UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Professional Contract Sterilization, Inc.,	)	**Docket No. CAA-01-2022-0059**
	)	
Respondent.	)	

ORDER ON COMPLAINANT'S MOTION FOR ACCELERATED DECISION AND TO STRIKE AFFIRMATIVE DEFENSES

I. RELEVANT PROCEDURAL HISTORY

This matter commenced on June 28, 2022, when the Director of the Enforcement and Compliance Assurance Division of the U.S. Environmental Protection Agency ("EPA"), Region 1 ("Complainant" or "Agency") filed a Complaint against Professional Contract Sterilization, Inc. ("Respondent" or "PCS"), pursuant to Section 113(a) of the Clean Air Act ("CAA" or "Act"), 42 U.S.C. § 7413(a). The Complaint alleges in two counts violations of CAA Section 114, 42 U.S.C. § 7414(a). Count 1 asserts that PCS failed to respond to an Information Collection Request EPA issued to it on September 13, 2021. Compl. ¶¶ 22-23. Count 2 asserts that PCS failed to submit a performance test plan to EPA by May 7, 2022, as required by the Agency's April 7, 2022 Testing Requirement Letter. Compl. ¶¶ 24-25. The Complaint proposes the imposition of a civil penalty in the amount of $126,781 for these violations. Compl. ¶ 26.

Respondent filed its Answer to Complaint, Affirmative Defenses and Request for Hearing ("Answer") on July 28, 2022. In the Answer, PCS denied the CAA violations, raised ten affirmative defenses, and requested a hearing. A Prehearing Order was issued on August 8, 2022. Complainant submitted its Initial Prehearing Exchange ("PHE") on October 28, 2022, and Respondent submitted its Prehearing Exchange on January 6, 2023. Thereafter, on January 20, 2023, Complainant submitted a Rebuttal Prehearing Exchange, and both parties have since supplemented their prehearing exchanges with Complainant's Supplement filed on February 17, 2023, and Respondent's on March 2, 2023.[1]

On February 6, 2023, Complainant filed a Motion for Accelerated Decision on Liability and to Strike Affirmatives Defenses ("Motion"). Respondent's Opposition to the Motion ("Opposition") was filed on February 21, 2023.

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[1] Any Prehearing Exchange Exhibit identified as containing claimed confidential business information pursuant to 40 C.F.R. § 2.203(b), or personally identifiable information under the Privacy Act of 1974 (codified at 5 U.S.C. § 552a), was submitted separately to the Tribunal and is omitted from the public record or included therein with redactions.

Complainant's Exhibits are cited as "CX," and Respondent's Exhibits are cited as "RX."

II. APPLICABLE ADJUDICATORY STANDARDS

This proceeding is governed by the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Rules of Practice"), set forth at 40 C.F.R. Part 22. Section 22.20(a) of the Rules of Practice authorizes an Administrative Law Judge to:

> render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, 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). This standard is analogous to the standard governing motions for summary judgment prescribed by Rule 56 of the Federal Rules of Civil Procedure, and while those Rules do not apply here, the Environmental Appeals Board ("EAB") has consistently looked to Rule 56 and its jurisprudence for guidance in adjudicating motions for accelerated decision filed under Section 22.20(a) of the Rules of Practice. *See, e.g.*, *Consumers Scrap Recycling, Inc.*, 11 E.A.D. 269, 285 (EAB 2004); *BWX Techs., Inc.*, 9 E.A.D. 61, 74-75 (EAB 2000); *Clarksburg Casket Co.*, 8 E.A.D. 496, 501-02 (EAB 1999). Federal courts have endorsed this approach. For example, the United States Court of Appeals for the First Circuit described Rule 56 as "the prototype for administrative summary judgment procedures" and the jurisprudence surrounding it as "the most fertile source of information about administrative summary judgment." *P.R. Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 607 (1st Cir. 1994) (rejecting the argument that federal court rulings on motions for summary judgment are "inapposite" to administrative proceedings).

As for the particular standard set forth in Rule 56, it directs a federal court to grant summary judgment upon motion by a party "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In construing this standard, the Supreme Court has held that a fact is material where, under the governing substantive law, it might affect the outcome of the proceeding. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In turn, a factual dispute is genuine if a fact finder could reasonably resolve the dispute in favor of the non-moving party under the evidentiary standards applicable to the particular proceeding. *Id.* at 248, 250-52.

The Supreme Court has held that the party moving for summary judgment bears the burden of showing an absence of a genuine dispute as to any material fact. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). This burden consists of two components: an initial burden of production, which shifts to the non-moving party once it is satisfied by the moving party, and the ultimate burden of persuasion, which always remains with the moving party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986) (Brennan, J., dissenting) (citing 10A Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice and Procedure* § 2727 (2d ed. 1983)). To establish that a dispute over a material fact does not or does exist, respectively, the movant and non-movant must cite to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other

materials" or show "that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1).

In determining whether a genuine issue of material fact exists for trial, a federal court is required to construe the evidentiary material and reasonable inferences drawn therefrom in a light most favorable to the non-moving party. *See Anderson*, 477 U.S. at 255 ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor."); *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) ("On summary judgment the inferences to be drawn from the underlying facts contained in [evidentiary] materials must be viewed in the light most favorable to the party opposing the motion."). The court is then required to consider whether a fact finder could reasonably find in favor of the non-moving party under the applicable evidentiary standards. *Anderson*, 477 U.S. at 252-55. Where the evidence viewed in the light most favorable to the non-moving party is such that the fact finder could not reasonably find in favor of that party, summary judgment is appropriate. *See id.* at 249-50; *Adickes*, 398 U.S. at 158-59. Conversely, where conflicting inferences may be drawn from the evidence and a choice among those inferences would amount to fact-finding, summary judgment is inappropriate. *Rogers Corp. v. EPA*, 275 F.3d 1096, 1105 (D.C. Cir. 2002). Even where summary judgment appears technically proper, sound judicial policy and the exercise of judicial discretion may support denial of the motion so the case may be more fully developed at hearing. *Roberts v. Browning*, 610 F.2d 528, 536 (8th Cir. 1979).

The EAB has applied the foregoing principles in adjudicating motions for accelerated decision under Section 22.20(a) of the Rules of Practice, holding that the moving party "assumes the initial burden of production on a claim, and must make out a case for presumptive entitlement to summary judgment in his favor." *BWX Techs.*, 9 E.A.D. at 76. Where the moving party bears the burden of persuasion on an issue, it is entitled to an accelerated decision only if it presents "evidence that is so strong and persuasive that no reasonable [fact finder] is free to disregard it[.]" *Id.* Where the moving party does not bear the burden of persuasion, it has the "lesser burden of 'showing' or 'pointing out' to the reviewing tribunal that there is an absence of evidence in the record to support the nonmoving party's case on that issue[.]" *Id.* Once the moving party has discharged this burden, the burden of production shifts to the non-moving party bearing the burden of persuasion on the issue to identify specific facts from which a finder of fact could reasonably find in its favor on each element of the claim. *Id.*

As noted by the EAB, "neither party can meet its burden of production by resting on mere allegations, assertions, or conclusions of evidence." *Id.* at 75. Likewise, a party opposing a properly supported motion for accelerated decision is required to "provide more than a *scintilla* of evidence on a disputed factual issue to show their entitlement to a[n] . . . evidentiary hearing: the evidence must be substantial and probative in light of the appropriate evidentiary standard of the case." *Id.* at 76.

