UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

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

RESPONDENT'S PREHEARING EXCHANGE

Respondent, Professional Contract Sterilization, Inc. ("PCS" or "Respondent") herewith submits the following initial prehearing exchange as directed by the "Prehearing Order," dated August 8, 2022, modified by the Court's "Order Granting Request for an Extension of Time," dated September 7, 2022 and the Court's "Order on Respondent's Request for Extension," dated November 15, 2022, and in accordance with the provisions of 40 C.F.R. § 22.19(a).

I. Respondent's Witnesses

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

a. Gary Cranston
President, Professional Contract Sterilization, Inc.
40 Myles Standish Blvd.,
Taunton, MA 02780

Gary Cranston will testify as a fact witness. Mr. Cranston is PCS's President and will testify about his education and employment background. He will also testify about PCS's operations including, but not limited to, its services, customers, the processes, finances, and staffing at PCS's sterilization facility in Taunton, Massachusetts. He is expected to testify how the COVID-19 Pandemic has impact PCS's operations. He will testify concerning the facts and evidence he has obtained from his decades of experience operating PCS. He is expected to testify

about his experiences in dealing with the U.S. Environmental Protection Agency ("EPA"), Massachusetts Department of Environmental Protection ("MADEP"), and other federal, state, and local regulatory agencies as well as PCS's consultants relative to the subject matter of this litigation. Mr. Cranston will testify about PCS's efforts to comply with the EPA's information requests. Mr. Cranston will testify about PCS's efforts to implement additional pollution control measures at the Taunton facility and the time/costs associated with those measures. Mr. Cranston will also testify as to why PCS does not have the financial ability to pay EPA's proposed penalties. Mr. Cranston will testify about the subjects and issues detailed in his January 6, 2023 affidavit submitted with Respondent's Prehearing Exchange as Exhibit RX 10. Mr. Cranston will testify as to any other matters raised by Complainant's Prehearing Exchange and/or Rebuttal as warranted.

b. Jonathan S. Shefftz
D/B/A JShefftz Consulting
14 Moody Field Road
Amherst, MA 01002

Jonathan Shefftz will testify as an expert witness. His expert report and CV are submitted with this Respondent's Prehearing Exchange as Exhibit RX 1. Mr. Shefftz will testify about his education and employment background, including his expert witness history on similar matters. He is expected to testify about his review of the financial documents and estimated costs for additional compliance equipment and operating costs provided by PCS which are submitted with Respondent's Prehearing Exchange as Exhibits RX 1, 3, 8, 10. He is expected to testify about his experience with and knowledge of EPA's ABEL ability-to-pay computer model. He will testify that in his professional opinion the EPA ABEL ability-to-pay compute model concludes that PCS is projected over the next five years PII 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. Mr.

Shefftz is expected to testify about the conclusions reached in his expert report and the bases thereof. Mr. Shefftz will testify as to any other matters raised by Complainant's Prehearing Exchange and/or Rebuttal as warranted.

c. Michael Burns, PE, TURP
Senior Project Manager, OccuHealth, Inc. ("OHI")
44 Wood Ave.,
Mansfield, MA 02048

Michael Burns, PE, TURP will testify as a fact witness. Mr. Burns is a Senior Project Manager at OHI and will testify about his education and employment background. He will also testify about OHI's provision of environmental, health, and safety ("EHS") services to PCS starting in August 2021 to the present. He will testify about his knowledge of PCS's operations. He is expected to testify about his experiences in dealing with the EPA, MADEP, and PCS relative to the subject matter of this litigation including, but not limited to, his communications with EPA concerning the EPA's September 2021 request for PCS to respond to Information Collection Requests ("ICRs"). He will testify about PCS's efforts to comply with the EPA's ICRs. Mr. Burns will testify about the subjects and issues detailed in his January 5, 2023 affidavit submitted with Respondent's Prehearing Exchange as Exhibit RX 2. Mr. Burns will testify as to any other matters raised by Complainant's Prehearing Exchange and/or Rebuttal as warranted.

Respondent reserves the right to identify additional fact or expert witnesses based upon the content of Complainant's Rebuttal. Respondent also reserves the right to call any witnesses identified by Complainant.

II. Respondent's Exhibits

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

RX #	Description
RX 1	Expert Report of Jonathan S. Shefftz dated January 6, 2023 with attached Curriculum Vitae
RX 2	Affidavit of Michael Burns, PE, TURP dated January 5, 2023
RX 3	PCS Tax Return History Report
RX 4	PCS Test Protocol dated July 5, 2022
RX 5	PCS Request for Extension to ICRs dated November 18, 2011
RX 6	Emails between OHI, PCS, and EPA regarding ICRs November 19, 2021 to February 8, 2022
RX 7	PCS Response to EPA ICRs dated July 5, 2022
RX 8	Anguil Peak Shave Estimate October 17, 2022
RX 9	Curriculum Vitae of Gary Cranston
RX 10	Affidavit of Gary Cranston dated January 6, 2023

PCS explicitly incorporates and reserves the right to utilize exhibits included in Complainant's Prehearing Exchange CX 1-19.

III. Length of Direct Case and Whether Interpreter is Necessary

PCS believes that it can present its direct case in approximately two days. PCS does not anticipate the need for an interpreter.

IV. Copies of Any Documents in Support of the Denials Made in Answer

Count 1 – Failure to Respond to Section 114 Information Request

Para. 22 – Respondent responded to the EPA's September 13, 2021, Information Request Letter on July 5, 2022. RX 7.

Para. 23 - Respondent responded to the EPA's September 13, 2021, Information Request Letter on July 5, 2022. RX 7. Moreover, the evidence demonstrates that the EPA suggested

Respondent would not be found to violate the Clean Air Act and be subject to penalty if it submitting an untimely response to the Information Request. RX 2, RX 6, RX 10.

V. Copies of Any Documents in Support of an Asserted Affirmative Defenses and an Explanation of the Argument in Support of any Such Affirmative Defenses

First Defense

Respondent maintains that any purported violation that serves as the basis for the EPA's Complaint created no danger to health or public safety or human welfare, nor any danger to the environment. EPA's CAA Civil Penalty Calculation Worksheet supports this position where no penalty is assessed for "Actual or Possible Harm (Includes level of violation and sensitivity to environment/toxicity of pollutant)." CX 17.

Second Defense

Amongst the other mitigating factors, the absence of harm has not been adequately considered relative to the proposed penalty assessments. As demonstrated by EPA's CAA Civil Penalty Calculation Worksheet, the EPA has not included "Actual or Possible Harm (Includes level of violation and sensitivity to environment/toxicity of pollutant)" into its penalty assessment. CX 17. Both Count I and Count II concern purely administrative violations against a first-time offender. The absence of harm resulting from these administrative violations should considered in the mitigation of the assessed penalties.

Third Defense

Respondent has received no economic benefit from the alleged non-compliance detailed in Count I or Count II of the Complaint. As is demonstrated in Jonathan Shefftz's report (attached as Exhibit RX 1) the Respondent has been operating at a loss for the past three years.

Sixth Defense

As described in more detail in Section VI, the proposed penalty is excessive, inappropriate and unwarranted, and Complainant has not provided adequate explanation as to how the penalty amount was calculated. Of note, Section VII of the EPA's preliminary statement provides nothing but a vague reference to the framework upon which penalties are assessed and wholly fails to explain what factors were deemed relevant in this present case, what monetary value was apportioned thereto, and what mitigating factors, if any, were considered in assessing the penalties.

Tenth Defense

As described in more detail in Section VI, Complainant's penalty assessment constitutes an abuse of discretion.

VI. All Factual Information that Respondent Considers Relevant to the Assessment of a Penalty and any Supporting Documentation

Respondent contends that Section 113 CAA and the CAA Civil Penalty Policy ("Penalty Policy") as amended by EPA's Penalty Inflation Adjustment Memorandum ("Inflation Adjustment Memo") do not support the level of penalty levied against it. See 42 U.S.C. § 7413(e); CX 1; CX 2.

Count 1 - Failure to Respond to Section 114 Information Request

Respondent admits it did not respond to EPA's September 13, 2021 CAA Section 114 Information Request (Information Request) by the November 19, 2021 deadline but maintains that relevant facts in relation to Section 113 CAA and the Penalty Policy do not support the proposed $60,391 penalty. Pursuant to Section 113(e) of the CAA[1], Respondent states that it is a small

[1] CAA 113(e) requires the EPA, when assessing a penalty, "shall take into consideration...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 credible evidence..., payment by the violator of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violation.

business with only 1-3 part-time and 4-6 full-time employees. See Gary Cranston Affidavit RX 10. Respondent's business has been and continues to be adversely impacted by the COVID-19 Pandemic. Id. It required significant time and resources to respond to the voluminous Information Request. Id. Respondent recognized that it would not be able to respond to the Information Request before the November 19, 2021 deadline and timely requested an extension. RX 2, 5. While the EPA denied the extension request their communications with Respondent and its consultant suggested that the Respondent would not be penalized for an untimely submittal and that Respondent should do its best to provide responses to the Information Requests. Id. From the time of receipt until its response on July 6, 2022, Respondent engaged in good faith efforts to respond to the Information Request. RX 10. Respondent expects its President, Gary Cranston, to provide testimony to support these claims.

Respondent maintains that the $15,000 penalty under the "Importance to the Regulatory Scheme" and $15,000 "Duration Penalty" are excessive where EPA representatives suggested Respondent would not be penalized for an untimely submission, Respondent worked in good-faith to respond, and Respondent has responded to the Information Request. Respondent also notes that the EPA has the wrong date, November 12, 2021, as the start date of the violation. It is undisputed that Respondent had until November 19, 2021 to submit its responses to the ICRs.

It is also important to note that Respondent has no prior non-compliance history. Moreover, as noted in Jonathan Shefftz's report, RX 1, Respondent has been operating PII and does not have the financial ability to pay the proposed penalty as well as the estimated compliance costs of $585,000 to purchase new Peak Shaver technological emission control improvements, plus $40,000 for installation and $30,000 in annually recurring costs for power and water. RX 1, 3, 8, 10.

Finally, Respondent did not derive any economic benefit from its untimely response to the Information Request as it was actively working and incurring the costs to gather the requested information but were unable to do so given PCS's limited resources, personnel, and significant time required to complete the ICRs before the November 19, 2021 deadline.

Count 2 - Failure to Respond to Section 114 Testing Requirement

Respondent admits it did not respond to EPA's April 7, 2022 request for Respondent to submit to EPA a Test Plan/Protocol before the May 7, 2022 deadline but maintains that relevant facts in relation to Section 113 CAA and the Penalty Policy do not support the proposed $40,260 penalty. Pursuant to Section 113(e) of the CAA[2], Respondent states that it is a small business with only 1-3 part-time and 4-6 full-time employees. RX 10. Respondent's business has been and continues to be adversely impacted by the COVID-19 Pandemic. Id. From the time of receipt until its response on May 7, 2022, Respondent engaged in good faith efforts to respond to the request for a Test Plan/Protocol. Id. Respondent expects its President, Gary Cranston, to provide testimony to support these claims.

Respondent maintains that the $15,000 penalty under the "Importance to the Regulatory Scheme" and $5,000 "Duration Penalty" are excessive where Respondent worked in good-faith to respond and has responded to the request for Test Plan/Protocol.

It is also important to note that Respondent has no prior non-compliance history. Moreover, as noted in Jonathan Shefftz's report, RX 1, Respondent has been PII and does not have the financial ability to pay the proposed penalty as well

[2] CAA 113(e) requires the EPA, when assessing a penalty, "shall take into consideration...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 credible evidence..., payment by the violator of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violation.

as the estimated compliance costs of $585,000 to purchase new Peak Shaver technological emission control improvements, plus $40,000 for installation and $30,000 in annually recurring costs for power and water. RX 1, 3, 8, 10.

Finally, Respondent did not derive any economic benefit from its untimely Test Plan/Protocol as it was actively working and incurring the costs to provide the requested information but were unable to do so before the May 7, 2022 deadline.

VII. Detailed Narrative Statement Explaining the Factual and Legal Bases for PCS's Inability to Pay and Documents in Support of Position.

As detailed in Jonathan S. Shefftz's expert report, the calculations generated by the EPA ABEL ability-to-pay compute model conclusively demonstrates that Respondent will not have the financial ability to pay the proposed penalty. RX 1.

Respectfully submitted,

Robert Fasanella
Counsel for Respondent

3/1/2023
Date

CERTIFICATE OF SERVICE

I hereby certify that the forgoing Preliminary Statement, dated March 1, 2023, was sent this day to the following parties in the matter indicated below.

Original by OALJ E-Filing System to:

Mary Angeles, Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
https://yosemite.epa.gov/OA/EAB-ALJ_Upload.nsf

Copy by Electronic Mail to:

Susan L. Biro, Chief Administrative Law Judge
U.S. Environmental Protection Agency
Office of Administrative Law Judges
https://yosemite.epa.gov/OA/EAB-ALJ_Upload.nsf

Jaegun Lee, Attorney-Advisor
U.S. Environmental Protection Agency, Region 1
5 Post Office Square, Suite 100 (Mail Code 04-3)
Boston, MA 02109-3912
Email: Lee.Jaegun@epa.gov
Counsel for Complainant

Dated: March 1, 2023

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

EXPERT OPINION
on
Economic Impact
of
Civil Penalty
and
Compliance Costs

In the Matter of:
Professional Contract Sterilization, Inc.

Submitted on:
January 6, 2023

Expert Report of:
Jonathan S. Shefftz

d/b/a JShefftz Consulting
14 Moody Field Road
Amherst MA 01002

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Curriculum Vitae
(including publications and public presentations for at least the last ten years and testimony history for at least the last four years)

Tables:

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   (Not Necessarily Reflective of PCS's Financial Status)
2. ABEL Model Results with Adjusted Annual Weights

Expert Opinion of Jonathan S. Shefftz

Economic Impact of Civil Penalty and Compliance Costs

January 6, 2023

1. Summary of Opinion

I have been asked to analyze financial economic factors relevant to the assessment of a civil penalty. Specifically, in this report, I address the potential economic impact on Respondent Professional Contract Sterilization, Inc. ("PCS") of the proposed penalty payment and anticipated compliance costs.

Complainant, United States Environmental Protection Agency, Region 1 ("EPA" or "Complainant"), seeks a combined total penalty of $126,781 for the two counts at issue in this matter. PCS also faces compliance costs of $585,000 to purchase new Peak Shaver technological emission control improvements, plus $40,000 for installation and $30,000 in annually recurring costs for power and water..

My opinion is that the U.S. Environmental Protection Agency ("EPA") ABEL ability-to-pay computer model concludes that PCS is projected over the next five years to generate PII pay either a civil penalty or purchase the necessary compliance equipment. I believe that the model's conclusion is reasonable based upon the information that I have been able to review.

I may revise my opinion as additional information becomes available to me or upon the reconsideration of existing information.

2. Bases for Opinion: Professional Expertise and Materials Considered

My opinion is based broadly on my expertise in financial economic analysis, as further detailed in the curriculum vitae included as Attachment A to this report. I hold both undergraduate and graduate degrees with a focus on economics in various contexts, including public policy, public finance, corporate finance, financial economics, and regulatory economics. I have been qualified numerous times as an expert witness on various economics matters – including financial capability, economic benefit, and economic damages – in United States district court trials and hearings, administrative court hearings of the United States Environmental Protection Agency ("EPA"), and state courts trials, on behalf of the United States, state agencies, citizen groups, and members of the regulated community.

My experience with financial analysis of civil penalty issues dates back to 1992, encompassing expert witness casework, computer model development, training of state and federal agency staff, as well as involvement in federal agency public comment, stakeholder input, and peer review processes.

For the assessment of the ability to pay for environmental expenditures and the economic impact of penalty amounts, I have been involved with the periodic revisions and modifications to the EPA's ABEL, INDIPAY, and MUNIPAY ability-to-pay computer models since 1992, first as an employee of the consulting firm Industrial Economics, Incorporated ("IEc"), then from 2006 and into 2017 as a subcontractor to IEc. Both federal and state environmental enforcement staff use these models to assess the ability of companies, individuals, and municipalities to afford penalties, Superfund cleanup costs, and other environmental expenditures. I managed IEc's development (under contract to EPA) of the current versions of these models for the Windows operating system. Over the period from 1992 into 2017, I worked on all aspects of IEc's support to EPA regarding these models, encompassing researching relevant tax code changes, implementing new features, supervising a helpline that assists EPA and state environmental agencies, developing training course materials, and delivering training courses. My intimate familiarity with these models even includes typing in individual formulas for the underlying spreadsheets that perform the models' calculations. I continue into the present to perform case-specific ability-to-pay and economic impact assessments on numerous cases for numerous clients.

Specifically for this case, I have reviewed the financial documentation for PCS, as provided separately by counsel for Respondent.

And as previously mentioned in the beginning of the section, further details on my background and experience follow the main body of this report in the form of my Curriculum Vitae as Attachment A. My Curriculum Vitae also includes a list of my publications and public presentations going back at least ten years, plus a list of the cases in which I have testified going back at least four years.

3. Bases for Opinion: Economic Impact

The EPA ABEL computer model is described by EPA in part in the model's integrated help system under the subsection entitled "Ability to Pay Policy" as follows:

> After providing summary financial statements and analyzing some basic financial ratios that reflect firm liquidity and solvency, ABEL assesses a firm's ability to pay by focusing on projected cash flows. The model explicitly calculates the value of projected, internally generated, cash flows from historical tax information, and compares these cash flows to the proposed environmental expenditure(s). ABEL assumes that the near future will resemble the immediate past. That is, the model projects future cash flows by assuming that the firm will continue to perform financially as it has over the recent past. ABEL's measure of ability to pay is more stringent than measures of cash or liquid assets on hand, but less stringent than the legal liability of the firm's owners.

I provide the ability-to-pay results from the ABEL model based upon two scenarios.

In Table 1, on the following page, I provide the results from ABEL when run applying ABEL's default values. For the inputs, I rely on PCS's Tax Return History Report using the 2018 through 2022 line items for Net receipts, Cost of goods sold, Depreciation, and Ordinary business income (or loss).

As can be seen in the model's output in Table 1, on the following page, ABEL projects at any confidence level (including the 70-percent confidence level that EPA commonly relies on as a benchmark when applying the ABEL model) that PCS PII This is even before the consideration of the civil penalty payment that EPA seeks, or the compliance costs that PCS is anticipated to incur, which comprise $585,000 for equipment, $40,000 for installation, and $30,000 in annually recurring power and water costs.

Table 1

ABEL MODEL RESULTS FROM ALL STANDARD DEFAULT VALUES
(Not Necessarily Reflective of PCS's Financial Status)

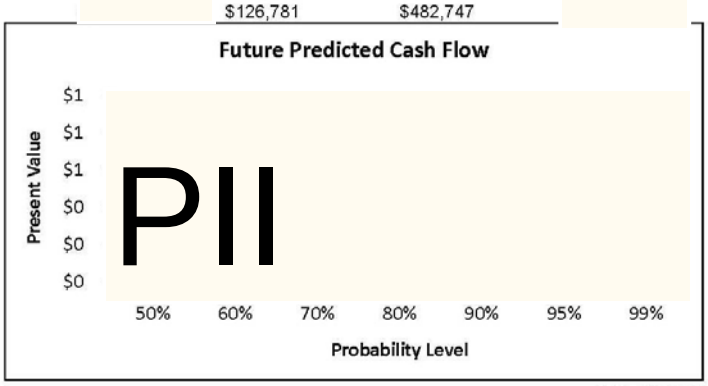
Ability to Pay Analysis

S-Corporation: Tax Form 1120S *Run Name: Baseline*

Penalty Amount:	$126,781 (2023 dollars)	
Reinvestment Rate:		0
Inflation & Discount Rates		2.6% & 7.4%
Weighted-Average Smoothing Constant:		0.3
Marginal Income Tax Rate:		33.1%
No. of Years of Considered Future Cash Flow:		5

Summary of Predicted Cash Flow *all tabular figures expressed in Dollars*

Probability of Cash Flow	Total Generated After-Tax Cash Flow	Penalty Payment	After-Tax Initial Pollution Control Expenditures	Present Value of Annual Pollution Control Costs	Cash Flow Net of Penalty and Compliance Costs
50%	PII	$126,781	$482,747	PII	PII
60%		$126,781	$482,747		
70%		$126,781	$482,747		
80%		$126,781	$482,747		
90%		$126,781	$482,747		
95%		$126,781	$482,747		
99%		$126,781	$482,747		



Conclusions *(All figures are expressed as of 2023.)*

- ABEL estimates PII hat PCS Inc. can currently afford a $126,781 penalty after meeting total Pollution Control Expenditures of $572,445 (see below for detailed breakout of expenditures).
- ABEL estimates a PII hat PCS Inc. could afford to pay a penalty of $0 after meeting meeting total Pollution Control Expenditures of $572,445 (see below for detailed breakout of expenditures).
- This is based only on cash flow the firm is projected to generate in the next 5 years. (Additional ability to pay could follow from an examination of unnecessary expenses, assets unrelated to business operations, and/or other sources.)
- EPA typically employs the 70% probability level for determining ability to pay, but the litigation team must ultimately determine the appropriate cutoff for the case.

PII

Please note that EPA requires respondents to pay civil administrative penalties in full within 30 days of the effective date of the final administrative order, unless a limited exception applies. See Section V. of EPA's "Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action" (June 29, 2015).

PII

A 0.7 smoothing constant is recommended to weight this year more heavily.

Pollution control expenditures include $585,000 for depreciable capital investment, $40,000 for tax-deductible one-time expenditure, $0 for non-tax-deductible one-time expenditure, and $30,000 for annually recurring costs.

Firm = PCS Inc.; Analyst = Jonathan Shefftz, JShefftz Consulting; 1/6/2023 ABEL v. 2022.0.0; p. 1 of 1

Note that the ABEL results as presented in Table 1 have included the following statement that is triggered by ABEL's assessment of PCS's recent financial performance:

PII

A 0.7 smoothing constant is recommended to weight this year more heavily.

For background, ABEL uses a series of weights to derive its annual average of historical cash flow: ABEL does not perform a straight average across all of the historical years, but rather applies a series of weights to increase the importance of more recent years (and hence decrease the important of more distant years). The default value of 0.3 is an input for what ABEL terms the weighted-average smoothing constant, from which ABEL derives a series of annual weights of up to five years (i.e., the maximum number of years for ABEL's financial inputs). Based upon PCI's recent historical performance pattern, the above quoted excerpt means that ABEL has determined that a higher value should be used for the weighted-average smoothing constant so as to apply more weight to the more recent years (and thereby less weight to the more distant years).

Therefore, in Table 2, on the following page, instead of the 0.3 default value, I use ABEL's recommended 0.7 value, as shown in the "Financial Parameters" section toward the top of Table 1.

As with Table 1, ABEL projects in Table 2 that PII This is once again even before the consideration of the civil penalty payment that EPA seeks, or the compliance costs that PCS is anticipated to incur. .

Table 2

ABEL Model Results with Adjusted Annual Weights

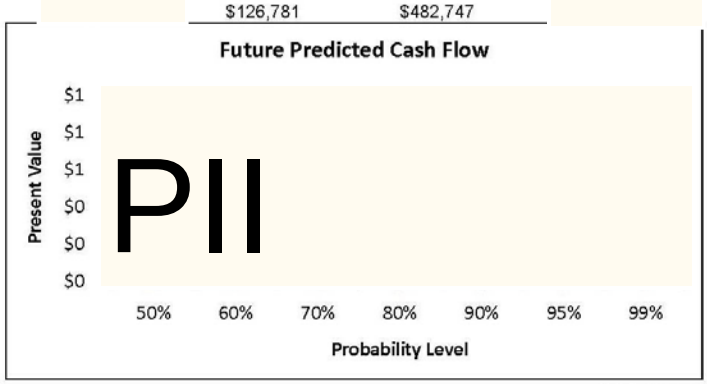
Ability to Pay Analysis

S-Corporation: Tax Form 1120S — *Run Name: More recent yrs weighted more heavily*

Penalty Amount:	$126,781 (2023 dollars)
Reinvestment Rate:	0
Inflation & Discount Rates	2.6% & 7.4%
Weighted-Average Smoothing Constant:	0.7
Marginal Income Tax Rate:	33.1%
No. of Years of Considered Future Cash Flow:	5

Summary of Predicted Cash Flow — *all tabular figures expressed in Dollars*

Probability of Cash Flow	Total Generated After-Tax Cash Flow	Penalty Payment	After-Tax Initial Pollution Control Expenditures	Present Value of Annual Pollution Control Costs	Cash Flow Net of Penalty and Compliance Costs
50%	PII	$126,781	$482,747	PII	PII
60%		$126,781	$482,747		
70%		$126,781	$482,747		
80%		$126,781	$482,747		
90%		$126,781	$482,747		
95%		$126,781	$482,747		
99%		$126,781	$482,747		



Conclusions — *(All figures are expressed as of 2023.)*

- ABEL estimates a PII hat PCS Inc. can currently afford a $126,781 penalty after meeting total Pollution Control Expenditures of $572,445 (see below for detailed breakout of expenditures).
- ABEL estimates PII hat PCS Inc. could afford to pay a penalty of $0 after meeting meeting total Pollution Control Expenditures of $572,445 (see below for detailed breakout of expenditures).
- PII (Additional ability to pay could follow from an examination of unnecessary expenses, assets unrelated to business operations, and/or other sources.)
- EPA typically employs the 70% probability level for determining ability to pay, but the litigation team must ultimately determine the appropriate cutoff for the case.
- For a payment schedule (which does not affect the ability to pay), 4 Quarterly payments (at a 7.4% interest rate) of $0.00 are the equivalent of the lump-sum affordable amount. Please note that EPA requires respondents to pay civil administrative penalties in full within 30 days of the effective date of the final administrative order, unless a limited exception applies. See Section V. of EPA's "Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action" (June 29, 2015).

PII

A 0.7 smoothing constant is recommended to weight this year more heavily.

Pollution control expenditures include $585,000 for depreciable capital investment, $40,000 for tax-deductible one-time expenditure, $0 for non-tax-deductible one-time expenditure, and $30,000 for annually recurring costs.

Firm = PCS Inc.; Analyst = Jonathan Shefftz, JShefftz Consulting; 1/6/2023 — ABEL v. 2022.0.0; p. 1 of 1

4. Qualifications

As previously noted under the section entitled Bases for Opinion, I have separately provided my Curriculum Vitae as this report's Attachment A, which also includes a list of my publications and public presentations going back at least ten years and testimony experience going back at least four years.

I declare under the penalty of perjury that the statements in this report are true and accurate to the best of my knowledge.

Attachment A: Curriculum Vitae

JONATHAN S. SHEFFTZ

d/b/a JShefftz Consulting
14 Moody Field Road
Amherst MA 01002

Mr. Shefftz is an independent consultant who specializes in the application of financial economics to litigation disputes, regulatory enforcement, and public policy decisions. Previously he was a consultant with Industrial Economics, Incorporated ("IEc") from 1992 until 2006 when he moved to western Massachusetts. Mr. Shefftz has extensive experience in settlement and litigation support, and has been qualified as an expert witness in U.S. District Court, a federal agency's Administrative Court, and state courts.

Mr. Shefftz's recent experience includes work in the following areas.

- Calculating the economic damages suffered by companies and individuals from alleged wrongful actions.
- Applying financial economics to civil penalty factors in regulatory enforcement actions.
- Analyzing financial economic issues related to public policy decisions.

Mr. Shefftz has performed this work in a variety of contexts, including expert witness testimony, computer model development, training course delivery, and regulatory review. He has supervised project teams comprising economists, accountants, paralegals, and software developers, as well as worked in parallel with engineers, scientists, lawyers, and lobbyists. His clients have included federal and state governmental agencies, private litigators, and other private-sector entities.

Mr. Shefftz holds a B.A. *magna cum laude* and *Phi Beta Kappa* in Economics and Political Economy from Amherst College, and an M.P.P. degree, with concentrations in Government & Business and Energy & Environmental Policy, from the John F. Kennedy School of Government at Harvard University.

Mr. Shefftz's positions have included Eastern Vice President for the National Association of Forensic Economics, Chair for the Town of Amherst Planning Board, referee for the *Journal of Forensic Economics*, Course Liaison for the "Engineering Economic Decision Making" course at the University of Massachusetts Amherst, Treasurer for the Jewish Community of Amherst, Board of Trustees member for the American Avalanche Association, and Treasurer for the U.S. Ski Mountaineering Association. He is also a member of the Government Finance Officers Association, American Academy of Economic and Financial Experts, and Amherst Area Chamber of Commerce.

Economic Damages

Mr. Shefftz has experience with the following work on economic damages, including expert witness testimony both in deposition and at trial. He has also applied his expertise in unjust enrichment calculation, financial statement analysis, municipal financial assessment, and corporate control / ownership issues in the context of environmental regulatory enforcement cases, as described in a separate section on a successive page.

Business Damages

Mr. Shefftz has modeled companies' cash flows under hypothetical "but-for" states of the world versus actual states of the world to calculate business damages in numerous cases. Sample contexts include allegations by: an engineering firm that lost business to a spin-off competitor, timber companies whose contracts were breached via implementation of Congressional legislation, a furniture company whose joint venture was interfered with by a key customer, a fixed base operator prohibited from selling jet fuel by a municipal airport commission, a brownfields remediation firm whose key principal became incapacitated, a state-chartered joint underwriting association whose servicing carrier incorrectly determined premiums, a transportation company that received contaminated fuel, a social networking website imperiled by a developer's nondelivery, an entrepreneur whose computer code was discarded by a demolition crew, an industrial facility whose environmental control facility was undersized by an engineering consultant, a data center operator whose contracting officer received kickbacks, a whistleblower under the New York False Claims Act, and a sports organization whose apparel licensee breached a contract.

Personal Damages

Mr. Shefftz has assessed lost earnings and household services along with incurred and anticipated medical costs in numerous cases involving wrongful death, personal injury, wrongful termination, estate disputes, credit card interest overcharges, and divorce. Sample contexts include allegations of employment discrimination, medical malpractice, workplace injuries, vehicular accidents, physical assault, retail store accidents, outdoor recreation, below-market earnings, lead poisoning, professional license revocation, violations of the Servicemembers Civil Relief Act, and an arrest instigated by a former spouse.

Economic Damages (continued)

Water Contamination

For a real estate development, Mr. Shefftz analyzed the diminution in value by projecting the groundwater contamination-induced delayed schedule versus the original schedule. On a claim to have developed groundwater assets but for contamination, he testified on the municipality's impaired financial condition at the time. On a class action lawsuit by property owners, he evaluated the defense economist's statistical analysis of property values. On other water contamination lawsuits, he has calculated the damages from the need to switch to alternative sources of water, including a desalination plant, whole-house drinking water systems, and a neighboring utility.

Intellectual Property

For defense counsel in a copyright infringement lawsuit, Mr. Shefftz assessed declarations from the plaintiff's expert economist who asserted that a "companion" book would damage the author of the original series of novels. He also assisted counsel with preparation for trial cross examination.

Computer Model Development

For the U.S. Department of Justice Commercial Litigation Branch, Mr. Shefftz developed a standalone computer model for statutorily determined interest under the Contract Disputes Act.

Financial Factors in Environmental Regulatory Enforcement

Mr. Shefftz has experience with the following work on environmental regulatory enforcement actions brought under the Asbestos Hazard Emergency Response Act (AHERA), Clean Air Act (CAA), Clean Water Act (CWA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Emergency Planning and Community Right-to-Know Act (EPCRA), False Claims Act (FSA), Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Oil Pollution Act (OPA), Resource Conservation and Recovery Act (RCRA), Safe Drinking Water Act (SDWA), Spill Prevention, Control and Countermeasure (SPCC) rule, Toxic Substances Control Act (TSCA), Underground Storage Tank (UST) program, as well as various state statutes. Mr. Shefftz has been qualified as an expert witness on numerous occasions in federal, administrative, and state courts. His clients for this work have included the U.S. Environmental Protection Agency (EPA), U.S. Department of Justice (DOJ), private litigators, state Attorneys General, and defense counsel.

Financial Statement Analysis / Ability-to-Pay / Economic Impact / Corporate Control & Ownership
Mr. Shefftz has examined the tax returns, financial statements, and other financial documentation for individuals, businesses, not-for-profits, municipalities, and all four unincorporated organized U.S. territories, to assess the ability to pay for – and/or economic impact of – sought environmental expenditures, e.g., compliance costs, penalty demands, and cleanup/remediation costs. He has reviewed discovery documents and conducted research in many cases to assess the extent to which subsidiaries can rely on their corporate parents for financial support and the extent to which corporate control of subsidiaries goes beyond that exercised by mere ownership.

Financial Gain / Economic Benefit / Unjust Enrichment
Mr. Shefftz has modeled companies' and municipalities' cash flows under hypothetical full and timely compliance states of the world versus actual delayed compliance states of the world to calculate the economic benefit (i.e., financial gain or unjust enrichment) on numerous enforcement actions. As part of this work, he has estimated the weighted-average cost of capital for a wide variety of companies and industries.

Other Financial Factors in Environmental Regulatory Enforcement Actions
Mr. Shefftz has performed work on other financial factors in regulatory enforcement actions: the "size of violator" penalty element; the relative weight of different financial indicators for establishing deterrence; and, the adequacy of financing plans to ensure environmental compliance.

Computer Model Development, Training, and Support
Mr. Shefftz has managed the development of the current versions of the BEN, PROJECT, ABEL, INDIPAY, and MUNIPAY computer models that U.S. EPA's Office of Enforcement and Compliance Assurance applies to financial economics issues in enforcement actions. He has prepared the models' help systems and training materials, as well as presented training courses and provided related support for federal and state enforcement staff. Mr. Shefftz has also assisted in several U.S. EPA academic peer reviews and public comment processes for the BEN computer model and related economic benefit recapture issues. And he has created versions of the models for other nations: Canada (BEN), Chile (BEN and ABEL), and El Salvador (BEN).

Public Policy

Cost of Capital Estimation
Mr. Shefftz assessed peer reviewer comments and then revised a draft report on cost of capital estimation for water systems. His work included applying the capital asset pricing model to the commercial drinking water industry and correcting for the earlier draft's assumptions regarding capital structure and industry-level business risk.

Financial Assurance
For a state agency, Mr. Shefftz proposed appropriate inflation forecasts and discount rates, drafted a guidance document, and then developed a stand-alone computer model to calculate the net present value of future remediation costs. For EPA's Office of Solid Waste, he provided recommendations on discounting future cleanup costs; for the Office of Site Remediation and Enforcement, he created a computer model to assess the combined affordability of financial assurance and cleanup costs; for another EPA office, he created a spreadsheet model to calculate the insurance and/or trust fund amounts necessary to provide for post-closure care. For the U.S. Department of the Interior's Office of Surface Mining Reclamation and Enforcement, he reviewed other agencies' approaches and developed a spreadsheet model to calculate initial trust fund amounts and then recalculate subsequent years' annual rebalancings to reflect actual returns and additional future costs. For a not-for-profit, he reviewed draft reports on the potential role of financial assurance in the regulation of hydraulic fracturing (i.e., "fracking").

Joint Cost Allocation
For a study of Bureau of Reclamation rate setting for California's Central Valley Project, Mr. Shefftz researched economically efficient methods for allocating water project costs to user classes.

Proposed Legislation
For an industry association, Mr. Shefftz designed and implemented a survey and analyzed its results to predict the impacts of a proposed national lead tax upon lead consumption and dependent industrial sectors. For a national waste management firm, he analyzed the financial impacts of a proposed state tax on hazardous waste land disposal.

Superfund Impacts
Mr. Shefftz examined the Department of Energy SURE model's predictions of economic impacts from Superfund liability and cost allocation reform. At a Superfund site, he critiqued a small city's claims that a proposed contaminated soil cleanup would lead to widespread economic disruptions.

Legislative Review
For the 1990 Clean Air Act amendments, Mr. Shefftz investigated the potential of fuel oxygenation requirements to cause petroleum refinery closures. For the Safe Drinking Water Act, he reviewed EPA's national-level drinking water affordability criteria, assessed their implications for small water systems' finances, proposed alternative criteria, created databases to predict how many systems would be judged unable to afford drinking water rules, evaluated public comments, and drafted report text to respond to a Congressional charge.

Representative Clients

Mr. Shefftz has been retained by the following clients, whether directly as an independent consultant, during his prior employment at Industrial Economics, Incorporated ("IEc"), and/or as an independent consultant via subcontract with IEc.

State Agencies:

California
Connecticut
Illinois
Indiana
Massachusetts
Michigan
New Hampshire
New Mexico
Ohio
Pennsylvania
Texas
Virginia
Washington
Wisconsin

Federal / National Agencies:

U.S. Department of Justice (Civil Division – Commercial Litigation Branch; Environment and Natural Resources Division – Environmental Enforcement Section, Environmental Defense Section)
U.S. Environmental Protection Agency (various Headquarters Offices and Regional Counsels)
U.S. Fish and Wildlife Service (within U.S. Department of Interior)
National Oceanic and Atmospheric Administration (within U.S. Department of Commerce)
Office of Surface Mining Reclamation and Enforcement (within U.S. Department of Interior)
Superintendecia del Medio Ambiente (Chile)
Ministerio de Medio Ambiente y Recursos Naturales (El Salvador)

Industry:

3M Company
Advanced Flow Engineering, Inc.
Bouncing Cranberries LLC
Circle Environmental, Inc.
Country Villa Bay Vista Healthcare Center
CWM Chemical Services, Incorporated
Frasco Fuel Oil
French Heritage, Inc.
Infinity Fluids Corporation
Keystone Automotive Operations, Inc.
Kinder Morgan
National Coating Corporation
Lead Industries Association
MedMal Joint Underwriting Ass'n of RI
Musco Family Olive
Prolerized New England Co., Inc.
Rectrix Aerodome Centers, Inc.
Stebbins-Duffy, Inc.
Taotao USA, Inc.

(In addition to the industry clients listed above, Mr. Shefftz has also performed work on behalf of numerous industry clients and their insurers on economic damages cases, but without any direct interaction with such parties and their insurers or any analytical focus on them.)

Representative Clients (continued)

Citizen Groups:

Advocates for the West
Alabama Environmental Council
Appalachian Mountain Advocates
Appalachian Voices
Biodiversity Conservation Alliance
Black Warrior Riverkeeper
Center for Biological Diversity
Center for Comm. Action & Environ. Justice
Center for Justice
Citizens Against Ruining the Environment
Clean Air Council
Communities for a Healthy Bay
Conservation Law Foundation
Earthjustice
Earthrise Law Center
Ecological Rights Foundation
Environment America Research & Policy
Environmental Advocates of New York
Environmental Defense Center
Environmental Integrity Project
Environmental Law and Policy Center
Environment Texas Citizen Lobby, Inc.
Food & Water Watch
Friends of Lick Creek
Friends of the Lower Keys
Frontier Group
Grand Canyon Trust
Gulf Restoration Network
High Country Conservation Advocates
Hoosier Environmental Council
Idaho Conservation League
Inland Empire Waterkeeper
Inst. for Governance & Sustainable Develop.
Louisiana Bucket Brigade
Louisiana Environmental Action Network
Lower Susquehanna Riverkeeper Association
National Environmental Law Center
National Parks Conservation Association
Natural Resources Defense Council
Newark Education Workers Caucus
Northwest Environmental Defense Center
Ohio Valley Environmental Coalition
Okanogan Highlands Alliance
Olympic Forest Coalition
Orange County Coastkeeper
Oregon Public Interest Research Group
Our Children's Earth Foundation
Pacific Environmental Advocacy Center
PennEnvironment
Potomac Riverkeeper
Prairie Rivers Network
Public Justice
Puget Soundkeeper Alliance
Raritan (NY/NJ) Baykeeper
RE Sources for Sustainable Communities
Respiratory Health Association
St. Bernard Citizens for Environ. Quality
San Antonio Bay Estuarine Waterkeeper
San Francisco Baykeeper
Sierra Club
South River Watershed Alliance, Inc.
Spokane Riverkeeper
Suncoast Waterkeeper
Tampa Bay Waterkeeper
Texas Rio Grande Legal Aid, Inc.
Toxics Action Center, Inc.
Tulane Environmental Law Clinic
United States Public Interest Research Group
Univ. of Denver Environmental Law Clinic
Waste Action Project
West Virginia Highlands Conservancy
Wild Fish Conservancy
WildEarth Guardians
Willamette Riverkeeper

Representative Clients (continued)

Law Firms:

Adler, Cohen, Harvey, Wakeman & Guekguezian
Allyn & Ball, P.C.
Arnold & Porter LLP
Bricklin & Newman, LLP
Brownstein Hyatt Farber Schreck, LLP
Cain, Sherry, Geller & Vachereau
Chihak & Martel
The Collins Law Firm, P.C.
D'Ambrosio Law Offices
Law Offices of John K. Dema, P.C.
Doherty, Wallace, Pillsbury & Murphy
Downey Brand LLP
Frederick, Perales, Allmon & Rockwell, PC
Gallagher & Cavanaugh LLP
German Rubenstein LLP
David S. Hammer, Esq.
George E. Hays, Esq.
Hoffner PLLC
Hunsucker Goodstein PC
Kaplan, Massamillo & Andrews, LLC
Keches Law Group
Keller Rohrback L.L.P.
James E. Kolenich, Esq.
Meryl A. Kukura, Esq.
Lozeau Drury LLP
Mackie Shea O'Brien, PC
Mark, Migdal & Hayden LLC
Meyers Nave
MFI Law Group PLLC
Morrison Mahoney LLP
Law Office of Jennifer F. Novak
Law Office of Michael D. Parker
Pierce Atwood LLP
Plaza Law Group
Law Office of Jacqueline L. Allen
Aqua Terra Aeris Law Group
Bayh, Connaughton and Malone
Brown Legal PLLC
Butler Snow LLP
ChasenBoscolo
The Law Offices of William Chu
Cooper & Lewand-Martin, Inc.
DeCotiis, FitzPatrick & Cole, LLP
DLA Piper
Donovan Hatem LLP
Dreyer Boyajian LLP
Law Office of Austin J. Freeley
The Garcia Law Firm
Gordon Rees Scully Mansukhani, LLP
Hanson Curran LLP
Henrichsen Siegel Moore, PLLC
Hogan Lovells US LLP
Kampmeier & Knutsen PLLC
Kasowitz, Benson, Torres & Friedman LLP
Law Office of David E. Keller
Kirby McInerney LLP
Law Office of Amy Kropke
Kenneth Lieberman, Esq.
Lucentini & Lucentini LLP
Manson Bolves Donaldson Varn
Marr Law Offices
Meyner and Landis LLP
Morrison & Foerster LLP
Motley Rice LLC
Nelson Mullins Riley & Scarborough LLP
Patton Boggs LLC
Edward M. Pikula, Esq.
Powell Environmental Law

Representative Clients (continued)

Law Firms (continued):

Ransmeier & Spellman P.C.
Reardon Law Office LLC
Rubin and Rudman LLP
Ryan & Kuehler PLLC
Ryan Whaley Coldiron Shandy PLLC
Sasson, Turnbull, Ryan & Hoose
Jon L. Schwartz, Attorney at Law, P.C.
Silverstein, Silverstein & Silverstein P.A.
Smith & Lowney, PLLC
Stoel Rives LLP
Todd & Weld LLP
Vorys, Sater, Seymour and Pease LLP
Waltzer Wiygul & Garside LLC
Reed Zars, Esq.
Raymond Law Group LLC
Reed Smith LLP
Law Offices of Russo & Minchoff
Ryan, Ryan, Johnson & Deluca, LLP
Sartini Law, PC
The Schreiber Law Firm
Richard Schwartz & Associates, P.A.
Simonds, Winslow, Willis & Abbott
Steve Harvey Law LLC
Sycamore Law
Van Ness Feldman LLP
Law Offices of Charles G. Walker
Wilson Elser Moskowitz Edelman & Dicker

JONATHAN S. SHEFFTZ

Publications and Presentations

Structural Changes in Interest Rates, paper discussant at Western Economic Association International Conference (on-line), 7/1/22.

