



PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 5-5344-00029/00011
Mod 0 Effective Date: 04/05/2000 Expiration Date: 02/03/2023
Mod 2 Effective Date: 12/12/2000 Expiration Date: 02/03/2023
Mod 3 Effective Date: 05/20/2004 Expiration Date: No expiration date.
Mod 4 Effective Date: 02/04/2013 Expiration Date: 02/03/2023

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

Contact: KATHLEEN A HOFFMAN
2015 SPRING RD
SUITE 650
OAK BROOK, IL 60523
(630) 928-1758

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

Description:

This facility is a sterilization facility. Medical instruments, cosmetics and pharmaceuticals are placed in chambers which are filled with ethylene oxide gas or propylene 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.

New York State Department of Environmental Conservation
Facility DEC ID: 5534400029



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: MARC S MIGLIORE
 NYSDEC
 232 GOLF COURSE RD
 WARRENSBURG, NY 12885

Authorized Signature: _____ Date: ____ / ____ / ____



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.



LIST OF CONDITIONS

DEC GENERAL CONDITIONS

General Provisions

- Facility Inspection by the Department
- Relationship of this Permit to Other Department Orders and Determinations
 - Applications for permit renewals, modifications and transfers
 - Permit modifications, suspensions or revocations by the Department
 - Applications for Permit Renewals and Modifications
 - Permit Modifications, Suspensions, and Revocations by the Department

Facility Level

- Submission of Applications for Permit Modification or Renewal
 - REGION 5 SUBOFFICE
- Submission of application for permit modification or renewal-REGION 5 SUBOFFICE - WARRENSBURG



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 4-1: Applications for permit renewals, modifications and transfers

Applicable State Requirement: 6 NYCRR 621.11

Item 4-1.1:

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 4-1.2:

The permittee must submit a renewal application at least 180 days before expiration of permits for Title V Facility Permits, or at least 30 days before expiration of permits for State Facility Permits.

Item 4-1.3:

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.



Department

Applicable State Requirement: 6 NYCRR 621.13

Item 4-2.1:

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.

Condition 3: Applications for Permit Renewals and Modifications

Applicable State Requirement: 6 NYCRR 621.13 (a)

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 expiration of permits for Title V Facility Permits, or at least 30 days before expiration of permits for State Facility Permits.

Condition 4: Permit Modifications, Suspensions, and Revocations by the Department

Applicable State Requirement: 6 NYCRR 621.14

Item 4.1:

The Department reserves the right to modify, suspend, or revoke this permit. The grounds for modification, suspension or revocation include:

- a) the scope of the permitted activity is exceeded or a violation of any condition of the permit or provisions of the ECL and pertinent regulations is found;
- b) the permit was obtained by misrepresentation or failure to disclose relevant facts;
- c) new material information is discovered; or
- d) environmental conditions, relevant technology, or applicable law or regulation have materially changed since the permit was issued.

**** Facility Level ****

Condition 5: Submission of Applications for Permit Modification or Renewal -REGION 5



Applicable State Requirement: 6 NYCRR 621.5 (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 Hudson St, PO Box 220
Warrensburg, NY 12885-0220
(518) 623-1281

Condition 4-3: Submission of application for permit modification or renewal-REGION 5

SUBOFFICE - WARRENSBURG

Applicable State Requirement: 6 NYCRR 621.6 (a)

Item 4-3.1:

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



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

Mod 0 Permit Effective Date: 04/05/2000

Permit Expiration Date: 02/03/2023

Mod 2 Permit Effective Date: 12/12/2000

Permit Expiration Date: 02/03/2023

Mod 4 Permit Effective Date: 02/04/2013

Permit Expiration Date: 02/03/2023



LIST OF CONDITIONS

FEDERALLY ENFORCEABLE CONDITIONS

Facility Level

- 4-1 6 NYCRR 200.6: Acceptable Ambient Air Quality
- 4-2 6 NYCRR 215.2: Open Fires - Prohibitions
- 4-3 6 NYCRR 200.7: Maintenance of Equipment
- 4-4 6 NYCRR 201-3.2 (a): Exempt Sources - Proof of Eligibility
- 4-5 6 NYCRR 201-3.3 (a): Trivial Sources - Proof of Eligibility
- 9 6 NYCRR 201-1.10 (a): Public Access to Recordkeeping
- 4-6 6 NYCRR 211.1: Air pollution prohibited

