



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

Clean Air Act Inspection Report

Drafted: April 15, 2022

Finalized: April 19, 2022

EPA Inspector: Darren Fortescue, Senior Enforcement Coordinator, Air Compliance Section /DEF/
Davianna Vasconcelos, Environmental Engineer, Air Compliance Section /DMV/

EPA Reviewer: Christine Sansevero, Chief, Air Compliance Section /CMS/

Date of Inspection: April 7, 2022

Facility Name: Professional Contract Sterilization, Inc.

ICIS Air ID#: MA0000002512000879

Facility Location: 40 Myles Standish Boulevard, Taunton, MA 02780

Mailing Address: As above

Disclaimer:

Unless otherwise noted, this report describes conditions at the facility/property as observed by EPA inspector(s), and/or through records provided to and/or information reported to EPA inspector(s) by facility representatives and as understood by the inspector(s). This report may not capture all operations or activities ongoing at the time of the inspection. This report does not make final determinations on potential areas of concern. Nothing in this report affects EPA's authorities under federal statutes and regulations to pursue further investigation or action.

Inspection Attendees:

Name	Title	Organization
Darren Fortescue	Senior Enforcement Coordinator	EPA Region 1
Davianna Vasconcelos	Environmental Engineer	EPA Region 1
Gary Cranston	President	Professional Contract Sterilization

Inspection Purpose:

On March 23, 2022, EPA conducted a Clean Air Act Inspection at Professional Contract Sterilization, Inc. (“PCS”) located at 40 Myles Standish Boulevard, Taunton, Massachusetts. On April 7, 2022, EPA returned to PCS to conduct a records review of documents not initially reviewed during the first inspection.

Ethylene Oxide Sterilization and Aeration:

The facility has five operational and one non-operational sterilization chambers (see Table 1). PCS uses 100% ethylene oxide for sterilization.

Table 1: Sterilization Chambers Installed at PCS

Vessel	Capacity (ft³)	Installation Year
1	1140	1990
2	670	1990
3	405	1990
4	250	1997
5	30	1997
6	1140	Not Operational

Three aeration rooms are installed at the facility. Two of the aeration rooms are used for ethylene oxide aeration, while the third is used for storage only.

Ethylene Oxide Pollution Control Systems:

Emissions from the operational sterilization chamber vents and the vacuum pump exhausts are ducted to a Damas Corporation tri-phase ethylene oxide scrubber. The scrubber is vented to the atmosphere.

Emissions from the two operational aeration rooms are ducted to a Anguil catalytic oxidizer. The oxidizer is vented to the atmosphere. The third aeration room also has the capacity to be ducted to the oxidizer; however, the ducting is currently shut off.

Potentially Applicable Clean Air Act Requirements:

40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities (“Subpart O”).

Opening Conference:

Entry

On April 7, 2022, at 09:30 am, EPA Region 1 representatives Darren Fortescue, and Davianna Vasconcelos arrived at the PCS facility, located at 40 Myles Standish Boulevard, Taunton, Massachusetts, and met Gary Cranston of PCS.

Records Review

The group proceeded to a conference room where several documents were located, and Mr. Fortescue and Ms. Vasconcelos conducted a records review.

Ethylene Oxide Usage

Mr. Fortescue reviewed a document titled “Memo to File Regarding ETO Usage for Years 2019, 2020 and 2022 for PCS.” Table 2 describes PCS’s annual ethylene oxide usage, as listed in the document.

Table 2: PCS Annual Ethylene Oxide Usage

Year	Ethylene Oxide Usage (lbs)	Ethylene Oxide Usage (tons)
2019	49,041.5	24.5
2020	45,032	22.5
2021	37,492	18.7

Daily Operational Checklist

Mr. Fortescue reviewed a document titled “Daily Operational Checklist.” The checklist described various operating parameters recorded by facility representatives for the period January 1 through March 31, 2022. The checklist described daily tank liquor levels for the Damas Corporation tri-phase ethylene oxide scrubber. The daily tank levels recorded in the document varied from 45 to 68 inches.

