White Paper

Commercial Sterilizer CEMS Compliance: Understanding PS-19 and Beyond

PICARRO

Figure 1. *The Picarro CEMS shown here is our demonstration platform designed to meet all current and upcoming performance requirements and regulations for EtO monitoring, including PS-19, OTM-47, and others.*

Summary

This paper outlines the regulatory framework behind the upcoming changes in the Commercial Sterilizer NESHAP (40 CFR 63 Subpart O). We will discuss how the US EPA decided on the continuous emissions monitoring requirements – including what those requirements are. Many in the sterilization industry have concerns about how to meet these requirements as previous technologies have struggled to demonstrate the response necessary to demonstrate compliance. This paper will go through Performance Specification 19 (PS-19), which provides the framework for a facility to certify its Continuous Emissions Monitoring System (CEMS). From there, this paper will dive into what happens after certification and how a facility maintains continual compliance. As this paper navigates the required components of CEMS compliance, it will discuss how Picarro, Inc. can make meeting federal and state/local regulations a simple feat. The results of Picarro's CEMS system are shown for each individual test – providing commercial sterilizers with confidence in a solution that far exceeds the requirements of the US EPA.

Commercial Sterilizer Landscape

The US EPA is expected to finalize the updates to 40 CFR 63, Subpart O (otherwise known as the Commercial Sterilizer National Emission Standards for Hazardous Air Pollutants/NESHAP) by March 2024. The updated rule came into effect through the Risk and Technology Review (RTR) and aims to address Ethylene Oxide (EtO, EO) emissions from point sources and room air emissions. Subpart O will include revised emissions monitoring and performance testing requirements to ensure emissions and exposure to EtO are low, consistent with the latest science around lifetime exposure risk from the EtO Integrated Risk Information System (IRIS). Improvements in technology mean that detection limits previously only possible with discrete sampling techniques and laborious effort are now not only possible but simple in real time at single-digit ppbv detection levels. One such requirement will be the implementation of EtO Continuous Emissions Monitoring Systems (CEMS) to monitor sources in real-time.

CEMS operate and generate data continuously, allowing for the most accurate documentation of a facility's real-time emissions. To ensure that CEMS data is valid and trustworthy, extensive quality assurance and quality control is required throughout the lifetime of the system(s). Part of this quality assurance is the certification of a CEMS – advanced installation requirements and testing to ensure the system meets

the minimum quality standards set forth by the US EPA to produce accurate emissions data. CEMS data is not considered valid until the facility is able to meet these requirements and submit documentation to the US EPA or the applicable state/local agency.

CEMS certification requirements are primarily found in 40 CFR 60, Appendix B – Performance Specifications. Performance Specification 19 (PS-19) provides the regulatory requirements for certifying an EtO CEMS. These requirements were determined utilizing the best available technologies, including Cavity Ring-Down Spectroscopy (CRDS) analyzers produced by Picarro.

Regulatory Landscape

The Clean Air Act (CAA) is the United States' primary federal air quality law first passed by Congress in 1963 and amended many times since. The CAA is codified in 40 Code of Federal Regulations (CFR) Parts 50 through 98. US EPA has been tasked with carrying out the law's mandates and has established several regulatory programs to do this. Two of which are relevant to PS-19; National Emission Standards for Hazardous Pollutants (NESHAP) [40 CFR Part 63] and New Source Performance Standards (NSPS) [40 CFR Part 60]. Briefly speaking, NSPS laid the groundwork for emissions monitoring and is most known for its regulations on criteria pollutants, whereas NESHAP's primary focus is on hazardous air pollutants.

In most of the U.S., the EPA delegates administrative responsibilities derived from CAA to the respective state and tribal authorities. PS-19 is included in Appendix B to Part 60 and describes the procedures required for installation and certification of a CEMS. Additionally, Part 60, Appendix F will contain Quality Assurance Procedure 7, providing the framework for maintaining CEMS compliance following certification.

What is PS-19?