Emission Unit Level

EU=1-11111

- 15 6 NYCRR 200.6: Compliance Demonstration
- 16 6 NYCRR 200.6: Compliance Demonstration
- 18 40CFR 63.364(b)(2), Subpart O: Compliance Demonstration
- 4-7 40CFR 63.364(c), Subpart O: Compliance Demonstration
- 20 40CFR 63.366(a)(3), Subpart O: Compliance Demonstration

EU=1-11111,Proc=S01

- 4-8 6 NYCRR 212.4 (a): Compliance Demonstration

EU=1-11111,Proc=S02

- 4-9 6 NYCRR 212.4 (a): Compliance Demonstration

EU=1-11111,Proc=S03

- 4-10 6 NYCRR 212.4 (a): Compliance Demonstration
- 4-11 40CFR 63.362(d), Subpart O: Compliance Demonstration

STATE ONLY ENFORCEABLE CONDITIONS

Facility Level

- 4-12 ECL 19-0301: Contaminant List
- 4-13 6 NYCRR 201-1.4: Unavoidable noncompliance and violations
- 28 6 NYCRR Subpart 201-5: General Provisions
- 29 6 NYCRR Subpart 201-5: Emission Unit Definition
- 4-14 6 NYCRR 211.2: Visible Emissions Limited

Emission Unit Level

- 32 6 NYCRR Subpart 201-5: Emission Point Definition By Emission Unit
- 33 6 NYCRR Subpart 201-5: Process Definition By Emission Unit



FEDERALLY ENFORCEABLE CONDITIONS
****** 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,



required to operate such device effectively.

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

If an existing emission source was subject to the permitting requirements of 6 NYCRR Part 201 at the time of construction or modification, and the owner and/or operator failed to apply for a permit for such emission source then the following provisions apply:

- (a) The owner and/or operator must apply for a permit for such emission source or register the facility in accordance with the provisions of Part 201.
- (b) The emission source or facility is subject to all regulations that were applicable to it at the time of construction or modification and any subsequent requirements applicable to existing sources or facilities.

Item E: Emergency Defense - 6 NYCRR 201-1.5

An emergency constitutes an affirmative defense to an action brought for noncompliance with emissions limitations or permit conditions for all facilities in New York State.

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

- (1) An emergency occurred and that the facility owner and/or operator can identify the cause(s) of the emergency;
- (2) The equipment at the permitted facility causing the emergency was at the time being properly operated;
- (3) During the period of the emergency the facility owner and/or operator took all reasonable steps to minimize levels of emissions that exceeded the emission standards, or other requirements in the permit; and
- (4) The facility owner and/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 corrective actions taken.

(b) In any enforcement proceeding, the facility owner and/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 upset provision contained in any applicable requirement.

Item F: 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 G: 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 H: 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 I: Proof of Eligibility for Sources Defined as Trivial 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 J: 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 K: 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 L: 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 M: Federally Enforceable Requirements - 40 CFR 70.6 (b)
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 4-1: Acceptable Ambient Air Quality



Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 200.6

Item 4-1.1:

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 4-2: Open Fires - Prohibitions

Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 215.2

Item 4-2.1:

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 4-2.2

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 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 4-3: Maintenance of Equipment
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 200.7

Item 4-3.1:

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, required to operate such device effectively.

Condition 4-4: Exempt Sources - Proof of Eligibility
Effective between the dates of 02/04/2013 and 02/03/2023

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

Item 4-4.1:

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 this Subpart. 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 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.

Condition 4-5: Trivial Sources - Proof of Eligibility
Effective between the dates of 02/04/2013 and 02/03/2023

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

Item 4-5.1:

The owner and/or operator of an emission source or unit that is listed as being trivial in this Part may be required to certify that it operates within the specific criteria described in this Subpart. 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 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.



