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

By Email – Dated by Electronic Signature below

URGENT LEGAL MATTER
REQUIRES PROMPT RESPONSE

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

Re: EPA Comments on PCS Performance Test Plan

Dear Mr. Cranston:

On April 7, 2022, the United States Environmental Protection Agency, Region 1 ("EPA") issued Professional Contact Sterilization, Inc. ("PCS") a Testing Requirement, under Section 114(a)(1) of the Clean Air Act ("CAA"), 42 U.S.C. § 7414(a)(1), directing PCS to conduct performance testing required by the Ethylene Oxide Emissions Standards for Sterilization Facilities, found at 40 CFR Part 63, Subpart O ("Subpart O"), and to submit a Performance Test Plan ("Plan") to EPA no later than May 7, 2022. The purpose of this testing is to evaluate the facility's compliance with Subpart O.

On June 7, 2022, 31 days after the due date, Robert A. Fasanella, Esq. of Rubin and Rudman LLP, on behalf of Professional Contact Sterilization, Inc. ("PCS") submitted to EPA, via email, the Plan required by the Testing Requirement. EPA has reviewed this plan and determined that it is deficient. The Plan lacks much of the information that must be included for the test to be successful. Attachment A to this letter describes EPA's comments on the Plan.

As directed by EPA's April 7, 2022 Testing Requirement, PCS must respond to EPA's comments and submit an updated Plan no later than 15 days from the date of the receipt of this letter.

If you have any questions regarding the comments you may contact Darren Fortescue, at fortescue.darren@epa.gov or (617) 918-1724, or have your legal counsel contact Michael Wagner, at wagner.michael@epa.gov or (617) 918-1735 to schedule a time to discuss them.

Sincerely,

CHRISTINE SANSEVERO

Digitally signed by CHRISTINE SANSEVERO
Date: 2022.06.17 12:35:55 -04'00'

Christine Sansevero, Chief of the Air Compliance Section
Enforcement and Compliance Assurance Division
Environmental Protection Agency
Region 1 – New England

Electronic cc: Dan DiSalvio, MassDEP
Glenn Keith, MassDEP
Robert A. Fasanella, Esq. Rubin and Rudman LLP

Attachment A: EPA Comments on PCS's Performance Test Plan Submitted 6/7/2022

I. General Scheduling, Test Conditions and Coordination

1. The Plan must include a proposed daily schedule for the Performance Test Plan ("Plan"). The schedule must indicate:
    a. How sterilized product will be produced for aeration room testing;
    b. When the three aeration room test runs will be conducted;
    c. How sterilization chambers will be prepared and staged for first purge testing; and
    d. When chamber runs will be conducted.
2. The Plan must indicate that sterilization chamber testing will be conducted on the first purge of chambers (the number of which will depend on which test scenario is being conducted).
3. The Plan must indicate that testing will be conducted at maximum normal operating conditions/load for both the sterilization chambers and aeration rooms.
4. The Plan must describe the specific maximum normal operating load (charged weight) of ethylene oxide ("EtO") for each sterilization chamber.
5. The Plan must describe how long (i.e., the duration) the first purge for each chamber will be and how the testing of the first purge of all five chambers will be coordinated.
6. The facility has two aeration rooms, it is unclear from the Plan if both rooms will be included during testing. Please clarify.
7. The Plan must describe the specific maximum normal operating load (number of pallets) for the aeration rooms at any one time, and that aeration room testing will occur at that load. Currently the Plan describes that each aeration room has a capacity of 36-54 pallets. The Plan must indicate the load at which the facility is capable of producing at any point in time (i.e., what is the maximum normal operating condition/load). If this would necessitate the use of the second aeration room, PCS must include a second room in the test.
8. The Plan must include a description of how testing will be coordinated between testing and facility representatives. This description must indicate:
    a. Who will be responsible for both testing and facility operations;
    b. Who will be responsible for recording process parameters; and
    c. How individuals will coordinate the start and end of each test run such that sampling occurs at the same time as the first purges start and stop.

