

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 1**

|   |   |                             |
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| In the Matter of:                         | ) |                             |
| Professional Contract Sterilization, Inc. | ) | COMPLAINANT’S MOTION FOR    |
| 40 Myles Standish Boulevard               | ) | ACCELERATED DECISION ON     |
| Taunton, MA 02780                         | ) | LIABILITY AND TO STRIKE     |
|   | ) | AFFIRMATIVE DEFENSES        |
| Respondent                                | ) |                             |
| Proceeding under Section 113              | ) | Docket No. CAA-01-2022-0059 |
| of the Clean Air Act                      | ) |                             |

**MOTION FOR ACCELERATED DECISION ON LIABILITY  
AND TO STRIKE AFFIRMATIVE DEFENSES**

Complainant, the United States Environmental Protection Agency, Region 1 (“EPA” or “Complainant”) respectfully submits the following Motion for Accelerated Decision on Liability and to Strike Affirmative Defenses. For the reasons set forth below, Complainant's motion should be granted.

**I. Procedural Background**

On June 28, 2022, EPA filed a civil administrative Complaint against Professional Contract Sterilization, Inc. (“PCS” or “Respondent”). The Complaint alleges that PCS violated the Clean Air Act (“CAA”), 42 U.S.C. §7401 et seq., on two instances. Specifically, the Complaint alleges that PCS failed to respond to EPA’s Information Collection Request Letter and failed to submit a Performance Test Plan to EPA in violation of Section 114(a) of the CAA, 42 U.S.C. § 7414(a).

The Complaint further alleges that under 40 C.F.R. §§ 63.2 and 63.6585(c), PCS’s Facility is an area source of hazardous air pollutant (“HAP”) emissions subject to the emissions

standards found at 40 C.F.R. § 63.362 because it operates a commercial sterilization facility that uses ten tons or more of ethylene oxide per year in sterilization or fumigation operations.

On or about July 28, 2022, Respondent filed its Answer to the Complaint. In its answer, Respondent raised 10 affirmative defenses. However, the affirmative defenses set forth in Respondent's Answer merely state legal conclusions that are not supported by facts or reasoning. On September 2, 2022, Complainant filed its Prehearing Status Report following an initial settlement conference on August 28, 2022. Respondent again failed to produce any specific facts or information during the initial settlement conference to support any of its affirmative defenses.

In Respondent's Prehearing Exchange filed on January 6, 2023, Respondent plainly admitted 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. On January 20, 2023, Complainant filed its Rebuttal Prehearing Exchange reasserting that Respondent is liable for the two violations and that the penalty amount is proper.

This Motion will request the Presiding Officer to grant an accelerated decision on liability in favor of the Complainant for each of the two counts alleged in its Complaint and will provide a basis for which the Motion should be granted. The Motion will demonstrate that, even in a light most favorable to the Respondent, there is no genuine issue of material fact as to any of the elements necessary to prove that a violation of CAA occurred as to each count.

Complainant will show that there can be no genuine issue or dispute that (1) Respondent is a "person," (2) Respondent operates a commercial sterilization facility at 40 Miles Standish Boulevard, Taunton, Massachusetts ("Facility"), (3) Respondent's Facility is a source of emissions, and (4) Respondent failed to provide information EPA requested under Section 114 of the CAA, 42 U.S.C. § 7414(a). To demonstrate that there are no genuine issues of material

fact in this matter, Complainant will rely on Respondent's Answer, Respondent's Prehearing Exchange and exhibits, and Complainant's exhibits filed with its Prehearing Exchange and Rebuttal Prehearing Exchange.

This Motion will also request a decision in favor of the Complainant to strike Respondent's affirmative defenses. Even when viewed in the light most favorable to Respondent, the asserted defenses are legally insufficient to defeat Respondent's liability for the violations alleged in the Complaint. In the arguments set forth below, Complainant will demonstrate that Respondent has failed to support its affirmative defenses with any facts or reasoning which show that there is a genuine issue for a hearing as to Respondent's liability, and that the law and interpretation of the law is so clear that a motion to strike must be granted.

## **II. Standard of Review**

Pursuant Rule 22.20(a) of the Consolidated Rules of Practice, the Presiding Officer may render an accelerated decision as to all or any part of the proceeding at any time "if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law." 40 C.F.R. § 22.20(a). These standards are akin to motions for summary judgment in federal practice that are rendered if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," show that there is no genuine issue of any material fact and that the moving party is entitled to a judgment as a matter of law. *In the Matter of Gerald Strubinger, et. al.*, Docket No. CWA-3-2001-001, 2002 WL 2005525, at \*2 (Aug. 22, 2002) (citing Fed. R. Civ. P. 56(c)).

