



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

Clean Air Act Inspection Report

Drafted: March 29, 2022

Finalized: March 30, 2022

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

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

Date of Inspection: March 23, 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
Marie Cranston	Administration	Professional Contract Sterilization

Facility/Process Description:

History

The facility, located at 40 Myles Standish Boulevard, Taunton, Massachusetts, is owned and operated by Professional Contract Sterilization, Inc. (“PCS”). The facility provides ethylene oxide contact sterilization services and sterilizes medical and veterinarian devices.

The facility was built in 1990 and at that time there were three sterilization chambers installed. In 1997, the facility doubled in size to approximately 34,000 ft³ and three more sterilization chambers were added (one is currently not operational).

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.

Ethylene Oxide Monitoring

Ethylene oxide monitoring is performed using a PID gas chromatograph system. The PID system monitors the following locations:

- Inlet to the catalytic oxidizer;
- Outlet from the catalytic oxidizer;
- Outlet from the scrubber;
- Ethylene oxide storage room 1;
- Ethylene oxide storage room 2;
- Scrubber room;
- Sterilizer room 1;
- Sterilizer room 2;
- Maintenance/mechanical room near the analyzer; and
- The rear of the maintenance/mechanical room (outside the ethylene oxide storage rooms).

Samples are collected from each location via teflon tubing. Each analysis cycle takes approximately two minutes to perform, and each location is sampled at least twice per hour.

Number of Employees and Working Hours:

PCS employs 6 full time employees. The facility is permitted to operate 24 hours per a day; however, it is currently operating on a 08:00 to 17:00 single shift, five days per week.

Potentially Applicable Clean Air Act Requirements:

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

Previous Enforcement Actions:

A “Detailed Facility Report” from EPA’s Enforcement and Compliance History Online database indicates that there have been no informal or formal enforcement actions taken against PCS in the past five years.

Opening Conference:

Entry

On March 23, 2022, at 10:00 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 and Marie Cranston of PCS. Mr. Fortescue presented his credentials, provided a copy of the US EPA Small Business Resources Information Sheet, and initiated an opening conference.

Conference

Mr. Fortescue asked about the annual ethylene oxide usage for the years 2019 through 2021. Facility representatives said they had not yet calculated the 2021 total but said they would supply the information via email after the inspection. Facility representatives indicated that the annual ethylene oxide usage for the years 2019 through 2021 had been more than 10 tons.

Facility representatives said sterilized devices are moved from sterilization chambers to aeration rooms using hand jacks or forklifts. Facility representatives said that sterilized devices are not moved from the chambers to aeration until the ethylene oxide concentration in the chambers drops below 1 ppm.

Facility representatives said the lines that supply ethylene oxide to the sterilization chambers are back flushed into the ethylene oxide tanks using nitrogen after each cycle.

Facility representatives said that the prior ethylene oxide monitoring system had used a HNU Systems gas chromatograph; however, this had been replaced with the PID gas chromatograph in 2022.

Facility representatives said the Damas scrubber uses a 5% sulfuric acid aqueous solution that absorbs ethylene oxide from the flue gas and then produces ethylene glycol in the presence of sulfuric acid that acts as the catalyst for the reaction. Facility representatives said PCS monitors and records the glycol level in the scrubber reservoirs daily. Facility representatives said the glycol concentration in the scrubber media is monitored using a hydrometer. Facility representatives said the scrubber media is periodically shipped offsite to be processed into other products, such as antifreeze.

Facility representatives said the Anguil Catalytic Oxidizer has a 20,000 cfm capacity but is only operated at 5,000 cfm. Facility representatives explained that while the oxidizer is designed to have two carbon bed catalysts, because the system is only operated at 5,000 cfm, only one bed is necessary. Facility representatives said the oxidation temperature is maintained at no less than 265 °F, and this limit is based on design criteria provided by the manufacturer. Facility representatives said the oxidation temperature is monitored using a type K thermocouple that is calibrated on an annual basis. Facility representatives said the oxidizer operates under negative pressure that pulls flue gas from the aeration rooms through the system.

Facility representatives said that stack testing of the control systems was performed in 1990 and in 1997. Facility representatives said copies of the full stack test reports would be provided via

email after the inspection. Facility representatives said MassDEP observed the stack tests in 1990 and 1997, but were not certain if EPA observed the testing.

Facility representatives said annual stack testing is not conducted on the catalytic oxidizer. Facility representatives explained that while the oxidizer catalyst bed material has been tested and replaced, it is not a routine process. Facility representatives said the ethylene oxide concentrations at the outlet from the oxidizer are monitored using the PID gas chromatograph system.

Facility representatives indicated they did not believe that PCS had been routinely submitting reports to EPA.

Facility Tour:

Mr. Cranston and Ms. Cranston led Mr. Fortescue and Ms. Vasconcelos on a tour of the facility.

The group proceeded to an area that facility representatives said was the receiving area. Facility representatives said no ethylene oxide monitoring is conducted in the receiving area.

The group entered a room that Mr. Fortescue noticed was significantly hotter and more humid than the receiving area. Facility representatives said it is the preconditioning room. Facility representatives said devices are preconditioned in the room for between 24 and 48 hours, prior to sterilization.