Cause and Effect: The Asymmetry in Deducing Effect and Inferring Cause, paper discussant at National Association of Forensic Economics Eastern Meeting (on-line), 2/25/22.

How Good Is My Degree? Economic Damages from False Claims by Colleges, paper discussant at Western Economic Association International Annual Conference (on-line), 6/27/21.

Social Security Losses in Personal Injury, paper discussant at Western Economic Association International Annual Conference (Portland OR), 7/1/16.

The "Loss of Chance" Rule in the Various States, paper discussant at Allied Social Sciences Association Annual Conference (Philadelphia PA), 1/4/14.

Foreign Net Discount Rates: The Case of Undocumented Mexican Workers, paper discussant at Western Economic Association International Annual Conference (Seattle WA), 6/30/13.

Evolving Transition Probabilities and Worklives, paper discussant at Allied Social Sciences Association Annual Conference (San Diego CA), 1/5/13.

Commercial Damages Calculations, panelist at Eastern Economic Association Annual Conference (Boston MA), 3/10/12.

Medical Net Discount Rates: 1980 - 2011, paper discussant at Eastern Economic Association Annual Conference (Boston MA), 3/10/12.

The Value of Future Earnings in Perfect Foresight Equilibrium, paper discussant at Allied Social Sciences Association Annual Conference (Denver CO), 1/8/11.

The Role of the Economic Expert in Litigation Directed at Piercing the Corporate Veil, presentation at Fall Forensic Economics Workshop (Durango CO), 10/8/10.

Alternative Perspectives for Breach-Nonbreach Scenario Specifications in Commercial Litigation, paper presentation at Western Economic Association International Annual Conference (Portland OR), 7/1/10.

Sampling Issues in Commercial Damages Cases, paper discussant at Western Economic Association International Annual Conference (Vancouver BC), 7/1/09.

Net Discount Rates: Does Duration Matter?, paper discussant at Eastern Economic Association Annual Conference (Boston MA), 3/7/08.

Publications and Presentations (continued)

Enforcement Economics: Deterrence, Economic Benefit, & Ability to Pay, presentation at California Environmental Protection Agency State Water Resources Control Board "Enforcenomics" Workshop (Berkeley CA), 1/11/08.

Alternative Focuses for "But-For" Scenario Specification in Commercial Litigation, paper presentation at Western Economic Association International Annual Conference (Seattle WA), 6/30/07.

Expert Witness Role Play, presentation at U.S. EPA 9th Financial Analyst Workshop (Atlanta GA), 5/3/07.

Working with Experts in Environmental Cases: An Expert Economist's Perspective on Expert Testimony, presentation at Public Interest Environmental Law Conference (Eugene OR), 3/2/07.

Alternative Measures and Focuses for Economic Damages Calculations, paper presentation at Eastern Economic Association Annual Conference (New York NY), 2/23/07.

Lost Profit as a Measure of Lost Earning Capacity, panelist at Western Economic Association International Annual Conference (San Francisco CA), 7/7/05

"EPA's Economic Benefit Analysis Policy and Practice," *Natural Resources and Environment*, Fall 2004.

"Taxation Considerations in Economic Damages Calculations," *Litigation Economics Review*, Summer 2004.

Economic Benefit and Wrongful Profits in the Calculation of Penalties for Environmental Violations, presentation to Boston Bar Association Environmental Litigation Committee, 9/23/04.

Business Valuation / Commercial Damages, panelist at Western Economic Association International Annual Conference (Vancouver BC), 7/1/04.

"Wrongful Profits: Setting the Record, and the Concept, Straight," *Environment Reporter*, 1/2/04.

Present Value Sensitivity to Ex Ante vs. Ex Post Perspective, paper presentation at Western Economic Association International Annual Conference (Denver CO), 7/12/03.

Taxation Considerations in Economic Damages Calculations, paper presentation at Eastern Economic Association Annual Conference (New York NY), 2/22/03.

Publications and Presentations (continued)

Economic Benefit from Illegal Competitive Advantage and *Complex Economic Benefit Scenarios*, presentation at U.S. EPA 5th Financial Analyst Workshop (Boston MA), 7/26/00.

Economic Benefit in Wetlands Cases: Financial Analysis Issues, presentation at U.S. EPA Wetlands Enforcement Conference (Alexandria VA), 3/22/00.

Economic Benefit, presentation at U.S. EPA 4th Analyst Workshop (Denver CO), 3/10/99.

JONATHAN S. SHEFFTZ

Testimony History

Amazon.com, Inc. and Amazon Data Services, Inc. v. WDC Holdings LLC dba Northstar Commercial Partners et al. (USDC ED Va), deposition 12/21/22.

Sierra Club, Inc. and Conservation Law Foundation, Inc. v. Granite Shore Power LLC et al. (USDC ED NH), deposition 11/11/20 and courtroom testimony 10/20/22.

Sierra Club et al. v. Midwest Generation, LLC (Pollution Control Board of the State of Illinois), deposition 10/28/21.

San Francisco Baykeeper v. City of Mountain View and *San Francisco Baykeeper v. City of Sunnyvale* (USDC ND Calif.), deposition 8/18/21.

Sierra Club v. Woodville Pellets, LLC (USDC ED Texas), deposition 7/29/21.

Environmental Law & Policy Center and Hoosier Environmental Council v. Cleveland-Cliffs Burns Harbor, LLC and Cleveland-Cliffs Steel (USDC ND Indiana), deposition 7/14/21.

PennEnvironment, Inc., and Clean Air Council v. United States Steel Corporation (USDC WD Penn), deposition 2/10/21.

Ohio Valley Environmental Coalition and The Sierra Club v. Eagle Natrium LLC (USDC ND West Virginia), deposition 8/19/20.

Gary and Anne Childress, et al. v. JP Morgan Chase & Co., et al. (USDC ED North Carolina), deposition 1/24/19 and affidavit 3/17/20.

Seneca Economics and Environment, LLC v. Manson Bolves Donaldson Varn, P.A. (Florida Circuit Court), affidavit 2/26/20.

Permit application for Plaquemines Liquids Terminal, LLC (Louisiana DEQ), affidavit 1/27/20.

Newark Education Workers Caucus and Natural Resources Defense Council, Inc. v. City of Newark et al. (USDC NJ), courtroom testimony 8/15/19.

Wild Fish Conservancy v. Cooke Aquaculture Pacific, LLC (USDC WD Wash), deposition 8/02/19.

Waste Action Project v. Port of Olympia (USDC WD Wash), deposition 7/17/19.

Toxics Action Center, Inc. and Conservation Law Foundation v. Casella Waste Systems, Inc. and North Country Environmental Services, Inc. (USDC NH), deposition 5/15/19.

Suncoast Waterkeeper, Our Children's Earth Foundation, and Ecological Rights Foundation v. City of Gulfport (USDC MD Fla), deposition 5/7/19.

Testimony History (continued)

San Antonio Bay Estuarine Waterkeeper and S. Diane Wilson v. Formosa Plastics Corp., Texas, et al. (USDC SD Tex), deposition 1/16/19.

Infinity Fluids Corporation v. Eemax, testimony at binding arbitration hearing, 12/6/18.

Puget Soundkeeper Alliance v. Seattle Iron & Metals, Corp. (USDC WD Wash), deposition 10/4/18.

Natural Resources Defense Council, Respiratory Health Association, and Sierra Club, Inc. v. Illinois Power Resources, LLC and Illinois Power Resources Generating, LLC (USDC CD Illinois), deposition 6/12/18.

Louisiana Environmental Action Network and Stephanie Anthony v. Exxon Mobil Corp. d/b/a/ ExxonMobil Chemical Co. (USDC MD Louisiana), deposition 10/26/17.

Jeffrey Palmer v. Inn Serve Corporation d/b/a Hampton Inn & Suites, Inn of Daphne, Inc. d/b/a Hampton Inn et al. (Court of Lauderdale County, Mississippi), affidavits 6/2/17 & 10/23/17.

In the Matter of Taotao USA, Inc., Taotao Group Co., Ltd., and Jinyun County Xiangyuan Industry Co., Ltd. (U.S. EPA Administrative Court), deposition 9/26/17, courtroom testimony 10/19/17.

Puget Soundkeeper Alliance v. Louis Dreyfus Commodities LLC et al. (USDC WD Wash), deposition 3/2/16.

Gulf Restoration Network, Louisiana Environmental Action Network, and Sierra Club v. United Bulk Terminals Davant, L.L.C. (USDC ED Louisiana), deposition 5/5/15.

Village of Stillwater, Town of Stillwater, Town of Waterford, Water Commissioners of the Town of Waterford, Village of Waterford, Town of Halfmoon, and County of Saratoga v. General Electric Company et al.; and *Saratoga County Water Authority v. General Electric Company* (USDC ND New York), deposition 4/2/14.

Environment Texas Citizen Lobby, Inc. and Sierra Club v. ExxonMobil Corporation, et al. (USDC SD Tex), deposition 6/1/12, courtroom testimony 2/14/14.

Waste Action Project v. Draper Valley Holdings LLC dba Draper Valley Farms (USDC WD Wash), deposition 1/21/14.

RE Sources for Sustainable Communities v. Pacific International Terminals, Inc. (USDC WD Wash), deposition 4/11/13.

WildEarth Guardians v. Lamar Utilities Board doing business as Lamar Light and Power, and Arkansas Power Authority (USDC Colo), deposition 3/22/13.

Testimony History (continued)

Tina A. Rhodes, Individually and as Administratrix of David C. Rhodes, et al. v. Tyrone Gadsen and GP&T Transport, Inc. (Mass. Superior Court), deposition 12/11/12, courtroom testimony 1/23/13.

Waste Action Project v. Sierra Pacific Industries dba Sierra Junction City Sawmills (USDC WD Wash), deposition 12/28/12.

People of the State of California and The City of San Diego v. Kinder Morgan Energy Partners, L.P., et al. (USDC SD Cal), deposition 4/26/12.

Marvin Evans v. Certain Underwriters at Lloyd's London, KMS Associates, Inc., Greenwich Insurance Company, W. Brown & Associates, Inc. and Hub International Gulf South Limited f/k/a/ Hibernia Rosenthal Insurance Agency, LLC d/b/a Hibernia Rosenthal (Florida Circuit Court), depositions 9/15/11 and 11/15/10.

Bouncing Cranberries LLC v. CommonPlaces eSolutions, LLC, testimony at binding arbitration hearing 8/18/11.

Puget Soundkeeper Alliance v. BNSF Railway Company (USDC WD Wash), deposition 7/7/11.

State of Texas v. BP Products North America Inc. (Texas District Court), deposition 6/7/11.

Chevron Corporation v. Jonathan S. Shefftz (USDC Mass) and *Maria Aguinda et al. v. Chevron Corporation* (Court of Justice of Nueva Loja, Ecuador), deposition 12/16/10.

Elizabeth Russell and Katherine Gates v. Joseph Reilly and James Georges, Executors of the Estate of K. Mildred Dooling, a/k/a Mildred K. Dooling, and Patrick Curtin, Individually and as Trustee of the M.D. Realty Trust (Mass. Superior Court), courtroom testimony 7/21/10.

Hildagarde Bartling, et al. v. Country Villa Bay Vista Healthcare Center, et al. (California State Court), deposition 1/29/10.

Joseph J. Zajac III v. Pamela J. Trueblood, et al. (USDC MD Fla), affidavit 9/16/09.

In the matter of 99 Cents Only Stores (U.S. EPA Administrative Court), courtroom testimony 6/24/09.

U.S. v. Government of Guam (USDC Guam), courtroom testimony 12/9/08 and 4/13/09.

U.S. v. James and Nancy Oliver d/b/a Safety Waste Incineration (USDC Alaska), courtroom testimony 3/25/09 and 3/27/09.

In the matter of Valimet, Inc. (U.S. EPA Administrative Court), courtroom testimony 12/10/08.

Testimony History (continued)

Rectrix Aerodome Centers, Inc. v. Barnstable Municipal Airport Commission, et al. (USDC Mass), deposition 12/2/08.

State of Ohio v. The Shelly Holding Company et al. (Franklin County Municipal Court), depositions 7/30/08 and 9/19/08, courtroom testimony 10/16/08 and 10/17/08.

In the matter of Lowell Vos Feedlot (U.S. EPA Administrative Court), courtroom testimony 9/17/08.

French Heritage, Inc. v. Ethan Allen, Inc. (Connecticut State Court), deposition 6/28/06 and 6/29/06.

Oregon Public Interest Research Group, Diane Heintz, and Rena Taylor v. Pacific Coast Seafoods Company, Pacific Surimi Joint Venture, LLC, Pacific Surimi Co., Inc., and Dulcich Inc. d/b/a Pacific Seafood Group (USDC Oregon), deposition 4/18/06.

In the matter of Rizing Sun LLC (U.S. EPA Administrative Court), courtroom testimony 2/7/06.

State of Ohio v. Container Recyclers, Inc. (Franklin County Municipal Court), deposition 4/1/05.

In the matter of Vico Construction Corporation and Smith Farm Enterprises (U.S. EPA Administrative Court), courtroom testimony 6/20/02 and 10/8/03.

U.S. v. The New Portland Meadows, Inc. (USDC Oregon), courtroom testimony 5/20/03.

In the matter of Vico Construction Corporation and Amelia Venture Properties (U.S. EPA Administrative Court), courtroom testimony 1/14/03.

United States Public Interest Research Group, Stephen E. Crawford, and Charles Fitzgerald v. Heritage Salmon, Inc.; U.S. PIRG et al. v. Stolt Sea Farm, Inc.; U.S. PIRG et al. v. Atlantic Salmon of Maine LLC (USDC Maine), deposition 6/5/01, courtroom testimony 10/15/02.

U.S. v. Murphy Oil USA, Inc. (USDC WD Wis), deposition 4/24/01.

U.S. v. Royal Oak Enterprises, Inc. (USDC ED Va), depositions 3/22/00 and 5/19/00.

In the matter of Titan Wheel Corp. of Iowa (U.S. EPA Administrative Court), affidavit 11/24/99.

U.S. v. Gulf States Steel, Inc. (USDC ND Ala), affidavit 12/30/98, deposition 10/22/99.

U.S. v. Koch Industries, Inc. (USDC ND Okla and SD Tex), depositions 5/24/99 and 6/1/99.

State of Wisconsin v. I-K-I Manufacturing Company, Inc., deposition 4/13/99.

U.S. v. Borden Chemicals & Plastics (USDC MD La), deposition 2/5/98.

State of New Hampshire v. Johnson Products, Incorporated, deposition 2/3/98.

Testimony History (continued)

In the matter of EK Associates, L.P., d/b/a EKCO/GLACO, and EK Management Corporation (U.S. EPA Administrative Court), courtroom testimony 8/14/97.

U.S. v. Smithfield Foods, Inc., et al. (USDC ED Va), deposition 7/9/97.

U.S. v. Nucor Corporation (USDC ND Ala), deposition 6/12/97.

U.S. v. U.S. Metallics, Inc., and Town of Onalaska, Wis. (USDC WD Wis), affidavit 10/21/96.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

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

AFFIDAVIT OF MICHAEL BURNS, PE, TURP

I, Michael Burns , attest to the following facts:

1. I am a Senior Project Manager at OccuHealth Inc. ("OHI"), which provides environmental health and safety (EH&S) consulting services for industrial, commercial and municipal clients throughout New England. I have been employed at OHI since March 1994. I am a Professional Engineer (PE) in the Commonwealth of Massachusetts, with a discipline in Mechanical Engineering, and I am certified by the Massachusetts Department of Environmental Protection (MADEP) as a Toxic Use Reduction Planner. I have a BS degree in Mechanical Engineering from Northeastern University, Boston, MA, graduating in 1987.

2. I have over thirty-five (35) years of experience as an EH&S consultant. My experience includes Environmental Protection Agency (EPA) Emergency Planning and Community Right-to-know Act (EPCRA) Toxics Release Inventory (TRI, Form R) reporting and EPCRA TIER 2 Reporting, MADEP Toxics Use Reduction Act (TURA) Reporting & Planning, MADEP Air Emissions Reporting, Industrial Hygiene, Indoor Air Quality (IAQ) and EHS Compliance Auditing. I am required to take continuing education courses to maintain my certifications & licenses.

3. While at OHI, I have been a subcontractor, providing part-time Industrial Hygiene and Health & Safety Consultant services at a pharmaceutical research facility since from 1999 to the present. Prior to that I provided similar services to a large manufacturing facility from 1995 to 2002. Prior to that I was a Project Manager for Certified Engineering and Testing (CETCO) which became Levine Fricke/Recon from 1987 to 1994.

4. Through OHI, I provided EHS Consulting services to Professional Contract Sterilization Inc. (PCS), starting in August 2021, to the present. During this time, I provided EPA EPCRA TRI related consulting services for PCS's Ethylene Oxide & Ethylene Glycol operations during 2019 – 2021. I also provided similar consulting services related to MADEP TURA Form S Reporting for the years 2019 – 2021. Lastly, I also provided consulting services in support of PCS's response to an EPA Information Collection Request (ICR).

5. In September 2021, PCS was requested by the United States Environmental Protection Agency (EPA) to respond to Information Collection Requests (ICRs) as part of adopting new regulatory guidelines for ETO to apply to the ETO industry standards. See Exhibit 1.

6. According to the published instructions that accompanied the ICR, the EPA states that "the average public reporting and recordkeeping burden for this collection of information is estimated to be approximately 108 hours per response."

7. EPA set a deadline of 11/19/21 for companies to respond to the ICRs.

8. During the years 2020 through 2022, PCS, like many similar companies and industries, was confronted with substantial losses of employees, resources and income due to conditions associated with the COVID-19 pandemic. PCS established strict restrictions on visitors at their facility.

9. PCS timely requested an Extension of time to complete the EPA ICRs. On behalf of PCS, I requested in writing a 60-day Extension of the 11/19/21 submittal deadline on 11/18/21 to Charlene Spells, of EPA. (See Exhibit 2); see also Exhibit 3 (email chain). The letter and email cover were sent by email and overnight mail service.

10. Ms. Spells responded to the formal Extension by stating: "As we have responded to other requests, EPA is not granting any extensions of the November 19, 2021, deadline for response to the information collection request." (See Exhibit 3-email dated 11/19/21).

11. The same day I sent an email reply and left two voice mail messages seeking clarification of these messages and to discuss our request for an extension to determine if EPA would issue any penalties to PCS if it failed to provide answers to the ICRs by the 11/19/21 deadline. (See Exhibit 3 – email dated 11/19/21).

12. Later that same day, 11/19/21, I had a phone call with Ms. Spells and Steve Fruh, who also worked for EPA in the Division responsible for collecting information related to the ICRs. During this conversation, Ms. Spells and Mr. Fruh 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.

13. I followed up to that call with an email to Ms. Spells and Mr. Fruh in which I stated, "Thank you Steve & Charlene for your time on the phone today….. 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." (See Exhibit 3 Email from M. Burns to Ms. Spells dated 11/19/21).

14. PCS reported to me that they continued to work on responding to the ICRs despite missing the 11/19/21 deadline but struggled to do so given the limited resources and personnel that PCS had as a result of the COVID-19 pandemic.

15. I kept in contact with PCS and EPA and communicated to EPA that PCS was having difficulties with the detailed and laborious ICRs but was still working on the providing the information.

16. During this time, I was in contact with Jeremy (Jerry) Guo, an outside consultant, from RTI International, hired by EPA to review the ICRs. Mr. Guo assured me that despite not meeting the 11/19/21 deadline, EPA was still interested in the information, that PCS should do its best to respond fully to the ICR questionnaire and that EPA would not be issuing penalties for failure to respond timely to the 11/19/21 deadline. See Exhibit 3.

17. In a January 18, 2022 email Mr. Guo, stated to me: "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." (See Exhibit 3- Email from Jeremy Guo to Mike Burns dated 1/18/22).

18. This email gave me the impression that the submission of the ICR information was more voluntary rather than mandatory – which reinforced my understanding that PCS would not be penalized for missing the 11/19/21 deadline.

19. On 1/19/22, I informed PCS of the voicemail and email that I received from Mr. Guo, and recommended that I get back to Mr. Guo and inform him and EPA of the status of the responses to the ICRs.

20. Later the same day on 1/19/22, I received another email from Mr. Guo which stated:

> "Hi Mike, 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. Please do not hesitate to let us know if you have any questions, comments or concerns. Thank you and best regards, Jerry." See Exhibit 3.

21. This email gave me the impression that EPA was seeking voluntary compliance, and the information that PCS could provide to EPA for the rulemaking update to the ETO would be helpful, but not essential and not necessary to be fully complete and that no penalties were threatened nor likely from PCS not providing the ICR responses as of the 11/19/21 deadline.

22. Nevertheless, I passed along the email promptly the next morning, 1/20/22, to PCS, who continued to work on gathering the requested information.

23. On 2/8/22 I sent a follow up email to Mr. Guo where I stated:

"Jerry, Thank-you for your call & emails from January 18 & 19, 2022. On behalf of Professional Contract Sterilization, Inc. (PCS), we appreciate your patience and consideration regarding the ICR. As described in previous communications, PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic. Despite these impacts and their limited resources, PCS has made some progress in preparing the ICR response. However, due to some confidential business information that has yet to redacted, it is not in a state where it can be released, even as a partial version. These efforts are ongoing." (See Exhibit 3 Email from Mike Burns to Jerry Guo dated 2/8/22).

24. It is my understanding that, on 3/23/2022 and again later on 4/7/2022 EPA conducted an inspection of the PCS facility. EPA requested several documents and records be supplied by email as soon as possible including stack testing going back to 1990. Also, EPA hand delivered a report dated 4/7/22 focused on specific aspects of 40 CFR Subpart O specifically warning PCS as to PCS's compliance with ETO Emissions Standards for sterilization facilities, and mentioning potential monetary penalties, lack of qualified stack testing in past, and acknowledging that ETO sterilizations firms are being similarly targeted by EPA.

25. On 4/11/22 OHI recommended that PCS seek specialized testing firms that have more experience in 40 CFR 63 Subpart O – ETO Emissions Standards and testing for Sterilization Facilities.

26. It is my understanding that, on May 26, 2022, EPA issued a Notice of Violation to PCS for its failure to respond to the ICR for which it assessed a fine for $60,391.

27. It is my understanding that, on July 5, 2022, PCS submitted its responses to the ICR to EPA.

I swear under pains and penalties of perjury that the above-stated facts are true and accurate to the best of my personal knowledge.

Michael Burns, PE, TURP
OccuHealth, Inc.

EXHIBIT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

September 13, 2021

Mr. Gary Cranston
President
Professional Contract Sterilization, Inc.
40 Myles Standish Boulevard
Taunton, MA 2780

Dear Mr. Cranston,

Pursuant to section 114 of the Clean Air Act (CAA), 42 U.S.C. §7414(a), the U.S. Environmental Protection Agency (EPA) is collecting information related to hazardous air pollutant emissions at ethylene oxide (EtO) commercial sterilization facilities to inform its review of the National Emission Standards for Hazardous Air Pollutants (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 information collection request (ICR) to the remaining EtO commercial sterilization companies that were not covered under previous information gathering efforts.[1] 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.

Specifically, we are collecting information regarding EtO commercial sterilization operations at the facilities listed below and wholly owned by Professional Contract Sterilization, Inc., as well as any EtO commercial sterilization facilities wholly owned by Professional Contract Sterilization, Inc. that are not included on this list:

Facility	Street Address	City	State
Professional Contract Sterilization	40 Myles Standish Boulevard	Taunton	MA

The current section 114 ICR consists of a main questionnaire and three (3) supplements in the form of Microsoft® Excel workbooks. The supplements only need to be used if additional space is needed. The Instructions Document, in the form of a Microsoft® Word file, includes

[1] On December 9, 2019, the EPA issued a section 114 questionnaire to 9 companies in the EtO commercial sterilization source category. While these data identified potential process controls and operational practices that may reduce the amount of EtO released, only a portion of the facilities in the source category was represented.

procedures for providing and submitting data and documents requested in this ICR. **You must complete and return the main questionnaire, along with any supplements, by November 19, 2021, following the procedures specified in the Instructions Document.** Please download the workbooks and Instructions Document at: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities. If there is a facility on this list not wholly owned by Professional Contract Sterilization, Inc., please indicate that in the response letter. A completed survey is not required for that facility.

This ICR is designed to collect information on facility operations and emissions from sources at EtO sterilization operations including sterilization chamber vents, aeration room vents, chamber exhaust vents, and fugitive emissions. Please note that emission data provided under section 114 of the CAA is not entitled to confidential treatment under 40 C.F.R. Part 2.[2] If there is any facility operations information, other than emission data, that you would like to claim as confidential business information (CBI), please follow the Instructions Document to ensure appropriate handling and submission of your response.

You are required to return all requested information to the EPA on or before the schedule due date specified in this letter. More information about this ICR is provided in the following enclosures:

Enclosure #	Description
Enclosure 1	EPA's Information Gathering Authority Under Section 114 of the Clean Air Act
Enclosure 2	Disclosure of Emissions Data Claimed as Confidential Under Sections 110 and 114(c) of the Clean Air Act
Enclosure 3	Summary of Procedures for Safeguarding Clean Air Act Confidential Business Information
Enclosure 4	Designation of Authorized Representative for Standards of Performance for New Stationary Sources (Section 111), National Emission Standards for Hazardous Air Pollutants (Section 112), Solid Waste Combustion (Section 129), and Federal Ozone Measures (Section 183)

This section 114 ICR is one step in an established public process for collecting foundational information as part of the NESHAP reviews. The public and stakeholders will continue to have an opportunity to comment on the EtO commercial sterilization NESHAP review in the future, including a formal notice-and-comment period on any proposed action.

CAA section 114(a) authorizes the Administrator of EPA to require the submission of information, including information from an owner or operator of an emission source for the purpose of developing or assisting in the development of NESHAP under CAA section 112. This authority has been delegated to the Director of the Sector Policies and Programs Division in the U.S. EPA Office of Air and Radiation, Office of Air Quality Planning and Standards.

Thank you for your assistance in this effort. Your response will provide comprehensive information about the EtO commercial sterilization source category, which will lead to a more

[2] For additional information on emission data, please see 40 C.F.R. §2.301 and Enclosure 2.

effective rulemaking. If you have questions regarding this ICR, please contact Charlene Spells in the EPA's Fuels and Incineration Group at 919-541-5255 or Spells.Charlene@epa.gov.

Sincerely,

Penny Lassiter
Director
Sector Policies and Programs Division

4 Enclosures

cc: Deborah Szaro, Acting Regional Administrator, U.S. EPA Region 1
Lynne Hamjian, U.S. EPA Region 1
Glenn Keith, Massachusetts Department of Environmental Protection

EXHIBIT 2

OHI
Occupational Health & Safety •Environmental Consultants

OccuHealth, Inc.
44 Wood Avenue
Mansfield, MA 02048

Tel. (800) 729-1035
(508) 339-9119
Fax (508) 339-2893
m_burns@occuhealth.com

November 18, 2021

Ms. Charlene Spells
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 2771

Re: Professional Contract Sterilization, Inc.
40 Myles Standish Blvd., Taunton, MA (PCS)
Information Collection Request (ICR), dated September 13, 2021

Dear Ms. Spells:

On behalf of Professional Contract Sterilization , Inc, Taunton, MA (PCS), please accept this formal request for a 60-day extension of the November 19, 2021 submittal deadline listed in the above-referenced ICR.

PCS is a small business, with fewer than ten employees. They are currently dealing with a manpower shortage and end-of-the-year production demands. They do not have the resources to dedicate the necessary personnel to extract, gather, review, prepare and compile the extensive documentation listed in the ICR. Their staff is approximately 50% of pre-COVID levels.

Furthermore, in response to the ongoing COVID-19 pandemic, PCS is currently restricting access to visitors; thus precluding the use of outside consultants and/or administrative support to assist with the ICR.

Thank you for your consideration in this matter. We respectfully request a confirmation of receipt of this response.

OCCUHEALTH, INC

Michael J. Burns, P.E.
Senior Project Manager

cc: Gary Cranston, Professional Contact Services Inc.
Robert A. Fasanella, Esq., Rubin and Rudman LLP

Mike Burns

From: Mike Burns
Sent: Tuesday, November 23, 2021 1:35 PM
To: Sue Hamilton
Subject: RE: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Thanks Sue
That address was directly of the EPA web page…..specifically stating to direct all written replies there

---

From: Sue Hamilton <shamilton@occuhealth.com>
Sent: Tuesday, November 23, 2021 12:23 PM
To: Mike Burns <mburns@occuhealth.com>
Subject: Fwd: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Get Outlook for iOS

From: UPS <pkginfo@ups.com>
Sent: Tuesday, November 23, 2021 10:33 AM
To: Results
Subject: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Hello, your package has been delivered.
Delivery Date: Tuesday, 11/23/2021
Delivery Time: 10:30 AM

Experience UPS My Choice® Premium Today
Be in total control of how, when and where your packages are delivered.
Upgrade to Premium Now

Set Delivery Instructions

Manage Preferences

View My Packages

OCCU HEALTH, INC.

Tracking Number:	1ZA667E80198960042
Ship To:	US EPA OFFICE-AIR QUALITY PLANNING 4930 OLD PAGE RD DURHAM, NC 27703 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	0.0 LBS
Reference Number:	PCS ICR EXT. LTR

 Download the UPS mobile app

EXHIBIT 3

From: Mike Burns <mburns@occuhealth.com>
Sent: Tuesday, February 8, 2022 1:56 PM
To: Guo, Jeremy J (Jerry) <jjg@rti.org>
Cc: gcranston@pcsinc.org; Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen <ksschaffner@rti.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: [EXTERNAL] RE: Information Collection Request (ICR) for Professional Contract Sterilization, Inc, Taunton, MA

Jerry,

Thank-you for your call & emails from January 18 & 19, 2022.

On behalf of Professional Contract Sterilization, Inc. (PCS), we appreciate your patience and consideration regarding the ICR.
As described in previous communications, PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic.
Despite these impacts and their limited resources, PCS has made some progress in preparing the ICR response.
However, due to some confidential business information that has yet to redacted, it is not in a state where it can be released, even as a partial version.

This efforts are ongoing.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Guo, Jeremy J (Jerry) <jjg@rti.org>
Sent: Wednesday, January 19, 2022 8:10 PM
To: Mike Burns <mburns@occuhealth.com>
Cc: gcranston@pcsinc.org; Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen

<ksschaffner@rti.org>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization, Inc, Taunton, MA

Hi Mike,

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. Please do not hesitate to let us know if you have any questions, comments or concerns.

Thank you and best regards,

Jerry

From: Guo, Jeremy J (Jerry)
Sent: Tuesday, January 18, 2022 13:06
To: mburns@occuhealth.com
Cc: Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen <ksschaffner@rti.org>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Hi Mike,

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.

Thank you and best regards,

Jerry

Jeremy J (Jerry) Guo

Air Quality Engineering
RTI International
Phone: (919) 541-8836
Email: jjg@rti.org

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Tuesday, January 18, 2022 8:26
To: Guo, Jeremy J (Jerry) <jjg@rti.org>
Cc: Schaffner, Karen <ksschaffner@rti.org>; Witt, Jon <Witt.Jon@epa.gov>
Subject: FW: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

As requested.

Charlene E. Spells
U.S. EPA

OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Friday, November 19, 2021 4:47 PM
To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Thank you Steve & Charlene 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.

PCS will continue to work on the ICR and will provide a response in a timely fashion with periodic updates over the next few weeks.

Thank your

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Friday, November 19, 2021 1:03 PM
To: Mike Burns <mburns@occuhealth.com>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Mr. Burns,

My apologies for the confusion. The recall was an error on my part. The information in the email is correct.

Charlene E. Spells
U.S. EPA
OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Friday, November 19, 2021 12:30 PM
To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Ms. Spells
We are in receipt of your email (below) stating that "EPA is not granting any extensions of the November 19, 2021 deadline".
We are also in receipt of the attached email, RECALLING said email.

I left (2) voice mail messages this morning seeking clarification of these messages and to discuss our request.

Please advise a good time to speak on this matter today.
I can be reached at 508-339-9119x214.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Friday, November 19, 2021 7:20 AM
To: Mike Burns <mburns@occuhealth.com>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Mr. Burns,

Thank you for your November 18, 2021, letter requesting an extension to complete the section 114 survey related to hazardous air pollutants at ethylene oxide (EtO) commercial sterilization facilities. As we have responded to other requests, EPA is not granting any extensions of the November 19, 2021, deadline for response to the information collection request.

If you have specific questions about completing the section 114 survey, please do not hesitate to contact me.

Regards,
Charlene E. Spells
U.S. EPA
OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Thursday, November 18, 2021 3:40 PM

To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Ms. Spells

On behalf of Professional Contract Sterilization , Inc, 40 Myles Standish Blvd., Taunton, MA (PCS);
Please accept the attached formal request for a 60-day extension of the November 19, 2021 submittal deadline listed in the above-referenced ICR.

PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic.
Please refer to the attached letter for further details.

Thank you for your consideration in this matter.
We respectfully request your confirmation and acknowledgement of this request.

A hard copy will be sent via overnight service.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

Form **1120-S** | **Tax Return History Report Page 1** | **2021**

Name

PII

Employer Identification Number

PII

	2017	2018	2019	2020	2021	2022
Net receipts	PII	PII				
Cost of goods sold						
Gross profit						
Gross profit percentage						
Other income (loss)						
Total income (loss)						
Officer compensation						
Salaries and wages						
Bad debts						
Taxes and licenses						
Interest						
Depreciation						
Depletion (other than oil and gas)						
Pension and employee benefits						
Other deductions	PII					
Total deductions						
Ordinary business income (loss)						

Tyler M. Franklin

From: Fortescue, Darren <Fortescue.Darren@epa.gov>
Sent: Tuesday, July 5, 2022 1:56 PM
To: chris@lchconsulting.com; Sansevero, Christine; Wagner, Michael; Vasconcelos, Davianna; Dan.DiSalvio@mass.gov; Glenn.Keith@mass.gov
Cc: 'gcranston pcsinc.org'; 'marie pcsinc.org'; 'Howard Humphreys'; Robert A. Fasanella; Tyler M. Franklin
Subject: [EXTERNAL] RE: Submittal of Stack Test Protocol for Professional Contract Sterilization, Inc. (Taunton, MA) - LCH P050622

Hello Chris,

Received.

Will let you know if we have any questions or comments.

Thanks,

Darren Fortescue
Senior Enforcement Coordinator, Air Compliance Section
Enforcement & Compliance Assurance Division
US EPA - Region I
5 Post Office Square, Suite 100
Mail code: 04-2
Boston, MA 02109-3912
Phone: 617-918-1162
Fax: 617-918 0162

From: chris@lchconsulting.com <chris@lchconsulting.com>
Sent: Tuesday, July 5, 2022 1:54 PM
To: Sansevero, Christine <Sansevero.Christine@epa.gov>; Fortescue, Darren <Fortescue.Darren@epa.gov>; Wagner, Michael <wagner.michael@epa.gov>; Vasconcelos, Davianna <Vasconcelos.Davianna@epa.gov>; Dan.DiSalvio@mass.gov; Glenn.Keith@mass.gov
Cc: 'gcranston pcsinc.org' <gcranston@pcsinc.org>; 'marie pcsinc.org' <marie@pcsinc.org>; 'Howard Humphreys' <h.humphreys@lchconsulting.com>; 'Robert A. Fasanella' <RFasanella@rubinrudman.com>; Tyler M. Franklin <TFranklin@rubinrudman.com>
Subject: Submittal of Stack Test Protocol for Professional Contract Sterilization, Inc. (Taunton, MA) - LCH P050622
Importance: High

Hello, attached is the stack test protocol as prepared by LCH on behalf of Professional Contract Sterilization, Inc.

Respectfully,

L. Christopher Heilner
Owner
LCH Consulting Associates, LLC
88 Glocker Way PMB 287
Pottstown, PA 19465

484 252 4335 direct
484 229 0881 fax
www.lchconsulting.com
"Stack Test Specialists"

July 4th, 2022

Gary Cranston, President

Professional Contract Sterilization, Inc.

40 Myles Standish Blvd,

Taunton, MA 02780

Re: Clean Air Act Testing Requirements

USEPA 40CFR Part 63 Subpart O Compliance Demonstration for Ethylene Oxide Emissions Standards for Sterilization Facilities

Dear Mr. Cranston:

Attached is a revised draft copy of the test protocol for the above referenced testing program. This is in response to the letter dated April 6th, 2022, and signed by Karen McGuire, Director of Enforcement and Compliance Assurance Division of Region 1 of the United States Environmental Protection Agency (USEPA) following comments received by USEPA on 6/27/22___.. The following tables summarize the test and data objectives.

Should there be any questions concerning the enclosed protocol, please contact me at (484) 252-4335.

Respectfully,

L. Christopher Heilner

L. Christopher Heilner

Owner, LCH Consulting Associates, LLC

Cc Dan DiSalvio, MADEP, SE

STACK TEST PROTOCOL

July 5th, 2022

Facility Name:

Professional Contract Sterilization, Inc.
40 Myles Standish Boulevard
Taunton, MA 02780

Test Objective:

USEPA 40CFR Part 63 Subpart O Compliance Demonstration for
Ethylene Oxide Emissions Standards for Sterilization Facilities

Submitted to:

U.S. Environmental Protection Agency Region 1
5 Post Office Square, Suite 100
Mail Code 04-2
Boston, MA 02109

Prepared by:

LCH Consulting Associates, LLC

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CERTIFICATION OF ACCURACY AND COMPLETION

I, Mr. L. Christopher Heilner, as the LCH Consulting Associates report author, certify under penalty of law the information provided in this document is true, accurate and complete. I am aware that there are significant civil and criminal penalties, including the possibility of fine or imprisonment, or both, for submitting false, inaccurate, or incomplete information.

Signed: L. Christopher Heilner Date: 07/05/22

L. Christopher Heilner
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1.0 EXECUTIVE SUMMARY

Professional Contract Sterilization (PCS) is a commercial ethylene oxide sterilization facility providing sterilization of pharmaceutical products and medical devices. This protocol and resulting stack test and subsequent report aim to satisfy the April 6, 2022, Clean Air Act Testing Requirement from the United States Environmental Protection Agency – Region I (EPA), reference Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1) following comments received from EPA on 6/27/22 to the initial draft submitted by PCS. LCH Consulting Services, LLC (LCH) of Pottstown, Pennsylvania, has been retained to prepare this protocol, perform the compliance stack test and resulting final test report. The following provides contact, facility, permit, and source information:

1.1 Contact Summary e

Facility (PCS) Responsible Official
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Table 1 Test Summary

Facility	Process	Air Pollution Control Device	Regulation	Compliance Standard	Compliance Test Method(s)
Professional Contract Sterilization, Inc.	Chambers 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22) Table 1 of §63.362	99% emission reduction	USEPA Methods 1,2, 3, 4 and 18 and 40 CFR §63.365(b)(1)(v)
Professional Contract Sterilization, Inc.	Chamber 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	99% emission reduction	USEPA Methods 1,2, 3, 4 and 18 and 40 CFR §63.365(b)(1)(v)
Professional Contract Sterilization, Inc.	Aeration Room Vent	Anguil Environmental Systems catalytic oxidizer	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	1 ppm maximum outlet concentration or 99% emission reduction	USEPA Methods 1,2, 3, 4 and 18 and 40 CFR §63.365(c)(2)

Table 1A Maximum Normal Operating Conditions Summary

Facility	Process	Air Pollution Control Device	Regulation	Maximum Normal Operating Condition
Professional Contract Sterilization, Inc.	Chambers 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22) Table 1 of §63.362	61 pounds of EtO charge to Chamber 1 with cycle 10002. 26, 14 and 9.5 pounds of EtO charged to chambers 2, 3 and 4 respectively, each with cycle 08008 and 1.5 pounds of EtO charged to chamber 1 with cycle 10002. 100% ethylene oxide is used for all sterilization cycles in all chambers.
Professional Contract Sterilization, Inc.	Chamber 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	1.5 pounds of EtO charged with cycle 10002
Professional Contract Sterilization, Inc.	Aeration Room Vent	Anguil Environmental Systems catalytic oxidizer	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Both aeration rooms filled with 45 pallets each. Total of 90 pallets in aeration.

Table 1B Proposed Personnel Responsibilities

Person	Company	Responsibility
Gary Cranston	PCS	Operation of sterilization chambers, aeration rooms, Damas Corporation tri-phase ethylene oxide scrubber, Anguil Environmental Systems catalytic oxidizer
Chris Heilner	LCH	Stack Test Coordination. Gas Chromatograph operation.
Cliff Still	LCH	Tedlar bag sampling, flow, and moisture determinations
Howard Humphreys	Enviromechanics	Verification and documentation of process parameters. Data entry and calculations for all sampling runs. Independent QA/QC auditing of the stack test program and detailed documentation of such.

Note on table 1B: All communications will go through cellular talk and text messaging as well as hand signals for velocity measurements. Each chamber's first evacuation has historically lasted for 30 minutes. Chris Heilner will be in cellular communication with Cliff Still before the first evacuation of the first chamber begins. We will give an audible countdown between Gary Cranston, Chris Heilner and Cliff Still. A start time will be called out and documented when the first chamber begins its first evacuation. Before the final chamber reaches its final vacuum of its first evacuation, cellular communication between Chris Heilner and Cliff Still will again be established. The communication will remain open until the final chamber completes its first evacuation and the end time will be documented. Cliff will continue reading velocity measurements until the nearest 15 second time reading. The entirety of the test run is predicted to be 30 minutes.