If the non-moving party fails to address the moving party's assertions of fact or establish that there is a genuine factual dispute by citing to specific materials in the record, the court may grant an accelerated decision. *In re Polo Development Inc., et. al.* Docket No. CWA-05-2015-0003, 2015 WL 627637 at \*7 (Feb. 6, 2015) (citing Fed. R. Civ. P. 56(c)(1)).

Likewise, with respect to affirmative defenses raised by the Respondent, the non-moving party must overcome the moving party's claims that the defenses lack factual support by citing to specific evidence in the record. Id. If unable to demonstrate a genuine factual dispute concerning affirmative defenses, the court may strike the defenses. Id.

### **III. Statutory and Regulatory Authorities**

Section 114(a) of the CAA, 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. EPA may assess civil penalties for failure to provide such information in violation of the CAA. 42 U.S.C. § 7413(d).

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. 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.

### **IV. Argument**

Complainant respectfully requests the Presiding Officer to (A) grant an accelerated decision in favor of the Complainant as to Respondent's liability for each of the two counts alleged in the Complaint, and (B) strike Respondent's affirmative defenses.

#### **A. MOTION FOR ACCELERATED DECISION ON LIABILITY SHOULD BE GRANTED BECAUSE THERE IS NO GENUINE ISSUE OF MATERIAL FACT AND COMPLAINANT IS ENTITLED TO JUDGMENT AS A MATTER OF LAW.**

Complainant alleges that PCS has violated the CAA on two separate occasions when it failed to respond to a Section 114 Information Collection Request and failed to submit a Performance Test Plan in a timely manner. ¶¶22-25 of Complaint. Section 114(a) of the CAA(a),

42 U.S.C. § 7414(a), authorizes EPA to require a person who owns or operates an emission source to provide information reasonably necessary for determining its compliance status. EPA may assess civil penalties for failure to provide such information in violation of the CAA. 42 U.S.C. § 7413(d).

As to each of the two counts in its Complaint, Complainant must therefore show that the following undisputed facts and evidence are already in the record: (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, in a timely manner.

*1. PCS is a “person”*

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.<sup>1</sup> Therefore, PCS is a person within the meaning of the CAA, and there is no genuine issue of material fact with respect to this element of proof for either of the two counts alleged in the Complaint. See 42 U.S.C. § 7602(e); 40 C.F.R. § 22.20(a).

*2. PCS operates the Facility*

In its Answer, PCS admits that it operates the Facility at 40 Miles Standish Boulevard, Taunton, Massachusetts. ¶5 of Respondent's Answer. Based on Respondent's own admission, there is no genuine issue of material fact with respect to this element of proof for either of the two counts alleged in the Complaint. See 40 C.F.R. § 22.20(a); ¶5 of Respondent's Answer.

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<sup>1</sup> See CX 4 (Professional Contract Sterilization, Inc., 2021 Annual Report, publicly available on the Internet at: [https://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSearchRedirector.aspx?Action=PDF&Path=CORP\\_DRIVE1/2022/0603/002192483/0039/202229012310\\_1.pdf](https://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSearchRedirector.aspx?Action=PDF&Path=CORP_DRIVE1/2022/0603/002192483/0039/202229012310_1.pdf)).

3. The Facility is a source of emissions

PCS is a source of hazardous air pollutant (“HAP”) emissions within the meaning of Section 114(a), 42 U.S.C. § 7412(a). Section 112 of the CAA defines an “area source” as “any stationary source of hazardous air pollutants that is not a major source” with “major source” meaning any “stationary source or group of stationary sources that emits or has the potential to emit 10 tons per year or more” of any HAP. 42 U.S.C. § 7412(a)(1)-(2). Ethylene oxide is one such HAP. See 40 C.F.R. 63.360 (“Ethylene Oxide Emissions Standards for Sterilization Facilities”). The CAA further defines a “stationary source” as any building, structure, facility, or installation which emits or may emit any air pollutant. 42 U.S.C. § 7411(a)(3).

PCS identifies its facility as an “area source.” Page 6 of RX 7. In its Answer, PCS admits that it uses 10 tons or more of ethylene oxide per year in sterilization or fumigation operations at the Facility at 40 Miles Standish Boulevard, Taunton, Massachusetts. ¶11 of Respondent's Answer. PCS claims that the Facility's air pollution control devices for the ethylene oxide sterilization process are held to a 99 percent emission reduction standard. Pages 10 and 27 of RX 4. Therefore, the Facility is considered a source of HAP emissions and is subject to relevant emissions standards. See 42 U.S. Code § 7412; 40 C.F.R. §§ 63.360 and 63.362. Based on Respondent’s own admissions, there is no genuine issue of material fact with respect to this element of proof as well. See ¶11 of Respondent's Answer; Pages 10 and 27 of RX 4; Page 6 of RX 7.