Condition 9: Public Access to Recordkeeping
Effective between the dates of 04/05/2000 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 201-1.10 (a)

Item 9.1:

Where emission source owners and/or operators keep records pursuant to compliance with the operational flexibility requirements of 6 NYCRR Subpart 201-5.4(b)(1) , and/or the emission capping requirements of 6 NYCRR Subparts 201-7.2(d), 201-7.3(f), 201-7.3(g), 201-7.3(h)(5), 201-7.3(i) and 201-7.3(j), the Department will make such records available to the public upon request in accordance with 6 NYCRR Part 616 - Public Access to Records. Emission source owners and/or operators must submit the records required to comply with the request within sixty working days of written notification by the Department of receipt of the request.

Condition 4-6: Air pollution prohibited
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 211.1

Item 4-6.1:

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 15: Compliance Demonstration
Effective between the dates of 04/05/2000 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 200.6

Item 15.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 15.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The rolling annual usage of ethylene oxide shall not exceed 550,000 pounds per year.

New York State Department of Environmental Conservation

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029



maximum liquor tank level will be established during the initial testing.

Monitoring Frequency: WEEKLY
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2000.
Subsequent reports are due every 6 calendar month(s).

Condition 4-7: Compliance Demonstration
Effective between the dates of 02/04/2013 and 02/03/2023

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

Item 4-7.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111

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

Item 4-7.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

The owner or operator shall continuously monitor and record the oxidation temperature at the outlet of the catalyst bed. The baseline oxidation temperature will be established during the most recent stack test. The current minimum operating temperature is 285 degrees F.

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.
The initial report is due 7/30/2013.
Subsequent reports are due every 6 calendar month(s).

Condition 20: Compliance Demonstration
Effective between the dates of 04/05/2000 and 02/03/2023

Applicable Federal Requirement:40CFR 63.366(a)(3), Subpart O

Item 20.1:

The Compliance Demonstration activity will be performed for:

New York State Department of Environmental Conservation

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029



Emission Unit: 1-11111

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 20.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

The owner or operator shall submit a semiannual monitoring system performance report. Reports of exceedences of control system parameters shall include information required in 40 CFR 63.10(c).

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2000.

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

Condition 4-8: Compliance Demonstration

Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement: 6 NYCRR 212.4 (a)

Item 4-8.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111

Process: S01

Regulated Contaminant(s):

CAS No: 000075-56-9 PROPANE, 1,2-EPOXY-

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 4-8.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

The exhaust from the 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: EPA Method 18



Monitoring Frequency: CONTINUOUS
Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED
Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 4-9: Compliance Demonstration
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 212.4 (a)

Item 4-9.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111
Process: S02

Regulated Contaminant(s):
CAS No: 000075-56-9 PROPANE, 1,2-EPOXY-
CAS No: 000075-21-8 ETHYLENE OXIDE

Item 4-9.2:

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

Parameter Monitored: DESTRUCTION EFFICIENCY
Lower Permit Limit: 99 percent
Reference Test Method: Method 19
Monitoring Frequency: CONTINUOUS
Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED
Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 4-10: Compliance Demonstration
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable Federal Requirement:6 NYCRR 212.4 (a)

Item 4-10.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111
Process: S03

Regulated Contaminant(s):
CAS No: 000075-56-9 PROPANE, 1,2-EPOXY-

New York State Department of Environmental Conservation

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029



Item 4-10.2:

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.

Parameter Monitored: DESTRUCTION EFFICIENCY

Lower Permit Limit: 99 percent

Reference Test Method: method 18

Monitoring Frequency: CONTINUOUS

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 4-11: Compliance Demonstration
Effective between the dates of 02/04/2013 and 02/03/2023

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

Item 4-11.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-11111

Process: S03

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 4-11.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

The exhaust from the aeration rooms shall be directed through a catalytic oxidizer which shall achieve 99% control or reduce the concentration to a maximum of 1 ppmv (whichever is less stringent). Testing frequency will be annually unless changed by the permitting authority. If the percent efficiency is less than 99%, the catalyst must be replaced as soon as practicable but no later than 180 days after conducting the performance test.

Alternately, the facility may comply with subparagraphs 364(b)(4)(ii) or (iii).

