

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1**

_____)
In the Matter of:)
)
Professional Contact Sterilization, Inc.)
40 Myles Standish Boulevard)
Taunton, MA 02780)
)
Proceeding under Section 113)
of the Clean Air Act)
_____)

NOTICE OF VIOLATION

INTRODUCTION

1. The United States Environmental Protection Agency, Region 1 (“EPA”), issues this Notice of Violation (“NOV”) to Professional Contract Sterilization, Inc. (“PCS”) regarding its commercial ethylene oxide sterilization operation at its facility on 40 Miles Standish Boulevard, Taunton, Massachusetts,
2. The NOV contains EPA’s findings that PCS has violated the Clean Air Act (“Act”) and the Ethylene Oxide Emissions Standards for Sterilization Facilities, found at 40 CFR Part 63, Subpart O (“Subpart O”) and the General Provisions of the National Emission Standards for Hazardous Air Pollutants found at 40 CFR Part 63, Subpart A.

BACKGROUND AND FACTUAL BASIS

3. PCS operates a commercial sterilization facility that is subject to Subpart O and uses more than ten tons or more of ethylene oxide (“EtO”) in sterilization or fumigation operations. Therefore, PCS is subject to the emissions standards found at 40 CFR § 63.362.

4. PCS is considered an area source of hazardous air pollutant (“HAP”) emissions. See 40 CFR §§ 63.2 and 63.6585(c).
5. On March 24, 1998, PCS submitted an initial notification to EPA as required by 40 CFR § 63.360 and 63.9(b)(2).
6. On September 13, 2021, EPA issued an Information Collection Request letter to PCS.
7. On March 23, 2022, and again on April 7, 2022, EPA conducted on-site inspections of PCS.
8. On April 7, 2022, EPA issued a Testing Requirement to PCS, 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.

FINDINGS

9. PCS failed to respond to EPA’s September 13, 2021, Information Collection Request letter.
10. PCS failed to submit a test protocol to EPA by May 7, 2022, as required by EPA’s April 7, 2022, Testing Requirement.
11. Accordingly, PCS has violated and continues to violate Section 114 of the CAA.
12. PCS failed to comply with 40 CFR Part 63, Subpart O and Subpart A including but not limited to the following provisions:
 - a. PCS failed to conduct the initial performance test required by Subpart O to determine initial compliance with the emission limits under § 63.362(c), and to establish applicable operating limits for the control devices.

- b. PCS failed to follow applicable required work practices required by Subpart O to demonstrate ongoing compliance as required by 40 CFR §§ 63.363 and 63.365.
 - c. PCS failed to maintain records suitable for inspection as required by 40 CFR § 63.367, 63.10(b) and 63.10(c).
 - d. With the exception of submitting an initial notification, PCS failed to meet the reporting requirements of 40 CFR §63.360 and 40 CFR Part 63, Subpart A.
13. Accordingly, PCS has violated and continues to violate 40 CFR Part 63, Subpart O and Subpart A.

ENFORCEMENT

14. EPA may take any or all of the following actions in accordance with the provisions of Section 113 of the Act: (a) issue an order requiring compliance with the Act; (b) issue an administrative penalty order; or (c) bring a civil action in federal district court for an injunction and/or monetary penalties. The Clean Air Act provides for administrative and judicial penalties up to \$25,000 per day per violation, which have been substantially increased for inflation as mandated by Congress. See Sections 113(a), (b) and (d) of the Act, 42 U.S.C. §§ 7413(a), (b) and (d), and EPA regulations at 40 C.F.R. Part 19.4.

15. If PCS has knowingly violated the requirements of the Act, PCS and its responsible corporate officers may be subject to criminal penalties under Title 18 of the United States Code, imprisonment for not more than five years, or both. See Section 113(c) of the Act, 42 U.S.C. § 7413(c).

16. Be advised that the issuance of this NOV does not preclude EPA from electing to pursue any other remedies or sanctions authorized by law that are available to address the violations alleged above.

OPPORTUNITY TO CONFER

17. PCS may confer with EPA concerning this NOV and the findings upon which it is based. To schedule a conference, please contact Darren Fortescue, Environmental Engineer, at (617) 918-1162, or have your legal counsel contact Michael Wagner, Senior Enforcement Counsel, at (617) 918-1735 within 7 days the date of issuance of this NOV. PCS may choose to be represented by counsel at the conference.

EFFECTIVE DATE

18. This NOV is effective on the date of issuance. This NOV applies to PCS, its officers, agents, servants, employees, successors, and assigns, and to all persons, firms, and corporations acting for PCS. This NOV is not subject to Office of Management and Budget review under the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

SO ISSUED:

KAREN MCGUIRE

Digitally signed by KAREN
MCGUIRE
Date: 2022.05.26 15:27:49 -04'00'

Karen McGuire Director
Enforcement and Compliance Assurance Division
U.S. EPA, Region 1

Date