

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1**

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

Complainant’s Rebuttal Prehearing Exchange

Complainant, United States Environmental Protection Agency, Region 1 ("EPA" or "Complainant") submits this Rebuttal Prehearing Exchange pursuant to the Tribunal’s "Prehearing Order," dated August 8, 2022, as modified by the "Order Granting Request for an Extension of Time," dated September 7, 2022, and "Order on Respondent’s Request for Extension," dated November 15, 2022, and in accordance with the provisions of 40 C.F.R. § 22.19(a).

In Respondent's Prehearing Exchange ("RPE") filed on January 6, 2023, Respondent Professional Contract Sterilization, Inc. ("PCS" or "Respondent") admits that it failed to respond to both the EPA’s Clean Air Act ("CAA") Section 114 Information Request and Section 114 Testing Requirement by their respective deadlines. As summarized below, Complainant reasserts that Respondent is liable for the two violations and that the penalty amount is proper.

I. Response to Respondent’s Documents in Support of Denials (Section IV of RPE)

Count 1: Failure to Respond to Section 114 Information Request

Respondent in its Prehearing Exchange and through its own exhibits supports Complainant's position that there is no dispute as to Respondent's liability for Count 1. Respondent plainly states that it "admits it did not respond to EPA's September 13, 2021, CAA Section 114 Information Request (Information Request) by the November 19, 2021 deadline," but Respondent nevertheless challenges the assessment of a penalty. Page 6 of RPE. Respondent further admits that it submitted the information requested on July 5, 2022, more than seven months past its due date. Page 4 of RPE; RX 7.

Respondent also contends that an EPA representative had suggested PCS would not be penalized for a late filing. Pages 4-5 of RPE. However, Respondent offers as proof an email written by Respondent's consultant stating that it was the consultant's understanding that the late submission would not result in a penalty. Page 16 of RX 2. The consultant's understanding of Respondent's culpability, or lack thereof, is immaterial to Respondent's liability and EPA's authority to assess a penalty for Section 114 violations. See 42 U.S.C. § 7413(d) (authorizing EPA to assess penalties for failure to provide information required under Section 114(a) of the CAA.); 42 U.S.C. § 7414(a) (Section 114(a) of the CAA authorizing EPA to require the provision of information reasonably necessary for determining the compliance status of any person, that owns or operates any emission source.). Notably, Respondent submitted the requested information to EPA in July 2022 only after EPA filed the Complaint in this action in June 2022. See Complaint; Page 4 of RPE; RX 7. Hence, Complainant reasserts that Respondent is liable for failure to respond to EPA's Information Request.

Count 2: Failure to Comply with Section 114 Testing Requirement

Respondent neither provides any supporting documents nor does it discuss its denial of the allegations in Count 2 in Section IV of its Prehearing Exchange. See Pages 4-5 of RPE

(discussing only Count 1). In a proceeding section, Respondent plainly states that it “admits it did not respond to EPA’s April 7, 2022 request for Respondent to submit to EPA a Test Plan/Protocol before the May 7, 2022 deadline,” but Respondent nevertheless challenges the assessment of a penalty. Page 8 of RPE. Therefore, as with Count 1, Respondent’s violation of CAA Section 114 for failure to respond to EPA’s Testing Requirement is undisputed, and Complainant reasserts that Respondent is liable for Count 2.

II. Additional Exhibits Complainant Seeks to Introduce in Response to RPE

Complainant intends to introduce the following additional exhibits:

CX #	Description
20	“CAA Civil Penalty Calculation Worksheet,” dated June 2, 2022 (amended January 9, 2023, to correct a typographical error and reorder violations), and prepared by EPA’s Darren Fortescue.
21	Copy of electronic correspondence from EPA to Robert A. Fasanella, attorney for Respondent Professional Contract Sterilization, Inc. (“PCS”), dated August 25, 2022, titled “FW: Document request”
22	Copy of attachment to EPA’s August 25, 2022, email to Robert A. Fasanella, attorney for PCS, titled “Initial Ability to Pay Document Request”
23	Copy of electronic correspondence from PCS to EPA, dated January 9, 2023, titled “Revised Test Plan – Professional Contract Sterilization 1/9/2023”
24	Copy of electronic correspondence from EPA to Robert A. Fasanella, attorney for PCS, dated January 19, 2023, titled “EPA Response to PCS Test Plan dated 1/9/23”
25	Copy of attachment to EPA’s January 19, 2023, email to Robert A. Fasanella, attorney for PCS, titled “EPA Comments on Professional Contact Sterilization, Inc. Revised Performance Test Plan Dated January 9, 2023”

III. Response to Respondent’s Affirmative Defense Arguments (Section V of RPE)

Respondent has the burden of persuasion regarding affirmative defenses. Section 22.15(b) of the Consolidated Rules of Practice states that Respondent’s “answer shall also state: the circumstances or arguments which constitute the grounds of any defense ...” 40 C.F.R. § 22.15(b). Furthermore, Section 22.24(a) of the Consolidated Rules of Practice states that “respondent has the burdens of presentation and persuasion” for its defenses. 40 C.F.R. §

22.24(a). Thus, under the applicable rules of practice, Respondent is required to state the “circumstances or arguments” which support the grounds of its defenses in its answer to the complaint. See 40 C.F.R. §§ 22.15(b) and 22.24(a).

