

Facility DEC ID: 5534400029

PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 5-5344-00029/00011
Effective Date:

Expiration Date:

Permit Issued To: STERIGENICS US LLC
SUITE 650
2015 SPRING RD
OAK BROOK, IL 60523

Contact: Laura Hartman
2015 Spring Brook Rd
Suite 650
Oak Brook, IL 60523
(630) 928-1724

Facility: STERIGENICS US LLC
84 PARK RD
QUEENSBURY, NY 12804

Contact: Kevin Wagner
2015 Spring Rd
Oak Brook, IL 60523
(630) 928-1771

Description:

This facility is a sterilization facility. Medical instruments, cosmetics and pharmaceuticals are placed in chambers which are filled with ethylene oxide gas. After sterilization, the gases are exhausted through control devices and the products are removed to aeration rooms which are also vented through control devices.

By acceptance of this permit, the permittee agrees that the permit is contingent upon strict compliance with the ECL, all applicable regulations, the General Conditions specified and any Special Conditions included as part of this permit.

Permit Administrator: BETH A MAGEE
NYSDEC - WARRENSBURG SUBOFFICE
232 GOLF COURSE RD
WARRENSBURG, NY 12885-1172

Authorized Signature: _____ Date: ____ / ____ / ____

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Notification of Other State Permittee Obligations**Item A: Permittee Accepts Legal Responsibility and Agrees to Indemnification**

The permittee expressly agrees to indemnify and hold harmless the Department of Environmental Conservation of the State of New York, its representatives, employees and agents ("DEC") for all claims, suits, actions, and damages, to the extent attributable to the permittee's acts or omissions in connection with the compliance permittee's undertaking of activities in connection with, or operation and maintenance of, the facility or facilities authorized by the permit whether in compliance or not in any compliance with the terms and conditions of the permit. This indemnification does not extend to any claims, suits, actions, or damages to the extent attributable to DEC's own negligent or intentional acts or omissions, or to any claims, suits, or actions naming the DEC and arising under article 78 of the New York Civil Practice Laws and Rules or any citizen suit or civil rights provision under federal or state laws.

Item B: Permittee's Contractors to Comply with Permit

The permittee is responsible for informing its independent contractors, employees, agents and assigns of their responsibility to comply with this permit, including all special conditions while acting as the permittee's agent with respect to the permitted activities, and such persons shall be subject to the same sanctions for violations of the Environmental Conservation Law as those prescribed for the permittee.

Item C: Permittee Responsible for Obtaining Other Required Permits

The permittee is responsible for obtaining any other permits, approvals, lands, easements and rights-of-way that may be required to carry out the activities that are authorized by this permit.

Item D: No Right to Trespass or Interfere with Riparian Rights

This permit does not convey to the permittee any right to trespass upon the lands or interfere with the riparian rights of others in order to perform the permitted work nor does it authorize the impairment of any rights, title, or interest in real or personal property held or vested in a person not a party to the permit.

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DEC GENERAL CONDITIONS
****** General Provisions ******
GENERAL CONDITIONS - Apply to ALL Authorized Permits.

Condition 1: Facility Inspection by the Department

Applicable State Requirement: ECL 19-0305

Item 1.1:

The permitted site or facility, including relevant records, is subject to inspection at reasonable hours and intervals by an authorized representative of the Department of Environmental Conservation (the Department) to determine whether the permittee is complying with this permit and the ECL. Such representative may order the work suspended pursuant to ECL 71-0301 and SAPA 401(3).

Item 1.2:

The permittee shall provide a person to accompany the Department's representative during an inspection to the permit area when requested by the Department.

Item 1.3:

A copy of this permit, including all referenced maps, drawings and special conditions, must be available for inspection by the Department at all times at the project site or facility. Failure to produce a copy of the permit upon request by a Department representative is a violation of this permit.

Condition 2: Relationship of this Permit to Other Department Orders and Determinations

Applicable State Requirement: ECL 3-0301 (2) (m)

Item 2.1:

Unless expressly provided for by the Department, issuance of this permit does not modify, supersede or rescind any order or determination previously issued by the Department or any of the terms, conditions or requirements contained in such order or determination.

Condition 3: Applications for permit renewals, modifications and transfers

Applicable State Requirement: 6 NYCRR 621.11

Item 3.1:

The permittee must submit a separate written application to the Department for renewal, modification or transfer of this permit. Such application must include any forms or supplemental information the Department requires. Any renewal, modification or transfer granted by the Department must be in writing.

Item 3.2:

The permittee must submit a renewal application at least 180 days before the expiration of permits for Title V and State Facility Permits.

Item 3.3

Permits are transferrable with the approval of the department unless specifically prohibited by the statute, regulation or another permit condition. Applications for permit transfer should be submitted prior to actual transfer of ownership.

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Condition 4: Permit modifications, suspensions or revocations by the Department
Applicable State Requirement: 6 NYCRR 621.13

Item 4.1:

The Department reserves the right to exercise all available authority to modify, suspend, or revoke this permit in accordance with 6NYCRR Part 621. The grounds for modification, suspension or revocation include:

- a) materially false or inaccurate statements in the permit application or supporting papers;
- b) failure by the permittee to comply with any terms or conditions of the permit;
- c) exceeding the scope of the project as described in the permit application;
- d) newly discovered material information or a material change in environmental conditions, relevant technology or applicable law or regulations since the issuance of the existing permit;
- e) noncompliance with previously issued permit conditions, orders of the commissioner, any provisions of the Environmental Conservation Law or regulations of the Department related to the permitted activity.

****** Facility Level ******

Condition 5: Submission of application for permit modification or renewal-REGION 5
SUBOFFICE - WARRENSBURG
Applicable State Requirement: 6 NYCRR 621.6 (a)

Item 5.1:

Submission of applications for permit modification or renewal are to be submitted to:
NYSDEC Regional Permit Administrator
Region 5 Sub-office
Division of Environmental Permits
232 Golf Course Road
Warrensburg, NY 12885-1172
(518) 623-1281

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Permit Under the Environmental Conservation Law (ECL)

ARTICLE 19: AIR POLLUTION CONTROL - AIR STATE FACILITY PERMIT

IDENTIFICATION INFORMATION

Permit Issued To: STERIGENICS US LLC
SUITE 650
2015 SPRING RD
OAK BROOK, IL 60523

Facility: STERIGENICS US LLC
84 PARK RD
QUEENSBURY, NY 12804

Authorized Activity By Standard Industrial Classification Code:
7389 - BUSINESS SERVICES, NEC

Permit Effective Date:

Permit Expiration Date:

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FEDERALLY ENFORCEABLE CONDITIONS

Renewal 1/DRAFT

**** Facility Level ****

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

This section contains terms and conditions which are federally enforceable. Permittees may also have other obligations under regulations of general applicability

Item A: Sealing - 6 NYCRR 200.5

The Commissioner may seal an air contamination source to prevent its operation if compliance with 6 NYCRR Chapter III is not met within the time provided by an order of the Commissioner issued in the case of the violation. Sealing means labeling or tagging a source to notify any person that operation of the source is prohibited, and also includes physical means of preventing the operation of an air contamination source without resulting in destruction of any equipment associated with such source, and includes, but is not limited to, bolting, chaining or wiring shut control panels, apertures or conduits associated with such source.

