temperature monitors as described in § 63.364(c)(4).
- (iii) Use the data collected during the performance test to calculate and record the average temperature at the inlet to the catalyst bed and the average temperature difference across the catalyst bed maintained for each test run, and then calculate the arithmetic averages of the test runs. These arithmetic averages of the test runs are the minimum operating limits for your catalytic oxidizer, unless it exceeds the recommended maximum oxidation temperature provided by the oxidation unit manufacturer. If this occurs, the minimum operating limit for your catalytic oxidizer consists of the recommended maximum oxidation temperature provided by the oxidation unit manufacturer.
- (iv) Paragraphs (e)(3)(i) through (iii) of this section must be completed for each catalytic oxidizer that is involved in the performance test.
- (4) Gas/solid reactors. During the performance test, you must monitor and record the gas/solid reactor pressure drop at least once every 15 minutes during each of the three test runs. Use the data collected during the most recent performance test to calculate the gas/solid reactor pressure measured. This gas/solid reactor pressure is the maximum operating limit for your gas/solid. Repeat this procedure for every gas/solid reactor that is included in the performance test.
- (5) Other control system for facility where EtO use is less than 100 pounds per year. If you seek to demonstrate compliance with a standard found at § 63.362 with a control device other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator the information requested under § 63.363(e). You must submit a monitoring plan that contains the following items: a description of the device; test results collected in accordance with § 63.363(e) verifying the performance of the device for controlling EtO emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored, identifying the ongoing QA procedures and performance specifications that will be conducted on the instruments; the frequency of conducting QA and performance checks; and the frequency of measuring and recording to establish continuous compliance with the standards. Your monitoring plan is subject to the Administrator's approval. Upon approval by the Administrator you must install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted in your monitoring plan. You must include in your monitoring plan proposed performance specifications and quality assurance procedures for your monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.
- (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.
- (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.

III. MONITORING REQUIREMENTS.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

- a) Temperature sensing and recording devices shall be installed to show that the inlet temperature to the catalyst bed meets or exceeds the minimum inlet temperature for effective oxidation based on manufacturer specifications.
- b) The company shall ensure that the control devices shall be equipped with the applicable monitoring equipment and the monitoring equipment shall be installed, calibrated, operated, and maintained according to the vendor's specifications at all times the control device is in use.
- c) Prior to the performance test, the inlet temperature to the catalyst bed shall be continuously monitored and operated at or above the minimum inlet temperature to the combustion bed per manufacturer specifications. After completion of the initial performance test, the temperature to the catalyst bed shall be continuously monitored and operated at or above the minimum inlet temperature to the oxidation catalyst, achieved during the performance test during which compliance was demonstrated.

005 [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. Alternatively, if you own or operate a facility where EtO use is less than 100 pounds/yr, you may demonstrate continuous compliance by conducting annual performance tests using the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365. If you elect to demonstrate compliance through periodic performance testing, you must also demonstrate continuous compliance with each operating limit required under this section according to the methods specified in § 63.364. If you own or operate an area source facility where EtO use is less than 100 pounds/yr where an existing collection of Group 2 room air emission is operated in accordance with the PTE requirements of EPA Method 204 of appendix M to part 51 of this chapter, you may instead conduct these performance tests once every three years.
- (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 40 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.
- (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.
- (c) Initial compliance demonstration where facility EtO use is less than 100 pounds per year. If you own or operate an affected source that is both subject to an emission standard in § 63.362 and located within a facility where EtO use is less than 100 pounds per year, you may comply with paragraphs (c)(1) and (2) of this section:
- (1) Conduct an initial compliance demonstration using the procedures listed in § 63.7 of this part according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365;
- (2) Complete the initial compliance demonstration within 180 days after the compliance date for the affected source as determined in § 63.360(j).
- (d) Operating limits for facility where EtO use is less than 100 lb/yr. If annual EtO use at the facility is less than 100 lb, the procedures in paragraphs (d)(1) through (5) of this section may be used to determine compliance with the standard(s) under § 63.362(c) through (g) and to establish operating limits for each of the control devices, as applicable:
- (1) You must determine the percent emission reduction of the control system used to comply with § 63.362(c) through (g) using the test methods and procedures in § 63.365(d)(1).
- (2) If an acid-water scrubber(s) is used to comply with a standard, then you must establish as an operating limit:
- (i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1)(i);
- (ii) The maximum liquor tank level using the procedures described in § 63.365(e)(1)(ii); or
- (iii) The maximum scrubber liquor pH using the procedures described in § 63.365(e)(1)(iii).
- (3) If a thermal oxidizer(s) is used to comply with a standard, you must establish as an operating limit the minimum temperature in or immediately downstream of the firebox using the procedures described in § 63.365(e)(2).
- (4) If a catalytic oxidizer(s) is used to comply with the standard, you must establish as operating limits both:
- (i) The minimum temperature at the inlet to the catalyst bed using the procedures described in § 63.365(e)(3); and
- (ii) The minimum temperature difference across the catalyst bed using the procedures described in § 63.365(e)(3).
- (5) If a gas/solid reactor(s) is used to comply with the standard, you must establish as an operating limit the pressure drop across the media beds and conduct weekly sampling and analysis of the media. Determine the maximum gas/solid reactor pressure drop using the procedures described in § 63.365(e)(4).
- (e) Other control technology for facility where EtO use is less than 100 lb/yr. If you are conducting a performance test using a control technology other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator information describing the design and operation of the air pollution control system, including recommendations for the parameters to be monitored that will demonstrate continuous compliance. Based on this information, the Administrator will determine the parameter(s) to be measured during the performance test. During the