In its Answer, Respondent initially set forth ten enumerated defenses without stating the circumstances or arguments which constitute the grounds of these defenses. See ¶¶34-43 of Respondent’s Answer. Accordingly, Complainant did not discuss the defenses in its Initial Prehearing Exchange and addresses them here. Respondent in its Prehearing Exchange only discusses five of its ten defenses. Pages 5-6 of RPE. Moreover, the defenses discussed appear to relate only to penalty mitigation rather than Respondent’s liability as explained below. See Pages 5-6 of RPE.

First Defense

Respondent states that it “created no danger to health or public safety or human welfare, nor any danger to the environment.” Page 5 of RPE. Actual harm is not an element of Section 114 violations. Section 114 of the CAA, 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. 42 U.S.C. § 7414(a). EPA may assess civil penalties for failure to provide such information in violation of the CAA. 42 U.S.C. § 7413(d). In the present matter, EPA need only demonstrate that (1) PCS is a “person,” (2) PCS operates the Facility at 40 Miles Standish Boulevard, Taunton, Massachusetts, (3) The Facility is an emission source, and (4) PCS failed to provide information EPA requested under Section 114 of the CAA, 42 U.S.C. § 7414(a) as to each of the two counts alleged. Hence, Respondent’s first defense fails because actual harm is immaterial to Respondent’s Section 114 liability.

Second Defense

Respondent argues that the “absence of harm resulting from these administrative violations” should be considered in “the mitigation of the assessed penalties.” Page 5 of RPE. While the lack of actual harm is not a mitigating factor under EPA’s CAA Stationary Source Civil Penalty Policy, “actual or possible harm” is a factor that allows EPA to make *upward* penalty adjustments. CX 1. EPA did not make an upward adjustment for actual or possible harm as shown in Complainant's Penalty Calculation Worksheet ("Penalty Calculation") attached as CX 20. As discussed above, the lack of actual harm also is immaterial to Respondent’s liability.

Third Defense

Respondent argues that it received “no economic benefit from the alleged non-compliance.” Page 5 of RPE. Economic benefit is immaterial to Respondent’s Section 114 liability as well. See 42 U.S.C. § 7414(a) (authorizing EPA to require the provision of information reasonably necessary for determining the compliance status of any person, that owns or operates any emission source.). Furthermore, EPA had made no upward penalty adjustments based on the economic benefit factor. CX 20. Lastly, any delays in incurring expenses associated with responding to requests for information would result in some benefit to Respondent.

Fourth and Fifth Defenses

Respondent does not discuss the fourth and fifth defenses that it raised in its Answer to the Complaint. See ¶¶37-38 of Respondent's Answer; Pages 5-6 of RPE.

Sixth Defense

Respondent argues that EPA’s proposed penalty is “excessive, inappropriate and unwarranted, and Complainant has not provided adequate explanation as to how the penalty amount was calculated.” Page 6 of RPE. Complainant's Penalty Calculation (CX 20) describes Complainant's reasoning and calculations for the penalties proposed for the two counts in

accordance with the CAA Civil Penalty Policy (CX 1) as amended by EPA’s Penalty Inflation Adjustment Memorandum (CX 2). Both aforementioned policy documents are publicly available.¹

Seventh, Eighth and Ninth Defenses

Respondent does not discuss the seventh through ninth defenses that it raised in its Answer to the Complaint. See ¶¶40-42 of Respondent's Answer; Pages 5-6 of RPE.

Tenth Defense

Respondent states that EPA’s assessment of penalties is an “abuse of discretion” without providing any factual or legal support for its assertion. See Page 6 of RPE. Respondent suggests that it would provide an explanation to its tenth defense in a proceeding section of its Prehearing Exchange. However, Respondent makes no further reference to the supposed abuse of discretion in any of the proceeding sections of its Prehearing Exchange. See Pages 6-9 of RPE.

As discussed above, Respondent is required to state the “circumstances or arguments” which support the grounds of its defenses in its answer to the complaint. See 40 C.F.R. §§ 22.15(b) and 22.24(a). In the present matter, not only did Respondent fail to state in its Answer the circumstances or arguments which constitute the grounds of any of its defenses, it also failed to provide any factual or legal support for these defenses in its Prehearing Exchange. See ¶¶34-43 of Respondent's Answer; Pages 4-9 of RPE.

Given that the Respondent has failed to submit any necessary evidence or arguments that support its defenses, these defenses should be deemed improperly pled. See 40 C.F.R. §§ 22.15(b) and 22.24(a).