Table 2 Proposed Daily Schedule

Date	Time	Goals
August 15th, 2022	0800-1600	Set up equipment and prepare for test. Perform leak check on all sampling bags and containers. Assign test duties to each of the people involved in the coming test. Ensure with PCS that all appropriate health and safety practices can be followed as per the FDA, OSHA and EPA Method 18 for all persons involved in the stack test.
August 16th, 2022	0800-1600	Conduct Method 18 calibrations using 0.75, 5 and 10ppm ethylene oxide certified calibration gases. Conduct the direct interface recovery study using the mid-range (5ppm) calibration gas. Conduct Method 3A pre-test calibration error and bias checks. Verify and document that both (2) aeration rooms are filled with at least 45 pallets each (90 total) of commercial product previously, but as recently as possible, sterilized by PCS. PCS can sterilize up to 27 pallets per shift and some product requires 8 days of aeration. The use of two aeration rooms is necessary to represent normal operation. Verify and document the Anguil Environmental System catalytic is at the factory recommended operating temperature of 260°F as recorded by the calibrated J-type Omega thermocouple. Conduct ARV testing at outlet of the Anguil Environmental Systems catalytic oxidizer controlling the emissions of both (2) aeration rooms containing at least 45 pallets each of previously sterilized commercial product. ARV testing to consist of three (3) sixty (60) minute tests conducted successively. Conduct the Method 18 calibration drift assessment using the mid-range calibration gas. Conduct Method 3A post-test bias checks. Verify and document the operating temperature of the Anguil Environmental Systems catalytic oxidizer is at the factory recommended operating temperature of 260°F as recorded by the calibrated J-type Omega thermocouple. Request and/or obtain the most recent calibration records for the catalyst bed thermocouple to

		include in the final report. Review all data collected for completeness, accuracy, and integrity.
August 17th, 2022	0800-1600	Conduct Method 18 calibrations using 100, 500 and 1000ppm ethylene oxide certified calibration gases. Verify and document that sterilization chambers 1,2,3,4 and 5 have been loaded with the maximum charge of ethylene oxide and that the chambers are empty of product. Chamber 1 shall be charged with 61 pounds of ethylene oxide for cycle 10002. Chamber 2 shall be charged with 26 pounds of ethylene oxide for cycle 08008. Chamber 3 shall be charged with 14 pounds of ethylene oxide for cycle 08008. Chamber 4 shall be charged with 9.5 pounds of ethylene oxide for cycle 08008. Chamber 5 shall be charged with 1.5 pounds of ethylene oxide for cycle 10002. Coordinate sampling personnel. Gary Cranston of PCS shall be responsible for operation of the chambers and the scrubber. Howard Humphreys will verify and document the scrubber liquor level. Chris Heilner of LCH will communicate by cell phone to the LCH technician from the PCS control room the status of each chamber. Each chamber will be brought to the exposure phase of the associated cycle and then aborted. Aborting the cycle will cause the chambers to go into the sterilant removal (purge, first evacuation) phase of the cycle. PCS will time all 5 chambers to evacuate within the same 60 second period. Chris Heilner will communicate to the LCH technician to start the integrated bag sampling at the beginning of the first evacuation. Concurrently with the bag sampling, the LCH technician will record Δp's and temperature from the calibrated and inspected standard pitot tube and calibrated K-type thermocouple, mounted in the scrubber outlet ductwork. Δp's and temperature will be recorded at one-minute intervals and started within 15 seconds of time zero, defined as the first pressure release of the first sterilization chamber and until the completion of the first evacuation of the final chamber, to the nearest 15 seconds. The integrated bag sample will immediately be analyzed by onsite GC/FID by Chris Heilner. Three replicant analyses of the bag will be performed until the chromatograms agree within 5% of their average instrument

		response. All chromatograms will be printed to .pdf and all notes and conditions will be documented. After analysis, the bag will be spiked with an EtO concentration that is 40 to 60 percent of the average concentration observed in the bag. If EtO is not detected, the spike concentration shall be 5 times the limit of detection. After the spiked bag sample is aged appropriately it will be analyzed. Spike recovery of the bag sample must yield a R value of 0.7 to 1.3. All bag sample results will be corrected to the recovery percentage by dividing the results by the recovery percentage or "R value" determined by the study. Howard Humphreys will collect, verify, and document all corresponding chamber conditions, ethylene oxide charges, flow rate measurements and corrected sample results to calculate destruction removal efficiency of the Damas Corporation Tri-phase Ethylene Oxide Scrubber. Gary Cranston will complete the cycles and reload the chambers for the subsequent second and third sample runs. All procedures listed here, except for the recovery study, will be repeated for the second and third runs. At the conclusion of sampling and analysis, Chris Heilner will perform the calibration drift assessment by introducing the mid-range calibration gas. If the results of the calibration drift assessment are within 5% of the daily original GC response to the mid-range calibration gas, only the initial calibration curve of the day will be used to calculate concentrations. Should the drift assessment show a greater than 5% agreement of the initial GC response to the mid-range calibration gas, a second curve will be developed using all three calibration gas standards from both the initial and the final daily calibration procedures. Howard Humphreys will verify and document the final scrubber liquor level. Howard Humphreys will review all data collected for completeness, accuracy and integrity and calculate all results
August 18th, 2022	0800-1600	Conduct Method 18 calibrations using 100, 500 and 1000ppm ethylene oxide certified calibration gases. Verify and document that sterilization chamber 5 has been loaded with the maximum charge of ethylene oxide and that the chambers are empty of product. Chamber 5 shall be charged with 1.5 pounds of ethylene oxide for cycle 10002.

		Coordinate sampling personnel. Gary Cranston of PCS shall be responsible for operation of the chambers and the scrubber. Howard Humphreys will verify and document the scrubber liquor level. Chris Heilner of LCH will communicate by cell phone to the LCH technician from the PCS control room the status of the chamber. The chamber will be brought to the exposure phase of the associated cycle and then aborted. Aborting the cycle will cause the chamber to go into the sterilant removal (purge, first evacuation) phase of the cycle. Chris Heilner will communicate to the LCH technician to start the integrated bag sampling at the beginning of the first evacuation. Concurrently with the bag sampling, the LCH technician will record Δp's and temperature from the calibrated and inspected standard pitot tube and calibrated K-type thermocouple, mounted in the scrubber outlet ductwork. Δp's and temperature will be recorded at one-minute intervals and started within 15 seconds of time zero, defined as the first pressure release of the first sterilization chamber and until the completion of the first evacuation of the final chamber, to the nearest 15 seconds. The integrated bag sample will immediately be analyzed by onsite GC/FID by Chris Heilner. Three replicant analyses of the bag will be performed until the chromatograms agree within 5% of their average instrument response. All chromatograms will be printed to .pdf and all notes and conditions will be documented. After analysis, the bag will be spiked with an EtO concentration that is 40 to 60 percent of the average concentration observed in the bag. If EtO is not detected, the spike concentration shall be 5 times the limit of detection. After the spiked bag sample is aged appropriately it will be analyzed. Spike recovery of the bag sample must yield a R value of 0.7 to 1.3. All bag sample results will be corrected to the recovery percentage by dividing the results by the recovery percentage or "R value" determined by the study. Howard Humphreys will collect, verify, and document all corresponding chamber conditions, ethylene oxide charges, flow rate measurements and corrected sample results to calculate destruction removal efficiency of the Damas Corporation Tri-phase Ethylene Oxide Scrubber. Gary Cranston will complete the

		cycles and reload the chambers for the subsequent second and third sample runs. All procedures listed here, except for the recovery study, will be repeated for the second and third runs. At the conclusion of sampling and analysis, Chris Heilner will perform the calibration drift assessment by introducing the mid-range calibration gas. If the results of the calibration drift assessment are within 5% of the daily original GC response to the mid-range calibration gas, only the initial calibration curve of the day will be used to calculate concentrations. Should the drift assessment show a greater than 5% agreement of the initial GC response to the mid-range calibration gas, a second curve will be developed using all three calibration gas standards from both the initial and the final daily calibration procedures. Howard Humphreys will verify and document the final scrubber liquor level. Howard Humphreys will review all data collected for completeness, accuracy and integrity and calculate all results

Table 3 Process Data to be Monitored by Howard Humphreys

Facility	Process	Air Pollution Control Device	Regulation	Sterilization Cycle/Process Data	Reference
Professional Contract Sterilization, Inc.	Chambers 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Total mass ethylene oxide loaded to each chamber	40 CFR §63.365(b)(1)(i)(A)
Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Residual mass of ethylene oxide in each chamber	40 CFR §63.365(b)(1)(ii)
Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Total mass of ethylene oxide at the inlet to the Damas Corporation	40 CFR §63.365(b)(1)(iii)

				tri-phase ethylene oxide scrubber	
Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	The mass of ethylene oxide emitted from the Damas Corporation tri-phase ethylene oxide scrubber outlet	40 CFR §63.365(b)(1)(iv)
Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Scrubber liquor tank level	40 CFR §63.365(e)(2)
Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Damas Corporation tri-phase ethylene oxide scrubber	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	All "CEMS" data collected by the PID GC system	USEPA Region 1 Letter dated 04/06/22 – PCS EPA Testing Requirement
Professional Contract Sterilization, Inc.	Aeration Room Vent	Anguil Environmental Systems catalytic oxidizer	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Pallets in aeration	USEPA Region 1 Letter dated 04/06/22 – PCS EPA Testing Requirement
Professional Contract Sterilization, Inc.	Aeration Room Vent	Anguil Environmental Systems catalytic oxidizer	40 CFR Part 63 Subpart O (up to date as of 5/18/22)	Catalyst bed temperature	USEPA Region 1 Letter dated 04/06/22 – PCS EPA Testing Requirement 40 CFR §63.364(c)(4)

Note on table 4: All of these process data are to be verified and documented by Howard Humphreys during the test. Should any one of these process data not be verified and documented at the time of field testing, the test program will be considered invalid, and it must be repeated.

Table 3A Process Parameter Data Quality Objectives to be Monitored by Howard Humphreys

Sterilization Cycle/Process Data	Facility	Process	Parameter	Frequency	Consequence if not performed
Total mass ethylene oxide loaded to each chamber	Professional Contract Sterilization, Inc.	Chambers 1,2,3,4 & 5 Vent	Use of properly calibrated scales and recorded weights to the nearest 0.1 pound.	Before and after every sterilization cycle.	Invalidation of test program
Residual mass of ethylene oxide in each chamber	Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Use of redundant data entry into two separate spreadsheets to verify the results are the same and all data entry is accuracy	After all testing is complete	Invalidation of test program
Total mass of ethylene oxide at the inlet to the Damas Corporation tri-phase ethylene oxide scrubber	Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Use of redundant data entry into two separate spreadsheets to verify the results are the same and all data entry is accuracy	After all testing is complete	Invalidation of test program
The mass of ethylene oxide emitted from the Damas Corporation tri-phase ethylene oxide scrubber outlet	Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Use of redundant data entry into two separate spreadsheets to verify the results are the same and all data entry is accuracy	After all testing is complete	Invalidation of test program
Scrubber liquor tank level	Professional Contract Sterilization, Inc.	Chamber 1,2,3,4 & 5 Vent	Monitor maximum liquor level during the test program to the nearest inch.	Before and after the test program, using the maximum liquor level as the baseline for compliance.	Invalidation of test program
Pallets in aeration	Professional Contract Sterilization, Inc.	Aeration Room Vent	Count, verify and document the pallets in aeration	Before ARV testing	Invalidation of test program or reduce aeration capacity

Catalyst bed temperature	Professional Contract Sterilization, Inc.	Aeration Room Vent	Verify and record temperature from properly calibrated thermocouple.	Before and after ARV testing.	Invalidation of test program

Table 4 Method Data Quality Objectives

Method	Parameter	Acceptance Criteria	Frequency	Consequence if not met
USEPA 1	Sample port and traverse point locations	Verify measurements onsite	Once, prior to testing	Invalidation of test program
USEPA 2C	Determination of Gas Velocity and Volumetric Flow Rate in Small Stacks or Ducts (Standard Pitot Tube)	Verification of proper construction such that a pitot coefficient of 0.99 can be assigned	Twice, prior to and after test program	Invalidation of test program
USEPA 2C	Determination of Gas Velocity and Volumetric Flow Rate in Small Stacks or Ducts (Standard Pitot Tube)	Maintain level and zeroed manometer, pitot leak check performed	Before, after, and as necessary during the test program	Invalidation of test run/program
USEPA 3A	Oxygen and Carbon Dioxide Concentration – Instrumental	Use of three certified EPA Traceability Protocol gases (0, 40-60, 100) % of spans	Once, prior to testing	Invalidation of test run/program
USEPA 3A	Oxygen and Carbon Dioxide Concentration – Instrumental	Calibration error test within ±2%	Once daily	Invalidation of test run/program
USEPA 3A	Oxygen and Carbon Dioxide Concentration – Instrumental	System bias test within ±5%	Before and after each test run	Invalidation of test run/program
USEPA 3A	Oxygen and Carbon Dioxide Concentration – Instrumental	System calibration drift within ±3%	After each test run	Invalidation of test run/program
USEPA 4	Determination of Moisture Content in Stack Gases	Use of calibrated metering console system	Before and after each test program	Invalidation of test program
USEPA 4	Determination of Moisture Content in Stack Gases	System leak rates <0.2 DSCFM	Before and after each test run	Invalidation of test run/program
USEPA 4	Determination of Moisture Content in Stack Gases	Use of calibrated scale with >0.5g resolution	Before and after each test run	Invalidation of test program
USEPA 4	Determination of Moisture Content in Stack Gases	Maintain impinger exit temperature <68°F	During each test run	Invalidation of test program

USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	Use of Ultra-High Purity carrier gas and FID fuels	During entire test program	Elevation of detection limit
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	Use of three certified calibration gases to develop three chromatograms per calibration gas within 5% of their average instrument response	Daily	Repeat analyses until the 5% precision criteria is met
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	Use of three certified calibration gases to develop a calibration curve response in the range of 5-10 relative standard deviation	Daily, Pre-test	Repeat analyses until the 5-10 RSD is met
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	Use of three certified calibration gases to develop a calibration curve response in the range of the expected emissions	Daily	Invalidation of data until calibration gas above emissions concentrations is introduced into the calibration curve
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	Use of mid-level certified calibration gas to determine calibration drift within 5% or less	Daily, after all samples have been analyzed	If calibration drift is <5%, the daily pre-test calibration curve will be used
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	Use of three certified calibration gases to develop a calibration curve response in the range of 5-10 relative standard deviation	Post-test, if mid-level calibration gas drifts >5%	The daily pre-test and post-test calibration curve will be used
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	§8.4.2.1 Recovery Study for Bag Sampling yields recovered fraction (R) $0.7 \leq R \leq 1.30$	Post-test after all samples is analyzed	Collection media is not valid for compound. Another collection technique must be evaluated.
USEPA 18	Measurement of Gaseous Organic Compound Emissions by Gas Chromatography	§8.4.1 Recovery Study for Direct Interface or Dilution Interface Sampling response within 10% of initial analyzer response using a mid-range calibration gas.	Pre-test before any samples is analyzed	Inspect and repair sampling system for leaks until criteria is met.

1.2 Permit and Source Summary

1.2.1 Applicable Regulation – 40CFR63.360 Subpart O: Ethylene Oxide Emissions Standards for Sterilization Facilities

1.2.2 Process Description – Professional Contract Sterilization, Inc. (PCS) is a commercial ethylene oxide sterilization facility providing sterilization of pharmaceutical products and medical devices. Product to be sterilized is processed in a pre-conditioning room with elevated temperature and humidity. Conditioned product is loaded into one of five chambers for exposure to EtO, nitrogen and humidity. Sterilization Chamber Vent (SCV) vacuum pumps remove sterilant gas from the chambers to a Damas acid gas wet scrubber abatement system for destruction of EtO. Product is then transferred to aeration rooms for final off-gassing. Aeration Room Vents (ARV) emissions are controlled by an Anguil Catalytic Thermal Oxidizer.

Sterilization Equipment Description –
Chamber No. 1 - Vacudyne - 10 pallet 1040 ft^3
Chamber No. 2 - Amsco - 6 pallet 670 ft^3
Chamber No. 3 - Amsco - 4 pallet 405 ft^3
Chamber No. 4 -Castle - 2 pallet 250 ft^3
Chamber No. 5 – Beverly Pacific <1 pallet 30 ft^3

Table 5 Chamber Conditions

PCS Sterilization Chamber Vent Compliance Test		Run one						
Run 1 August 14th, 2022		cycle number	10002	8008	8008	8008	10002
	chamber number		1	2	3	4	5
Description	nomenclature	units					
Chamber I Volume	Vchamber	cf	1140	670	405	250	30
Standard Molar Volume	SMV	cf	385.32	385.32	385.32	385.32	385.32
Mol. Wt. EO	MWEtO	# / #-mol	44.05	44.05	44.05	44.05	44.05
Mol. Wt.H2O	MWH2O	# / #-mol	18	18	18	18	18
Mol. Wt. N2	MWN2	# / #-mol	28	28	28	28	28
Mol. Wt. O2	MWO2	#/#-mo	32	32	32	32	32
Standard Temperature	Tstd	degree R	528	528	528	528	528
Standard Pressure	Pstd	in Hg	29.92	29.92	29.92	29.92	29.92
Gas Constant	R	psia*ft^3/mol^o R	10.73	10.73	29.83	29.83	29.83
FIRST DILUTION EVACUTION							
Chamber pressure after initial vacuum	P1	in Hg	1.2	1.2	1.2	1.2	1.2
Chamber temperature after initial evac	T1	degree F	116	116	116	116	116
Chamber temperature after initial evac	T1	degree R	576	576	576	576	576
Volume air in chamber	V1	scf	41.91	24.63	14.89	9.19	1.10
Percent N2 in air		%	0.79	0.79	0.79	0.79	0.79
Volume N2 in chamber	VN2	scf	33.11	19.46	11.76	7.26	0.87
Pound moles N2 in chamber		#-mols	0.0032	0.0019	0.0011	0.0007	0.0001
Total mass N2 in chamber	WtN2	pounds	0.09	0.05	0.03	0.02	0.00
Percent O2 in chamber		%	0.21	0.21	0.21	0.21	0.21
Volume of O2 in chamber	VO2	scf	8.80	5.17	3.13	1.93	0.23
Pound mols O2 in chamber		#-moles	0.0010	0.0006	0.0004	0.0002	0.0000
Mass O2 in chamber	WtO	pounds	0.03	0.02	0.01	0.01	0.00
NITROGEN INJECTION							
Chamber pressure after N2 injection	P2	in Hg	4	4	4	4	4
Pressure changes due to N2 injection	Pchange	in Hg	2.8	2.8	2.8	2.8	2.8
Chamber temperature after N2 injection	T2	degree F	115	115	115	115	115
Chamber temperature after N2 injection	T2	degree R	575	575	575	575	575
Volume N2 injected into chamber	VN2	scf	97.96	57.58	34.80	21.48	2.58
Total volume of N2 in the chamber	VN2total	scf	131.07	77.04	46.57	28.74	3.45
Total volume of gas in chamber	VO2	scf	139.88	82.21	49.69	30.67	3.68
Total Pound moles N2 in chamber		pounds	0.34	0.20	0.12	0.07	0.01
Total mass N2 in chamber	WtN2	pounds	9.52	5.60	3.38	2.09	0.25
Total mass O2 in chamber	WtO2	pounds	0.032	0.019	0.011	0.007	0.001
Percent N2 in chamber		%	0.914	0.914	0.914	0.914	0.914
Percent O2 in chamber		%	0.086	0.086	0.086	0.086	0.086
SECOND DILUTION EVACUATION							
Chamber pressure after second evac	P3	inHg	1.2	1.2	1.2	1.2	1.2

Chamber temperature after second evac	T3	degree F	120.0	120.0	120.0	120.0	120.0
Chamber temperature after second evac	T3	degree R	580.0	580.0	580.0	580.0	580.0
Volume of gas in chamber after 2nd evac	V3	scf	41.62	24.46	14.79	9.13	1.10
Percent gas remaining in chamber after 2nd evac		%	0.30	0.30	0.30	0.30	0.30
Volume of N2 in chamber after 2nd evac	VN2	scf	39.00	22.92	13.86	8.55	1.03
Volume of O2 in chamber after 2nd evac	VO2	scf	2.62	1.54	0.93	0.57	0.07
Pound moles of N2 in chamber after 2nd evac		#-mols	0.101	0.059	0.036	0.022	0.003
Pound moles of O2 in chamber after 2nd evac		#-mols	0.007	0.004	0.002	0.001	0.000
Mass of N2 in chamber after 2nd evac	WtN2	pounds	2.83	1.67	1.01	0.62	0.07
Mass O2 in chamber after 2nd evac	WtO	pounds	0.22	0.13	0.08	0.05	0.01

HUMIFICATION INJECTION

Chamber pressure after humidity inject	P4	inHg	1.8	2.8	2.8	2.8	2.8
Chamber pressure change from humification	Pchange	in Hg	0.6	1.6	1.6	1.6	1.6
Chamber Temperature after humidity inject	T4	degree F	120	120	120	120	120
Chamber temperature after humidity inject	T4	degree R	580	580	580	580	580
Volume of H2O vapor injected into chamber	VH2O	scf	20.81	32.62	19.72	12.17	1.46
Pound moles of H2O injected		#-mols	0.05	0.08	0.05	0.03	0.00
Mass H2O injected into chamber	WtH2O	pounds	0.97	1.52	0.92	0.57	0.07
Weight percent N2 in chamber	Wt%N2	%	0.704	0.502	0.502	0.502	0.502
Weight percent O2 in chamber	Wt%O2	%	0.054	0.039	0.039	0.039	0.039
Weight percent H2O in chamber	Wt%H2O	%	0.242	0.459	0.459	0.459	0.459
Molecular weight of balance gas mixture in chamber	MWx	# / #-mol	25.800	23.561	23.561	23.561	23.561

ETO INJECTION

Total mass EO charged to chamber s	WT EtO	pounds	61	26	14	9.5	1.5
Chamber pressure after EtO injection	P5	inHg	15.4	13.7	13.7	13.7	13.7
Chamber Temperature after EtO injection	T5	degree F	120	120	120	120	120
Chamber Temperature after EtO injection	T5	degree R	580	580	580	580	580
Total volume gas in chamber	Vtotal	scf	2215.77	1464.15	885.41	546.90	66.43
Weight percent balance of gas in chamber	Wx	%	0.06	0.11	0.13	0.12	0.09
Weight percent EtO in chamber	Weo	%	0.94	0.89	0.87	0.88	0.91
Percent volume fraction EO in chamber	%EOv	%	0.90	0.81	0.79	0.80	0.84

FIRST CHAMBER EVACUATION FOR TESTING

Chamber pressure after first evac	P6	inHg	1.2	1.5	1.5	1.5	1.5
Chamber Temperature after first evaC	T6	degree F	120	120	120	120	120
Chamber Temperature after first evaC	T6	degree R	580	580	580	580	580
Volume of gas remaining in chamber after 1st evac	Vfinal	scf	50.22	36.90	22.30	13.77	1.65
Percent chamber Gas evacuated		%	0.98	0.97	0.97	0.97	0.98
Residual Mass EtO in the chamber	Wr	pounds	1.853	1.529	0.325	0.204	0.026
Mass of EO at the scrubber inlet sum of all chambers	Wi	pounds	59.147	24.471	13.675	9.296	1.474

Mass of EtO at scrubber inlet	wi	pounds	108.063
Concentration EtO in bag sample	Csample	ppm	1000
Scrubber outlet flow rate	Q	dscf	2211

Concentration EtO at scrubber Outlet	Co	lb/dscf	0.00011
Mass flow rate EtO exiting scrubber	Wo	pounds	0.25225
Control Device Efficiency	% Eff	%	99.7665

Before and after every sterilization cycle, pursuant to 40CFR§63.365(b)(1)(i)(A) the amount of EtO (100% EOV) charged to each chamber is documented to the nearest 0.1 pound by Gary Cranston using a gravimetric scale and documented on the process run record. An example process run record is available in Attachment E and will be included in the final report. PCS has each of their scales calibrated annually. The calibration results are available in Attachment I and will be included in the final report.

The total mass of EtO discharged to the Damas Corporation Tri-phase Ethylene Oxide Scrubber will be calculated using the resulting residual mass from the equation from 40 CFR 63.365(b)(1)(ii) and subtracting it from the charged weight of EtO. Each individual sterilization chamber will be calculated and summated. The following equation will be used to calculate residual mass at each individual chamber:

$$W_r = \frac{MW \; x \; \%EO_V \; x \; P \; x \; V}{R \; x \; T}$$

PCS operates two identical heated aeration rooms. Each of those rooms has a capacity of 45 pallets. PCS sterilizes commercial product that is typically in aeration for eight days. The following is a description of the aeration rooms:

- Aeration Room 1 10,515 ft ^{3} – 45 Pallet Capacity heated to 110 -120 ^{o} F
- Aeration Room 2 10,515 ft ^{3} – 45 Pallet Capacity heated to 110 -120 ^{o} F

1.2.3 ABATEMENT SYSTEMS DESCRIPTION

1.2.3.1 Damas Corporation tri-phase ethylene oxide scrubber

PCS uses a Damas acid gas wet scrubber to control Sterilization Chamber Vent (SCV) emissions. Vacuum pumps transfer EtO laden SCV gases to the Damas where it is chemically converted to ethylene glycol in the presence of sulfuric acid and water. PCS monitors the

scrubber liquor level in inches in two tanks, the liquor temperature, and the chiller tank temperature in degrees Fahrenheit. The example logbook for scrubber parameters is available in Attachment E. Howard Humphreys will collect all scrubber data during the test, and it will be included in the final report.

1.2.3.2 Anguil Catalytic Thermal Oxidizer

An Anguil Catalytic Thermal Oxidizer to control Aeration Room Vent (ARV) emissions. Induced draft fans transport EtO laden ARV gases to the Anguil Catalytic Thermal Oxidizer where it is destroyed in an accelerated thermal oxidation reaction. The chemical process of catalytic oxidation is VOC laden process gas is heated to a VOC catalyst reaction temperature and then passed through a catalyst, where a rapid oxidation reaction takes place. This breaks the bonds that hold the VOC molecules together and converts them to combinations of carbon dioxide and water vapor, while also releasing heat.

The manufacturer's maximum oxidation temperature is *260°F* or *126.7*°C. The catalyst bed temperature is monitored by an Omega Type J Thermocouple located in the center of the catalyst bed. The recordkeeping device is a Honeywell Trueline chart recorder. The thermocouple probe is calibrated twice every calendar year against a collocated NIST traceable reference thermocouple. The accuracy of the thermocouple shall be maintained at ±10°F. The manufacturer's recommendations and thermocouple calibrations are available in Attachment H. This information and the information from the last two performance evaluations conducted in the previous 12 months will be included in the final report.

The following are the proposed test methods to be used for SCV and ARV tests:

USEPA Method 1 – Sampling Point Determination and Cyclonic Flow Checks

USEPA Method 2 – Volumetric Flow Rate Determination

USEPA Method 3 – Stack Gas Molecular Weight Determination

USEPA Method 4 - Moisture Content of Stack Gas

USEPA Method 18 – Volatile Organic Compound Determination by Gas Chromatograph

Subpart O 40CFR63.365 (b) – Calculations

3.0 SCOPE AND OBJECTIVES

The objective of the testing program is demonstrated compliance with 40 CFR Part 63 Subpart O (up to date as of 5-18-22) §63.362 Table 1 and EPA Region 1 letter dated 040622 regarding PCS EPA Testing Requirement. PCS does not have a CEM system in place. PCS elects to monitor liquor scrubber level daily and replace the catalytic oxidizer catalyst bed every five years as its ongoing compliance demonstration.

The performance of the Damas Corporation tri-phase ethylene oxide scrubber will be determined by testing the SCV. The test procedures of 40CFR63.365 (b)(1)(v) will be used to demonstrate the compliance status. During the sample runs EtO samples will be obtained for analysis by GC/FID and volumetric flow rates will be determined at the outlet of the scrubber. The total mass at the inlet to the scrubber will be determined using the procedures described in 40CFR §63.365(b)(1)(iii). Outlet concentrations will include SCV exhaust emissions and calculated using 40CFR §63.365(b)(1)(iv). Damas Corporation tri-phase ethylene oxide scrubber emissions reductions will be calculated on a three-run average for two different scenarios. The first scenario is all five chambers, charged with a maximum amount of ethylene oxide and empty of product, advanced simultaneously to the sterilant removal phase and released to the scrubber. The second scenario is chamber five, charged with an average amount of ethylene oxide and empty of product, advanced to the sterilant removal phase and released to the scrubber. The scrubber is held to 99% emission reduction as per Table 1 of §63.362 of 40CFR.

The performance of the Anguil Environmental Systems catalytic oxidizer will be determined by testing the ARV. The test procedures in 40CFR §63.365(c)(2) will be used demonstrate compliance on an outlet concentration. Both aeration rooms will be loaded to within 90% of the maximum normal operating capacity of the aeration room. The aeration rooms have a capacity of 45 pallets each. The oxidizer is held to ethylene oxide emissions of 99% emission reduction or 1ppm or less, whichever is less stringent, as per Table 1 of §63.362 of 40CFR.

There is a process schematic for the Anguil Environmental Systems catalytic oxidizer in Attachment D the depicts the capture of other fugitive emissions. PCS has confirmed there is no

additional fugitive emissions streams as to not dilute the aeration room vents emissions. The process schematic is in error.

4.0 FIELD TESTING PROGRAM

4.1 Testing Location and Program Summary Description

Sampling will be conducted at two locations: the outlet of the Damas Corporation tri-phase ethylene oxide scrubber and the outlet of the Anguil Environmental Systems catalytic oxidizer. Both locations will be accessed with ladders. The gas (EtO) sampling probes will be installed at the centroid of the ducts. Before testing the scrubber, two ports will be used, maximum eight points per port resulting in a maximum sixteen-point velocity traverse. The stack inside geometry will be determined for Method 1 compliant traverse points. Traverse point locations will be determined on site. A preliminary traverse will yield the point of average velocity at the outlet. This point of average velocity will be used for flow determinations during each scrubber SCV sampling run. Heated sampling lines and probes will be used for both bag sampling (SCV) and direct interface sampling (ARV).

4.2 Sampling Procedures

The following sections provide descriptions of sampling procedures and the sampling trains that will be used for emissions testing.

4.2.1 Gas Flow and Temperature Measurements

EPA methods 1 and 2 will be used to determine velocity and temperature measurements during each SCV test run. EPA Subpart O regulations require ΔPs and temperature at the outlet of the TO to be measured every minute for the duration of the test run. A standard pitot and an oil-filled manometer with sensitivity of 0.001" H2O.

4.2.2 Oxygen and Carbon Dioxide Emission Concentration Determinations

The dry molecular of the SCV gas will be assumed to be 28.00 as it is steam-heated nitrogen.

Oxygen and Carbon Dioxide Emission Concentration measurements of the ARV will be conducted following procedures of Method 3A. A California Analytical Inc, Model 700 NDIR

CO2/Parametric O2 analyzer will be used to monitor oxygen and carbon dioxide concentrations during each sample ARV sample runs. Prior to testing and daily a calibration error test as EPA Method 7E will be conducted. Calibration error within 2.0% of the calibration gas span value will be considered acceptable. Once the calibration error test is complete and before any sampling has occurred a system bias test will be conducted. System bias error within 5.0% of the analyzer calibration span will be considered acceptable. System bias will be calculated after every test run. Calibration drift will be calculated after every run. Calibration drift within 3.0% will be considered acceptable.

4.2.3 Moisture Content Sampling

Moisture content of the SCV sample gas will be determined by comparison of stack temperature to a psychometric chart. The sample gas will be considered saturated at that temperature.

4.2.4 Determination of Ethylene Oxide Emissions

Procedures outlined in 40 CFR 60 Methods 18 and Subpart O 40CFR63.365 calculations will be used to determine Ethylene Oxide emission concentrations (if applicable), and are discussed as follows:

SCV ETO samples will be collected in sample bags and analyzed using the procedures described in §8.2.1.2 Direct Pump Sampling Procedures. Prior to test, new, unused Tedlar sample bags and the rigid sampling container will be leak-checked and labeled for use as per §8.2.1. One sample bag will be filled with nitrogen and aged for 24 hours or longer to determine desorption of organics from the bag. Each bag sample will be analyzed immediately after the sample run. Triplicate analyses will be performed until each sample analysis agrees with the median value by 5% or less. After all samples are collected and analyzed, the sample bag recovery study will be performed as per §8.4.2. using a spike concentration of EtO that is equivalent to 40 to 60 percent of the average concentration observed in the bags. If EtO is not detected, the spike concentration shall be 5 time the limit of detection. A sample recovery fraction of 0.7 to 1.3 will be considered valid. All bag sample results will be corrected to the resulting recovery fraction of the study by dividing the results by the recovery fraction. Should moisture be observed in the bag samples, the sample run will be considered invalid and shall be repeated. The equipment used for bag sampling is described

in the graphic below. As per section 8.2.1.2 of Method 18 the direct pump technique will be used eliminating the use of the rigid sample container.

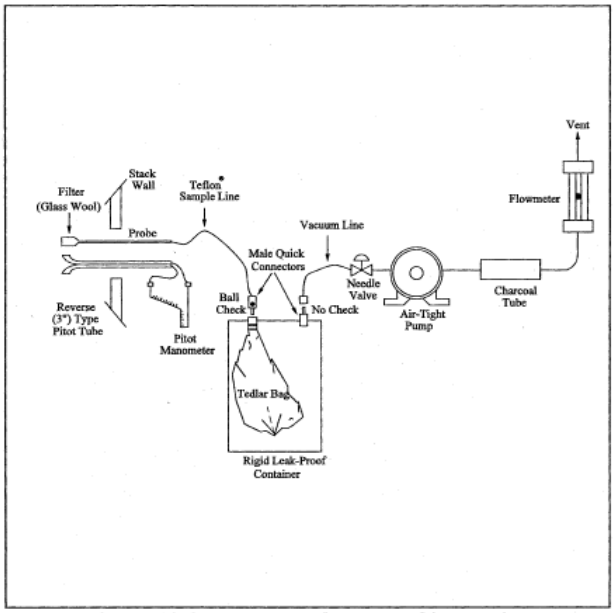

Figure 18-9. Integrated Bag Sampling Train.

ARV ETO samples will be collected and analyzed using the Direct Interface Sampling and Analysis Procedure of Method 18 section 8.2.2. A stainless-steel shrouded glass lined sample probe will be placed in the Anguil Environmental Systems catalytic thermal oxidizer outlet sample port. A heated Teflon sample line will connect to a Teflon lined diaphragm pump. A sample rate of two liters per minute will be established. A slip stream of approximately ten milliliters per minute of the sample will be connected to the gas chromatograph sample loop. An analysis will be conducted once per three-minutes for the duration of the test run. LCH uses dedicated, unused Teflon sample lines for each low-level ethylene oxide source test. Several ambient samples will be analyzed pulling through the Teflon sample system to ensure clean background analyses before stack analyses are conducted. Sample lines will be replaced if background analyses are not acceptable. Prior to sampling, and after each day, the direct interface recovery study will be performed as per §8.4.1. If the mean of the mid-range calibration gas response sampled through the probe is within 10% of the analyzer response, the sample system will be considered valid and leak-free. If it is greater than 10% the sample system will be checked for leaks, repaired and the recovery study will be repeated.

4.3 Sample Analysis

All samples will be analyzed onsite by an experienced LCH technician operating a GC FID. All QA/QC measures inherit to the analyzer and the methodology will be followed.

4.3.1 GC Description

Samples will be analyzed by gas chromatography using an SRI 8610C gas chromatograph with dual column, dual detector (PID and FID) with heated sample loops, injectors, and 3-meter packed columns. Gas in the sample loops is injected directly into the GC's analytical columns by the gas sampling valve. The GC will be operated with carrier gas flow of 15 to 18 ml/minute and column temperature of 130˚C. The carrier gas is ultra-high purity helium. Hydrogen and air are used to maintain the FID. Nitrogen is used to flush and zero the GC. The MDL of the SRI 8610C gas chromatograph using the FID detector has been previously determined at 0.5ppm. LCH will follow the guidelines in 40 CFR 136 Appendix B Revision 2 user friendly stand-alone document of December 2016 to determine the detection limit.

4.3.2 Calibration Standards

Three cylinders of calibration standard, ETO in nitrogen, in a range of concentrations will be used to create the most appropriate calibration curve to calculate ETO concentration in ppm given instrument response in millivolts. The low range calibration gases available are 0.75ppm, followed by 5.0ppm and 10.0ppm ethylene oxide in nitrogen for ARV emissions. The high range calibration gases available are 100, 500 and 1000ppm ethylene oxide in nitrogen for SCV emissions. Calibration standards will be analyzed, by direct cylinder injection, in triplicate and the average value of the samples will be calculated. An analytical result is considered valid if its value is within 5% of the average value. A calibration curve will be generated using Microsoft Excel chart function by constructing a linear XY-Scatter graph that solves the quadratic equation of the line Y=mX+b where "y" is the calculated concentration of EtO, "x" is the instrument response, "m" is the constant and "b" is the y-coordinate intercept. The option forcing the graph through zero will be enabled so "b" = zero. The least squares R^2 value and the equation of the line will be shown. An R^2 value of 95% is acceptable according to Method 18. The gas chromatograph routinely exceeds the 95% R^2 value.

4.3.3 Chromatograms

The chromatogram log sheet is a Microsoft Excel spreadsheet that transposes run information in an easy-to-read format that also provides the calculating capabilities to assess the QA/QC requirements of the method. The chromatograms are logged by the file path directory of the hard drive storage.

The chromatograms are automatically printed at the conclusion of each analysis in .pdf format. Each chromatogram includes information identifying the type of analysis, i.e., set up, calibration, sample, recovery study, date and time of analysis, comments, retention time and integrated peak area. The results are in units of millivolts. The operator will initiate field corrections.

4.3.4 QA/QC Measures

4.3.4.1 Calibration Drift Assessment

The mid-range calibration standard will be analyzed daily at the conclusion of testing and the results will be compared to the initial analysis to determine if calibration drift has occurred. A 5% deviation between results is allowable. Should excessive calibration drift be observed all calibration standards will be re-analyzed and a new calibration curve using the pre-test and post-test data will be generated following the procedures of Method 18. The SRI gas chromatograph has historically met the 5% criteria.

4.3.4.2 Direct Interface Sampling Train Recovery Study

Once the initial calibration standards have been recorded the mid-range standard will be introduced at the probe end of the sample train. The mean of the calibration gas response sampled through the probe shall be within 10 percent of the analyzer response. If the results show a deviation greater than 10%, the sample train will be checked for leaks or other causes and analysis will be repeated. The sample trains have historically met the 10% criteria. The recovery study shall be performed prior to and at the end of each test day.

5.0 DATA EVALUATION AND REPORT PREPARATION

5.1 Emission Calculations

The destruction removal efficiency is calculated using the mass of ETO evacuated from the chambers and the mass at the outlet of the scrubber. The mass of ETO at the inlet will be calculated following the procedures of Subpart O section 63.365(b). Emissions will be calculated according to the appropriate EPA methodologies. Equations are presented in the Protocol Attachments.

5.2 Report Preparation

Testing and pertinent operating data will be reviewed by LCH to prepare a full comprehensive test report, including but not limited to, the following:

1. Brief description of work undertaken for complete and incomplete test runs and an outline of sampling techniques employed.
2. An Executive Summary, which includes a summary table and discussion comparing actual emissions with allowable emission limits specified in Section 3.0 of this protocol.
3. Facility information.
4. Source description and actual site information (diameters, dimensions, etc.).
5. All raw field sampling data generated during testing.
6. Equations utilized in calculating test results.
7. All operating data, listed in Section 4.3 of this protocol, recorded during testing.
8. Equipment calibration records.
9. A detailed assessment, not just a statement, that a detailed review of all data, both test and process data, will be included to assess whether all data quality objectives were met.

ATTACHMENT A
EQUATIONS

EQUATIONS FOR MOISTURE CONTENT,
AND FLOW RATE CALCULATIONS
(Based on Standard Conditions of 70ºF and 29.92"Hg)

1. $V_{w\,(std)} = 0.0473\ V_{wc}$

2. $V_{m\,(std)} = 17.71\, V_m\, \dfrac{P_{bar} + (0.07355\,\Delta H)}{T_m + 460}\,\gamma$

3. $B_{wo} = \dfrac{V_{w\,(std)}}{V_{m\,(std)} + V_{w\,(std)}}$

4. $B_{WS} = (B_{WO})\ (100)$

5. $M_d = 0.44\ (\%CO_2) = 0.28\ (\%CO) + 0.32\ (\%O_2) + 0.28\ (\%N_2)$

6. $M_s = M_d\ (1 - B_{wo}) + 18\ B_{wo}$

7. $P_s = P_{bar} + \dfrac{P_A}{13.6}$

8. $V_s = (85.49)(60)(C_p)\ \sqrt{\Delta P}\ \sqrt{\dfrac{T_s + 460}{(P_s)\ (M_s)}}$

9. $A_s = \dfrac{(\pi)\ (D/2)^2}{144}$

10. $Q_s = V_s\ A_s$

11. $Q_{s\,(std)} = Q_s\ (1\text{-}B_{wo})\ 17.71\ \dfrac{P_s}{T_s + 460}$

LEGEND

A_S =	Area of stack, ft^2
B_{wo} =	Moisture content of gas stream, fractional value
B_{ws} =	Moisture content of gas stream, percent by volume
C_p =	Pitot correction factor, dimensionless
D =	Inside diameter of stack, in.
ΔH =	Orifice pressure drop, in. H_2O
M_d =	Dry molecular weight of stack gas, lb/lb-mole
M_s =	Molecular weight of stack gas, lb/lb-mole
P_A =	Stack static pressure, in. H_20
P_{bar} =	Barometric pressure, in. Hg
P_s =	Absolute stack pressure, in. Hg
$\sqrt{\Delta P}$ =	Average of square roots of pitot pressure differential, in. H_2O
Q_s =	Stack gas flow rate, acfm
$Q_{s(std)}$ =	Stack gas flow rate, dscfm
T_m =	Average dry gas meter temperature, ºF
T_s =	Average stack temperature, ºF
V_m =	Dry sample volume (meter conditions), cf
$V_{m(std)}$ =	Dry sample volume (standard conditions), dscf
V_s =	Stack gas velocity, ft/min
V_{wc} =	Volume of liquid collected in impingers and silica gel, ml
$V_{w(std)}$ =	Volume of liquid collected, cf
γ =	Meter box calibration factor, dimensionless

EQUATIONS FOR EMISSION CALCULATIONS

(Based on Standard Conditions of 70°F and 29.92 in Hg)

O_2, CO_2 Concentration Calculation (% or ppmv), Eq. 7E-5

$C_{gas} = (C_{avg}-C_o)\,[C_{ma}/(C_m-C_o)]$

where:
- C_{gas} = Emission concentration corrected for instrument bias and drift, ppmvd or %
- C_{avg} = Average test run instrument response, ppmvd or %
- C_o = Average system calibration response to zero span gas during pre and post test bias check, ppmvd or %
- C_m = Average system calibration response to upscale span gas during pre and post test bias check, ppmvd or %
- C_{ma} = Span gas concentration, ppmvd or %

TOC Emission Concentration Conversion from Wet to Dry Basis

$TOC_{dry} = TOC_{wet}\,[100 / (100-B_{ws})]$

where:
- TOC_{dry} = TOC emission concentration, dry basis, ppmvd
- TOC_{wet} = TOC emission concentration as measured by Method 25A analyzer, ppmv wet
- B_{ws} = Stack gas moisture content, % by volume

PCS will operate 5 chambers for testing. A calculation spreadsheet is used to determine removal efficiency. There are two spreadsheets used for that calculation depicted as Example Scrubber Outlet Volumetric Flow Rate Calculation and Example EtO Removal Efficiency Spreadsheet. In each case the calculations is explained and the specific key strokes for each cell are shown.

The Sterilization cycles employed by PCS all conform the following phases starting with closure of the chamber door:

1. Initial dilution evacuation
2. Nitrogen injection
3. Second dilution evacuation
4. Humidity injection
5. EtO injection
6. First SCV evacuation

Pressure and temperature will be recorded at each phase completion P1. T1 through P6, T6.

