



RHODE ISLAND
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

OFFICE OF AIR RESOURCES
235 Promenade Street
Providence, Rhode Island 02908

13 May 2021

Mr. John Kummailil
Boston Scientific Corporation
8 Industrial Drive
Coventry, RI 02816

Dear Mr. Kummailil:

The Department of Environmental Management, Office of Air Resources has reviewed and approved your application for the installation of process equipment and air pollution control equipment to be located at your 8 Industrial Drive, Coventry facility.

Enclosed is a minor source permit issued pursuant to our review of your application (Approval Nos. 2114, 2131 – 2134, 2497 & 2498).

The permit conditions and emission limitations in this permit also incorporate and include those in Approval No. 2114 issued on 30 September 2010, Approval No. 2131-2134 issued on 7 October 2011, and Air Toxics Operating Permit (ATOP 1083/2010) issued on December 22, 2010. Hereinafter, the design, construction, and operation of all the equipment addressed in this approval shall be subject to the permit conditions and emission limitations contained in this minor source permit.

Any source with the potential to emit greater than major source thresholds as defined under Operating Permits, 250-RICR-120-05-29, is subject to the Operating Permit Program. With the issuance of this permit your facility located at 8 Industrial Drive, Coventry is subject to the Operating Permit Program as an Emissions Cap Source, with allowable emissions restricted to below the major source threshold. An emissions cap means any emission limitation or physical or operational limitation, imposed in a federally enforceable document that establishes the maximum quantity of emissions which may be released from a stationary source. The Office of Air Resources considers this minor source permit an emissions cap. Operating Permit Fees, 250-RICR-120-05-28, requires stationary sources with an emissions cap to pay an annual compliance/assurance fee of \$350.00. Notification concerning the payment of this fee will be mailed to you this upcoming fall.

If there are any questions concerning this permit, please contact me by telephone at 401-222-2808, extension 77154 or by email at Jikku.samuel@dem.ri.gov.

Sincerely,

Jikku Samuel
Air Quality Specialist
Office of Air Resources

cc: Coventry Building Official

STATE OF RHODE ISLAND
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR RESOURCES

MINOR SOURCE PERMIT

BOSTON SCIENTIFIC CORPORATION

APPROVAL Nos. 2114, 2131 – 2134, 2497 & 2498

Pursuant to the provisions of Air Pollution Control Permits, 250-RICR-120-05-9, this minor source permit is issued to:

Boston Scientific Corporation.


For the following:

Installation of two (2) primary tray aerators to be operated in parallel to reduce emissions of ethylene oxide (EtO) from wastewater produced during the sterilization process (Approval No 2497). Process air containing ethylene oxide will be routed to existing Verantis wet acid scrubber and then to the existing three (3) AAT dry bed scrubbers operated in parallel. Installation of four (4) new identical AAT dry bed scrubbers operated in parallel to treat EtO exhaust from the processed warehouse (Approval No 2498).

Located at: *8 Industrial Drive, Coventry, RI 02816*

This permit shall be effective from the date of its issuance and shall remain in effect until revoked by or surrendered to the Department. This permit does not relieve Boston Scientific Corporation from compliance with applicable state and federal air pollution control rules and regulations. The design, construction and operation of this equipment shall be subject to the attached permit conditions and emission limitations.


Laurie Grandchamp, P.E., Chief
Office of Air Resources


Date of Issuance

**STATE OF RHODE ISLAND
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR RESOURCES**

Permit Conditions and Emission Limitations

BOSTON SCIENTIFIC CORPORATION

APPROVAL Nos. 2114, 2131 – 2134, 2497 & 2498

A. Emission Limitations

1. Sterilization Process

- a. Emissions of ethylene oxide discharged from each sterilizer chamber vent, primary tray aerators, ethylene glycol tanks vents, and the wastewater tanks vents shall be captured, contained, and routed to an air pollution control system (APCS) consisting of a wet acid scrubber in combination with three (3) dry bed scrubbers ducted in parallel for treatment prior to discharge to the atmosphere.
- b. Emissions of ethylene oxide discharged from each sterilizer back vent shall be captured, contained, and routed in a combined gas stream to the (3) dry bed scrubbers ducted in parallel of the APCS for treatment prior to discharge to the atmosphere.
- c. Emissions of ethylene oxide discharged from the aeration cells shall be captured, contained, and routed to a dedicated dry bed scrubber (aeration cells dry bed scrubber) for treatment prior to discharge to the atmosphere.
- d. The emissions of ethylene oxide captured, contained, and routed to the APCS and the aeration cells dry bed scrubber shall be reduced by 99.9% or greater before discharge to the atmosphere.
- e. The concentration of ethylene oxide discharged to the atmosphere from the APCS and the aeration cells dry bed scrubber shall not exceed 4.4 ppm_v calculated as a 24-hour daily average.