performance test required in paragraph (a) of this section, using the methods approved in § 63.365(e)(5), you must determine the site-specific operating limit(s) for the operating parameters approved by the Administrator. You must submit the information at least sixty days before the performance test is scheduled to begin. The information on the control technology must include the five items listed in paragraphs (1) through (5) of this section:

- (1) Identification of the specific parameters you propose to use as additional operating limits;
- (2) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;
- (3) A discussion of how you will establish the upper and/or lower values which will establish the operating limits for these parameters;
- (4) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and
- (5) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.
- (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).

006 [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.
- (2) If you own or operate an affected source at a facility where EtO use is less than 100 lb/yr that is subject to an emission standard in § 63.362, you may monitor the parameters specified in paragraphs (b), (c), (d), (e), (g), and (i) of this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.





- (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) Acid-water scrubbers. If you are demonstrating continuous compliance through periodic performance testing on an acid-water scrubber(s), you must:
- (1) Ethylene glycol concentration. Sample the scrubber liquor from the acid-water scrubber(s) and analyze and record at least once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in § 63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated. You must maintain the weekly ethylene glycol concentration below the operating limit established during the most recent performance test;
- (2) Scrubber liquor tank level. Measure and record at least once per day the level of the scrubber liquor in the recirculation tank(s). You must install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a day only if the scrubber unit has been operated. You must maintain the daily scrubber liquor height in each recirculation tank below the applicable operating limit established during the most recent performance test; or
- (3) pH. Monitor and record at least every 15 minutes the scrubber liquor pH. Monitoring is required when the scrubber is operating. A data acquisition system for the pH monitor shall compute and record each 3-hour average scrubber liquor pH value, rolled hourly. This must be done by first averaging the scrubber liquor pH readings obtained over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even if the scrubber unit is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average scrubber liquor pH. You must maintain the 3-hour rolling average scrubber liquor pH below the applicable operating limit established during the most recent performance test. You must ensure the pH monitoring system meets the following requirements:
- (i) The pH sensor must be installed in a position that provides a representative measurement of scrubber liquor pH;
- (ii) The sample must be properly mixed and representative of the fluid to be measured; and
- (iii) A performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system must be conducted in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.
- (c) Oxidizers. If you are demonstrating continuous compliance through periodic performance testing on a catalytic oxidizer or thermal oxidizer, the requirements in paragraphs (c)(1) and (2) of this section apply:
- (1) For thermal oxidizers, you must monitor and record at least every 15 minutes the temperature in or immediately downstream of the firebox using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the thermal oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature value, rolled hourly. This must be done by first averaging the temperature readings over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even if the thermal oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature in or immediately downstream of the firebox. You must maintain the 3-hour rolling average temperature above the operating limit established during the most recent performance test.





- (2) For catalytic oxidizers, you must monitor and record at least every 15 minutes the temperature at the inlet to the catalyst bed using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the catalytic oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature, rolled hourly. This must be done by first averaging the temperature readings over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even if the catalytic oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature at the inlet to the catalyst bed. You must maintain the 3-hour rolling average temperature above the operating limit established during the most recent performance test.
- (3) For catalytic oxidizers, you must monitor and record at least every 15 minutes the temperature increase across the catalyst bed, immediately downstream of the catalytic bed, using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the catalytic oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature increase, rolled hourly. This must be done by first computing the difference in outlet temperature minus inlet temperature (monitored under paragraph (c)(2)), and second averaging the temperature difference values over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even if the catalytic oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature increase across the catalyst bed. You must maintain the 3-hour average temperature increase above the operating limit established during the most recent performance test.
- (4) You must install, calibrate, operate, and maintain a temperature monitor with a minimum accuracy of ±1 percent over the normal range of the temperature measured, expressed in degrees Celsius, or 2.8 degrees Celsius, whichever is greater. You must verify the accuracy of the temperature monitor twice each calendar year at least five months apart with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy of the temperature monitor may be verified in a calibrated oven (traceable to NIST standards).
- (5) For catalytic oxidizers, if the monitor indicates that the temperature is below the operating limit, within 7 calendar days you must:
- (i) Correct the temperature or temperature increase so that it falls within the established operating range; or
- (ii) Replace the catalyst bed. Following replacement of the catalyst bed, you must conduct a new performance test within 180 days and re-establish the operating limits.
- (d) Gas-solid reactors. If you are demonstrating continuous compliance through periodic performance testing on a gas/solid reactor(s), you must:
- (1) Media analysis. Sample the media from the gas/solid reactor(s) and have the manufacturer analyze at least once per week. Monitoring is required during a week only if the gas/solid reactor unit has been operated; and
- (2) Pressure drop. Monitor and record at least every 15 minutes the pressure drop. Monitoring is required when the gas/solid reactor is operating. A data acquisition system for the pressure drop monitor shall compute and record each 3-hour average gas/solid reactor pressure drop value, rolled hourly. This must be done by first averaging the gas/solid reactor pressure drop readings obtained over a clock hour, i.e., beginning and ending on the hour. All data collected during the operating hour must be used, even if the gas/solid reactor unit is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average gas/solid reactor pressure drop below the applicable operating limit established during the most recent performance test.
- (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.