¹ U.S. EPA’s Clean Air Act Stationary Source Civil Penalty Policy is publicly available on the Internet at: <https://www.epa.gov/enforcement/clean-air-act-stationary-source-civil-penalty-policy-october-25-1991>; Amendments to EPA’s Civil Penalty Policies to Account for Inflation is publicly available on the Internet at: https://www.epa.gov/system/files/documents/2022-01/2022amendmentstopenaltypoliciesforinflation_0.pdf.

IV. Response to Respondent’s Rejection of Penalty (Section VI of RPE)

Complainant's Penalty Calculation describes Complainant's reasoning and calculations for the penalties proposed for the two counts in this case. CX 20. Respondent's Prehearing Exchange contains statements admitting the violations but generally objecting to EPA’s penalty proposal without stating what Respondent believes to be an appropriate penalty amount. Page 6-9 of RPE.

Count 1: Failure to Respond to Section 114 Information Request

Respondent states that the proposed penalty is “excessive,” however, Respondent does not provide a legal argument or factual support for its conclusion. Respondent admits that it did not respond to the Information Request by the November 2021 deadline. Page 6 of RPE. Furthermore, Respondent’s own exhibit shows that PCS’s request for a deadline extension was explicitly denied. Page 17 of RX 2.

Respondent correctly states that there was a typographical error in the violation start date for Count 1. The typographical error has been corrected in Complainant’s Exhibit CX 20, and the amendment does not affect the penalty calculation under EPA’s CAA Civil Penalty Policy since the duration of violation remains between seven and 12 months. See CX 1.² Respondent also provides an exhibit in which Respondent’s consultant expressed his understanding that penalties would not be assessed for a late submittal. Page 16 of RX 2. As discussed above, whether such a representation was made is immaterial to the EPA’s authority to assess a penalty for Section 114

² Page 12 of EPA’s CAA Civil Penalty Policy contains the following matrix determining the appropriate pre-inflation adjustment penalty based on the duration of a violation:

Months	Dollars
0 - 1	\$ 5,000
2 - 3	8,000
4 - 6	12,000
7 - 12	15,000
...	

violations in this matter. See 42 U.S.C. § 7413(d) (authorizing EPA to assess penalties for failure to provide information required under Section 114(a) of the CAA.); 42 U.S.C. § 7414(a) (Section 114(a) of the CAA authorizing EPA to require the provision of information reasonably necessary for determining the compliance status of any person, that owns or operates any emission source.). As Respondent admits, Respondent responded to the September 2021 Information Request in July 2022, only after Complainant initiated this action in June 2022. See Complaint; Page 4 of RPE; RX 7.

Respondent also appears to suggest that the penalty is excessive given the lack of prior non-compliance history and since it did not derive any economic benefit from the violations. However, EPA never made an upward penalty adjustment based on these factors in its penalty proposal. CX 20.

Count 2: Failure to Comply with Section 114 Testing Requirement

As discussed in Section I of this Rebuttal Prehearing Exchange, Respondent does not dispute that it failed to respond to EPA's Testing Requirement. Respondent nevertheless contends that the penalty is "excessive" since it "worked in good-faith to respond." Respondent admits that it did not respond to EPA's Testing Requirement by its May 7, 2022, deadline. Page 8 of RPE. Respondent did not request an extension and submitted its initial Test Plan only after EPA informed Respondent that its Test Plan was overdue. CX 11. In response to EPA's May 18, 2022, email regarding the overdue Test Plan, Respondent stated 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. Not only did Respondent submit its initial Test Plan as required by EPA's Testing Requirement late,

Respondent is yet to conduct the required performance testing with a revised Test Plan free of deficiencies. See CX 23; CX 24; CX 25.

V. Response to Respondent's Penalty Reduction Request (Section VII of RPE)

Respondent objects to the Complainant's penalty proposal of \$126,781 for the two violations but does not propose a specific penalty in its Prehearing Exchange. Respondent simply claims that it does not have the financial ability to pay the proposed penalty. However, Respondent has not provided documents necessary for EPA to make an initial ability-to-pay determination. These financial documents were originally requested by EPA on August 25, 2022. CX 21; CX 22. Even in Respondent's Prehearing Exchange, Respondent fails to provide financial documents necessary for EPA to determine whether PCS is unable to pay the penalty. Instead, Respondent presents an "expert opinion" as an exhibit regarding its inability to pay the proposed penalty based on unverifiable financial information. RX 1. Thus, in the absence of the necessary financial information, Complainant asserts that EPA's proposed penalty of \$126,781 remains appropriate.

VI. Reservation of Rights

Complainant respectfully reserves the right to supplement its list of witnesses and/or its list of exhibits upon reasonable notice to the Tribunal and Respondent, or by order of the Tribunal.

RESPECTFULLY SUBMITTED on January 20, 2023.

Jaegun Lee
Attorney-Advisor
U.S. EPA, Region 1

CERTIFICATE OF SERVICE

I certify that the foregoing Complainant's Rebuttal 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 RFasanella@rubinrudman.com.

Dated: January 20, 2023

Respectfully Submitted,

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