Example EtO Removal Efficiency Calculation Spreadsheet

PCS Sterilization Chamber Vent Compliance Test		Run 1							
Run 1 August 14th, 2022		cycle number	10002	8008	8008	8008	10002		
chamber number			1	2	3	4	5	key strokes	formula
description	nomenclature	units							
Chamber I Volume	Vchamber	cf	1140	670	405	250	30	870	
Standard Molar Volume	SMV	cf	385.32	385.32	385.32	385.32	385.32	385.32	
Mol. Wt. EO	MWEtO	# / #-mol	44.05	44.05	44.05	44.05	44.05	44.05	
Mol. Wt.H2O	MWH2O	# / #-mol	18	18	18	18	18	18	
Mol. Wt. N2	MWN2	# / #-mol	28	28	28	28	28	28	
Mol. Wt. O2	MWO2	#/#-mo	32	32	32	32	32	32	
Standard Temperature	Tstd	degree R	528	528	528	528	528	528	
Standard Pressure	Pstd	in Hg	29.92	29.92	29.92	29.92	29.92	29.92	
Gas Connstant	R	psia*ft^3/mol^{o}R	10.73	10.73	29.83	29.83	29.83	29.83	
FIRST DILUTION EVACUTION									
Chamber pressure after initial vacum	P1	in Hg	1.2	1.2	1.2	1.2	1.2	1.2	
Chamber temperature after initial evac	T1	degree F	116	116	116	116	116	116	
Chamber temperature after initial evac	T1	degree R	576	576	576	576	576	=E21+460	
Volume air in chamber	V1	scf	41.91	24.63	14.89	9.19	1.10	=E10*E20/E17*E16/E22	Vol gas in chamber = Vchamber x P1/Pstd x Tstd/T1
Percent N2 in air		%	0.79	0.79	0.79	0.79	0.79	0.79	Assumed % N2 in air
Volume N2 in chamber	VN2	scf	33.11	19.46	11.76	7.26	0.87	=E23*E24	Vol N2 in chamber = vol air in chamber x 0.79
Pound moless N2 in chamber		#-mols	0.0032	0.0019	0.0011	0.0007	0.0001	=E25/E11	#-mols N2 in chamber = Vol N2 / SMV
Total mass N2 in chamber	WtN2	pounds	0.09	0.05	0.03	0.02	0.00	= E26*E14	Mass N2 in chaber = #-mols N2 x MWN2
Percent O2 in chamber		%	0.21	0.21	0.21	0.21	0.21	0.21	Assumed % O2 in air
Volume of O2 in chamber	VO2	scf	8.80	5.17	3.13	1.93	0.23	=E23*E28	Volume O2 In chamber = Vol air in chamber x 0.21
Pound mols O2 in chamber		#-moles	0.0010	0.0006	0.0004	0.0002	0.0000	=E29/E11*E20/E17*E22/E16	#-mols O2 in chamber = Vol O2 / SMV
Mass O2 in chamber	WtO	pounds	0.03	0.02	0.01	0.01	0.00	=E30*E15	Mass O2 in chamber = #-mols O2 x MWO2
NITROGEN INJECTION									
Chamber pressure after N2 injection	P2	in Hg	4	4	4	4	4	4	
Pressurechange due to N2 injection	Pchange	in Hg	2.8	2.8	2.8	2.8	2.8	=E33-I20	Change in chamber pressure from N2 injection = P2 - P1
Chamber temperature after N2 injection	T2	degree F	115	115	115	115	115	115	
Chamber temperature after N2 injection	T2	degree R	575	575	575	575	575	575	
Volume N2 injected into chambber	VN2	scf	97.96	57.58	34.80	21.48	2.58	=E10*E34/E17*E16/E36	Vol N2 injected = Vchamber x P2 /Pstd x Tstd/T2
Total volume of N2 in the chamber	VN2total	scf	131.07	77.04	46.57	28.74	3.45	=E25+E37	Total Vol N2 in chamber = Vol N2 remaining from 1st evac plus Vol N2 injected
Total volume of gas in chamber	VO2	scf	139.88	82.21	49.69	30.67	3.68	=E38+E29	Total Vol gas in chamber = total Vol N2 plus total Vol O2
Total Pound moles N2 in chamber		pounds	0.34	0.20	0.12	0.07	0.01	=E38/E11	#-mols N2 in chamber = total Vol N2 / SMV
Total mass N2 in chamber	WtN2	pounds	9.52	5.60	3.38	2.09	0.25	=E39+E46	Mass N2 in chamber = #-mols x MWN2
Total mass O2 in chamber	WtO2	pounds	0.032	0.019	0.011	0.007	0.001	=E31	no chamge in mass of O2
Percent N2 in chamber		%	0.914	0.914	0.914	0.914	0.914	=E40/(E40+E42)	Percent N2 = mass N2 / (mass N2 + mass O2)
Percent O2 in chamber		%	0.086	0.086	0.086	0.086	0.086	=E42/(E40+E42)	Percent O2 = mass O2 / (mass N2 + mass O2)
SECOND DILUTION EVACUATION									
Chamber pressure after second evac	P3	inHg	1.2	1.2	1.2	1.2	1.2	1.2	
Chamber temperature after second evac	T3	degree F	120.0	120.0	120.0	120.0	120.0		
Chamber temperature after second evac	T3	degree R	580.0	580.0	580.0	580.0	580.0	=E47+460	
Volume of gas in chamber after 2nd evac	V3	scf	41.62	24.46	14.79	9.13	1.10	=E10*E46/E17*E16/E48	Vol gas in chamber = Vchamber x P3/Pstd x Tstd/T3
Percent gas remaining in chamber after 2nd evac		%	0.30	0.30	0.30	0.30	0.30	=E49/E39	Percent gas in chamber = vol after 2nd evac/total vol gas after N2 inject
Volume of N2 in chamber after 2nd evac	VN2	scf	39.00	22.92	13.86	8.55	1.03	=E36*E45	Vol N2 in chamber = total Vol N2 after inject x % reduction of gas in chamber
Volume of O2 in chamber after 2nd evac	VO2	scf	2.62	1.54	0.93	0.57	0.07	=(E39-E38)*E50	Vol O2 in chamber = Vol gas in chamber minus total Vol N2 in chamber x % gas remaining
Pound moles of N2 in chamber after 2nd evac		#-mols	0.101	0.059	0.036	0.022	0.003	=E51/E11	#-mols N2 = Vol N2 / SMV
Pound moles of O2 in chamber after 2nd evac		#-mols	0.007	0.004	0.002	0.001	0.000	=E46/E11	#-mols O2 - Vol O2 / SMV
Mass of N2 in chamber after 2nd evac	WtN2	pounds	2.83	1.67	1.01	0.62	0.07	=E53*E14	Mass of N2 = #-mols N2 x MWN2
Mass O2 in chamber after 2nd evac	WtO	pounds	0.22	0.13	0.08	0.05	0.01	=E54*E15	Mass of O2 = #-mols O2 x MWO2
HUMIFICATION INJECTION									
Chamber pressure after humidity inject	P4	inHg	1.8	2.8	2.8	2.8	2.8	2.8	
Chamber pressure change from humification	Pchange	in Hg	0.6	1.6	1.6	1.6	1.6	=E58-E46	Presssure change = pressure after humidity inject minus pressure after 2nd evac
Chamber Temperature after humidity inject	T4	degree F	120	120	120	120	120	120.00	
Chamber temperature after humidity inject	T4	degree R	580	580	580	580	580	=E60+460	
Volume of H2O vapor injected into chamber	VH2O	scf	20.81	32.62	19.72	12.17	1.46	=E10*E59/E17*E16/E61	Vol H2O in chamber = Vchamber x Pstd/P4 x T4/Tstd
Pound moles of H2O injedcted		#-mols	0.05	0.08	0.05	0.03	0.00	=E62/E11	#-mols H2O = Vol of H2O / SMV
Mass H2O injected into chamber	WtH2O	pounds	0.97	1.52	0.92	0.57	0.07	=E63*E13	Mass H2O injected = #-mols H2O x MWH2O
Weight percent N2 in chamber	Wt%N2	%	0.704	0.502	0.502	0.502	0.502	=E55/(E55+E56+E64)	Wt % N2 = mass N2 / (massN2 + massO2 + massH2O)
Weight percent O2 in chamber	Wt%O2	%	0.054	0.039	0.039	0.039	0.039	=E56/(E55+E56+E64)	Wt % O2 = mass O2 / (mass N2 + mass O2 + mass H2O)
Weight percent H2O in chamber	Wt%H2O	%	0.242	0.459	0.459	0.459	0.459	=E64/(E55+E56+E64)	Wt % H2O = mas H2O / (mass N2 + mass O2 + mass H2O)
Molecular weight of balance gas mixture in chamber	MWx	# / #-mol	25.800	23.561	23.561	23.561	23.561	=E65*E14+E66*E15+E67*13	MW chamber gas = Wt%N2 x MWN2 + Wt%O2 x MWO2 +Wt%H2O x MWH2O
ETO INJECTION									
Total mass EO sharged to chamber s	WT EtO	pounds	61	26	14	9.5	1.5	61	weight measured on tank scale
Chamber pressure after EtO injection	P5	inHg	15.4	13.7	13.7	13.7	13.7	13.7	
Chamber Temperature after EtO injection	T5	degree F	120	120	120	120	120	120	
Chamber Temperature after EtO injection	T5	degree R	580	580	580	580	580	=E73+460	
Total volume gas in chamber	Vtotal	scf	2215.77	1464.15	885.41	546.90	66.43	=E10*E17/E71+E16/E73	Vtotal, total Vol gas in chamber = Vchamber x P5/Pstd x Tstd/T5
Weight percent balance of gas in chamber	Wx	%	0.06	0.11	0.13	0.12	0.09	=(E55+E56+E64)/(E55+E56+E64+E70)	Wt % balance of gas in chamber = mass (N2 + O2 + H2O) / mass(N2 + O2 + H2O + EtO)
Weight percent EtO in chamber	Weo	%	0.94	0.89	0.87	0.88	0.91	=E70/(E55+E56+E64+E70)	Wt % EtO in chamber = mass EtO / mass(N2 + O2 + H2O + EtO)
Percent volume fraction EO in chamber	%EOv	%	0.90	0.81	0.79	0.80	0.84	=E76/(E76+(E75*E12/E68))	%Vol fraction EtO = Wt % EtO/(Wt % EtO + (Wt % balance of gas / MWbalance of gas))
FIRST CHAMBER EVACUATION FOR TESTING									
Chamber pressure after first evac	P6	inHg	1.2	1.5	1.5	1.5	1.5		
Chamber Temperature after first evaC	T6	degree F	120	120	120	120	120		
Chamber Temperature after first evaC	T6	degree R	580	580	580	580	580		
Volume of gas remaining in chamber after 1st evac	Vfinal	scf	50.22	36.90	22.30	13.77	1.65	EJ10*E75/E17*E76/E16	Vfinal, total Vol EtO plus Vol balance = Vchamber x P6/Pstd x Tstd/T6
Percent chamber Gas evacuated		%	0.98	0.97	0.97	0.97	0.98	=1-E73/E67	Percent gas evacuated = 1 - Vfinal / Vol after 1st evac
Residual Mass EtO in the chamber	Wr	pounds	1.853	1.529	0.325	0.204	0.026	=E12*E77*E71*E73/(E18*E72)	Residual Mass EtO = (MWEtO x P6 x Vfinal/ (R x T6)
Mass of EO at the scrubber inlet sum of all chambers	Wi	pounds	59.147	24.471	13.675	9.296	1.474	=EJ63-E75	Mass EtO at scrubber inlet = mass EtO charged - residual mass EtO
Mass of EtO at scrubber inlet	wi	pounds	108.063					=SUM(E76:i76)	sum of all chambers
Concentration EtO in bag sample	Csample	ppm	1000					from GC analysis records	
Scrubber outlet flow rate	Q	dscf	2211					from accompanying spreadsheet	
Concentration EtO at scrubber Outlet	Co	lb/dscf	0.00011409					=E88*0.00000000259*E12	Pollutant Concentration = analytical result in ppm x 2.59 E-9 x MW EtO
Mass flow rate EtO exiting scrubber	Wo	pounds	0.252252					=E89*E90	scrubber otlet EtO mass flow rate = outlet gas vol x pollutant concentration
Control Device Efficiency	% Eff	%	99.76657					=(E87-E91)/(E87)*100	% Eff = (mass EtO inlet - mass EtO outlet)/mass EtO inlet x 100

Example Scrubber Outlet Volumetric Flow Rate Calculation

Run 1 - 1/29/2014 Chamber I

Pbar	29.83	in Hg	Bws, Avg Moisture %		-0.0446
Ps	-0.015	in H2O	mol wtstack gas		28
Ds	8	inch	Cp		0.84
Kp	85.49		stack area		0.35
Ps	29.83	in Hg	Ms		30.00

Traverse Point	Delta P in. H20	SQRT Delta P	Ts (deg F)
1	0.025	0.158114	88
2	0.03	0.173205	88
3	0.03	0.173205	88.1
4	0.03	0.173205	88.1
5	0.025	0.158114	88
6	0.03	0.173205	88
1	0.03	0.173205	88.1
2	0.025	0.158114	88.1
3	0.03	0.173205	88.1
4	0.03	0.173205	88.1
5	0.03	0.173205	88.1
6	0.035	0.187083	88.1
avg		0.171	88.067

Ms assigned value of 30 per Method 3

Vs = Kp x Cp x SQRTDPavg x (Ts/(Ps x Ms))^.5

Vs = N99 x R98 x O115 x ((P115+460)/(N100 x R100))^.5

Vs 9.59 fps

Bws fro Method 4 sample

Q = 60*(1-Bws)*Vs*A*((Tstd*Ps)/(Ts*Pstd))

Q = 60 x (1 - R96) x R104 x R99 x (528 x N100) / ((P115 +460) x 29.92)

Q 192.93 dscfm

t 12 minutes

Q total = flow rate in dscfm x time of test in minutes

Qtotal 2315.2 dscf

ATTACHMENT B
USEPA REGION 1 LETTER DATED 040622

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

Clean Air Act Inspection Report

Drafted: March 29, 2022
Finalized: March 30, 2022

EPA Inspector: Darren Fortescue, Senior Enforcement Coordinator, Air Compliance Section /DEF/
Davianna Vasconcelos, Environmental Engineer, Air Compliance Section

EPA Reviewer: Christine Sansevero, Chief, Air Compliance Section /CMS/

Date of Inspection: March 23, 2022

Facility Name: Professional Contract Sterilization, Inc.

ICISAir ID#: MA0000002512000879

Facility Location: 40 Myles Standish Boulevard, Taunton, MA 02780

Mailing Address: As above

Disclaimer:

Unless otherwise noted, this report describes conditions at the facility/property as observed by EPA inspector(s), and/or through records provided to and/or information reported to EPA inspector(s) by facility representatives and as understood by the inspector(s). This report may not capture all operations or activities ongoing at the time of the inspection. This report does not make final determinations on potential areas of concern. Nothing in this report affects EPA's authorities under federal statutes and regulations to pursue further investigation or action.

Inspection Attendees:

Name	Title	Organization
Darren Fortescue	Senior Enforcement Coordinator	EPA Region 1
Davianna Vasconcelos	Environmental Engineer	EPA Region 1
Gary Cranston	President	Professional Contract Sterilization
Marie Cranston	Administration	Professional Contract Sterilization

Facility/Process Description:

History

The facility, located at 40 Myles Standish Boulevard, Taunton, Massachusetts, is owned and operated by Professional Contract Sterilization, Inc. ("PCS"). The facility provides ethylene oxide contact sterilization services and sterilizes medical and veterinarian devices.

The facility was built in 1990 and at that time there were three sterilization chambers installed. In 1997, the facility doubled in size to approximately 34,000 ft^3 and three more sterilization chambers were added (one is currently not operational).

Ethylene Oxide Sterilization and Aeration

The facility has five operational and one non-operational sterilization chambers (see Table 1). PCS uses 100% ethylene oxide for sterilization.

Table 1: Sterilization Chambers Installed at PCS.

Vessel	Capacity (ft^3)	Installation Year
1	1140	1990
2	670	1990
3	405	1990
4	250	1997
5	30	1997
6	1140	Not Operational

Three aeration rooms are installed at the facility. Two of the aeration rooms are used for ethylene oxide aeration, while the third is used for storage only.

Ethylene Oxide Pollution Control Systems

Emissions from the operational sterilization chamber vents and the vacuum pump exhausts are ducted to a Damas Corporation tri-phase ethylene oxide scrubber. The scrubber is vented to the atmosphere.

Emissions from the two operational aeration rooms are ducted to a Anguil catalytic oxidizer. The oxidizer is vented to the atmosphere. The third aeration room also has the capacity to be ducted to the oxidizer; however, the ducting is currently shut off.

Ethylene Oxide Monitoring

Ethylene oxide monitoring is performed using a PID gas chromatograph system. The PID system monitors the following locations:

- Inlet to the catalytic oxidizer;
- Outlet from the catalytic oxidizer;
- Outlet from the scrubber;
- Ethylene oxide storage room 1;
- Ethylene oxide storage room 2;
- Scrubber room;
- Sterilizer room 1;
- Sterilizer room 2;
- Maintenance/mechanical room near the analyzer; and
- The rear of the maintenance/mechanical room (outside the ethylene oxide storage rooms).

Samples are collected from each location via teflon tubing. Each analysis cycle takes approximately two minutes to perform, and each location is sampled at least twice per hour.

Number of Employees and Working Hours:

PCS employs 6 full time employees. The facility is permitted to operate 24 hours per a day; however, it is currently operating on a 08:00 to 17:00 single shift, five days per week.

Potentially Applicable Clean Air Act Requirements:

40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities ("Subpart O").

Previous Enforcement Actions:

A "Detailed Facility Report" from EPA's Enforcement and Compliance History Online database indicates that there have been no informal or formal enforcement actions taken against PCS in the past five years.

Opening Conference:

Entry

On March 23, 2022, at 10:00 am, EPA Region 1 representatives Darren Fortescue, and Davianna Vasconcelos arrived at the PCS facility, located at 40 Myles Standish Boulevard, Taunton,

Massachusetts and met Gary Cranston and Marie Cranston of PCS. Mr. Fortescue presented his credentials, provided a copy of the US EPA Small Business Resources Information Sheet, and initiated an opening conference.

Conference

Mr. Fortescue asked about the annual ethylene oxide usage for the years 2019 through 2021. Facility representatives said they had not yet calculated the 2021 total but said they would supply the information via email after the inspection. Facility representatives indicated that the annual ethylene oxide usage for the years 2019 through 2021 had been more than 10 tons.

Facility representatives said sterilized devices are moved from sterilization chambers to aeration rooms using hand jacks or forklifts. Facility representatives said that sterilized devices are not moved from the chambers to aeration until the ethylene oxide concentration in the chambers drops below 1 ppm.

Facility representatives said the lines that supply ethylene oxide to the sterilization chambers are back flushed into the ethylene oxide tanks using nitrogen after each cycle.

Facility representatives said that the prior ethylene oxide monitoring system had used a HNU Systems gas chromatograph; however, this had been replaced with the PID gas chromatograph in 2022.

Facility representatives said the Damas scrubber uses a 5% sulfuric acid aqueous solution that absorbs ethylene oxide from the flue gas and then produces ethylene glycol in the presence of sulfuric acid that acts as the catalyst for the reaction. Facility representatives said PCS monitors and records the glycol level in the scrubber reservoirs daily. Facility representatives said the glycol concentration in the scrubber media is monitored using a hydrometer. Facility representatives said the scrubber media is periodically shipped offsite to be processed into other products, such as antifreeze.

Facility representatives said the Anguil Catalytic Oxidizer has a 20,000 cfm capacity but is only operated at 5,000 cfm. Facility representatives explained that while the oxidizer is designed to have two carbon bed catalysts, because the system is only operated at 5,000 cfm, only one bed is necessary. Facility representatives said the oxidation temperature is maintained at no less than 265 °F, and this limit is based on design criteria provided by the manufacturer. Facility representatives said the oxidation temperature is monitored using a type K thermocouple that is calibrated on an annual basis. Facility representatives said the oxidizer operates under negative pressure that pulls flue gas from the aeration rooms through the system.

Facility representatives said that stack testing of the control systems was performed in 1990 and in 1997. Facility representatives said copies of the full stack test reports would be provided via

email after the inspection. Facility representatives said MassDEP observed the stack tests in 1990 and 1997, but were not certain if EPA observed the testing.

Facility representatives said annual stack testing is not conducted on the catalytic oxidizer. Facility representatives explained that while the oxidizer catalyst bed material has been tested and replaced, it is not a routine process. Facility representatives said the ethylene oxide concentrations at the outlet from the oxidizer are monitored using the PID gas chromatograph system.

Facility representatives indicated they did not believe that PCS had been routinely submitting reports to EPA.

Facility Tour:

Mr. Cranston and Ms. Cranston led Mr. Fortescue and Ms. Vasconcelos on a tour of the facility.

The group proceeded to an area that facility representatives said was the receiving area. Facility representatives said no ethylene oxide monitoring is conducted in the receiving area.

The group entered a room that Mr. Fortescue noticed was significantly hotter and more humid that the receiving area. Facility representatives said it is the preconditioning room. Facility representatives said devices are preconditioned in the room for between 24 and 48 hours, prior to sterilization.

The group exited the preconditioning room and proceeded past equipment mounted to the wall of the facility. Facility representatives said the equipment is used to heat water to be used in the hot water jackets for the sterilization chambers.

Mr. Cranston opened a bay door that allowed the EPA inspectors to see inside a large room. Facility representatives said the room contained Sterilization Chambers 3, 4, 5 and 6. Mr. Fortescue observed several chambers were installed in the room. Mr. Cranston pointed out a partially dismantled chamber, he said is Sterilization Chamber 6. Mr. Cranston said Sterilization Chamber 6 had never been operational.

Facility representatives pointed out a metal cart that they said is used to place devices ready for sterilization into one of the smaller sterilization chambers. Facility representatives said pallets are used for the larger chambers.

Mr. Cranston said the sterilization chambers are all located in a secondary containment area designed to contain water in the event it is necessary to control a fire. Mr. Cranston said rollers are used to facilitate pallet insertion and removal from the sterilization chambers.

Mr. Fortescue observed that the sterilization chambers had fume hoods above the doors. Mr. Cranston said there are also fume capture grates below the doors. Mr. Fortescue asked if the hoods and grates feed into either the scrubber or catalytic oxidizer ductwork. Mr. Cranston said he did not know and would check and confirm via email after the inspection.

Mr. Cranston said both the rooms that house the ethylene oxide sterilization chambers have ethylene oxide monitoring lines to the PID gas chromatograph system.

The group proceeded through a control room into a maintenance room. EPA representatives met with John Marshall of Eastland Engineering. Mr. Fortescue observed a PID gas chromatograph analyzer. Mr. Marshall said the analyzer monitors several locations throughout the facility and it monitors each location at least twice every hour. Mr. Marshall said the gas chromatographs for each analysis performed are stored on the analyzer. Mr. Marshall said he produced an ethylene oxide monitoring data report for PCS on a weekly basis. Mr. Marshall said the column used in the system is a metal capillary column. Mr. Marshall said the analyzer performs a self-calibration once per day. Mr. Marshall said he did not know if the PID gas chromatograph system meets either Performance Specifications 8 or 9 (found at 40 CFR Part 60, Appendix B).

The group proceeded to a room that Mr. Cranston said is Ethylene Oxide Storage Room 1. Mr. Fortescue observed several metal storage containers, some of which were placed on scales. Mr. Cranston said some of the storage containers contain ethylene oxide and the others contain nitrogen. Mr. Cranston said that quality assurance and quality control checks are performed on the scales used to monitor ethylene oxide usage both before and after each cycle.

Mr. Cranston said both the ethylene oxide storage rooms have ethylene oxide monitoring lines to the PID gas chromatograph system. Mr. Cranston said the ethylene oxide storage rooms are not vented to either the scrubber or the catalytic oxidizer. Mr Cranston said that the ethylene oxide storage rooms are not ducted to control devices, due to the inherent explosion risk.

The group proceeded to a room that Mr. Cranston said housed the Damas ethylene oxide scrubber. Mr. Cranston said the ethylene oxide is passed through the scrubber media and reacts to form ethylene glycol. Mr. Fortescue observed markings on the side of a tank. Mr. Cranston said that when the liquid level in the tank reaches 70 it is pumped to a storage tank. Mr. Cranston said once the combined tank capacity is reached, PCS contacts an environmental waste company located in Chicago to arrange to have the ethylene glycol shipped offsite. Mr. Cranston said the scrubber room has an ethylene oxide monitoring line to the PID gas chromatograph system.

The group exited the rear of the building. Mr. Fortescue observed a piece of control equipment located on the roof of the facility. Mr. Cranston staid the control equipment is the catalytic oxidizer that controls ethylene oxide emissions from the aeration rooms. Mr. Fortescue observed

two stacks, Mr. Cranston said one is connected ot the oxidizer and the other is connected directly to the ethylene oxide storage rooms.

The group proceeded to a room that Facility representatives said is one of the aeration rooms. Mr. Cranston said there are no ethylene oxide monitoring lines located in any of the aeration rooms.

The group proceeded to an area that Mr. Cranston said is the final shipping area. Mr. Cranston said there are no ethylene oxide monitoring lines located in the final shipping area.

Closing Conference:

Mr. Fortescue and Ms. Vasconcelos thanked Mr. Cranston and Ms. Cranston for their time.

Mr. Fortescue said that Subpart O is not delegated to the state in the event that a facility is not a Title V facility (PCS is not a Title V facility). Mr. Fortescue recommended that PCS review Subpart O to ensure they are meeting all the requirements of the regulation.

Mr Fortescue requested the following information be supplied by email as soon as practicable:

- The company's NAICS Code;
- The annual ethylene oxide usage for the facility for 2019, 2020 and 2021;
- If the sterilizer bay areas are vented to the catalytic oxidizer;
- Full copies of the stack test reports for the tests conducted in 1990 and 1997;
- The name of the US EPA employees that attended or were involved with any stack testing, in the event any were;
- Documentation describing the daily glycol liquor levels for the last three months;
- To confirm if the PID gas chromatograph system meets either Performance Specification 8 or 9 described in 40 CFR Part 60, Appendix B; and
- Copies of the temperature charts for the last 5 days.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

URGENT LEGAL MATTER
REQUIRES PROMPT RESPONSE

Dated by Electronic Signature below

Gary Cranston, President
Professional Contract Sterilization, Inc.
40 Myles Standish Boulevard
Taunton, MA 02780

Re: Clean Air Act Testing Requirement

Dear Mr. Cranston:

The United States Environmental Protection Agency ("EPA") is evaluating whether Professional Contract Sterilization, Inc. ("PCS") is in compliance with the Clean Air Act ("CAA") and requirements promulgated under the CAA at its facility located at 40 Myles Standish Boulevard Taunton, Massachusetts. 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 ("Subpart O").

Section 114(a)(1) of the Act, 42 U.S.C. § 7414(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.

EPA is evaluating emissions of the hazardous air pollutant, ethylene oxide, from the sterilization and aeration processes operated at the facility. To do so, EPA is requiring PCS to test emissions from the Damas Corporation tri-phase ethylene oxide scrubber and the Anguil Environmental Systems catalytic oxidizer used to control ethylene oxide emissions from the sterilization and aeration processes. Preparations and performance testing shall be conducted as described below.

Testing Requirement

PCS shall develop a performance test plan for EPA approval that describes the following elements in detail and shall subsequently conduct performance testing of ethylene oxide emissions.

Sterilization Chamber Performance Testing

1) Sterilization chamber performance testing shall consist of two sets of three runs.
   a) The first three run set shall be conducted under maximum operating conditions, i.e., while venting the maximum "permitted"[1] number of chambers.
   b) The second three run set shall be conducted while venting the smallest chamber, i.e., Vessel 5, which has a 30 ft^3 capacity.

2) All test runs conducted on sterilization chambers shall be performed during the first evacuation of all applicable chambers and the chambers must be empty of products and devices.

3) All test runs conducted on sterilization chambers shall be performed when the chambers are charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature). The performance test plan shall include documentation that verifies the typical amount of ethylene oxide usage, and the normal operating conditions for each chamber being tested. The final test report shall document ethylene oxide usage and operating conditions during the performance testing.

4) The total mass of ethylene oxide loaded into each applicable sterilization chamber shall be determined using the procedures described at 40 C.F.R. § 63.365(b)(1)(i).

5) The residual mass of ethylene oxide in each applicable the sterilizer chamber shall be determined using the procedures described at 40 C.F.R. § 63.365(b)(1)(ii).

6) The total mass of ethylene oxide at the inlet to the Damas Corporation tri-phase ethylene oxide scrubber shall be determined using the procedures described in 40 C.F.R. § 63.365(b)(1)(iii).

7) The mass of ethylene oxide emitted from the Damas Corporation tri-phase ethylene oxide scrubber outlet shall be determined using the procedures described in 40 C.F.R. § 63.365(b)(1)(iv).

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[1] If the maximum sterilization operating conditions are not restricted by a federally enforceable limit documented in a permit issued by MassDEP, PCS shall provide documentation describing what the maximum operating conditions are for the facility.

8) The control efficiency of the Damas Corporation tri-phase ethylene oxide scrubber for each test scenario shall be determined using the procedures described in 40 C.F.R. § 63.365(b)(1)(v).

9) If ethylene glycol concentration is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(e)(1) shall be used to determine a baseline operating parameter for the Damas Corporation tri-phase ethylene oxide scrubber. All glycol concentrations determined during performance testing shall be documented in the final test report.

10) If the scrubber liquor tank level is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(e)(2) shall be used to determine a baseline operating parameter for the Damas Corporation tri-phase ethylene oxide scrubber. All scrubber liquor tank levels determined during performance testing shall be documented in the final test report.

11) All continuous emissions monitoring system ("CEMS") data collected by the PID gas chromatograph system during the performance testing of the sterilization chambers shall be provided in the final test report.

Aeration Room Performance Testing

12) Aeration room performance testing shall consist of three one-hour runs. The one-hour runs shall be conducted under maximum operating conditions, i.e., while aerating the maximum "permitted"[2] volume of products and devices in both functional aeration rooms. Documentation shall be provided in the performance test plan that describes the maximum permitted volume of products and devices.

13) Aeration room performance testing shall be performed while the temperature at the outlet from the catalyst bed of a Anguil Environmental Systems catalytic oxidizer is at, or above, the manufacturer's recommended temperature. Documentation describing the manufacturer's recommended temperature at the outlet from the catalyst bed shall be supplied in the performance test plan. Documentation describing the outlet from the catalyst bed used during performance testing shall be documented in the final test report.

14) If the ethylene oxide concentration at the outlet from the Anguil Environmental Systems catalytic oxidizer is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(c)(2) shall be used.

[2] If the maximum volume of products and devices is not restricted by a federally enforceable limit documented in a permit issued by Mass DEP, PCS shall provide documentation describing the maximum volume of products and devices the facility is capable of aerating at any point in time.

15) If the ethylene oxide removal efficiency of the Anguil Environmental Systems catalytic oxidizer is being used to demonstrate compliance with Subpart O, then the procedures described in 40 C.F.R. § 63.365(d) shall be used.

16) All continuous emissions monitoring system ("CEMS") data collected by the PID gas chromatograph system during the performance testing of the aeration rooms shall be provided in the final test report.

PCS shall prepare for and conduct performance testing according to the following schedule:

17) Within 15 days of the date PCS receives this letter, contact EPA Senior Enforcement Coordinator Darren Fortescue, at (617) 918-1162, or fortescue.darren@epa.gov to schedule a conference. At this conference, EPA will review with PCS the testing procedures, monitoring procedures, and testing methods described above and discuss the development of a performance test plan.

18) Within 30 days of the date PCS receives this letter, prepare and email to EPA for review a performance test plan that incorporates the procedures/methods described above.

19) Within 15 days of receiving EPA comments on the performance test plan, PCS shall 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.

20) Within 15 days of the date EPA approves the performance test plan, PCS shall hold a pre-test meeting with EPA and schedule the testing date(s). The testing must take place no later than 30 days after the pre-test meeting.

21) Within 45 days of completing the testing, PCS must submit a complete test report to EPA.

Provide all documents electronically[3] via email to fortescue.darren@epa.gov.

Be aware that if PCS does not provide the information and perform the testing required in a timely manner, EPA may order it to comply and may assess monetary penalties under Section 113 of the Clean Air Act. Federal law also establishes criminal penalties for providing false information to EPA. This letter is not subject to Office of Management and Budget review pursuant to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

[3] Note that EPA cannot receive email messages with files larger than 25 MB. If your submissions are larger than 25 MB, please contact Darren Fortescue for other options.

You may assert a business confidentiality claim covering part or all of the information requested, in the manner described by 40 CFR § 2.203(b). Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2, Subpart B. Note that certain categories of information, such as emission data, are not properly the subject of such a claim. If no such claim accompanies the information when EPA receives it, EPA may make the information available to the public without further notice to you.

If you have any questions regarding this Testing Requirement, please contact Darren Fortescue at (617) 918-1162 or fortescue.darren@epa.gov, or have your attorney contact Michael Wagner at (617) 918-1735 or wagner.michael@epa.gov.

Sincerely,

KAREN MCGUIRE Digitally signed by KAREN MCGUIRE
Date: 2022.04.06 13:16:49 -04'00'

Karen McGuire, Director
Enforcement and Compliance Assurance Division

Enclosures:

cc: Dan DiSalvio, MassDEP

ATTACHMENT C

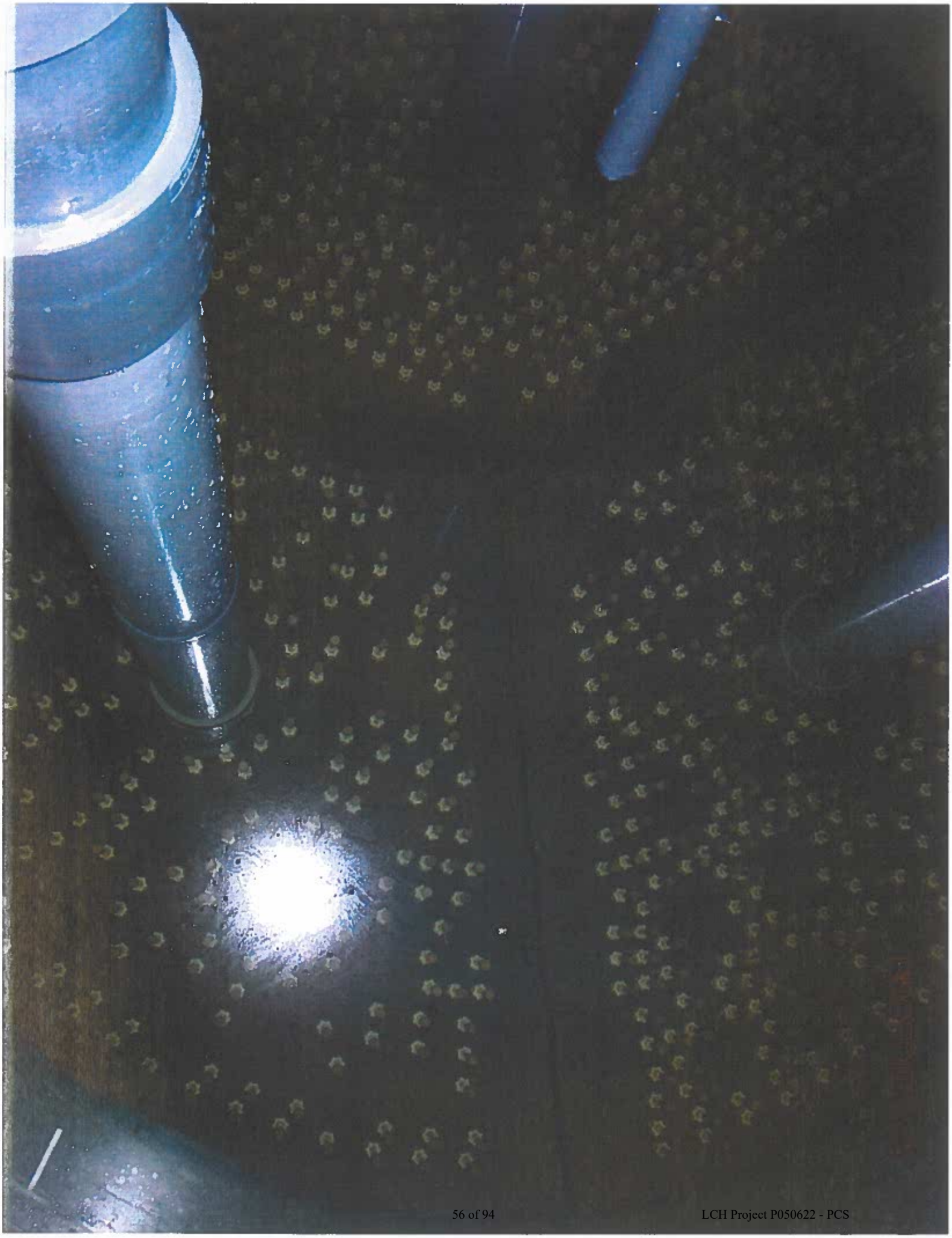
DAMAS CORPORATION TRI-PHASE ETHYLENE OXIDE SCRUBBER PICTURE AND BOILER PLATE INFORMATION

CBI

Figure 4.4

CBI

CBI



ATTACHMENT D

ANGUIL ENVIRONMENTAL SYSTEMS CATALYTIC THERMAL OXIDIZER PICTURE AND BOILER PLATE INFORMATION

CBI

ANGUIL

CBI

CBI

CBI

CBI

CBI

ATTACHMENT E

EXAMPLE PROCESS (STERILIZATION CYCLE) RUN RECORDS

CBI

CBI

CBI

ATTACHMENT F
CALIBRATION GAS CERTIFICATES

Calibration gases for this project are ordered, but not yet received. When the cylinders and their accompanying certifications sheets become available, the certification sheets will be forwarded to your attention immediately.

ATTACHMENT G
FIELD DATA SHEETS

Analyzer Calibration Error Check

Facility: Professional Contract Sterilization
Source: Anguil Outlet
Date: 08/15/22

Runs: 1, 2, and 3
Operator: C. Heilner

Analyzer Make and Model	Span Gas Concentration (ppmv or %)	Analyzer Span (ppmv or %)	Analyzer Calibration Response (ppmv or %)	Absolute Difference (ppmv or %)	Calibration Error (% of Span)
CAI700					
O_2		0.0			
Zero		to		0.0	#DIV/0!
Mid		0.0		0.0	#DIV/0!
High		%		0.0	#DIV/0!
CAI700					
CO_2		0.0			
Zero		to		0.00	#DIV/0!
Mid		0.0		0.00	#DIV/0!
High		%		0.00	#DIV/0!

Note:

1) Eq. 7E-1 for analyzer calibration error: ACE = $[(C_{Dir} - C_V) / CS]$ 100
2) For all analyzers, except TOC, calibration gases are introduced directly to the analyzer and analyzer calibration error must be within ± 2% of calibration span.
3) For TOC analyzer, calibration gases are introduced through the entire measurement system and analyzer calibration error must be < 5% of calibration gas value.

Analyzer Bias and Drift Check and
Emission Concentration Calculations

Facility: Professional Contract Sterilization
Source: Anguil Outlet
Date: 8/15/22
Run No: One

Time Start: 10:00
Time Stop: NA
Time Restart: NA
Time End: 11:00

Analyzer	Analyzer Span (ppm or %)	(Cma) Bias Gas Concentration (ppm or %)	Analyzer Calibration Response (ppm or %)	Initial Bias Sys. Cal. Response (ppm or %)	Initial Bias (SB) Sys. Bias (% of Span)	Final Bias Sys. Cal. Response (ppm or %)	Final Bias (SB) Sys. Bias (% of span)	(D) Drift (% of span)	(C) Average Test Run Response (ppm or %)	(Cm & Co) Average Sys Cal Response (ppm or %)	(Cgas) Average Emission Concentration (ppm or %)
O_2	0.0 %										
Zero	-	0.00	0.00		#DIV/0!		#DIV/0!	#DIV/0!		0.000	#DIV/0!
Upscale	-	0.00	0.00		#DIV/0!		#DIV/0!	#DIV/0!		0.000	
CO_2	0.0 %										
Zero	-	0.00	0.00		#DIV/0!		#DIV/0!	#DIV/0!		0.000	#DIV/0!
Upscale	-	0.00	0.00		#DIV/0!		#DIV/0!	#DIV/0!		0.000	

Note: 1) Eq. 7E-2 for system bias: $SB = [(C_S - C_{Dir}) / CS] 100$

2) Eq. 7E-4 for analyzer drift: $D = [(SB_{final} - SB_i) / CS] 100$

3) Eq. 7E-5 for average effluent gas concentration adjusted for bias: $C_{Gas} = (C_{Avg} - C_O) [C_{MA} / (C_M - C_O)]$

4) Initial and final system bias (SB) must be within ± 5% of calibration span (CS), bias requiremnt not applicable for Method 25A TOC

5) Zero and upscale analyzer drift (D) must be ≤ 3% of calibration span (CS)

6) TOC is expressed as propane.

Analyzer Bias and Drift Check and
Emission Concentration Calculations

Facility: Professional Contract Sterilization
Source: Anguil Outlet
Date: 8/15/22
Run No: Two

Time Start: 11:15
Time Stop: NA
Time Restart: NA
Time End: 12:15

Analyzer	Analyzer Span (ppm or %)	(Cma) Bias Gas Concentration (ppm or %)	Analyzer Calibration Response (ppm or %)	Initial Bias Sys. Cal. Response (ppm or %)	Initial Bias (SB) Sys. Bias (% of Span)	Final Bias Sys. Cal. Response (ppm or %)	Final Bias (SB) Sys. Bias (% of span)	(D) Drift (% of span)	(C) Average Test Run Response (ppm or %)	(Cm & Co) Average Sys Cal Response (ppm or %)	(Cgas) Average Emission Concentration (ppm or %)
O_2	0.0 %										
Zero	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	#DIV/0!
Upscale	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	
CO_2	0.0 %										
Zero	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	#DIV/0!
Upscale	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	

Note: 1) Eq. 7E-2 for system bias: $SB = [(C_S - C_{Dir}) / CS] 100$

2) Eq. 7E-4 for analyzer drift: $D = [(SB_{final} - SB_i) / CS] 100$

3) Eq. 7E-5 for average effluent gas concentration adjusted for bias: $C_{Gas} = (C_{Avg} - C_O) [C_{MA} / (C_M - C_O)]$

4) Initial and final system bias (SB) must be within ± 5% of calibration span (CS), bias requiremnt not applicable for Method 25A TOC

5) Zero and upscale analyzer drift (D) must be ≤ 3% of calibration span (CS)

6) TOC is expressed as propane.

Analyzer Bias and Drift Check and
Emission Concentration Calculations

Facility: Professional Contract Sterilization
Source: Anguil Outlet
Date: 8/15/22
Run No: Three

Time Start: 12:30
Time Stop: NA
Time Restart: NA
Time End: 13:30

Analyzer	Analyzer Span (ppm or %)	(Cma) Bias Gas Concentration (ppm or %)	Analyzer Calibration Response (ppm or %)	Initial Bias Sys. Cal. Response (ppm or %)	Initial Bias (SB) Sys. Bias (% of Span)	Final Bias Sys. Cal. Response (ppm or %)	Final Bias (SB) Sys. Bias (% of span)	(D) Drift (% of span)	(C) Average Test Run Response (ppm or %)	(Cm & Co) Average Sys Cal Response (ppm or %)	(Cgas) Average Emission Concentration (ppm or %)
O_2	0.0 %										
Zero	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	#DIV/0!
Upscale	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	
CO_2	0.0 %										
Zero	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	#DIV/0!
Upscale	-	0.00	0.00	0.00	#DIV/0!		#DIV/0!	#DIV/0!		0.000	

Note: 1) Eq. 7E-2 for system bias: $SB = [(C_S - C_{Dir}) / CS] 100$

2) Eq. 7E-4 for analyzer drift: $D = [(SB_{final} - SB_i) / CS] 100$

3) Eq. 7E-5 for average effluent gas concentration adjusted for bias: $C_{Gas} = (C_{Avg} - C_O) [C_{MA} / (C_M - C_O)]$

4) Initial and final system bias (SB) must be within ± 5% of calibration span (CS), bias requiremnt not applicable for Method 25A TOC

5) Zero and upscale analyzer drift (D) must be ≤ 3% of calibration span (CS)

6) TOC is expressed as propane.

PCS

Date	Unit ID	Diameter

Pitot ID	Pitot Cp	Pitot Leak Check Pre-Test	Pitot Leak Check Post-Test
STD6	0.99		

USEPA Method 2C Field Data Run No._____

Clock Time	Elapsed Minutes	ΔP ("H2O)	Stack Temperature (ºF)
	1		
	2		
	3		
	4		
	5		
	6		
	7		
	8		
	9		
	10		
	11		
	12		
	13		
	14		
	15		
	16		
	17		
	18		
	19		
	20		
	21		
	22		
	23		
	24		
	25		
	26		
	27		
	28		
	29		
	30		

Static Pressure ("H2O) 1		Barometric Pressure ("Hg) 1	
Personnel			

USEPA Method 2C Field Data Run No._____Cont.