Mscv,n = Mcharge*%EOw (EQ. 1)

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.

Mscv,n = (Qm*Tn*%EOv*(MW/SV))(Eq. 2)

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/lbmole) 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.

f = 0.99-(i/Mfac)(Eq. 3)

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)

See equation 4 in paragraph (f)(1)(i)(B)





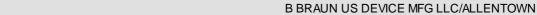
(C)(1) Determine the mass rate of EtO sent to controls during the previous 30 days using equation 5 to this paragraph.

See equation 5 in paragraph (f)(1)(i)(C)(1)

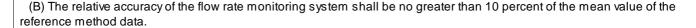
- (2) If both this approach is chosen and the SCV is (or SCVs are) combined with another emission stream, then the owner or operator cannot monitor the point after the combination occurs.
- (ii) Room air emissions. If room air emissions are both subject to an emission standard and split between two or 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:
- (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, 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.



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- (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 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.

See equation 6 in paragraph (i)(2)

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

IV. RECORDKEEPING REQUIREMENTS.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall maintain records which demonstrate compliance with the limit set in condition above and may be used by the Department for enforcement purposes. The records shall be updated on a monthly basis, shall be kept on site, and shall be provided to the Department personnel upon request.

008 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Catalyst inlet temperature shall be recorded continuously whenever the unit is in operation. The temperature at the inlet to the catalyst bed shall be monitored and maintained to show that the unit is operating at or above the minimum inlet temperature to the oxidation catalyst achieved during the performance test in which compliance with the EtO destruction efficiency requirement is demonstrated. The recording charts shall be made available to the Department personnel upon request. These records shall be maintained for a period of time not less than five years.

009 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to 25 Pa. Code § 135.5 (relating to recordkeeping), the owner or operator shall maintain and make available, upon request by the Department, such records as may be necessary to emonstrate compliance with 25 Pa. Code § 135.3 (relating to reporting). These 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. The records shall be retained for a minimum of five (5) years and shall be made available to the Department upon request.

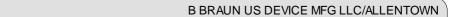
010 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.367]

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.

V. REPORTING REQUIREMENTS.

011 [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. The owner or operator must also fulfill any additional reporting requirements pursuant to any extension requests approved by the Department. 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 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-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:
- (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 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. You must fulfill all requirements for construction or reconstruction of a facility in § 63.5, according to the applicability in table 6 to this subpart, and in this paragraph.
- (1) Applicability.
- (i) This paragraph (d) and § 63.5 implement the preconstruction review requirements of section 112(i)(1) for facilities subject to these emissions standards. In addition, this paragraph (d) and § 63.5 include other requirements for constructed and reconstructed facilities that are or become subject to these emissions standards.
- (ii) After April 5, 2024, the requirements in this section and in § 63.5 apply to owners or operators who construct a new facility or reconstruct a facility subject to these emissions standards after April 5, 2024. New or reconstructed facilities subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) and (e).
- (2) Advance approval. After April 5, 2024, whether or not an approved permit program is effective in the jurisdictional authority in which a facility is (or would be) located, no person may construct a new facility or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and § 63.5(d)(3) and (4) and (e).
- (3) Application for approval of construction or reconstruction. The provisions of paragraph (b)(3) of this section and § 63.5(d)(3) and (4) implement section 112(i)(1) of the Act.
- (i) General application requirements.
- (A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new facility subject to these emissions standards, the reconstruction of a facility subject to these emissions standards, or the reconstruction of a facility such that the facility





becomes a facility subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (e)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

- (B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:
 - (1) The applicant's name and address.
- (2) A notification of intention to construct a new facility subject to these emissions standards or make any physical or operational change to a facility subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2.
 - (3) The address (i.e., physical location) or proposed address of the facility.
 - (4) An identification of the relevant standard that is the basis of the application.
 - (5) The expected commencement date of the construction or reconstruction.
 - (6) The expected completion date of the construction or reconstruction.
 - (7) The anticipated date of (initial) startup of the facility.
- (8) The type and quantity of hazardous air pollutants emitted by the facility, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the facility reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.
 - (9) Other information as specified in paragraph (b)(3)(ii) of this section and § 63.5(d)(3).
- (C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(8) and (b)(3)(ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.
- (ii) Application for approval of construction. Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the facility subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.
- (4) Approval of construction or reconstruction based on prior jurisdictional authority preconstruction review.