1992 Performance Testing

Mr. Fortescue and Ms. Vasconcelos reviewed a document that described ethylene oxide performance testing, which occurred February 24 through 26, 1992. The document described two sets of three runs. The first set of runs were conducted while venting sterilization chamber vessels 1, 2 and 3. The second set of test runs were conducted while venting sterilization chamber 3.

Mr. Fortescue and Ms. Vasconcelos noted that the document described a pollution control configuration that did not include a Anguil catalytic oxidizer. Ms. Vasconcelos noted that the document described that a primary scrubber received emissions from the sterilization chambers and a secondary scrubber received emissions from the aeration rooms and fugitive emissions.

Ms. Vasconcelos noted that the document described that a compliance test was scheduled for the secondary scrubber; however, the measured value of ethylene oxide at the outlet of the scrubber appeared to be more than the measured value at the inlet. A "field-developed" performance evaluation was completed on the secondary scrubber to determine the cause of the problem. Ms. Vasconcelos noted the document concluded that ethylene glycol was being transported from the primary scrubber to the secondary scrubber via a closed-loop system. The secondary scrubber was not tested for compliance and the test was postponed until the problem was addressed.

1996 Performance Testing

Mr. Fortescue and Ms. Vasconcelos reviewed a document that appeared to be an email from PCS to EPA representative Jack Harvanek. The email provided responses by PCS to comments that appeared to have been provided by EPA on a previously submitted protocol regarding performance testing that was scheduled to be conducted in 1996.

Mr. Fortescue and Ms. Vasconcelos reviewed two documents, one a protocol and the other a performance test report, which described ethylene oxide emissions performance testing conducted on July 31 and August 1, 1996. The documents described two sets of three test runs.

The documents described that the first set of three test runs were conducted on emissions from the Damas Corporation tri-phase ethylene oxide scrubber. Mr. Fortescue documented the following details about the runs:

- The test objective was to determine the scrubber ethylene oxide removal efficiency;
- The test load was based on the first evacuations from sterilization chamber vessels 1, 2 and 3;
- Sterilization chambers 4 and 5 were not included in the testing, as they had not been installed at the time of testing;
- The sterilization chamber vessels were charged with what was described as representative amounts of ethylene oxide that reflected normal operating conditions;
- The load of ethylene oxide to the scrubber was determined by measuring the weight of ethylene oxide injected into the vessels then subtracting the residual ethylene oxide in the vessels after the first evacuations;
- EPA Method 18 and EPA Method 2 were used to determine the amount of ethylene oxide observed at the outlet of the scrubber;
- Tedlar bags were used to collect effluent samples;

- There did not appear to be any observations recorded that described the presence or absence of moisture in the Tedlar bag samples;
- The Tedlar bag samples were analyzed onsite using a gas chromatograph (“GC”) analyzer;
- The GC analyzer was also run during the test runs to produce nonintegrated ethylene oxide run data;
- Operating parameters recorded for the Damas Corporation tri-phase ethylene oxide scrubber included differential pressure and solution pH;
- There did not appear to be any reference to liquor levels being recorded for the Damas Corporation tri-phase ethylene oxide scrubber tanks;
- There did not appear to be any reference to the collection of scrubber media samples for ethylene glycol analysis;
- The scrubber fan shutdown for four minutes during the second and third evacuations of the vessels during the first test run; and
- The Damas Corporation tri-phase ethylene oxide scrubber removal efficiency was described as 99.95%.