Lower Permit Limit: 99 percent reduction by weight

Reference Test Method: EPA Method 18

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING
DESCRIPTION



Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED
Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE



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

Where emission source owners and/or operators keep records pursuant to compliance with the operational flexibility requirements of 6 NYCRR Subpart 201-5.4(b)(1), and/or the emission capping requirements of 6 NYCRR Subparts 201-7.2(d), 201-7.3(f), 201-7.3(g), 201-7.3(h)(5), 201-7.3(i) and 201-7.3(j), the Department will make such records available to the public upon request in accordance with 6 NYCRR Part 616 - Public Access to Records. Emission source owners and/or operators must submit the records required to comply with the request within sixty working days of written notification by the Department of receipt of the request.

Item B: 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 4-12: Contaminant List
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable State Requirement:ECL 19-0301

Item 4-12.1:

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: 000075-56-9
Name: PROPANE, 1,2-EPOXY-

Condition 4-13: Unavoidable noncompliance and violations
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable State Requirement:6 NYCRR 201-1.4

Item 4-13.1:

At the discretion of the commissioner a violation of any applicable emission standard for necessary scheduled equipment maintenance, start-up/shutdown conditions and malfunctions or upsets may be excused if such violations are unavoidable. The following actions and recordkeeping and reporting requirements must be adhered to in such circumstances.

(a) The facility owner and/or operator shall compile and maintain records of all equipment maintenance or start-up/shutdown activities when they can be expected to result in an exceedance of any applicable emission standard, and shall submit a report of such activities to the commissioner's representative when requested to do so in writing or when so required by a condition of a permit issued for the corresponding air contamination source except where conditions elsewhere in this permit which contain more stringent reporting and notification provisions for an applicable requirement, in which case they supercede those stated here. Such reports shall describe why the violation was unavoidable and shall include the time, frequency and duration of the maintenance and/or start-up/shutdown activities and the identification of air contaminants, and the estimated emission rates. If a facility owner and/or operator is subject to continuous stack monitoring and quarterly reporting requirements, he need not submit reports for equipment maintenance or start-up/shutdown for the facility to the commissioner's representative.

(b) In the event that emissions of air contaminants in excess of any emission standard in 6 NYCRR Chapter III Subchapter A occur due to a malfunction, the facility owner and/or operator shall report such malfunction by telephone to the commissioner's representative as soon as possible during normal working hours, but in any event not later than two working days after becoming aware that the malfunction occurred. Within 30 days thereafter, when requested in writing by the commissioner's representative, the facility owner and/or operator shall submit a written report to the commissioner's representative describing the malfunction, the corrective action taken, identification of air contaminants, and an estimate of the emission rates. These reporting requirements are superceded by conditions elsewhere in this permit which contain reporting and notification provisions for applicable requirements more stringent than those



Emission Unit Description:

This emission unit consists of 11 sterilization chambers and 6 aeration rooms which are exhausted through one of two control devices and out a combined stack.

Building(s): PLANT

Condition 4-14: Visible Emissions Limited
Effective between the dates of 02/04/2013 and 02/03/2023

Applicable State Requirement:6 NYCRR 211.2

Item 4-14.1:

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.

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

Condition 32: Emission Point Definition By Emission Unit
Effective between the dates of 04/05/2000 and 02/03/2023

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 32.1(From Mod 4):

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

Emission Unit: 1-11111

Emission Point: 11111

Height (ft.): 78 Diameter (in.): 12
NYTMN (km.): 4800.14 NYTME (km.): 613.455 Building: PLANT

Condition 33: Process Definition By Emission Unit
Effective between the dates of 04/05/2000 and 02/03/2023

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 33.1(From Mod 4):

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. There are 11 sterilization chambers which are charged with ethylene oxide or propylene 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.

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
Design Capacity: 1,333 cubic feet

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

Item 33.2(From Mod 4):

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. There are 11 sterilization chambers which are charged with ethylene oxide or propylene oxide gas to sterilize medical equipment, pharmaceuticals, cosmetics, etc. After of 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.



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

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

Item 33.3(From Mod 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. The materials offgas for an appropriate time as the rooms are exhausted through a catalytic oxidizer.

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

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

New York State Department of Environmental Conservation

Permit ID: 5-5344-00029/00011

Facility DEC ID: 5534400029



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

