



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

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**URGENT LEGAL MATTER
REQUIRES PROMPT RESPONSE**

Dated by Electronic Signature below

Gary Cranston, President
Professional Contract Sterilization, Inc.
40 Myles Standish Boulevard
Taunton, MA 02780

Re: Clean Air Act Testing Requirement

Dear Mr. Cranston:

The United States Environmental Protection Agency (“EPA”) is evaluating whether Professional Contract Sterilization, Inc. (“PCS”) is in compliance with the Clean Air Act (“CAA”) and requirements promulgated under the CAA at its facility located at 40 Myles Standish Boulevard Taunton, Massachusetts. In particular, EPA is evaluating PCS’s compliance with the Ethylene Oxide Emissions Standards for Sterilization Facilities, found at 40 C.F.R. Part 63, Subpart O (“Subpart O”).

Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1), gives EPA the authority to require any person who owns or operates any emission source to establish and maintain records, make reports, sample emissions, and provide such other information as may reasonably be required to enable EPA to determine whether such person is in compliance with the CAA and its implementing regulations.

EPA is evaluating emissions of the hazardous air pollutant, ethylene oxide, from the sterilization and aeration processes operated at the facility. To do so, EPA is requiring PCS to test emissions from the Damas Corporation tri-phase ethylene oxide scrubber and the Anguil Environmental Systems catalytic oxidizer used to control ethylene oxide emissions from the sterilization and aeration processes. Preparations and performance testing shall be conducted as described below.

Testing Requirement

PCS shall develop a performance test plan for EPA approval that describes the following elements in detail and shall subsequently conduct performance testing of ethylene oxide emissions.

Sterilization Chamber Performance Testing

- 1) Sterilization chamber performance testing shall consist of two sets of three runs.
 - a) The first three run set shall be conducted under maximum operating conditions, i.e., while venting the maximum “permitted”¹ number of chambers.
 - b) The second three run set shall be conducted while venting the smallest chamber, i.e., Vessel 5, which has a 30 ft³ capacity.
- 2) All test runs conducted on sterilization chambers shall be performed during the first evacuation of all applicable chambers and the chambers must be empty of products and devices.
- 3) All test runs conducted on sterilization chambers shall be performed when the chambers are charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature). The performance test plan shall include documentation that verifies the typical amount of ethylene oxide usage, and the normal operating conditions for each chamber being tested. The final test report shall document ethylene oxide usage and operating conditions during the performance testing.
- 4) The total mass of ethylene oxide loaded into each applicable sterilization chamber shall be determined using the procedures described at 40 C.F.R. § 63.365(b)(1)(i).
- 5) The residual mass of ethylene oxide in each applicable the sterilizer chamber shall be determined using the procedures described at 40 C.F.R. § 63.365(b)(1)(ii).
- 6) The total mass of ethylene oxide at the inlet to the Damas Corporation tri-phase ethylene oxide scrubber shall be determined using the procedures described in 40 C.F.R. § 63.365(b)(1)(iii).
- 7) The mass of ethylene oxide emitted from the Damas Corporation tri-phase ethylene oxide scrubber outlet shall be determined using the procedures described in 40 C.F.R. § 63.365(b)(1)(iv).

¹ If the maximum sterilization operating conditions are not restricted by a federally enforceable limit documented in a permit issued by MassDEP, PCS shall provide documentation describing what the maximum operating conditions are for the facility.

- 8) The control efficiency of the Damas Corporation tri-phase ethylene oxide scrubber for each test scenario shall be determined using the procedures described in 40 C.F.R. § 63.365(b)(1)(v).
- 9) If ethylene glycol concentration is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(e)(1) shall be used to determine a baseline operating parameter for the Damas Corporation tri-phase ethylene oxide scrubber. All glycol concentrations determined during performance testing shall be documented in the final test report.
- 10) If the scrubber liquor tank level is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(e)(2) shall be used to determine a baseline operating parameter for the Damas Corporation tri-phase ethylene oxide scrubber. All scrubber liquor tank levels determined during performance testing shall be documented in the final test report.
- 11) All continuous emissions monitoring system (“CEMS”) data collected by the PID gas chromatograph system during the performance testing of the sterilization chambers shall be provided in the final test report.