- (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) if the owner or operator of a new or reconstructed facility who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:
- (A) The owner or operator of the new or reconstructed facility subject to these emissions standards has undergone a preconstruction review and approval process in the jurisdictional authority in which the facility is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the facility will meet these emissions standards as proposed, if the facility is properly built and operated;
- (B) In making its finding, the jurisdictional authority has considered factors substantially equivalent to those specified in § 63.5(e)(1).
- (ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in § 63.5. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.
- (e) Notification requirements. The owner or operator of an affected source subject to an emissions standard in § 63.362 shall fulfill all notification requirements in § 63.9, according to the applicability in table 6 to this subpart, and in this paragraph (e).
- (1) Initial notifications.
- (i) If you own or operate an affected source subject to an emissions standard in § 63.362, you may use the application for approval of construction or reconstruction under paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, if relevant to fulfill the initial notification requirements.
- (ii) The owner or operator of a new or reconstructed facility subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (d)(3) of this section and § 63.5(d)(3) and (4) shall provide the following information in writing to the Administrator:
- (A) A notification of intention to construct a new facility subject to these emissions standards, reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (d)(3)(i)(A) of this section:
- (B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards:
- (C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked no later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;
- (D) A notification of the anticipated date of startup of the facility, delivered or postmarked not more than 60 days nor less than 30 days before such date; and
- (E) A notification of the actual date of initial startup of the facility, delivered or postmarked within 15 calendar days after that date.
- (iii) After the effective date, whether or not an approved permit program is effective in the jurisdictional authority in which a facility subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new facility subject to these emissions standards, or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that it becomes a facility subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or





reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (d)(3) of this section and § 63.5(d)(3) and (4). For facilities subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.9.

- (2) If an owner or operator of a facility subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, in place of the actual emissions data or control efficiencies required in paragraphs (d)(3)(i)(B)(8) and (b)(3)(ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.
- (3) If you own or operate an affected source subject to an emissions standard in § 63.362, you must also include the amount of EtO used at the facility during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3). For new sterilization facilities subject to this subpart, the amount of EtO used at the facility shall be an estimate of expected use during the first consecutive 12-month period of operation.
- (4) Beginning October 7, 2024, you must submit all subsequent Notification of Compliance Status reports in PDF formatto the EPA following the procedure specified in § 63.9(k), except any medium submitted through mail must be sent to the attention of the Commercial Sterilization Sector Lead.
- (f) Performance test submission. Beginning on June 4, 2024, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (f)(1) through (3) of this section.
- (1) Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test. Submit the results of the performance test to the EPA via the CEDRI, which can be accessed through the EPA's CDX (https://cdx.epa.gov/). 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) Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test. The results of the performance test 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 (f)(1)(i) or (ii) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the 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 (f)(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.
- (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 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;
- (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.

VI. WORK PRACTICE REQUIREMENTS.

012 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The facility shall be:

- a. Operated in such a manner as not to cause air pollution as that term is defined in 25 Pa. Code § 121.1;
- b. Operated and maintained in a manner consistent with good operating and maintenance practices;
- c. Operated and maintained in accordance with practices based on the "manufacturer's specifications;"

013 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The aforementioned source(s) may only be operated as long as the associted air pollution control devices are operationed and maintained in accordance with the specifications set forth in the respective plan approval(s) and the application(s) submitted for said plan approval(s) (as approved by the Department), and in accordance with any conditions set forth herein.

VII. ADDITIONAL REQUIREMENTS.

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







Group Name: **GROUP 2**

Group Description: EMERGENCY INTERNAL COMBUSTION ENGINES

Sources included in this group

ID	Name
003	EMERGENCY GENERATOR - 635HP
004	FIRE PUMP - 149HP
111	EMERGENCY GENERATOR - 173 HP
113	FIRE PUMP - 110 HP

I. RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §123.13]

Processes

The permittee may not permit the emission into the outdoor atmosphere of particulate matter, expressed as PM, from each source of this group in excess of the following rate:

(i) .04 grain per dry standard cubic foot, when the effluent gas volume is less than 150,000 dry standard cubic feet per minute.

002 [25 Pa. Code §123.21]

General

The permittee may not permit the emission into the outdoor atmosphere of sulfur oxides from a source in a manner that the concentration of the sulfur oxides, expressed as SO2, from each source of this group in excess of the following rate: (1) 500 parts per million, by volume, dry basis.

003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- a) Source ID 003 and 004 in Group 2 are subject to 40 CFR 60 Subpart IIII Standards of Performance for Stationary Compression Ignition Internal Combustion Engines.
- b) Source ID 111 and 113 in Group 2 are subject to 40 CFR Part 63 Subpart ZZZZ, for Stationary Reciprocating Internal Combustion Engines.