2. Processed Warehouse

- a. The total quantity of emissions discharged to the atmosphere from the processed warehouse, of ethylene oxide and any other listed toxic air contaminant, shall not exceed the minimum quantity for that contaminant as specified in 250-RICR-120-05-9.17, Appendix A, based upon a 12-month rolling total. Emissions from activities

exempted from the provisions of "Air Toxics" 250-RICR-120-05-22.5(B) are not included in this limitation.

- b. Emissions of ethylene oxide of the ventilation exhaust from the Processed Warehouse Exhaust Fan (EF-8) shall be captured, contained, and routed to four dedicated dry bed scrubbers (EF-8 dry bed scrubbers) operated in parallel for treatment prior to discharge to the atmosphere.

3. Facility Wide

- a. Emissions of ethylene oxide from the entire facility shall not exceed:

- (1) 67 lbs per day

- (2) 1,298 lbs per consecutive 12-month period.

B. Operating Requirements

- 1. Ethylene oxide shall only be used for the sterilization process which includes validation, Ethylene Oxide sensor calibration and chamber testing.
- 2. The maximum daily usage of ethylene oxide at the facility shall not exceed 1,500 lbs.
- 3. The vacuum pump used to evacuate the sterilizer during the sterilization cycles shall recirculate coolant.
- 4. No more than nine sterilizer chambers and three aeration cells shall be discharged to the APCS at any time.
- 5. No more than one primary tray aerator system shall be discharged to the APCS at any time.
- 6. Reactant media shall be replaced after the concentration of ethylene oxide at the final outlet of the applicable dry bed scrubber measures 0.25 ppm over a 24-hour period.
- 7. There shall be no bypassing of the air pollution control systems during times when the processes emitting ethylene oxide vented to the APCS, aeration cells dry bed scrubber, and EF-8 dry bed scrubbers are operated.

C. Monitoring

- 1. The owner/operator shall, if complying with Condition A.1.d of this permit using a control technology other than acid-water scrubbers or catalytic or

thermal oxidizers, provide to the Administrator of the USEPA (Administrator) information describing the design and operation of the air pollution control system, including recommendations for operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameters to be measured during the performance test. During the performance test required in Condition D.1 of this permit, using the methods approved in 40 CFR 63.365(g), the owner/operator shall determine site-specific operating limits for the operating parameters approved by the Administrator.

2. The owner/operator shall monitor and record the concentration of ethylene oxide at the final outlet of the APCS. Measurements shall be recorded at least once per hour. Monitoring is required during those times when the APCS is in operation.
3. The owner/operator shall monitor and record the concentration of ethylene oxide at the final outlet of the aeration cells dry bed scrubber. Measurements shall be recorded at least once per hour. Monitoring is required during those times when the aeration cells dry bed scrubber is in operation.
4. The owner/operator shall monitor and record the concentration of ethylene oxide at the final outlet of the EF-8 dry bed scrubbers. Measurements shall be recorded at least once per hour. Monitoring is required during those times when the EF-8 dry bed scrubbers are in operation.
5. The pressure drop across each EF-8 dry bed scrubber shall be monitored and shall be recorded at the frequency of not less than once per week.

D. Stack Testing

1. Within 180 days of initial start start-up of both the primary tray aerators and the EF-8 dry bed scrubbers, stack testing shall be conducted to demonstrate compliance with Condition A.1.d and A.2.a.
2. A stack testing protocol shall be submitted to the Office of Air Resources for review at least 60 days prior to the performance of any stack tests.
3. The owner/operator shall provide the Office of Air Resources at least 60 days prior notice of any stack test.
4. All test procedures used for stack testing shall be approved by the Office of Air Resources prior to the performance of any stack test.
5. The owner/operator shall install any and all test ports or platforms necessary to conduct the required emissions testing, provide safe access to any platforms, and provide the necessary utilities for sampling and testing equipment.