PS-19 is perhaps the most in-depth and quality assurance-focused performance specification to date. It consists of six primary tests, as well as stipulation on the use of a time-shared system. Those tests are briefly summarized below and will be described in further detail later.

Required Test	Description	Criteria	Picarro Performance
Interference Test, PS-19 Section 11.1	Establishes concentration ranges of the background matrix in which the measurement of EtO remains valid. This is typically completed by the manufacturer of the gas analyzer.	≤10 times LOD or ≤ 30 ppbv [1] (Section 13.5)	1.3 ppbv
Level of Detection (LOD) PS-19 Section 11.2	Determines the smallest concentration the CEMS is capable of detecting.	< 20 of applicable limit or action level (Section 13.1)	0.2 ppbv
Response Time Determination, PS-19 Section 11.3	Determines the amount of time it takes for gas to be transported from the certified calibration cylinders to the probe, and then through the entire system to the analyzer. *For a time-shared CEMS, the sampling time for each measurement point must be 3x the calculated response time, with the overall sample time for each measurement point having to be a 15 minute or less cycle time.*	N/A	10 seconds
Measurement Error Test, PS-19 Section 11.4	Determines the CEMS can provide linear responses across the entire range of the instrument.	≤ 5.0% of span or ± 10 ppbv (Section 13.3)	0.15%
Calibration Drift Test, PS-19 Section 11.5	A daily Quality Assurance test that establishes that a CEMS measurements remain accurate by checking the system against gas standards on the low end and high end of the instrument.	≤ 5.0% of span or ±10 ppbv for 7-days (Section 13.2)	0.16%
Relative Accuracy Test Audit (RATA), PS-19 Section 11.6	The CEMS is compared to a US EPA reference method conducted by a certified source testing firm. This is to ensure the measurement point captures representative emissions.	≤ 20% of RM [2] (Section 13.4)	< 1% of RM [3]

[1] *Interference test also allows for a passing response if the sum of interference responses are not greater than 2.5% of the calibration span or ±3.0% of the equivalent EtO concentration used.*
[2] *If the average RM emission level is less than 50% of EtO concentration or emission standard, the emission standard can be used in denominator of RA calculation and results must be ≤15%.*
[3] *Utilizing OTM-47 for the initial RATA testing.*

PS-19 starts off with similar requirements to most CEMS – it requires the use of certified reference gases, meeting the "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards." However, as PS-19 deals with extremely low concentration gases, protocol gases can be diluted using EPA Method 205 to meet the required values.

To ensure the measurement point is free of stratification and provides accurate measurements, the CEMS must also be installed at a location that is at least (2.0) equivalent duct diameters downstream of a control device or flow disturbance, and (0.5) equivalent duct diameters from the exhaust or any control device.

PS-19 also requires a way to measure volumetric flow rate and, if the EtO measurements need to be corrected for moisture content. The flow monitor needs to be installed at a location meeting the above criteria, but that is also no more than (0.5) duct diameters away from the CEMS probe. If moisture is required, the monitoring system must either contain a continuous moisture sensor and oxygen analyzer capable of measuring oxygen on both a wet and dry basis, or be an optical measurement system validated by EPA Method 301.

The CEMS system must be able to take at least one valid measurement for each measurement point once every 15 minutes. This requirement allows for the use of time-sharing (i.e. monitoring multiple measurement points with one analyzer).

If these requirements are met, and the system is installed, set up, and calibrated correctly, then the facility can begin the Performance Specification Test Procedures. The following tests are required:

Interference Test, PS-19 Section 11.1

Interferences are common with many technologies when measuring EtO – especially when looking at sources that have fluctuations in the gas matrix (i.e. combustion sources). An interference gas is any gas other than the target gas, EtO, that can cause the detection technology to misreport the true levels of EtO. To ensure the CEMS can adequately measure EtO, the EPA is requiring the manufacturer to provide verification that their system is able to provide accurate measurements while exposed to select interference gases. In a laboratory environment, the manufacturer must conduct the interference test with a mixture of an EtO reference gas concentration at approximately 10 times the limit of detection and the following interferents (either introduced individually or as a blend):

- Carbon Dioxide (0.8% - 1.2%)
- Methane (15 ppm - 25 ppm)
- Water (4% - 6%)
- Nitrogen (as the balance gas)

The results of the sum of responses from the interference test must not exceed 2.5% of the calibration span or 3.0% of the equivalent EtO concentration used to pass this test. Alternatively, the test passes if the results do not exceed 10 times the limit of detection or 30 ppbv.