Consistent with the jurisprudence of Rule 56, the EAB has held that a tribunal adjudicating a motion for accelerated decision is required to consider whether the parties have met their respective burdens in the context of the applicable evidentiary standard. *Id.* at 75. As prescribed by Section 22.24(b) of the Rules of Practice, 40 C.F.R. § 22.24(b), the evidentiary

standard that applies here is proof by a preponderance of the evidence. Section 22.24(a) provides that a complainant bears the burdens of presentation and persuasion that a violation occurred as set forth in the complaint and that the relief sought is appropriate, while a respondent bears the burdens of presentation and persuasion for any affirmative defenses.

III. SUBSTANTIVE LAW

Enacted in 1970, the CAA "was intended comprehensively to regulate, through guidelines and controls, the complexities of restraining and curtailing modern day air pollution." *Bunker Hill Co. Lead & Zinc Smelter v. EPA*, 658 F.2d 1280, 1284 (9th Cir. 1981); *see also* 42 U.S.C. § 7401(b) ("The purposes of this subchapter are— (1) to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population . . . .").

Subchapter (or Title) I of the Act addresses stationary (non-moving) sources of air pollutants, such as buildings, structures, facilities, or installations. 42 U.S.C. § 7401 *et seq.*; *see also id.* §§ 7411(a)(3), 7412(a)(3). It gives EPA the authority to establish National Ambient Air Quality Standards to limit levels of certain pollutants; requires development of EPA-approved State Implementation Plans to implement, maintain, and enforce those standards; and provides for enforcement of the requirements by both federal and state authorities. *Id.* §§ 7409, 7410, 7413.

The Act also regulates hazardous air pollutants. Section 112(a) of the CAA defines the term "hazardous air pollutant" ("HAP") to mean "any air pollutant listed pursuant to subsection (b)." *Id.* § 7412(a)(6). Ethylene oxide ("EtO") (CAS number 75218) was included on the initial list of 189 HAPs set out in subsection (b) at the time the CAA was enacted, and remains on the list today.[2] *Id.* § 7412(b)(1); 40 C.F.R. §§ 63.60 to 63.64 (delineating deletions and additions to the list). In 1994, EPA issued regulations establishing National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Ethylene Oxide Commercial Sterilization and Fumigation Operations. *See* 59 Fed. Reg. 62,585 (Dec. 6, 1994). Those regulations are codified in Subpart O of 40 C.F.R. Part 63, and include requirements for reporting, recordkeeping, and enforcement. 40 C.F.R. §§ 63.360 to 63.368.

Regarding stationary sources of hazardous air pollutants, the Act differentiates between "major sources" and "area sources." 42 U.S.C. § 7412(a)(1), (a)(2). Major sources are defined as an individual 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." *Id.* § 7412(a)(1). An area source means "any stationary source of hazardous air pollutants that is not a major source." *Id.* § 7412(a)(2).

[2] EtO is a colorless gas and, among other things, is "used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment." EPA, Hazardous Air Pollutants: Ethylene Oxide (EtO), https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide (last accessed August 28, 2023).

To facilitate its implementation and enforcement, Section 114(a) of the CAA authorizes EPA to "reasonably require" the production of information from "any person who owns or operates any emission source." *Id.* § 7414(a)(1)(G). Further, Section 113(d) 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 this subchapter," he may "issue an administrative penalty order in accordance with subsection (d)." *Id.* § 7413(a)(3)(A).

IV. FACTUAL BACKROUND

Respondent PCS is a small, privately-held business, incorporated in 1989 under the laws of Massachusetts. CX 4; RX 10 ¶¶ 1, 2;[3] RX 14 at 13-24. PCS operates an ethylene oxide commercial sterilization facility located at 40 Miles Standish Boulevard; Taunton, MA 02780 (the "Facility"). Compl. ¶ 5; Answer ¶¶ 5, 11; CX 4; CX 15 at 2; RX 10 ¶ 1; RX 14 at 15. In 1997, the Facility doubled in size to 34,000 cubic feet, and since that time PCS has operated five of its six sterilization chambers using 100% ethylene oxide for sterilization. CX 15 at 2; CX 16 at 2. On March 24, 1998, PCS submitted to EPA an initial notification of coverage under Subpart O. Compl. ¶ 13; Answer ¶ 13; 40 C.F.R. §§ 63.360, 63.9(b)(2) (within 120 days of becoming subject to a national emission standard for hazardous air pollutants, emission sources are required to submit an "initial notification"). The Facility used approximately 18 to 25 tons of ethylene oxide annually in its sterilization operations in calendar years 2019 through 2021. Compl. ¶ 11; Answer ¶ 11; CX 16 at 3.

In 2019, EPA issued public notice of its intent to review and revise the Subpart O regulations. *See* National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67,889 (Dec. 12, 2019) (Advance notice of proposed rulemaking). On or around September 14, 2021, pursuant to CAA Section 114 and in furtherance of such review, EPA sent PCS, by mail and email, an Information Collection Request ("ICR") letter, dated September 13, 2021.[4] Compl. ¶ 14; Answer ¶ 14; CX 5; CX 6; RX 2 at 6-8;[5] RX 10 at 5. The ICR sought from PCS "information on facility operations and emissions from sources . . . including sterilization chamber vents, aeration room vents, chamber exhaust vents, and fugitive emissions." CX 5 at 2. EPA advised PCS that "**[y]ou must complete and return the main questionnaire . . . by November 19, 2021[.]**" CX 5 at 2; RX 10 ¶ 5.

[3] RX 10 is the Affidavit of Gary Cranston, PCS's President and sole shareholder. RX 10 ¶ 1; RX 11 at 7; RX 13; RX 14. The Affidavit is identified in PCS's PHE as dated January 6, 2023, although the document itself is dated January 6, 2022. RX 10 at 5.

[4] Both parties omitted the enclosures to the ICR from the copies of the ICR letter they filed as exhibits. *See* CX 5; RX 2 at 6-8.

[5] RX 2 is the Affidavit of Michael Burns, PE, TURP, an environmental health and safety consultant. RX 2 ¶¶ 1, 2, 4. The Affidavit was submitted with PCS's PHE and identified as dated January 5, 2023. PCS's PHE at 4. In his Affidavit, Mr. Burns avers that he has provided environmental health and safety consulting services to PCS, including regarding its ICR response, "starting in August 2021, to the present." RX 2 ¶ 4.

On November 18, 2021, one day prior to the deadline for responding, PCS's environmental consultant, Michael Burns, sent EPA a request for a 60-day extension of time to respond to the ICR. RX 5; RX 6 at 4-5; RX 2 ¶ 9; RX 2 at 10; RX 10 at 11. EPA replied by email the following day stating that "EPA is not granting any extensions of the November 19, 2021, deadline for response to the information collection request." RX 6 at 4; RX 2 ¶ 10; RX 2 at 17; RX 10 at 18. Later that day, Mr. Burns spoke with EPA staff by telephone, and then sent an email to the EPA stating "Thank you . . . for your time on the phone today. We acknowledge your expressed policy of not granting formal extensions of the deadline. Based on our conversations, it is our understanding that EPA will not be issuing penalties for PCS's failure to fully respond to the ICR as of today's deadline."[6] RX 2 ¶¶ 12, 13; RX 2 at 16; RX 6 at 3.