No person shall operate any air contamination source sealed by the Commissioner in accordance with this section unless a modification has been made which enables such source to comply with all requirements applicable to such modification.

Unless authorized by the Commissioner, no person shall remove or alter any seal affixed to any contamination source in accordance with this section.

Item B: Acceptable Ambient Air Quality - 6 NYCRR 200.6

Notwithstanding the provisions of 6 NYCRR Chapter III, Subchapter A, no person shall allow or permit any air contamination source to emit air contaminants in quantities which alone or in combination with emissions from other air contamination sources would contravene any applicable ambient air quality standard and/or cause air pollution. In such cases where contravention occurs or may occur, the Commissioner shall specify the degree and/or method of emission control required.

Item C: Maintenance of Equipment - 6 NYCRR 200.7

Any person who owns or operates an air contamination source which is equipped with an emission control device shall operate such device and keep it in a satisfactory state of maintenance and repair in accordance with ordinary and necessary practices, standards and procedures, inclusive of manufacturer's specifications,

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required to operate such device effectively.

Item D: Unpermitted Emission Sources - 6 NYCRR 201-1.2

(a) Except as otherwise provided by this Part, construction or operation of a new, modified or existing air contamination source without a registration or permit issued pursuant to this Part is prohibited.

(b) If an existing facility or emission source was subject to the permitting requirements of this Part at the time of construction or modification, and the owner or operator failed to apply for a permit or registration as described in this Part, the owner or operator must apply for a permit or registration in accordance with the provisions of this Part. The facility or emission source is subject to all regulations that were applicable to it at the time of construction or modification and any subsequent requirements applicable to existing emission sources.

Item E: Recycling and Salvage - 6 NYCRR 201-1.7

Where practical, any person who owns or operates an air contamination source shall recycle or salvage air contaminants collected in an air cleaning device according to the requirements of 6 NYCRR.

Item F: Prohibition of Reintroduction of Collected Contaminants to the Air - 6 NYCRR 201-1.8

No person shall unnecessarily remove, handle, or cause to be handled, collected air contaminants from an air cleaning device for recycling, salvage or disposal in a manner that would reintroduce them to the outdoor atmosphere.

Item G: Proof of Eligibility for Sources Defined as Exempt Activities - 6 NYCRR 201-3.2 (a)

The owner and/or operator of an emission source or unit that is eligible to be exempt, may be required to certify that it operates within the specific criteria described in 6 NYCRR Subpart 201-3. The owner or operator of any such emission source must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request.

Department representatives must be granted access to any facility which contains emission sources or units subject to 6 NYCRR Subpart 201-3, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

Item H: Proof of Eligibility for Sources Defined as Trivial

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Activities - 6 NYCRR 201-3.3 (a)

The owner and/or operator of an emission source or unit that is listed as being trivial in 6 NYCRR Part 201 may be required to certify that it operates within the specific criteria described in 6 NYCRR Subpart 201-3. The owner or operator of any such emission source must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility which contains emission sources or units subject to 6 NYCRR Subpart 201-3, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

Item I: Required Emission Tests - 6 NYCRR 202-1.1

An acceptable report of measured emissions shall be submitted, as may be required by the Commissioner, to ascertain compliance or noncompliance with any air pollution code, rule, or regulation. Failure to submit a report acceptable to the Commissioner within the time stated shall be sufficient reason for the Commissioner to suspend or deny an operating permit. Notification and acceptable procedures are specified in 6 NYCRR Subpart 202-1.

Item J: Open Fires Prohibitions - 6 NYCRR 215.2

Except as allowed by section 215.3 of 6 NYCRR Part 215, no person shall burn, cause, suffer, allow or permit the burning of any materials in an open fire.

Item K: Permit Exclusion - ECL 19-0305

The issuance of this permit by the Department and the receipt thereof by the Applicant does not and shall not be construed as barring, diminishing, adjudicating or in any way affecting any legal, administrative or equitable rights or claims, actions, suits, causes of action or demands whatsoever that the Department may have against the Applicant for violations based on facts and circumstances alleged to have occurred or existed prior to the effective date of this permit, including, but not limited to, any enforcement action authorized pursuant to the provisions of applicable federal law, the Environmental Conservation Law of the State of New York (ECL) and Chapter III of the Official Compilation of the Codes, Rules and Regulations of the State of New York (NYCRR). The issuance of this permit also shall not in any way affect pending or future enforcement actions under the Clean Air Act brought by the United States or any person.

Item L: Federally Enforceable Requirements - 40 CFR 70.6 (b)

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All terms and conditions in this permit required by the Act or any applicable requirement, including any provisions designed to limit a facility's potential to emit, are enforceable by the Administrator and citizens under the Act. The Department has, in this permit, specifically designated any terms and conditions that are not required under the Act or under any of its applicable requirements as being enforceable under only state regulations.

FEDERAL APPLICABLE REQUIREMENTS**The following conditions are federally enforceable.****Condition 1: Acceptable Ambient Air Quality
Effective for entire length of Permit****Applicable Federal Requirement: 6 NYCRR 200.6****Item 1.1:**

Notwithstanding the provisions of 6 NYCRR Chapter III, Subchapter A, no person shall allow or permit any air contamination source to emit air contaminants in quantities which alone or in combination with emissions from other air contamination sources would contravene any applicable ambient air quality standard and/or cause air pollution. In such cases where contravention occurs or may occur, the Commissioner shall specify the degree and/or method of emission control required.

