

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance
in the Sterilization Industry

OCTOBER 28-30



ATLANTA, GEORGIA

PICARRO

FALL 2024

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PICARRO

Best Practices in Data Management and Reporting

Ethylene Oxide

October 30, 2024

Introduction

Best Practices in Data Management and Reporting

Federal, state, and local regulatory bodies mandate reporting requirements when there is an emission limit defined in a specific regulation.

- Oftentimes, these requirements tend to be standard across many regulations. They tend to only differ in the following areas:
- Regulatory reports are legally binding and reporting false data can cause you and your company a lot of problems:
 - Notice of violation (NOV)
 - Consent Decree (CD)
 - Prison

Introduction Cont.

Best Practices in Data Management and Reporting

A well-designed system should generate reports with all the required data in the format specified in the applicable regulation for submission.

- Even with a system capable of doing this, proactive quality assurance plays a major role in report submission.
- This presentation will cover the best practices for emissions reporting.

Multi-Component Data Report (1-hour average)

Location:

Report Period: From 9/20/2024 8:00:00 AM to 9/20/2024 8:00:00 PM

| Component | EtO (ppb) | EtO Mass Rate (lb/hr) | Normalized Stack Flow (scfm) |
|-------------------|-----------|-----------------------|------------------------------|
| Sep 20, 8:00 AM | 0.61 | 0.000026 | 5999.8 |
| Sep 20, 9:00 AM | 0.27 | 0.000011 | 5995.4 |
| Sep 20, 10:00 AM | 0.26 | 0.000011 | 5986.8 |
| Sep 20, 11:00 AM | 0.29 | 0.000012 | 5974.4 |
| Sep 20, 12:00 PM | 0.28 | 0.000012 | 5976.9 |
| Sep 20, 1:00 PM | 0.31 | 0.000013 | 5974.3 |
| Sep 20, 2:00 PM | 0.31 | 0.000013 | 5973.8 |
| Sep 20, 3:00 PM | 0.29 | 0.000012 | 5978.0 |
| Sep 20, 4:00 PM | 0.37 | 0.000016 | 5965.9 |
| Sep 20, 5:00 PM | 0.55 | 0.000023 | 5991.0 |
| Sep 20, 6:00 PM | 0.34 | 0.000014 | 5992.8 |
| Sep 20, 7:00 PM | 0.39 | 0.000016 | 6003.5 |
| Minimum | 0.26 | 0.000011 | 5965.9 |
| Maximum | 0.61 | 0.000026 | 6003.5 |
| Average | 0.36 | 0.000015 | 5984.4 |
| Total | | 0.000179 | |
| Valid Records | 12 | 12 | 12 |
| Operating Time | 12:00:00 | 12:00:00 | 12:00:00 |
| Data Availability | 100.00 % | 100.00 % | 100.00 % |

Report created: Thursday, October 17, 2024 9:45:25 AM

Agenda

Best Practices in Data Management and Reporting

| | | |
|---|----------------------------|---|
| 1 | Reporting Requirements | An overview of the reporting requirements currently applicable to facilities using ethylene oxide. |
| 2 | EHS Best Practices | Best practices for environmental staff and management to ensure reporting is done accurately and effectively. |
| 3 | Maintenance Best Practices | Best practices for maintenance staff and/or contractors to ensure environmental staff has everything they need to complete their reports. |
| 4 | Report Generation & Review | Best practices for generating reports, making edits where needed, and reviewing prior to submission. |
| 5 | Submission | A review on how to submit reports to federal, state, and local regulatory bodies. |

Reporting Requirements

40 CFR 63, Subpart O Reporting Requirements

40 CFR 63.366 specifies the reporting requirements for commercial sterilizers that are required to be submitted to the Administrator's address or electronically.