According to Mr. Burns, after the deadline for responding expired, PCS continued to work to gather its data responsive to the ICR, and he established contact with EPA's outside consultant, Jeremy (Jerry) Guo, hired to review the ICR responses. RX 2 ¶¶ 15, 16. Mr. Burns asserts that Mr. Guo similarly assured him that "EPA would not be issuing penalties" for untimely ICR responses. RX 2 ¶ 16. The record shows that on both January 18, 2022, and January 19, 2022, Mr. Guo emailed Mr. Burns. In the first email, Mr. Guo wrote: "I just called your office phone number and left a voicemail. Please let us know whether you are still interested in submitting your response to the EtO section 114 ICR, as well as any questions you may have that we can help with. We look forward to hearing from you." RX 2 at 15; RX 6 at 2. In the later email, Mr. Guo wrote:

> Please allow me to follow up with you regarding this EtO section 114 ICR as mentioned in my voicemail and email from yesterday. Your response to this ICR is very important for us to understand the operations at this PCS facility. Without your response, the information for PCS may not be accurately reflected in the upcoming rulemaking. If you would still like to share your data with us, please feel free to do so even if the questionnaire is only partially completed. We will take any data that you have entered in the questionnaire for now, and wait for you to fully complete it at your earliest availability and convenience.

RX 2 at 14-15;[7] RX 6 at 1-2.

On February 8, 2022, Mr. Burns replied:

> On behalf of Professional Contract Sterilization, Inc. (PCS), we appreciate your patience and consideration regarding the ICR.
>
> . . . .
>
> Despite these impacts and their limited resources, PCS has made

[6] In his Affidavit, Mr. Burns states that during his conversation, EPA staff "assured me that EPA would not issue penalties to PCS for missing the 11/19/21 deadline but that PCS should do its best to respond to as many ICRs as possible since this information would be useful in promulgating the new regulations related to ETOs." RX 2 ¶ 12.

[7] Mr. Burns asserts in his Affidavit that "[t]his email gave me the impression that EPA was seeking voluntary compliance [as to the ICR] . . . and that no penalties were threatened nor likely[.]" RX 2 ¶ 21.

> some progress in preparing the ICR response. However, due to some confidential business information that has yet to redacted [sic], it is not in a state where it can be released, even as a partial version.

RX 2 at 14; RX 6 at 1.

On March 23, 2022, and April 7, 2022, EPA inspected the PCS facility. Compl. ¶ 15; Answer ¶ 15; CX 15 (EPA CAA Inspection Report finalized March 30, 2022); CX 16 (EPA CAA Inspection Report finalized April 19, 2022); RX 10 ¶ 21. At the conclusion of the April 7, 2022 inspection, EPA advised PCS that it needed to conduct a performance test of its sterilization chambers to ensure it meets the emission requirements of Subpart O.[8] CX 16 at 7; RX 10 ¶ 24.

Also, on or about April 7, 2022, but no later than April 11, 2022, EPA sent PCS a letter, by certified mail, dated April 6, 2022, formally advising it that, pursuant to CAA Section 114(a)(1), the Agency was imposing upon PCS a "Clean Air Act Testing Requirement" ("TR Letter"). Compl. ¶ 16; Answer ¶ 16; CX 7 at 1-2; CX 8. The TR Letter explained that—

> EPA is evaluating emissions of the hazardous air pollutant, ethylene oxide . . . . To do so, EPA is requiring PCS to test emissions from the . . . tri-phase ethylene oxide scrubber and the . . . catalytic oxidizer used to control ethylene oxide emissions from the sterilization and aeration processes.

CX 7 at 1.

Specifically, EPA declared that "**PCS shall develop a <u>performance test plan</u> for EPA approval that describes the following elements in detail and shall subsequently <u>conduct performance testing</u> of ethylene oxide emissions.**"[9] CX 7 at 2. The TR Letter further advised that "**PCS shall prepare for and conduct performance testing according to the following <u>schedule</u>**" which included the requirement that Respondent prepare and submit to EPA for review "a performance test plan" within 30 days of receipt. CX 7 at 4. After the performance test plan was approved by EPA, Respondent was required to complete the testing and submit a test report to EPA within 90 days. CX 7 at 4. The TR Letter advised PCS that "if PCS does not provide the information and perform the testing required in a timely manner, EPA may order it to comply and assess monetary penalties under Section 113 of the [CAA]." CX 7 at 4; *see also* RX 10 ¶ 24.

On April 25, 2022, EPA and PCS held a conference call.[10] Compl. ¶ 17; Answer ¶ 17.

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[8] Records reviewed by EPA during the April 7, 2022 inspection indicated that PCS had previously conducted some performance testing of its sterilization chambers in 1992, 1996, and 2016. CX 16 at 3-7.

[9] The "following elements" identified in the letter detailed the testing and monitoring procedures, and testing methods, to be used regarding the sterilization chamber and aeration room. CX 7 at 2-4.

[10] The record is unclear whether this conference call was the call required by the schedule set out in the TR Letter. CX 7 at 4.

On May 17, 2022, EPA advised PCS by email that it had not received the performance test plan mandated by the TR Letter by the deadline of "on or about May 7, 2022."[11] CX 9; CX 11 at 2. The email also stated that "[i]f PCS requires an extension, please submit a formal written request as soon as possible." CX 9; CX 11 at 2. That same day, in response, PCS emailed EPA a work proposal dated May 6, 2022, from LCH Consulting Associates Inc. ("LCH") to "provide PCS with . . . the above-referenced testing project [to] satisfy the [CAA] Testing Requirements as set forth in the Region 1 Certified Mail letter dated April 6, 2022." CX 9; CX 10 at 1, 3; CX 11 at 2. LCH's proposal indicates that "[b]y the date of June 1, 2022, or 30 days prior to the scheduled date for testing, LCH will submit a test protocol for PCS for certification by signature and retention for submittal to Region 1 EPA." CX 10 at 2.

The next day, May 18, 2022, EPA emailed PCS stating "I believe there has been a misunderstanding. The actual Performance Test Plan (Protocol) was due on or about May 7, 2022." CX 11 at 1. The email continued: "In the event that PCS cannot meet the deadlines set out in the 114, PCS should be requesting an extension in writing prior to not meeting the deadline. It appears this has not been done, so the Performance Test Plan is now overdue." CX 11 at 1.

On May 20, 2022, PCS replied via email. Compl. ¶ 20; Answer ¶ 20; CX 11 at 1. In its reply, PCS stated in full: "As indicated PCS has retained [named consultant] of LCH Consulting Associates LLC to prepare the performance test plan (protocol) addressing the test methods for the emission testing to be tentatively performed in July. He has indicated that should be able to be forward [sic] over to you next week." CX 11 at 1.

On May 24, 2022, PCS emailed EPA to request a one-month extension of the May 7, 2022 deadline for submitting the performance test plan. CX 19 at 1. EPA responded to the extension request by letter dated May 26, 2022. CX 19 at 2. That letter stated that—

> PCS submitted the [extension] request more than two weeks after the deadline EPA established to submit the testing protocol and only after repeated inquiries from EPA staff. In addition, PCS offered no reason for an extension. While EPA acknowledges that the test protocol will now be submitted late, EPA does not approve the request for extension or waive the ability for the agency to seek penalties for any periods of noncompliance with the CAA. We urge PCS to move forward expeditiously with the required testing.

