

17 October 2011

Mr. Leonard Sarapas
Boston Scientific Corporation
8 Industrial Drive
Coventry, RI 02816

Dear Mr. Sarapas:

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 pursuant to our review of your application (Approval Nos. 2131-2134).

The permit conditions and emission limitations in this permit also incorporate and include those in Approval No. 2114 issued on 30 September 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.

If there are any questions concerning this permit, please contact me at 222-2808, extension 7028.

Sincerely,

Aleida M. Whitney
Air Quality Specialist
Office of Air Resources

cc: Coventry Building Official

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR RESOURCES

MINOR SOURCE PERMIT

BOSTON SCIENTIFIC CORPORATION

APPROVAL NOS. 2114 and 2131 - 2134

Pursuant to the provisions of Air Pollution Control Regulation No. 9, this minor source permit is issued to:

Boston Scientific Corporation.

For the following:

Installation of three sterilization chambers (Approval Nos. 2131-2133) and installation

of a new air pollution control system (Approval No. 2134) to reduce emissions of

ethylene oxide from the sterilization process.

Located at: *8 Industrial Drive, Coventry*

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.

Douglas McVay, Acting Chief
Office of Air Resources

Date of Issuance

**STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR RESOURCES**

BOSTON SCIENTIFIC CORPORATION

APPROVAL NOs. 2114 and 2131 - 2134

Permit Conditions and Emission Limitations

A. Emission Limitations

1. Emissions of ethylene oxide from each sterilizer chamber vent shall be treated by an air pollution control system consisting of a Verantis wet acid scrubber in combination with up to four Advanced Air Technologies (AAT) dry bed scrubbers.
2. Emissions of ethylene oxide discharged from the aeration cells and each sterilizer rear exhaust/chamber exhaust vent shall be treated in a combined gas stream in the dry bed scrubber section of the air pollution control system.
3. The emissions of ethylene oxide shall be reduced by 99.9% or greater before discharge to the atmosphere.
4. The concentration of ethylene oxide discharged to the atmosphere from the air pollution control system shall not exceed 4.4 ppmv.
5. Emissions of ethylene oxide from the entire facility shall not exceed:
 - a. 67 lbs per day
 - b. 1298 lbs per year

B. Operating Requirements

1. The average daily usage of ethylene oxide at the facility shall not exceed 1,114.2 lbs (calendar month average).
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 be of a recirculating design.

4. No more than nine sterilizer chamber vents shall be discharged to the air pollution control system at any time.
5. No more than five aeration cells and five sterilizer rear exhausts/chamber exhaust vents shall be discharged to the air pollution control system at any time.

C. Monitoring

1. The owner/operator shall, if complying with Condition A.3 of this minor source 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 minor source 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 the parameters as approved by the Administrator in Condition C.1 of this minor source permit using the methods and procedures in 40 CFR 63.365(g).
3. The owner/operator shall collect and record once per week the concentration of a 15-minute ethylene oxide bag sample at the final outlet of the air pollution control system. Monitoring is required during a week only if the air pollution control system has been operated.

D. Emission Testing

1. Within 180 days of start up of the new air pollution control system, and approval of the operating parameters by the Administrator, emissions testing shall be conducted to demonstrate compliance with Conditions A.3 following the procedures in 40 CFR 63.365 (b) and A.4 following the procedures in 40 CFR 63.365 (c).
2. An emission testing protocol shall be submitted to the Office of Air Resources for review at least 60 days prior to the performance of any emissions tests. The owner/operator shall provide the Office of Air Resources at least 60 days prior notice of any emissions test.

3. All test procedures used for compliance testing shall be approved by the Office of Air Resources prior to the performance of any emissions test.
4. 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.
5. 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.
6. 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.
7. 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 average amount of ethylene oxide, in pounds, loaded into the sterilizers calculated as the amount of ethylene oxide, in pounds, loaded into the sterilizers per month divided by the number of operating days in that month.
 - b. The amount of ethylene oxide, in pounds, discharged from the entire facility per month. If the amount of ethylene oxide discharged from the entire facility in a month exceeds the allowable daily emissions specified in Condition A.5.a of this permit, the facility shall provide, to the Office of Air Resources, additional supporting documentation to demonstrate that the allowable daily emissions were not exceeded during that month.
 - c. The concentration of ethylene oxide at the final outlet of the air pollution control system as required in Condition C.3 of this minor source permit.
 - d. The dates the reactant media is changed in the dry bed scrubber section of the air pollution control system.

2. The owner/operator shall notify the Office of Air Resources, in writing, of the date of initial start-up of the new sterilization chambers and the new air pollution control system no later than fifteen days after start-up.
3. 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.
4. 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 APC Regulation No. 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.

5. 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. There shall be no bypassing of the air pollution control system during times when ethylene oxide emissions are being discharged to the device.
2. 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 March 3, 2011 prepared by ARCADIS.
3. 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.
4. 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.
5. 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. 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.
6. 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, including any monitoring required pursuant to Condition C.1, 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.

7. Approval No. 1280 issued on 5 May 1994 for the installation of a Donaldson catalytic oxidizer, Approval No. 1394 issued on 15 October 1996 for the installation of a Glygen 2000 scrubber and Approval No. 1612 issued on 14 August 2001 for the installation of a Lantec Q-Pac scrubber shall be revoked effective with the successful testing and acceptance of the Verantis wet acid scrubber/AAT dry bed scrubber air pollution control system. The owner/operator shall notify the Office of Air Resources upon acceptance of the air pollution control system.
8. 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 minor source 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 Pollution Control Regulation No. 22.

G. Malfunctions

1. Malfunction means a sudden and unavoidable breakdown of process or control equipment. In the case of a malfunction of any air pollution control system, all reasonable measures shall be taken to assure resumption of the designed control efficiency as soon as possible. In the event that the malfunction of an air pollution control system is expected or may reasonably be expected to continue for longer than 24 hours and if the owner/operator wishes to operate the source on which it is installed at any time beyond that period, the Director shall be petitioned for a variance under Section 23-23-15 of the General Laws of Rhode Island, as amended. Such petition shall include, but is not limited to, the following:
 - a. Identification of the specific air pollution control system and source on which it is installed;
 - b. The expected period of time that the air pollution control system will be malfunctioning or out of service;
 - c. The nature and quantity of air contaminants likely to be emitted during said period;

- d. Measures that will be taken to minimize the length of said period;
 - e. The reasons that it would be impossible or impractical to cease the source operation during said period.
2. 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 Air Pollution Control Regulation No. 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.