Clock Time	Port/Traverse Point	ΔP ("H2O)	Stack Temperature (ºF)
	31		
	32		
	33		
	34		
	35		
	36		
	37		
	38		
	39		
	40		
	41		
	42		
	43		
	44		
	45		
	46		
	47		
	48		
	49		
	50		
	51		
	52		
	53		
	54		
	55		
	56		
	57		
	58		
	59		
	60		

Static Pressure ("H2O) 1		Barometric Pressure ("Hg) 1	
Personnel			

Date		Controller ID	
Unit ID	Scrubber Outlet	Tank ID	
Diameter	6"	Bag ID	

USEPA Method 18 Data Run No._____

Clock Time	Elapsed Time (Minutes)	Flow Rate	Vaccum
	0		
	5		
	10		
	15		
	20		
	25		
	30		

Date		Controller ID	
Unit ID		Tank ID	
Diameter		Bag ID	

USEPA Method 18 Data Run No._____

Clock Time	Elapsed Time (Minutes)	Flow Rate	Vaccum
	35		
	40		
	45		
	50		
	55		
	60		

ATTACHMENT H

ANGUIL OPERATING PROCEDURES AND THERMOCOUPLE CALIBRATION RECORDS

Instrument Calibration Record

Instrument: Chart Recorder 1&2 TC	Model No: DR45AT-1110-40-001-0-000P00-0	Range/Grade: 0-900F	Asset No: I9C1A
MFR: Honeywell	Serial No: 94730Y417365500001	Use Point: Varies	Location: Angwin Control Rm
Prepared BY: PCS	Approved By: PCS	Increments: 10°F	Accuracy: 5%

	As Found Status	Reason For Service	Final Test Status	
Cal Freq: 6 months	(✓) In Tolerance	(✓) Scheduled	(✓) Calibrated	( ) Reference Only
Cal Date: 5/26/22	( ) Out of Tolerance	( ) Unscheduled	( ) Limited Cal	( ) Do NOT Use
Due Date: 11/23	( ) In Operative		( ) Verification	

Parameter and Units Measured	As Found Test Data #1/#2			Final Test Data #1/#2							
				Test 1		Test 2 1/2		Test 3		Average	
	Standard	Instrument	Tolerance (+/-)	Standard	Instrument	Standard	Instrument	Standard	Instrument	Standard	Instrument
100 F	100	100/101	5	100	100/101	100	100/101	100	98/101	100	99/101
200 F	200	198/201	5	200	198/201	200	198/201	200	198/201	200	198/201
300 F	300	298/301	5	300	298/301	300	298/301	300	298/301	300	298/301

Comments: TC - Type "J"

Time of Calibration
Temperature: 80°F
Humidity: 46%
Asset #: 21905423

Calib. SOP: QA-06-103

Standards Used	Asset No.	Due Date
Transmation 1000	E416	3/23

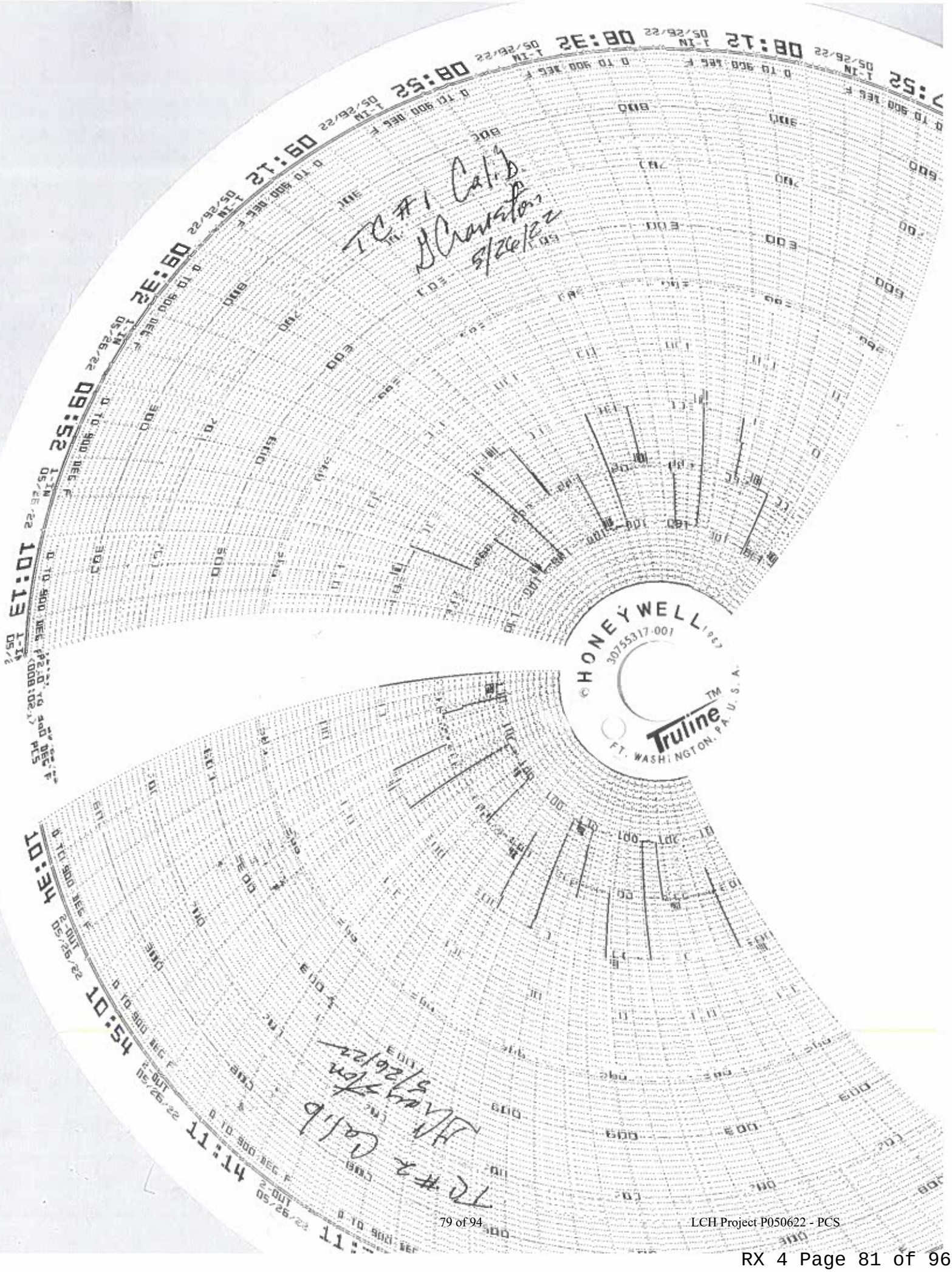
Expired Calibration Label
PCS, Inc.
Equip.# I9C1A
Techn. JCranston
Cal. Performed 5/9/21
Cal. Due Date 5/5/22
Form #1-01-004CF Rev. 7/98

Form #1-01-004aF
Rev. 1 12/00
PCS, Inc.

Calibrator: JONATHAN DAROS & JCranston
Date: 05/26/2022
Reviewer: Marie Cranston
Date: 5/27/22

EFFECTIVE
DEC 2 2 2000

COPY


TC #1 Calib.
J Cranston
5/26/22
HONEYWELL
30755317-001
Truline
FT. WASHINGTON, PA. U.S.A.
TC #2 Calib.
J Cranston
5/26/22

Instrument Calibration Record

Instrument: Chart Recorder 3&4	Model No. DR45 A1-1110-40-001-0-000P000-0	Range/Grade 0-900F	Asset No. I9CIA
MFR: Honeywell	Serial No. 947307417365500001	Use Point:	Location:
Prepared BY: PCS	Approved By: PCS	Increments: 10F	Accuracy:

	As Found Status	Reason For Service	Final Test Status	
Cal Freq: 6 months	(Y) In Tolerance	(Y) Scheduled	(Y) Calibrated	( ) Reference Only
Cal Date: 5/26/2022	( ) Out of Tolerance	( ) Unscheduled	( ) Limited Cal	( ) Do NOT Use
Due Date: 11/22	( ) In Operative		( ) Verification	

Parameter and Units Measured	As Found Test Data TC 3/4			Final Test Data TC 3/4							
				Test 1		Test 2		Test 3		Average	
	Standard	Instrument	Tolerance (+/-)	Standard	Instrument	Standard	Instrument	Standard	Instrument	Standard	Instrument
100 °F	100	102/103	5	100	102/103	100	102/102	100	102/103	100	102/103
200 °F	200	203/203	5	200	202/202	200	202/202	200	202/203	200	202/202.5
300 °F	300	302/302	5	300	302/302	300	302/302	300	302/302	300	302/302

Comments: TC - Type "J"

Time of Calibration
Temperature: 80°F
Humidity: 46%
Asset #: 210905423

Calib. SOP: QA-06-103

Standards Used	Asset No.	Due Date
transmation 1000	E416	3/23

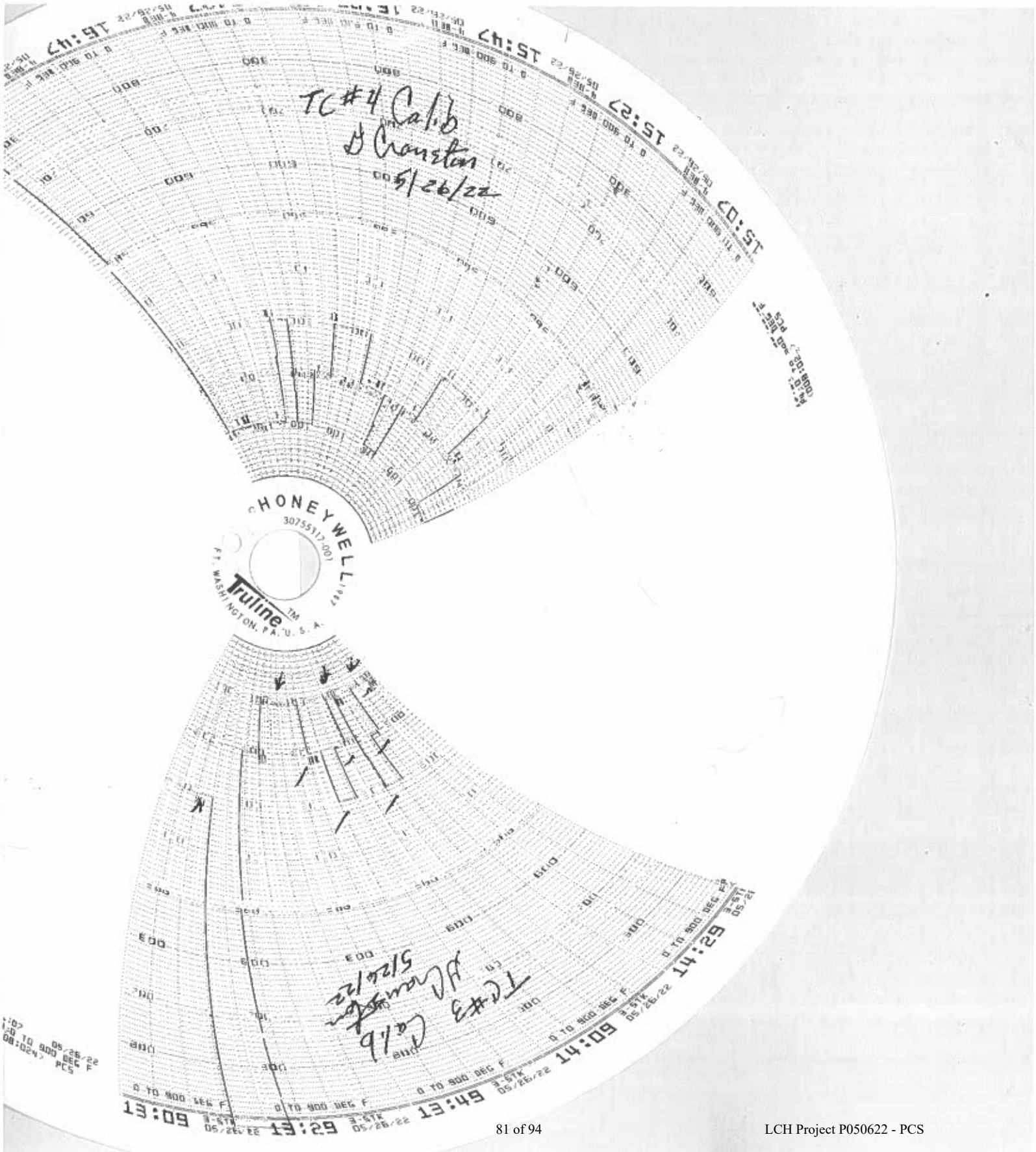
Expired Calibration Label

Form #1-01-004aF
Rev. 1 12/00
PCS, Inc.

Calibrator: JOHNATAN D ROSA
Date: 05/26/2022
Reviewer: Marc Cross
Date: 5/27/22

EFFECTIVE
DEC 22 2000

COPY


TC#4 Calib
D Cranston
5/26/22
HONEYWELL
Truline
FT. WASHINGTON, PA. U.S.A.
TC#3 Calib
5/26/22
0 TO 900 DEG F
13:09
13:29
13:49
14:09
14:29

Angwil

Instrument Calibration Record

Instrument: High Temp Limit Temp Controller	Model No. DC200H-2000-1F0000-0	Range/Grade 0-900F	Asset No. I9IA
MFR: Honeywell	Serial No. 9430Y4173656000001	Use Point:	Location: Angwil Control Panel
Prepared BY: DCS	Approved By: PCS	Increments: 1°F	Accuracy: 5% FS

	As Found Status	Reason For Service	Final Test Status	
Cal Freq: Biyearly	(✓) In Tolerance	(✓) Scheduled	(✓) Calibrated	( ) Reference Only
Cal Date: 5/26/22	( ) Out of Tolerance	( ) Unscheduled	( ) Limited Cal	( ) Do NOT Use
Due Date: 11/22	( ) In Operative		( ) Verification	

Parameter and Units Measured		As Found Test Data			Final Test Data							
					Test 1		Test 2		Test 3		Average	
		Standard	Instrument	Tolerance (+/-)	Standard	Instrument	Standard	Instrument	Standard	Instrument	Standard	Instrument
100	°F	100	98	5	100	98	100	98	see		100	98
200	°F	200	198	5	200	198	200	198	As	found	200	198
300	°F	300	298	5	300	298	300	298	test		300	298
600	°F	600	598	5	600	598	600	598	Data		600	598

Comments: Type J TC

Time of Calibration
Temperature: 80°F
Humidity: 46%
Asset #: 2109054/23

Calib. SOP: QA-06-103

Standards Used	Asset No.	Due Date
Transmation	E416	3/23

Expired Calibration Label
PCS, Inc.
Equip.# I9I/A
Techn. DCranston
Cal. Performed 5,19,21
Cal. Due Date 5-1-,22
Form #1-01-004aF
Rev. 1 12/00
PCS, Inc.

Calibrator: Gary Cranston
Date: 5/26/22
Reviewer: Mary Cranston
EFFECTIVE Date: 5/27/22
DEC 2 2 2000

Anguil

Instrument Calibration Record

Instrument: Temp Controller	Model No: DC5062-0-0-F03-110-0000-000-0	Range/Grade: 0-900°F	Asset No: I9I1A
MFR: Honeywell	Serial No: 9433173658001	Use Point:	Location: Anguil Cont. Panel
Prepared BY: PCS	Approved By: PCS	Increments: 1°F	Accuracy: 5%

	As Found Status	Reason For Service	Final Test Status	
Cal Freq: 6 months	(✓) In Tolerance	(✓) Scheduled	(✓) Calibrated	( ) Reference Only
Cal Date: 5/26/22	( ) Out of Tolerance	( ) Unscheduled	( ) Limited Cal	( ) Do NOT Use
Due Date: 11/22	( ) In Operative		( ) Verification	

Parameter and Units Measured	As Found Test Data			Final Test Data							
				Test 1		Test 2		Test 3		Average	
	Standard	Instrument	Tolerance (+/-)	Standard	Instrument	Standard	Instrument	Standard	Instrument	Standard	Instrument
100 °F	100	100	5	100	100	100	100	Same		100	100
200 °F	200	200	5	200	200	200	200	As found		200	200
300 °F	300	300	5	300	300	300	300	test		300	300
600 °F	600	600	5	600	600	600	600	Data		600	600

Comments: NA Type J

Time of Calibration
Temperature: 80°F
Humidity: 46%
Asset #: 210905423

Calib. SOP: QA-06-103

Standards Used	Asset No.	Due Date
Transmation 1000	E416	3/23

Expired Calibration Label

Form #1-01-004aF
Rev. 1 12/00
PCS, Inc.

Calibrator: G Cranston
Date: 5/26/22
Reviewer: Mauri Ceart
Date: 5/27/22

EFFECTIVE
DEC 2 2 2000

COPY

COASTAL CALIBRATION LABORATORIES, INC.

Certificate of Calibration

Certificate: CC175722 **On-site Calibration: No**

Customer: Professional Contract Sterilization, Inc.
Contact: Marie Cranston
Account No.: AN0444 (PCS)

Manufacturer: Transmation
Model: Checkmate 1000
Description: Calibrator, Process
Range: See Attached
Accuracy: See Attached
Instrument ID: E416
Serial No 249932

Location: N/A
System Desc.: N/A
System ID.: N/A
P&ID Tag: N/A

Type of Cal.: Normal
As Found: In Tolerance
As Left: Left as Found
Technician: Brian Sams
Procedure: CP0008: Resistance Devices; CP0017: Voltage Devices; CP0018: Current Devices
Comments: Instrument Specific: N/A
Calibration Specific: N/A
Cal. Date: 07Mar22
Cal. Interval: 12 Month (End of Month)
Date Due: 31Mar23
Temp. / Humidity: 22 °C / 34 %

For purposes of determining pass/fail criteria, indicated deviations shall be rounded to the same resolution as the UUT's specified accuracy per the rounding method of ASTM Practice E29. The measurement results contained in this certificate were obtained using standards with uncertainties traceable through an unbroken chain of comparisons to the National Institute of Technologies (NIST), or through another National Metrology Institute (NMI) to the SI (International System of Units) via reference to national measurement standards, established natural constants, or consensus standards. A TAR (Test Accuracy Ratio) of 4:1 is maintained unless otherwise stated. CCL's quality system satisfies applicable requirements of ISO/IEC 17025 and ISO9001. Results contained in this certificate relate only to the item calibrated. This certificate shall not be reproduced except in full, without written approval from CCL.

Brian Sams, President

Calibration Data

Standard	UUT As-Found	UUT As-Found Deviation	UUT As-Left	UUT As-Left Deviation
Current Calibration (Source)				
0.0004 mA	0.00	-0.0004	Left As Found	
4.0013 mA	4.00	-0.0013	Left As Found	
8.0011 mA	8.00	-0.0011	Left As Found	
12.0004 mA	12.00	-0.0004	Left As Found	
15.9997 mA	16.00	0.0003	Left As Found	
20.0004 mA	20.00	-0.0004	Left As Found	
23.9985 mA	24.00	0.0015	Left As Found	
Current Calibration (Measure)				
0.0000 mA	0.00	0.	Left As Found	
4.0000 mA	3.99	-0.01	Left As Found	
8.0000 mA	7.99	-0.01	Left As Found	
12.0000 mA	12.00	0.	Left As Found	
16.0000 mA	16.00	0.	Left As Found	
20.0000 mA	20.00	0.	Left As Found	
24.0000 mA	24.00	0	Left As Found	
DC Millivolts Calibration (Source)				
0.0061 mV	0.00	-0.0061	Left As Found	
29.9920 mV	30.00	0.008	Left As Found	

COASTAL CALIBRATION LABORATORIES, INC.

Certificate of Calibration

Certificate: CC175722

On-site Calibration: No

59.9910 mV	60.00	0.009	Left As Found	
89.9950 mV	90.00	0.005	Left As Found	
109.9870 mV	110.00	0.013	Left As Found	
DC Millivolts Calibration (Measure)				
0.0000 mV	0.00	0.	Left As Found	
30.0000 mV	30.01	0.01	Left As Found	
60.0000 mV	60.01	0.01	Left As Found	
90.0000 mV	90.00	0.	Left As Found	
109.9000 mV	109.91	0.01	Left As Found	
DC Voltage Calibration (Source)				
-0.0005 V	0.00	0.0005	Left As Found	
2.4997 V	2.50	0.0003	Left As Found	
5.0003 V	5.00	-0.0003	Left As Found	
7.4998 V	7.50	0.0002	Left As Found	
10.2499 V	10.25	0.0001	Left As Found	
DC Voltage Calibration (Measure)				
0.0000 V	0.00	0.	Left As Found	
2.500 V	2.50	0.	Left As Found	
5.000 V	5.00	0.	Left As Found	
7.500 V	7.51	0.01	Left As Found	
10.200 V	10.21	0.01	Left As Found	
DC Voltage Calibration (Measure)				
0.00 V	0.0	0.	Left As Found	
100.00 V	100.0	0	Left As Found	
200.00 V	199.9	-0.1	Left As Found	
AC Voltage Calibration (Measure) @ 60 Hz				
0.00 V	0.0	0	Left As Found	
100.00 V	99.8	-0.2	Left As Found	
200.00 V	199.9	-0.1	Left As Found	
250.00 V	249.9	-0.1	Left As Found	
Frequency Calibration (Measure)				
1.0 CPM	1	0	Left As Found	
240.0 CPM	240	0.	Left As Found	
480.0 CPM	480	0.	Left As Found	
720.0 CPM	720	0.	Left As Found	
1000.0 CPM	1000	0.	Left As Found	
1.0 Hz	1	0.	Left As Found	
500.0 Hz	500	0	Left As Found	
1000.0 Hz	1000	0.	Left As Found	
0.010 kHz	0.01	0.	Left As Found	
5.000 kHz	5.00	0.	Left As Found	
10.000 kHz	10.00	0.	Left As Found	
Frequency Calibration (Source)				

COASTAL CALIBRATION LABORATORIES, INC.

Certificate of Calibration

Certificate: CC175722 **On-site Calibration: No**

1.00 CPM (16.667 mHz)	1	0.	Left As Found	
480.02 CPM (8.000 Hz)	480	-0.02	Left As Found	
1000.04 CPM (16.667 Hz)	1000	-0.04	Left As Found	
0.87 Hz	1	0.13	Left As Found	
499.28 Hz	500	0.72	Left As Found	
998.99 Hz	1000	1.01	Left As Found	
0.011 kHz	0.01	-0.001	Left As Found	
4.997 kHz	5.00	0.003	Left As Found	
10.000 kHz	10.00	0.	Left As Found	
2W Resistance Calibration (Measure)				
0.00 ohm	0.1	0.1	Left As Found	
100.00 ohm	100.0	0.	Left As Found	
400.00 ohm	399.9	-0.1	Left As Found	
1000.00 ohm	999.9	-0.1	Left As Found	
2W Resistance Calibration (Source)				
25.02 ohm	25.0	-0.02	Left As Found	
99.98 ohm	100.0	0.02	Left As Found	
400.05 ohm	400.0	-0.05	Left As Found	
3W RTD Pt100 Calibration (Measure)				
-100.0 °C (60.256 ohm)	-100	0.	Left As Found	
0.0 °C (100.000 ohm)	0	0.	Left As Found	
850.0 °C (390.481 ohm)	850	0.	Left As Found	
3W RTD Pt100 Calibration (Source)				
60.270 ohm (-100 °C)	60.256	-0.014	Left As Found	
99.981 ohm (0 °C)	100.000	0.019	Left As Found	
390.281 ohm (850 °C)	390.481	0.2	Left As Found	
Type K TC Calibration (Measure)				
-100.0 °C (-3.554 mV)	-100	0.	Left As Found	
0.0 °C (0.000 mV)	0	0.	Left As Found	
1370.0 °C (54.819 mV)	1370	0.	Left As Found	
Type K TC Calibration (Source)				
-3.5615 mV (-100 °C)	-3.554	0.0075	Left As Found	
-0.008 mV (0 °C)	0.000	0.008	Left As Found	
54.7915 mV (1370 °C)	54.819	0.0275	Left As Found	

UUT = Unit Under Test

Calibration Standards

Standard ID	Description	Due Date
SD0033	Counter	30Apr22
SD0067	Standard, Rubidium Frequency	31Jul23
SD0121	Generator, Arbitray Waveform	30Nov22
SD0123	Multimeter	30Apr22
SD0191	RTD, Intelligent	30Jun22
SD0834	Meter, Humidity/Temperature	30Apr22
SD0930	Calibrator, Multi-Product	31Aug22

End of Data

Transmation 1000 Process Calibrator
Source: Spec Sheet

Nominal Set Point	Minimum	Maximum
****Current Calibration (Source)****		
0.00 mA	-0.02	0.02
4.00 mA	3.98	4.02
8.00 mA	7.98	8.02
12.00 mA	11.98	12.02
16.00 mA	15.98	16.02
20.00 mA	19.98	20.02
24.00 mA	23.98	24.02
****Current Calibration (Measure)****		
0.00 mA	-0.02	0.02
4.00 mA	3.98	4.02
8.00 mA	7.98	8.02
12.00 mA	11.98	12.02
16.00 mA	15.98	16.02
20.00 mA	19.98	20.02
24.00 mA	23.98	24.02
****DC MilliVolts Calibration (Source)****		
0.00 mV	-0.07	0.07
30.00 mV	29.93	30.07
60.00 mV	59.93	60.07
90.00 mV	89.93	90.07
110.00 mV	109.93	110.07
****DC MilliVolts Calibration (Measure)****		
0.00 mV	-0.07	0.07
30.00 mV	29.93	30.07
60.00 mV	59.93	60.07
90.00 mV	89.93	90.07
109.90 mV	109.93	110.07
****DC Voltage Calibration (Source)****		
0.00 V	-0.02	0.02
2.50 V	2.48	2.52
5.00 V	4.98	5.02
7.50 V	7.48	7.52
10.25 V	10.23	10.27
****DC Voltage Calibration (Measure)****		
0.00 V	-0.02	0.02
2.50 V	2.48	2.52
5.00 V	4.98	5.02
7.50 V	7.48	7.52
10.20 V	10.18	10.22
****DC Voltage Calibration (Measure)****		
0.0 V	-4.1	4.1
100.0 V	95.9	104.1

200.0 V	195.9	204.1
AC Voltage Calibration (Measure) @ 60 Hz		
0.0 V	-5.1	5.1
100.0 V	94.9	105.1
200.0 V	194.9	205.1
250.0 V	244.9	255.1
Frequency Calibration (Measure)		
1 CPM	-1	3
240 CPM	238	242
480 CPM	478	482
720 CPM	718	722
1000 CPM	998	1002
1 Hz	-1	3
500 Hz	498	502
1000 Hz	998	1002
0.01 kHz	-0.01	0.03
5.00 kHz	4.98	5.02
10.00 kHz	9.98	10.02
Frequency Calibration (Source)		
1 CPM (16.667 mHz)	-1	3
480 CPM (8.000 Hz)	478	482
1000 CPM (16.667 Hz)	998	1002
1 Hz	-1	3
500 Hz	498	502
1000 Hz	998	1002
0.01 kHz	-0.01	0.03
5.00 kHz	4.98	5.02
10.00 kHz	9.98	10.02
2W Resistance Calibration (Measure)		
0.0 ohm	-0.6	0.6
100.0 ohm	99.4	100.6
400.0 ohm	399.4	400.6
1000 ohm	998	1002
2W Resistance Calibration (Source)		
25.0 ohm	24.7	25.3
100.0 ohm	99.7	100.3
400.0 ohm	399.7	400.3
3W RTD Pt100 Calibration (Measure)		
-100 °C (60.256 ohm)	-101	-99
0 °C (100.000 ohm)	-1	1
850 °C (390.481 ohm)	849	851
3W RTD Pt100 Calibration (Source)		
60.272 ohm (-100 °C)	59.862	60.682
100.000 ohm (0 °C)	99.610	100.390
390.481 ohm (850 °C)	390.191	390.771
Type K TC Calibration (Measure)		
-100 °C (-3.554 mV)	-102	-98

0 °C (0.000 mV)	-1	1
1370 °C (54.819 mV)	1369	1371
****Type K TC Calibration (Source)****		
-3.554 mV (-100 °C)	-3.614	-3.494
0.000 mV (0 °C)	-0.039	0.039
54.819 mV (1370 °C)	54.786	54.852

ATTACHMENT I
ETO DRUM SCALE CALIBRATION RECORDS.

Bay State Scale & Systems Calibration Report
With Traceability To NIST

Customer Name: PCS

Address: 40 Myles Standish Blvd

Taunton, MA 02780

Date 9/2/21

Contact: Gary Cranston

Scale Mfg. Model/sn#	Test Weight Applied	Reading Before Cal	Reading After Cal	Cal Date	Due Date	Comments
1. Gold Brand A5E1F	306lb	306lb	306lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
	100lb	406lb	406lb			
	400lb	706lb	706lb			
2. Gold Brand A6E1F	0	0	0	8/31/21	8/31/22	Bean sensitivity 1/2lb
	100lb	100	100			
	500lb	500	500			
	500lb	500lb	500lb			
	700lb	700lb	700lb			
3.						
4.						

Test Weight Information

	Calibration Test Weights Used or Weight Set Used	Classification Of Test Weight(s)	Tolerance Of Test Weight	NIST Traceable #	Certification Date
1	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
2	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
3					
4					

BAY STATE SCALE & SYSTEMS, INC.
7 Ray Avenue, Burlington, Massachusetts 01803-4720
(781) 993-9035 - (800) 696-8282 - FAX (781) 993-9033
www.baystatescale.com - sales@baystatescale.com

Michael Rinaldi
Technician's Signature

Bay State Scale & Systems Calibration Report
With Traceability To NIST

Customer Name: PCS

Address: 40 Myles Standish Blvd

Taunton, MA 02780

Date 9/2/21

Contact: Gary Cranston

	Scale Mfg. Model/sn#	Test Weight Applied	Reading Before Cal	Reading After Cal	Cal Date	Due Date	Comments
1.	Gold Brand A1E1F	62llb 100lb	62llb 72llb	62llb 72llb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
2.	Gold Brand A2E1F	494LB 100lb 200lb	494LB 594lb 694lb	494LB 594lb 694lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
3.	Gold Brand A3E1F	609lb 100lb	609lb 709lb	609lb 709lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
4.	Gold Brand A4E1F	320lb 100lb 400lb	320lb 420lb 720lb	320lb 420lb 720lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb

Test Weight Information

	Calibration Test Weights Used or Weight Set Used	Classification Of Test Weight(s)	Tolerance Of Test Weight	NIST Traceable #	Certification Date
1	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
2	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
3	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
4	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18

Michael Rinaldi
Technician's Signature

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Bay State Scale & Systems Calibration Report
With Traceability To NIST

Customer Name: PCS

Address: 40 Myles Standish Blvd

Taunton, MA 02780

Date 9/2/21

Contact: Gary Cranston

Scale Mfg. Model/sn#	Test Weight Applied	Reading Before Cal	Reading After Cal	Cal Date	Due Date	Comments
1. Gold Brand A5E1F	306lb	306lb	306lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
	100lb	406lb	406lb			
	400lb	706lb	706lb			
2. Gold Brand A6E1F	0	0	0	8/31/21	8/31/22	Bean sensitivity 1/2lb
	100lb	100	100			
	500lb	500	500			
	500lb	500lb	500lb			
	700lb	700lb	700lb			
3.						
4.						

Test Weight Information

	Calibration Test Weights Used or Weight Set Used	Classification Of Test Weight(s)	Tolerance Of Test Weight	NIST Traceable #	Certification Date
1	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
2	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
3					
4					

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Michael Rinaldi
Technician's Signature

Bay State Scale & Systems Calibration Report
With Traceability To NIST

Customer Name: PCS

Address: 40 Myles Standish Blvd

Taunton, MA 02780

Date 9/2/21

Contact: Gary Cranston

Scale Mfg. Model/sn#	Test Weight Applied	Reading Before Cal	Reading After Cal	Cal Date	Due Date	Comments
1. Gold Brand A1E1F	621lb	621lb	621lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
	100lb	721lb	721lb			
2. Gold Brand A2E1F	494LB	494LB	494LB	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
	100lb	594lb	594lb			
	200lb	694lb	694lb			
3. Gold Brand A3E1F	609lb	609lb	609lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
	100lb	709lb	709lb			
4. Gold Brand A4E1F	320lb	320lb	320lb	8/31/21	8/31/22	Added weight to loaded scale Bean sensitivity 1/2lb
	100lb	420lb	420lb			
	400lb	720lb	720lb			

Test Weight Information

	Calibration Test Weights Used or Weight Set Used	Classification Of Test Weight(s)	Tolerance Of Test Weight	NIST Traceable #	Certification Date
1	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
2	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
3	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18
4	50 LB, s/n 058D-067D	F	2.3g	1718-F217	6/29/18

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www.baystatescale.com - sales@baystatescale.com

Michael Rinaldi
Technician's Signature

OHI
Occupational Health & Safety •Environmental Consultants

OccuHealth, Inc.
44 Wood Avenue
Mansfield, MA 02048

Tel. (800) 729-1035
(508) 339-9119
Fax (508) 339-2893
m_burns@occuhealth.com

November 18, 2021

Ms. Charlene Spells
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 2771

Re: Professional Contract Sterilization, Inc.
40 Myles Standish Blvd., Taunton, MA (PCS)
Information Collection Request (ICR), dated September 13, 2021

Dear Ms. Spells:

On behalf of Professional Contract Sterilization , Inc, Taunton, MA (PCS), please accept this formal request for a 60-day extension of the November 19, 2021 submittal deadline listed in the above-referenced ICR.

PCS is a small business, with fewer than ten employees. They are currently dealing with a manpower shortage and end-of-the-year production demands. They do not have the resources to dedicate the necessary personnel to extract, gather, review, prepare and compile the extensive documentation listed in the ICR. Their staff is approximately 50% of pre-COVID levels.

Furthermore, in response to the ongoing COVID-19 pandemic, PCS is currently restricting access to visitors; thus precluding the use of outside consultants and/or administrative support to assist with the ICR.

Thank you for your consideration in this matter. We respectfully request a confirmation of receipt of this response.

OCCUHEALTH, INC

Michael J. Burns, P.E.
Senior Project Manager

cc: Gary Cranston, Professional Contact Services Inc.
Robert A. Fasanella, Esq., Rubin and Rudman LLP

Mike Burns

From: Mike Burns
Sent: Tuesday, November 23, 2021 1:35 PM
To: Sue Hamilton
Subject: RE: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Thanks Sue
That address was directly of the EPA web page…..specifically stating to direct all written replies there

---

From: Sue Hamilton <shamilton@occuhealth.com>
Sent: Tuesday, November 23, 2021 12:23 PM
To: Mike Burns <mburns@occuhealth.com>
Subject: Fwd: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Get Outlook for iOS

From: UPS <pkginfo@ups.com>
Sent: Tuesday, November 23, 2021 10:33 AM
To: Results
Subject: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Hello, your package has been delivered.

Delivery Date: Tuesday, 11/23/2021
Delivery Time: 10:30 AM

Experience UPS My Choice® Premium Today

Be in total control of how, when and where your packages are delivered.

Upgrade to Premium Now

Set Delivery Instructions

Manage Preferences

View My Packages

OCCU HEALTH, INC.

Tracking Number:	1ZA667E80198960042
Ship To:	US EPA OFFICE-AIR QUALITY PLANNING 4930 OLD PAGE RD DURHAM, NC 27703 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	0.0 LBS
Reference Number:	PCS ICR EXT. LTR

 Download the UPS mobile app

From: Mike Burns <mburns@occuhealth.com>
Sent: Tuesday, February 8, 2022 1:56 PM
To: Guo, Jeremy J (Jerry) <jjg@rti.org>
Cc: gcranston@pcsinc.org; Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen <ksschaffner@rti.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: [EXTERNAL] RE: Information Collection Request (ICR) for Professional Contract Sterilization, Inc, Taunton, MA

Jerry,

Thank-you for your call & emails from January 18 & 19, 2022.

On behalf of Professional Contract Sterilization, Inc. (PCS), we appreciate your patience and consideration regarding the ICR.
As described in previous communications, PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic.
Despite these impacts and their limited resources, PCS has made some progress in preparing the ICR response.
However, due to some confidential business information that has yet to redacted, it is not in a state where it can be released, even as a partial version.

This efforts are ongoing.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Guo, Jeremy J (Jerry) <jjg@rti.org>
Sent: Wednesday, January 19, 2022 8:10 PM
To: Mike Burns <mburns@occuhealth.com>
Cc: gcranston@pcsinc.org; Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen

<ksschaffner@rti.org>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization, Inc, Taunton, MA

Hi Mike,

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. Please do not hesitate to let us know if you have any questions, comments or concerns.

Thank you and best regards,

Jerry

From: Guo, Jeremy J (Jerry)
Sent: Tuesday, January 18, 2022 13:06
To: mburns@occuhealth.com
Cc: Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen <ksschaffner@rti.org>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Hi Mike,

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.

Thank you and best regards,

Jerry

Jeremy J (Jerry) Guo

Air Quality Engineering
RTI International
Phone: (919) 541-8836
Email: jjg@rti.org

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Tuesday, January 18, 2022 8:26
To: Guo, Jeremy J (Jerry) <jjg@rti.org>
Cc: Schaffner, Karen <ksschaffner@rti.org>; Witt, Jon <Witt.Jon@epa.gov>
Subject: FW: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

As requested.

Charlene E. Spells
U.S. EPA

OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Friday, November 19, 2021 4:47 PM
To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Thank you Steve & Charlene 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.

PCS will continue to work on the ICR and will provide a response in a timely fashion with periodic updates over the next few weeks.

Thank your

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Friday, November 19, 2021 1:03 PM
To: Mike Burns <mburns@occuhealth.com>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Mr. Burns,

My apologies for the confusion. The recall was an error on my part. The information in the email is correct.

Charlene E. Spells
U.S. EPA
OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Friday, November 19, 2021 12:30 PM
To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Ms. Spells
We are in receipt of your email (below) stating that "EPA is not granting any extensions of the November 19, 2021 deadline".
We are also in receipt of the attached email, RECALLING said email.

I left (2) voice mail messages this morning seeking clarification of these messages and to discuss our request.

Please advise a good time to speak on this matter today.
I can be reached at 508-339-9119x214.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Friday, November 19, 2021 7:20 AM
To: Mike Burns <mburns@occuhealth.com>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Mr. Burns,

Thank you for your November 18, 2021, letter requesting an extension to complete the section 114 survey related to hazardous air pollutants at ethylene oxide (EtO) commercial sterilization facilities. As we have responded to other requests, EPA is not granting any extensions of the November 19, 2021, deadline for response to the information collection request.

If you have specific questions about completing the section 114 survey, please do not hesitate to contact me.

Regards,
Charlene E. Spells
U.S. EPA
OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Thursday, November 18, 2021 3:40 PM

To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Ms. Spells

On behalf of Professional Contract Sterilization , Inc, 40 Myles Standish Blvd., Taunton, MA (PCS);
Please accept the attached formal request for a 60-day extension of the November 19, 2021 submittal deadline listed in the above-referenced ICR.

PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic.
Please refer to the attached letter for further details.

Thank you for your consideration in this matter.
We respectfully request your confirmation and acknowledgement of this request.

A hard copy will be sent via overnight service.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

Tyler M. Franklin

From: Robert A. Fasanella
Sent: Tuesday, July 5, 2022 12:44 PM
To: Sansevero, Christine; fortescue.darren (fortescue.darren@epa.gov); Vasconcelos.Davianna@epa.gov; McGuire.Karen@epa.gov; Wagner, Michael
Cc: chris@lchconsulting.com; 'Howard Humphreys'; 'gcranston pcsinc.org'; 'marie pcsinc.org'; Tyler M. Franklin; Dan.DiSalvio@mass.gov; Glenn.Keith@mass.gov
Subject: FW: CAA Section 114 Information Collection Request- PCS
Attachments: Finished EtO_114ICR_Main_v5.5.3_P2_Final.xlsx

ALL

Attached are PCs Responses to EPA's CAA Section 114 Information Collection Request.

Chris Heilner of LCH will be sending under separate email today a Revised Protocol Plan for testing that addresses all of EPA's Comments dated 6/27/22 sent to PCS on the initial Protocol Plan previously submitted to EPA.

PCS reserves the right to make additional submissions to the EPA NOV and Administrative Complaint.

Please confirm receipt of the attached. Let us know if you need any further information.

Thank you,

Robert A. Fasanella, Esq.
Rubin and Rudman LLP
53 State Street
Boston, MA 02109
617-330-7018 (T)
617-330-7550 (F)
rfasanella@rubinrudman.com

From: marie pcsinc.org <marie@pcsinc.org>
Sent: Friday, July 1, 2022 5:13 PM
To: Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: [EXTERNAL] finished EPA survey

Thank you,
Marie
PCS, Inc.

Click Here to Visit Our COVID-19 Resource Center

RUBIN and RUDMAN LLP
Attorneys at Law

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

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

OMB Control No. 2060-0733
Approval Expires 09/30/2024

Paperwork Reduction Act Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2060-0733). Responses to this collection of information mandatory under section 114(a) of Clean Air Act. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The average public reporting and recordkeeping burden for this collection of information is estimated to be proximately 108 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Introduction

The U.S. Environmental Protection Agency (EPA) is requesting facility data and information to inform the Technology Review project for 40 CFR part 63, subpart O, Ethylene Oxide (EtO) Commercial Sterilization source category. The purpose of this ICR is to enable facilities to submit accurate facility information. For more detailed instructions on how to fill out, name and submit the main questionnaire, supplements and additional documents, refer to the Instructions Document for the Ethylene Oxide Commercial Sterilization Section 114 ICR at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities* (click to visit).

About the Main Questionnaire

This main questionnaire contains worksheets and data fields shaded in different colors:

Worksheets and data fields shaded in green indicate that facility shall provide inputs according to the corresponding instructions
Worksheets and data fields shaded in gold contain instructions and supporting information that help facility with this questionnaire
Data fields shaded in gray indicate that these either do not need to be filled out or will be automatically filled out based on facility's inputs in relevant fields
Data fields shaded in red by facility indicate that these fields contain confidential business information (CBI), and relevant data needs special handling *
"Certification" worksheet in blue must be completed by facility before submission

If any information entered contains CBI, be sure to select "Yes" in the designated cell (Cell N2) on each worksheet, shade in red all cells with real CBI data in the CBI version, then follow the instructions in Section V of the Instructions Document to create the non-CBI version of your response.