CX 19 at 1. Included with EPA's response letter was a Notice of Violation ("NOV"). CX 19 at 2; CX 18; RX 10 ¶¶ 26, 29. The NOV formally asserted that PCS had failed to timely respond to EPA's September 13, 2021 ICR, and May 7, 2022 TR Letter, and thus "violated and continues to violate Section 114 of the CAA" and the Act's regulations set forth in 40 C.F.R. Part 63, Subparts A and O. CX 18 at 2-3. The NOV further advised PCS that for these violations, EPA could issue an administrative penalty order, seeking penalties up to $25,000 per day per violation

[11] Mr. Cranston avers in his Affidavit that "[u]nfortunately, LCH [the company hired to prepare the performance test plan] did not submit, as PCS understood they would, a request for an Extension of Time for the submittal of a Test Plan/Protocol [] prior to [the] May 7, 2022 deadline." RX 10 ¶ 28.

"which have been substantially increased for inflation as mandated by Congress." CX 18 at 3 (citing 42 U.S.C. § 7413(a), (b), (d); 40 C.F.R. § 19.4).

In response to the NOV and TR Letter, on June 7, 2022, PCS submitted to EPA by email its draft "Subpart O Performance Test Protocol" prepared by LCH. Compl. ¶ 21; Answer ¶ 21; CX 12; RX 10 ¶ 30.[12] About ten days later, on or around June 17, 2022, EPA sent PCS its "Comments on PCS Performance Test Plan" marked "**URGENT LEGAL MATTER REQUIRES PROMPT RESPONSE.**" CX 13 at 1. That letter states in part—

> EPA has reviewed this plan and determined that it is deficient. The Plan lacks much of the information that must be included for the test to be successful. . . .
>
> As directed by EPA's April 7, 2022 Testing Requirement, PCS must respond to EPA's comments and submit an updated Plan no later than 15 days from the date of the receipt of this letter.

CX 13 at 1. Included with the letter, as Attachment A, was EPA's six-page outline of the shortcomings of PCS's draft Performance Test Plan. CX 13 at 3-8.

On July 5, 2022, Respondent submitted its responses to EPA's ICR dated September 14, 2021. CX 14 at 1; RX 7. By separate email sent the same day, LCH submitted a Revised Protocol Plan for testing on PCS's behalf. CX 14 at 1; RX 4. On July 18, 2022, EPA responded to PCS's second draft performance test protocol, and PCS submitted its third draft on July 29, 2022. CX 25 at 1. On August 24, 2022, EPA approved PCS's third draft of the Testing Protocol Plan and advised PCS that it had 15 days to proceed and conduct a pre-site visit. CX 25 at 1. On September 8 and 16, 2022, PCS advised EPA that LCH, its consultant, was no longer available to conduct the pretest site visit and testing, and that it was securing another consultant. CX 25 at 1-2. On December 9, 2022, PCS submitted a fourth version of its Testing Protocol Plan prepared by its new consultant, Montrose Air Quality Services LLC ("Montrose"). CX 25 at 2; CX 23. EPA provided comments on that fourth draft on December 23, 2022, and on January 9, 2023, Montrose submitted to EPA a revised performance test plan. CX 25 at 2. On January 19, 2023, EPA provided its comments on the fifth version of PCS's Testing Protocol Plan, and set a 15-day deadline for response. CX 25 at 2; CX 24. The record does not indicate if and when PCS's final performance test plan was approved and executed at the Facility, nor the specific results thereof, if any. However, in its PHE, PCS represented that its expert witness, Jonathan Shefftz, would testify at hearing that Respondent lacks the ability to pay "either a civil penalty or purchase the equipment the EPA has deemed necessary for PCS's compliance with the Clean Air Act, namely the purchase of new Peak Shaver technological emission control improvements." PCS's PHE at 2; *see also* PCS's PHE at 7; RX 1; RX 10 ¶ 30.[13]

[12] There are multiple paragraphs numbered 29 and 30 in RX 10. This citation is to the first ¶ 30.

[13] This citation refers to the third ¶ 30 in RX 10.

V. COMPLAINANT'S PRIMA FACIE CASE AS TO LIABILITY

Complainant's Motion seeks accelerated decision as to liability only, on both counts of the Complaint. In Count 1, the Agency alleges that Respondent "violated Section 114 of the Clean Air Act" when it "failed to respond to EPA's September 13, 2021, Information Collection Request letter."[14] Compl. ¶¶ 22, 23. Count 2 of the Complaint alleges that Respondent "violated Section 114 of the Clean Air Act" when it "failed to submit a performance test plan to EPA by May 7, 2022, as required by EPA's April 7, 2022, Testing Requirement." Compl. ¶¶ 24, 25. Complainant argues in its Motion that the undisputed material facts support finding Respondent liable for violating CAA Section 114(a), 42 U.S.C. § 7414(a), as alleged in the two counts. Mot. at 7-8.

In its Motion, Complainant asserts that establishing a violation of CAA Section 114 requires it show 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, in a timely manner.

Mot. at 5.

As to Respondent being a "person" under the Act, Complainant notes that CAA Section 302(e) defines a "person" to include a corporation. Mot. at 5 (citing 42 U.S.C. § 7602(e)). Complainant notes that in its Answer, Respondent admitted it was "Professional Contract Sterilization, Inc." Mot. at 5 (citing Answer ¶ 3). Complainant states "Professional Contract Sterilization, Inc." "is a corporation organized under the laws of the state of Massachusetts." Mot. at 5 & n.1 (citing CX 4). Therefore, Complainant concludes, "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." Mot. at 5 (citing 42 U.S.C. § 7602(e); 40 C.F.R. § 22.20(a)).

As to PCS being an "operator," again Complainant states that PCS admitted in its Answer that it operates the Facility at 40 Miles Standish Boulevard, Taunton, Massachusetts. Mot. at 5 (citing Answer ¶ 5). Thus, Complainant avers that "[b]ased on Respondent's own admission, there is no genuine issue of material fact with respect to this element of proof for either of the

[14] The Complaint was filed prior to PCS submitting its response to the ICR. The allegation of the Complaint as to PCS's "failure to respond" to the ICR is hereby deemed amended to conform to the evidence of record to "failure to respond by November 19, 2021," the deadline for responding set forth in the ICR, as Respondent has litigated the amended violation and will suffer no prejudice from such minor amendment. Fed. R. Civ. P. 15(b)(2) ("When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings."); *H.E.L.P.E.R., Inc.*, 8 E.A.D. 437, 450-51, (EAB 1999) (complaint held as "implicitly amended" to conform to evidence presented where respondent did not claim surprise or prejudice); *Ohio Waste Sys. of Toledo*, EPA Docket No. V-W-83 R-066, 1984 WL 50079, at *16 (ALJ, July 2, 1984) (allowing amendment to complaint post-hearing to state violation conforming to the evidence presented as respondent raised no objection and litigated amended issue); *Goodman Oil Co.*, EPA Docket No. RCRA-10-2000-0113, 2003 WL 733882, at *17 (ALJ, Jan. 30, 2003) (citing *H.E.L.P.E.R.*, 8 E.A.D. at 449) (complaint "deemed amended to conform to the evidence at the hearing" since parties fully litigated the issue).

two counts alleged in the Complaint." Mot. at 5 (citing 40 C.F.R. § 22.20(a)).

Complainant claims that proof that PCS is a source of emissions is found among Respondent's own pleadings and exhibits. In support, Complainant notes that "PCS identifies its facility as an 'area source.'" Mot. at 6 (citing RX 7 at 6). Complainant also points out that "PCS admits that it uses 10 tons or more of ethylene oxide per year in sterilization or fumigation operations at the Facility" and that "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." Mot. at 6 (citing Answer ¶ 11; RX 4 at 10, 27). Complainant declares that "[t]herefore, the Facility is considered a source of HAP emissions and is subject to relevant emissions standards." Mot. at 6 (citing 42 U.S.C. § 7412; 40 C.F.R. §§ 63.360, 63.362).