**Condition 2: Open Fires - Prohibitions
Effective for entire length of Permit****Applicable Federal Requirement: 6 NYCRR 215.2****Item 2.1:**

Except as allowed by Title 6 NYCRR Section 215.3, no person shall burn, cause, suffer, allow or permit the burning of any materials in an open fire.

Item 2.2

Per Section 215.3, burning in an open fire, provided it is not contrary to other law or regulation, will be allowed as follows:

- (a) On-site burning in any town with a total population less than 20,000 of downed limbs and branches (including branches with attached leaves or needles) less than six inches in diameter and eight feet in length between May 15th and the following March 15th. For the purposes of this subdivision, the total population of a town shall include the population of any village or portion thereof located within the town. However, this subdivision shall not be construed to allow burning within any village.
- (b) Barbecue grills, maple sugar arches and similar outdoor cooking devices when actually used for cooking or processing food.
- (c) Small fires used for cooking and camp fires provided that only charcoal or untreated wood is used as fuel and the fire is not left unattended until extinguished.
- (d) On-site burning of agricultural wastes as part of a valid agricultural operation on contiguous

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agricultural lands larger than five acres actively devoted to agricultural or horticultural use, provided such waste is actually grown or generated on those lands and such waste is capable of being fully burned within a 24-hour period.

(e) The use of liquid petroleum fueled smudge pots to prevent frost damage to crops.

(f) Ceremonial or celebratory bonfires where not otherwise prohibited by law, provided that only untreated wood or other agricultural products are used as fuel and the fire is not left unattended until extinguished.

(g) Small fires that are used to dispose of a flag or religious item, and small fires or other smoke producing process where not otherwise prohibited by law that are used in connection with a religious ceremony.

(h) Burning on an emergency basis of explosive or other dangerous or contraband materials by police or other public safety organization.

(i) Prescribed burns performed according to Part 194 of this Title.

(j) Fire training, including firefighting, fire rescue, and fire/arson investigation training, performed under applicable rules and guidelines of the New York State Department of State's Office of Fire Prevention and Control. For fire training performed on acquired structures, the structures must be emptied and stripped of any material that is toxic, hazardous or likely to emit toxic smoke (such as asbestos, asphalt shingles and vinyl siding or other vinyl products) prior to burning and must be at least 300 feet from other occupied structures. No more than one structure per lot or within a 300 foot radius (whichever is bigger) may be burned in a training exercise.

(k) Individual open fires as approved by the Director of the Division of Air Resources as may be required in response to an outbreak of a plant or animal disease upon request by the commissioner of the Department of Agriculture and Markets, or for the destruction of invasive plant and insect species.

(l) Individual open fires that are otherwise authorized under the environmental conservation law, or by rule or regulation of the Department.

Condition 3: Exempt Sources - Proof of Eligibility
Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 201-3.2 (a)

Item 3.1:

The owner or operator of an emission source or activity that is listed as being exempt may be required to certify that it is operated within the specific criteria described in this Subpart. The owner or operator of any such emission source or activity must maintain all records necessary for demonstrating compliance with this Subpart on-site for a period of five years, and make them available to representatives of the department upon request.

Condition 4: Trivial Sources - Proof of Eligibility
Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 201-3.3 (a)

Item 4.1:

The owner or operator of an emission source or activity that is listed as being trivial in this Section may be required to certify that it is operated within the specific criteria described in this Subpart. The owner or operator of any such emission source or activity must maintain all required records on-site for a period of five years and make them available to representatives of the department upon request.

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Condition 5: Visible Emissions Limited
Effective for entire length of Permit

Applicable Federal Requirement:6 NYCRR 211.2

Item 5.1:

Except as permitted by a specific part of this Subchapter and for open fires for which a restricted burning permit has been issued, no person shall cause or allow any air contamination source to emit any material having an opacity equal to or greater than 20 percent (six minute average) except for one continuous six-minute period per hour of not more than 57 percent opacity.

Condition 6: Compliance Demonstration
Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement:6 NYCRR 212-1.5 (d)

Item 6.1:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):
 CAS No: 000075-21-8 ETHYLENE OXIDE

Item 6.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
 DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The rolling annual emissions of ethylene oxide shall not exceed 96.4 pounds per year. The annual emission limitation is based on an estimated mass balance from individual emission units (SCV, ARV, CEV, Group 1 and Group 2) and installation of the LESNI and indoor air dry beds emission control equipment. The modeled off site ambient concentrations were within the DAR-1 residual risk management range for ethylene oxide. This also ensures compliance with the facility's toxic impact analysis submitted to the Department.

The owner or operator shall install, maintain and use a continuous emissions monitoring system (CEMS) to measure and record the ethylene oxide actual emissions from the common stack. Monthly ethylene oxide emissions shall be calculated and recorded using the CEMS data. All data needed to calculate emissions shall be kept as part of the monthly records. Methods used to determine compliance shall be approved by the department by the effective date of this condition.

An extension to the effective date of this requirement may

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be granted by the Department.

Parameter Monitored: ETHYLENE OXIDE
Upper Permit Limit: 96.4 pounds per year
Monitoring Frequency: MONTHLY
Averaging Method: 12-MONTH TOTAL, ROLLED MONTHLY
Reporting Requirements: QUARTERLY (CALENDAR)
Reports due 30 days after the reporting period.
Subsequent reports are due every 3 calendar month(s).

Condition 7: Compliance Demonstration
Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 6 NYCRR 212-1.5 (d)

Item 7.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 7.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The owner or operator must install, operate, calibrate, and maintain a continuous pressure differential monitoring system to verify the presence of a permanent total enclosure (PTE) when the facility is in operation.

This monitoring system must measure the pressure differential between the interior and exterior of the PTE. The pressure differential must be maintained at or above 0.007 inches of water over a three-hour rolling average. 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. A data acquisition system for the monitoring system shall compute and record each 3-hour average pressure differential value.

An extension to the effective date of this requirement may be granted by the Department.

Parameter Monitored: PRESSURE CHANGE
Lower Permit Limit: 0.007 inches of water
Monitoring Frequency: CONTINUOUS
Averaging Method: 3-HOUR ROLLING AVERAGE
Reporting Requirements: QUARTERLY (CALENDAR)
Reports due 30 days after the reporting period.
Subsequent reports are due every 3 calendar month(s).

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Condition 8: Compliance Demonstration
Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement:6 NYCRR 212-1.5 (d)

Item 8.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 8.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES
Monitoring Description:

In instances where a facility owner or operator can demonstrate, to the satisfaction of the department that the facility owner or operator can apply BACT for criteria air contaminants or T-BACT for non-criteria air contaminants, the department may specify a less restrictive permissible emission rate or degree of air cleaning for the process emission source or emission point than required under Subpart 212-2 of this Part.