- All reporting will eventually be submitted within the Central Data Exchange (CDX) via the Compliance and Emissions Data Reporting Interface (CEDRI).
- Provides specifications on the following:
 - Initial Compliance Reports
 - Quarterly Compliance Report
 - Construction/Reconstruction Applications
 - Notifications
 - Performance Test Submissions
 - Performance Evaluation Submissions
 - Extensions due to CDX/CEDRI Outages or Force Majeure

Reporting Requirements

Facility Compliance Reports

If an ETO CEMS is used to demonstrate continuous compliance, the following is required to be reported:

- The information required in Section 11 of Appendix A of 40 CFR 63, Subpart O
- Affected sources included in each inlet being monitored with EtO
- The IDs of each inlet(s) and outlet(s) of each control system
- The daily sum of EtO for each inlet, along with 30-operating day rolling sums
- The daily sum of EtO emissions for each outlet, along with 30-operating day rolling sums
- Daily mass emission limit that the control system must achieve or the 30-operating day mass emission limit
- The mass of EtO emitted from control system over previous 30-operating days

Reporting Requirements

Facility Quarterly Compliance Reports

Facilities must report the following information on a quarterly basis:

- Information specified in 63.366(b)1(i) through (vi)
 - Exception that EtO use, in tons, only needs to be reported for previous 12 months
- If the facility demonstrates compliance through periodic performance testing, report ID of any control system that has not operated since the end of the period covered by previous performance test.
- Report ID of any sterilization chamber that has not operated since end of the period covered by previous compliance report or any information that changed.
- Report ID for any room where there has not been potential for EtO emissions if your rooms are subject to emission standards
- Report all required CEMS information
- Provide certification from RO that approach is being followed to limit sterilization chamber concentration limit to 1 ppmv prior to opening if you are complying with that rule
- If you use less than 4 tpy and have Group 2 emissions at an area source, you must report ID for any room where Group 2 air emissions have ceased
- Report the number of deviations to meet an applicable standard:
 - Date, Time, Cause, and Duration of each

Reporting Requirements Cont.

CEMS Quarterly Compliance Reports

Quarterly CEMS reports require the following information to be submitted electronically through CEDRI and submitted by the 30th day following the end of the quarter:

- Date of report generation
- Facility identification information
- Hourly CEMS data
 - Date and hour
 - Pollutant concentration (ppbv)
 - Stack gas volumetric flow rate (scfm)
 - ETO Mass emission rate (lb/hr)
 - Special code signaling whether data is quality assured or not
 - Monitoring availability
- Results of all daily calibrations and flow interference checks

Calibration Drift Check Results:

| Check Time | Reference Value (ppb) | Actual Value (ppb) | Calibrated Range (ppb) | Calibration Drift (ppb) | Calibration Drift (% full scale) | Drift Specification (% full scale) | Excessive Calibration Drift Check |
|-----------------------|-----------------------|--------------------|------------------------|-------------------------|----------------------------------|------------------------------------|-----------------------------------|
| SPAN | | | | | | | |
| 10/15/2024 8:12:56 AM | 25.00 | 24.62 | 0 - 25 | -0.38 | -1.54 | 5.00 | pass |
| 10/16/2024 8:12:56 AM | 25.00 | 25.00 | 0 - 25 | 0.00 | 0.02 | 5.00 | pass |
| 10/17/2024 8:12:56 AM | 25.00 | 24.71 | 0 - 25 | -0.29 | -1.16 | 5.00 | pass |
| 10/18/2024 8:12:58 AM | 25.00 | 24.65 | 0 - 25 | -0.35 | -1.39 | 5.00 | pass |
| 10/19/2024 8:12:58 AM | 25.00 | 25.05 | 0 - 25 | 0.05 | 0.19 | 5.00 | pass |
| 10/20/2024 8:12:58 AM | 25.00 | 24.86 | 0 - 25 | -0.14 | -0.58 | 5.00 | pass |
| 10/21/2024 8:12:56 AM | 25.00 | 24.76 | 0 - 25 | -0.24 | -0.95 | 5.00 | pass |
| 10/21/2024 4:03:18 PM | 25.00 | 25.32 | 0 - 25 | 0.32 | 1.27 | 5.00 | pass |
| 10/22/2024 8:13:16 AM | 25.00 | 25.35 | 0 - 25 | 0.35 | 1.41 | 5.00 | pass |
| ZERO | | | | | | | |
| 10/15/2024 8:10:10 AM | 0.00 | -0.13 | 0 - 25 | -0.13 | -0.52 | 5.00 | pass |
| 10/16/2024 8:10:08 AM | 0.00 | 0.03 | 0 - 25 | 0.03 | 0.11 | 5.00 | pass |
| 10/17/2024 8:10:12 AM | 0.00 | -0.33 | 0 - 25 | -0.33 | -1.30 | 5.00 | pass |
| 10/18/2024 8:10:10 AM | 0.00 | 0.01 | 0 - 25 | 0.01 | 0.05 | 5.00 | pass |
| 10/19/2024 8:10:08 AM | 0.00 | 0.12 | 0 - 25 | 0.12 | 0.48 | 5.00 | pass |
| 10/20/2024 8:10:12 AM | 0.00 | -0.22 | 0 - 25 | -0.22 | -0.87 | 5.00 | pass |
| 10/21/2024 8:10:10 AM | 0.00 | -0.28 | 0 - 25 | -0.28 | -1.11 | 5.00 | pass |
| 10/21/2024 4:00:30 PM | 0.00 | -0.14 | 0 - 25 | -0.14 | -0.56 | 5.00 | pass |
| 10/22/2024 8:10:10 AM | 0.00 | -0.27 | 0 - 25 | -0.27 | -1.07 | 5.00 | pass |