004 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4207]

Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What fuel requirements must I meet if I am an owner or operator of a stationary CI internal combustion engine subject to

- (a) Beginning October 1, 2007, owners and operators of stationary CI ICE subject to this subpart that use diesel fuel must use diesel fuel that meets the requirements of 40 CFR 80.510(a).
- (b) Beginning October 1, 2010, owners and operators of stationary CI ICE subject to this subpart with a displacement of less than 30 liters per cylinder that use diesel fuel must use diesel fuel that meets the requirements of 40 CFR 1090.305 for nonroad diesel fuel, except that any existing diesel fuel purchased (or otherwise obtained) prior to October 1, 2010, may be used until depleted.

Operation Hours Restriction(s).

005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Each source in this group shall operate no more than 242 hours during the May 1 through September 30 ozone season of each year, and no more than 500 hours during any consecutive 12-month period.

II. TESTING REQUIREMENTS.

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







III. MONITORING REQUIREMENTS.

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006 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4209] Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What are the monitoring requirements if I am an owner or operator of a stationary CI internal combustion engine?

If you are an owner or operator, you must meet the monitoring requirements of this section. In addition, you must also meet the monitoring requirements specified in §60.4211.

(a) If you are an owner or operator of an emergency stationary CI internal combustion engine, you must install a nonresettable hour meter prior to startup of the engine.

IV. RECORDKEEPING REQUIREMENTS.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall record the total hours of operation for each source on a monthly basis. The data recorded shall include, but not be limited to:

- (1) The name of the source which was operated.
- (2) The hours of operation of each source.

[25 Pa. Code §127.511]

Monitoring and related recordkeeping and reporting requirements.

[40 CFR Part 63 NESHAPS for source categories 40 CFR 63.6655 and 63.6660]

- a) Records must be kept of any occurrence and the duration of each malfunction of operation, all required maintence performed on the air pollution control device or monitoring equipment, any actions taken during the periods of malfunction to minimize emissions including corrective actions, any maintenance conducted on the RICE to demonstrate that the engine was operated and maintained according to the maintenance plan. Records must be maintained for the previous five (5) years.
- b) Record the hours of operation of the engine that is recorded through the non-resettable hour meter. Document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency.

[40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4214] # 009 Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines What are my notification, reporting, and recordkeeping requirements if I am an owner or operator of a stationary CI internal combustion engine?

The owner or operator must keep records of the operation of the engine in emergency and non-emergency service that are recorded through the non-resettable hour meter. The owner must record the time of operation of the engine and the reason the engine was in operation during that time.

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.

010 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The sources shall be operated in accordance with the manufacturer's specifications and the source shall also be operated and maintained in accordance with good air pollution practices.

[40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4211] Subpart IIII - Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

(f) If you own or operate an emergency stationary ICE, you must operate the emergency stationary ICE according to the requirements in paragraphs (f)(1) through (3) of this section. In order for the engine to be considered an emergency stationary ICE under this subpart, any operation other than emergency operation, maintenance and testing, and operation in





non-emergency situations for 50 hours per year, as described in paragraphs (f)(1) through (3), is prohibited. If you do not operate the engine according to the requirements in paragraphs (f)(1) through (3), the engine will not be considered an emergency engine under this subpart and must meet all requirements for non-emergency engines.

- (1) There is no time limit on the use of emergency stationary ICE in emergency situations.
- (2) You may operate your emergency stationary ICE for the purpose specified in paragraph (f)(2)(i) of this section for a maximum of 100 hours per calendar year. Any operation for non-emergency situations as allowed by paragraph (f)(3) of this section counts as part of the 100 hours per calendar year allowed by this paragraph (f)(2).
- (i) Emergency stationary ICE may be operated for maintenance checks and readiness testing, provided that the tests are recommended by federal, state or local government, the manufacturer, the vendor, the regional transmission organization or equivalent balancing authority and transmission operator, or the insurance company associated with the engine. The owner or operator may petition the Administrator for approval of additional hours to be used for maintenance checks and readiness testing, but a petition is not required if the owner or operator maintains records indicating that federal, state, or local standards require maintenance and testing of emergency ICE beyond 100 hours per calendar year.
- (ii)-(iii) [Reserved]
- (3) Emergency stationary ICE may be operated for up to 50 hours per calendar year in non-emergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (f)(2) of this section. Except as provided in paragraph (f)(3)(i) of this section, the 50 hours per calendar year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to an electric grid or otherwise supply power as part of a financial arrangement with another entity.
- (i) The 50 hours per year for non-emergency situations can be used to supply power as part of a financial arrangement with another entity if all of the following conditions are met:
 - (A) The engine is dispatched by the local balancing authority or local transmission and distribution system operator;
- (B) The dispatch is intended to mitigate local transmission and/or distribution limitations so as to avert potential voltage collapse or line overloads that could lead to the interruption of power supply in a local area or region.
- (C) The dispatch follows reliability, emergency operation or similar protocols that follow specific NERC, regional, state, public utility commission or local standards or guidelines.
 - (D) The power is provided only to the facility itself or to support the local transmission and distribution system.
- (E) The owner or operator identifies and records the entity that dispatches the engine and the specific NERC, regional, state, public utility commission or local standards or guidelines that are being followed for dispatching the engine. The local balancing authority or local transmission and distribution system operator may keep these records on behalf of the engine owner or operator.