6. All emissions testing shall be conducted under operating conditions deemed acceptable and representative for the purpose of assessing compliance with the applicable emission limitations or air quality standards.
7. A final report of the results of emissions testing shall be submitted to the Office of Air Resources no later than 60 days following completion of the testing.
8. All emissions testing must be observed by the Office of Air Resources or its authorized representatives to be considered acceptable, unless the Office of Air Resources provides authorization to the owner/operator to conduct the testing without an observer present.

E. Recordkeeping and Reporting

1. The owner/operator shall maintain the following records:
 - a. The daily amount of ethylene oxide, in pounds, loaded into the sterilizers.
 - b. The daily and twelve-month rolling total amount of ethylene oxide, in pounds, discharged from the entire facility. If the amount of ethylene oxide discharged from the entire facility exceeds the allowable emissions specified in Conditions A.3.a.(1)-(2) of this permit, the facility shall provide, to the Office of Air Resources, additional supporting documentation to demonstrate that the allowable facility-wide emissions were not exceeded.
 - c. The volume of water treated by the primary tray aerators each month.
 - d. The concentration of ethylene oxide at the final outlet of the air pollution control system as required in Condition C.1-C.4 of this permit.
 - e. The dates the reactant media is changed in each dry bed scrubber.
2. The owner/operator shall, on a monthly basis, no later than 15 days after the first of the month, determine the total quantity of each listed toxic air contaminant specified in 250-RICR-120-05-9.17, Appendix A, discharged to the atmosphere from the processed warehouse. Twelve-month rolling totals shall be calculated. The 12-month rolling total shall be used for comparison with the minimum quantities of 250-RICR-120-05-9.17, Appendix A. The owner/operator shall keep records of this determination and provide such records to the Office of Air Resources upon request.

3. The owner/operator shall demonstrate compliance with Condition A.1.d of this permit by using the following equation. This will be calculated annually:

$$\left(\frac{(\text{MEtO used}) - (\text{MEtO post APCS and aeration cells dry bed scrubber})}{\text{MEtO used}} \right) \times 100\%$$

Where:

MEtO: Mass of ethylene oxide

EtO concentration measurements will be recorded by a RIDEM approved monitoring device. Currently a Gas Chromatograph {GC} is the approved monitoring device.

4. The owner/operator shall notify the Office of Air Resources, in writing, of the date of initial start-up of the primary tray aerators and the EF-8 dry bed scrubbers no later than fifteen days after start-up.
5. The owner/operator shall notify the Office of Air Resources of any noncompliance with the terms of this permit, in writing, within 48 hours of becoming aware of the occurrence.
6. The owner/operator shall notify the Office of Air Resources in writing of any noncompliance with the terms of this permit or any other air pollution control rule or regulation within 30 calendar days of becoming aware of such occurrence and supply the director with the following information:
- a. The name and location of the facility;
 - b. The subject source(s) that caused the noncompliance with the permit term;
 - c. The time and date of first observation of the incident of noncompliance;
 - d. The cause and expected duration of the incident of noncompliance;
 - e. The estimated rate of emissions (expressed in lbs/hr or lbs/day) during the incident and the operating data and calculations used in estimating the emission rate; and,
 - f. The proposed corrective actions and schedule to correct the conditions causing the incident of noncompliance.

7. The owner/operator shall notify the Office of Air Resources in writing of any planned physical or operational change to any equipment that would:
 - a. Change the representation of the facility in the application.
 - b. Alter the applicability of any state or federal air pollution rules or regulations.
 - c. Result in the violation of any terms or conditions of this permit.
 - d. Qualify as a modification under 250-RICR-120-05-9.

Such notification shall include:

- Information describing the nature of the change.
- Information describing the effect of the change on the emission of any air contaminant.
- The scheduled completion date of the planned change.

Any such change shall be consistent with the appropriate regulation and have the prior approval of the Director.

8. The Office of Air Resources shall be notified, in writing within 30 calendar days of becoming aware, if the quantity of EtO emitted from the sterilization process exceeds 4.4 ppm_v calculated as a 24-hour daily average.
9. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of emissions discharged to the atmosphere from the processed warehouse, of any listed toxic air contaminant, exceeds the minimum quantity for that contaminant as specified in 250-RICR-120-05-9.17, Appendix A.
10. The Office of Air Resources shall be notified, in writing within 15 calendar days of becoming aware, if the concentration of ethylene oxide at the final outlet of any dry bed scrubber exceeds 0.25 ppm over a 24-hour period.
11. All records required in this permit shall be maintained for a minimum of five years after the date of each record and shall be made available to representatives of the Office of Air Resources upon request.