Reporting Requirements Cont.

Performance Testing Reports

Performance tests and/or RATA tests require notification to the Administrator and approval of the test plan and results shall be submitted electronically within 60 days of completion.

- Include the date and time of testing
- Facility identification information
- Measurement location ID
- Results of performance test
- All relevant QA documentation
- Test company information



EHS Best Practices

Overview



Be Involved

Open communications and regular touchpoints with maintenance/contractors.

- 1 Set up an alert schedule for OOC periods or maintenance
- 2 Provide trainings on the importance of your system(s)
- 3 Provide reference documents and logbooks for use
- 4 Reach out to stack testers the quarter before it is due.



Regular Reviews

Set up regular intervals for process/data reviews.

- 1 Ensure CD results and alarms are reviewed daily
- 2 Review process/instrument operation(s) weekly
- 3 Review downtime and plan accordingly
- 4 Hold regular calls with maintenance staff



Be Proactive

Proactive action makes reporting more effective and accurate.

- 1 Take regular notes in DAS or logbook for flagged data
- 2 Set reminders to complete requirements before deadline
- 3 Schedule maintenance/QA to avoid unexpected issues
- 4 Always maintain a minimum stock of critical parts



Ask for Help

Regulations and CEMS can be difficult. Do not be ashamed to ask experts for help!

- 1 Maintain communications with vendor and/or consultants
- 2 US EPA is responsive and willing to help when needed
- 3 Clarify QA needed following major maintenance events
- 4 Encourage cross trainings with maintenance team to better your program

EHS Best Practices

Common Issues

Reporting includes more than just generating emissions data – it involves an expertise in the regulations and triggering events.

- There are common issues seen throughout multiple industries:
 - Interpretation of downtime (quadrant rule, grace periods, etc.)
 - Maintenance triggered QA testing requirements
- Oftentimes, maintenance staff is not as aware of these requirements or how crucial CEMS uptime is
- It is recommended to conduct regularly trainings
- Providing printouts near instrument has proven to be very beneficial