The predicted maximum off site concentration for ethylene oxide shall be less than 10-in-a-million excess cancer risk. The modeled off site fence line ambient air concentrations of ethylene oxide shall remain within the Acceptable Risk Management Range as described in DAR-1 section V. F.1.c. To ensure compliance with the above, facility wide emissions of ethylene oxide shall be controlled at the efficiencies proposed in their Toxic Impact Analysis (TIA) Modeling Report submitted in January 2025.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 9: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement:6 NYCRR 212-1.5 (g)

Item 9.1:

The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: 1-11111

Regulated Contaminant(s):
CAS No: 000075-21-8 ETHYLENE OXIDE

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Item 9.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The owner or operator shall continuously monitor and record the oxidation temperature at the outlet of the catalyst bed whenever the associated process equipment is operating except during quality assurance and routine maintenance activities. The baseline oxidation temperature will be established during the most recent stack test. The current minimum operating temperature is 285 degrees F. This requirement is in effect until the LESNI system is installed and commissioned.

Parameter Monitored: TEMPERATURE

Lower Permit Limit: 285 degrees Fahrenheit

Monitoring Frequency: CONTINUOUS

Averaging Method: MINIMUM - NOT TO FALL BELOW STATED
VALUE - SEE MONITORING DESCRIPTION

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 6 calendar month(s).

Condition 10: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 212-1.5 (g)

Item 10.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: 1-11111

Process: S01

Item 10.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

Scrubber liquor flow rate for wet acid scrubber will be monitored and recorded on a continuous basis whenever the associated process equipment is operating except during quality assurance and routine maintenance activities. The scrubber liquor flow rate must be maintained at or above the minimum level. The current limit is a minimum of 150 gallons per minute (gpm) for these scrubbers. This requirement is in effect until the LESNI system is installed and commissioned.

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Parameter Monitored: FLOW RATE
 Lower Permit Limit: 150 gallons per minute
 Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION
 Averaging Method: 3-HOUR BLOCK AVERAGE
 Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
 Reports due 30 days after the reporting period.
 Subsequent reports are due every 6 calendar month(s).

Condition 11: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 212-1.5 (g)

Item 11.1:

The Compliance Demonstration activity will be performed for the facility:
 The Compliance Demonstration applies to:

Emission Unit: 1-11111

Regulated Contaminant(s):
 CAS No: 000075-21-8 ETHYLENE OXIDE

Item 11.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES
 Monitoring Description:

Measure and record once per week the level of the scrubber liquor in the residence tank. The owner or operator shall install, maintain and use a liquor level indicator to measure the scrubber liquor tank level. The maximum liquor tank level will be established during the initial testing. This requirement is in effect until the LESNI system is installed and commissioned.

Monitoring Frequency: WEEKLY
 Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
 Reports due 30 days after the reporting period.
 Subsequent reports are due every 6 calendar month(s).

Condition 12: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 212-1.5 (g)

Item 12.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 12.2:

Compliance Demonstration shall include the following monitoring:

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Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Once the LESNI system is operational, the owner or operator shall continuously monitor and record the oxidation temperature at the outlet of the LESNI catalyst bed whenever the associated process equipment is operating except during quality assurance and routine maintenance activities. The baseline oxidation temperature will be the manufacturer's recommended minimum temperature or established during the most recent stack test.

Monitoring Frequency: CONTINUOUS

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 6 calendar month(s).

Condition 13: Compliance Demonstration**Effective between the dates of Permit Effective Date and 04/06/2026****Applicable Federal Requirement: 6 NYCRR 212-2.3 (b)****Item 13.1:**

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: 1-11111

Process: S02

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 13.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL

DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The exhaust from backventing sterilization chambers shall be directed through a control device which achieves at least 99% control of ethylene oxide emissions. Testing shall be conducted annually.

Parameter Monitored: DESTRUCTION EFFICIENCY

Lower Permit Limit: 99 percent

Reference Test Method: 40 CFR 60 Appendix B Performance Specification 19

Monitoring Frequency: ANNUALLY

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 14: Compliance Demonstration

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Effective between the dates of Permit Effective Date and 04/06/2026

Applicable Federal Requirement:6 NYCRR 212-2.3 (b)

Item 14.1:

The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: 1-11111
Process: S03

Regulated Contaminant(s):
CAS No: 000075-21-8 ETHYLENE OXIDE

Item 14.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The exhaust from the aeration rooms shall be directed through a control device which achieves at least 99% control of ethylene oxide emissions. Testing shall be conducted annually.

Parameter Monitored: DESTRUCTION EFFICIENCY

Lower Permit Limit: 99 percent

Reference Test Method: 40 CFR 60 Appendix B Performance Specification 19

Monitoring Frequency: ANNUALLY

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 15: Compliance Demonstration

Effective between the dates of Permit Effective Date and 04/06/2026

Applicable Federal Requirement:6 NYCRR 212-2.3 (b)

Item 15.1:

The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: 1-11111
Process: S01

Regulated Contaminant(s):
CAS No: 000075-21-8 ETHYLENE OXIDE

Item 15.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL

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DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The exhaust from the evacuation of the sterilization chambers shall be directed through a control device that achieves 99.9% control of ethylene oxide emissions. Testing frequency will be once during the term of the permit unless changed by the permitting authority.

Parameter Monitored: DESTRUCTION EFFICIENCY

Lower Permit Limit: 99.9 percent

Reference Test Method: 40 CFR 60 Appendix B Performance Specification 19

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING

DESCRIPTION

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST METHOD INDICATED

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

**Condition 16: Compliance Demonstration
Effective for entire length of Permit**

Applicable Federal Requirement: 6 NYCRR 212-2.4 (b)

Item 16.1:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 0NY075-00-0 PARTICULATES

Item 16.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

Emissions from any process emission source for which an application was received by the department after July 1, 1973 are restricted as follows:

No facility owner or operator shall cause or allow emissions of particulate that exceed 0.050 grains per cubic foot of exhaust gas, expressed at standard conditions on a dry gas basis, except in instances where determination of permissible emission rate using process weight for a specific source category emitting solid particulate is based upon Table 5 and Table 6 of 6 NYCRR 212-2.5 (a) and (b).

