

Facility DEC ID: 9024800243

PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 9-0248-00243/00001
Effective Date: 10/05/2021 Expiration Date: 10/04/2031

Permit Issued To: SPS MEDICAL SUPPLY CORP
6789 W HENRIETTA RD
RUSH, NY 14543

Contact: Ryan Carney
6789 W Henrietta Rd
Rush, NY 14543
(585) 831-9748

Facility: SPS MEDICAL SUPPLY CORP
31 Water St
Cuba, NY 14727

Description:

(1) SPS Medical Supply Corporation is located at 31 Water Street, City of Cuba, New York where the facility manufactures biological indicator products for sterilization processes, primarily in support of the dental industry. This permit action is for a new Air State Facility permit to authorize the operation of two (2) ethylene oxide resistometers (sterilizer units) and a catalytic oxidizer to reduce emissions. The facility has seven (7) exempt natural gas heating sources as specified in 6NYCRR 201-3.2(c)(1)(i).

(2) The two (2) ethylene oxide sterilizer units at the facility are subject to the Federal National Emission Standards for Hazardous Air Pollutants (NESHAP), Subpart O: Ethylene Oxide Emissions Standards for Sterilization Facilities - 40 CFR 63 Subpart O. The facility is categorized as a 'Source using less than 1 ton' as defined in §63.361. Sterilization sources using less than 1 ton of ethylene oxide within all consecutive 12-month periods are not subject to the emissions standards in §63.362 but the recordkeeping requirements of §63.367(c) apply.

(3) As per 6NYCRR 212-1.5(e)(2), a process emission source subject to a NESHAP can satisfy the requirements of Part 212 by meeting the mass emission limit (MEL) identified in Section 212-2.2, Table 2. The facility is capping actual ethylene oxide emissions below the MEL of 25 pounds per year by routing 100% of the ethylene oxide emissions through a catalytic oxidizer having a minimum 90% removal efficiency. Since the facility ethylene oxide emissions are subject to the Federal NESHAP Subpart O and the facility is limiting the annual actual emissions below the MEL, the facility is in compliance with Section 212-1.5(e)(2) and no further review is required. The facility shall certify annually that the ethylene oxide emissions do not exceed 24 pounds during any consecutive 12-month period.

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(4) In accordance with 6 NYCRR 212-1.7(b), the facility is authorized to monitor the inlet gas temperature to the catalytic oxidizer as opposed to the exhaust gas temperature. The inlet temperature is more critical to monitoring the proper destruction of the catalytic oxidizer. Specifically, the manufacturer recommends a minimum Catalyst Inlet Temperature of 600 degrees Fahrenheit (F) and a minimum cold start time to reach operating temperature of 30 minutes.

(5) In accordance with 6 NYCRR 212-1.7(b)(2), the catalyst inlet and outlet temperature is monitored using a 2-channel digital chart recorder to obtain the temperature rise across the catalytic oxidizer bed.

(6) The renewal application for this Air State Facility Permit must be submitted to the department at least 180 days, but not more than 18 months, prior to the date of permit expiration. While the renewal application is being processed by the department, the owner or operator of the facility may continue to operate under the terms and conditions of the existing permit, provided the application is submitted in accordance with 6NYCRR Part 201-5.2(c).

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: MARK F PASSUITE
NYSDEC - REGION 9
270 MICHIGAN AVE
BUFFALO, NY 14203-2915

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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- 6 4 Permit modifications, suspensions or revocations by the Department

Facility Level

- 6 5 Submission of application for permit modification or renewal-REGION 9 HEADQUARTERS

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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 9 HEADQUARTERS
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 9 Headquarters
Division of Environmental Permits
270 Michigan Avenue
Buffalo, NY 14203-2915
(716) 851-7165

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ARTICLE 19: AIR POLLUTION CONTROL - AIR STATE FACILITY PERMIT

IDENTIFICATION INFORMATION

Permit Issued To: SPS MEDICAL SUPPLY CORP
6789 W HENRIETTA RD
RUSH, NY 14543

Facility: SPS MEDICAL SUPPLY CORP
31 Water St
Cuba, NY 14727

Authorized Activity By Standard Industrial Classification Code:
3843 - DENTAL EQUIPMENT AND SUPPLIES

Permit Effective Date: 10/05/2021

Permit Expiration Date: 10/04/2031

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- 6 2 40CFR 63.360(b), Subpart O: Compliance Demonstration
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FEDERALLY ENFORCEABLE CONDITIONS

FINAL

**** 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: Visible Emissions Limited
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement: 6 NYCRR 211.2

Item 1.1:

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 2: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement: 40CFR 63.360(b), Subpart O

Item 2.1:

The Compliance Demonstration activity will be performed for the Facility.