As to the allegation in Count 1 that PCS failed to provide information EPA requested under Section 114, Complainant notes Respondent has admitted that it received EPA's ICR dated September 13, 2021; that the ICR set a deadline for responding of November 19, 2021; and that it responded to the ICR on July 5, 2022, "more than seven months past its due date and only after Complainant initiated this action in June 2022." Mot. at 7 (citing Answer ¶ 14; PCS's PHE at 4, 6 ("Respondent admits it did not respond to EPA's September 13, 2021 CAA Section 114 Information Request . . . by the November 19, 2021 deadline[.]")).

Similarly, as to Count 2, alleging that PCS violated CAA Section 114 by failing to submit its Performance Test Plan to EPA by the deadline set, the Agency advises that—

> 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. 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[.]"

Mot. at 7-8 (citing Answer ¶ 16; PCS's PHE at 8).

Based upon the foregoing, Complainant argues in its Motion 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 of the two counts in a timely manner." Mot. at 8. On this basis, the Agency requests that this Tribunal grant its Motion for Accelerated Decision on Liability. Mot. at 8 (citing 40 C.F.R. § 22.20(a)).

VI. RESPONDENT'S ARGUMENTS IN OPPOSITION

Respondent's Opposition states that "[i]n its Prehearing Exchange filed on January 6, 2023, PCS acknowledged that it did not respond to the EPA's Clean Air Act . . . Section 114 Information Request and Section 114 Testing Requirement by their respective deadlines but did not admit to any purported violation of the CAA." Opp'n at 2. PCS argues that its denials of liability were well founded based upon the facts set forth in—

> the affidavits of Michael Burns and Gary Cranston, and associated exhibits, [averring] how representations made by EPA staff and its agents caused PCS to understand that any untimely submittal of

> information to EPA's ICR and/or request for a test plan would not result in violation of the CAA so as to justify penalization.

Opp'n at 2. Respondent goes on to argue that "EPA's repeated representations that PCS would not be penalized for responding to its Section 114 Information Collection Requests . . . after the sixty . . . day deadline creates a genuine issue of material fact as to whether Respondent violated the Clean Air Act so as to support Count 1 of the Complaint[.]" Opp'n at 4 (citing RX 2; RX 10). PCS further suggests that entry of judgment is unwarranted because "these requests were explained to the EtO industry as an effort by EPA to take into consideration public comments on new EtO regulation rather than a mandatory requirement of all companies" and "PCS endeavored in good faith to respond in a timely fashion." Opp'n at 4-5 (citing RX 10 ¶¶ 5, 6).

As to Count 2, Respondent argues that "there is a genuine issue of material fact as to whether PCS's production of a Proposed Test Plan - 31 days after the May 7, 2022 deadline - is a violation of the CAA where the EPA's subsequent actions in requiring PCS to submit at least three more iterations of the test plan demonstrate that the deadline was arbitrary." Opp'n at 5. It notes that it has taken PCS "over 7 months to date . . . work[ing] in good faith with EPA" to draft the final Test Plan protocol. Opp'n at 5.

VII. DISCUSSION

Section 114(a) of the Clean Air Act reads in relevant part as follows:

> For the purpose (i) of developing or assisting in the development of any implementation plan under section 7410 or section 7411(d) of this title, any standard of performance under section 7411 of this title, any emission standard under section 7412 of this title, . . . (ii) of determining whether any person is in violation of any such standard or any requirement of such a plan, or (iii) carrying out any provision of this chapter . . .
>
> (1) the Administrator may require any person who owns or operates any emission source, . . . who the Administrator believes may have information necessary for the purposes set forth in this subsection, or who is subject to any requirement of this chapter . . . on a one-time, periodic or continuous basis 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[.]

42 U.S.C. § 7414(a)(1). My reading of the statute suggests that proof of a violation of Section 114 may require evidence of several factual elements not identified by Complainant in its Motion, although not necessarily in dispute. All such elements are addressed below.

1. Respondent is a "person" under the CAA. The Clean Air Act defines a "person" as "an individual, corporation, partnership, association, State, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof." 42 U.S.C. § 7602(e). In its Answer, Respondent declined to respond to the allegation that it is a "person" under the Act, and denied the allegation to the extent a response is required. Compl. ¶ 4; Answer ¶ 4. However, as Complainant correctly notes in its Motion, Respondent identified itself in its Answer using the nomenclature of a corporate entity, "Professional Contract Sterilization, *Inc*." Answer at 2, 10 (emphasis added).[15] Additionally, PCS submitted as part of its Supplemental Prehearing Exchange, in support of its claimed inability to pay, its 2017-2021 "U.S. Income Tax Return for an S Corporation," Organizational Chart, Bylaws, and Articles of Organization under the laws of the Commonwealth of Massachusetts, filed on December 12, 1989. PCS's Suppl. PHE at 2, 5; RX 11; RX 13; RX 14. Moreover, in its Motion, Complainant further proffers in support of this element an "Annual Report for Domestic and Foreign Corporations," for "Professional Contract Sterilization," dated March 9, 2022, and a citation to its formal public filing with the Secretary of the Commonwealth's office. Mot. at 5; CX 4. Based on the above, Respondent PCS is found to be a corporation and, as such, a "person" under the Clean Air Act.

2. Respondent owns or operates the Facility. In the Answer, Respondent admitted that "PCS operates a commercial ethylene oxide sterilization facility at 40 Miles Standish Boulevard, Taunton, Massachusetts[.]" Compl. ¶ 5; Answer ¶ 5. Accordingly, it is undisputed that Respondent operates the Facility.

3. The Facility is a "source of emissions." As indicated above, the CAA 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), 7412(a)(3). A "major source" is "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." *Id.* § 7412(a)(1). An "area source" is "any stationary source of hazardous air pollutants that is not a major source." *Id.* § 7412(a)(2). A "hazardous air pollutant" is any chemical listed pursuant to subsection (b) of 42 U.S.C. § 7412. *Id.* § 7412(a)(6).

It is undisputed that ethylene oxide (EtO) is a hazardous air pollutant included on the

[15] As the pages of the Answer are unnumbered, the page numbers cited herein are those reflected in the Tribunal's Case Tracking System.

Initial List of HAPs in CAA Section 112(b). *Id.* § 7412(b)(1). Emissions from facilities utilizing EtO for sterilization are subject to the regulations known as "Subpart O," promulgated by EPA pursuant to the authority granted it under the CAA. 40 C.F.R. pt. 63, subpt. O; National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 62,585 (Dec. 6, 1994). Respondent's Facility *uses* more than 10 tons of EtO per year for sterilization. Compl. ¶ 11; Answer ¶ 11. Still, Complainant concludes that the Facility is an "area source," not a major source of emissions, because EPA accepts that the use of control equipment reduces emissions by 99 percent, and so the facility emits, or "has the potential to emit considering controls," less than 10 tons of EtO per year. Mot. at 6 (citing RX 4). In further support, Complainant points out that Respondent itself identified its Facility as an "area source" in its response to the ICR. Mot. at 6 (citing RX 7). Integrating all of the above, I find that the Facility is an "emissions source" under the CAA.

