



**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 as indicated below in electronic signature*

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

Re: Request for Extension and Clean Air Act Notice of Violation

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 the facility to conduct the performance testing required by Subpart O, and to submit a test protocol to EPA no later than May 7, 2022. EPA required this testing to evaluate emissions of the hazardous air pollutant ethylene oxide from the processes at the facility and to determine the facility’s compliance with the CAA and EPA’s regulations.

On May 24, 2022, PCS, emailed EPA to request a one-month extension to the May 7 deadline. PCS submitted the request more than two weeks after the deadline EPA established to submit the testing protocol and only after repeated inquiries from EPA staff. In addition, PCS offered no reason for an extension. While EPA acknowledges that the test protocol will now be submitted late, EPA does not approve the request for extension or waive the ability for the agency to seek penalties for any periods of noncompliance with the CAA. We urge PCS to move forward expeditiously with the required testing.

In addition, EPA is issuing PCS the enclosed Notice of Violation (“NOV”) regarding Clean Air Act violations at its facility. The NOV describes EPA’s findings that PCS has violated and continues to violate certain CAA requirements relating to Section 114 of the CAA, the Ethylene Oxide Emissions Standards for Sterilization Facilities, found at 40 CFR Part 63, Subpart O, and the General Provisions of the National Ambient Air Quality Standards, found at 40 CFR Part 63, Subpart A.

You may confer with EPA concerning this NOV and the findings contained therein. To schedule a conference, please contact Darren Fortescue, at [fortescue.darren@epa.gov](mailto:fortescue.darren@epa.gov) or (617) 918-1724, or have your legal counsel contact Michael Wagner, at [wagner.michael@epa.gov](mailto:wagner.michael@epa.gov) or (617) 918-1735.

Sincerely,

**KAREN**

**MCGUIRE**

Karen McGuire, Director  
Enforcement and Compliance Assurance Division  
Environmental Protection Agency  
Region 1 – New England

Digitally signed by KAREN  
MCGUIRE  
Date: 2022.05.26 15:30:01  
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cc: Dan DiSalvio, MassDEP  
Glenn Keith, MassDEP