Picarro CEMS Interference Test Results

Picarro conducted interference tests on its CEMS system with a blend of CO_2, CH_4, and H_2O in N_2 with 50 ppbv of EtO (Table 1). The interference changes were negligible, demonstrating average results of ~1.3 ppbv drift. This demonstrates incredibly precise readings that reduce the risk of over reporting emissions due to other gases in their matrices.

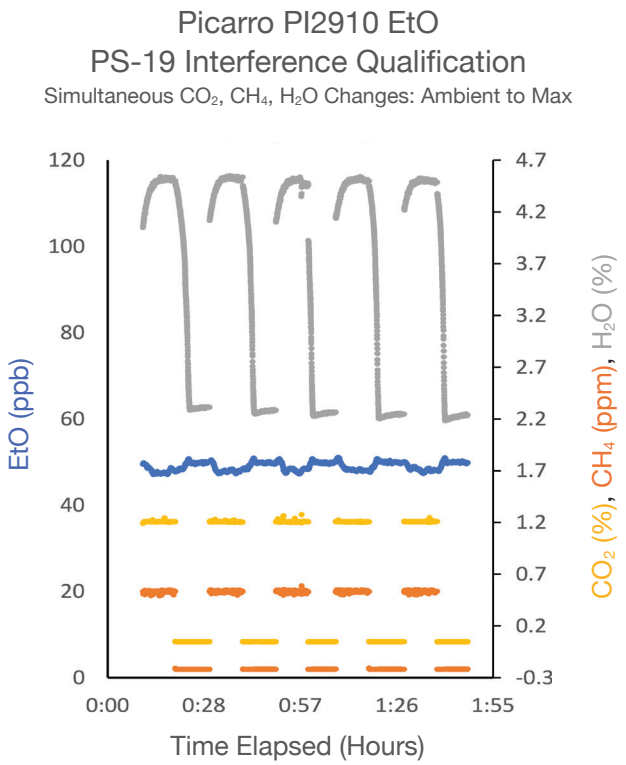

Figure 2. *Interference Gas Test*

Please note that there are a number of other known analytes that interfere with EtO and can lead to skewed results. If you have concerns about your gas matrix, please reach out to Picarro personnel to see a comprehensive list of other interference gases and their measured effects.

Level of Detection (LOD), PS-19 Section 11.2

LOD must be determined to ensure that EtO can be detected above a background in a gas matrix. This test is to be conducted with the above interference gases. In a lab setting, a blend of the interference gases and an EtO concentration, no greater than 10 times the estimated limit of detection[4], are injected into the inlet of the analyzer for 15 minutes, recording and averaging the results. This is repeated a total of seven times. The LOD is calculated as 3 times the standard deviation of the average of these measurements. The LOD may not be greater than 20% of the applicable emission limit.

From there, the controlled environment LOD must be verified by performing dynamic spikes through the entire installed CEMS system to calculate a site-specific standard addition detection level that must be <20% of the applicable emission limit.

Picarro CEMS LOD Results

Picarro conducted LOD tests internally with 6 ppbv of EtO and 1 ppbv of EtO to demonstrate compliance with PS-19 as it stands at the time of this writing (Figure 2). The measured results showed an LOD of < 0.2 ppbv for each series of testing. These results let clients know they are always recording accurate emissions, even when their process is showing single digit ppbv concentrations.