II. Sterilization Chambers

1. The Plan must include, for each sterilization chamber, the proposed chamber conditions at the start and end of each first purge (e.g., pressure, temperature and volume).
2. The Plan must describe the specific method that will be used to determine the amount of EtO that will be loaded into the sterilization chambers, see 40 CFR § 63.365(b)(1)(i).
3. If the provisions described in 40 CFR § 63.365(b)(1)(i)(A) are proposed to be used, the Plan must describe:
    a. How data describing the load charged to each chamber will be documented, including reference to the sample logbook page included in Appendix E, when the data will be recorded, and by whom.
    b. What QA/QC procedures are in place for the EtO scales used to determine the weights of EtO charged. The Plan must describe all QA/QC activities that are implemented by the facility, and data collected during these activities. The Plan must indicate that the results of the last QA/QC check will be provided in the final report.
4. The Plan must describe the specific equations that will be used to calculate the residual mass of EtO in the chambers after the first purge, see 40 CFR § 63.365(b)(1)(ii). This description must include how the total mass will be calculated when 5 chambers are being purged concurrently.

III. Damas Corporation Tri-phase Ethylene Oxide Scrubber

1. The Plan must describe the baseline operating parameter for the scrubber and describe how this parameter will be established during the performance testing (see 40 CFR § 63.365(e)). The Plan must include a description of the specific data that will be collected for the proposed operating parameter, when it will be collected, and by whom. Note that if the sample logbook page included in Attachment E is relevant, the Plan must refer to it with respect to establishing the baseline operating parameter.

IV. Anguil Environmental Systems Catalytic Oxidizer

1. Section 3.0 of the Plan erroneously describes that the catalytic oxidizer is held to EtO emissions of 1 ppm or less. The Plan must describe that 40 CFR § 63.362(d) requires each owner or operator of a sterilization source using 10 tons or more of EtO annually to reduce ethylene oxide emissions to the atmosphere from each

aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent.

2. The process schematic for the catalytic oxidizer, included in Attachment D, describes the capture of other fugitive emissions. The Plan must describe what these emissions are and how PCS plans to demonstrate that the requirements of 40 CFR § 63.362(d) are being met, particularly if fugitive emission capture is diluting aeration room emissions.
3. The plan must include documentation from the manufacturer describing the recommended minimum oxidation temperature of the catalytic oxidizer.
4. In Attachment D of the Plan an example temperature plot for the catalytic oxidizer oxidation temperature has been provided. The Plan must describe that the final test report will include all applicable temperature plots as well as the calculated average temperatures from each test run. The Plan must describe that the temperature plots in the final test report will be clearly annotated to indicate when test runs are started and ended, and will include the test run number.
5. The Plan must describe that documentation describing the results from the last two performance evaluations, conducted in the previous 12 months, for the oxidizer thermocouples used to record the minimum oxidation temperature for the catalytic oxidizer, as required by 40 CFR § 63.364(c)(4), will be provided in the final report.
6. If PCS is proposing to use an EtO continuous emissions monitoring system ("CEMS") for ongoing compliance with 40 CFR Part 63, Subpart O (see 40 CFR §§ 63.363(b)(4)(ii) and 63.364(e)), the Plan must describe that the following CEMS data will be provided in the final test report:
    a. A description of the expected measured concentration of EtO for the CEMS (Note: The aeration room ethylene oxide standard in Subpart O, for PCS's configuration, is 99% removal efficiency or 1 ppm).
    b. Gas certifications for the three calibration gasses used during the initial and monthly back of the analyzer multi-point calibrations of the CEMS (Note: The Low-level gas should be 40-60 percent of the expected measured concentration; the Mid-level gas should be 90-110 percent of measured concentration; and the High-level gas should be 140-160 percent of measured concentration).
    c. The gas certification for the audit gas used to perform quarterly audits of the CEMS.
    d. Documentation describing the results from the initial multi-point calibration and for the last months multi-point calibration, including calibration error results, and precision and linearity data.

e. Documentation describing the results from the initial seven-day calibration error study.
f. Documentation describing the results of the initial performance audit test and for the last quarterly audit test, confirmation that the audits are being conducted throughout the entire sampling and analyzer system, and an indication of whether PCS is auditing all CEMS sample collection locations or just those at the outlet to the oxidizer.
g. Documentation describing the results of the daily calibrations using the mid-level calibration gas for the duration of testing.
h. Confirmation that the entire sampling system for the CEMS is heat traced and maintained at a minimum of 120 °C with no cold spots, including the probe, calibration valve, sample lines, and sample introduction system.