This main questionnaire contains the following worksheets (you may click on the links below to visit each individual worksheet):

Introduction (this worksheet)	Introduction and instructions for completing and submitting this questionnaire
Terms (link)	Definitions or explanations of certain technical terms that are mentioned throughout this questionnaire
Facility Details (link)	Information about facility registration, ownership, general characteristics, facility-level data, legal documents, etc.
Room Area (link)	Characteristics, inventory of components and control of individual room areas where EtO is used or emitted
EtO & EG Storage (link)	Questions regarding EtO storage in drums and containers, and ethylene glycol (EG) tanks
Sterilizer Chambers (link)	Operation, monitoring and control characteristics of sterilizer chambers
Aeration (link)	Details of aeration equipment
APCD Summary (link)	Information about all air pollution control devices operated by facility
APCD Details (link)	Details regarding air pollution control devices such as scrubbers, catalytic oxidizers, thermal oxidizers, and others
EtO Monitoring (link)	Information about workspace monitoring, personal monitoring, room monitoring, etc. conducted by facility
Miscellaneous (link)	Questions regarding facility's wastewater treatment and other items of EtO commercial sterilization operation
Additional Info (link)	Use this worksheet if you need extra space to provide any additional information requested within this questionnaire
Documents (link)	Designated space to attach documents requested throughout this questionnaire
Certification (link)	Reporter's information and certification for completing and submitting this questionnaire

About the Supplements

There are 3 supplements to this main questionnaire, including:
Supplement 1 for Section B, Table 3
Supplement 2 for Section B, Table 4
Supplement 3 for Section I, Table 1

The supplements may be used should you need more space than what is available in the original tables to provide the data requested. **If you prefer to fill out any supplement in lieu of the original table, please leave the original table blank in the main questionnaire. Be sure to select "Yes" in the designated cell above each original table where a supplement will be used, and the data fields will be automatically shaded in gray.**

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

OMB Control No. 2060-0733
Approval Expires 09/30/2024

Click here to go to "Introduction"

1. Definitions

Term	Definition
Accelerated aeration	Aeration conducted in a heated aeration chamber or cell, not an aeration room, combined with: (1) use of vacuum cycles, and/or (2) high turbulence air created by multiple inlet ports along the length of the aeration cell and multiple outlet points along the top of the cell to provide even distribution of air flow
Aeration cell/chamber	Any vessel that is used to facilitate off-gassing of ethylene oxide at a sterilization facility. If single-item sterilization occurs, the vessel is classified as a sterilization chamber
Aeration room	Any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility. If single-item sterilization occurs, the vessel or room is classified as a sterilization chamber
Aeration room area	Any room areas that surround the aeration cell, aeration chamber, or aeration room. For example, aeration room areas may include either the room areas that sterilized materials move through as they are placed in the equipment where aeration occurs, or the room areas that aerated materials move through following the aeration process itself. Note that an "aeration room area" is different from an "aeration room." Aeration room area would include fugitive emissions, while aeration room itself would be a point source of emissions.
Aeration room vent (ARV)	The point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs
Balancer/abator system	An air pollution control device (APCD) that consists of a combination of a water balancer and a catalytic oxidizer
Cascading air	Ventilation air removed from one room area or process, with a lower EtO concentration, is vented as the input ventilation air or intake ventilation air directly to another room area or process (e.g., ventilation air from a warehouse is used as intake air to the aeration room or aeration cell). Ventilation air removed from one room area or process must have an equivalent or lower EtO concentration than the room air concentration or process concentration of the room area or process in which it is reused
Chamber exhaust vent (CEV)	The point(s) through which ethylene oxide-laden gas is removed from the sterilization chamber during chamber unloading, following the completion of sterilization and associated air washes. Also known as "back vent"
Combination-chamber sterilizer	Any enclosed vessel in which both the sterilization process and the aeration process occur within the same vessel, e.g., the vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by off-gassing of ethylene oxide
Dwell period	The length of time that the product is exposed to ethylene oxide in sterilizer chamber for the purpose of sterilizing or fumigating the product
Engineering test	A test that measures the amount of pollutants being emitted, demonstrates the capture efficiency, or determines the destruction or removal efficiency of a control device used to reduce emissions at a facility. This testing is not related to compliance or regulatory requirements
Ethylene oxide (EtO) service	A piece of equipment either contains or contacts ethylene oxide as a liquid or gas at any concentration
Fugitive emissions	Emissions (of ethylene oxide) which are not routed through the existing control equipment
Natural draft opening (NDO)	Any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct in which a fan is installed
Non-colocated warehouse/distribution center	A warehouse or distribution center, used to store products that are sterilized with ethylene oxide, that is not part of a facility subject to the ethylene oxide commercial sterilizer rule under 40 CFR part 63, subpart O
Performance test	A test that measures the amount of pollutants being emitted, demonstrates the capture efficiency, or determines the destruction or removal efficiency of a control device used to reduce emissions at a facility. Used to determine a facility's compliance with an emission limit, capture efficiency, or control efficiency requirement
Research and laboratory facility	Any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically trained personnel and is not engaged in the manufacturer of products for commercial sale in commerce, except in a de minimis manner
Single-item sterilizer	Any enclosed vessel in which sealed pouches containing product and ethylene oxide gas for the purpose of sterilizing are placed, and the ethylene oxide sterilizes and aerates
Sterilization chamber vent (SCV)	The point (prior to vacuum pump) through which the evacuation of ethylene oxide from the sterilizer chamber occurs following sterilization or fumigation, including any subsequent air washes
Sterilization facility	Any stationary source where ethylene oxide is used in the sterilization or fumigation of materials
Sterilization operation	Any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent
Sterilizer chamber	Any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility. Includes any vessels or rooms where both ethylene oxide sterilization and aeration occur within one chamber

2. Acronyms

Acronym	Term	Acronym	Term
APCD	air pollution control device	ID	identifier
ARV	Aeration room vent	in. H2O	inches of water
CAA	Clean Air Act	kWh	kilowatt hour
CBI	Confidential business information	LEL	lower explosive limit
CEMS	Continuous emissions monitoring system	mg/L	milligrams per liter
CEV	Chamber exhaust vent	NAICS	North American Industrial Classification System
cfm	Cubic feet per minute	NDO	natural draft opening
CFR	Code of Federal Regulations	ppmv	parts per million, volume
EG	ethylene glycol	psig	pressure per square inch, gauge
EIS	Emission Inventory System	QA	quality assurance
EPA	Environmental Protection Agency	QC	quality control
EtO	ethylene oxide	R&D	research and development
ICR	information collection request	SCV	sterilization chamber vent

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

Click here to go to "Introduction" | *Click here to go to "Terms"* | *Click here to go to "Additional Info"*

Does any information entered on this worksheet contain confidential business information (CBI)? Specify in ***Cell N2*** *on the right →* ***Be sure to shade in red all cells with real CBI data in the CBI version*** *After creating the* ***non-CBI version****, select and copy the Sample CBI Cell (Cell O2) and paste directly into each cell with real CBI data.* ***Make sure all cells that contained CBI look the same as the Sample CBI Cell (Cell O2)*** *before saving the non-CBI version of your response*		**CBI** Sample CBI Cell (above)

EIS ID (auto-populated)	
OMB Control No. 2060-0733 **Approval Expires 09/30/2024**	

A. Facility Details

Table 1. Facility Information

Field #	A-1	A-2	A-3	A-4	A-5	A-6	A-7	A-8	A-9	A-10		A-11		A-12	
Data	Primary NAICS code	EIS ID	Facility name	Facility address	Facility city	Facility state	Facility zip code	Phone number	Number of employees at facility	Operating status in current year	Comments	Operating hours		Is there a plan to expand/modify/close this facility in the near future?	
Instruction	Enter the primary NAICS code for the facility [1]	Enter EIS ID for the facility	Enter facility name	Enter the street address of facility verified by U.S. Postal Service (USPS). Do not include P.O. box in this field	Enter facility city	Select from the dropdown menu in this column	Enter facility zip code verified by U.S. Postal Service (USPS)	Provide a contact phone number at the facility	Select from the dropdown menu. Full-time, part-time, and temporary employees should be counted equally	Select from the dropdown menu in this column	If you choose an option other than "operating" in the previous column, please add a brief comment in this column	Enter the daily operating hours on average of the facility **(hours)**	Enter the annual operating hours on average of the facility **(hours)**	Select from the dropdown menu in this column	Provide a short explanation if you select "Yes" on the left
Response	561910		Professional Contract Sterilization, Inc.	40 Myles Standish Blvd.	Taunton	MA	02780	508-822-5524	≤ 100	Operating		16.00	4992.00	Yes	increase production hours

[1] *For assistance in determining your facility's NAICS code, see the website for the North American Industry Classification System (NAICS), maintained by the U.S. Census Bureau: https://www.census.gov/eos/www/naics/. (click to visit)*

Table 2. Parent Company Information

Field #	A-13	A-14	A-15	A-16	A-17	A-18	A-19	A-20
Data	Parent company	Parent company address	Parent company city	Parent company state	Parent company zip code	Phone number	Is parent company a small business?	Number of employees at parent company
Instruction	Enter parent company name	Enter the street address of parent company verified by U.S. Postal Service (USPS). Do not include P.O. box in this field	Enter parent company city	Select from the dropdown menu in this column	Enter parent company zip code verified by U.S. Postal Service (USPS)	Provide a contact phone number at the parent company	Select from the dropdown menu in this column [2]	Select from the dropdown menu in this column
Response								

[2] *To determine the employee threshold for a small business, you may look up the small business size standard using six-digit NAICS codes. The size standards used to define Small Businesses are provided in 13 CFR 121, Small Business Size Regulations. See §121.201, "What size standards has SBA identified by North American Industry Classification System codes?", table "Small Business Size Standards by NAICS Industry", column "Size standards in number of employees*
Website for the Small Business Administration: https://www.sba.gov/. (click to visit)
Code of Federal Regulations (CFR), part 121: https://www.ecfr.gov/cgi-bin/text-idx?SID=85df5b1185a8b127a9b324c6583f72c6&mc=true&node=pt13.1.121&rgn=div5 (click to visit)

Table 3. Facility Documents

Field #	A-21	A-22	A-23	A-24	A-25
Data	Facility diagrams	Process flow diagrams	Most recent air permit(s)	Application documents for the most recent air permit(s)	Startup, shutdown and malfunction (SSM) plan
Instruction	Provide diagrams of your facility indicating all rooms, primary EtO emission points (e.g., regulated emission points), and secondary EtO emission points (e.g., fugitive emission points). Ensure that all NDOs are adequately labeled	Provide process flow diagrams of the EtO processes at your facility	Provide the most recent air permit(s) approved for your facility	Provide the application documents for the most recent air permit(s) approved for your facility	Provide the startup, shutdown and malfunction (SSM) plan approved for your facility
Response	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet

Table 4. Facility Buildings

Field #	A-26	A-27	A-28		A-29		A-30		A-31		A-32		A-33		A-34		A-35
Data	Building ID	Building height	Building corner 1		Building corner 2		Building corner 3		Building corner 4 (if any)		Building corner 5 (if any)		Building corner 6 (if any)		Building corner 7 (if any)		Additional comments
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each building	Enter the (average) height of the building **(feet)**	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter any additional comments that you may have regarding the information provided in this table about buildings and building corners
Response	NA	34.00	1.748090	2.965729													

Table 5. Facility-level Data

Field #	A-36		A-40		A-41		A-42	A-43		A-44		A-45	A-46	A-47
Data	EtO usage at your facility for the last 5 calendar years		Annual EtO stack emissions of facility for the last 5 years		Annual EtO fugitive emissions of facility for the last 5 years		Documentation for annual EtO emissions calculations	Average annual energy cost of facility operation (include the last 5 years in the average)		Average annual growth rate in revenues from EtO sterilization services for the last 5 years		Size category of facility with respect to hazardous air pollutant (HAP) emissions	As a percentage of all products sterilized at your facility, what is the percentage of products sterilized with EtO?	As a percentage of all products sterilized at your facility, what is the percentage of products sterilized using non-EtO techniques or approaches?
Instruction	Specify the calendar year. Select from the dropdown menu in this column	Enter the corresponding EtO usage in this column **(pounds)**	Specify the calendar year. Select from the dropdown menu in this column	Enter the value of annual EtO emissions in this column **(pounds)**	Specify the calendar year. Select from the dropdown menu in this column	Enter the value of annual EtO emissions in this column **(pounds)**	Provide calculations and supporting documentation for both stack emissions and fugitive emissions, including all emission factors used to determine the annual EtO emissions	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the amount in this column **(dollars/year)**	Specify the dollar year in this column	Select from the dropdown menu in this column [3]	Specify the percentage of products sterilized with EtO, based on all products sterilized at your facility, including both EtO sterilization and non-EtO sterilization. Note that the values entered in this field and Field A-47 should sum to 100% **(%)**	Specify the percentage of products sterilized with non-EtO approaches, based on all products sterilized at your facility, including both EtO sterilization and non-EtO sterilization. Note that the values entered in this field and Field A-46 should sum to 100% **(%)**
Response	2016	61,278.00					See instructions in "Documents" worksheet	$115,554.00	2020	$0.00	2020	Area source	100.00%	0.00%
	2017	50,334.00												
	2018	51,637.00												
	2019	49,041.50												
	2020	45,032.00												

[3] *For definitions of major source and area source, see section 112, Hazardous Air Pollutants, paragraph (a)(1) and (2), respective https://www3.epa.gov/ttn/atw/112a_def.htm. (click to visit)*
"Synthetic minor" for HAP means a source that otherwise has the potential to emit HAPs in amounts that are at or above those for major sources of HAP in 40 CFR 63.2, but that have taken a restriction so that its potential to emit (PTE) is less than such amounts for major sources. Such restrictions must be enforceable as a practical matter. See 40 CFR 63.2, Definitions for the definition of federally enforceable: https://www.ecfr.gov/cgi-bin/text-idx?SID=e4db7138e51ff76ffa723d3162b8169d&mc=true&node=se40.11.63_12&rgn=div8. (click to visit)

Table 6. Materials Sterilized with EtO

Field #	A-37	A-38	A-39	A-39.1		A-39.2	
Data	Materials sterilized with EtO (e.g., medical products, pharmaceutical products, spices, etc.) at your facility in 2020	Percentage of each type of materials sterilized with EtO in 2020 based on volume of throughput	Percentage of each type of materials sterilized with EtO in 2020 based on dollar amount	Packaging material used for products sterilized with EtO		Pallet material used for products sterilized with EtO	
Instruction	List all types of materials sterilized with EtO at your facility in 2020. Enter one type in each cell. If you have more than 10 types, enter "Other materials sterilized with EtO" in Cell C89, then specify. For example: "Other materials sterilized with EtO (Type 10, Type 11, Type 12, etc.)"	Provide the approximate percentage of each type of materials sterilized with EtO in 2020 based on volume of material throughput **(%)**	Provide the approximate percentage of each type of materials sterilized with EtO in 2020 based on dollar amount **(%)**	Specify the packaging material used for products sterilized with EtO at your facility	Enter the percent by volume of product sterilized with EtO that uses this packaging material **(%)**	Specify the pallet materials used in EtO sterilizer chambers	Enter the percent by volume of each type of pallet material used for EtO sterilization **(%)**
Response	medical devices	100.00%	100.00%	tyvec	100.00%	wood	100.00%

Table 7. Materials Sterilized with Non-EtO Techniques and Approaches

Field #	A-48	A-49	A-50	A-51	
Data	Materials sterilized with non-EtO approaches (e.g., medical products, pharmaceutical products, spices, etc.) at your facility in 2020	Percentage of each type of material sterilized with non-EtO approaches in 2020 based on volume of throughput	Percentage of each type of material sterilized with non-EtO approaches in 2020 based on dollar amount	Packaging material used for products sterilized with non-EtO approaches	
Instruction	List all types of materials sterilized with non-EtO approaches at your facility in 2020. Enter one type in each cell. If you have more than 10 types, enter "Other materials sterilized with non-EtO" in Cell C105, then specify. For example: "Other materials sterilized with non-EtO (Type 10, Type 11, Type 12, etc.)"	Provide the approximate percentage of each type of material sterilized with non-EtO approaches in 2020 based on volume of material throughput **(%)**	Provide the approximate percentage of each type of material sterilized with non-EtO approaches in 2020 based on dollar amount **(%)**	Specify the packaging material used for products sterilized with non-EtO approaches at your facility	Enter the percent by volume of product sterilized with non-EtO approaches that uses this packaging material **(%)**
Response	0	0.00%	0.00%	0	0.00%

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info

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EIS ID (auto-populated)	
OMB Control No. 2060-0733 Approval Expires 09/30/2024	

B. Individual Room Area (All Areas where EtO is Used or Emitted)

Table 1. Characteristics of Room Areas

Field #	B-1	B-2	B-3	B-4	B-5	B-6			B-7	B-8		B-9	B-10	B-11
Data	Room area ID for all rooms and areas where EtO is used or emitted	Category of room area	Activities conducted in room area	Floor area	Room height	Temperature			Relative humidity	Pressure drop		Air flow (ventilation)	Air flow (conditioned)	Number of air changes per hour
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses	Provide a brief explanation of the activities conducted in each room area	(square feet)	(feet)	Enter temperature set point or range for summer in this column (Fahrenheit)	Enter temperature set point or range for winter in this column (Fahrenheit)	Enter temperature set point or range for intermediate seasons in this column (Fahrenheit)	Enter average or range of relative humidity (%)	Enter the pressure drop across room area (inch H2O)	Specify definition of pressure drop, or locations based on which pressure drop is measured (e.g., farthest point to control device inlet)	Enter average or range of ventilation air flow (actual cubic feet per minute, acfm)	Enter average or range of conditioned air flow (actual cubic feet per minute, acfm)	Enter average or range of number of air changes per hour
Response	102	Sterilizer room area	Sterilization of product	920.00	20.00	70.00	70.00	70.00	5.00%	0.010	no room goes to atmosphere	9.2	0	5
	103	Sterilizer room area	Sterilization of product	820.00	20.00	70.00	70.00	70.00	5.00%	0.010	no room goes to atmosphere	8.2	0	5
	105	ETO Gas Room	Drum Room	88.00	10.00	70.00	70.00	70.00	5.00%	0.010	no room goes to atmosphere	88	0	5
	107	ETO Gas Room	Drum Room	88.00	10.00	70.00	70.00	70.00	5.00%	0.010	no room goes to atmosphere	88	0	5

Table 2. Natural Draft Openings (NDO)

Field #	B-1	B-12								
Data	Room area ID for all rooms and areas where EtO is used or emitted	Natural draft opening (NDO) 1 (if any)								
Instruction	This column will be auto-populated based on your entries in the previous fields	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)
Response	102									
	103									
	105									
	107									

Field #	B-13								
Data	Natural draft opening (NDO) 2 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-14								
Data	Natural draft opening (NDO) 3 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-15								
Data	Natural draft opening (NDO) 4 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-16								
Data	Natural draft opening (NDO) 5 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-17								
Data	Natural draft opening (NDO) 6 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-18								
Data	Natural draft opening (NDO) 7 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-19								
Data	Natural draft opening (NDO) 8 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-20								
Data	Natural draft opening (NDO) 9 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Field #	B-21								
Data	Natural draft opening (NDO) 10 (if any)								
Instruction	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)

Table 3. Leak Checks of Components in EtO Service **No (default)** ← Switch to "Yes" in Cell F92 on the left if Supplement 1 is used in lieu of this table

If leak checks are performed on multiple types of components in a room area, use another row in this table, repeat your entries in Fields B-1 and B-22, then fill out the other fields as necessary

*** Note: If you need to enter more than 30 rows of data, please select "Yes" in Cell F92 above, leave this table below BLANK, then fill out SUPPLEMENT 1 to the Section 114 ICR. Refer to the Instructions Document for more details ***

Field #	B-1	B-22	B-23	B-24	B-25	B-26	B-27	B-28	B-29	B-30		B-31
Data	Room area ID for all rooms and areas where EtO is used or emitted	Are leak checks performed in the room area?	Component type	Total component count	What is the percentage of components that are included in regular leak checks?	Frequency of leak checks	Average length of time to perform leak checks	Instrument and standard method for leak checks	Leak check procedure	Average cost per inspection		Average percentage of leaking components identified
Instruction	Select from the dropdown menu. Scroll up to see options, that are auto populated based on your entries in the	Select from the dropdown menu in this column	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your component)"	Specify the total number of component of this type	Specify the percentage of components that are included in regular leak checks (%)	Specify how often leak checks are performed	Enter average length of time to perform leak checks per component type, per inspection (hours)	Briefly describe the instrument and standard method used for leak checks	Describe the leak check procedure for each room area. Specifically, provide any action level	Enter the dollar amount in this column	Specify the dollar year in this column	Enter average percentage of leaking components identified during each leak check (%)
Response												

Field #	B-32	B-33	B-34	B-35		B-36		B-37	
Data	Definition of leak	Applicable state/local regulations	Repair method/procedure for the leaks identified	Average cost per repair for leaks identified		Are there any specialty components that are not readily available on site and that need to be ordered in the event of a component replacement?		Are there any other impediments that would prevent immediate repair of leaks?	
Instruction	If applicable, specify the definition or criteria of leak in the state/local regulations that require leak checks, or the definition that facility refers to	Specify any state/local regulations applicable to your facility for leak checks	Provide a brief description of the repair method/procedure for the leaks identified	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	How long does it take, on average, for the facility to receive the components? (days) (if you select "Yes" on	Select from the dropdown menu in this column	List the impediments that would prevent immediate repair of leaks (if you select "Yes" on the left)
Response									

Table 4. Room Area Controls **No (default)** ← Switch to "Yes" in Cell F130 on the left if Supplement 2 is used in lieu of this table

Fill out at least 1 row for each room area. If any of your room area is routed to more than 3 APCDs, more than 1 stack or more than 1 usage, use another row in this table, repeat the room area ID in Field B-1, then fill out the other fields as necessary

*** Note: If you need to enter more than 30 rows of data, please select "Yes" in Cell F130 above, leave this table below BLANK, then fill out SUPPLEMENT 2 to the Section 114 ICR. Refer to the Instructions Document for more details ***

Field #	B-1	B-38	B-39			B-40			B-41		
Data	Room area ID for all rooms and areas where EtO is used or emitted	Is air from the room area vented to an APCD, used as cascading air, vented to the atmosphere, or handled in any other ways?	APCD 1 for room area			APCD 2 for room area (if any)			APCD 3 for room area (if any)		
Instruction	Select from the dropdown menu. Scroll up to see options, that are auto populated based on your entries in the	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the room to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the room to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the room to this APCD (actual cubic feet per minute, acfm)
Response											

Field #	B-42	B-43	B-44	B-45	B-46	B-47	B-48	B-49	B-50		B-51		B-52	
Data	Material of duct work for room area venting	Total length of duct work for room area venting	Average thickness of duct work for room area venting	Is the cross section of duct work for room area venting circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter of duct work (For circular duct work only)		Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)	
Instruction	Specify the material of duct work	Enter the total length of duct work (feet)	Enter the average thickness of duct work (inches)	Select from the dropdown menu in this column	Enter the average diameter of duct work (feet)	Enter the average cross-sectional height of duct work (feet)	Enter the average cross-sectional width of duct work (feet)	Select from the dropdown menu in this column	Enter the maximum diameter of duct work (feet)	Enter the minimum diameter of duct work (feet)	Enter the maximum cross-sectional height of duct work (feet)	Enter the minimum cross-sectional height of duct work (feet)	Enter the maximum cross-sectional width of duct work (feet)	Enter the minimum cross-sectional width of duct work (feet)
Response														

Field #	B-53	B-54	B-55		B-56		B-57	B-58	B-59					B-60		B-60.1	B-61	B-62			
Data	Installation year of duct work	Lifetime of duct work	Capital cost of duct work for room area venting (estimated or actual)		Installation cost of duct work for room area venting (estimated or actual) (Continue to B-62 for room areas vented to APCD.)		Room area air used as cascading air for reuse in another room or unit (For cascading only) (Continue to B-62 for room areas vented to cascading.)	Stack ID to which the uncontrolled room area vents (For room area vented to the atmosphere only)	Stack parameter (For room area vented to the atmosphere only)					Stack coordinates (For room area vented to the atmosphere only)		Distance from room area outlet to stack (For room area vented to the atmosphere only)	Other handling of air from room area	Room Air Capture			
Instruction	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Specify the room area ID or unit ID the air is vented to if the room area air is used as cascading air for reuse in another room or unit (i.e., vented as the input air to another area). If multiple room areas/units are involved, list all the IDs and separate by commas (,). Ensure that any room area ID entered in this field is consistent with your entries in Field B-1 of this worksheet, and that any unit ID is consistent with your entries elsewhere in this questionnaire.	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height (feet)	Enter the stack diameter (feet)	Enter the temperature at stack outlet (Fahrenheit)	Enter the exhaust velocity at stack outlet (feet/second)	Enter the volumetric flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point	Enter the distance from outlet of the room area to the stack (feet)	Provide a brief description of any air pollution control or handling procedure if air from this room area is not: vented to an APCD; used as cascading air; or vented to the atmosphere	Is there a structure or approach to capture the air emitted from the room area? Select from the dropdown menu in this column	If yes, specify the capture efficiency for this room area (%)	If yes, specify the structure type or approach used to capture the room area (e.g., permanent total enclosure)	If yes, specify the method(s) used to verify the capture efficiency of room air (e.g., Method 204)
Response																					

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

Click here to go to "Introduction"	Click here to go to "Forms"	Click here to go to "Additional Info"

Have any information entered on this worksheet contain confidential business information (CBI)? Specify in **Cell N2** *on the right -->* ***Be sure to shade in red all cells with real CBI data in the CBI version*** *After creating the* ***non-CBI version****, select and copy the Sample CBI Cell (Cell D2) and paste directly into each cell with real CBI data.* ***Make sure all cells that contained CBI look the same as the Sample CBI Cell (Cell D2)*** *- before saving the non-CBI version of your response*

	CBI
	Sample CBI Cell (above)

EIS ID (auto-populated)	
OMB Control No. 2060-0733 Approval Expires 09/30/2024	

C. EtO Drum and Container Storage

Field #	Data	Instruction	Response
C-0	What companies supply EtO drums or cartridges to your facility? Specify the name and percent (%) by weight for each company	Separate data for each company by commas (,). For example: Company 1 - 70%, Company 2 - 30%	Nov Chemical 100%
C-1	How many EtO drums and/or containers are typically stored at the facility at once?		GS-12 drums
C-2	Permitted amount of EtO storage	**(pounds)**	4,800.00
C-3	Is there a designated area for storing EtO drums and/or containers?	Select from the dropdown menu	yes
C-4	Describe the designated area for EtO drum and/or container storage		ETO drum room
C-5	Describe the storage location for full and empty storage media (e.g., indoors in an enclosed room)		Indoor and enclosed area
C-6	Specify the maximum number of full EtO storage media (e.g., twelve 55-gallon drums) kept at the facility in the last 12 months		12
C-7	Is the ambient air in the storage areas continually monitored for ethylene oxide?	Select from the dropdown menu	yes
C-8	Describe the make/model and range of the instrumentation used for continuous monitoring of the storage areas		Sensidyne
C-9	How often are new drums or containers delivered to facility and empty drums or containers picked up and sent offsite?		weekly or bi-weekly
C-10	What is the procedure for checking drums or containers before accepting them onsite? If drums or containers do not meet the requirements, what corrective actions are taken, and how many drums or containers per year are the corrective actions performed on?		verify drum documentation, check drums for leaks and any failures the drums are refused. None have failed.
C-11	Are drums or containers placed next to sterilizer chambers when they are in use?	Select from the dropdown menu	no
C-12	Describe how EtO is charged to the sterilizer chamber		ive hard piping

D. Ethylene Glycol (EG) Tanks

Field #	D-1	D-2	D-3	D-4	D-5	D-6	D-7	D-8	D-9	D-10	D-11	D-12	D-13	D-14	D-15	D-16	D-17	D-18	D-19	D-20	D-21	D-22	D-23	D-24	D-25	D-26	D-27	D-28	D-29	D-30	D-31
Data	Ethylene glycol (EG) tank ID	Material of EG tank	Capacity of EG tank	Throughput of EG tank	Installation year of EG tank	Expected lifetime of EG tank	Capital cost of EG tank		Installation cost of EG tank		Annual cost of EG tank		Is the EG tank routed to any control device?	APCD 1 for EG tank			APCD 2 for EG tank (if any)				Diameter of duct work (For circular duct work only)		Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work	Lifetime of duct work	Capital cost of duct work for EG tank (estimated or actual)		Installation cost of duct work for EG tank (estimated or actual)		Stack ID to which the uncontrolled EG tank vents (For uncontrolled EG tank only)	Stack parameter (For uncontrolled EG tank only)					Stack coordinates (For uncontrolled EG tank only)		Distance from EG tank outlet to stack (For uncontrolled EG tank only)
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each EG tank	Specify the material of EG tank	Enter the capacity of EG tank **(gallons)**	Enter the average daily throughput of EG tank **(gallons per day)**	Enter the calendar year in which EG tank was installed	Enter the expected lifetime of EG tank **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	APCD ID: Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average or flow routed from the tank to this APCD **(actual cubic feet per minute, acfm)**	APCD ID: Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average or flow routed from the tank to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**	Enter the average thickness of duct work **(inches)**	Select from the dropdown menu in this column	Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**	Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column	Enter the maximum diameter of duct work **(feet)**	Enter the minimum diameter of duct work **(feet)**	Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**	Enter the stack diameter **(feet)**	Enter the temperature at stack outlet **(Fahrenheit)**	Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for the emission source at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 4th decimal point	Enter the longitude of stack. Specify to the 4th decimal point	Enter the distance from outlet of the uncontrolled EG tank to the stack **(feet)**
Response	scrubber room	plastic tank	1500.00	5.00	1990	50.0																									

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

Click here to go to "Introduction" | *Click here to go to "Terms"* | *Click here to go to "Additional Info"*

Does any information entered on this worksheet contain confidential business information (CBI)? Specify Cell N2 on the right → Be sure to shade in red all cells with real CBI data in the C6 version
After creating the non-CBI version, select and copy the Sample CBI Cell (Cell D2) and paste directly into each cell with real CBI data. Make sure cell cells that contained CBI look the same as the Sample CBI Cell (Cell D2) before saving the non-CBI version of your response

C6:
Sample CBI Cell (above)

EIS ID (auto-populated)	
OMB Control No. 2060-0733 Approval Expires 09/30/2024	

E. Sterilization Chambers

Table 1. Summary for Sterilizer Chambers

Field #	Data	Response
E-0	Enter the total number of sterilizer chambers at your facility	5

Table 2. Sterilizer Chamber Operation and Monitoring Characteristics

Field #	E-1	E-2	E-3	E-4	E-5	E-6	E-7	E-8	E-9	E-10	E-11	E-12	E-13	E-14	E-15	E-16	E-17	E-18	E-19	E-20	E-21	E-22	E-23	E-24	E-25	E-26	E-27
Data	Sterilizer unit ID	Associated EIS release point ID	Is this an R&D chamber (under the definition of research and laboratory facility)?	Does aeration of the sterilized product occur in the same sterilizer chamber?	Is this a single-item chamber?	Volume of sterilizer chamber	How many cycles per year are conducted in the sterilizer chamber?	Temperature (For combination sterilizers, enter temperature for sterilization mode only)	Relative humidity	Pressure	Does the sterilizer chamber have positive pressure cycles?	EtO dose per cycle	Number of nitrogen washes per cycle	Nitrogen used for washes during each cycle	Annual cost of nitrogen washes	Number of air washes per cycle	Air used for washes during each cycle	Annual cost of air washes	Average electricity used per gas wash (nitrogen washes and air washes combined)	Annual cost of electricity for gas washes (nitrogen washes and air washes combined)	Are leak checks performed on sterilizer chamber?	Frequency of leak checks for sterilizer chamber	Average length of time to perform a leak check	Leak check procedure(s) for sterilizer chamber	Annual cost of leak checks for sterilizer chamber	Average quantity of leaks identified per year	
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each sterilizer	Select from the dropdown menu. Scroll up to see options that are auto-populated based on your entries in the previous fields.	Select from the dropdown menu in this column	Select from the dropdown menu in this column. IF any sterilizers remember to fill out Table 3 on "Aeration" worksheet!	Select from the dropdown menu in this column	Enter the total number of cycles conducted in the sterilizer chamber each year	Enter the average temperature of sterilizer chamber when in operation (Fahrenheit)	Enter the minimum temperature of sterilizer chamber when in operation (Fahrenheit)	Enter the average relative humidity within sterilizer chamber when in operation(%)	Enter the minimum relative humidity within sterilizer chamber when in operation (%)	Enter the maximum relative humidity within sterilizer chamber when in operation (%)	Enter the average pressure within the chamber during EtO dwell period (psig)	Enter the threshold, if vacuum or pressure that is applied during evacuation (psig)	Select from the dropdown menu in this column	Enter the average EtO dose per cycle (mg/L)	Enter the maximum EtO dose per cycle (mg/L)	Enter the minimum EtO dose per cycle (mg/L)	Enter the average number of nitrogen washes per cycle	Enter the maximum number of nitrogen washes per cycle	Enter the minimum number of nitrogen washes per cycle	Enter the average amount of nitrogen used during each cycle (pounds)	Enter the maximum amount of nitrogen used during each cycle (pounds)	Enter the minimum amount of nitrogen used during each cycle (pounds)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the average number of air washes per cycle	Enter the maximum number of air washes per cycle	Enter the minimum number of air washes per cycle	Enter the average amount of air used during each cycle (pounds)	Enter the maximum amount of air used during each cycle (pounds)	Enter the minimum amount of air used during each cycle (pounds)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Specify the frequency of leak checks for sterilizer chamber	Enter average length of time to perform a leak check (minutes)	Provide a brief description of the leak check procedure(s) for sterilizer chamber	Enter the dollar amount in this column	Specify the dollar year in this column	Enter average quantity of leaks found per year	Provide a brief descrip
Response	1	102	306	no	no	no	1140.00	252	125.00	160.00	120.00	75.000%	100.000%	45.00%	-13.80	-29.00	no	660.00	650.00	570.00	2	4	1	50.00	65.00	35.00			2	3	1	0.00	0.00	0.00				yes	monthly	12.00	Pull vacuum and hold for 12 hour			12.0	Tighten the leak or rep
	2	102	306	no	no	no	405.00	110	125.00	150.00	100.00	75.00%	85.00%	40.00%	-13.80	-29.00	no	660.00	650.00	570.00	2	4	1	25.00	35.00	15.00			2	3	1	0.00	0.00	0.00				yes	monthly	12.00	Pull vacuum and hold for 12 hour			12.0	Tighten the leak or rep
	3	103	109	no	no	no	405.00	110	125.00	150.00	100.00	75.00%	85.00%	40.00%	-13.80	-29.00	no	660.00	650.00	570.00	2	4	1	25.00	35.00	15.00			2	3	1	0.00	0.00	0.00				yes	monthly	12.00	Pull vacuum and hold for 12 hour			12.0	Tighten the leak or rep
	4	103	109	no	no	no	250.00	310	125.00	140.00	100.00	75.00%	85.00%	40.00%	-13.80	-29.00	no	660.00	650.00	570.00	2	4	1	10.00	20.00	5.00			2	3	1	0.00	0.00	0.00				yes	monthly	12.00	Pull vacuum and hold for 12 hour			12.0	Tighten the leak or rep
	5	103	106	no	no	no	50.00	300	125.00	140.00	85.00	85.00%	100.00%	35.00%	-13.80	-29.00	no	660.00	650.00	570.00	2	4	1	5.00	15.00	5.00			2	3	1	0.00	0.00	0.00				yes	monthly	12.00	Pull vacuum and hold for 12 hour			12.0	Tighten the leak or rep

Table 3. Control Characteristics for Sterilizer Chambers

Field #	E-1	E-52	E-53	E-54	E-55	E-56	E-57	E-58	E-59	E-60	E-61	E-62	E-63	E-64	E-65	E-66	E-67	E-68	E-69	E-70	E-71	E-72	E-72.1	E-73	E-74	E-74.1	E-74.2	E-75	E-76
Data	Sterilizer unit ID	Is the sterilizer chamber vent (SCV) routed to any control device?	APCD 1 for sterilizer chamber vent (SCV)	APCD 2 for sterilizer chamber vent (SCV) (if any)	APCD 3 for sterilizer chamber vent (SCV) (if any)	Material of duct work for sterilizer chamber vent (SCV)	Total length of duct work for sterilizer chamber vent (SCV)	Average thickness of duct work for sterilizer chamber vent (SCV)	Is the cross section of duct work for sterilizer chamber vent (SCV) circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Installation year of duct work	Lifetime of duct work	Capital cost of duct work for sterilizer chamber vent (SCV) (estimated or actual)	Installation cost of duct work for sterilizer chamber vent (SCV) (estimated or actual)	Stack ID to which the sterilizer chamber vent (SCV) vents (For uncontrolled SCV only)	Stack parameter (For uncontrolled SCV only)				Stack coordinates (For uncontrolled SCV only)		Distance from SCV to stack (For uncontrolled SCV only)	Is there a chamber exhaust vent (CEV)?	Is there a target EtO concentration that is reached before activation of the CEV?	Duration of CEV operation in each sterilization cycle	Average EtO concentration during CEV operation	Is an interlock system present that prevents activation of the CEV and opening of the sterilizer door until a set EtO concentration is reached?	Installation year of interlock system
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average air flow routed from the duct work to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average air flow routed from the duct work to this APCD (actual cubic feet per minute, acfm)	Select from the dropdown menu in this column	Enter the average diameter of duct work (feet)	Enter the average cross-sectional height of duct work (feet)	Enter the average cross-sectional width of duct work (feet)	Select from the dropdown menu in this column	Enter the maximum diameter of duct work (feet)	Enter the minimum diameter of duct work (feet)	Enter the maximum cross-sectional height of duct work (feet)	Enter the minimum cross-sectional height of duct work (feet)	Enter the maximum cross-sectional width of duct work (feet)	Enter the minimum cross-sectional width of duct work (feet)	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height (feet)	Enter the stack diameter (feet)	Enter the temperature at stack outlet (Fahrenheit)	Enter the exhaust velocity at stack outlet (feet/second)	Enter the volumetric flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the 4th decimal point	Enter the longitude of stack. Specify to the 4th decimal point	Enter the distance from the uncontrolled SCV to the stack (feet)	Select from the dropdown menu in this column	Enter the value if you select "Yes" on the left	Enter the time that the CEV is in operation for each sterilization cycle (minutes)	Enter the average EtO concentration during the CEV operation if available. This should NOT be the EtO concentration at the start of operation (ppm)	Select from the dropdown menu in this column. If your answer is "Yes" in any row below, fill out Table 3	Enter the calendar year in which the interlock system was installed
Response	1	Yes (fill out E-52 through E-69)	Damas	Wet scrubber	70.00																#3	34.50	2.50	75.00							yes	No (skip to E-74.1)				No (skip to E-81)	
	2				40.00																#3	34.50	2.50	75.00							yes	No (skip to E-74.1)				No (skip to E-81)	
	3				35.00																#3	34.50	2.50	75.00							yes	No (skip to E-74.1)				No (skip to E-81)	
	4				15.00																#3	34.50	2.50	75.00							yes	No (skip to E-74.1)				No (skip to E-81)	
	5				2.00																#3	34.50	2.50	75.00							yes	No (skip to E-74.1)				No (skip to E-81)	

Table 4. Control Characteristics for Sterilizer Chambers (continued)

Field #	E-1	E-111	E-112	E-113	E-114	E-115	E-116	E-117	E-118	E-119	E-120	E-121	E-122	E-123	E-124	E-125	E-126	E-127	E-128	E-129	E-130	E-131	E-132	E-132.1	E-133
Data	Sterilizer unit ID	Is the cover hood or vent routed to any control device?	APCD 1 for cover hood or vent	APCD 2 for cover hood or vent (if any)		Material of duct work for cover hood or vent	Total length of duct work for cover hood or vent	Average thickness of duct work for cover hood or vent	Is the cross section of duct work for the cover hood or vent circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Installation year of duct work	Lifetime of duct work	Capital cost of duct work for cover hood or vent (estimated or actual)	Installation cost of duct work for cover hood or vent (estimated or actual) (Continue to E-131 for cover hood or vent routed to APCD)	Stack ID to which the cover hood or vent vents (For uncontrolled cover hood or vent only)	Stack parameter (For uncontrolled cover hood or vent only)			Stack coordinates (For uncontrolled cover hood or vent only)		Distance from cover hood or vent to stack (For uncontrolled cover hood or vent only)	Is any SCV or CEV of the sterilizer unit routed to a vacuum pump?
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average air flow routed from the duct work to this APCD (actual cubic feet per minute, acfm)	Specify the material of duct work	Enter the total length of duct work (feet)	Enter the average thickness of duct work	Select from the dropdown menu in this column	Enter the maximum diameter of duct work (feet)	Enter the minimum diameter of duct work (feet)	Enter the maximum cross-sectional height of duct work (feet)	Select from the dropdown menu in this column	Enter the maximum diameter of duct work (feet)	Enter the minimum diameter of duct work (feet)	Enter the maximum cross-sectional height of duct work (feet)	Enter the minimum cross-sectional height of duct work (feet)	Enter the maximum cross-sectional width of duct work (feet)	Enter the minimum cross-sectional width of duct work (feet)	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height (feet)	Enter the stack diameter (feet)	Enter the temperature at stack outlet (Fahrenheit)	Enter the exhaust velocity at stack outlet (feet/second)	Enter the volumetric flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the 4th decimal point	Enter the longitude of stack. Specify to the 4th decimal point	Enter the distance from the uncontrolled SCV to the stack (feet)	Select from the dropdown menu in this column. If your answer is "Yes" in any row below, fill out Table 5
Response	1	Yes	No (fill out E-130 through E-132.1)																		#3	34.50	2.50	70.00						Yes (fill out E-134 through E-143)
	2		No (fill out E-130 through E-132.1)																		#3	34.50	2.50	70.00						Yes (fill out E-134 through E-143)
	3		No (fill out E-130 through E-132.1)																		#3	34.50	2.50	70.00						Yes (fill out E-134 through E-143)
	4		No (fill out E-130 through E-132.1)																		#3	34.50	2.50	70.00						Yes (fill out E-134 through E-143)
	5		No (fill out E-130 through E-132.1)																		#3	34.50	2.50	70.00						Yes (fill out E-134 through E-143)

Table 5. Vacuum Pumps

Field #	E-134	E-135	E-136		E-137	E-138	E-139	E-140	E-141	E-142		E-143
Data	Unit ID of vacuum pump	Associated sterilizer unit ID(s) and vent(s)	Basic information of vacuum pump		Seal type of vacuum pump	Capacity of vacuum pump	Installation year of vacuum pump	Expected lifetime of the vacuum pump	Capital cost of vacuum pump	Annual cost of vacuum pump		Handling and disposal of water for once-through vacuum pump
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each pump	Specify ID of the sterilizer unit associated with this vacuum pump. If multiple sterilizer units serviced by this vacuum pump, list all sterilizer unit IDs and separate by commas (,). Ensure that any sterilizer unit ID entered in this field is consistent with your entries in Field E-1 of the worksheet. Also specify which vents on the sterilizer unit are routed to the vacuum pump. For example: "SC-1 (SCV, CEV)"	Specify make of pump	Specify model of pump	Specify type of pump. Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses.	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your pump)"	Capacity (cubic feet per minute, cfm)	Enter the calendar year in which the vacuum pump was installed	Enter the expected lifetime of the EtO concentration monitor (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	If you selected "once-through" as the type of vacuum pump, provide a brief description about how water is handled and disposed
Response	A 1 Vacuum Pump	Sterilizer # 1	SHI/Kinney		Recirculating							
	A 2 Vacuum Pump	Sterilizer # 1	SHI/Kinney		Recirculating							
	A 3 Vacuum Pump	Sterilizer # 2	SHI/Kinney		Recirculating							
	A 4 Vacuum Pump	Sterilizer # 2	SHI/Kinney		Recirculating							
	A 5 Vacuum pump	Sterilizer # 3	SHI/Kinney		Recirculating							

E-27	E-28		E-29	E-30						E-31	E-32	E-33		E-34		E-35		E-36	E-37			E-38			E-39				E-40	E-41	E-42	E-43	E-44		E-45	E-46	E-47	E-48		E-49		E-50	
Repair method/procedure for the leaks identifie	Average cost per repair for the leaks identified		Is an EtO concentration monitor used within this sterilizer chamber?	Description of the EtO concentration monitor used within this sterilizer chamber						Installation year of EtO concentration monitor	Expected lifetime of EtO concentration monitor	Capital cost of the EtO concentration monitor used within this sterilizer chamber		Installation cost of the EtO concentration monitor used within this sterilizer chamber		Annual cost of the EtO concentration monitor used within this sterilizer chamber		Standards or work practices followed for the EtO concentration monitor used within this sterilizer chamber	Duration of product dwell time within the chamber at EtO dosing concentration			Total duration of time product stays within the sterilizer chamber before it is moved out			Concentration that EtO is reduced to before moving the product out of this sterilizer chamb				Is EtO from sterilizer captured for re-use?	Is water used during this process?	Amount of water disposed annually	Method of water disposal	Annual costs associated with water disposal		What is the percentage of EtO recovered by this system?	Year in which the EtO recovery system was installed	Expected lifetime of the EtO recovery system	Capital cost of the EtO recovery system used with this sterilizer chamber		Installation cost of the EtO recovery system used with this sterilizer chamber		Annual cost of the EtO recovery system used with this sterilizer chamber (excluding costs associated with wastewater treatment and disposal)	
tion of the repair method/procedure for the leaks identi	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Enter the type of EtO concentration monitor	Enter the manufacturer of EtO concentration monitor	Enter the model of EtO concentration monitor	Specify the method of detection of EtO concentration monitor	Enter the value of detection level of EtO concentration monitor	Specify the unit of detection level of EtO concentration monitor	Enter the calendar year in which the EtO concentration monitor was installed	Enter the expected lifetime of the EtO concentration monitor **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of any standards or work practices followed for the EtO concentration monitor used within the chamber	Enter the average duration **(hours)**	Enter the maximum duration **(hours)**	Enter the minimum duration **(hours)**	Enter the average duration **(hours)**	Enter the maximum duration **(hours)**	Enter the minimum duration **(hours)**	Specify the unit of concentration. Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the	Enter the average concentration that EtO is reduced to **(ppm or % LEL)**	Enter the maximum concentration that EtO is reduced to **(ppm or % LEL)**	Enter the minimum concentration that EtO is reduced to **(ppm or % LEL)**	Select from the dropdown menu in this column	Select from the dropdown menu in this column	**(gallons)**	Provide a brief description about how water is disposed after being used to capture EtO for re-use	Enter the dollar amount in this column	Specify the dollar year in this column	**(%)**	Enter the calendar year	Enter the expected lifetime of the EtO recovery system **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column
lace the iter			No (skip to E-37																3.00	9.00	2.00	9.00	14.00	7.00	1-5ppm	3.00	10.00	1.00	No (skip to E-51														
lace the iter			No (skip to E-37																3.00	4.00	2.00	8.00	10.00	7.00	1-5ppm	3.00	10.00	1.00	No (skip to E-51														
lace the iter			No (skip to E-37																3.00	4.00	2.00	8.00	10.00	7.00	1-5ppm	3.00	10.00	1.00	No (skip to E-51														
lace the iter			No (skip to E-37																3.00	4.00	2.00	8.00	10.00	7.00	1-5ppm	3.00	10.00	1.00	No (skip to E-51														
lace the iter			No (skip to E-37																3.00	4.00	2.00	8.00	9.00	7.00	1-5ppm	3.00	10.00	1.00	No (skip to E-51														