Maintenance Best Practices

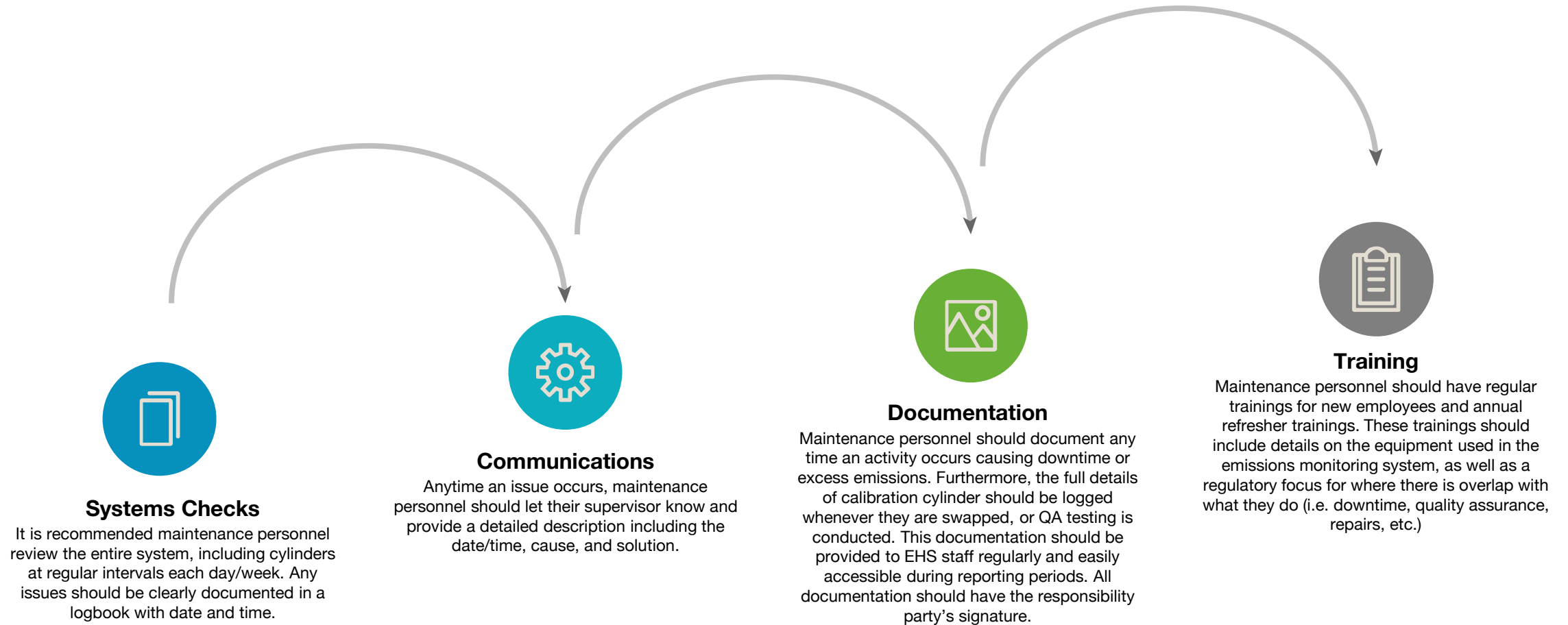
Overview

A key factor in emissions monitoring is having qualified personnel to conduct maintenance to maintain its functionality. Maintenance and/or process events being recorded properly are critical to reporting.

- Emissions monitoring systems are designed to last decades with proper preventative maintenance being conducted
- Facilities should maintain an activity matrix of preventative maintenance based off manufacturer specifications and previous experience
- It is recommended to conduct regular trainings for maintenance teams to understand the importance of these systems running correctly and what the consequences could be if they do not

Maintenance Best Practices

Highlights



Maintenance Best Practices

Daily Review

Maintenance should review the CEMS each day following calibration drift test completion to check for any alarms that may impact reporting, or, for EtO CEMS, if an above span calibration check was required and completed.



Report Generation and Review

Introduction

The first step in report generation and review is organization and proactive note taking.

- Report generation requires a blend of emission monitoring data, process operating conditions, and maintenance notes to be completed optimally.
- As soon as the reporting window opens, compile the following:
 - Process upsets, outages, and/or other conditions
 - Emissions monitoring system maintenance logs
 - Emissions monitoring quality assurance testing logs
 - Monitoring data in units of emission standard for reporting interval



Report Generation and Review

Report Generation – First Steps

The recommended first step for reporting emissions data is to ensure your downtime (or OOC periods) are flagged properly and following the requirements of the appropriate regulation.

- For CEMS, a facility must not have more than 10% downtime per quarter to meet the federal requirements
 - This may be different for state/local regulations
- It is recommended to generate all calibration logs and emissions data and compare periods that have been flagged due to calibration failures.
 - If calibration failed, ensure the system has flagged the appropriate amount of downtime for that period

Validation Sequence: All

Calibration Drift Check Results:

| Check Time | Reference Value (ppb) | Actual Value (ppb) | Calibrated Range (ppb) | Calibration Drift (ppb) | Calibration Drift (% full scale) | Drift Specification (% full scale) | Excessive Calibration Drift Check |
|----------------------|-----------------------|--------------------|------------------------|-------------------------|----------------------------------|------------------------------------|-----------------------------------|
| SPAN | | | | | | | |
| 9/17/2024 8:22:58 AM | 25.00 | 1.23 | 0 - 25 | -23.77 | -95.07 | 5.00 | fail |
| 9/18/2024 8:22:58 AM | 25.00 | 26.60 | 0 - 25 | 1.60 | 6.39 | 5.00 | pass |
| 9/19/2024 8:22:56 AM | 25.00 | 25.04 | 0 - 25 | 0.04 | 0.15 | 5.00 | pass |
| 9/20/2024 8:22:56 AM | 25.00 | 24.93 | 0 - 25 | -0.07 | -0.30 | 5.00 | pass |
| 9/21/2024 8:22:56 AM | 25.00 | 25.21 | 0 - 25 | 0.21 | 0.85 | 5.00 | pass |
| ZERO | | | | | | | |
| 9/17/2024 8:20:08 AM | 0.00 | 0.10 | 0 - 25 | 0.10 | 0.41 | 5.00 | pass |
| 9/18/2024 8:20:08 AM | 0.00 | 0.48 | 0 - 25 | 0.48 | 1.93 | 5.00 | pass |
| 9/19/2024 8:20:08 AM | 0.00 | -0.10 | 0 - 25 | -0.10 | -0.39 | 5.00 | pass |
| 9/20/2024 8:20:08 AM | 0.00 | -0.16 | 0 - 25 | -0.16 | -0.62 | 5.00 | pass |
| 9/21/2024 8:20:10 AM | 0.00 | -0.12 | 0 - 25 | -0.12 | -0.48 | 5.00 | pass |

Report Generation and Review

Report Generation – First Steps Cont.

From there, all excess emissions should be generated and verified against your process operating conditions or maintenance that could have caused the exceedance.

- For any excess emissions, you should know:
 - Date/Time
 - Duration
 - Magnitude
 - Cause/Solution
- Excess emissions resulting in two consecutive hours of data 200% of your span or more require an above span calibration check (QA Procedure 7)
 - Calibration must run within **24 hours**
 - A failed, or not completed above span calibration will result in having to normalize the data

EXCEEDANCE CALIBRATION

| | |
|------------------------|--|
| Automatic SYS1 Enable: | <input checked="" type="checkbox"/> ON |
| Automatic SYS2 Enable: | <input checked="" type="checkbox"/> ON |
| Unused Enable: | <input type="checkbox"/> OFF |
| Exc. Request Limit: | 5000.0 ppb |
| Exc. Setpoint: | 4823.0 ppb |

Report Generation and Review

CMS Summary Report

If excess emissions are less than 1% of operating time and downtime is less than 5% of operating time, you only need to submit a summary report.

- Company name and ID #
- Dates of reporting period
- Description of units and emission limits
- Monitoring equipment make and model #
- Total operating time
- Emission data summary
- CMS performance summary
- Changes to CMS, process, or controls
- Name and signature
- Date

Report Generation and Review

Quality Assurance Test Results

It is also important to cleanly package up all Quality Assurance testing results (i.e., cylinder gas audit, dynamic spike, RATA, etc.)