The owner or operator shall maintain the LESNI burner in accordance with the manufacturer recommendations to demonstrate compliance with this condition.

Parameter Monitored: PARTICULATES

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Upper Permit Limit: 0.050 grains per dscf

Reference Test Method: EPA Method 5

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING

DESCRIPTION

Averaging Method: Arithmetic average of stack test runs

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 17: Standards for capture systems

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40CFR 63.362(h), Subpart O

Item 17.1:

Room air emissions for which numerical limits are prescribed must be captured and routed under negative pressure to a control system. The owner or operator may assume the capture system efficiency is 100 percent if both conditions in paragraphs (1) and (2) 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.

Condition 18: SWEL based on emission streams

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40CFR 63.362(j)(2), Subpart O

Item 18.1:

An owner or operator that elects to comply with a site-wide emission limitation (SWEL) based upon emissions streams must follow requirements of paragraphs (i) through (iii) to determine the applicable SWEL and demonstrate compliance. Under this approach, for each non-SCV affected source, the owner or operator must determine the mass of EtO sent to controls and apply the applicable emission reduction standard. For each SCV affected source, the owner or operator must determine the mass of EtO sent to controls as specified in 40 CFR 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. The owner or operator 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 40 CFR 63.362(j)(2)(i).

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to 40 CFR 63.362(j)(1)(ii).

(iii) Compliance with the SWEL based upon emission streams shall be determined by demonstrating that EF_{ac}, as calculated in accordance with paragraph (ii), for each 30-operating

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day period is at or below SWELStreams, as calculated in paragraph (i).

The boundary for this approach includes all affected sources at the facility.

Condition 19: Compliance Demonstration**Effective between the dates of 04/06/2026 and Permit Expiration Date****Applicable Federal Requirement: 40 CFR 63.363(a), Subpart O****Item 19.1:**

The Compliance Demonstration activity will be performed for the Facility.

Item 19.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator 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 40 CFR 60. Alternatively, for a facility where EtO use is less than 100 pounds/yr, the owner or operator may demonstrate continuous compliance by conducting annual performance tests using the performance testing requirements in 40 CFR 63.7, according to the applicability in table 6 Subpart O, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. An owner or operator that elects to demonstrate compliance through periodic performance testing must also demonstrate continuous compliance with each operating limit required under 40 CFR 63.363 according to the methods specified in 40 CFR 63.364. An owner or operator of 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 40 CFR 51 may instead conduct these performance tests once every three years.

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 20: Compliance Demonstration**Effective between the dates of 04/06/2026 and Permit Expiration Date****Applicable Federal Requirement: 40 CFR 63.363(b), Subpart O****Item 20.1:**

The Compliance Demonstration activity will be performed for the Facility.

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Item 20.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

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 40 CFR 60. 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). The owner or operator must follow the procedures in appendix A to Subpart O.

(1) The CEMS performance test must demonstrate compliance with the applicable EtO standards in tables 1 through 5 to Subpart O. Alternatively, the CEMS performance test may demonstrate compliance with 40 CFR 63.362(i) or (j).

(i) The owner or operator may time-share the 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) The owner or operator must collect hourly data from auxiliary monitoring systems during the performance test period, to convert the pollutant concentrations to pounds per hour.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 21: Compliance Demonstration
Effective for entire length of Permit

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Applicable Federal Requirement: 40 CFR 63.364(a)(5), Subpart O

Item 21.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 21.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator must keep the written procedures required by 40 CFR 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 Part 63, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator 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 40 CFR 63.8(d)(2).

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 22: Compliance Demonstration

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40 CFR 63.364(f)(1), Subpart O

Item 22.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 22.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

An owner or operator of an EtO CEMS must 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 Subpart O, with the exception for SCV emission streams to the control system.

The following caveats apply:

(i) If the facility does not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that

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are comprised only of SCVs, the owner or operator 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 ($M[\text{SCV},n]$) of EtO used for each charge and at each sterilization chamber used during the previous 30 days using the procedures in either paragraph (1) or (2).

(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 ($M[c]$) vented to the controls using equation 1 to 40 CFR 63.364(f)(1)(i)(A)(1).

(2) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate ($Q[m]$) and duration of each sterilizer charge. Calculate the theoretical mass ($M[\text{SCV},n]$) vented to the controls using equation 2 to 40 CFR 63.364(f)(1)(i)(A)(2).

(B) Determine the adjustment factor (f) using equation 3 to 40 CFR 63.364(f)(1)(i)(B). Determine the mass of EtO sent to controls from all non-SCV affected sources, I , using equation 4 to 40 CFR 63.364(f)(1)(i)(B). 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.

(C)(1) Determine the mass rate of EtO sent to controls during the previous 30 days using equation 5 to 40 CFR 63.364(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) 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.

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 23: Single unit/stack EtO exhaust

Effective between the dates of 04/06/2026 and Permit Expiration Date

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Applicable Federal Requirement: 40CFR 63.364(f)(2)(i), Subpart O**Item 23.1:**

The owner or operator of an emission source that exhausts to the atmosphere through a single, dedicated stack 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.

Condition 24: Compliance Demonstration**Effective between the dates of 04/06/2026 and Permit Expiration Date****Applicable Federal Requirement: 40CFR 63.364(g)(1), Subpart O****Item 24.1:**

The Compliance Demonstration activity will be performed for the Facility.

Item 24.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator of a sterilization facility under PTE conditions must demonstrate initial procedures in 40 CFR 63.365(g)(1) and continued compliance with the provisions in 40 CFR 63.364(g). The owner or operator must follow the requirements of either 40 CFR 63.364(g)(2) and (3) or (g)(4).

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 25: Compliance Demonstration**Effective between the dates of 04/06/2026 and Permit Expiration Date****Applicable Federal Requirement: 40CFR 63.364(g)(4), Subpart O****Item 25.1:**

The Compliance Demonstration activity will be performed for the Facility.

Item 25.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The owner or operator must instead install, operate, calibrate, and maintain a continuous pressure differential monitoring system, as follows, to verify the presence of PTE. The owner or operator must operate this system whenever the facility is in operation. The owner or operator must also maintain the pressure differential at

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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, the owner or operator must manually record the measured data at least hourly.

