

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 1**

_____ )	
In the Matter of: )	
)	
Professional Contract Sterilization, Inc. )	COMPLAINANT’S
40 Myles Standish Boulevard )	PREHEARING EXCHANGE
Taunton, MA 02780 )	
)	
Respondent )	
)	
Proceeding under Section 113 )	Docket No. CAA-01-2022-0059
of the Clean Air Act )	
_____ )	

**Complainant’s Prehearing Exchange**

Complainant, United States Environmental Protection Agency, Region 1 ("EPA" or "Complainant") herewith submits the following initial prehearing exchange as directed by the "Prehearing Order," dated August 8, 2022, as such order was modified by the Court's "Order Granting Request for an Extension of Time," dated September 7, 2022, and in accordance with the provisions of 40 C.F.R. § 22.19(a).

**I. Preliminary Statement**

Complainant commenced this administrative proceeding to assess a civil penalty against Respondent Professional Contract Sterilization, Inc. ("PCS" or "Respondent") for having allegedly committed acts made unlawful under the provisions of the Clean Air Act ("CAA"), 42 U.S.C. §7401 et seq. on two separate occasions. PCS is a corporation organized under Massachusetts State Law that sterilizes medical equipment and materials using ethylene oxide ("EtO") at its commercial sterilization facility at 40 Miles Standish Boulevard, Taunton,

Massachusetts (“Facility”). The Complaint, dated June 28, 2022, asserts that PCS failed to respond to EPA’s Information Collection Request Letter regarding EtO emissions from the Facility and subsequently failed to submit a Performance Test Plan to EPA in violation of Section 114(a) of the CAA, 42 U.S.C. § 7414(a). EPA seeks a combined total penalty of \$126,781 for the two counts. The total penalty amount was determined based upon information EPA had available prior to issuance of the Complaint and were developed using the guidance of the applicable CAA penalty policy; they are consistent with the CAA criteria set forth in Section 114(a) of the CAA, 42 U.S.C. § 7414(a).

Respondent timely filed its Answer on or about July 28, 2022. The Answer admits some of the underlying predicate allegations; it either denies or does not admit the allegations pertinent to a finding of liability. The Answer sets forth ten separately enumerated affirmative defenses but does not state facts or reasoning to support the grounds of the affirmative defenses.

The parties held an initial settlement conference on August 28, 2022, but have not reached a negotiated settlement.

## **II. Complainant’s Witnesses**

The following witnesses may testify on direct and/or on rebuttal:

Darren Fortescue  
Senior Enforcement Coordinator  
U.S. EPA Region 1  
5 Post Office Square, Suite 100 (Mail Drop 4-WO)  
Boston, MA 02109

Darren Fortescue will testify as a fact witness. Mr. Fortescue is EPA’s principal inspector in this matter. He will testify about his educational and employment background. He will also testify about his 2022 inspections of Respondent’s sterilization facility in Taunton,

Massachusetts, and his review of records and other information obtained from Respondent. Mr. Fortescue will testify concerning the facts and evidence he obtained during and after the inspection, and the basis for the determination that Respondent violated the Clean Air Act. Mr. Fortescue also will testify as to how the penalty proposed in the Complaint was calculated, and to matters raised by Respondent’s Prehearing Exchange and defenses as warranted.

**III. Complainant’s Exhibits**

EPA anticipates offering into evidence the following documents and records, copies of which are annexed hereto (unless otherwise specifically noted below) and will be identified as "Complainant's Exhibit," with each exhibit numbered with the following Arabic numerals:

CX #	Description
1	“Clean Air Act Stationary Source Civil Penalty Policy,” issued by the United States Environmental Protection Agency, dated October 25, 1991 (178 pages). Publicly available on the Internet at: <a href="https://www.epa.gov/enforcement/clean-air-act-stationary-source-civil-penalty-policy-october-25-1991">https://www.epa.gov/enforcement/clean-air-act-stationary-source-civil-penalty-policy-october-25-1991</a>
2	“Amendments to EPA’s Civil Penalty Policies to Account for Inflation (effective January 15, 2022) and Transmittal of the 2022 Civil Monetary Penalty Inflation Adjustment Rule” issued by the United States Environmental Protection Agency, dated January 12, 2022 (12 pages). Publicly available on the Internet at: <a href="https://www.epa.gov/system/files/documents/2022-01/2022amendmentstopenaltypoliciesforinflation_0.pdf">https://www.epa.gov/system/files/documents/2022-01/2022amendmentstopenaltypoliciesforinflation_0.pdf</a>
3	Copy of electronic correspondences between EPA and Robert A. Fasanella, attorney for Respondent Professional Contract Sterilization, Inc. (“PCS”), dated September 28, 2022, titled “[EXTERNAL] PCS” and “RE: PCS”
4	PCS’s Fiscal Year 2021 Annual Report filed with the Massachusetts Secretary of State, dated March 9, 2022, signed by PCS President Gary Cranston.
5	Copy of EPA’s CAA Information Collection Request letter to PCS, dated September 13, 2021
6	Copy of EPA’s electronic correspondence to PCS, dated September 16, 2021, titled “CAA 114 Request for Ethylene Oxide Commercial Sterilization Facilities”
7	Copy of EPA’s CAA Testing Requirement letter to PCS, dated April 6, 2022
8	U.S. Postal Service Certified Mail Receipt for EPA’s CAA Testing Requirement letter to PCS, dated April 11, 2022
9	Copy of electronic correspondences between EPA and PCS, dated May 17, 2022, titled “EPA Information Request and Testing Order” and “Re: EPA Information Request and Testing Order”

10	Copy of LCH Consulting Associates' testing project proposal letter to PCS, dated May 6, 2022, titled "LCH Proposal Q050622"
11	Copy of electronic correspondences between EPA and PCS, dated May 18 and May 20, 2022, titled "RE: EPA Information Request and Testing Order" and "Re: EPA Information Request and Testing Order"
12	Copy of electronic correspondence from Robert A. Fasanella, attorney for PCS, to EPA, dated June 7, 2022, titled "RE: PCS Stack Test Protocol 2nd Draft"
13	Copy of EPA's letter to Respondent, dated June 17, 2022, titled "Re: EPA Comments on PCS Performance Test Plan"
14	Copy of electronic correspondence from PCS to EPA, dated July 5, 2022, titled "FW: CAA Section 114 Information Collection Request- PCS"
15	PCS Inspection Report 1, dated March 30, 2022 (lead inspector: Darren Fortescue)
16	PCS Inspection Report 2, dated April 19, 2022 (lead inspector: Darren Fortescue)
17	"CAA Civil Penalty Calculation Worksheet," dated June 2, 2022 (amended October 5, 2022, for terminological consistency and formatting), and prepared by EPA's Darren Fortescue.
18	United States Environmental Protection Agency, "Notice of Violation," dated May 26, 2022, issued to Professional Contract Sterilization, Inc.
19	Cover letter for EPA's Notice of Violation to PCS, dated May 26, 2022, titled "Re: Request for Extension and Clean Air Act Notice of Violation"

**IV. Length of Direct Case and Whether Interpreter is Necessary**

EPA believes that it can present its direct case in approximately one day. EPA's witness does not require an interpreter.

**V. Documentation of Proof of Service of the Complaint**

Complainant's Exhibit CX 3 contains acknowledgement of service of the Complaint by Respondent's counsel.

**VI. Factual and Legal Bases for Allegations Denied or Otherwise Not Admitted in Respondent's Answer**

EPA's Complaint is divided into nine sections. The Complaint's first six sections (Sections I through VI) allege legal matters and facts that Respondent denies or otherwise does

not admit in its Answer dated July 28, 2022. The Complaint's last three sections (Sections VII through XI) pertain to procedural matters and contain no factual or legal allegations, and thus are not discussed below. This narrative also does not discuss paragraphs or allegations that Respondent admits, or for which Respondent states that cited statutory, regulatory, or other text speaks for itself, or for which Respondent claims that a legal conclusion requires no response, except in those circumstances where such discussion is warranted because it is relevant to matters discussed herein.

### **Section I of the Complaint – Preliminary Statement (Paragraphs 1-5)**

For Paragraph 1, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required.

Complainant reasserts that it commenced this proceeding to assess administrative civil penalties under Section 113(a) of the Clean Air Act, 42 U.S.C. § 7413(a).

For Paragraph 2, Respondent denies the identity of the Complainant because it lacks sufficient knowledge. Complainant responds that the Complainant's identity as stated in the Complaint is accurate.

For Paragraph 4, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required. Under Section 302(e) of the CAA, a "person" is defined to include a corporation. 42 U.S.C. § 7602(e). PCS admits that it is "Professional Contract Sterilization, Inc.," ¶3 of Respondent's Answer, which is a corporation organized under the laws of the state of Massachusetts, CX 4. Thus, Respondent is a person within the meaning of the Section 302(e) of CAA. See 42 U.S.C. § 7602(e).