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

Item 2.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

National Emission Standards for Hazardous Air Pollutants
(NESHAP)
40 CFR Part 63 Subpart O - Ethylene Oxide Emission
Standards for Sterilization Facilities

(1) The two (2) ethylene oxide sterilizer units at the facility are applicable to the Federal NESHAP 40 CFR 63

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Subpart O. The facility is categorized as a ‘Source using less than 1 ton’ as defined in §63.361.

(2) Sterilization sources using less than 1 ton of ethylene oxide within all consecutive 12-month periods are not subject to the emissions standards in §63.362. [§63.360(b) and §63.361]

(3) The recordkeeping requirements of §63.367(c) apply. [§63.360(b)]

(4) There are no reporting requirements for this permit condition.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 3: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement:40CFR 63.367(c), Subpart O

Item 3.1:

The Compliance Demonstration activity will be performed for the Facility.

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

Item 3.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

National Emission Standards for Hazardous Air Pollutants (NESHAP)
40 CFR Part 63 Subpart O - Ethylene Oxide Emission Standards for Sterilization Facilities

RECORDKEEPING REQUIREMENTS

(1) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to §63.362). [§63.367(c)]

(2) Maintain records on-site for 5 years and make them available upon request.

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(3) Submit a report annually to DEC by January 30 for the previous year data including the monthly and 12-month rolling usage records.

Parameter Monitored: ETHYLENE OXIDE
 Upper Permit Limit: 1 tons per year
 Monitoring Frequency: MONTHLY
 Averaging Method: 12-MONTH TOTAL, ROLLED MONTHLY
 Reporting Requirements: ANNUALLY (CALENDAR)
 Reports due 30 days after the reporting period.
 The initial report is due 1/30/2022.
 Subsequent reports are due every 12 calendar month(s).

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

Condition 4: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement: 6 NYCRR 212-1.5 (e) (2)

Item 4.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

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

Item 4.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

(1) A process emission source subject to the Federal National Emission Standards for Hazardous Air Pollutants (NESHAP) under 40 CFR Part 63 satisfies the requirements of Part 212 for the respective air contaminant regulated by the Federal standard if the facility owner or operator can demonstrate that the process emission source is meeting the mass emission limit (MEL) identified in Section 212-2.2, Table 2. [6 NYCRR 212-1.5(e)(2)]

(2) The facility is capping actual ethylene oxide emissions below the MEL of 25 pounds per year in accordance with permit conditions cited under 6 NYCRR 212-2. Since the facility ethylene oxide emissions are subject to the Federal NESHAP Subpart O and the facility is limiting the annual actual emissions below the MEL, the facility is in compliance with Section 212-1.5(e)(2) and

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no further review is required.

(3) There are no reporting or recordkeeping requirements for this permit condition.

Monitoring Frequency: UPON PERMIT RENEWAL

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 5: Maintain all process emission sources, including the associated air pollution control and monitoring equipment Effective between the dates of 10/05/2021 and 10/04/2031

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

Item 5.1:

This Condition applies to Emission Unit: U-00001

Item 5.2:

At all times, the facility owner or operator must operate and maintain all process emission sources, including the associated air pollution control and monitoring equipment, in a manner consistent with safety, good air pollution control practices, good engineering practices and manufacturers' recommendations for minimizing emissions.

Condition 6: Compliance Demonstration Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement:6 NYCRR 212-1.6 (a)

Item 6.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

Item 6.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

PROCESS SOURCES
PART 212 - OPACITY LIMIT

(1) As required by 6NYCRR Part 212-1.6(a), no person shall cause or allow emissions having an average opacity during any six consecutive minutes of 20 percent or greater from any process emission source, except only the

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emission of uncombined water.