012 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6603]

Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal **Combustion Engines**

What emission limitations, operating limitations, and other requirements must I meet if I own or operate an existing stationary RICE located at an area source of HAP emissions?

For SI engines:

- a. Change oil and filter every 500 hours of operation or annually, whichever comes first;
- b. Inspect spark plugs every 1,000 hours of operation or annually, whichever comes first, and replace as necessary; and,
- c. Inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary.

For CI engines:

- a. Change oil and filter every 500 hours of operation or annually, whichever comes first;
- b. Inspect air cleaner every 1,000 hours of operation or annually, whichever comes first, and replace as necessary, and,





c. Inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary.

013 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6625]

Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

What are my monitoring, installation, operation, and maintenance requirements?

(h) Minimize the engine's time spent at idle and minimize the engine's startup time at startup to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes, after which time the non-startup emission limitations apply.

014 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6640]

Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

How do I demonstrate continuous compliance with the emission limitations, operating limitations, and other requirements?

40 CFR 63 Subpart ZZZZ

Emergency Stationary RICE (40 CFR 63.6640(f)):

- (f) If you own or operate an emergency stationary RICE, you must operate the emergency stationary RICE according to the requirements in paragraphs (f)(1) through (4) of this section. In order for the engine to be considered an emergency stationary RICE under this subpart, any operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in paragraphs (f)(1) through (4), is prohibited. If you do not operate the engine according to the requirements in paragraphs (f)(1) through (4), the engine will not be considered an emergency engine under this subpart and must meet all requirements for non-emergency engines.
- (1) There is no time limit on the use of emergency stationary RICE in emergency situations.
- (2) You may operate your emergency stationary RICE for the purpose specified in paragraph (f)(2)(i) of this section for a maximum of 100 hours per calendar year. Any operation for non-emergency situations as allowed by paragraphs (f)(3) and (4) of this section counts as part of the 100 hours per calendar year allowed by this paragraph (f)(2).
- (i) Emergency stationary RICE may be operated for maintenance checks and readiness testing, provided that the tests are recommended by federal, state or local government, the manufacturer, the vendor, the regional transmission organization or equivalent balancing authority and transmission operator, or the insurance company associated with the engine. The owner or operator may petition the Administrator for approval of additional hours to be used for maintenance checks and readiness testing, but a petition is not required if the owner or operator maintains records indicating that federal, state, or local standards require maintenance and testing of emergency RICE beyond 100 hours per calendar year.
- (ii)-(iii) [Reserved]
- (3) Emergency stationary RICE located at major sources of HAP may be operated for up to 50 hours per calendar year in nonemergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (f)(2) of this section. The 50 hours per year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to supply power to an electric grid or otherwise supply power as part of a financial arrangement with another entity.
- (4) Emergency stationary RICE located at area sources of HAP may be operated for up to 50 hours per calendar year in nonemergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (f)(2) of this section. Except as provided in paragraphs (f)(4)(i) and (ii) of this section, the 50 hours per year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to an electric grid or otherwise supply power as part of a financial arrangement with another entity.
- (i) Prior to May 3, 2014, the 50 hours per year for non-emergency situations can be used for peak shaving or non-emergency demand response to generate income for a facility, or to otherwise supply power as part of a financial arrangement with another entity if the engine is operated as part of a peak shaving (load management program) with the



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local distribution system operator and the power is provided only to the facility itself or to support the local distribution system.

- (ii) The 50 hours per year for non-emergency situations can be used to supply power as part of a financial arrangement with another entity if all of the following conditions are met:
 - (A) The engine is dispatched by the local balancing authority or local transmission and distribution system operator.
- (B) The dispatch is intended to mitigate local transmission and/or distribution limitations so as to avert potential voltage collapse or line overloads that could lead to the interruption of power supply in a local area or region.
- (C) The dispatch follows reliability, emergency operation or similar protocols that follow specific NERC, regional, state, public utility commission or local standards or guidelines.
 - (D) The power is provided only to the facility itself or to support the local transmission and distribution system.
- (E) The owner or operator identifies and records the entity that dispatches the engine and the specific NERC, regional, state, public utility commission or local standards or guidelines that are being followed for dispatching the engine. The local balancing authority or local transmission and distribution system operator may keep these records on behalf of the engine owner or operator.

015 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6640]

Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

How do I demonstrate continuous compliance with the emission limitations, operating limitations, and other requirements?

Operate and maintain the stationary RICE according to the manufacturer's emission related operation and maintenance instructions; or develop and follow your own maintenance plan which must provide to the extent practicable for the maintenance and operation of the engine in a manner consistent with good air pollution control practice for minimizing emissions.

016 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.6640]

Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

How do I demonstrate continuous compliance with the emission limitations, operating limitations, and other requirements?