4. PCS failed to timely provide information EPA requested

For each of the two counts alleged in the Complaint, PCS failed to timely provide information EPA requested under Section 114 of the CAA, 42 U.S.C. § 7414(a). To show that there is no genuine issue of any material fact and that the moving party is entitled to a judgment as a matter of law, EPA may rely on the pleadings, admissions on file, and affidavits or

declarations. See Fed. R. Civ. P. 56(c); *In the Matter of Gerald Strubinger*, 2002 WL 2005525, at \*2.

*a. Count 1*

In Count 1, Complainant alleges that PCS violated the CAA when it failed to comply with a Section 114 Information Collection Request (“Information Request”) dated September 13, 2021. ¶¶22-23 of Complaint. In Respondent’s Answer to the Complaint, Respondent admits that it received EPA’s Information Request. ¶¶14 and 22-23 of Respondent’s Answer. In Respondent’s Prehearing Exchange (“RPE”), Respondent 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”. Page 6 of RPE. Respondent further admits that it responded to the September 2021 Information Request on July 5, 2022, Page 4 of RPE, more than seven months past its due date and only after Complainant initiated this action in June 2022. See Complaint (dated June 28, 2022). There is no genuine issue of material fact as to Respondent’s failure to comply in a timely manner with EPA’s Information Request, and Complainant is therefore entitled to a finding that Respondent failed to respond to EPA’s Information Collection Request by its deadline in violation of Section 114 of the CAA. See 42 U.S.C. § 7414(a); 40 C.F.R. § 22.20(a).

*b. Count 2*

In Count 2, Complainant alleges that PCS violated a CAA Section 114 Performance Testing Requirement (“Testing Requirement”) when it failed to submit a Performance Test Plan (“Test Plan”) to EPA by its deadline. ¶¶24-25 of Complaint. In its Answer, Respondent admits that it received EPA’s letter dated April 7, 2022, requiring it to submit a Test Plan by May 7, 2022. ¶¶16 and 24-25 of Respondent’s Answer. In its Prehearing Exchange, Respondent 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”. Page 8 of RPE. Therefore, there is no genuine issue of material fact as to Respondent’s failure to submit a Test Plan by its deadline, and Complainant is entitled to a finding that Respondent failed to timely comply with the Testing Requirement. See 42 U.S.C. § 7414(a); 40 C.F.R. § 22.20(a).

In sum, even in a light most favorable to the Respondent, there is no genuine issue of material fact as to any of the elements necessary to prove that a violation of CAA occurred as to each of the two counts in a timely manner. Given all the information in the record, Complainant respectfully requests that this Tribunal grant this Motion for Accelerated Decision on Liability. See 40 C.F.R. § 22.20(a).

**B. MOTION TO STRIKE RESPONDENT’S AFFIRMATIVE DEFENSES SHOULD BE GRANTED BECAUSE THE DEFENSES ARE NOT SUPPORTED BY FACTS OR REASONING AND ARE INADEQUATE AS A MATTER OF LAW.**

Respondent raised 10 affirmative defenses in its Answer to the Complaint. See ¶¶34-43 of Respondent's Answer. Respondent in its Prehearing Exchange only discusses five of those defenses, all of which relate only to penalty mitigation rather than Respondent’s liability. See Pages 5-6 of RPE. Because Respondent has failed to submit necessary evidence or arguments to support its affirmative defenses, Respondent’s defenses are improperly pled and should be stricken. See 40 C.F.R. §§ 22.15(b), 22.20(a) and 22.24(a).

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 any affirmative 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 affirmative defenses in its answer to the complaint. See 40 C.F.R. §§ 22.15(b) and 22.24(a). Furthermore, Respondent must



overcome the moving party's claims that the defenses lack factual support by citing to specific evidence in the record. *In re Polo Development Inc.* at \*7 (citing Fed. R. Civ. P. 56(c)(1)). The court may strike the defenses if Respondent is unable to demonstrate a genuine factual dispute concerning its affirmative defenses. Id.

#### First Defense: No Danger Created

Respondent states that it created no danger to health or public safety or human welfare, nor any danger to the environment. ¶34 of Respondent's Answer; Page 5 of RPE. Actual harm, however, 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). As explained above, EPA need only to 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 in a timely manner that 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: Absence of Harm Not Adequately Considered

Respondent argues that the absence of harm resulting from these administrative violations should be considered in the mitigation of the assessed penalties. ¶35 of Respondent's Answer; Page 5 of RPE. As discussed above, the lack of actual harm is immaterial to Respondent's liability. 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.).