## **Section II of the Complaint – Jurisdiction (Paragraphs 6-7)**

For Paragraph 6, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required.

Complainant reasserts that this action is brought under section 113(a) of the CAA, 42 U.S.C. § 7413(a), in accordance with the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits at 40 C.F.R. Part 22 (“Consolidated Rules”).

For Paragraph 7, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required. Section 113 of the CAA, 42 U.S.C. § 7413, provides that “whenever, on the basis of any information available to the Administrator, the Administrator finds that any person has violated, or is in violation of, any other requirement or prohibition of” Subchapter I of the CAA, ... the Administrator may ... issue an administrative penalty order” among other things. The failure to provide information required under Section 114(a) of the CAA, 42 U.S.C. § 7414(a), is a violation of that section, a provision of Subchapter I of the CAA, and thus Section 113(a) of the Act, 42 U.S.C. § 7413(a), authorizes EPA to assess violations for such failures.

## **Section III of the Complaint – Governing Law (Paragraphs 8-10)**

For Paragraph 8, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required. Section 114 of the Act, 42 § 7414, provides, among other things, that:

For the purpose (i) of developing or assisting in the development . . . any emission standard under section 7412 of this title, . . . {and} (ii) of determining whether any person is in violation of any such standard or any requirement of such a plan, . . .

The Administrator may require any person who owns or operates any emission source, . . . or who is subject to any requirement of this chapter . . . to—

(A) establish and maintain such records;

(B) make such reports;

(C) install, use, and maintain such monitoring equipment, and use such audit procedures , or methods;

(D) sample such emissions (in accordance with such procedures or methods, at such locations, at such intervals, during such periods and in such manner as the Administrator shall prescribe);

(E) keep records on control equipment parameters, production variables or other indirect data when direct monitoring of emissions is impractical;

(F) submit compliance certifications in accordance with subsection (a)(3); and

(G) provide such other information as the Administrator may reasonably require.

Complainant reasserts the characterization of this language set forth in Paragraph 8 of the Complaint.

For Paragraph 9, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required. The failure to comply with requirements established under Section 114 of the Act, 41 U.S.C. § 7214, constitutes a violation of “requirements” of Subchapter I of the Act for which penalties and other relief are available under Section 113 of the Act, 41 U.S.C. § 7413(a).

For Paragraph 10, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required.

Complainant reasserts the statements set forth in Paragraph 10 of the Complaint.<sup>1</sup>

#### **Section IV of the Complaint – General Allegations (Paragraphs 11-21)**

For Paragraph 11, Respondent admits that it operates the Facility and uses 10 tons or more of EtO per year in its sterilization or fumigation operations but denies the allegations as to

---

<sup>1</sup> See 42 U.S.C. § 7524(c)(1) (“Civil penalties”); 40 C.F.R. § 19.4, table 1 (“Civil Monetary Penalty Inflation Adjustments”).

the applicable emission standards to the extent that a response is required. Forty C.F.R. § 63.360 provides that “{a}ll sterilization sources using 1 ton (see definition) in sterilization or fumigation operations are subject to the emissions standards in § 63.362. Therefore, PCS is subject to the emissions standards found at 40 CFR § 63.362.

For Paragraph 12, Respondent states that the allegations contain legal conclusions that require no response but denies the allegations to the extent that a response is required. Forty C.F.R. § 63.2 defines “area Source” as “any stationary source of hazardous air pollutants that is not a major source as defined in this part” and “major source” as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants, unless the Administrator establishes a lesser quantity, or in the case of radionuclides, different criteria from those specified in this sentence. Complainant does not have information to conclude that Respondent is a Major Source. Therefore, Complainant asserts that under 40 CFR §§ 63.2 and 63.6585(c) Respondent’s Facility is an area source of hazardous air pollutant (“HAP”) emissions subject to the emissions standards found at 40 CFR § 63.362 because it operates a commercial sterilization facility that uses ten tons or more of ethylene oxide (“EtO”) per year in sterilization or fumigation operations. See 40 CFR § 63.2 (“Definitions”); 40 CFR § 63.6585(c) (defining, among other terms, an “area source” of hazardous air pollutant emissions).