E-77	E-78		E-79		E-80	E-81	E-82			E-83			E-84			E-85	E-86	E-87	E-88	E-89	E-90	E-91	E-92	E-93		E-94		E-95		E-96	E-97	E-98		E-99		E-100	E-101	E-102	E-103	E-104		E-105		E-106	
Expected lifetime of interlock system	Capital cost of interlock system		Annual cost of interlock system		Standards or work practices followed for interlock system	Is the chamber exhaust vent (CEV) routed to any control device?	APCD 1 for chamber exhaust vent (CEV)			APCD 2 for chamber exhaust vent (CEV) (if any)			APCD 3 for chamber exhaust vent (CEV) (if any)			Material of duct work for chamber exhaust vent (CEV)	Total length of duct work for chamber exhaust vent (CEV)	Average thickness of duct work for chamber exhaust vent (CEV)	Is the cross section of duct work for chamber exhaust vent (CEV) circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter of duct work (For circular duct work only		Cross-sectional height of duct work (For rectangular duct work only		Cross-sectional width of duct work (For rectangular duct work only		Installation year of duct work	Lifetime of duct work	Capital cost of duct work for chamber exhaust vent (CEV) (estimated or actual)		Installation cost of duct work for chamber exhaust vent (CEV) (estimated or actual)		Is any APCD installed solely for the purpose of controlling emissions from the CEV?	If not, was a damper system installed for the purpose of adjusting the flow rate to the control device upon CEV activation?	Year in which the damper system was installed	Expected lifetime of the damper system	Capital cost of the damper system		Installation cost of the damper system		Annual cost of the damper system	
Enter the expected lifetime of the interlock system **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of any standards or work practices followed for interlock system that prevents activation of the CEV until a set concentration is reached	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this colum If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this colum If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this colum If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**	Enter the average thickness of duct work **(inches)**	Select from the dropdown menu in this column	Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**	Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column	Enter the maximum diameter of duct work **(feet)**	Enter the minimum diameter of duct work **(feet)**	Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Select from the dropdown menu in this column	Enter the calendar year	Enter the expected lifetime of the damper system **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column
						No (fill out E-108 through E-110 1																																							
						No (fill out E-108 through E-110 1																																							
						No (fill out E-108 through E-110 1																																							
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						No (fill out E-108 through E-110 1																																							

II-107	II-108	II-109					II-110		II-110.1
APCD installed solely for the purpose of controlling emissions from the CEV	Stack ID to which the uncontrolled/bamber exhaust vent (CEV) vents (For uncontrolled CEV only)	Stack parameter (For uncontrolled CEV only)					Stack coordinates (For uncontrolled CEV only)		Distance from CEV to stack (For uncontrolled CEV only)
Specify ID of the APCD installed solely for controlling CEV emissions. If multiple APCDs are involved, list all APCD IDs and separate by commas (,). Ensure that any APCD ID entered in this field is consistent with your entry regarding in this questionnaire*	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stackheight above ground **(feet)**	Enter the stack diameter **(feet)**	Enter thetemperature at stack outlet **(Fahrenheit)**	Enter theexhaust velocity at stack outlet **(feet/second)**	Enter thevolumetric flow rate for the uncontrolled emission sourceat stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 4th decimal point	Enter the longitude of stack. Specify to the 4th decimal point	Enter the distance from the uncontrolled CEV to the stack **(feet)**
	1	34.50	2.00	70.00					
	2								
	3								
	4								
	5								

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info

Does any information entered on this worksheet contain confidential business information (CBI)? Specify in Cell N2 on the right → Be sure to shade in red all cells with real CBI data in the CBI version. After creating the non-CBI version, select and copy the Sample CBI Cell (Cell O2) and paste directly into each cell with real CBI data. Make sure all cells that contained CBI look the same as the Sample CBI Cell (Cell O2) before saving the non-CBI version of your response		CBI / Sample CBI Cell (above)

EIS ID (auto-populated)	
OMB Control No. 2060-0733 Approval Expires 09/30/2024	

F. Aeration

Table 1. Aeration that Occurs in Separate Unit (Aeration Room & Aeration Cell/Chamber)

Field #	F-1	B-1	F-2	F-3	F-4	F-5	F-6			F-7		
Data	Aeration unit ID	Room area in which aeration unit is located	Associated EIS release point ID	Type of aeration unit	Does the aeration unit use accelerated aeration?	Characteristics of accelerated aeration	Dimensions of aeration cell/chamber (For aeration cell/chamber only. Dimensions of aeration rooms should already have been provided on "Room Area" worksheet)			Temperature		
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each aeration unit	Select from the dropdown menu. Scroll up to see options that are auto populated based on your entries in the	Enter the EIS release point ID associated with the aeration unit, if any	Select from the dropdown menu in this column	Select from the dropdown menu in this column	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your equipment)"	Enter the height of aeration unit (feet)	Enter the width of aeration unit (feet)	Enter the length of aeration unit (feet)	Enter the average temperature of aeration room when in operation (Fahrenheit)	Enter the maximum temperature of aeration room when in operation (Fahrenheit)	Enter the minimum temperature of aeration room when in operation (Fahrenheit)
Response	#1	102		Aeration room	Yes	Other (maintain under negative air pressure with heat)	13.00	16.00	39.00	113.00	131.00	109.00
	#2	103		Aeration room	Yes	Other (maintain under negative air pressure	13.00	16.00	39.00	113.00	131.00	109.00

Field #	F-8		F-8.1	F-9	F-10		F-11	F-12	F-13			F-14
Data	Relative humidity		Average EtO concentration	Pressure (For aeration cell/chamber only)	Pressure drop (For aeration room only)		Facial velocity (For aeration room only)	Location and length of time that sterilized product is placed in aeration room area before being placed in the aeration chamber	Length of time that product is being held in aeration unit before being transferred			Are leak checks performed on aeration unit?
Instruction	Is a specific humidity needed for aeration? Select from the dropdown menu in this column	If yes, enter the specific humidity that is needed for aeration (%)	Enter the average EtO concentration in the aeration unit (ppm)	Enter the average pressure within the unit (psig)	Enter the pressure drop across aeration room (inch H2O) (you may choose to fill out either F-10, F-	Specify definition of pressure drop, or locations based on which pressure drop is measured (e.g., farthest point to inlet of control device)	Enter the facial velocity in aeration room (feet per minute, fpm) (you may choose to	Provide details on where the sterilized product is placed in the aeration room area (e.g., placed in hallway area outside door of aeration chamber), and the length of time the sterilized product sits in the aeration room area before being placed in the aeration chamber	Enter the average length of time that products are being held in aeration room (hours)	Enter the maximum length of time that products are being held in aeration room (hours)	Enter the minimum length of time that products are being held in aeration room (hours)	Select from the dropdown menu in this column
Response	No (skip to F-8.1)		10.00	0.03	0.030		1500.00	Product is moved directly to the aeration room and all product is kept together.Product may reside in aeration for 12 hours up to 8 days.	12.00	192.00	8.00	No (skip to F-22)
	No (skip to F-8.1)		10.00	0.03	0.030		1500.00	Product is moved directly to the aeration room and all product is kept together.Product	12.00	192.00	8.00	No (skip to F-22)

Field #	F-15	F-16	F-17	F-18		F-19	F-20	F-21		F-22
Data	Frequency of leak checks for aeration unit	Average length of time to perform a leak check	Leak check procedure(s) for aeration unit	Annual cost of leak checks for aeration unit		Average quantity of leaks identified per year	Repair method/procedure for leaks identified	Average cost per repair for leaks identified		Is aeration room vent (ARV) routed to any control device?
Instruction	Specify the frequency of leak checks for sterilizer chamber	Enter average length of time to perform a leak check (minutes)	Provide a brief description of the leak check procedure(s) for aeration unit	Enter the dollar amount in this column	Specify the dollar year in this column	Enter average quantity of leaks found per year	Provide a brief description of the repair method/procedure for the leaks identified	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column
Response										Yes (fill out F-23 through F-39)
										Yes (fill out F-23

Field #	F-23			F-24			F-25	F-26	F-27	F-28	F-29	F-30	F-31	F-32
Data	APCD 1 for aeration room vent (ARV)			APCD 2 for aeration room vent (ARV) (if any)			Material of duct work for aeration room vent (ARV)	Total length of duct work for aeration room vent (ARV)	Average thickness of duct work for aeration room vent (ARV)	Is the cross section of duct work for aeration room vent (ARV) circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?
Instruction	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	Specify the material of duct work	Enter the total length of duct work (feet)	Enter the average thickness of duct work (feet)	Select from the dropdown menu in this column	Enter the average diameter of duct work (feet)	Enter the average cross-sectional height of duct work (feet)	Enter the average cross-sectional width of duct work (feet)	Select from the dropdown menu in this column
Response	Anguil	Catalytic oxidizer	1800.00				Stainless steel duct	60.00	0.13	Circular (fill out F-29 & F-33 as	2.50			Yes (skip to F-36)
	Anguil	Catalytic oxidizer	1800.00											

Field #	F-33		F-34		F-35		F-36	F-37	F-38		F-39	
Data	Diameter of duct work (For circular duct work only)		Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work	Lifetime of duct work	Capital cost of duct work for aeration room vent (ARV) (estimated or actual)		Installation cost of duct work for aeration room vent (ARV) (estimated or actual)	
Instruction	Enter the maximum diameter of duct work (feet)	Enter the minimum diameter of duct work (feet)	Enter the maximum cross-sectional height of duct work (feet)	Enter the minimum cross-sectional height of duct work (feet)	Enter the maximum cross-sectional width of duct work (feet)	Enter the minimum cross-sectional width of duct work (feet)	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column
Response	2.50	2.00					1994	50.0				

Field #	F-40	F-41					F-42		F-42.1
Data	Stack ID to which the aeration room vents (ARV) is routed to (For uncontrolled ARV only)	Stack parameter (For uncontrolled ARV only)					Stack coordinates (For uncontrolled ARV only)		Distance from ARV to stack (For uncontrolled ARV only)
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height (feet)	Enter the stack diameter (feet)	Enter the temperature at stack outlet (Fahrenheit)	Enter the exhaust velocity at stack outlet (feet/second)	Enter the volumetric flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the fifth decimal point	Enter the longitude of stack. Specify to the fifth decimal point	Enter the distance from the uncontrolled ARV to the stack (feet)
Response		34.50	2.00	215.00	5600.00				50.00
		34.50							

Table 2. Aeration that Occurs within Sterilizer Chamber

If no data is auto-populated in Field F-1 of this table, skip to Table 3.

Field #	F-1	F-43			F-44		F-45	F-46		
Data	Sterilizer unit ID	Temperature			Relative humidity		Pressure	Length of time that products are being held in aeration room before being transferred		
Instruction	This column will be auto-populated based on your entries in the previous fields	Enter the average temperature of aeration room when in operation (Fahrenheit)	Enter the maximum temperature of aeration room when in operation (Fahrenheit)	Enter the minimum temperature of aeration room when in operation (Fahrenheit)	Is a specific humidity needed for aeration? Select from the dropdown menu in this column	If yes, enter the specific humidity that is needed for aeration (%)	Specify pressure condition during aeration process	Enter the average length of time that products are being held in aeration room (hours)	Enter the maximum length of time that products are being held in aeration room (hours)	Enter the minimum length of time that products are being held in aeration room (hours)
Response										

Table 3. Movement of Sterilized Products through the Facility

Describe how sterilized product is moved from one area of the facility to another. For each product move through the facility provide, provide details on the following variables: (1) length of time that product sits, (2) where the product is placed, (3) distance

Field #	Data	Instruction	Response
F-47	From sterilizer chamber to aeration room/chamber	Provide details on where the sterilized product is placed in the sterilizer room area following removal from the chamber, the length of time the sterilized product sits in the sterilizer room area, the distance sterilized product is moved from the sterilizer room area to the aeration room area	
F-48	From aeration room/chamber to warehouse area	Provide details on where the sterilized and aerated product is placed after being removed from aeration chamber, length of time the sterilized and aerated product sits after being removed from aeration room, and distance the sterilized and aerated product is moved to warehouse area	
F-49	At warehouse area	Provide details on length of time sterilized and aerated product is held in the warehouse before being loaded on truck or other conveyance for shipment offsite	

Ethylene Oxide (EtO) Commercial Sterilization
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CBI
Sample CBI Cell (above)

EIS ID (auto-populated)	
OMB Control No. 2060-0733 Approval Expires 09/30/2024	

G. Summary of Air Pollution Control Devices

Table 1. APCD Characteristics
If an APCD consists by more than one stage, provide the information requested in Fields G-3 through G-7 for each additional stage on "Additional Info" worksheet Decks

Field #	G-1	G-2	G-3	G-4			G-5	G-6				G-7	G-8	G-9	G-10		G-11		G-12		G-13		G-14		G-15		G-16	G-17		G-18
Data	APCD ID	Type of APCD	Associated EIS release point ID	Description of APCD			Stack ID to which the APCD vents	Stack parameter				Stack centriod			Capital cost of APCD		Installation cost of APCD		Other one-time costs of APCD		Annual monitoring cost of APCD		Annual repair and routine maintenance cost of APCD		Other annual costs of APCD		Is a balancing/ancillary system used to moderate EtO concentration before the gas stream enters the control device (e.g., a water bath that absorbs EtO)?	Performance test performed in the last 5 years (if any)			How does the APCD handle variability in flow rate and other relevant parameters?
Instruction	This column will be auto-populated based on your entries in the previous fields	This column will be auto-populated based on your entries in the previous fields	Enter the EIS release point ID associated with this APCD, if any	Specify the manufacturer of APCD	Specify the model of APCD	Enter the value of maximum capable volumetric flow of APCD	Specify the unit of maximum capable volumetric flow of APCD	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height (feet)	Enter the stack diameter (feet)	Enter the temperature at stack outlet (Fahrenheit)	Enter the exhaust velocity at stack outlet (feet/second)	Enter the volumetric flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the fifth decimal point	Enter the longitude of stack. Specify to the fifth decimal point	Enter the calendar year in which APCD was installed	Enter the expected lifetime of APCD (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	If any, specify other one-time costs of APCD (e.g., programming a data acquisition system)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Describe other annual costs of APCD	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Specify the dates of any performance test performed for each APCD in the last 5 years (mm/dd/yyyy). If there are multiple dates, separate by commas [1]	Enter the average dollar amount for each performance test in this column	Specify the dollar year in this column	Provide a copy of each performance test performed in the last 5 years in its entirety for each APCD	Provide a brief description about how the APCD handles variability in flow rate and other relevant parameters
Response	Damco	Wet scrubber		Damco		300	scfm	scrubber stack	34.5	0.67	75	10.00	300.00			1994	50.0														Fixed flow rate is a constan
	Angul	Catalytic oxidizer		Angul	model 100	10000.00	scfh	#1	34.50	2.00	109.00	26.00	3000.00			1994	50.0														

Table 2. Emissions and CEMS

Field #	G-1	G-2	G-19	G-20	G-21					G-22	G-23	G-24		G-25		G-26		G-27	G-28			
Data	APCD ID	Type of APCD	Peak hourly emission rate of APCD		Is any continuous emissions monitoring system (CEMS) used to measure EtO concentration from the APCD?	Description of the CEMS used to measure EtO concentration from the APCD				Installation year of CEMS	Expected lifetime of CEMS	Capital cost of CEMS used to measure EtO concentration from the APCD		Installation cost of CEMS used to measure EtO concentration from the APCD		Annual cost of CEMS used to measure EtO concentration from the APCD		Standards or work practices followed for CEMS used to measure EtO concentration from the APCD	Engineering or non-regulatory emission test performed in the last 5 years (if any)		
Instruction	This column will be auto-populated based on your entries in the previous fields	This column will be auto-populated based on your entries in the previous fields	Enter the value of peak hourly emission rate	Specify the unit of peak hourly emission rate	Select from the dropdown menu in this column	Enter the type of CEMS	Enter the manufacturer of CEMS	Enter the model of CEMS	Specify the method of detection of CEMS	Enter the value of detection level of CEMS	Specify the unit of detection level of CEMS	Enter the calendar year in which the CEMS was installed	Enter the expected lifetime of the CEMS (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of any standards or work practices followed for the CEMS used to measure EtO concentration from the APCD	Specify the dates of any engineering or non-regulatory emission test performed for each APCD in the last 5 years (mm/dd/yyyy). If there are multiple dates, separate by commas [1]	Enter the average dollar amount for each engineering emission test in this column	Specify the dollar year in this column	Provide a copy of each engineering or non-regulatory emission test performed in the last 5 years in its entirety for each APCD
Response	Damco	Wet scrubber																				
	Angul	Catalytic oxidizer																				

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EIS ID (auto-populated)	
OMB Control No. 2060-0733 **Approval Expires 09/30/2024**	

H. Details of Air Pollution Control Devices

Table 1. Wet Scrubber & Glygen Absorber Unit

Field #	G-1	H-1	H-2		H-3	H-4	H-5		H-6
Data	APCD ID	Design and operation specifications	Ethylene glycol (EG) generated annually		Ethylene glycol (EG) tank ID(s) to which wet scrubber/glygen absorber unit feeds	Ethylene glycol (EG) disposal	Annual cost of ethylene glycol (EG) disposal		Process/APCD monitoring plan for wet scrubber/glygen absorber unit
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the wet scrubber/glygen absorber unit	Enter the amount in this column	Specify the unit in this column	Specify the EG tank ID each wet scrubber/glygen absorber unit feeds EG to, if applicable. If there are multiple EG tanks involved, list all EG tank IDs and separate by commas (,). Ensure that any EG tank ID entered in this field is consistent with your entries in "EtO & EG Storage" worksheet, Field D-1	Provide a brief explanation of how ethylene glycol is disposed (e.g., municipal sewer, industrial sewer, manufacturer pickup, etc.)	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of the process/APCD monitoring plan for the wet scrubber/glygen absorber unit. Specify if measurements of the gas stream or sorbent material are part of these plans
Response	Damas	Damas Scrubber is a water and surfuric acid liquor used to convert ETO to EG			two 1500 gallon tanks are used for scrubbing ETO, one is for sterilizers #1, #2, and #5 and the other tank is for sterilizers #3, #4, and future/spare sterilizer.	All EG is hauled away for repossing into bearing grease or equivalent			monitoring tank levels in scrubber tanks

Field #	H-7					H-8				
Data	Parameter 1 monitored for wet scrubber/glygen absorber unit					Parameter 2 monitored for wet scrubber/glygen absorber unit (if any)				
Instruction	Name of Parameter 1	Set value of Parameter 1	Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2
Response	tank level		inches	each production day	inspect and remedy concern/event					

Field #	H-9					H-10					H-11
Data	Parameter 3 monitored for wet scrubber/glygen absorber unit (if any)					Parameter 4 monitored for wet scrubber/glygen absorber unit (if any)					Monitoring records for wet scrubber/glygen absorber unit from the last calendar year
Instruction	Name of Parameter 3	Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
Response											See instructions in "Documents" worksheet

Table 2. Dry-bed Scrubber

Field #	G-1	H-12	H-13	H-14	H-14.1			H-15	H-16	H-16.1		H-16.2		H-17
Data	APCD ID	Design and operation specifications	Type of media/sorbent used	Volume of media/sorbent	Unit cost of media/sorbent			Installation year of current media/sorbent	Expected lifetime of media/sorbent	Initial Capital cost of media/sorbent		Annual Replacement cost of media/sorbent		Can the media/sorbent be regenerated?
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the dry-bed scrubber	Specify the type of media/sorbent used for the dry-bed scrubber	Enter the volume of media/sorbent used for the dry-bed scrubber **(cubic feet)**	Enter the dollar amount in this column	Specify the unit of measurement in this column. For example: $ per cubic feet, $ per ton, etc.	Specify the dollar year in this column	Enter the calendar year in which the current media/sorbent was installed	Enter the expected lifetime of the media/sorbent used **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column
Response														

Field #	H-18				H-19		H-20	H-21		H-22		H-23	H-24
Data	Media/sorbent renegeration				Average cost of a media/sorbent regeneration event		Sorbent disposal	Annual cost of sorbent disposal		Is the media/sorbent activity monitored or tested in any way?		Is the media/sorbent change out done based on manufacturer suggestion?	Process/APCD monitoring plan for dry-bed scrubber
Instruction	How frequently is the media/sorbent regenerated, if applicable?	What method is used to regenerate the media/sorbent, if applicable?	How many times is the media/sorbent regenerated prior to disposal, if applicable?	To what removal efficiency is the media/sorbent restored after regeneration? **(%)**	Enter the dollar amount in this column	Specify the dollar year in this column	Specify how sorbent is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	If yes, provide a brief description in this column	Select from the dropdown menu in this column. If you select "No (double click and type here)", be sure to enter your response between the parentheses. Example: "No (your explanation)"	Provide a brief description of the process/APCD monitoring plan for the dry-bed scrubber. Specify if measurements of the gas stream or sorbent material are part of these plans
Response													

Field #	H-25					H-26				
Data	Parameter 1 monitored for dry-bed scrubber					Parameter 2 monitored for dry-bed scrubber (if any)				
Instruction	Name of Parameter 1	Set value of Parameter 1	Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2
Response										

Field #	H-27					H-28					H-29
Data	Parameter 3 monitored for dry-bed scrubber (if any)					Parameter 4 monitored for dry-bed scrubber (if any)					Monitoring records for dry-bed scrubber from the last calendar year
Instruction	Name of Parameter 3	Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
Response											See instructions in "Documents" worksheet

Table 3. Catalytic Oxidizer & Combination Water Balancer/Catalytic Oxidizer

Field #	G-1	H-30	H-31	H-32	H-32.1			H-33	H-34	H-34.1		H-34.2		H-35	H-35.1	
Data	APCD ID	Design and operation specifications	Type of catalyst	Volume of catalyst	Unit cost of catalyst			Installation year of current catalyst	Expected lifetime of catalyst	Initial Capital cost of catalyst		Annual Replacement cost of catalyst		Operating temperature of catalyst bed	Cost of catalyst replacement	
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the catalytic oxidizer or combo water balancer/catalytic oxidizer	Specify the type of catalyst used in catalytic oxidizer or combo water balancer/catalytic oxidizer	**(cubic feet)**	Enter the unit cost in this column	Specify the unit of measurement in this column. For example: $ per cubic feet, $ per ton, etc.	Specify the dollar year in this column	Enter the calendar year in which the current catalyst was installed	Enter the expected lifetime of the catalyst used **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the operating temperature of catalyst bed **(Fahrenheit)**	Enter the dollar amount in this column	Specify the dollar year in this column
Response	Anguil															

Field #	H-35.2	H-35.3	H-36		H-37		H-38		H-39	H-40			
Data	Frequency of catalyst replacement	Average volume of catalyst replacement	Annual natural gas usage to maintain the operating temperature		Annual cost of natural gas used by the catalytic oxidizer or combo water balancer/catalytic oxidizer		Annual cost of electricity used by the catalytic oxidizer or combo water balancer/catalytic oxidizer		Can the catalyst be regenerated?	Catalyst renegeration			
Instruction	Specify how often on average the catalyst is replaced **(years)**	Enter the average volume of catalyst replaced every time **(cubic feet)**	Enter the amount in this column	Specify the unit in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	How frequently is the catalyst regenerated, if applicable?	What method is used to regenerate the catalyst, if applicable?	How many times is the catalyst regenerated prior to disposal, if applicable?	To what removal efficiency is the catalyst restored after regeneration? **(%)**
Response													

Field #	H-41		H-42	H-43		H-44
Data	Average cost of a catalyst regeneration event		Catalyst disposal	Annual cost of catalyst disposal		Process/APCD monitoring plan for catalytic oxidizer or combo water balancer/catalytic oxidizer
Instruction	Enter the dollar amount in this column	Specify the dollar year in this column	Specify how catalyst is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of the process/APCD monitoring plan for the catalytic oxidizer or combo water balancer/catalytic oxidizer. Specify if measurements of the gas stream or sorbent material are part of these plans
Response						

Field #	H-45					H-46				
Data	Parameter 1 monitored for catalytic oxidizer & balancer/abator					Parameter 2 monitored for catalytic oxidizer & balancer/abator (if any)				
Instruction	Name of Parameter 1	Set value of Parameter 1	Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2
Response										

Field #	H-47					H-48					H-49
Data	Parameter 3 monitored for catalytic oxidizer & balancer/abator (if any)					Parameter 4 monitored for catalytic oxidizer & balancer/abator (if any)					Monitoring records for catalytic oxidizer & combo water balancer/catalytic oxidizer from the last calendar year
Instruction	Name of Parameter 3	Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
Response											See instructions in "Documents" worksheet

Table 4. Thermal Oxidizer

Field #	G-1	H-50	H-51	H-52	H-53		H-54		H-55
Data	APCD ID	Design and operation specifications	Average operating temperature	Operating temperature records for thermal oxidizer from the last calendar year	Annual natural gas usage to maintain the operating temperature		Annual cost of natural gas used to maintain the operating temperature		Process/APCD monitoring plan for thermal oxidizer
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the thermal oxidizer	Enter the average operating temperature of thermal oxidizer **(Fahrenheit)**	Provide the operating temperature records for thermal oxidizer from the last calendar year	Enter the amount in this column	Specify the unit in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of the process/APCD monitoring plan for the thermal oxidizer. Specify if measurements of the gas stream are part of these plans
Response				See instructions in "Documents" worksheet					

Field #	H-56					H-57				
Data	Parameter 1 monitored for thermal oxidizer					Parameter 2 monitored for thermal oxidizer (if any)				
Instruction	Name of Parameter 1	Set value of Parameter 1	Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2
Response										

Field #	H-58					H-59					H-60
Data	Parameter 3 monitored for thermal oxidizer (if any)					Parameter 4 monitored for thermal oxidizer (if any)					Monitoring records for thermal oxidizer from the last calendar year
Instruction	Name of Parameter 3	Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
Response											See instructions in "Documents" worksheet

Table 5. Other APCDs

Field #	G-1	H-61	H-62
Data	APCD ID	Design and operation specifications	Process/APCD monitoring plan for APCD
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the APCD	Provide a brief description of the process/APCD monitoring plan for the APCD. Specify if measurements of the gas stream or sorbent material are part of these plans
Response			

Field #	H-63					H-64				
Data	Parameter 1 monitored for APCD					Parameter 2 monitored for APCD (if any)				
Instruction	Name of Parameter 1	Set value of Parameter 1	Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2
Response										

Field #	H-65					H-66					H-67
Data	Parameter 3 monitored for APCD (if any)					Parameter 4 monitored for APCD (if any)					Monitoring records for APCD from the last calendar year
Instruction	Name of Parameter 3	Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
Response											See instructions in "Documents" worksheet

Ethylene Oxide (EtO) Commercial Sterilization
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			OMB Control No. 2060-0733 Approval Expires 09/30/2024	

I. EtO Monitoring

Table 1. Personal Monitoring (Badges) for EtO

No (default)	*← Switch to "Yes" in Cell F10 on the left if Supplement 3 is used in lieu of this table*

List all personal monitoring events during the last 5 years

***** Note: If you need to enter more than 30 rows of data, please select "Yes" in Cell F10 above, leave this table below BLANK, then fill out SUPPLEMENT 3 to the Section 114 ICR. Refer to the Instructions Document for more details *****

Field #	I-1	I-2	I-2.1	I-3	I-3.1	I-3.2		I-4			I-5	I-6	I-7			I-8		
Data	Unique ID	Date	Room area(s) involved and time spent on this personal (badge) monitoring event	Description of work conditions	Sampling method of personal (badge) monitoring	Level of detection (LOD) required by the sampling method		Monitoring result			Monitoring result flag	Averaging periods	Instrument 1			Instrument 2 (if any)		
Instruction	Enter from test report or documentation, if available. Otherwise, use a unique identifier for each personal monitoring event	Enter date of the personal monitoring event **(mm/dd/yyyy)**	Specify ID(s) of the room area(s) involved in this personal (badge) monitoring event, and provide an estimate of the percentage of time spent in each room area in parentheses "()". If there are multiple room areas involved, separate your entries by commas (,). Example: "Room Area 1 (40%), Room Area 2 (25%), Room Area 3 (35%)". Ensure that any room area ID entered in this field is consistent with your entries in "Room Area" worksheet, Table 1, Field B-1	Provide a brief description of the work conditions of facility during each personal monitoring event	Specify the sampling method used for the personal (badge) monitoring	Enter the value of Detection Level in this column	Enter the units of Detection Level in this column	Enter the average concentration monitored **(ppm)**	Enter the maximum concentration monitored **(ppm)**	Enter the minimum concentration monitored **(ppm)**	Specify any action level, error, or flag of monitoring result	Specify any averaging periods for each personal monitoring event	Specify the instrument used during each personal monitoring event	Enter the value of detection level of instrument	Specify the unit of detection level of instrument	Specify the instrument used during each personal monitoring event	Enter the value of detection level of instrument	Specify the unit of detection level of instrument
Response																		

Table 2. Room Area Monitoring for EtO

Field #	B-1	I-9	I-9.1	I-9.2		I-10			I-11	I-12	I-13			I-14			I-15
Data	Room area ID for all rooms and areas where EtO is used or emitted	Description of room area monitoring	Sampling method of room area monitoring	Level of detection (LOD) as required by the sampling method		EtO concentration of room area where EtO is used or emitted			How many measurement points are there within the room area?	What is the frequency of monitoring at each point within the room area?	Instrument 1			Instrument 2 (if any)			Action levels and SOPs for room area monitoring
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the monitoring procedure for each room	Specify the sampling method used for the room area monitoring	Enter the value of LOD in this column	Enter the unit of LOD in this column	Enter the average EtO concentration **(ppmv)**	Enter the maximum EtO concentration **(ppmv)**	Enter the minimum EtO concentration **(ppmv)**	Enter the amount of measurement points within the room area	Specify the frequency of monitoring at each point within the room area	Specify the instrument used to monitor the room area	Enter the value of detection level of instrument	Specify the unit of detection level of instrument	Specify the instrument used to monitor the room area	Enter the value of detection level of instrument	Specify the unit of detection level of instrument	Provide documents specifying action levels and SOPs for room area monitoring
Response	102	LEL monitors	continous monitoring and alarms			0.00	10.00	0.00	1	continous	Senidyne						See instructions in "Documents" worksheet
	103	LEL monitors	continous monitoring and alarms				10.00	0.00	1	continous	Senidyne						
	105	LEL monitors	continous monitoring and alarms				10.00	0.00	1	continous	Senidyne						
	107	LEL monitors	continous monitoring and alarms				10.00	0.00	1	continous	Senidyne						

Table 3. Other Monitoring for EtO

Field #	**Data**	**Response**
I-16	Describe any other types of EtO monitoring that have been conducted by the facility, such as near-source, ambient air sampling, or fenceline monitoring efforts	
I-17	Describe any dispersion modeling efforts conducted by the facility	
I-18	Provide the records for any type of monitoring or modeling efforts noted in I-16 and I-17	See instructions in "Documents" worksheet

Ethylene Oxide (EtO) Commercial Sterilization
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After creating the ***non-CBI version*** *, select and copy the Sample CBI Cell (Cell O2) and paste directly into each cell with real CBI data.* ***Make sure all cells that contained CBI look the same as the Sample CBI Cell (Cell O2)*** *before saving the non-CBI version of your response*

	CBI
	Sample CBI Cell (above)

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J. Wastewater

Field #	J-1	J-2		J-3	J-4	J-5	J-6		J-7	J-8	J-9	J-10	J-11		J-12
Data	Daily average wastewater flow rate for EtO commercial sterilization activities at the facility	Annual EtO emissions from wastewater at facility for the last 5 years		Average EtO concentration in wastewater when it leaves the vacuum pump or liquid-gas separator	Average EtO concentration in wastewater when collected in a holding tank or basin	Wastewater disposal or treatment for EtO commercial sterilization activities	Annual average cost of wastewater disposal or treatment for EtO commercial sterilization activities		Are there any other processes within the facility that generate EtO-laden wastewater?	Other processes generating EtO-laden wastewater within the facility	Daily average wastewater flow rate for each process other than EtO commercial sterilization	Wastewater disposal or treatment for each process other than EtO commercial sterilization	Annual cost of wastewater disposal or treatment for each process other than EtO commercial sterilization		Annual average wastewater flow for all operations at the facility (includes both EtO commercial sterilization and other activities)
Instruction	**(gallons/day)**	Specify the calendar year. Select from the dropdown menu in this column	Enter the value of annual EtO emissions in this column **(pounds)**	**(ppmv)**	**(ppmv)**	Briefly specify how wastewater is disposed of or treated for EtO commercial sterilization activities	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	List all other processes generating EtO-laden wastewater within the facility. Enter one process per each row	**(gallons/day)**	For each process, briefly specify how wastewater is disposed of or treated	Enter the dollar amount in this column	Specify the dollar year in this column	**(gallons/year)**
Response	25.00					All vacuum pump water is pumped to storage tank and is hauled away with the EG liquor for reprocessing into grease			No (skip to J-12)						9125.00

K. Unique Cycles and EtO Reduction

Enter data for each individual category, respectively.
If the facility does not plan to re-validate cycles in an effort to reduce EtO use, responses are not required for Fields K-2 through K-4 and K-7 through K-13

Field #	K-1	K-2	K-3	K-4		K-5	K-6	K-7	K-8	K-9	K-10	K-11	K-12	K-13	
Data	How many unique cycles are run at this facility?	How many unique cycles have been re-validated thus far?	How many unique cycles does the facility still have left to re-validate	How long will it take to complete re-validation of these cycles?		Cost of validating unique cycles	What is the current average EtO dose among the products?	What is the target average EtO dose?	What is the anticipated average percent change in number of nitrogen washes upon completion of the re-validations?	What is the anticipated average percent change in number of air washes upon completion of the re-validations?	What is the anticipated average percent change in time spent on gas washing upon completion of the re-validations?	What is the anticipated average percent change in dwell period time upon completion of the re-validations?	What is the anticipated average percent change in aeration time upon completion of the re-validations?	What are the anticipated annual cost savings from reduced EtO use?	
Instruction	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the value in this column	Specify the unit in this column	Provide information on the cost to validate a sterilization cycle, including: (1) hours of time for R&D engineers, operators, technicians, etc. to complete the sterilization cycle runs, compile the reports and file with the FDA; (2) costs for laboratory analyses; and (3) information on the length of time from start to finish **(weeks)** required to complete validation for a sterilization cycle	**(mg/L)**	**(mg/L)**	**(%)**	**(%)**	**(%)**	**(%)**	**(%)**	**(%)**	Enter the dollar amount in this column	Specify the dollar year in this column
Response for all products in total	5	5	3	2.00	months		600.00	600.00	0.00%	0.00%	0.00%	0.00%	0.00%	$0.00	
Response for 510(k) products (Class I and Class II devices)	5	5	3	3.00	months		600.00	600.00	0.00%	0.00%	0.00%	0.00%	0.00%	$0.00	
Response for Pre-Market Approval (PMA) products (Class III devices)	2	2	1	3.00	months		600.00	600.00	0.00%	0.00%	0.00%	0.00%	0.00%	$0.00	

L. Other Questions regarding EtO Commercial Sterilization

Table 1. EtO and Facility Operation

Field #	Data	Instruction	Response
L-1	How is EtO handled during malfunction events of process equipment (vented, held within chamber/room, etc)?		held until safely evacuted
L-2	How is EtO handled during malfunction events of APCD (vented, held within chamber/room, etc)? Also provide standard operation practices or protocol in the event of a power outages		Held until power is restored
L-3	Provide documentation of any studies done on quantifying EtO residuals in your products		See instructions in "Documents" worksheet
L-4	Are there generators on site to keep facility running in the event of a power outage?	Select from the dropdown menu	No
L-5	Provide percent emission reduction, associated costs, and description of QA/QC for voluntary measures		none
L-6	Is the facility operating at full capacity or can current capacity increase to accommodate higher volumes of product? If not operating at full capacity, provide estimate of feasible increase in capacity as a percentage (%) of current output		45 percent
L-7	Provide any process and instrumentation diagrams (P&ID) that are not included in other documents requested		See instructions in "Documents" worksheet

Table 2. Standalone Non-Colocated Warehouse, Distribution Center, or Enclosed Building for Sterilized Products

Field #	L-8		L-9	L-10					L-11
Data	Offsite locations sterilized products are sent		Are any of the products sterilized in your facility shipped to a separate standalone non-colocated warehouse, distribution center, or enclosed building that is not currently subject to §63.360 and where sterilized product is stored for a time period longer than 24 hours prior to re-shipment?	Information on the standalone non-colocated warehouse, distribution center, or enclosed building that is not currently subject to §63.360 and where sterilized product is stored for a time period longer than 24 hours prior to re-shipment					How long are the products sterilized in your facility generally held in the separate standalone non-colocated warehouse, distribution center, or enclosed building listed in Field L-10 on the left?
Instruction	When the products sterilized in your facility are moved offsite, where are they sent to (e.g., standalone non-colocated warehouse, manufacturer, hospital, etc.)?	Enter the percent by weight of the sterilized products sent to each type of offsite location (w-)	Select from the dropdown menu in Cell F49 below	Name of the standalone non-colocated warehouse, distribution center, or enclosed building	Street address verified by U.S. Postal Service (USPS). Do not include P.O. box in this field	City	State. Select from the dropdown menu in this column	Zip code verified by U.S. Postal Service (USPS)	**(Days)**
Response	back to the manufacturer	100.00%	No (skip to L-12)						

Table 3. Alternative Sterilization

Field #	L-12	L-13								
Data	Alternative sterilization method	Details of alternative sterilization method								
Instruction	Specify the alternative sterilization method(s) that can be applied to each product class, if any. Select from the dropdown menu. If you select "Other (double click and type here)", be sure to enter your response between the parentheses. Example: "Other (your alternative)"	Percentage of this product that may be sterilized with the alternative method **(%)**	Time needed to switch from EtO to the alternative **(months)**	Capital cost to switch from EtO to the alternative. Enter the dollar amount in this column	Capital cost to switch from EtO to the alternative. Specify the dollar year in this column	Annual cost to switch from EtO to the alternative. Enter the dollar amount in this column	Annual cost to switch from EtO to the alternative. Specify the dollar year in this column	Change in annual cost with respect to using EtO. If alternative costs are less than EtO, please enter a negative value. Enter the dollar amount in this column	Change in annual cost with respect to using EtO. Specify the dollar year in this column
Response for 510(k) products (Class I and Class II devices)	unknown	0.00%	12.00						
Response for Pre-Market Approval (PMA) products (Class III devices)	unknown								

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

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Does any information entered on this worksheet contain confidential business information (CBI)? Specify in ***Cell N2*** *on the right →* ***Be sure to shade in red all cells with real CBI data in the CBI version*** *After creating the* ***non-CBI version*** *, select and copy the Sample CBI Cell (Cell O2) and paste directly into each cell with real CBI data.* ***Make sure all cells that contained CBI look the same as the Sample CBI Cell (Cell O2)*** *before saving the non-CBI version of your response*		**CBI**
		Sample CBI Cell (above)

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M. Additional Information

If you need extra space to provide additional information requested throughout this questionnaire, fill out this table below unless you may use any of the supplements to the Section 114 ICR. For each entry, specify the worksheet and field number to which your data refers

Worksheet	Field #	Response
certification		I reviewed information PCS entered into this document but did not verify the accuracy of the information but I assumed it was accurate. There are many areas that need more input from PCS that I have not reviewed such as vacuum pump data, APCD data and documents.

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

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Does any information entered on this worksheet contain confidential business information (CBI)? Specify in ***Cell N2*** *on the right →* ***Be sure to shade in red all cells with CBI files in the CBI version***
After creating the non-CBI version, remove all the CBI documents and preserve only the non-CBI documents. ***Do not change the total number of CBI vs. non-CBI documents entered in Column G and Column H***

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N. Documents

The documents requested throughout this questionnaire and the associated field numbers and descriptions are summarized in this table below.**Please refer to Sections V of the Instructions Document and properly name your documents first before proceeding.**

Specify in Column G and Column H of the table below the total number of CBI and non-CBI documents of each category that you intend to submit to the EPA.**Do not change these quantities between the CBI and non-CBI version of your response.**

Option 1 (recommended for submitting more than 12 documents in any category): Submit your documents as standalone PDF files via email (non-CBI documents only) or a media (e.g., thumb drive, CD or DVD) following Section VI of the Instructions Document;
Option 2: Add your documents to the table below as attachments. Please attach only 1 document to each cell (maximum of 12 documents in each category). If your documents attached here contain CBI,**shade in red all cells containing CBI documents, and select "Yes" in Cell N2 of this worksheet.**
Instructions on how to attach documents are provided in Cell O10 on the right.

If you choose Option 2, make sure that the CBI version of your response contains all the CBI and non-CBI documents, while the non-CBI version contains only the non-CBI documents you would like to submit to the EPA.

Steps to attach documents to the table below

(1) Click on the field to attach files;
(2) Go to the Insert tab → Text, click Object;
(3) In the Object dialog box, click the Create from File tab;
(4) Click Browse, and select the file you want to insert;
(5) Select the Display as Icon check box, then click OK.

Repeat the above steps to attach any additional files

Field #	Data	Instruction	Total Quantity of CBI Documents	Total Quantity of non-CBI Documents	Documents											
A-21	Facility diagrams	Provide diagrams of your facility indicating all rooms, primary EtO emission points (e.g., regulated emission points), and secondary EtO emission points (e.g., fugitive emission points)														
A-22	Process flow diagrams	Provide process flow diagrams of the EtO processes at your facility														
A-23	Most recent air permit(s)	Provide the most recent air permit(s) approved for your facility														
A-24	Application documents for the most recent air permit(s)	Provide the application documents for the most recent air permit(s) approved for your facility														
A-25	Startup, shutdown and malfunction (SSM) plan	Provide the startup, shutdown and malfunction (SSM) plan approved for your facility														
A-42	Documentation for annual emissions calculations	Provide calculations and supporting documentation for all emission factors used to determine the annual emissions														
G-17	Performance test performed in the last 5 years (if any)	Provide a copy of each performance test performed in the last 5 years in its entirety for each APCD														
G-28	Engineering emission test performed in the last 5 years (if any)	Provide a copy of each engineering emission test performed in the last 5 years in its entirety for each APCD														
H-11	Monitoring records for wet scrubber from the last calendar year	Provide all monitoring records from the last calendar year														
H-29	Monitoring records for dry-bed scrubber from the last calendar year	Provide all monitoring records from the last calendar year														
H-49	Monitoring records for catalytic oxidizer & combo water balancer/catalytic oxidizer from the last calendar year	Provide all monitoring records from the last calendar year														
H-52	Operating temperature records for thermal oxidizer from the last calendar year	Provide the operating temperature records for thermal oxidizer from the last calendar year														
H-60	Monitoring records for thermal oxidizer from the last calendar year	Provide all monitoring records from the last calendar year														
H-67	Monitoring records for APCD from the last calendar year	Provide all monitoring records from the last calendar year														
I-15	Action levels and SOPs for room area monitoring	Provide documents specifying action levels and SOPs for room area monitoring														
I-18	Provide the records for any type of monitoring efforts you have mentioned in Fields I-16 and I-17															
L-3	Provide documentation of any studies done on quantifying EtO residuals in your products															
L-7	Provide any process and instrumentation diagrams (P&ID) that are not included in other documents requested															

Ethylene Oxide (EtO) Commercial Sterilization
CAA Section 114 Information Collection Request (ICR)

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Click here to go to "Introduction"

Acknowledgment of CBI Handling

Before certifying and submitting this questionnaire, please make sure that you have ***selected "Yes" in Cell N2 on all the worksheets where CBI data were entered, and shaded in red all cells with real CBI data*** in the CBI version of your response.