4. Authorized purpose. Ostensibly, CAA Section 114(a) authorizes EPA to issue information requests only for certain enumerated purposes. Those purposes are very broadly written as follows—

> (i) developing or assisting in the development of [a] any implementation plan under section 7410 or section 7411(d) of this title, [b] any standard of performance under section 7411 of this title, [c] any emission standard under section 7412 of this title,, [sic] or [d] any regulation of solid waste combustion under section 7429 of this title, or [e] any regulation under section 7429 of this title (relating to solid waste combustion),[16]
>
> (ii) . . . determining whether any person is in violation of any such standard or any requirement of such a plan, or
>
> (iii) carrying out any provision of this chapter [Chapter 85] (except a provision of subchapter II with respect to a manufacturer of new motor vehicles or new motor vehicle engines) . . . .

42 U.S.C. § 7414(a). One provision of Chapter 85 (42 U.S.C. §§ 7401-7675), which EPA is authorized to carry out, is "to prescribe such regulations as are necessary to carry out [the] functions under this chapter." *Id.* § 7601(a).

The Complaint states that "Section 114 . . . 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." Compl. ¶ 8. Beyond this, the Complaint does not refer to an enumerated purpose for which the ICR or TR Letter were issued in furtherance. However, the ICR itself states that—

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[16] In the Clean Air Act, Section 7410 mandates the creation of state implementation plans for national primary and secondary ambient air quality standards; Section 7411(d) mandates EPA prescribe regulations for state plans for existing sources of air pollutants for which standards have not been issued; Section 7411 generally applies to standards of performance for new stationary sources of pollutants; Section 7412, as discussed above, defines eleven key terms used in the Act, provides a list of hazardous air pollutants, and requires the promulgation of emissions standards; and Section 7429 requires EPA to establish performance standards for solid waste combustion units. 42 U.S.C. §§ 7410, 7411, 7412, 7429.

> Pursuant to section 114 of the [CAA], [EPA] is collecting information related to hazardous air pollutant emissions at [EtO] commercial sterilization facilities to inform its review of the [NESHAP] for Sterilization Facilities, 40 C.F.R. part 63, subpart O. As part of this effort, the EPA requires your assistance in providing information related to these emissions. The EPA is issuing this section 114 [ICR] to the remaining EtO commercial sterilization companies that were not covered under previous information gathering efforts. Your response will fill important information gaps and allow all EtO commercial sterilization facilities in the U.S. to be represented in the final rulemaking.

CX 5 at 1 (footnote omitted); *see also* CX 5 at 2 (noting the EPA Administrator has authority pursuant to Section 114 to require submission of information for the purpose of developing NESHAP, and that this authority has been delegated to the Director of the Sector Policies and Program Division). Further, the TR Letter requiring the submission of the performance test plan declares that "Section 114(a)(1) . . . gives EPA the authority to require any person who owns or operates any emission source to establish and maintain records, make reports, sample emissions, and provide such other information as may reasonably be required to enable EPA to determine whether such person is in compliance with the CAA and its implementing regulations." CX 7 at 1.

PCS has not specifically challenged the lawful basis upon which EPA issued to it either the ICR or TR Letter in its Answer or Opposition. As to the ICR, in fact, PCS's consultant, Mr. Burns, appeared to acknowledge in his Affidavit that EPA had a proper purpose for the ICR's issuance, advising that "[i]n September 2021, PCS was requested by [EPA] to respond to [the ICR] as part of adopting new regulatory guidelines for ETO to apply to ETO industry standards." RX 2 ¶ 5. Further, Mr. Burns avers that he was told by EPA's consultant, Mr. Guo, that the ICR responses received by EPA would be "reflected in the upcoming rulemaking." RX 2 ¶¶ 20, 21. Because Section 114(a) allows EPA to request information for the purpose of developing an emission standard for a hazardous air pollutant under Section 112, the ICR has an authorized purpose.

With respect to the TR Letter, it itself states explicitly that EPA "is evaluating whether [PCS] is in compliance with the [CAA] and requirements promulgated under the CAA at its facility . . . . In particular, EPA is evaluating PCS's compliance with the Ethylene Oxide Emissions Standards for Sterilization Facilities, found at 40 C.F.R. Part 63, Subpart O . . . ." CX 7 at 1. In addition, Mr. Burns admits that EPA twice inspected the facility, and "warn[ed] PCS as to PCS's compliance with ETO Emissions Standards for sterilization facilities, . . . mentioning potential monetary penalties, lack of qualified stack testing in past, and acknowledging that ETO sterilizations firms are being similarly targeted by EPA." RX 2 ¶ 24. As a result, Mr. Burns's entity (OccuHealth, Inc.) recommended that PCS retain a specialized testing firm with experience "in 40 CFR Subpart O – ETO Emissions Standards and testing for Sterilization Facilities." RX 2 ¶ 25. As CAA Section 114 explicitly authorizes EPA to seek information in furtherance of "determining whether any person is in violation of any such standard or any requirement of such a plan," the issuance of the TR Letter seems well grounded. Based upon the

foregoing, I find that both the ICR and TR Letter were properly issued by EPA as authorized by Section 114(a) of the Act.

5. Authorized Request. CAA Section 114 authorizes EPA to "require" owners and operators of covered facilities to undertake only certain enumerated activities, described as follows:

> (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[.]

42 U.S.C. § 7414(a)(1).

The Complaint does not identify with specificity which subsection of Section 114(a)(1) the ICR or TR Letter fall within. On the other hand, Respondent has not asserted that either the ICR or TR Letter seeks from it something beyond what the CAA permits, and has not characterized either request as "unreasonable."[17] Concerning the ICR, this Tribunal is limited in its review of the requests as the record does not contain the complete ICR, with all enclosures, including the main and supplementary questionnaires. However, among Respondent's exhibits is an unsigned copy of its responses to the ICR. RX 7. It appears that the ICR requested PCS to fill in an electronic form providing basic data on the company, Facility, operations, equipment, and EtO emissions over the prior five years, as well as provide certain diagrams related thereto. RX 7. None of the inquiries in the ICR seem patently unrelated to establishing or reviewing EtO emission standards, or unreasonable. As to the TR Letter, it required emissions testing as to EtO. Such "sampling" from covered facilities is explicitly authorized by CAA Section 114(a)(1)(D). Therefore, I find the information requested in the ICR and TR Letter falls within what EPA may require from a facility as authorized by CAA Section 114(a)(1).

(6) Failure to respond. The final element required to prove a CAA Section 114(a) violation is proof that Respondent failed to respond to the Agency's information requests.

[17] Respondent's Opposition does, however, characterize the ICR as "voluminous" and asserts that it spent a total of 120 hours to complete its responses, rather than the "average" time of 108 hours estimated in the ICR's Paperwork Reduction Act Burden Statement. Opp'n at 4 (citing RX 10 ¶ 7); RX 7 at 3.

Count 1

Respondent "admits it did not respond to EPA's September 13, 2021 CAA Section 114 Information Request . . . by the November 19, 2021 deadline[.]" PCS's PHE at 6. It is undisputed that PCS's responses to the ICR were submitted on July 5, 2022, over seven months past the deadline. CX 14 at 1; RX 7 at 1. Even so, Respondent argues in its Opposition against entry of liability on this count on the basis that the day its responses were due—

> in a conference call between PCS's consultant Michael Burns of Occupational Health and Safety and Steve Fruh and Charlene Spells of EPA's Fuels and Incineration Group, Mr. Fruh and Ms. Spells represented to Mr. Burns that PCS would not be penalized for an untimely submittal. This representation was subsequently reinforced and reiterated by Jeremy (Jerry) Guo, an outside consultant from RTI International, hired by the EPA to review responses to the ICR. These statements and representations indicate that, irrespective of the deadline, EPA did not consider an untimely response to the ICR as a violation of the Clean Air Act so as to justify penalization; and repeatedly represented same to PCS. Accordingly, these statements and representations create a genuine issue of material fact as to whether PCS violated the Clean Air Act and Complainant's Motion for Accelerated Decision on Liability should be denied.