Operate and maintain the stationary RICE in accordance with requirements in Table 6 of 40 CFR 63, Subpart ZZZZ.

VII. ADDITIONAL REQUIREMENTS.

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







Group Name: GROUP 3
Group Description: BOILERS
Sources included in this group

	ID	Name
(033	BOILER- 21.0 MMBTU/HR
()34	BOILER- 21.0 MMBTU/HR

I. RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to the Best Available Technology provision of 25 Pa. Code §§127.1 & 127.12(a)(5), the PM10 emissions from each boiler shall not exceed 0.15 lb/hr, 0.69 TPY (based on 12 month rolling sum) while firing Natural Gas as a fuel.

002 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to the Best Available Technology provision of 25 Pa. Code §§127.1 & 127.12(a)(5), the NOX emissions from each boiler shall not exceed 30 PPM at 3% O2 while firing Natural Gas as a fuel.

003 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to the Best Available Technology provision of 25 Pa. Code §§127.1 & 127.12(a)(5), the CO emissions from each boiler shall not exceed 300 PPM at 3% O2 while firing Natural Gas as a fuel.

004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

These boilers are subject to 40 CFR Part 60 Subpart Dc, of the Standards of Performance for New Stationary Sources and shall comply with all applicable requirements of this Subpart.

005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Pursuant to the provision of 25 Pa. Code, Chapter 123, Section 123.41, the visible air contaminant from the boilers shall not be emitted in such a manner that the opacity of the emissions is equal to or greater than 20 % for a period or periods aggregating more than 3 minutes in any one hour; or equal to or greater than 60% at any time.

Throughput Restriction(s).

006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The maximum heat input to each boiler shall not exceed 21.0 million Btu's per hour at any time from firing natural gas as a fuel.

II. TESTING REQUIREMENTS.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- (a) If the results of a stack test, performed as required by this operating permit, exceed the level specified in any condition of this operating permit, the Permitee shall take appropriate corrective actions. Within 30 days of the Permitee receiving the stack test results, a written description of the corrective actions shall be submitted to the Department. The Permitee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. The Department shall notify the Permitee within 30 days, if the corrective actions taken are deficient. Within 30 days of receipt of the notice of deficiency, the Permitee shall submit a description of additional corrective actions to the Department. The Department reserves the authority to use enforcement activities to resolve noncompliant stack tests.
- (b) If the results of the required stack test exceed any limit defined in this operating permit, the test was not performed in accordance with the stack test protocol or the source and/or air cleaning device was not operated in accordance with the



operating permit, then another stack test shall be performed to determine compliance. Within 120 days of the Permitee receiving the original stack test results, a retest shall be performed. The Department may extend the retesting deadline if the Permitee demonstrates, to the Department's satisfaction, that retesting within 120 days is not practicable. Failure of the second test to demonstrate compliance with the limits in the operating permit, not performing the test in accordance with the stack test protocol or not operating the source and/or air cleaning device in accordance with the operating permit may be grounds for immediate revocation of the permit to operate the affected source.

III. MONITORING REQUIREMENTS.

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008 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall install, operate and maintain the necessary meter(s) to determine and to record amount of fuel usage.

IV. RECORDKEEPING REQUIREMENTS.

009 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall calculate the emissions from each boiler using the rates found in the application, or as approved by the Department. The emission rates may be reviewed after results of testing are approved by the Department. Emission rates from approved test results shall be used to calculate emissions once approved.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

- 1. The permittee shall record fuel (s) used in each boiler.
- 2. The company shall maintain following records:
- (a) Data which clearly demonstrates that the heat input for each boiler never exceeds its rated capacity.
- (b) The records shall provide sufficient data to clearly demonstrate that the requirements of operating permit conditions are met.
- (c) Monthly hours of operation for each boiler on a 12-month rolling sum basis.
- (d) The permittee shall maintain monthly fuel consumption records in accordance with 40 CFR §60.48c (g). Records shall be kept for the fuel firing rates of the combustion unit on a 12-month rolling sum basis.
- (e) The permittee shall maintain records of monthly heat input on a 12-month rolling sum basis for each boiler.
- (f) The supporting calculations used to verify the PM10 emission limitations.
- (g) The emission of NOX, and CO on a monthly basis and calculations to verify compliance with the NOX, & CO emission limitations in any 12 consecutive month period.
- (h) These records shall be kept for a minimum of five (5) years and shall be made available to the Department upon request.

011 [25 Pa. Code §127.441]

Operating permit terms and conditions.

Inspection, maintenance and repair log (s) that, at minimum, shall include the following information:

- A. Identification of equipment, with date, time, responsible employee and type of activity.
- B. For inspections, a description of the inspection, findings, and any recommended actions, with reason.
- C. For maintenance and repair activity, a description actions taken, reason for action, e.g., preventative measure or corrective action as a result of inspection, and the condition of equipment following completion of the activity.

[25 Pa. Code §127.441]

Operating permit terms and conditions.