Refer to Section V in the Instructions Document when creating the non-CBI version of your response. Confirm that ***all cells that contained CBI before look the same as the Sample CBI Cell (Cell O2), and any attached CBI document is deleted from the "Documents" worksheet*** before saving the non-CBI version.

Please submit both the CBI and non-CBI version of your response to the EPA. The non-CBI version will be made available to the public.

☐ By checking this box, I acknowledge that I have read, understand, and agree to the instructions and procedure of handling CBI data and documents submitted within this response.

☐ (Check this box only if this is the non-CBI version of your response) By checking this box, I confirm that all CBI data and documents have been removed from this response.

Certification by Reporter

Complete the fields below for the person who completes the questionnaire and who is available for follow-up questions, if any, on the information provided in this questionnaire

Name	Howard Humphreys
Title	
Organization	EnviroMechancis
Email	enmech@aol.com
Phone	(508) 868-4256
Fax	
General comments	

☑ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

Certification by Facility Personnel

Please complete the fields below for the facility personnel who certifies the information provided in this questionnaire (may be the owner or legal operator of the facility)

Name	Gary Cranston
Title	
Organization	PCS, Inc.
Email	gcranston@pcsinc.org
Phone	508-822-5524
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

Certification by Professional Engineer

Complete the fields below for the professional engineer (PE) who certifies the information provided in this questionnaire

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

Certification by Certified Industrial Hygienist

Complete the fields below for the certified industrial hygienist (CIH) who certifies the information provided in this questionnaire

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

Anguil Environmental Systems, Inc.
Peak Shaver Budget Proposal

Date: October 17, 2022
Proposal #: BUDGET

Prepared for:

Howard Humphries
Phone: (508) 868-4256
Email: enmech@aol.com

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The Anguil Advantage

- Business stabliity and unparalleled expertise with over 40 years in business.
- Single source provider of fully integrated air and water pollution control systems for lowest cost of ownership.
- Over half of Anguil staff are degreed engineers.
- Regulatory compliance is guaranteed.
- Broad range of technology solutions ensure an unbiased equipment selection.
- Comprehensive Quality Assurance program and procedures.
- An established safety program with continuous training for Anguil field service engineers.
- Custom solutions developed specific to your application that maximize efficiency and minimize system life operation costs.

40 Years in Clean Air and Water

AIR TECHNOLOGIES

Air pollution control systems for VOC, HAP, and odor abatement—capable of 99+% destruction efficiency.

- Regenerative thermal oxidizers (RTO)
- Catalytic, recuperative, and direct-fired thermal oxidizers and vapor combustors
- Emission concentrator systems

Over 1,900 oxidizers installed on six continents in a wide variety of applications!

ENERGY RECOVERY

Heat and energy recovery systems for improved efficiency and reduced operating costs.

- Air-to-air heat exchangers
- Air-to-liquid heat exchangers
- Heat-to-power
- Energy evaluations

WASTEWATER TREATMENT

Wastewater treatment technologies for industrial and remediation applications.

- Fully integrated and turnkey systems
- Single source provider
- Engineering assistance, rentals, and pilot programs available
- Technology agnostic approach
- Advanced instrumentation, controls, and automation

AFTERMARKET & SERVICE

Service and maintenance on any make or model, regardless of original manufacturer.

- 24/7 emergency service response
- Operating cost reviews
- System upgrades and retrofits
- Spare parts and component packages
- Preventive Maintenance Evaluations

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Executive Summary

1. Equipment Description

PCS has requested a budgetary proposal for a Peak Shaver to control the EO concentrations from their ethylene oxide sterilization operation. The sterilizer emissions will be sent to a new Peak Shaver, and then subsequently sent to the existing Anguil Catalytic Recuperative Oxidizer (Catox) where the ethylene oxide will be oxidized and destroyed. The Catox will also control emissions from the aeration rooms and sterilizer backvents.

2. Facility to be Controlled

PCS facility located in Taunton, MA

3. Processes Controlled

Ethylene Oxide sterilizer vessel chambers, backvents, and an aeration rooms

4. Proposed Equipment

Peak Shaver

6. Anguil Benefits

* Seamless integration with the current process
* Fully automated PLC based controls
* Ethernet communications for remote diagnostics
* Field Tested and proven technology
* Full equipment warranty
* Factory test prior to shipment
* 24-hour service support

7. Results

* Anguil guarantees the EO will be delivered from the chambers into water solution, then stripped from the water and pulled from the Peak Shaver in a more uniform overall concentration to the existing Anguil Catalytic Oxidizer.

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Customer Process Specifications

- Process Producing Emissions: Ethylene Oxide Gas Sterilization
- Design Basis: Up to Six chambers, 175 lbs EO/cycle, three cycles per day

Sterilizing chamber exhaust is directed to Peak Shaver. The shaver exhaust, aeration cell flow, and backvent flows are sent to the oxidizer. Chamber Backvents and Aeration room flows are expected to have low EO concentration, and are intermittent. Sterilizers can be vented up to three times per 24 hours. Backvents are interlocked to prevent opening when chamber is loaded with EO.

- Chamber Backvents: 3,000 SCFM (intermittent)
  Aeration Flow: 4,000 SCFM (portion is used to strip the EO from PS
- Ethylene Oxide Loading to Shaver: Up to 175 lbs/cycle, over 30 minutes, every 8 hrs
- Ethylene Oxide Loading to Oxidizer: 4.24 lbs/min from PS to Catox
  Estimated 4-5 ppmv in aeration room flows
- PS Control Panel Location: Mounted indoors within 50' of oxidizer in a temperature controlled environment (85ºF)
- Available Power: 460 V / 60 Hz / 3 Ph

Desired Results

- Process emission compliance with the local regulatory agency by achieving an EO transfer to Catox at more uniform concentrations. Assumed Catox EO destruction efficiency of **99%** or an outlet of 1 ppmv
- Keep the overall cost of the project to a minimum
- Minimize yearly operational cost of the system
- Create no adverse effects on the operation of the current process

Equipment Recommendation

- One (1) New Peak Shaver and One (1) Existing Anguil Model 100 Catalytic Recuperative Oxidizer built in 1994

Equipment Benefits

- Fully automated PLC based control system
- Remote diagnostic capabilities
- Peak Shaver exhaust fan
- Peak Shaver Mixer in the sump
- Variable Frequency Drive (VFD) to control peak shaver fan
- Full equipment warranty

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Peak Shaver Design Specifications

Size and Weight

- Exhaust / Stripping Flow: 2,500 SCFM
- Tank Approximate Diameter / Height: 12’ diameter / 10’ height
- Buffer Tank Volume: 8,000 Gallon
- Scrubber Tower Height / Diameter: 25’ tall / 3’ diameter
- Approximate Weight: ~75,000 lbs (filled)
- Preliminary Foundation Size: 15’ x 15’

NOTE: Alternate system arrangements can be provided to allow the system to fit completely within the intended building. These arrangements would require multiple scrubber towers mounted on the Sump Tank, and additional pumps to allow the system operation. Anguil welcomes discussion on the topic.

Utilities Required

- Electrical Power: 460V / 60 Hz / 3 Ph
- Soft Water: 0-60 mg/L @ 70ºF

Operation Information

- EO Concentration in PS Outlet: <50% LEL (<15,000 ppmv)
- Peak Shaver Exhaust Fan HP: Induced, 5 HP
- **Design EtO Loading to PS: 4.24 lbs/min for 30 min every 8 hours**

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Ethylene Oxide Peak Shaver

SYSTEM DISCUSSION

The proposed peak shaver system has been sized for the peak EO emissions of 175 lbs/cycle. 2,500 SCFM of aeration room air is routed to the Peak Shaver that is used as the stripping air to remove the EO transferred from the chamber vacuum pumps into the Peak Shaver sump water. The buffer tank and recirculation water rate has been sized to scrub the vented EO from the chambers. When the EO is transferred into the water, the stripping air and water recirculation will strip the EO from the water and delivered into the Peak Shaver exhaust fan. The Peak Shaver will allow a reduced EO loading to the oxidizer by spreading out the EtO emissions from the sterilizers over eight hours prior to the start of the next cycle. This prevents high LEL conditions from reaching the oxidizer.

Aeration Room air shall be routed through the peak shaver to provide stripping air.

The proposed system consists of a vertical packed tower scrubber, buffer tank, exhaust fan. Interconnecting ductwork between shaver and oxidizer has not been included at this time, to be addressed during installation. Ductwork to the peak shaver from the sterilizers and aeration rooms is not included. All ladders and platforms shall be provided by others, from drawings supplied by Anguil.

VERTICAL PACKED TOWER SCRUBBER

The proposed scrubber / stripper will be a vertical packed column with a packing height approximately **16'.** A recirculation pump with manual isolation valves will be provided with the recirculation piping. The scrubber will have a bed of packing and an entrainment separator section consisting of a composite mesh pad. The pressure drop across the scrubber/stripper unit is approximately 4.5" wc.

- All FRP equipment shall be fabricated Product Standard PS-1569.
- Standard Anguil gray topcoat with UV inhibitor
- The design pressure shall be –25" W.C. vacuum to +25" W.C. pressure
- Design temperature 180ºF
- Operates with water recirculated from the sump tanks at approximately 225 GPM and 10 psig spray nozzle pressure
- Composite mesh pad mist eliminator
- PP or FRP spray header with polypropylene spray nozzles for liquid distribution
- High efficiency polypropylene packing
- Packing access door
- Open bottom / body flange for connection to the buffer tank
- Recycle piping to be CPVC

Material of construction for the scrubber will be FRP, Quacorr or Hetron 800 furan resin reinforced with approximately 25% glass. The spray nozzle and packing will be constructed of polypropylene.

RECIRCULATION BUFFER TANK

To accommodate the amount EO loading one (1) recirculation buffer tank is provided.

The recirculation buffer tank will be of sufficient volume to absorb the amount EO from the sterilizers at the rate provided above. The water in the tank will be stripped of EO over the 8 hours before the next sterilizer chamber cycle begins. The tank shall have a flanged manway, a mounting flange for the tower, and shall be designed to support the tower. Material of construction for the sump tank shall be Furan FRP.

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PEAK SHAVER EXHAUST FAN

The proposed fan will be a centrifugal type, having an impeller rated at 2,500 SCFM and 10" W.C. All parts in contact with the airstream are constructed of FRP. The fan will be statically and dynamically balanced at operating speed prior to shipment. The fan is mounted approximately 20' above grade on a platform provided by others.

INTERCONNECTING DUCTWORK – Peak Shaver to Peak Shaver Fan

The proposed ductwork will connect the peak shaver gas outlet to the peak shaver fan inlet. The ductwork is based on the fan being mounted 20' above grade (platform and ladder provided by others) and not more than 5' laterally from the scrubber. The ductwork will be shipped loose for field installation by others. Material of construction for the proposed ductwork will be vinyl ester resin reinforced with approximately 25% glass. The ductwork does not include flex connectors.

INTERCONNECTING DUCTWORK – Peak Shaver Fan to Catalytic Oxidizer

The ductwork that will connect the peak shaver fan outlet to the oxidizer is **not included in the equipment scope and will need to be provided as part of installation.**

RECIRCULATION PUMP AND PIPING

A recirculation pump is provided on a skid to provide recirculation of the water / EO solution. CPVC recycle piping from the pump to the scrubber and from the sump to the pump is included, with the necessary strainers and valving.

- Ansimag sealless horizontal mag drive pump
- PTFE-lined ductile iron casing, shaft, and radial bushing
- 460V / 60Hz / 3Ph TEFC (Totally Enclosed Fan Cooled) motor
- Sized to provide the necessary water flowrate and pressure for the peak shaver tower
- *An option for a redundant pump with the necessary valving and strainer is provided*

NOTE: **The system is currently proposed assuming 70ºF peak shaver recirculating water. Anguil recommends utilizing a water cooler to maintain this temperature during summer, by others. Anguil shall assist in sizing of the cooler during detailed design, or can provide this water recirculation cooler.**

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SYSTEM CONTROLS

The system controls are located in a NEMA 12 control panel enclosure. In the event of a system shutdown, the touch screen will indicate the cause of the shutdown via a digital message in English.

- NEMA 12 control panel enclosure to be mounted in a temperature-controlled environment (85°F)
- Allen Bradley Logix family PLC (Programmable Logic Controller) controls
- Allen Bradley 10" Color" Touchscreen HMI
- Communications to existing Catalytic Oxidizer to allow both pieces of equipment to operate as a system
- Ethernet communications for remote diagnostics and service support

START-UP AND TRAINING SERVICES

- Service technicians will be provided to start-up Peak Shaver and integrate operation with existing Catalytic Oxidizer
- Provided at a daily rate as described later in proposal
- Operator training will be conducted during start-up

OPERATION & MAINTENANCE MANUALS

- Anguil to provide a link to the Operation and Maintenance manual, available for electronic download. Paper hard copies available by request only.
- USB flash drive of all vendor bulletins

FINAL ASSEMBLY AND SHOP TEST

- Temporary assembly of peak shaver
- Instrumentation and piping assembly
- Run electrical conduit
- Customer is invited to witness shop testing

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Additional Equipment Included

LEL MONITOR

- Control Instruments PrevEx LEL Monitor for ethylene oxide
- Includes calibration kit with regulator and span gas cylinder
- Includes hydrogen fuel delivery system
- Includes compressed air filter
- Includes remote HMI
- Includes start-up by Controls Instruments field service engineer
- **Ships loose for installation by others**

NOTE: In order to implement the LEL monitor(s) Anguil would like to discuss the intended control / operating methodology to ensure proper placement and operation of the device(s), as well as the necessary oxidizer isolation in case of high LEL detection. Anguil recommends this item be discussed during the equipment HAZOP.

REDUNDANT RECIRCULATION PUMP

Anguil can provide a second pump sized for 100% duty in parallel with the primary pump to provide redundancy in case of one pump failure.

- Addition of a second Ansimag pump with motor
- Includes necessary instrumentation, piping, valving, and strainers
- Includes manual shut off valve at inlet and outlet

OXIDIZER INLET LINE PURGE SYSTEM

A purge fan with flame arrestor can be provided at the oxidizer inlet to allow purging of the inlet duct to the oxidizer in case of high LEL detection. If a high LEL condition is detected, the oxidizer isolation damper will close and the purge line isolation damper would open. The purge fan would start and move the process to atmosphere.

This system requires two (2) of the optional LEL detectors described above – one (1) is used for alarm and one (1) is used as the interlock device that shall isolate the oxidizer and open the purge line isolation valve.

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Exceptions and Clarifications to the Specifications

All items, components, and equipment proposed within this document are Anguil standard unless indicated otherwise. Any customer specifications that may alter the included device selections are not included at this time.

Items Not Included

- Concrete pad / platform
- Dumpster
- Isolation dampers for peak shaver / oxidizer
- Mounting and wiring of dampers, ship loose instrumentation, wiring to process equipment
- Interconnecting wiring between control panel and Anguil supplied motors
- All natural gas piping to the oxidizer fuel train
- Winterization of sensing lines, if required
- Power source to the control panel
- Ductwork/dampers from process to peak shaver inlet
- Filtration for aeration room flow
- Ductwork from the peak shaver exhaust fan to the oxidizer inlet
- Soft water supply
- Platform / ladders (Anguil shall supply drawings, material supply by others)
- Personnel protection, security fencing and lighting
- Moving of equipment obstructions, fencing, landscaping, etc.
- Multiple installation / startup trips if delays beyond Anguil's control
- All roof and building penetrations, if applicable
- All required sound abatement equipment, if applicable
- HAZOP / PHA Participation (charged at daily rate plus T&L)
- Compliance testing
- Internet connection
- Taxes, permits
- Overtime, holiday or weekend work
- Installation Supervision (Can be quoted as an option)
- Mechanical and electrical installation (Can be quoted as an option)
- UL Inspection & Label for Main Control Panel
- Budget Freight (Can be quoted as an option)

*Note: All weights, dimensions, horsepower ratings, burner sizing, and specific engineering details within the proposal are approximate and will be confirmed by Anguil Environmental following order placement.

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Budget Pricing and Delivery

One (1) Peak Shaver as described previously

PEAK SHAVER EQUIPMENT PRICE	**$ 585,000**
INSTALLATION PRICE	**Not Quoted at this Time**
STARTUP AND TRAINING	$1,600/day plus travel and living
HAZOP PARTICIPATION	$1,600/day plus travel and living
PACKAGING AND FREIGHT	**Billed at Cost**

FCA (Origin), per Incoterms 2010, price listed reflects product only

ADDITIONAL EQUIPMENT ITEMIZED PRICING

LEL MONITOR	**$ 40,000**
RECIRCULATION PUMP REDUNDANCY Including instrumentation, piping, valving, and strainer	**$ 25,000**
PURGING SYSTEM	**$ 30,000**

TERMS

- **40% down payment due upon order placement**
- **30% due 8 weeks after receipt of purchase order, net 30**
- **20% due prior to shipment or notification of readiness to ship**
- **10% due upon start-up, not to exceed 60 days from shipment, net 30**

28-34 Weeks after approval of drawings (General Arrangement and Process and Instrumentation Diagram), based on current shop workloads.

ALL PRICES HAVE BEEN QUOTED IN US DOLLARS. ALL PRICES WILL REMAIN FIRM FOR 14 DAYS. THEREAFTER, A RE-QUOTE MAY BE REQUIRED

The Contract Price and Contract Time have been calculated based on the prices and availability of the component materials as indicated by Anguil's suppliers as of the date of this Agreement. However, the market for the materials necessary to complete the Work are considered to be highly volatile, and sudden price increases and changes in material availability are likely to occur. Anguil agrees to use commercially reasonable efforts to obtain the prices quoted herein within the time frames indicated in the project schedule, but should there be an increase in the prices of these materials after execution of this Agreement, or should any materials subsequently become unavailable or the delivery of such materials be delayed, the parties shall enter into a Change Order to increase the Contract Price and extend the Contract Time accordingly. For the avoidance of doubt, Anguil shall not be liable for cost increases or delay costs (including, without limitation, any liquidated or consequential damages associated with delay) which result from changes in the cost or availability of materials.

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FIELD SERVICE RATES

Field Service Engineer and Installation Supervision *Weekdays, 8 hours/day; minimum of 4 hours

Straight Time *	$1,600/day
International Labor Rate *	$1,725/day
Emergency Service Rate *	$2,000/day
(Site visit within 48 hours of call)	
Overtime (More than 8 hours/day and Saturdays)	$ 250/hour
Sundays and Holidays	$ 275/hour
Travel Time	$ 125/hour
Trip Preparation	$ 125/visit
Report Writing	$ 125/visit
Technical Phone Support (Minimum of 4 hours)	$ 125/hour
Remote Safety Training and Drug Screening (Anguil Office)	$ 100/hour

Engineering *Weekdays, 8 hours/day; minimum of 4 hours

Project Engineer *	$1,800/day
Project Manager *	$1,800/day
Electrical Engineer / Programming*	$1,800/day

Travel and Living Expenses

Airline ticket, Hotel, Car rental, Car service and Expenses	Cost + 15% Administrative fee
Meal allowance - Domestic	$ 55/day
Meal allowance - International	$ 75/day
Airport parking	$ 35/day
Mileage	$ 0.85/mile

Terms

Net 30 days
Terms subject to change upon credit review

Holiday Schedule

New Year's Day
Good Friday
Memorial Day
Independence Day
Labor Day
Thanksgiving (11/24/22 to 11/25/22)
Christmas (12/24/22 to 12/25/22)
New Year's Eve

- When an Anguil Employee is scheduled to work on-site but not granted access, due to no fault of Anguil, customer will be billed at the daily rate for 8 hours in addition to expenses.
- Pre-negotiated days off will not be billed for service labor unless reports/training are being compiled.
- If receipts or time sheets are required, a 10% handling charge will be applied to the total invoice for report generation.

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Professional Summary

Name: Gary N. Cranston

Expertise: Project Management, Sterilization/Validations/Calibrations

Education: B.S., Microbiology
M.S., Civil Engineering

Professional Affiliations:
American Society for Quality Control
American Society of Microbiologists
Association for the Advancement of Medical Instrumentation (AAMI)
Chairperson for TIR14 Contract Eto Sterilization
EOSA, Past President, Treasurer and Secretary
National Fire Prevention Association
US Delegate to ISO/TC 98 working committee on Eto Sterilization (11135)
US Delegate to CEN TC 102 WG 6 committee on Gas Sterilizers

Work Experience:

- have forty two years of experience working in the manufacturing, all areas of sterilization, validations and laboratory area.

- Been directly involved with five pilot plants and three manufacturing plant start-ups for the medical device industry. These were considered "state of the art" plants.

-Additional work experience has been in establishing procedural specifications and standard operating procedures.

- Initiated and developed QA and QC programs including written procedures (SOP & Specifications), auditing, document control and document tracking.

-Worked with FDA, DHSS, and ISO from inspections to product registration.

- Developed, established and implemented product manufacturing programs.

Specific Experience:

-President/Owner of Consulting and Technical Services, Inc. (CATS)
-President/Owner of Professional Contract Sterilization, Inc. (PCS)
-Haemonetics Corporation
-Skyland Scientific Services, Inc.
-Baxter-Travenol Laboratories

Calibration and Validation Specific Experiences

In 1975 while employed with Baxter-Travenol Laboratories (BT), a device manufacturing plant, I was instrumental in developing, implementing, and performing the calibrations and validations of four – 100 percent Ethylene Oxide (ETO) sterilizers and two environmental preconditioner chambers (EPC). Once initial validations were complete then I implemented the cycle optimization program. Promoted to Corporate Sterilization, I was also responsible for additional cycle optimization, cycle standardization and basic sterilization research and development for all domestic plants.

Being aware of the umbrella GMP's coming into affect, I joined a small team to form Skyland Scientific Services. At Skyland I was responsible for facility installation start-up to product market operation for a penicillium batch plant, a plant installation start-up to validations completion for a LVP solution plant and a total calibration and validation package for a LVP and SVP plant. In addition, I was involved with numerous calibrations and/or validation and/or facility audits and documentation programs (written and/or computer systems) . One additional benefit of Skyland was that I was the middleman between the FDA and Clients and thus received valuable first hand regulatory training.

At Haemonetics Corporation in 1983, I was given the task of establishing calibration and validation programs for the EPC, ETO, steam sterilizers, aeration chamber, gamma sterilization, and the laboratories (biological and toxicology) programs. While at Haemonetics I was also involved in an off-site plant start-up operation for manufacturing and contract sterilization. My involvement included facility engineering reviews and designs as well as establishing company policies and programs.

Also in 1983 Consulting And Technical Services, Inc. (CATS) was formed. The corporation has been actively involved in sterilizer calibrations and validations, facility installation reviews, HVAC operation inspections and performance testing, standards writing committees and seminars to the FDA and industry.

In 1989-1990 Professional Contract Sterilization, Inc. (PCS) was started. PCS offers clients a 100% Eto contract sterilization facility in New England and World Wide. PCS has a full quality operation in a "State-of-the-Art" facility. Currently PCS is ISO13485:2003 and EN ISO 11135-1:2007 certified with a full compliment laboratory testing.

CATS/PCS worked in China in 1995 aiding in the setup of an ETO sterilization operation on a United Nations funded project. During this time CATS was involved in full validations including Calibration, Installation Qualification (IQ), Operational Qualification and Process Qualification (PQ).

CATS/PCS finished a startup 100% Eto Facility in 2005 with involvement from site review, facility review, through IQ, OQ and product PQ. This included FDA, EPA, emission testing, and safety inspection final approvals

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION I

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

AFFIDAVIT OF GARY CRANSTON

I, Gary Cranston, attest to the following facts:

1. I am President of Professional Contract Sterilization Inc. ("PCS") founded in 1990 based in Taunton, MA. PCS operates a commercial sterilization facility that uses ethylene oxide ("EtO") in sterilization and fumigation operations. I have been in the sterilization business approximately 45 years. I have worked for Baxter Corporation,, Skyland Inc. and Hemonetics Corporation. At Baxter I was responsible for 54 ETO sterilizer at 14 facilities, for both engineering and microbiological aspects s. At Skyland I was in charge of in-house and numerous client of Skyland. At Hemonetics I was responsible for the ETO sterilization and all laboratory applications. In all of these years, I have never had an incident with EPA or FDA or DEP or OSHA.

2. PCS is a small business with only 1-3 part and 4-6 full time employees.

3. During the years 2020 through 2022, PCS, like many similar companies and industries, was confronted with substantial losses of employees, resources and income due to conditions associated with the COVID-19 Pandemic. PII PCS established strict restrictions on visitors at their facility.

4. In September 2021, Professional Contract Sterilization Inc. (PCS) was requested by the United States Environmental Protection Agency (EPA) to respond to Information Collection Requests (ICRs) as part of adopting new regulatory guidelines for ETO to apply to the ETO industry standards. See Exhibit I.

5. EPA set a deadline of 11/19/21 for companies to respond to the ICRs. The collection of the ICRs was explained to the industry as an effort by EPA to take into consideration public comments on new EtO regulation rather than a mandatory requirement of all companies in the industry and more geared towards larger industry companies.

6. From the time PCS received the ICRs, PCS began to invest what time and resources they could to respond to them in a timely manner. PCS was told by EPA and consultant that to fully answer the ICRs questionnaire it could take as long as 45 man-days to complete.

7. PCS estimates that, ultimately, it took its staff and consultants 120 hours to respond to the ICRs.

8. PCS recognized that in light of its prior business obligations and constraints caused by COVID-19 Pandemic it did not have the time and/or resources to respond to the ICRs before November 19, 2021 and timely requested an Extension of time to complete.

9. On behalf of PCS, OccuHealth, Inc., requested in writing a 60 day Extension of the 11/19/21 submittal deadline on 11/18/21 to Charlene Spells, of EPA. See Exhibit 2; see also Exhibit 3 (email chain). The letter and email cover were sent by email and overnight mail service.

10. Ms. Spells responded to the formal extension request by stating: "As we have responded to other requests, EPA is not granting any extensions of the November 19, 2021, deadline for response to the information collection request." See Exhibit 3-email dated 11/19/21.

11. The same day, Michael Burns of OccuHealth, Inc., sent an email reply and left two voice mail messages seeking clarification of these messages and to discuss our request for an extension to determine if EPA would issue any penalties to PCS if it failed to provide answers to the ICRs by the 11/19/21 deadline. See Exhibit 3–email dated 11/19/21).

12. Later that same day, 11/19/21, Michael Burns of OccuHealth, Inc., sent an email to Ms. Spells and Mr. Fruh in which he stated, "Thank you Steve & Charlene for your time on the phone today.... 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." See Exhibit 3 Email from M. Burns to Ms. Spells dated 11/19/21.

13. PCS continued to work on responding to the ICRs in good faith, despite missing the 11/19/21 deadline, but struggled to do so given the limited resources and personnel that PCS had as a result of the COVID-19 Pandemic.

14. Mr. Burns kept in contact with PCS and EPA and communicated to EPA that PCS was having difficulties with the detailed and laborious ICRs but was still working on the providing the information.

15. During this time, Mr. Burns was also in contact with Jeremy (Jerry) Guo, an outside consultant, from RTI International, hired by EPA to review the ICRs. Mr. Guo assured Mr. Burns that despite not meeting the 11/19/21 deadline, EPA was still interested in the information, that PCS should do its best to respond fully to the ICR questionnaire and that EPA would not be issuing penalties for failure to respond timely to the 11/19/21 deadline. See Exhibit 3.

16. In a January 18, 2022 email Mr. Guo, stated to Mr. Burns: "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." See Exhibit 3- Email from Jeremy Guo to Mike Burns dated 1/18/22.

17. This email gave Mr. Burns and PCS the impression that the submission of the ICR information was more voluntary rather than mandatory – which reinforced PCS's and Mr. Burn's understanding that PCS would not be penalized for missing the 11/19/21 deadline.

18. Later the same day on 1/19/22, Mr. Burns received another email from Mr. Guo which stated:

> "Hi Mike, 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. Please do not hesitate to let us know if you have any questions, comments or concerns. Thank you and best regards, Jerry." See Exhibit 3.

19. This email gave Mr. Burns and PCS the impression that EPA was seeking voluntary compliance, and the information that PCS could provide to EPA for the rulemaking update to the ETO would be helpful, but not essential and not necessary to be fully complete and that no penalties were threatened nor likely from PCS not providing the ICR responses as of the 11/19/21 deadline.

20. On 2/8/22 Mr. Burns sent a follow up email to Mr. Guo wherein he stated:

> "Jerry, Thank-you for your call & emails from January 18 & 19, 2022. On behalf of Professional Contract Sterilization, Inc. (PCS), we appreciate your patience and consideration regarding the ICR. As described in previous communications, PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic. Despite these impacts and their limited resources, PCS has made some progress in preparing the ICR response. However, due to some confidential business information that has yet to redacted, it is not in a state where it can be released, even as a partial version. These efforts are ongoing." (See Exhibit 3 Email from Mike Burns to Jerry Guo dated 2/8/22).

21. On 3/23/2022 and again later on 4/7/2022 EPA conducted an inspection of the PCS facility.

22. As part of these inspections, EPA requested several documents and records be supplied by email as soon as possible including stack testing going back to 1990. These requests for records dated back more than 40 years.

23. Also, EPA hand delivered a report dated 4/7/22 focused on specific aspects of 40 CFR Subpart O specifically warning PCS as to PCS's compliance with ETO Emissions Standards for sterilization facilities, and mentioning potential monetary penalties, alleging lack of qualified stack testing in past, and acknowledging that ETO sterilizations firms are being similarly targeted by EPA.

24. Also on April 7, 2022, EPA submitted a request to PCS to submit a Test Plan/Protocol before May 7, 2022. PCS retained LCH Consulting Associates ("LCH") to prepare a Test Protocol Plan based on LCH's prior testing and knowledge of PCS's system to be presented in draft form on or before May 7, 2022. If necessary, PCS expected that LCH would request an Extension of Time from EPA to prepare the first draft Protocol.

25. Preparing for and attending these additional inspections, as well as working on gathering the additional requested information, required PCS to pull resources from responding to the ICRs.

26. On May 26, 2022, EPA issued a Notice of Violation to PCS for its failure to respond to the ICR for which it assessed a fine for $60,391.

27. On July 5, 2022, PCS submitted its responses to the ICR to EPA.

28. Unfortunately, LCH did not submit, as PCS understood they would, a request for an Extension of Time for the submittal of a Test Plan/Protocol was made prior to May 7, 2022 deadline.

29. On May 26, 2022, EPA issued a Notice of Violation to PCS for its failure to respond to the request for Test Plan/Protocol for which it assessed a fine for $40,260.

30. On June 7, 2022, PCS submitted a draft Test Plan/Protocol to EPA.

30. PCS has no prior history of non-compliance or enforcement action under the Clean Air Act.

29. PII

30. PCS does not have the financial ability to pay the proposed penalty as well as pay for an estimated $ 565,000 to install advance Peak Shaver Technological emission control improvements at its facility.

31. PII PII

I swear under pains and penalties of perjury that the above-stated facts are true and accurate to the best of my personal knowledge.

Gary Cranston, President

Gary Cranston 1/6/2022

EXHIBIT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

September 13, 2021

Mr. Gary Cranston
President
Professional Contract Sterilization, Inc.
40 Myles Standish Boulevard
Taunton, MA 2780

Dear Mr. Cranston,

Pursuant to section 114 of the Clean Air Act (CAA), 42 U.S.C. §7414(a), the U.S. Environmental Protection Agency (EPA) is collecting information related to hazardous air pollutant emissions at ethylene oxide (EtO) commercial sterilization facilities to inform its review of the National Emission Standards for Hazardous Air Pollutants (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 information collection request (ICR) to the remaining EtO commercial sterilization companies that were not covered under previous information gathering efforts.[1] 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.

Specifically, we are collecting information regarding EtO commercial sterilization operations at the facilities listed below and wholly owned by Professional Contract Sterilization, Inc., as well as any EtO commercial sterilization facilities wholly owned by Professional Contract Sterilization, Inc. that are not included on this list:

Facility	Street Address	City	State
Professional Contract Sterilization	40 Myles Standish Boulevard	Taunton	MA

The current section 114 ICR consists of a main questionnaire and three (3) supplements in the form of Microsoft® Excel workbooks. The supplements only need to be used if additional space is needed. The Instructions Document, in the form of a Microsoft® Word file, includes

[1] On December 9, 2019, the EPA issued a section 114 questionnaire to 9 companies in the EtO commercial sterilization source category. While these data identified potential process controls and operational practices that may reduce the amount of EtO released, only a portion of the facilities in the source category was represented.

procedures for providing and submitting data and documents requested in this ICR. **You must complete and return the main questionnaire, along with any supplements, by November 19, 2021, following the procedures specified in the Instructions Document.** Please download the workbooks and Instructions Document at: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities. If there is a facility on this list not wholly owned by Professional Contract Sterilization, Inc., please indicate that in the response letter. A completed survey is not required for that facility.

This ICR is designed to collect information on facility operations and emissions from sources at EtO sterilization operations including sterilization chamber vents, aeration room vents, chamber exhaust vents, and fugitive emissions. Please note that emission data provided under section 114 of the CAA is not entitled to confidential treatment under 40 C.F.R. Part 2.[2] If there is any facility operations information, other than emission data, that you would like to claim as confidential business information (CBI), please follow the Instructions Document to ensure appropriate handling and submission of your response.

You are required to return all requested information to the EPA on or before the schedule due date specified in this letter. More information about this ICR is provided in the following enclosures:

Enclosure #	Description
Enclosure 1	EPA's Information Gathering Authority Under Section 114 of the Clean Air Act
Enclosure 2	Disclosure of Emissions Data Claimed as Confidential Under Sections 110 and 114(c) of the Clean Air Act
Enclosure 3	Summary of Procedures for Safeguarding Clean Air Act Confidential Business Information
Enclosure 4	Designation of Authorized Representative for Standards of Performance for New Stationary Sources (Section 111), National Emission Standards for Hazardous Air Pollutants (Section 112), Solid Waste Combustion (Section 129), and Federal Ozone Measures (Section 183)

This section 114 ICR is one step in an established public process for collecting foundational information as part of the NESHAP reviews. The public and stakeholders will continue to have an opportunity to comment on the EtO commercial sterilization NESHAP review in the future, including a formal notice-and-comment period on any proposed action.

CAA section 114(a) authorizes the Administrator of EPA to require the submission of information, including information from an owner or operator of an emission source for the purpose of developing or assisting in the development of NESHAP under CAA section 112. This authority has been delegated to the Director of the Sector Policies and Programs Division in the U.S. EPA Office of Air and Radiation, Office of Air Quality Planning and Standards.

Thank you for your assistance in this effort. Your response will provide comprehensive information about the EtO commercial sterilization source category, which will lead to a more

[2] For additional information on emission data, please see 40 C.F.R. §2.301 and Enclosure 2.

effective rulemaking. If you have questions regarding this ICR, please contact Charlene Spells in the EPA's Fuels and Incineration Group at 919-541-5255 or Spells.Charlene@epa.gov.

Sincerely,

Penny Lassiter
Director
Sector Policies and Programs Division

4 Enclosures

cc: Deborah Szaro, Acting Regional Administrator, U.S. EPA Region 1
Lynne Hamjian, U.S. EPA Region 1
Glenn Keith, Massachusetts Department of Environmental Protection

EXHIBIT 2

OHI
Occupational Health & Safety •Environmental Consultants

OccuHealth, Inc.
44 Wood Avenue
Mansfield, MA 02048

Tel. (800) 729-1035
(508) 339-9119
Fax (508) 339-2893
m_burns@occuhealth.com

November 18, 2021

Ms. Charlene Spells
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 2771

Re: Professional Contract Sterilization, Inc.
40 Myles Standish Blvd., Taunton, MA (PCS)
Information Collection Request (ICR), dated September 13, 2021

Dear Ms. Spells:

On behalf of Professional Contract Sterilization , Inc, Taunton, MA (PCS), please accept this formal request for a 60-day extension of the November 19, 2021 submittal deadline listed in the above-referenced ICR.

PCS is a small business, with fewer than ten employees. They are currently dealing with a manpower shortage and end-of-the-year production demands. They do not have the resources to dedicate the necessary personnel to extract, gather, review, prepare and compile the extensive documentation listed in the ICR. Their staff is approximately 50% of pre-COVID levels.

Furthermore, in response to the ongoing COVID-19 pandemic, PCS is currently restricting access to visitors; thus precluding the use of outside consultants and/or administrative support to assist with the ICR.

Thank you for your consideration in this matter. We respectfully request a confirmation of receipt of this response.

OCCUHEALTH, INC

Michael J. Burns, P.E.
Senior Project Manager

cc: Gary Cranston, Professional Contact Services Inc.
Robert A. Fasanella, Esq., Rubin and Rudman LLP

Mike Burns

From: Mike Burns
Sent: Tuesday, November 23, 2021 1:35 PM
To: Sue Hamilton
Subject: RE: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Thanks Sue
That address was directly of the EPA web page…..specifically stating to direct all written replies there

---

From: Sue Hamilton <shamilton@occuhealth.com>
Sent: Tuesday, November 23, 2021 12:23 PM
To: Mike Burns <mburns@occuhealth.com>
Subject: Fwd: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Get Outlook for iOS

From: UPS <pkginfo@ups.com>
Sent: Tuesday, November 23, 2021 10:33 AM
To: Results
Subject: UPS Delivery Notification, Tracking Number 1ZA667E80198960042

Hello, your package has been delivered.
Delivery Date: Tuesday, 11/23/2021
Delivery Time: 10:30 AM

Experience UPS My Choice® Premium Today
Be in total control of how, when and where your packages are delivered.
Upgrade to Premium Now

Set Delivery Instructions

Manage Preferences

View My Packages

OCCU HEALTH, INC.

Tracking Number:	1ZA667E80198960042
Ship To:	US EPA OFFICE-AIR QUALITY PLANNING 4930 OLD PAGE RD DURHAM, NC 27703 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	0.0 LBS
Reference Number:	PCS ICR EXT. LTR

 Download the UPS mobile app

EXHIBIT 3

From: Mike Burns <mburns@occuhealth.com>
Sent: Tuesday, February 8, 2022 1:56 PM
To: Guo, Jeremy J (Jerry) <jjg@rti.org>
Cc: gcranston@pcsinc.org; Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen <ksschaffner@rti.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: [EXTERNAL] RE: Information Collection Request (ICR) for Professional Contract Sterilization, Inc, Taunton, MA

Jerry,

Thank-you for your call & emails from January 18 & 19, 2022.

On behalf of Professional Contract Sterilization, Inc. (PCS), we appreciate your patience and consideration regarding the ICR.
As described in previous communications, PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic.
Despite these impacts and their limited resources, PCS has made some progress in preparing the ICR response.
However, due to some confidential business information that has yet to redacted, it is not in a state where it can be released, even as a partial version.

This efforts are ongoing.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Guo, Jeremy J (Jerry) <jjg@rti.org>
Sent: Wednesday, January 19, 2022 8:10 PM
To: Mike Burns <mburns@occuhealth.com>
Cc: gcranston@pcsinc.org; Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen

<ksschaffner@rti.org>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization, Inc, Taunton, MA

Hi Mike,

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. Please do not hesitate to let us know if you have any questions, comments or concerns.

Thank you and best regards,

Jerry

From: Guo, Jeremy J (Jerry)
Sent: Tuesday, January 18, 2022 13:06
To: mburns@occuhealth.com
Cc: Witt, Jon <Witt.Jon@epa.gov>; Spells, Charlene <Spells.Charlene@epa.gov>; Schaffner, Karen <ksschaffner@rti.org>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Hi Mike,

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.

Thank you and best regards,

Jerry

Jeremy J (Jerry) Guo

Air Quality Engineering
RTI International
Phone: (919) 541-8836
Email: jjg@rti.org

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Tuesday, January 18, 2022 8:26
To: Guo, Jeremy J (Jerry) <jjg@rti.org>
Cc: Schaffner, Karen <ksschaffner@rti.org>; Witt, Jon <Witt.Jon@epa.gov>
Subject: FW: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

As requested.

Charlene E. Spells
U.S. EPA

OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Friday, November 19, 2021 4:47 PM
To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Thank you Steve & Charlene 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.

PCS will continue to work on the ICR and will provide a response in a timely fashion with periodic updates over the next few weeks.

Thank your

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Friday, November 19, 2021 1:03 PM
To: Mike Burns <mburns@occuhealth.com>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Mr. Burns,

My apologies for the confusion. The recall was an error on my part. The information in the email is correct.

Charlene E. Spells
U.S. EPA
OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Friday, November 19, 2021 12:30 PM
To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Ms. Spells
We are in receipt of your email (below) stating that "EPA is not granting any extensions of the November 19, 2021 deadline".
We are also in receipt of the attached email, RECALLING said email.

I left (2) voice mail messages this morning seeking clarification of these messages and to discuss our request.

Please advise a good time to speak on this matter today.
I can be reached at 508-339-9119x214.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com

From: Spells, Charlene <Spells.Charlene@epa.gov>
Sent: Friday, November 19, 2021 7:20 AM
To: Mike Burns <mburns@occuhealth.com>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>; Fruh, Steve <Fruh.Steve@epa.gov>; Hunt, Virginia <Hunt.Virginia@epa.gov>
Subject: RE: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Mr. Burns,

Thank you for your November 18, 2021, letter requesting an extension to complete the section 114 survey related to hazardous air pollutants at ethylene oxide (EtO) commercial sterilization facilities. As we have responded to other requests, EPA is not granting any extensions of the November 19, 2021, deadline for response to the information collection request.

If you have specific questions about completing the section 114 survey, please do not hesitate to contact me.

Regards,
Charlene E. Spells
U.S. EPA
OAQPS/SPPD
RTP, NC 27711
Phone: (919) 541-5255 Fax: (919) 541-0516
spells.charlene@epa.gov

From: Mike Burns <mburns@occuhealth.com>
Sent: Thursday, November 18, 2021 3:40 PM

To: Spells, Charlene <Spells.Charlene@epa.gov>
Cc: Gary Cranston <gcranston@pcsinc.org>; Robert A. Fasanella <RFasanella@rubinrudman.com>
Subject: Information Collection Request (ICR) for Professional Contract Sterilization , Inc, Taunton, MA

Ms. Spells

On behalf of Professional Contract Sterilization , Inc, 40 Myles Standish Blvd., Taunton, MA (PCS);
Please accept the attached formal request for a 60-day extension of the November 19, 2021 submittal deadline listed in the above-referenced ICR.

PCS is a small business and their resources have been significantly impacted by the COVID-19 pandemic.
Please refer to the attached letter for further details.

Thank you for your consideration in this matter.
We respectfully request your confirmation and acknowledgement of this request.

A hard copy will be sent via overnight service.

Michael Burns, P.E., TURP
OCCUHEALTH, INC.
44 WOOD AVENUE
MANSFIELD, MA 02048
508-339-9119 X214
mburns@occuhealth.com