For Paragraph 13, Respondent admits that it submitted an initial notification to EPA on March 24, 1998, but denies the allegations as to what the applicable regulations are to the extent

that a response is required. Complainant responds that the regulations cited, 40 CFR §§ 63.630 and 63.9(b)(2), required the submission of such initial notification.

For Paragraph 18, Respondent admits that it emailed EPA on May 17, 2022, but denies the allegations that the email provided a proposal made by its environmental consultant, LCH Consulting Associates Inc. (“LCH”), to develop a Test Plan. Complainant’s Exhibit CX 9 is a copy of the email in question from Respondent that contains LCH’s proposal to develop a Test Plan (CX 10).

For Paragraph 19, Respondent admits that it received an email from EPA on May 18, 2022, but denies the allegations as to the contents of EPA’s email to the extent that a response is required. Complainant’s Exhibit CX 11 includes a copy of EPA’s email informing Respondent that its Test Plan was overdue.

For Paragraph 20, Respondent admits that it emailed EPA on May 20, 2022, but denies the allegations that Respondent indicated it would provide a Test Plan in the following week. Complainant’s Exhibit CX 11 includes a copy of Respondent’s reply email to EPA in which it indicates that its consultant should be able to forward the Test Plan “next week”.

For Paragraph 21, Respondent admits that it submitted a Test Plan on May 20, 2022, but denies that EPA had determined the Test Plan deficient and provided detailed comments the deficient Test Plan via email on June 17, 2022. Complainant’s Exhibit CX 13 is a copy of EPA’s email to Respondent dated June 17, 2022, providing it with detailed comments identifying deficiencies in Respondent’s Test Plan.

## **Section V of the Complaint – Findings (Paragraphs 22-25)**

Respondent denies the finding of liability as to both alleged counts of CAA violations in its Answer without stating any supporting facts or reasoning. Each count in this Section is discussed separately below.

Count 1 (Paragraphs 22-23): Failure to Respond to Section 114 Information Request

Respondent in its own Answer admits that EPA had issued it a CAA Section 114 Information Collection Request (“Information Request”) on September 13, 2021. ¶14 of Respondent's Answer. Complainant’s Exhibit CX 5 is a copy of EPA’s Information Request letter to Respondent dated September 13, 2021, indicating a response was due by November 19, 2021. Complainant’s Exhibit CX 14 is a copy of Respondent's email dated July 5, 2022, submitting the information requested more than seven months past its due date. If necessary, EPA Senior Enforcement Coordinator Darren Fortescue’s testimony will further demonstrate that Respondent has not met its obligation to respond to the Information Request by its due date.

Count 2 (Paragraphs 24-25): Failure to Comply with Section 114 Testing Requirement

Respondent in its own Answer admits that EPA had issued a Testing Requirement to Respondent directing it to submit a Test Plan. ¶16 of Respondent's Answer. Respondent also admits that it received EPA’s email on May 18, 2022. ¶19 of Respondent's Answer. That email informed Respondent that its Test Plan was overdue. CX 11. Furthermore, Respondent replied to EPA’s email stating that its consultant should be able to submit its Test Plan to EPA in the following week, which demonstrates that Respondent was both aware of the requirement to submit a Test Plan and of its due date. Id. If necessary, EPA Senior Enforcement Coordinator Darren Fortescue’s testimony will further demonstrate that Respondent has submitted its Test Plan late.

## **Section VI of the Complaint – Relief Sought: Civil Penalty (Paragraphs 26-30)**

Respondent denies any CAA violations in its Answer without stating any supporting facts or reasoning. See ¶¶26-30 of Respondent's Answer. Complainant asserts that the proposed penalties are appropriate and were calculated in accordance with the CAA Civil Penalty Policy as amended by EPA's Penalty Inflation Adjustment Memorandum. See CX 1 ("Clean Air Act Stationary Source Civil Penalty Policy"); CX 2 ("Amendments to EPA's Civil Penalty Policies to Account for Inflation"). In this prehearing exchange's Section VII ("Proposed Penalty Amount Determination"), Complainant describes the proposed penalties determination in detail below. If necessary, EPA Senior Enforcement Coordinator Darren Fortescue's testimony will further demonstrate the appropriateness of the proposed penalty.

### **Respondent's Additional Defenses**

Respondent's Answer also asserts a number of general affirmative defenses. See ¶¶ 34-43 of Respondent's Answer. Because these defenses are presented generally rather than in response to specific allegations in the Complaint, Complainant is not addressing them herein. Pursuant to the Initial Prehearing Order, if Respondent raises any of these affirmative defenses in its prehearing exchange, Complainant will address them in its rebuttal prehearing exchange. See Initial Prehearing Order, pp. 3-4.