Parameter Monitored: PRESSURE CHANGE

Lower Permit Limit: 0.007 inches of water

Monitoring Frequency: CONTINUOUS

Averaging Method: 3-HOUR ROLLING AVERAGE

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 26: Compliance Demonstration

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40CFR 63.364(i), Subpart O

Item 26.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 26.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator of a sterilization facility subject to the requirements of Subpart O must monitor and record on a daily basis the daily and 30-operating day EtO usage according to the requirements of 40 CFR 63.364(i). Additionally, the owner or operator must record EtO usage

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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 40 CFR 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 40 CFR 63.364(i)(2).

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

Monitoring Frequency: DAILY

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 27: Compliance Demonstration

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40 CFR 63.365(f), Subpart O

Item 27.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 27.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

An owner or operator which is required to operate any portion of the facility with PTE must demonstrate initial compliance with the requirements of Subpart O by following the procedures of paragraphs (1) through (3), 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 40 CFR 51 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

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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) An owner or operator demonstrating continuous compliance through monitoring the volumetric flow rate 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.

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 28: Compliance Demonstration

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40CFR 63.366(b), Subpart O

Item 28.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 28.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator 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 the owner or operator. Do not use CEDRI to submit information the owner or operator claims as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed CBI. The owner or operator must use the

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appropriate electronic report template on the CEDRI website (<https://www.epa.gov/electronic-reporting-air-emissions/cedri>) for Subpart O. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in Subpart O, regardless of the method in which the report is submitted. Although EPA does not expect persons to assert a claim of CBI, if the owner or operator wishes 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 40 CFR 63.10(c)(5) through (13), as applicable in table 6 to Subpart O, 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 40 CFR 60 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 the 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 the information stated in 40 CFR 63.366(b)(1) through (10).

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

Condition 29: Compliance Demonstration

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Applicable Federal Requirement: 40CFR 63.366(c), Subpart O**Item 29.1:**

The Compliance Demonstration activity will be performed for the Facility.

Item 29.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator 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 Subpart O 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 the owner or operator. Do not use CEDRI to submit information claimed as CBI. Anything submitted using CEDRI cannot later be claimed CBI. The owner or operator must use the appropriate electronic report template on the CEDRI website (<https://www.epa.gov/electronicreporting-air-emissions/cedri>) for Subpart O. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in Subpart O, regardless of the method in which the report is submitted. Although EPA does not expect persons to assert a claim of CBI, if the owner or operator wishes 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 40 CFR 63.366(c). 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

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deviations from an operating limit shall include all information required in 40 CFR 63.10(c)(5) through (13), as applicable in table 6 to Subpart O, 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 40 CFR 60 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 the 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 the information stated in 40 CFR 63.366(c)(1) through (10).

Reporting Requirements: QUARTERLY (CALENDAR)
Reports due 30 days after the reporting period.
Subsequent reports are due every 3 calendar month(s).

Condition 30: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement: 40 CFR 63.366(f), Subpart O

Item 30.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 30.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Beginning on June 4, 2024, within 60 days after the date of completing each performance test required by Subpart O, the owner or operator must submit the results of the performance test following the procedures specified in 40 CFR 63.366(f)(1) through (3).

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 31: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement: 40 CFR 63.366(g), Subpart O

Item 31.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 31.2:

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Beginning on June 4, 2024, within 60 days after the date of completing each CEMS performance evaluation (as defined in 40 CFR 63.2), the owner or operator must submit the results of the performance evaluation following the procedures specified in 40 CFR 63.366(g)(1) through (3).

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 32: Compliance Demonstration

Effective between the dates of 04/06/2026 and Permit Expiration Date

Applicable Federal Requirement: 40 CFR 63.367, Subpart O

Item 32.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 32.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator of a source subject to Subpart O must comply with the recordkeeping requirements in 40 CFR 63.367.

Reporting Requirements: QUARTERLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 3 calendar month(s).

****** Emission Unit Level ******

Condition 33: Compliance Demonstration

Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 212-1.5 (d)

Item 33.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 33.2:

Compliance Demonstration shall include the following monitoring:

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

The rolling 12 month usage of ethylene oxide shall not exceed 375,000 pounds per year. All data needed to calculate usage shall be kept as part of the monthly records.

Parameter Monitored: ETHYLENE OXIDE

Upper Permit Limit: 375,000 pounds per year

Monitoring Frequency: MONTHLY

Averaging Method: 12-MONTH TOTAL, ROLLED MONTHLY

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

Subsequent reports are due every 6 calendar month(s).

Condition 34: Compliance Demonstration
Effective for entire length of Permit

Applicable Federal Requirement: 6 NYCRR 212-2.3 (b)

Item 34.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111

Emission Point: 11111

Item 34.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The facility owner or operator shall not allow emissions of an air contaminant to violate the requirements specified in Subdivision 212-2.3(b), Table 4 – Degree of Air Cleaning Required for Non-Criteria Air Contaminants for the environmental rating assigned to the contaminant by the department.

A process emission source emitting an air contaminant and having an emission rate potential (ERP) of less than 0.1 pound per hour and an Environmental Rating of A must meet the annual and short term guideline concentrations for the air contaminant at the fence line of the facility and be less than the PB trigger mass emission limit.

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

STATE ONLY ENFORCEABLE CONDITIONS****** Facility Level ********NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS**

This section contains terms and conditions which are not federally enforceable. Permittees may also have other obligations under regulations of general applicability

Item A: Emergency Defense - 6 NYCRR 201-1.5

An emergency, as defined in 6 NYCRR subpart 201-2, constitutes an affirmative defense to penalties sought in an enforcement action brought by the department for noncompliance with emissions limitations or permit conditions for all facilities in New York State.

(a) The affirmative defense of emergency shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) an emergency occurred and that the facility owner or operator can identify the cause(s) of the emergency;

(2) the equipment at the facility was being properly operated and maintained;

(3) during the period of the emergency the facility owner or operator took all reasonable steps to minimize the levels of emissions that exceeded the emission standards, or other requirements in the permit; and

(4) the facility owner or operator notified the department within two working days after the event occurred. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and any corrective actions taken.

(b) In any enforcement proceeding, the facility owner or operator seeking to establish the occurrence of an emergency has the burden of proof.

(c) This provision is in addition to any emergency or malfunction provision contained in any applicable requirement.

Item B: Public Access to Recordkeeping for Facilities With State Facility Permits - 6 NYCRR 201-1.10 (a)

Where facility owners and/or operators keep records pursuant to compliance with the requirements of 6 NYCRR Subpart 201-5.4, and/or the emission capping requirements of 6 NYCRR Subpart 201-7, the Department will make such records available to the public upon request in accordance

Permit ID: 5-5344-00029/00011

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with 6 NYCRR Part 616 - Public Access to Records.
Facility owners and/or operators must submit the records
required to comply with the request within sixty working
days of written notification by the Department.