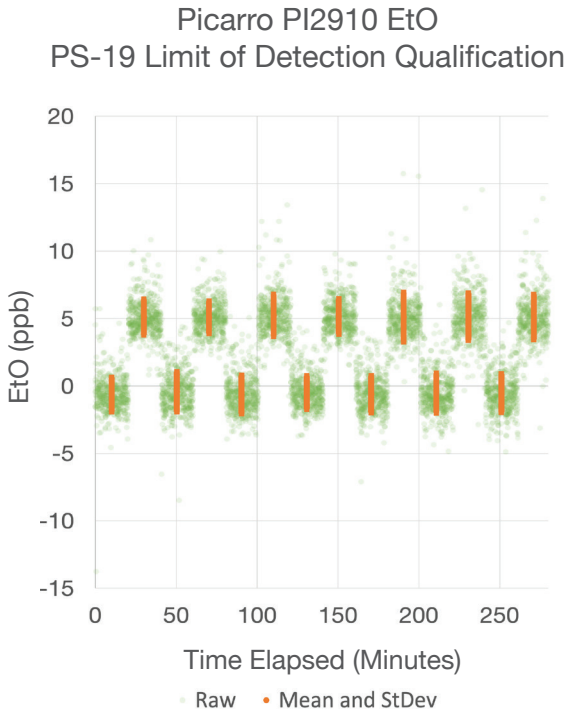

Figure 3. *LOD Test Results – Picarro CEMS*

Response Time Determination, PS-19 Section 11.3

While conducting the Measurement Error Test (Section 11.4), the response time of the CEMS system must be calculated. This is done by achieving a stable zero reading for 30 seconds and recording the time this was collected (hh:mm:ss) and then introducing the high-level upscale gas. The time the upscale gas achieves 95% of the final stable value shall also be recorded. Once this value is recorded, zero gas should be introduced, where the time that a stable value is reached is also recorded.

[4] *Please note, many manufacturers are displaying results where the EtO concentration used to detect LOD is many factors higher than 10x the LOD they are advertising. As of the writing of this document, this would not meet the criteria explicitly specified in PS-19.*

This is done three times until the mean upscale and downscale response times are recorded.

Response time is incredibly important if using a time-shared, multi-stack CEMS. Each measurement point needs to sample for at least 3x as long as the measured response time. When time-sharing a system, the total duration of measurement across all measurement points shall not exceed 15 minutes, effectively limiting the number of measurement points a system can handle.

The primary limiting factors for response time tests included the length of the sample line and the sample pump being used by the CEMS system. Picarro uses a robust sample pump, allowing for comfortable time-sharing capabilities of 3 measurement points, even with longer than average sample lines.

Measurement Error Test, PS-19 Section 11.4

The Measurement Error Test involves sending reference gases to the CEMS probe and through the entire system to validate linearity. A zero gas and three upscale EtO reference gases must be introduced to the probe in non-consecutive order. The gases will flow until a response is stable, meaning two measurements are collecting and displaying concentrations within 1% of the span of the instrument or 5 ppbv. This process is repeated 3 times for each gas, making a total of 12 measurements. Each measurement must provide results that are within 5.0% of the instrument's span, or an absolute difference of 10.0 ppbv at the low, mid, and high-level concentrations.

Picarro CEMS Measurement Error Test Results

Picarro conducted measurement error testing over a period of multiple days, recording the results of step changes across different spans. Table 2 demonstrates a randomized section of results from this specific test (100 ppbv span) that demonstrate just how precise CRDS is measuring EtO across the span of an instrument.