### **VII. Proposed Penalty Amount Determination**

EPA's 1991 Clean Air Act Stationary Source Civil Penalty Policy ("CAA Civil Penalty Policy") and EPA's 2022 Penalty Inflation Adjustment Memorandum ("Inflation Adjustment

Memo”) have been listed above as part of Complainant's exhibits. For the reasons set forth below, EPA will be seeking in this proceeding a total penalty of \$126,781.

a. General framework

Page 2 of the Complaint indicates the general framework by which the proposed penalty was determined consistent with the CAA Civil Penalty Policy.

Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a), among other things, authorizes EPA to require the provision of information reasonably necessary for determining the compliance status of any person, that owns or operates any emission source.

The failure to provide information EPA requested under Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a), is a violation of the Clean Air Act.

Where violations occurred after November 2, 2015, and a penalty is assessed on or after January 12, 2022, an administrative civil penalty may not exceed \$414,364 against each violator, unless the Administrator of the EPA and the Attorney General jointly determine that a matter involving a larger penalty amount is appropriate for administrative penalty assessment. CAA § 205(c)(1), 42 U.S.C. § 7524(c)(1); 40 C.F.R. § 19.4, table 1. The penalty sought in this matter does not exceed \$414,364.

b. Relevant factual information and supporting documentation

The factual information relevant to the assessment of a penalty is contained in EPA’s Penalty Calculation Worksheet. See CX 17; see also CX 9-14 (electronic correspondences between EPA and PCS). The proposed penalty was calculated pursuant to the CAA Civil Penalty Policy as amended by EPA’s Inflation Adjustment Memo. See CX 1; CX 2.

c. EPA guidance documents and/or policies relied on in Complaint

The proposed penalty was calculated pursuant to the CAA Civil Penalty Policy, as amended by EPA's Penalty Inflation Adjustment Memo. See CX 1; CX 2.

d. Explanation of factors considered and methodology utilized

Complainant determined the proposed penalty in accordance with Section 113 of the CAA and with the method described in the CAA Civil Penalty Policy ("Penalty Policy") as amended by EPA's Penalty Inflation Adjustment Memorandum ("Inflation Adjustment Memo"). See 42 U.S.C. § 7413(e); CX 1; CX 2. For each violation, Complainant took into consideration the statutory penalty factors listed in CAA Section 113(e) including the size of the violator's business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violations, payment by the violator of penalties previously assessed for the same violations, the economic benefit of the violations, the seriousness of the violations, and such other factors as justice may require. See 42 U.S.C. § 7413(e) ("Penalty assessment criteria"). Complainant also has taken into account the Penalty Policy (CX 1) which allows for upward penalty adjustments based on the seriousness or the gravity of the violations and the size of the violator's business, and further provides for upward adjustments to recover the estimated economic benefit Respondent derived from the violations. These penalty adjustments are considered in light of the violator's degree of willfulness or negligence in committing the violations, its degree of cooperation with the EPA, any good faith efforts to comply, and any pertinent compliance history or previous penalty payments for the same violation. Lastly, in accordance with the Inflation Adjustment Memo (CX 2), the penalty was adjusted upwards using the applicable inflation multiplier of 2.01302 for CAA Stationary Source Civil Penalties.

RESPECTFULLY SUBMITTED on October 28, 2022.

---

Jaegun Lee  
Attorney-Advisor  
U.S. EPA, Region 1  
5 Post Office Square (Mail Code: 4-WD)  
Boston, MA 02109  
(617) 918-1511  
[Lee.Jaegun@epa.gov](mailto:Lee.Jaegun@epa.gov)

CERTIFICATE OF SERVICE

I certify that the foregoing Complainant's Prehearing Exchange, Docket No. CAA-01-2022-0059, has been submitted electronically using the OALJ E- Filing System.

A copy was sent by email to:

Robert A. Fasanella, attorney for Respondent, at [Fasanella@rubinrudman.com](mailto:Fasanella@rubinrudman.com).

Dated: October 28, 2022

Respectfully Submitted,

---

Jaegun Lee  
Attorney-Advisor  
U.S. EPA, Region 1  
5 Post Office Square (Mail Code: 4-WD)  
Boston, MA 02109  
(617) 918-1511  
[Lee.Jaegun@epa.gov](mailto:Lee.Jaegun@epa.gov)