



53 STATE STREET | BOSTON, MA 02109 | P: 617-330-7000
600 UNICORN PARK DRIVE | WOBURN, MA 01801 | P: 781-933-5505

Robert A. Fasanella
Direct Dial: 617-330-7018
E-mail: RFasanella@rubinrudman.com
Return Address: Boston

RECEIVED

July 28, 2022

JUL 28 2022

EPA ORG WE
Office of Regional Hearing Clerk

By Hand Delivery

Ms. Wanda Rivera
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 1
5 Post Office Square — Suite 100 (Mail Code ORA18-1)
Boston, Massachusetts 02109-3912

RE: Professional Contract Sterilization, Inc.
40 Myles Standish Boulevard, Taunton, MA

Dear Ms. Rivera:

Enclosed for filing please find an original and one copy of Professional Contract Sterilization, Inc.'s Answer to Complaint, Affirmative Defenses, and Request for Hearing.

Thank you for your attention to this filing.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Robert A. Fasanella'.

Robert A. Fasanella

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

RECEIVED

JUL 28 2022

EPA ORC WJS
Office of Regional Hearing Clerk

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

Docket No. CAA-01-2022-0059

**ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES,
AND REQUEST FOR HEARING**

Respondent, Professional Contract Sterilization, Inc. (“PCS” or “Respondent”), through the undersigned attorney, presents its Answer to the Administrative Complaint (“Complaint”) issued by the United States Environmental Protection Agency Region 1 (“EPA” or “Complainant”), and respectfully states, alleges, and prays as follows:

I. PRELIMINARY STATEMENT

1. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

2. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

3. Respondent admits the allegation in this paragraph.

4. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form

a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

5. Respondent admits the allegation in this paragraph.

II. JURISDICTION

6. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

7. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

III. GOVERNING LAW

8. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

9. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

10. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form

a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

IV. GENERAL ALLEGATIONS

11. Respondent admits that it operates a commercial sterilization facility and that it uses more than ten tons of ethylene oxide (“EO”) in sterilization or fumigation operations. The remainder of this paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

12. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

13. Respondent admits that on March 24, 1998 it submitted an initial notification to EPA. The remainder of this paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

14. Respondent admits the allegation in this paragraph.

15. Respondent admits the allegation in this paragraph.

16. Respondent admits the allegation in this paragraph.

17. Respondent admits that on April 25, 2022, EPA and PCS held a conference call. Respondent denies the remainder of the allegations in this paragraph.

18. Respondent admits that on May 17, 2022, PCS emailed the EPA. Respondent denies the remainder of the allegations in this paragraph.

19. Respondent admits that on May 18, 2022, PCS received an email from EPA. The remainder of this paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

20. Respondent admits that on May 20, 2022, PCS emailed the EPA. Respondent denies the remainder of the allegations in this paragraph.

21. Respondent admits that on Jun 7, 2022, PCS submitted a Test Plan to EPA. The remainder of this paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

V. FINDINGS

Count 1 – Failure to Respond to Section 114 Information Request

22. Respondent denies the allegations in this paragraph.

23. Respondent denies the allegations in this paragraph.

Count 2 – Failure to Comply with Section 114 Testing Requirement

24. Respondent denies the allegations in this paragraph.

25. Respondent denies the allegations in this paragraph.

VI. RELIEF SOUGHT: CIVIL PENALTY

26. Respondent denies any violation of the Clean Air Act. The remainder of this paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

27. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

28. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

29. Respondent denies that it has not been responsive to the EPA. Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

30. This paragraph sets forth legal conclusions to which no response is required. To the extent further response is required, Respondent, is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations states in this paragraph, and the allegations are therefore denied.

**VII. OPPORTUNITY TO REQUEST A HEARING
AND FILE AN ANSWER**

31. Paragraphs 31-34 contain legal conclusions and procedures to which no response is required. To the extent further response is required, it is contained in this Answer, Affirmative Defenses, and Request for Hearing.

VIII. DEFAULT ORDER

32. Paragraph 35 contains legal conclusions and procedures to which no response is required. To the extent further response is required, it is contained in this Answer, Affirmative Defenses, and Request for Hearing.

IX. SETTLEMENT CONFERENCE

33. Paragraphs 36-37 contain legal conclusions and procedures to which no response is required. To the extent further response is required, it is contained in this Answer, Affirmative Defenses, and Request for Hearing.

X. AFFIRMATIVE DEFENSES

FIRST DEFENSE

34. Respondent has created no danger to health and public safety or human welfare, nor any danger to the environment.

SECOND DEFENSE

35. The absence of harm has not adequately been considered as a mitigating factor in connection with the penalty assessment.

THIRD DEFENSE

36. Any and all alleged acts or omissions concerning Respondent's compliance with Section 114 of the Clean Air Act, 42 U.S.C. §7414(a) have not resulted in any economic benefit to Respondent.

FOURTH DEFENSE

37. The Complaint fails to state a claim upon which relief can be granted against Respondent.

FIFTH DEFENSE

38. The Complaint is barred in whole or in part by the doctrines of waiver and/or estoppel.

SIXTH DEFENSE

39. The proposed penalty is excessive, inappropriate and unwarranted, and Complainant has not provided adequate explanation as to how the penalty amount was calculated.

SEVENTH DEFENSE

40. Complainant's allegations are barred by laches.

EIGHTH DEFENSE

41. Complainant's allegations are barred by the applicable statute of limitations.

NINTH DEFENSE

42. Complainant's allegations are not supported by substantial evidence.

TENTH DEFENSE

43. Complainant's penalty assessment constitutes an abuse of discretion.

**RESERVATION OF RIGHT TO AMEND ANSWER AND ADD
AFFIRMATIVE DEFENSES**

44. Respondent reserves the right to amend this Answer and to add further Affirmative Defenses, including those, which may become apparent through discovery and the development of this case.

XI. REQUEST FOR HEARING

45. PCS hereby requests an Administrative Hearing on the issues raised by the Administrative Penalty Complaint and this Answer.

Respectfully Submitted,
Professional Contract Sterilization, Inc.
By its attorneys,


Robert Fasanella, Esq.
Rubin and Rudman LLP
53 State Street, 15th Floor
Boston, MA 02109
Tel (617) 330-7000
rfasanella@rudinrudman.com

Dated: July 28, 2022

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

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

Docket No. CAA-01-2022-0059

CERTIFICATE OF SERVICE

I hereby certify that the forgoing Answer, Affirmative Defenses and Request for Hearing was sent to the following persons on the date noted below:

Original and One Copy by Hand Delivery

Ms. Wanda Rivera
Regional Hearing Clerk U.S. EPA, Region I
5 Post Office Square, Suite 100 (ORA18-1)
Boston, MA 02109-3912

Copy by Certified Mail, Return Receipt Requested

Michael Wagner, Senior Enforcement Counsel
U.S. Environmental Protection Agency, Region 1
5 Post Office Square, Suite 100 (Mail Code 04-3)
Boston, MA 02109-3912

Dated: July 28, 2022



Robert Fasanella, Esq.
Rubin and Rudman, LLP
53 State Street
Boston, MA 02109
Tel (617) 330-7000
rfasanella@rudinrudman.com