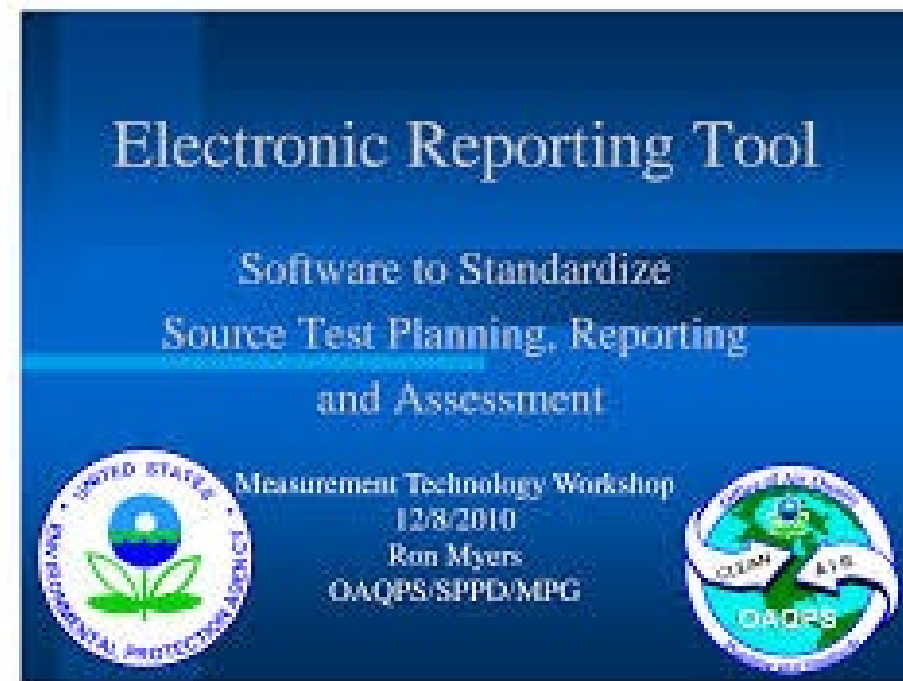
| Cylinder Gas Audit Test Report | | | | | |
|--------------------------------|--------------|-------------------------|--------------------|--------------------|---------------------|
| Company: | | Customer Name | <div>PICARRO</div> | | |
| City, State: | | Customer Facility | | | |
| Unit ID: | | Unit 1 | | | |
| Parameter: | | EtO | | | |
| Analyzer Serial #: | | 6357-UVA1083 | | | |
| Analyzer Model: | | Picarro PI2910 CRDS | | | |
| Span (ppb): | | 2500 | | | |
| Day of Test: | | 09/09/2024 | | | |
| | | Certified Value (ppb) | Cylinder ID # | Certification Date | Expiration Date |
| Certified Gas Concentration | | 5558.00 | CC424510 | 07/18/2024 | 07/18/2025 |
| MFC Diluted Concentrations | | Gas Concentration (ppb) | | Percent of SPAN | |
| Low Gas | | 625.00 | | 25% | |
| Mid Gas | | 1250.00 | | 50% | |
| High Gas | | 2500.00 | | 100% | |
| | | Reference Value | CEM Response (ppb) | % Error | Absolute Difference |
| Run #1 | Zero | 0.00 | 5.21 | 0.21 | 5.21 |
| | Mid | 1250.00 | 1219.97 | 1.20 | 30.03 |
| | High | 2500.00 | 2500.05 | 0.00 | 0.05 |
| Run #2 | Zero | 0.00 | 3.90 | 0.16 | 3.90 |
| | Mid | 1250.00 | 1217.34 | 1.31 | 32.66 |
| | High | 2500.00 | 2471.92 | 1.12 | 28.08 |
| Run #3 | Zero | 0.00 | 4.54 | 0.18 | 4.54 |
| | Mid | 1250.00 | 1219.72 | 1.21 | 30.28 |
| | High | 2500.00 | 2462.97 | 1.48 | 37.03 |
| | Average Zero | 0.00 | 4.55 | 0.18 | 4.55 |
| | Average Mid | 1250.00 | 1219.01 | 1.24 | 30.99 |
| | Average High | 2500.00 | 2478.31 | 0.87 | 21.72 |

Submission

Overview

Commercial sterilizers are subject to quarterly reporting windows federally; however, state/local regulations may have different timelines.

- Reports will need to be submitted electronically using CDX/CEDRI/ERT
- This includes quality assurance testing reports, as well



Submission

The Electronic Reporting Tool

The Electronic Reporting Tool (ERT) is a MS Access based program that will be used for emissions reporting.

- Incredibly slow and tedious process
- A single RATA can take 3+ hours of data entry
- Emissions reporting templates will be provided to sterilizers
- There is a specific manner you need to enter data into the ERT

The screenshot displays the 'ERT - Main Menu' interface. It features a blue header with the title 'ERT - Main Menu'. Below the header, there are five main columns of buttons. The first column, 'Setup / Test Plan', includes 'Test Plan' and a 'Quick Jumps' sub-menu with 'SCC', 'Process Info', and 'Locations/Methods'. The second column, 'Test Data', includes 'Run Data', 'Process Data', 'Tester DQ Assessment', 'Attachments', 'Completeness Check', and 'Report Verification'. The third column, 'Regulatory Agency Review', includes 'Test Plan Review', 'Regulatory Field Observation Documentation', 'Regulatory Assessment of Supporting Documentation', 'Emissions Results', and 'Comprehensive Regulatory Test Assessment'. The fourth column, 'Printed Reports', includes 'Select Report / Data Table' and an 'Administration' sub-menu with 'Help / Sys. Reports'. The fifth column, 'Wood Heaters', includes 'Wood Heater Application', 'Wood Heater Lab Data Entry', 'Wood Heater Summary Tables', 'Wood Heater Checklist', and 'Wood Heater Attachments Checklist'. Below these columns is a section with four buttons: 'Select Project Data Set', 'Create New Project Data Set', 'Save Project Data Set As', and 'Compact Project Data Set'. Below these buttons is a text field labeled 'Current Project Data Set:' containing the path 'C:\Users\scronin\Documents\ProjectData\Training.accdb - Date Created: 8/26/2024'. At the bottom, there is a 'Project Submittal History:' section with a 'Create ERT Submission Package File' button and a table with columns: Action, SubmitDate, SubmittedTo, SubmittedFrom, and Comment.