(2) Compliance with this requirement shall be determined by the facility owner/operator conducting a routine survey of visible emissions when a process is in operation. Visible emission observations shall be performed, as best as possible, at a location to obtain the proper sun angle, background, and line of sight. The observer must be knowledgeable regarding the effects on the visibility of emissions caused by background contrast, ambient lighting, observer position relative to lighting, wind, and the presence of uncombined water (condensing water vapor).

(3) Visible emissions are not expected from the facility processes when properly operated. If any visible emissions are identified, inspect the source and restore operation of the emission unit (including the control device, if any, and the associated capture system) to its normal operation as expeditiously as practicable.

(4) Records of any visible emission event shall be maintained to include the date and length of time any visible emissions were observed, and the corrective action taken. The records shall be kept on-site and made available to the Department upon request. Documentation is not required when no visible emissions are observed during an inspection.

(5) The Department reserves the right to perform or require the performance of a Method 9 opacity evaluation from any process emission source.

(6) Upon request, a written report of any visible emission event shall be submitted to the Department.

Parameter Monitored: OPACITY

Upper Permit Limit: 20 percent

Reference Test Method: EPA Method 9

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Averaging Method: MAXIMUM - NOT TO EXCEED STATED VALUE - SEE MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 7: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement: 6 NYCRR 212-1.7 (a)

Item 7.1:

The Compliance Demonstration activity will be performed for:

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Emission Unit: U-00001

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

Item 7.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

- (1) Facility owners and/or operators of a process emission source required by the department to demonstrate compliance with Part 212 may be required to conduct capture efficiency and/or stack emissions testing using acceptable and approved procedures pursuant to 6 NYCRR Part 202. [212-1.7(a)]
- (2) The facility is required to capture 100% of all exhaust gas streams containing ethylene oxide and duct the gases to the catalytic oxidizer which is vented through a single stack.
- (3) Upon request and if deemed necessary, the facility may be required to determine the capture efficiency in accordance with 40 CFR Part 51 Appendix M, Method 204.
- (4) There are no on-going reporting or recordkeeping requirements for this permit condition.

Parameter Monitored: CAPTURE EFFICIENCY

Upper Permit Limit: 100 percent

Reference Test Method: Method 204

Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST
METHOD INDICATED

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 8: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable Federal Requirement: 6 NYCRR 212-1.7 (b)

Item 8.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

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

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Item 8.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

CATALYST OPERATING TEMPERATURE RANGE

- (1) The facility must install a continuous monitor and data recorder on the catalytic oxidizer to measure the catalyst inlet and outlet temperature and to obtain the temperature rise across the catalytic oxidizer bed.
- (2) In accordance with manufacturer documentation, a minimum Catalyst Inlet Temperature of 600 degrees Fahrenheit (F) is recommended and the estimated time to reach the Operating Temperature is 30 minutes from cold start. In addition, the maximum catalyst operating temperature is 1,200 degrees F.
- (3) The facility will verify the minimum inlet temperature is above 600F before the sterilization process is started. During operation, the 2-channel digital chart recorder will record the catalyst inlet and outlet temperature to verify the temperature rise.
- (4) Continuous monitors must be operated at all times when the catalytic oxidizer is operating except during any quality assurance and routine maintenance activities. Each monitor must be operated, calibrated and maintained according to the manufacturer quality assurance program.
- (5) Maintain monitoring records on-site for 5 years and make them available upon request.
- (6) There are no on-going reporting requirements for this condition. Notify the department within the time frame specified in 6NYCRR 201-1.4 of any equipment malfunctions resulting in emissions of air contaminants in excess of any emission standard.