The documents described that the second set of three test runs were conducted on emissions from the Anguil catalytic oxidizer. Mr. Fortescue documented the following details about the runs:

- The test objective was to determine the catalytic oxidizer ethylene oxide removal efficiency;
- The test load was based on the first evacuations from sterilization chamber vessels 1, 2 and 3;
- Sterilization chambers 4 and 5 were not included in the testing, as they had not been installed at the time of testing;
- The sterilization chamber vessels were charged with what was described as representative amounts of ethylene oxide that reflected normal operating conditions;
- The load of ethylene oxide was determined by measuring the weight of ethylene oxide injected into the vessels then subtracting the residual ethylene oxide in the vessels after the first evacuations;
- EPA Method 18 and EPA Method 2 were used to determine the amount of ethylene oxide observed at the outlet of the oxidizer;
- Tedlar bags were used to collect effluent samples;
- There did not appear to be any observations recorded that described the presence or absence of moisture in the Tedlar bag samples;
- The Tedlar bag samples were analyzed onsite using a GC analyzer;
- The GC analyzer was also run during the test runs to produce non integrated ethylene oxide run data;

- Operating parameters recorded for the Anguil catalytic oxidizer were inlet and outlet catalyst temperature;
- There appeared to be a mechanical issue with the oxidizer that resulted in two of the runs producing a removal efficiency of between 80 and 90%;
- The report rejected the runs where the oxidizer did not meet the required removal efficiency of 99% and only reported the final results based on one run; and
- The removal efficiency was described as 99.83%.

Table 3 describes the calibration gases used in the performance testing, as described on the calibration gas certifications located in the appendices to the 1996 Performance Test Report.

Table 3: Calibration Gases Used in the 1996 Performance Testing

Cylinder Number	Concentration (ppm)
CLM009251	4.98
CLM011449	47.9
CLM003003	456
CLM007878	1740
SA16403	28.6
FF20917	81.1
SA35	157.3
SA7321	6.4

Ms. Vasconcelos photographed the GC analyzer data located in the appendices of the test report (photos are in the inspection file).

Subsequent Testing

Mr. Fortescue told Mr. Cranston that the 1996 Performance Test Report did not appear to describe testing of sterilization chamber vessels 4 and 5, or aeration room emissions. Mr. Cranston said PCS had performed subsequent testing that included testing of sterilization chambers 4 and 5, and aeration room emissions.

Mr. Cranston produced several test reports that he said described subsequent testing activities. Mr. Fortescue reviewed a test report that appeared to describe testing that occurred in 2016. Mr. Fortescue noted that the test report described a single test run that appeared to include all functional sterilization chambers (Vessels 1 through 5). Mr. Fortescue also noted the test report described a single run that appeared to be conducted on aeration room emissions. Mr. Cranston said that all the subsequent testing, post 1996, was performed using single runs, rather than three runs.

Mr. Fortescue and Mr. Cranston were unable to find documentation of liquor levels for the Damas Corporation tri-phase ethylene oxide scrubber at the time of testing, in the 2016 test report.

Closing Conference:

Mr. Fortescue and Ms. Vasconcelos thanked Mr. Cranston for his time.

Ms. Vasconcelos asked Mr. Cranston to confirm the numbers and capacities of the sterilizers from the information given during the first inspection.

Mr. Cranston said there is no permit restriction preventing PCS from operating all sterilization chamber vessels at the same time.

Mr. Fortescue said that a performance test that met all the requirements of Subpart O, under the current facility configuration, may not have been conducted. Mr. Fortescue explained Subpart O requires comprehensive testing of all sterilization chambers including vessels 4 and 5, and comprehensive aeration room emissions testing. Mr. Fortescue said it also appears that an operating limit, either ethylene glycol concentrations or liquor levels for the Damas Corporation tri-phase ethylene oxide scrubber, may not have been established during any of the testing reviewed.

Mr. Fortescue handed Mr. Cranston a document requiring PCS to conduct a performance test that meets the requirements of Subpart O.

Mr. Fortescue confirmed that PCS still planned to provide EPA with the remaining information, EPA requested at the first inspection on March 23, by email as soon as practicable. The information requested includes:

- The company's NAICS Code;
- If the sterilizer bay areas are vented to the catalytic oxidizer;
- A full copy of the stack test report for the test conducted in 1996; and
- To confirm if the PID gas chromatograph system meets either Performance Specification 8 or 9 described in 40 CFR Part 60, Appendix B.

In addition, Mr. Fortescue requested that PCS provide copies of reports describing all testing activities that had been performed since the performance testing that occurred in 1996.

The inspectors left the facility at: 01:30 pm.