Reference Gas Value	CEMS Response	(Ref-Obs)	Meas. Error (Ref-Obs)/Span
ppb	ppb	ppb	%
0.0	0.18	-0.18	-0.18
25.0	24.75	0.24	0.24
50.0	49.67	0.33	0.33
100.0	100.08	-0.08	-0.08
50.0	50.07	-0.07	-0.07
25.0	25.09	-0.09	-0.09
0.0	0.16	-0.16	-0.16
25.0	24.87	0.13	0.13
50.0	49.81	0.19	0.19
100.0	100.19	-0.19	-0.19
50.0	50.09	-0.09	-0.09
25.0	25.08	-0.08	-0.08
0.0	0.16	-0.16	-0.16

***Table 2**. Partial Measurement Error Test Table*

Calibration Drift Test (7-Day Drift Test), PS-19 Section 11.5

The calibration drift test, or 7-day drift test, is one that will be conducted for the lifetime of the CEMS. However, this test is an effort to establish initial stability of the system for certification purposes.

For this test, the system (defined as all components from the probe to analyzer) is challenged with a zero gas and a span gas on 24-hour intervals to maintain a quality assured CEMS. PS-19 requires the CEMS to achieve a <5.0% drift from span for both the zero and span gas for 7-consecutive days. Alternatively, the zero and span can deviate by 10 ppbv and be considered passing.

7-Day Drift Assessment of Picarro

Picarro has conducted the calibration drift assessment across many sites. The dataset in Table 3 shows a completed 7-day drift assessment conducted on an instrument with a span of 100 ppbv. Note the results are consistently precise.

Reference Value (ppb)	Actual Value (ppb)	Span Value (ppb)	Calibration Drift (ppb)	Calibration Drift (% of span)	Excessive Calibration Drift Check
100.00	100.49	100.00	0.49	0.49	pass
100.00	100.60	100.00	0.60	0.60	pass
100.00	100.48	100.00	0.48	0.48	pass
100.00	100.39	100.00	0.39	0.39	pass
100.00	100.44	100.00	0.44	0.44	pass
100.00	100.53	100.00	0.53	0.53	pass
100.00	100.52	100.00	0.52	0.52	pass
0.00	0.27	100.00	0.27	0.27	pass
0.00	0.11	100.00	0.11	0.11	pass
0.00	0.06	100.00	0.06	0.06	pass
0.00	0.16	100.00	0.16	0.16	pass
0.00	0.18	100.00	0.18	0.18	pass
0.00	0.14	100.00	0.14	0.14	pass
0.00	0.16	100.00	0.16	0.16	pass

Table 3. *Example 7-Day Drift Assessment*

Relative Accuracy Test Audit (RATA), PS-19 Section 11.6

Finally, CEMS measurements will be compared to a Reference Method (RM), displayed in terms of the emission standard. PS-19 states Method 320 is an approved RM, however, OTM-47, the only method specific to EtO, can be alternatively approved. OTM-47 utilizes Cavity Ring-Down Spectroscopy (CRDS), which provides sub ppbv measurements in 2-second intervals with minimal interference issues. It is recommended to request OTM-47 if your facility has low levels of EtO to ensure the measured data is accurately represented.

A RATA consists of at least 9, 21-minute runs, where a certified source testing firm takes pollutant, diluent, and flow measurements (if applicable to the emission standard). At the end of the RATA, the overall Relative Accuracy (RA) is calculated based on the results of the CEMS and RM. The RA must be ≤20% of the reference method, if used in the denominator of the RA calculation. Alternative specifications are available for calculating RA with the emission standard in the denominator if certain criteria are met.

Picarro RATA Solution

Picarro helped develop OTM-47 – the only test specific for EtO. OTM-47 has been conducted across the United States and its territories and is the best option for performance testing at low detection levels. Picarro does not own the rights to the results of any performance testing.