Parameter Monitored: TEMPERATURE

Lower Permit Limit: 600 degrees Fahrenheit

Upper Permit Limit: 1200 degrees Fahrenheit

Monitoring Frequency: CONTINUOUS

Averaging Method: RANGE-NOT TO FALL OUTSIDE OF STATED
RANGE EXCEPT DURING STARTUP/SHUTDOWN

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

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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

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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 9: Contaminant List
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable State Requirement: ECL 19-0301

Item 9.1:

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

Condition 10: Malfunctions and Start-up/Shutdown Activities
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable State Requirement: 6 NYCRR 201-1.4

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Item 10.1:

(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 11: Emission Unit Definition**Effective between the dates of 10/05/2021 and 10/04/2031****Applicable State Requirement: 6 NYCRR Subpart 201-5****Item 11.1:**

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

Emission Unit: U-00001

Emission Unit Description:

Emission Unit U-00001 consists of two (2) ethylene oxide resistometers (sterilizer units) that perform cycles of sterilization on biological indicators intended for use in end-user ethylene oxide sterilizers.

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Building(s): Cuba1

Condition 12: Renewal deadlines for state facility permits
Effective between the dates of 10/05/2021 and 10/04/2031

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

Item 12.1:

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 13: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

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

Item 13.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 13.2:

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 9
270 Michigan Ave.
Buffalo, NY 14203

Reporting Requirements: ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 1/30/2022.

Subsequent reports are due every 12 calendar month(s).

Condition 14: Air pollution prohibited
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable State Requirement:6 NYCRR 211.1

Item 14.1:

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,

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pollen, toxic or deleterious emission, either alone or in combination with others.

Condition 15: Compliance Demonstration
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable State Requirement: 6 NYCRR 212-2.2

Item 15.1:

The Compliance Demonstration activity will be performed for the Facility.

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
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

Section 212-2.2 Table 2 – High Toxicity Air Contaminant
List

CAS 75-21-8, Ethylene oxide, Mass Emission Limit 25 pounds
per year

(1) The emissions of ethylene oxide from the facility shall not exceed 24 pounds during any consecutive 12-month period.

(2) Compliance with this emission limit shall be determined by monitoring and recording actual ethylene oxide usage and control. The first determination of compliance with the annual limit shall address the 12-month period that begins with the first whole month after the control improvements have been completed.

(3) To ensure the catalytic oxidizer is achieving the proper emission reductions, the facility shall have the manufacturer complete an annual calibration and inspection of the oxidizer and associated monitoring equipment. The facility shall complete all manufacture recommended maintenance and catalyst replacement or replenishment.

(4) The facility shall keep a log and other applicable records to document the ethylene oxide usage and the operation, calibration and maintenance of the monitoring systems and instrumentation.

(5) Submit the initial compliance report 30-days after 12-months of operation. After the initial compliance

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report, submit a report annually to DEC by January 30 for the previous year data including the individual monthly and 12-month rolling usage records. Provide a certification to the department that the facility has operated within the limits imposed by the emission cap.

Parameter Monitored: ETHYLENE OXIDE
 Upper Permit Limit: 24 pounds per year
 Monitoring Frequency: MONTHLY
 Averaging Method: ANNUAL TOTAL ROLLED MONTHLY
 Reporting Requirements: ANNUALLY (CALENDAR)
 Reports due 30 days after the reporting period.
 The initial report is due 1/30/2022.
 Subsequent reports are due every 12 calendar month(s).

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

Condition 16: Emission Point Definition By Emission Unit
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 16.1:

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

Emission Unit: U-00001

Emission Point: EP001

Height (ft.): 20 Diameter (in.): 6
 NYTMN (km.): 4679.209 NYTME (km.): 229.037 Building: Cuba1

Condition 17: Process Definition By Emission Unit
Effective between the dates of 10/05/2021 and 10/04/2031

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 17.1:

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

Emission Unit: U-00001

Process: 001 Source Classification Code: 3-15-020-01

Process Description:

Process 001 is the use of ethylene oxide to evaluate sterilizer test strips in two (2) resistomers (sterilizers). Effluent from these units is routed through a catalytic oxidizer having a minimum 90% removal efficiency for ethylene oxide.

Emission Source/Control: COX01 - Control

Control Type: CATALYTIC OXIDATION

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Emission Source/Control: STR01 - Process
Design Capacity: 100 grams per hour

Emission Source/Control: STR02 - Process
Design Capacity: 100 grams per hour

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