Aeration Room Performance Testing

- 12) Aeration room performance testing shall consist of three one-hour runs. The one-hour runs shall be conducted under maximum operating conditions, i.e., while aerating the maximum “permitted”² volume of products and devices in both functional aeration rooms. Documentation shall be provided in the performance test plan that describes the maximum permitted volume of products and devices.
- 13) Aeration room performance testing shall be performed while the temperature at the outlet from the catalyst bed of a Anguil Environmental Systems catalytic oxidizer is at, or above, the manufacturer’s recommended temperature. Documentation describing the manufacturer’s recommended temperature at the outlet from the catalyst bed shall be supplied in the performance test plan. Documentation describing the outlet from the catalyst bed used during performance testing shall be documented in the final test report.
- 14) If the ethylene oxide concentration at the outlet from the Anguil Environmental Systems catalytic oxidizer is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(c)(2) shall be used.

² If the maximum volume of products and devices is not restricted by a federally enforceable limit documented in a permit issued by Mass DEP, PCS shall provide documentation describing the maximum volume of products and devices the facility is capable of aerating at any point in time.

- 15) If the ethylene oxide removal efficiency of the Anguil Environmental Systems catalytic oxidizer is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(d) shall be used.
- 16) All continuous emissions monitoring system (“CEMS”) data collected by the PID gas chromatograph system during the performance testing of the aeration rooms shall be provided in the final test report.

PCS shall prepare for and conduct performance testing according to the following schedule:

- 17) Within 15 days of the date PCS receives this letter, contact EPA Senior Enforcement Coordinator Darren Fortescue, at (617) 918-1162, or fortescue.darren@epa.gov to schedule a conference. At this conference, EPA will review with PCS the testing procedures, monitoring procedures, and testing methods described above and discuss the development of a performance test plan.
- 18) Within 30 days of the date PCS receives this letter, prepare and email to EPA for review a performance test plan that incorporates the procedures/methods described above.
- 19) Within 15 days of receiving EPA comments on the performance test plan, PCS shall revise and resubmit the performance test plan in accordance with EPA’s comments or required changes. EPA shall approve, approve with conditions, or disapprove the revised performance test plan in writing.
- 20) Within 15 days of the date EPA approves the performance test plan, PCS shall hold a pre-test meeting with EPA and schedule the testing date(s). The testing must take place no later than 30 days after the pre-test meeting.
- 21) Within 45 days of completing the testing, PCS must submit a complete test report to EPA.

Provide all documents electronically³ via email to fortescue.darren@epa.gov.

Be aware that if PCS does not provide the information and perform the testing required in a timely manner, EPA may order it to comply and may assess monetary penalties under Section 113 of the Clean Air Act. Federal law also establishes criminal penalties for providing false information to EPA. This letter is not subject to Office of Management and Budget review pursuant to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

³ Note that EPA cannot receive email messages with files larger than 25 MB. If your submissions are larger than 25 MB, please contact Darren Fortescue for other options.

You may assert a business confidentiality claim covering part or all of the information requested, in the manner described by 40 CFR § 2.203(b). Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2, Subpart B. Note that certain categories of information, such as emission data, are not properly the subject of such a claim. If no such claim accompanies the information when EPA receives it, EPA may make the information available to the public without further notice to you.

If you have any questions regarding this Testing Requirement, please contact Darren Fortescue at (617) 918-1162 or fortescue.darren@epa.gov, or have your attorney contact Michael Wagner at (617) 918-1735 or wagner.michael@epa.gov.

Sincerely,

KAREN MCGUIRE Digitally signed by KAREN
MCGUIRE
Date: 2022.04.06 13:16:49 -04'00'

Karen McGuire, Director
Enforcement and Compliance Assurance Division

Enclosures:

cc: Dan DiSalvio, MassDEP