F. Other Permit Conditions

1. To the extent consistent with the requirements of this permit and applicable federal and state laws, the facility shall be designed, constructed and

operated in accordance with the representation of the facility in the permit application dated July 01, 2019 prepared by Environmental Strategies & Management, Inc (ES&M) and later supplemented by:

- a. ES&M on December 17, 2019 and September 04, 2020.
 - b. Boston Scientific Corporation on December 21, 2020.
2. Employees of the Office of Air Resources and its authorized representatives shall be allowed to enter the facility at all times for the purpose of inspecting any air pollution source, investigation any condition it believes may be causing air pollution or examining any records the Office of Air Resources requires to be maintained.
 3. The owner/operator is subject to the requirements of the General Duty Clause, Section 112(r)(1) of the Clean Air Act. Under this clause, the facility is responsible for but not limited to:
 - a. identifying hazards that may result from accidental releases;
 - b. designing and maintaining a safe facility; and,
 - c. minimizing the consequences of releases when they occur.
 4. At all times, including periods of startup, shutdown and malfunction, the owner/operator shall, to the extent practicable, maintain and operate the facility in a manner consistent with good air pollution control practice for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by this permit have been achieved. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Office of Air Resources, which may include, but is not limited to, monitoring results, opacity observations, review of operating maintenance procedures and inspection of the source.
 5. The facility is subject to the requirements of 40 CFR 63, Subpart A, "General Provisions" and Subpart O, "Ethylene Oxide Emissions Standards for Sterilization Facilities". Compliance with all applicable provisions therein is required unless otherwise stated in this permit. If there is any conflict between any term or condition of this permit and the applicable provisions of 40 CFR 63, the owner/operator shall comply with the most stringent requirement.
 6. The emission and dispersion characteristics of all sources of ethylene oxide at the facility shall be consistent with the parameters used in the air quality modeling to demonstrate that the emissions of ethylene oxide does not cause

an impact, at or beyond the property line of the facility, which exceeds the Acceptable Ambient Level for that substance. The Office of Air Resources, in its sole discretion, may reopen this permit if it determines that the emission and dispersion characteristics have changed significantly and that emission limitations must be revised to ensure compliance with "Air Toxics", 250-RICR-120-05-22.

7. The Office of Air Resources may reopen and revise this permit if it determines that:
 - a. a material mistake was made in establishing the operating restrictions; or,
 - b. inaccurate emission factors were used in establishing the operating restrictions; or,
 - c. emission factors have changed as a result of stack testing or emissions monitoring; or
 - d. revisions that are necessary due to additional applicable requirements pursuant to state or federal law or from any regulatory agency.

G. Malfunctions

1. The owner/operator may seek to establish that a malfunction of any air pollution control system that would result in noncompliance with any of the terms of this permit or any other applicable air pollution control rules and regulations was due to unavoidable increases in emissions attributable to the malfunction. To do so, the owner/operator must demonstrate to the Office of Air Resources that:
 - a. The malfunction was not attributable to improperly designed equipment, lack of preventative maintenance, careless or improper operation or operator error;
 - b. The malfunction is not part of a recurring pattern indicative of inadequate design, operation or maintenance;
 - c. Repairs were performed in an expeditious fashion. Off-shift labor and overtime should be utilized, to the extent practicable, to ensure that such repairs were completed as expeditiously as practicable.
 - d. All possible steps were taken to minimize emissions during the period of time that repairs were performed.

- e. Emissions during the period of time that repairs were performed will not:
 - (1) Cause an increase in the ground level ambient concentration at or beyond the property line in excess of that allowed by 250-RICR-120-05-22 and any Calculated Acceptable Ambient Levels; and
 - (2) Cause or contribute to air pollution in violation of any applicable state or national ambient air quality standard.
- f. The reasons that it would be impossible or impractical to cease the source operation during said period.
- g. The owner/operator's actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs or other relevant evidence.

This demonstration must be provided to the Office of Air Resources within two working days of the time when the malfunction occurred and contain a description of the malfunction, any steps taken to minimize emissions and corrective actions taken.

The owner/operator shall have the burden of proof in seeking to establish that noncompliance was due to unavoidable increases in emissions attributable to the malfunction.