Item C: **General Provisions for State Enforceable Permit Terms and
Condition - 6 NYCRR Part 201-5**

Any person who owns and/or operates stationary sources
shall operate and maintain all emission units and any
required emission control devices in compliance with all
applicable Parts of this Chapter and existing laws, and
shall operate the facility in accordance with all
criteria, emission limits, terms, conditions, and
standards in this permit. Failure of such person to
properly operate and maintain the effectiveness of such
emission units and emission control devices may be
sufficient reason for the Department to revoke or deny a
permit.

The owner or operator of the permitted facility must
maintain all required records on-site for a period of five
years and make them available to representatives of the
Department upon request. Department representatives must
be granted access to any facility regulated by this
Subpart, during normal operating hours, for the purpose of
determining compliance with this and any other state and
federal air pollution control requirements, regulations or
law.

STATE ONLY APPLICABLE REQUIREMENTS

The following conditions are state only enforceable.

Condition 35: Contaminant List
Effective for entire length of Permit

Applicable State Requirement:ECL 19-0301

Item 35.1:

Emissions of the following contaminants are subject to contaminant specific requirements in
this permit(emission limits, control requirements or compliance monitoring conditions).

CAS No: 000075-21-8
Name: ETHYLENE OXIDE

CAS No: 0NY075-00-0
Name: PARTICULATES

Condition 36: Malfunctions and Start-up/Shutdown Activities
Effective for entire length of Permit

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Applicable State Requirement:6 NYCRR 201-1.4

Item 36.1:

(a) The facility owner or operator shall take all necessary and appropriate actions to prevent the emission of air pollutants that result in contravention of any applicable emission standard during periods of start-up, shutdown, or malfunction.

(b) The facility owner or operator shall compile and maintain records of all equipment maintenance and start-up/shutdown activities when they are expected to result in an exceedance of any applicable emission standard, and shall submit a report of such activities to the department when required by a permit condition or upon request by the department. Such reports shall state whether an exceedance occurred and if it was unavoidable, include the time, frequency and duration of the exceedance, and an estimate of the emission rates of any air contaminants released. Such records shall be maintained for a period of at least five years and made available for review to department representatives upon request. Facility owners or operators subject to continuous monitoring and quarterly reporting requirements need not submit additional reports of exceedances to the department.

(c) In the event that air contaminant emissions exceed any applicable emission standard due to a malfunction, the facility owner or operator shall notify the department as soon as possible during normal working hours, but not later than two working days after becoming aware that the malfunction occurred. In addition, the facility owner or operator shall compile and maintain a record of all malfunctions. Such records shall be maintained at the facility for a period of at least five years and must be made available to the department upon request. When requested by the department, the facility owner or operator shall submit a written report to the department describing the malfunction, the corrective action taken, the air contaminants emitted, and the resulting emission rates and/or opacity.

(d) The department may also require the facility owner or operator to include, in reports described under Subdivisions (b) and (c) of this Section, an estimate of the maximum ground level concentration of each air contaminant emitted and the effect of such emissions.

(e) A violation of any applicable emission standard resulting from start-up, shutdown, or malfunction conditions at a permitted or registered facility may not be subject to an enforcement action by the department and/or penalty if the department determines, in its sole discretion, that such a violation was unavoidable. The actions and recordkeeping and reporting requirements listed above must be adhered to in such circumstances.

Condition 37: Emission Unit Definition
Effective for entire length of Permit

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 37.1:

The facility is authorized to perform regulated processes under this permit for:

Emission Unit: 1-11111

Emission Unit Description:

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

This emission unit consists of: 11 sterilization chambers (vacuum pumps) which exhaust through the wet scrubber and polishing dry beds (existing) or the LESNI (once installed)

11 sterilization chamber exhaust vents (backvents) and 6 aeration rooms (until 1 is converted to a preconditioning room) which exhaust through the catalytic oxidizer (existing) or the LESNI (once installed); and

Indoor room air (INAIR) from areas with EtO ,which will be collected and exhausted through indoor air dry beds (once installed),

All which exhaust through a combined stack.

Building(s): PLANT

**Condition 38: Renewal deadlines for state facility permits
Effective for entire length of Permit**

Applicable State Requirement:6 NYCRR 201-5.2 (c)

Item 38.1:

The owner or operator of a facility having an issued state facility permit shall submit a complete application at least 180 days, but not more than eighteen months, prior to the date of permit expiration for permit renewal purposes.

**Condition 39: Compliance Demonstration
Effective for entire length of Permit**

Applicable State Requirement:6 NYCRR 201-5.3 (c)

Item 39.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 39.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Any reports or submissions required by this permit shall be submitted to the Regional Air Pollution Control Engineer (RAPCE) at the following address:

Division of Air Resources
NYS Dept. of Environmental Conservation
Region 5
232 Golf Course Rd.
Warrensburg, NY 12885

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
Subsequent reports are due every 12 calendar month(s).

Condition 40: Air pollution prohibited
Effective for entire length of Permit

Applicable State Requirement:6 NYCRR 211.1

Item 40.1:

No person shall cause or allow emissions of air contaminants to the outdoor atmosphere of such quantity, characteristic or duration which are injurious to human, plant or animal life or to property, or which unreasonably interfere with the comfortable enjoyment of life or property. Notwithstanding the existence of specific air quality standards or emission limits, this prohibition applies, but is not limited to, any particulate, fume, gas, mist, odor, smoke, vapor, pollen, toxic or deleterious emission, either alone or in combination with others.

****** Emission Unit Level ******

Condition 41: Emission Point Definition By Emission Unit
Effective for entire length of Permit

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 41.1:

The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 1-11111

Emission Point: 11111

Height (ft.): 100

Diameter (in.): 56

NYTMN (km.): 4800.578 NYTME (km.): 613.577 Building: PLANT

Condition 42: Process Definition By Emission Unit
Effective for entire length of Permit

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 42.1:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 1-11111

Process: L01

Source Classification Code: 3-15-020-01

Process Description:

Natural gas combustion and Ethylene Oxide oxidation in the LESNI control system.

