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 Professional Contact Sterilization, Inc. Revised Performance Test Plan Dated January 9, 2023

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 to EPA no later than May 7, 2022.

On June 7, 2022, Robert A. Fasanella, Esq. of Rubin and Rudman LLP, on behalf of PCS, submitted a Performance Test Plan (the "Plan") to EPA. On June 17, 2022, EPA provided detailed comments on the first version of the Plan. On July 5, 2022, Christopher Heilner of LCH Consulting Associates, LLC ("LCH"), on behalf of PCS, submitted to EPA a second version of the Plan. On July 18, 2022, EPA provided detailed comments on the second version of the Plan. On July 29, 2022, Christopher Heilner of LCH, on behalf of PCS, submitted to EPA a third version of the Plan. On August 24, 2022, EPA approved the third version of the Plan and indicated that a pretest site visit must now occur within 15 days of the approval.

On September 8, 2022, PCS emailed EPA to indicate that Christopher Heilner of LCH would no longer be available for the pretest site visit. On September 16, 2022, PCS emailed EPA to

indicate that LCH would no longer be able to conduct the performance testing, and that PCS is looking for a new stack test consultant.

On December 9, 2022, Anthony Stratton of Montrose Air Quality Services, LLC, on behalf of PCS, submitted to EPA a fourth version of the Plan. On December 23, 2022, EPA provided detailed comments on the fourth version of the Plan. On January 9, 2023, Anthony Stratton of Montrose Air Quality Services, LLC, on behalf of PCS, submitted to EPA a fifth version of the Plan.

Attachment A to this letter contains EPA's comments on the fifth version of the Plan. PCS must revise the Plan to address these comments and resubmit it 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 Jaegun Lee, at lee.jaegun@epa.gov or (617) 918-1511 to schedule a time to discuss them.

Sincerely,

DOUGLAS KOOPMAN

Digitally signed by DOUGLAS KOOPMAN
Date: 2023.01.18 16:52:41 -05'00'

Douglas Koopman, Acting Manager of the Air Compliance Section
Enforcement and Compliance Assurance Division
Environmental Protection Agency
Region 1 – New England

Electronic cc: Robert A. Fasanella, Esq. Rubin and Rudman LLP

Attachment A: EPA Comments on PCS's Performance Test Plan Dated 1/9/2023

I. General Scheduling, Test Conditions and Coordination

1. On Page 8, Table 1-3 of the Plan continues to only describe the timing of the testing schedule generally. Table 1-3 of the Plan must be updated to identify more specifically when chambers will be run for both product preparation for aeration room testing and for sterilization chamber testing, and when the specific test runs will take place throughout each day.
2. Page 11 of the Plan states that VHF radios will be used to facilitate continuous communication. Please confirm that these radios will be intrinsically safe.

II. Sterilization Chambers

1. Page 13, Section 2.2.1 of the Plan states that *"The mass of EtO loaded into each chamber is determined gravimetrically by weighing the EtO storage drum before and after the EtO injection phase of the cycle on a calibrated scale. PCS will rent two calibrated scales, each with a precision of 45 grams, to perform all gravimetric determinations."* Please confirm that PCS does not currently have scales permanently installed at the facility with this accuracy.
2. Page 14, Section 2.2.2 of the Plan states that *"A range of approximate time ranges"* are listed for each step of the sterilization cycles. Step 7 states that *"a test run will commence – 7 to 30 minutes."* Step 8 describes that *"Additional nitrogen and air evacuations to complete cycle – as required."* For the purposes of planning and understanding how the performance test will be conducted, the Plan must document how long (maximum amount of time) each step of the sterilization cycle/s will take, most importantly, how long test runs will take (i.e., the first purge), and what will be *required* to complete sterilization cycles. This information will be necessary to complete Table 1-3 on Page 8. See the comment made in Section I.1.

III. Aeration Rooms

Page 16, Section 2.3.1 of the Plan states that *"At 10:00 a.m. of the ARV test day (Tuesday), the products of final (fourth) sterilization batch of the five chambers will be transferred to the aeration rooms immediately upon the completion of the cycle."* While on Page 8, Table 1-3 states that the three 60-minute runs for aeration room testing will be conducted between 12:00 and 17:00 on the same day. This does not appear to match the requirement to initiate aeration room performance testing immediately following the placement of the last load of sterilized products into the aeration rooms. The Plan must be modified to address this discrepancy.

IV. Methodology and Data Calculations

1. Page 22, Section 4.1.1 of the Plan states that *"One sample per source or condition will have a spike & recovery performed where ~50% of the native concentration of each analyte (or ~10 ppm if the analyte is non-detect) is added to one of the bags."* EPA Method 18 requires that if a target compound is not detected in a bag sample, the concentration of that compound to be spiked for the recovery study shall be 5 times the limit of detection for that compound. The Plan must be updated to reflect this requirement.
2. Page 23, Section 4.1.3 of the Plan states that *"Calibration standards will be analyzed by direct cylinder injection and on site gas blending, in triplicate, and the average value of the samples will be calculated. An analytical result is considered valid if its value is within 5% of the triplicate average value."* EPA Method 205 requires that no single injection shall differ by more than ±2% from the average instrument response for that dilution (see Section 3.2.4 of the Method). The Plan must be updated to reflect this correction.