V. Data Calculations and Test QA/QC

1. The Plan must describe how the removal efficiencies and maximum concentrations of ETO will be calculated. Inaccurate partial equations are listed in Attachment A; however, the Plan does not describe the full methods for calculating emission reductions. Documentation of all equations used must be provided, including all applicable equations described in 40 CFR Part 63, Subpart O and all applicable underlying EPA Methods (i.e., 2C, 3A, 4 and 18).
2. The Plan must describe the volume fraction of EtO in the sterilization chambers during the first purge (100% or other). If a calculation is necessary, it must be included.
3. Section 5.1 of the Plan describes that "The destruction removal efficiency is calculated using the mass of EtO evacuated from the chamber and the mass at the outlet of the TO." It is unclear what specific requirement of 40 CFR Part 63, Subpart O this is referring to. 40 CFR Part 63, Subpart O establishes separate emissions standard for sterilization chamber vents and for aeration room vents. Any calculation of removal efficiency must refer to emissions from one or the other, and the Plan must reflect this (see EPA's previous comment on providing all equations that will be used to calculate emissions). In addition, the acronym "TO" does not appear to be defined in the Plan. Please either define or remove this reference.
4. In Attachment A to the Plan, Equation 3 describing the Destruction/Removal Efficiency calculation for the sterilization chamber vents appears to reference parameters related to the aeration room vents. Equation 3 must be corrected to

accurately reflect the configuration at the facility, or a more detailed description of why these parameters are included in the calculation must be added.

5. The Plan must include a more detailed description of the tedlar bag collection system and components.
6. The Plan must indicate that the applicable leak check of the tedlar bag sampling system will include both the bags and sampling container, in accordance with EPA Method 18 (see Section 8.2.1.1.2 of EPA Method 18).
7. The Plan must describe that tedlar bag recovery studies will be performed using a spike concentration of EtO that is equivalent to 40 to 60 percent of the average concentration observed in the bags. The Plan must indicate that if EtO is not detected, the spike concentration shall be 5 times the limit of detection.
8. The Plan must describe that tedlar bag sample data will be adjusted based on the results of the recovery study (i.e., results will be divided by the recovery percentage or "R value" determined during the study).
9. The Plan must indicate that if moisture is observed in any tedlar bag samples, that bag and associated test run will be invalidated and the specific run will need to be performed again.
10. Section 4.2.4 of the Plan states that "Should moisture be observed in the bag samples, the first course of action will be to consider using direct interface sampling technique for the SCV." It is unclear how an adequate integrated sample for sterilizer emissions can be produced using direct sampling. If moisture is identified as an issue, heated bag samples should be used. EPA recommends that prior to any performance test, PCS determine the expected stack gas temperature and moisture content and if there is a need to use heated bag samples.
11. The Plan must describe that the Recovery Study for direct interface analysis proposed to be performed, will be done using the mid-level calibration gas.
12. The Plan must include example EPA Method datasheets for all Methods used in the Performance Test.
13. The Plan must describe that if heated bag samples are collected, EPA Method 4 will be used to determine water vapor concentrations and a moisture correction factor will be applied to those data.
14. The lowest calibration standard documented in the Plan appears to be 1 ppm; however, if the facility plans to demonstrate compliance with the aeration room standard, described in 40 CFR § 63.362(d), of 1 ppm, rather than meeting the 99% removal efficiency, a low calibration standard of less than the actual emission limit should be used when calibrating the SRI 8610C gas chromatograph for direct sampling during aeration room testing (note calibration standards of less than 1 ppm have previously been available for stack testing).

15. The Plan does not appear to include a description of data quality objectives for process parameters. Several of EPA's previous comments include references to these objectives. The Plan must include this description. This may be achieved by adding an additional table to the Plan, such as Table 3, which describes the method data quality objectives.
16. In Section 5.2 of the Plan, the list describing the items that will be included in the final test report must be updated to include a line item stating that a detailed review of all data, both test and process data, will be included to assess whether all data quality objectives were met. (Note that in the final report this must be a detailed assessment, not just a statement that it was performed).
17. The Plan must describe that appropriate health and safety practices will be followed as required by EPA Method 18.