Emission Source/Control: LESNI - Control

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Control Type: CATALYTIC OXIDATION

Emission Source/Control: A0001 - Process
Design Capacity: 125,963 cubic feet

Emission Source/Control: A0004 - Process
Design Capacity: 11,718 cubic feet

Emission Source/Control: A0005 - Process
Design Capacity: 11,340 cubic feet

Emission Source/Control: A0006 - Process
Design Capacity: 11,340 cubic feet

Emission Source/Control: A0007 - Process
Design Capacity: 3,764 cubic feet

Emission Source/Control: A0008 - Process
Design Capacity: 78,000 cubic feet

Emission Source/Control: S0001 - Process
Design Capacity: 1,155 cubic feet

Emission Source/Control: S0002 - Process
Design Capacity: 1,155 cubic feet

Emission Source/Control: S0003 - Process
Design Capacity: 1,333 cubic feet

Emission Source/Control: S0004 - Process
Design Capacity: 1,200 cubic feet

Emission Source/Control: S0006 - Process
Design Capacity: 347 cubic feet

Emission Source/Control: S0008 - Process
Design Capacity: 347 cubic feet

Emission Source/Control: S0009 - Process
Design Capacity: 1,200 cubic feet

Emission Source/Control: S000B - Process
Design Capacity: 2,996 cubic feet

Emission Source/Control: S000C - Process
Design Capacity: 1,333 cubic feet

Emission Source/Control: S000D - Process
Design Capacity: 1,333 cubic feet

Emission Source/Control: S000E - Process
Design Capacity: 1,333 cubic feet

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Item 42.2:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 1-11111

Process: S01

Source Classification Code: 3-15-020-01

Process Description:

Evacuation of sterilization chambers (Sterilization chamber vent). There are 11 sterilization chambers which are charged with ethylene oxide gas to sterilize medical equipment, pharmaceuticals, cosmetics, etc. At the end of the sterilization period, the gas is pumped out through a wet acid scrubber and polishing dry bed (existing) or LESNI (once installed and commissioned).

Emission Source/Control: LESNI - Control

Control Type: CATALYTIC OXIDATION

Emission Source/Control: POBED - Control

Control Type: SCRUBBER - PACKED BED

Emission Source/Control: SCRUB - Control

Control Type: WET SCRUBBER

Emission Source/Control: S0001 - Process

Design Capacity: 1,155 cubic feet

Emission Source/Control: S0002 - Process

Design Capacity: 1,155 cubic feet

Emission Source/Control: S0003 - Process

Design Capacity: 1,333 cubic feet

Emission Source/Control: S0004 - Process

Design Capacity: 1,200 cubic feet

Emission Source/Control: S0006 - Process

Design Capacity: 347 cubic feet

Emission Source/Control: S0008 - Process

Design Capacity: 347 cubic feet

Emission Source/Control: S0009 - Process

Design Capacity: 1,200 cubic feet

Emission Source/Control: S000B - Process

Design Capacity: 2,996 cubic feet

Emission Source/Control: S000C - Process

Design Capacity: 1,333 cubic feet

Emission Source/Control: S000D - Process

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Design Capacity: 1,333 cubic feet

Emission Source/Control: S000E - Process

Design Capacity: 1,333 cubic feet

Item 42.3:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 1-11111

Process: S02

Source Classification Code: 3-15-020-01

Process Description:

Exhausting sterilization chambers (Chamber exhaust vent).

There are 11 sterilization chambers which are charged with ethylene oxide gas to sterilize medical equipment, pharmaceuticals, cosmetics, etc. After the sterilization period and evacuation cycles of process S01 are completed, the chamber vacuum is broken and the chamber is vented through a catalytic oxidizer (existing) or LESNI (once installed and commissioned).

Emission Source/Control: CATOX - Control

Control Type: CATALYTIC AFTERBURNER

Emission Source/Control: LESNI - Control

Control Type: CATALYTIC OXIDATION

Emission Source/Control: S0001 - Process

Design Capacity: 1,155 cubic feet

Emission Source/Control: S0002 - Process

Design Capacity: 1,155 cubic feet

Emission Source/Control: S0003 - Process

Design Capacity: 1,333 cubic feet

Emission Source/Control: S0004 - Process

Design Capacity: 1,200 cubic feet

Emission Source/Control: S0006 - Process

Design Capacity: 347 cubic feet

Emission Source/Control: S0008 - Process

Design Capacity: 347 cubic feet

Emission Source/Control: S0009 - Process

Design Capacity: 1,200 cubic feet

Emission Source/Control: S000B - Process

Design Capacity: 2,996 cubic feet

Emission Source/Control: S000C - Process

Design Capacity: 1,333 cubic feet

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Emission Source/Control: S000D - Process
Design Capacity: 1,333 cubic feet

Emission Source/Control: S000E - Process
Design Capacity: 1,333 cubic feet

Item 42.4:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 1-11111

Process: S03

Source Classification Code: 3-15-020-01

Process Description:

Aeration room venting. There are six aeration rooms where production materials are staged after sterilization. One aeration room (A006) will be converted to a preconditioning room leaving a total of five aeration rooms. Some room air cascades into aeration rooms. The materials offgas for an appropriate time as the rooms are exhausted through a catalytic oxidizer (existing) or the LESNI (once installed and commissioned).

Emission Source/Control: CATOX - Control
Control Type: CATALYTIC AFTERBURNER

Emission Source/Control: LESNI - Control
Control Type: CATALYTIC OXIDATION

Emission Source/Control: A0001 - Process
Design Capacity: 125,963 cubic feet

Emission Source/Control: A0004 - Process
Design Capacity: 11,718 cubic feet

Emission Source/Control: A0005 - Process
Design Capacity: 11,340 cubic feet

Emission Source/Control: A0006 - Process
Design Capacity: 11,340 cubic feet

Emission Source/Control: A0007 - Process
Design Capacity: 3,764 cubic feet

Emission Source/Control: A0008 - Process
Design Capacity: 78,000 cubic feet

Emission Source/Control: INAIR - Process

Item 42.5:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 1-11111

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029

Process: S04

Source Classification Code: 3-15-020-01

Process Description:

Group 1 and Group 2 air emissions as defined by 40 CFR 63
Subpart O captured by the indoor air capture and control
system and is exhausted to the indoor air dry beds (once
installed) or cascades into aeration rooms controlled by
the LESNI.

Emission Source/Control: IABED - Control

Control Type: SCRUBBER - PACKED BED

Emission Source/Control: LESNI - Control

Control Type: CATALYTIC OXIDATION

Emission Source/Control: INAIR - Process

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029