Opp'n at 5 (citations omitted). I disagree: Viewing the statements of EPA employees the light most favorable to Respondent—assuming arguendo that two EPA employees did, in fact, tell Respondent's consultant "Respondent will not be issued a penalty for the late submission of its responses to the Information Collection Request" during a phone conversation that took place on the day those responses were due—does not create a genuine issue of material fact as to Respondent's *liability* for a violation of the Clean Air Act. At best, these statements pertain to penalty mitigation and do not implicate Respondent's liability. As to the later statements of EPA's consultant in January 2022, by the time those emails were sent, the deadline had already lapsed and liability for a Clean Air Act violation had already attached. Thus, these emails also do not nullify Respondent's liability.

The Motion for Accelerated Decision as to liability for Count 1 is **GRANTED**.

Count 2

Respondent admits that "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[.]" PCS's PHE at 8. It is undisputed that Respondent submitted its initial response to the TR Letter on June 7, 2022, a month after the deadline. CX 12; CX 13. Nonetheless, Respondent offers an argument opposing holding it liable at this point on the second count, stating—

> Complainant's Motion for Accelerated Decision as to Count 2 of the Complaint should be denied where there is a genuine issue of material fact as to whether PCS's production of a Proposed Test

> Plan - 31 days after the May 7, 2022 deadline - is a violation of the CAA where the EPA's subsequent actions in requiring PCS to submit at least three more iterations of the test plan demonstrate that the deadline was arbitrary. Indeed, the process of evaluating necessary components of a Test Plan is a time consuming process that has taken over 7 months to date for PCS to work in good faith with EPA which has provided extensive comments and modification to the Test Plan protocol. This circumstance is not a unique one. PCS's good faith efforts to comply with the Section 114 request and the parties ongoing efforts to agree on a Test Plan undermines a finding that a violation of the CAA has occurred and, therefore, EPA's Motion for Accelerated Decision as to Count 2 should be denied.

Opp'n at 5-6. This argument is unavailing.

The back and forth between Respondent and EPA after the Performance Test Plan was submitted has no bearing on the violation. Upon evaluation by EPA, the Performance Test Plan that was submitted 31 days late was characterized as "deficient" and "lack[ing] much of the information that must be included for the test to be successful[,]" thus requiring the comments and modifications mentioned above. CX 13 at 1. EPA asking Respondent to revise the test plan does not demonstrate that the deadline was arbitrary or that no violation of the Clean Air Act has taken place, because even if the June 7, 2022 Performance Test Plan had been accepted by EPA, it would have been late. What it does indicate is that EPA does not accept just *any* performance test plan from a regulated entity: A requested performance test plan must be deemed sufficient or EPA will require revision. Moreover, these rounds of revision were anticipated by EPA. The TR Letter stated that if Respondent received comments on its Performance Test Plan, it had 15 days to "revise and resubmit the performance test plan in accordance with EPA's comments or required changes. EPA shall approve, approve with conditions, or disapprove the revised performance test plan in writing." CX 7 at 4. Therefore, "the parties' ongoing efforts to agree on a Test Plan" does not "undermine a finding that a violation of the CAA has occurred[.]"

The only factor that matters is *when* Respondent sent its first Performance Test Plan to EPA. The TR Letter requesting submission of the Performance Test Plan was clear: "Within 30 days of the date PCS receives this [TR] letter, prepare and email to EPA for review a performance test plan that incorporates the procedures/methods described above." CX 7 at 4. Respondent did not meet this deadline. Nor did Respondent request and receive an extension of this deadline. Even under the interpretation of the facts most favorable to Respondent, Respondent violated Section 114 of the Clean Air Act based upon its untimely response to the TR Letter.

The Motion for Accelerated Decision is **GRANTED** as to liability for Count 2.

VIII. MOTION TO STRIKE

In its Answer, Respondent includes what it identifies as ten "affirmative defenses." *See* Answer ¶¶ 34-43. Those defenses are:

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

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

(3) Any and all alleged acts or omissions concerning Respondent's compliance with Section 114 of the Clean Air Act . . . have not resulted in any economic benefit to Respondent.

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

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

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

(7) Complainant's allegations are barred by laches.

(8) Complainant's allegations are barred by the applicable statute of limitations.

(9) Complainant's allegations are not supported by substantial evidence.

(10) Complainant's penalty assessment constitutes an abuse of discretion.

Answer ¶¶ 34-43.

In its Motion, Complainant seeks to strike Respondent's "10 affirmative defenses," implying that they do not foreclose entry of judgment as to liability at this juncture. Mot. at 8. In support, Complainant declares that Respondent has the burdens of presentation and persuasion for its affirmative defenses and that it was required in its Answer to state the "circumstances or arguments" for its affirmative defenses. Mot. at 8 (citing 40 C.F.R. §§ 22.15(b), 22.20(a), 22.24(a)). It advises that PCS's Answer did not include the required "circumstances or arguments" for its ten affirmative defenses, and more significantly, its Prehearing Exchange only discussed five of the ten defenses, "all of which relate only to penalty mitigation rather than Respondent's liability." Mot. at 8, 12 (citing Answer ¶¶ 34-43; PCS's PHE at 5-6). Complainant concludes that "[b]ecause Respondent has failed to submit necessary evidence or arguments to support its affirmative defenses, Respondent's defenses are improperly pled and should be stricken." Mot. at 8 (citing 40 C.F.R. §§ 22.15(b), 22.20(a), 22.24(a)). Moreover, Complainant contends that "[e]ven 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." Mot. at 3; *see also* Mot. at 12.

In response to Complainant's request to strike its affirmative defenses, Respondent represents in its Opposition that it "will waive the Fourth, Fifth, Seventh, Eighth, and Ninth

Affirmative Defenses asserted in its Answer."[18] Opp'n at 6 n.1. However, Respondent argues that the balance of such defenses should not be stricken because "PCS has demonstrated with its Answer, Pre-Hearing Exchange, and this Opposition that these defenses are properly pled, supported by facts, and are relevant to mitigation of the proposed penalties." Opp'n at 6 (discussing 42 U.S.C. § 7413(e), 40 C.F.R. § 22.15(b)). In support of such penalty mitigation, Respondent advises that it has submitted in its Prehearing Exchange, inter alia, the "expert report of Jonathan Shefftz detailing PCS's inability to pay the proposed penalties and an affidavit of PCS's President, Gary Cranston, providing information regarding PCS's operations which support penalty mitigation pursuant to Section 113(e) of the CAA." Opp'n at 2. Respondent also individually discusses (and bolsters) its arguments as to its First, Second, Third, Sixth, and Tenth Defenses. Opp'n at 7-10.

IX. DISCUSSION

This Tribunal has previously observed—

> As motions to strike are not addressed in the Rules of Practice applicable to this administrative proceeding, federal court practice following the Federal Rules of Civil Procedure ("FRCP") may be looked to for guidance. Motions to strike under FRCP 12(f) are the appropriate remedy for the elimination of impertinent or redundant matter in any pleading, and are the primary procedure for objecting to an insufficient defense. However, Rule 12(f) motions to strike are "generally viewed with disfavor 'because striking a portion of a pleading is a drastic remedy and because it is often sought by the movant simply as a dilatory tactic.'"
>
> As a general matter, pleadings should be treated liberally and a party should have the opportunity to support its contentions at trial. Furthermore, even if the arguments raised by Respondent do not constitute complete defenses to liability, they may raise issues that are relevant to the determination of any penalty. Thus, a motion to strike will not be granted if the insufficiency of the defense is not clearly apparent, or if it raises factual issues that should be determined at a hearing on the merits.