The permittee shall maintain the following records related to emissions of CO, NOx, and PM10 from each boiler:

A. A file, which shall be kept current, containing the maximum emission rates of each pollutant from each boiler, along with supporting documentation and calculations. For pollutants for which emission testing has been performed, these rates shall be based on emission rates measured in the most recent emissions testing.

B. Monthly and annual emissions of each pollutant, (tons/month on a 12 moth rolling basis and tons/year), along with supporting calculations.

V. REPORTING REQUIREMENTS.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

These boilers are subject to 40 CFR Part 60 Subpart Dc, of the Standards of Performance for New Stationary Sources and shall comply with all applicable requirements of this Subparts. Submit copies of all requests, reports, applications, submittals, and other communications to both EPA and the Department. The EPA copies shall be forwarded to:

United States Environmental Protection Agency

Region III, Air and Radiation Division

Permits Branch (3AD10)

Four Penn Center

1600 John F. Kennedy Boulevard

Philadelphia, Pennsylvania 19103-2852

VI. WORK PRACTICE REQUIREMENTS.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

The company shall maintain and operate each boiler in accordance with the manufacturer's specification and with good engineering practice.

015 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall utilize low NOx burners (LNB) technology to control NOx emissions from each boiler. Each boiler shall be operated with the operation of LNB at all the times.

[25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall perform an annual adjustment and/or tune-up on each boiler, which shall include the following:

- i. Inspection, adjustment, cleaning or replacement of fuel-burning equipment, including the burners and moving parts necessary for proper operation as specified by the manufacturer;
- ii. Inspection of flame pattern of characteristics and adjustments necessary to minimize emissions of NOX, and to the extent practicable minimize emissions of CO;
- iii. Inspection of the air-to-fuel ratio control system and adjustments necessary to ensure proper calibration and operation as specified by the manufacturer.

VII. ADDITIONAL REQUIREMENTS.

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





SECTION F. Alternative Operation Requirements.

No Alternative Operations exist for this State Only facility.





SECTION G. Emission Restriction Summary.

No emission restrictions listed in this section of the permit.



SECTION H. Miscellaneous.

- (a) The Synthetic Minor Operating Permit application was received on July 15, 2024. The annual operating permit maintenance fee shall be submitted to the Department in accordance with 25 Pa. Code, Chapter 127, Section 127.703. The annual maintenance fees are due no later than December 31, annually.
- (b) The permittee previously operated under Title V permit TV-39-00055.
- (c) Plan Approvals include:
- 39-332-001 issued 3/23/2010 for reactivation of Source 109 (was not reactivated)
- 39-332-002 issued 2/29/2012 for reactivation of Source 109 (was not reactivated)
- (d) Requests for Determination (RFDs) include:
- #39-0700 approved 5/24/2011 installation of a new pharmacy assembly line; F-Line (removed).
- #39-0777 approved 8/19/2013 operation of equipment used to dispose of medical devices; Introcan Operation.
- #39-0801 approved 3/25/2014 ceased firing #6 fuel oil in boiler #032.
- #39-0802 approved 3/25/2014 operation of 115-Fire Pump (removed)
- #39-0874 approved 2/16/17 for one cooling tower
- #39-0898 approved 4/25/18 to analyze DEHP as a HAP from the extrusion processes
- #39-0899 approved 5/24/18 for a water evaporator
- #39-0902 approved 6/28/18 for two existing offset printers
- #39-0927 approved 9/5/19 for a dry bed air cleaning device
- (e) In addition to the sources governed by the RFDs listed in subparagraph (e), the following is a list of sources that have been determined by the Department to be of minor significance under 25 Pa. Code, Chapter 127, Section 127.14(a)(8) and are not regulated in this State-Only Operating Permit. However, this determination does not exempt the sources from compliance with all applicable air quality regulations specified in 25 Pa. Code Chapters 121-143:
- Introcan Process
- Injection Molding Process
- Extrusion Operations
- Misc heaters and exempt boilers with total combined heating value of 35.5588 MMBtu/hr
- Cooling Towers 2CT5, 2CT6, 5CT1, 5CT2, and 5CT3
- (f) On 9/1/2021 this Operating permit was administratively amended to include newly applicable requirements from Plan Approval no. 39-00055B.
- (g) On September 13, 2022 this Operating permit was administratively amended to include newly applicable requirements from Plan Approval no. 39-00055A.
- (h) This permit includes Mold shop Operations as an insignificant source, which were installed under Plan Approval 39-00055A.
- (i) On 9/16/2024 the Department granted the Facility a two-year extension for compliance with the subpart O requirements including the 99.99% destruction removal efficiency (DRE) requirement for the Sterilization Chamber Vent (SCV) found in 40 CFR §63.362(c), the 99.9% DRE requirement for the Aeration Room Vent (ARV) found in 40 CFR §63.362(d) and the 98% DRE requirement for Groups 1 and 2 room air emissions and related permanent total enclosure (PTE) requirement found in 40 CFR §63.362 (f) through





***** End of Report *****