Submission

The Electronic Reporting Tool Common Issues

There are some common problems associated with the ERT.

- Incredibly slow and tedious process
- A single RATA can take 3+ hours of data entry
- Emissions reporting templates will be provided to sterilizers
- There is a specific manner you need to enter data
- Calculations not matching
- Calibration cylinders not being referenced correctly
- Method 205 being incorrect
- Process conditions not calculating properly
- Etc.

Submission

The Electronic Reporting Tool Common Issues

There are some common problems associated with the ERT.

- Incredibly slow and tedious process
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- There is a specific manner you need to enter data
- Calculations not matching
- Calibration cylinders not being referenced correctly
- Method 205 being incorrect
- Process conditions not calculating properly
- Etc.

Submission

The Electronic Reporting Tool Tips

Do your stack test plan before testing begins

Facility/Tester Permit/SCC Locations/Methods Regulations Process/APCD Methods cont. Audit/Calibrations Schedule Reviewers Attach.

Facility Name: *

Address: *

City: *

State/Zip: *

County: *

Contact: *

Phone: *

email: *

ORIS Code:

AFS Number:

Industry NAICS:

FRS: *

State ID:

Latitude: *

Longitude:

Test Number:

[Search on the Web](#)

[Search on the Web](#)

Testing Company: *

Address: *

City: *

State/Zip: *

Contact: *

Phone: *

email: *

Testing Company Project Number:

Attach Field documentation of competence as an AETB and QI for stationary source testing.

Next Page

(* required fields)

Submission

The Electronic Reporting Tool Tips

Make sure you have all attachments added properly

ERT Package *
Name:

Test Plan Date*

Open Expanded ☒

Facility/Tester Permit/SCC Locations/Methods Regulations Process/APCD Methods cont. Audit/Calibrations Schedule Reviewers Attach.

| AttachDesc | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| Source/Process Flow Diagram | | | | | | | | | |
| Alternate Method Request and Approval (Item 8) (optional) | | | | | | | | | |
| EPA Method 1 Location Supporting Documentation (Item 9) (optional) | | | | | | | | | |
| Cyclonic Flow Absence Supporting Documentation (Item 10) | | | | | | | | | |
| Pre-Test Meter Boxes/DGMs Calibrations | | | | | | | | | |
| Post-Test Meter Boxes/DGMs Calibrations | | | | | | | | | |
| Nozzles Calibrations | | | | | | | | | |
| Pitots Calibrations | | | | | | | | | |
| Thermocouples Calibrations | | | | | | | | | |
| Sampling Locations Dimensions and Point Locations | | | | | | | | | |
| Run Field Data Sheets (raw data sheets for field sampling) | | | | | | | | | |
| Moisture Recovery | | | | | | | | | |
| Lab Data (raw data sheets for field and laboratory analysis) | | | | | | | | | |
| Chain-of-Custody | | | | | | | | | |
| Observer Comments | | | | | | | | | |
| Documentation of competence as an AETB and QI for stationary so | | | | | | | | | |
| Laboratory Accreditation Certification | | | | | | | | | |

Record: 1 of 32 No Filter Search

To add or view an attachment:

- double click on the "paper clip" symbol
- select "add" to add a file
- select "view" to view a file

Note: Effective October 31, 2016 according to 60.8(f)(v) "Where test methods requires you record or report, the following shall be included: Record

To add more attachment items, enter the description of the attachment in the bottom row of the attachdesc column. Then add your attachment.