Dearborn Refining Co., EPA Docket No. RCRA-05-2001-0019, 2003 WL 21213218, at *3 (ALJ, Jan. 17, 2003) (Order on Complainant's Motion to Strike Defenses) (citations omitted).

Upon consideration of the record as a whole, this Tribunal does not find sufficient justification for granting Complainant's Motion to Strike Respondent's Affirmative Defenses.

First, as Respondent has waived its Fourth, Fifth, Seventh, Eighth, and Ninth Defenses, Complainant's Motion to Strike is **MOOT** with respect to those five defenses. *See* Opp'n at 6 n.1.

[18] Although phrased in future tense, this Tribunal deems the filing of the Opposition as effectuating PCS's waiver of its Fourth, Fifth, Seventh, Eighth, and Ninth affirmative defenses.

Second, the parties agree that the Respondent's remaining five "affirmative defenses" relate only to penalty, which is not an element of a violation under CAA Section 114.[19] Citing to the discussion of the First, Second, Third, Sixth, and Tenth Defenses in PCS's PHE, Complainant states in its Motion that "Respondent in its Prehearing Exchange only discusses five of those defenses, all of which *relate only to penalty mitigation rather than Respondent's liability*." Mot. at 8 (emphasis added). In its Opposition, PCS declares that its five remaining defenses "were properly pled, supported by facts, *and are relevant to mitigation of proposed penalties*." Opp'n at 6 (emphasis added). As such, Respondent's five remaining defenses have no impact on the findings as to its liability rendered above. Rather, the issue of the appropriate penalty will be ruled upon by this Tribunal in the future after a hearing.

Third, as to Complainant's argument that Respondent has not sufficiently pled or supported its penalty defenses, the Rules of Practice provide that the answer shall state "[t]he circumstances or arguments which are alleged to constitute the grounds of any defense" and "*the basis for opposing any proposed relief*[.]" 40 C.F.R. § 22.15(b). As such, the Rule appears to require a Respondent to provide *less* in support of its opposition to the proposed relief (only "the basis" therefor) than what it requires be provided as to any defense to liability ("the circumstances or arguments in support"). *Id.* Respondent's Answer clearly meets or exceeds this standard as to those five defenses as they relate directly to the penalty criteria applicable here.

As to the criteria for penalty assessment, the CAA provides that—

> In determining the amount of any penalty to be assessed under this section . . . , the Administrator or the court, as appropriate, shall take into consideration (in addition to such other factors as justice may require) the size of the 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 violation as established by any credible evidence (including evidence other than the applicable test method), payment by the violator of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violation. *The court shall not assess penalties for noncompliance with . . . actions under section 7414 of this title, where the violator had sufficient cause to violate or fail or refuse to comply with such subpoena or action.*

42 U.S.C. § 7413(e)(1) (emphasis added).

Respondent's First and Second Defenses assert a lack of harm caused by the violation and, as such, relate to the penalty factor the "seriousness of the violation." The Third Defense

[19] An affirmative defense excuses the respondent's conduct even if the complainant is able to establish a prima facie case, as compared to a general defense which negates an element of complainant's prima facie case. *Donohoe v. Am. Isuzu Motors, Inc.*, 155 F.R.D. 515, 518 (M.D. Pa. 1994). Thus, although labeled as such, many of the defenses raised by Respondent are not technically "affirmative defenses."

asserts a lack of economic benefit, which is an explicitly enumerated penalty factor. The Sixth and Tenth Defenses, characterizing the penalty as excessive, inappropriate, unwarranted and an abuse of discretion, raise issues which fall either within the factor as to "the economic impact of the penalty on the business," the broad factor of "as justice may require," or for consideration under the ultimate sentence of the penalty criteria as to "sufficient cause" for the violation. Therefore, all of these Defenses constitute valid "bases" for Respondent's opposition to the proposed penalty and so are appropriately pled in the Answer.

As to Complainant's allegation that Respondent has not proffered sufficient evidence in support of its defenses, it is true that, in its Opposition, PCS does not point to any specific evidence supporting its First and Second Defenses that its violations caused no harm. Opp'n at 7-8. However, EPA appears to have conceded the absence of harm caused by the violations in that no penalty component for harm was included in the penalty calculations.[20] CX 20. Therefore, additional evidence on this undisputed point would be superfluous.

Likewise, the Agency's penalty calculation indicates that "[n]o economic benefit has been assessed for failure to respond to the reporting requirement." CX 20. Therefore, while Respondent offers RX 1, the report of its financial expert on its inability to pay, and other facts, in support of its Third Defense, this issue, too, appears undisputed. Opp'n at 8.

With regard to its Sixth and Tenth Defenses (excessive, inappropriate, unwarranted penalty, and abuse of discretion), Respondent offers in support a variety of facts such as its small size, lack of prior violations, the adverse impact of the pandemic on its business, inability to pay, etc. Opp'n at 8-10. To buttress these Defenses, it cites among other evidence, its expert witness report on inability to pay (RX 1) and its PHE, which relies upon the Affidavit of its President, Mr. Cranston (RX 10). Opp'n at 8-10 (citing RX 1; PCS's PHE at 6-9). Upon review, the Tribunal concludes that such documents offer a sufficient evidentiary foundation for these Defenses and Respondent may proceed at hearing with these claims challenging the proposed penalty.

Therefore, the Motion to Strike Affirmative Defenses is **DENIED** with respect to the First, Second, Third, Sixth, and Tenth Defenses.

[20] This Tribunal notes, however, that EPA's penalty calculation does identify as a factor in support of the appropriateness of the proposed monetary penalty the "Importance to Regulatory Scheme," presumably of the statutory requirement and/or compliance therewith. CX 20.

ORDER

Based upon the foregoing, Complainant's Motion for Accelerated Decision on liability for Count 1 and Count 2 of the Complaint is hereby **GRANTED**, and its Motion to Strike is found **MOOT** as to Respondent's Fourth, Fifth, Seventh, Eighth, and Ninth Defenses, and **DENIED** as to Respondent's First, Second, Third, Sixth, and Tenth Defenses.

This matter shall be set for hearing to determine the appropriate penalty to be imposed for the violations found.

This Tribunal offers the parties an opportunity to participate in Alternative Dispute Resolution ("ADR") prior to the hearing. If both parties agree, a Neutral may be appointed to conduct ADR in an effort to resolve this matter. The parties are **ORDERED** to confer about this offer of ADR; Complainant shall submit a **Status Report** as to whether the parties have agreed to participate in ADR on or before **September 15, 2023**.

SO ORDERED.

Susan L. Biro
Chief Administrative Law Judge

Dated: September 1, 2023
Washington, D.C.

In the Matter of *Professional Contract Sterilization, Inc.*, Respondent.
Docket No. CAA-01-2022-0059

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Order on Complainant's Motion for Accelerated Decision and to Strike Affirmative Defenses**, dated September 1, 2023, and issued by Chief Administrative Law Judge Susan L. Biro, was sent this day to the following parties in the manner indicated below.

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Dated: September 1, 2023
Washington, D.C.