The group exited the preconditioning room and proceeded past equipment mounted to the wall of the facility. Facility representatives said the equipment is used to heat water to be used in the hot water jackets for the sterilization chambers.

Mr. Cranston opened a bay door that allowed the EPA inspectors to see inside a large room. Facility representatives said the room contained Sterilization Chambers 3, 4, 5 and 6. Mr. Fortescue observed several chambers were installed in the room. Mr. Cranston pointed out a partially dismantled chamber, he said is Sterilization Chamber 6. Mr. Cranston said Sterilization Chamber 6 had never been operational.

Facility representatives pointed out a metal cart that they said is used to place devices ready for sterilization into one of the smaller sterilization chambers. Facility representatives said pallets are used for the larger chambers.

Mr. Cranston said the sterilization chambers are all located in a secondary containment area designed to contain water in the event it is necessary to control a fire. Mr. Cranston said rollers are used to facilitate pallet insertion and removal from the sterilization chambers.

Mr. Fortescue observed that the sterilization chambers had fume hoods above the doors. Mr. Cranston said there are also fume capture grates below the doors. Mr. Fortescue asked if the hoods and grates feed into either the scrubber or catalytic oxidizer ductwork. Mr. Cranston said he did not know and would check and confirm via email after the inspection.

Mr. Cranston said both the rooms that house the ethylene oxide sterilization chambers have ethylene oxide monitoring lines to the PID gas chromatograph system.

The group proceeded through a control room into a maintenance room. EPA representatives met with John Marshall of Eastland Engineering. Mr. Fortescue observed a PID gas chromatograph analyzer. Mr. Marshall said the analyzer monitors several locations throughout the facility and monitors each location at least twice every hour. Mr. Marshall said the gas chromatographs for each analysis performed are stored on the analyzer. Mr. Marshall said he produced an ethylene oxide monitoring data report for PCS on a weekly basis. Mr. Marshall said the column used in the system is a metal capillary column. Mr. Marshall said the analyzer performs a self-calibration once per day. Mr. Marshall said he did not know if the PID gas chromatograph system meets either Performance Specifications 8 or 9 (found at 40 CFR Part 60, Appendix B).

The group proceeded to a room that Mr. Cranston said is Ethylene Oxide Storage Room 1. Mr. Fortescue observed several metal storage containers, some of which were placed on scales. Mr. Cranston said some of the storage containers contain ethylene oxide and the others contain nitrogen. Mr. Cranston said that quality assurance and quality control checks are performed on the scales used to monitor ethylene oxide usage both before and after each cycle.

Mr. Cranston said both the ethylene oxide storage rooms have ethylene oxide monitoring lines to the PID gas chromatograph system. Mr. Cranston said the ethylene oxide storage rooms are not vented to either the scrubber or the catalytic oxidizer. Mr. Cranston said that the ethylene oxide storage rooms are not ducted to control devices, due to the inherent explosion risk.

The group proceeded to a room that Mr. Cranston said housed the Damas ethylene oxide scrubber. Mr. Cranston said the ethylene oxide is passed through the scrubber media and reacts to form ethylene glycol. Mr. Fortescue observed markings on the side of a tank. Mr. Cranston said that when the liquid level in the tank reaches 70 it is pumped to a storage tank. Mr. Cranston said once the combined tank capacity is reached, PCS contacts an environmental waste company located in Chicago to arrange to have the ethylene glycol shipped offsite. Mr. Cranston said the scrubber room has an ethylene oxide monitoring line to the PID gas chromatograph system.

The group exited the rear of the building. Mr. Fortescue observed a piece of control equipment located on the roof of the facility. Mr. Cranston said the control equipment is the catalytic oxidizer that controls ethylene oxide emissions from the aeration rooms. Mr. Fortescue observed

two stacks, Mr. Cranston said one is connected to the oxidizer and the other is connected directly to the ethylene oxide storage rooms.

The group proceeded to a room that Facility representatives said is one of the aeration rooms. Mr. Cranston said there are no ethylene oxide monitoring lines located in any of the aeration rooms.

The group proceeded to an area that Mr. Cranston said is the final shipping area. Mr. Cranston said there are no ethylene oxide monitoring lines located in the final shipping area.

Closing Conference:

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

Mr. Fortescue said that Subpart O is not delegated to the state in the event that a facility is not a Title V facility (PCS is not a Title V facility). Mr. Fortescue recommended that PCS review Subpart O to ensure they are meeting all the requirements of the regulation.

Mr Fortescue requested the following information be supplied by email as soon as practicable:

- The company's NAICS Code;
- The annual ethylene oxide usage for the facility for 2019, 2020 and 2021;
- If the sterilizer bay areas are vented to the catalytic oxidizer;
- Full copies of the stack test reports for the tests conducted in 1990 and 1997;
- The name of the US EPA employees that attended or were involved with any stack testing, in the event any were;
- Documentation describing the daily glycol liquor levels for the last three months;
- To confirm if the PID gas chromatograph system meets either Performance Specification 8 or 9 described in 40 CFR Part 60, Appendix B; and
- Copies of the temperature charts for the last 5 days.