Figure 4. *Picarro mobile OTM-47 solution*

Test	Performance Specifications	PICARRO	OE-FTIR	Commentary
Interference (Section 11.1)	Sum of interference responses ≤ 30 ppb (Section 13.5)	1.3 ppb	≤ 20 ppb	Picarro conducted the interference testing with all interference gases present in one sample stream. This is believed to be more representative to real-life conditions and is the more difficult option for conducting this test.
Limit of Detection (LOD) (Section 11.2)	LOD < 20% of the regulatory limit, typically 10 ppb (Section 13.1)	0.2 ppb	≤ 1 ppb	LOD was calculated using EtO concentrations of 1 ppb and 6 ppb. The LOD testing was not conducted with higher concentrations as it exceeded the 10x LOD requirement defined by PS-19.
Response Time (RT) (Section 11.3)	Not Specified	< 10 sec	15 - 30 sec	Response time was determined with a 100 ft sample line.
Measurement Error (ME) (Section 11.4)	≤ 5.0 % of span (Section 13.3)	0.15%	≤ 2%	Picarro conducted the measurement error tests with a 100 ppb span. 0.15% was the highest error collected during the ME tests. The results for each individual component are as follows: 0.15% (Zero), 0.05% (25 ppb), 0.09% (50 ppb), 0.14% (100 ppb).
7-Day Calibration Drift (Section 11.5)	≤ 5.0 % of span (Section 13.2)	0.16%	≤ 2%	Picarro utilized pure nitrogen as zero gas and a 105 ppb EtO span gas for testing.

Picarro CRDS vs Alternative Technology PS-19 Testing Results

Picarro and the US EPA have vigorously conducted PS-19 testing using CRDS prior to the finalization Subpart O and PS-19. The table above demonstrates Picarro's internal results for the required tests, compared to the results published by a competitor.

Maintaining CEMS Compliance

Once the required quality assurance tests are completed, the facility will submit results to the applicable administrator to provide approval on the certification of the CEMS. From there, the facility is subject to maintaining their CEMS with regular preventative maintenance and the required Quality Assurance Procedure 7.

Understanding these requirements and the CEMS maintenance needed to ensure operation can be difficult for a facility that does not have previous experience working with these elaborate systems. All CEMS systems have consumable parts, as well as critical parts that can fail if components are not regularly reviewed and/or repaired. It is required by 40 CFR Part 63, Subpart A for a facility to maintain spare parts and a spare parts list in the event a repair is needed.

Each facility is also required to have a quality assurance plan, detailing how to perform the required functions necessary to a functioning CEMS system. This can be a tricky task, as even power generation facilities with years of CEMS experience will delegate the creation or updates of these plans to consulting firms. This was an obvious need for most facilities, leading Picarro to provide each customer with a site-specific plan that covers the required components and additional details as part of their purchase.

Commercial sterilizers will also be federally obligated to submit semi-annual compliance reports and quality assurance test reports. It is expected that these reports will be required to be submitted through the EPA's Electronic Reporting Tool (ERT).

Procedure 7 Details

Procedure 7, as it currently stands, includes the requirements for maintaining a compliant CEMS. This includes daily calibration drift assessments, quarterly audits, and annual RATA testing.

Daily calibration drift assessments will need to demonstrate results meeting a set performance specification, otherwise the CEMS system will be out-of-control (OOC), resulting in invalid data and potential penalties if this is not remedied. Quarterly audits and

annual RATAs are also subject to specifications that, if not met, result in the system being considered OOC.

Quarterly audits need to be conducted no less than 60 days apart and cannot be completed for more than 3 quarters in a row without a RATA to stay in compliance. The required quarterly audit can be any of the following:

Cylinder Gas Audit (CGA)

- A CGA involves challenging the entire CEMS system with a zero gas and two upscale gas concentrations in triplicate succession. Section 5.1.3 of Procedure 7 calls for the upscale gases to be a mid-gas (50 - 60% of span) and a high-gas (80 - 100% of span).
- Average results of each triplicate injection must be ≤10% of the span.

Dynamic Spiking Audit (DSA)

- The DSA is similar to the CGA but involves spiking the gas stream with known standards. This involves specialty equipment in most cases.
- To pass a DSA, the results shall be either less than 5% of the span value at zero, mid, and high audit points or ≤ 20% of applicable emission standard.

Relative Accuracy Audit (RAA)

- An RAA consists of a stack test firm coming on site and conducting an abbreviated RATA. At least 3 runs must be completed with the RA calculated similarly to the RATA testing described above.
- To successfully complete an RAA, the RA must be ≤ 20% of Reference Method in the denominator.

