UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

APR 2 3 2014

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

URGENT LEGAL MATTER
REQUIRES PROMPT RESPONSE

Leonard Sarapas, Corporate Director, Environment, Health and Safety
Boston Scientific Corporation
100 Boston Scientific Way
Marlboro, MA 01752

Re: Testing Order under Section 114 of the Clean Air Act; EPA Conditional Approval of Boston Scientific Corporation's Revised Emissions Testing Protocol of September 26, 2013

Dear Mr. Sarapas:

On February 20, 2013, EPA issued Boston Scientific Corporation ("BSC") a Testing Order under Section 114 of the Clean Air Act, requiring BSC to prepare an emissions testing protocol for its new ethylene oxide ("EO") air pollution control system at its Coventry, Rhode Island sterilization facility and to conduct emissions testing as required by the National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emission Standards for Sterilization Facilities found at 40 CFR Part 63, Subpart O ("Subpart O"). BSC submitted an emissions testing protocol to EPA on March 26, 2013 and then resubmitted the protocol on July 3, 2013. On August 20, 2013, EPA issued BSC a notice of intent to disapprove the protocol and directed BSC to submit a revised protocol. BSC submitted a revised emissions testing protocol dated September 26, 2013.

This letter, issued under the authority of Section 114 of the Clean Air Act and 40 CFR §§63.7(c)(3), 63.365(g), and 63.365(h), conditionally approves BSC's revised emissions testing protocol of September 26, 2013, provided BSC makes revisions to the protocol to incorporate comments 1 through 6 below. BSC must resubmit to EPA and to the Rhode Island Department of Environmental Management an emissions testing protocol addressing the comments below within two weeks of the date of receipt of this letter:

The emissions testing protocol shall be revised to incorporate the following elements:

1. The use of EPA Method 18, and all the requirements contained within, at all sampling locations where EPA Method 25A has been proposed to be used. EPA also recommends

the use of Method 25A at the final stack sampling location for the purposes of characterizing the emissions profile.

2. An explanation of how the sampling time for EPA Method 18 will be determined, including a calculation of the residence time for purged gasses in the air pollution control system. (Note that Method 18 involves the use of Tedlar bags to collect a single integrated sample over the duration of an emissions test. In addition, Subpart O requires that an emissions test for a sterilization chamber be conducted for the duration of the first purge).

3. A discussion of how and when BSC will conduct the prescreening for EPA Method 18. This prescreening of volatile organic compounds ("VOCs") will characterize the waste stream. EPA recommends that BSC discuss the prescreening with EPA's stack tester, Bill Osbahr. Prescreening shall be conducted no later than May 31, 2014.

4. A discussion of how and when BSC will conduct the moisture study using EPA Method 4. The moisture study will characterize the moisture of the waste gas stream emitted from the sterilization chambers. The study is required to be performed under emissions testing operating conditions. Operating conditions for this study will include, but not be limited to, identifying the purge chambers which will be purged and the ethylene glycol concentration in the wet scrubber at the time of the study. The study must be conducted prior to the emissions testing.

5. The proposed method used to calculate the stack flow rate at the scrubber outlet under the "Low EO" condition, including any quality assurance activities performed in support of the calculation.

6. Emissions testing of the sterilization chambers and the aeration rooms as described in the final protocol shall begin no later than July 7, 2014.

Mail all submissions to:

Susan Studlien, Director Office of Environmental Stewardship Attn: Darren Fortescue US EPA Region 1 5 Post Office Square, Suite 100 Mail Code: OES-04-2 Boston, MA 02109-3912	William Osbahr US EPA Region 1 11 Technology Drive Mail Code: EIA North Chelmsford, MA 01863-2431	Ted Burns Rhode Island Department of Environmental Management 235 Promenade Street Providence, RI 02908-5767

If you have any questions regarding this letter, please contact Darren Fortescue, Environmental Engineer, at (617) 918-1162, or have your attorney call Thomas T. Olivier, Senior Enforcement Counsel at (617) 918-1737.

Sincerely,

Susan Studlien

Susan Studlien, Director
Office of Environmental Stewardship

cc: Ted Burns, RI DEM
Doug McVay, RI DEM
Scott Throwe, US EPA
William Osbahr, US EPA