Third Defense: No Economic Benefit

Respondent argues that it received “no economic benefit from the alleged non-compliance.” Page 5 of RPE. Economic benefit also is immaterial to Respondent’s Section 114 liability. See 42 U.S.C. §§ 7413(d) and 7414(a).

Fourth and Fifth Defenses: No Relief for Claim and Estoppel

In Respondent’s Answer to the Complaint, Respondent asserted that EPA’s Complaint failed to state a claim upon which relief can be granted, and that the Complaint is barred by the doctrines of waiver and/or estoppel. ¶37-38 of Respondent’s Answer. However, Respondent failed to state in its Answer the circumstances or arguments which constitute the grounds of these defenses. Id. Respondent also did not discuss nor provide any factual or legal support for the defenses in its Prehearing Exchange. See Pages 5-6 of RPE.

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). Because Respondent has failed to submit any necessary evidence or argument supporting the fourth and fifth affirmative defenses, these defenses are improperly pled and should be stricken. See 40 C.F.R. §§ 22.15(b), 22.20(a) and 22.24(a).

Sixth Defense: Excessive Penalty and Inadequate Explanation of Penalty Calculation

Respondent argues that EPA’s proposed penalty is “excessive, inappropriate and unwarranted” and that “Complainant has not provided adequate explanation as to how the penalty amount was calculated.” ¶39 of Respondent’s Answer; Page 6 of RPE. Contrary to Respondent’s assertions, 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). Respondent's sixth defense also relates only to penalty mitigation and is immaterial to Respondent's Section 114 liability. See 42 U.S.C. §§ 7413(d) and 7414(a). Thus, Respondent's sixth affirmative defense should also be deemed improperly pled. See 40 C.F.R. §§ 22.15(b) and 22.24(a) (requiring Respondent to state the circumstances or arguments which support the grounds of its defenses in its answer to the complaint.).

Seventh, Eighth and Ninth Defenses: Laches, Statute of Limitations and Lack of Substantial Evidence

In Respondent's Answer, Respondent asserted that the allegations in EPA's Complaint were barred by laches, barred by the applicable statute of limitations, and are not supported by substantial evidence. ¶¶40-42 of Respondent's Answer. However, Respondent neither states in its Answer the circumstances or arguments which constitute the grounds of the defenses, nor does it discuss any of these defenses in its Prehearing Exchange. See ¶¶40-42 of Respondent's Answer; Pages 5-6 of RPE. Because Respondent has failed to submit any necessary evidence or argument supporting the seventh, eighth and ninth affirmative defenses, these defenses are improperly pled and should be stricken. See 40 C.F.R. §§ 22.15(b), 22.20(a) and 22.24(a).

Tenth Defense: Abuse of Discretion

Respondent argues that EPA's assessment of penalties is an "abuse of discretion." See ¶43 of Respondent's Answer. Respondent, however, failed to state in its Answer the circumstances or arguments which constitute the grounds of the defense. See ¶¶34-43 of Respondent's Answer. Respondent further failed to provide any factual or legal support for the defense in its Prehearing Exchange. See Pages 4-9 of RPE. In its Prehearing Exchange, Respondent suggests that it would provide an explanation to the defense in a proceeding section of its Prehearing Exchange yet makes no further reference to the supposed abuse of discretion.

See Pages 6-9 of RPE. Thus, Respondent’s tenth affirmative defense should also be deemed improperly pled. See 40 C.F.R. §§ 22.15(b) and 22.24(a) (requiring Respondent to state the “circumstances or arguments” which support the grounds of its defenses in its answer to the complaint.).

In sum, not only did Respondent fail to state in its Answer the circumstances or arguments which constitute the grounds of any of its affirmative defenses, it also failed to provide any factual or legal support for its affirmative defenses to date. See ¶¶34-43 of Respondent's Answer; Pages 5-6 of RPE. Respondent’s affirmative defenses are thus insufficient as a matter of law, immaterial to the issue of liability and should be stricken from the pleading. See 40 C.F.R. §§ 22.15(b), 22.20(a) and 22.24(a).

**V. Conclusion**

For reasons stated above, Complainant hereby respectfully requests that this Motion for Accelerated Decision on Liability and to Strike Affirmative Defenses be granted. In the alternative, should such relief not be granted, Complainant requests an accelerated decision resolving any of the issues in this case to aid in narrowing the scope of the hearing.

RESPECTFULLY SUBMITTED on February 6, 2023.

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CERTIFICATE OF SERVICE

I certify that the foregoing Complainant's Motion for Accelerated Decision on Liability and to Strike Affirmative Defenses, 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](mailto:RFasanella@rubinrudman.com).

Dated: February 6, 2023

Respectfully Submitted,

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