Tips to reduce the PDF file size:

- Create PDF directly from application,
- Attach individual components not compiled material
- Use descriptive file names (i.e. M29-field-data_11-11-11.pdf)
- Attach compressed image files (JPG, GIF, PNG) or CGM
- Scan paper documents at 200 dpi

Previous Page

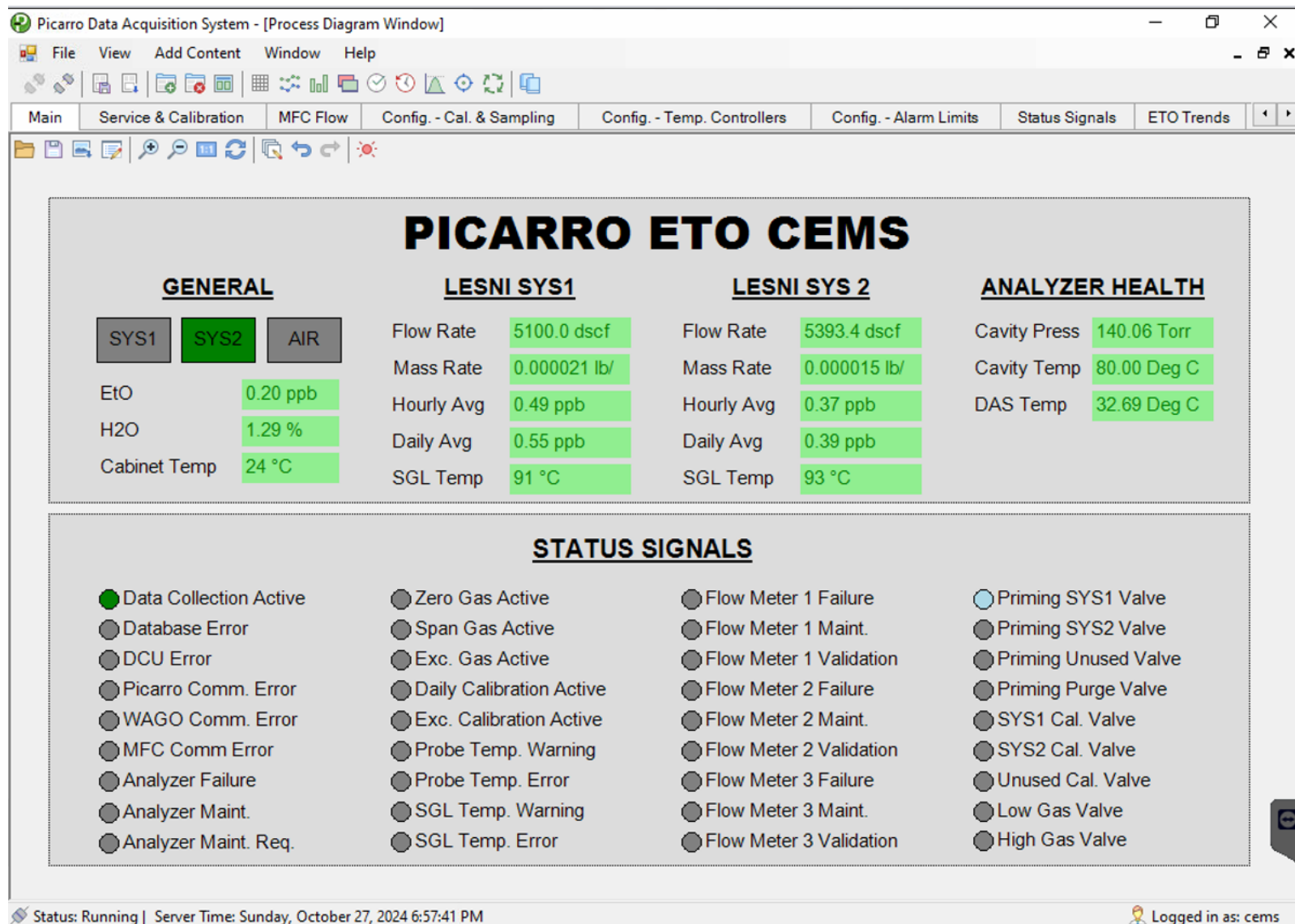
Finished

Submission

The Electronic Reporting Tool Tips

Designated representative needs to submit the package to EPA (contractors can do the data entry).

- Need to be credentialed in the CDX database
 - Preparer
 - Certifier
 - Delegated certifier



Thank You



Sean Cronin

CEMS Program Manager

Email: scronin@picarro.com

Phone: (1) 815-954-0857