Historically, these audits would require the facility to pay an additional contractor to complete them and provide the facility reports on a quarterly basis.

Procedure 7 also specifies that each facility is subject to the Above Span Calibration provisions. Any time 2 consecutive hours have average concentrations in excess of 200% of the instrument's span, the facility has 24 hours to conduct an above span calibration. For many systems, this requires regular monitoring of alarm thresholds and concentration averages, as well as trained personnel capable of conducting this test any time the threshold is exceeded, including weekends and holidays.

The RATA is to be conducted annually and requires a notification to be delivered to the applicable administrator that the test is to be conducted. As stated previously, it is recommended to request alternative approval for OTM-47, especially if your facility has demonstrated low-level EtO concentrations for a more accurate audit.

How Picarro Simplifies PS-19 Compliance

Commercial sterilizers provide an essential service to our medical supply chain, ensuring doctors and patients have access to lifesaving medical devices. Picarro empowers sterilizers to focus on what they do best – sterilize! With decades of experience Picarro has the tools and managed services expertise to make compliance with these new CEMS rules easy. We've built our EtO system to be seamlessly integrated into any facility and our Environmental Systems (ESYS) team will help you every step of the way. With thousands of systems installed and operating on every continent, Picarro has built a reputation for having the most accurate, and reliable systems on the planet.

Every Picarro system is built in America at our headquarters in Santa Clara, CA. Picarro does not contract out key components. Everything is designed, built, and tested at our headquarters. What does this mean for you? If there is an issue, the people who designed the system are literally just a phone call away to help get you a solution fast. Gone are the days when the company who installed your CEMS tells you to contact the CEMS manufacturer yourself for troubleshooting. With Picarro, you can focus on the business of sterilizing products while we handle the monitoring.

Our systems are designed with a robust Data Acquisition System perfectly configured for easy reporting to the ERT. They come in a portable, robust cabinet that is factory equipped with automated Above Span Calibration checks, remote Cylinder Gas Audits, and remote access for expert CEMS support. Our environmental experts develop all Quality Assurance documents to comply with federal regulations and operating permits, and they assist clients with all of their reporting needs. Our team of trained field

technicians provide all preventative maintenance and emergency support. We also schedule annual RATAs and will communicate with your Administrator about why OTM-47 is the best option for conducting your RATA.

And all of this support comes at a fixed cost – meaning Picarro will not be charging hourly rates for additional support. Your budget is set from the beginning, and you know you are in good hands.

The benefits of a Picarro system are vast, but the top three are:

1. Rapid response times. This allows for timeshare systems, saving overall costs as one analyzer can provide up to 3 measurement points.
2. The lowest-in-class detection limit. There is no need to overreport emissions with Picarro solutions, nor do we need 15 minutes to generate a low response. Our results are generated on 2-second averages, meaning you get the best data – FAST.
3. End-to-End emissions monitoring solutions. Our team takes care of everything doing what we do best, so you can do what you do best – sterilize.

About the Author

Sean Cronin is a Project Manager with Picarro, Inc. focusing on the regulatory aspect of Continuous Emissions Monitoring Systems (CEMS). He has 10+ years' experience in emissions monitoring with certifications for major criteria pollutant CEMS, gas chromatographs, sample system design, and several process analyzers. Prior to joining Picarro, he was a Subject Matter Expert (SME) for CEMS and Source Testing for a large consulting firm. His primary duties there were assisting clients with high-profile projects, regularly interacting with state and federal agencies. It was in that role he first learned about Picarro. Coming from an FTIR background, he was amazed at how effective and easy to use the Picarro technology was and how committed the Picarro team was to finding complete solutions for their clients.

Contact Information

Have questions regarding Picarro ethylene oxide monitoring systems? Please contact the Picarro Environmental Systems (ESYS) team via email at: **eto@picarro.com**

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