

Appendix F to Part 60—Quality Assurance Procedures

Procedure 7. Quality Assurance Requirements for Gaseous Ethylene Oxide (ETO) Continuous Emission Monitoring Systems Used for Compliance Determination

1.0 Applicability and Principle

1.1 Applicability. Procedure 7 is used to evaluate the effectiveness of quality control (QC) and quality assurance (QA) procedures and to evaluate the quality of data produced by any ethylene oxide (EtO) gas, CAS: 75-21-8, continuous emission monitoring system (CEMS) that is used for determining compliance with emission standards for EtO on a continuous basis as specified in an applicable permit or regulation.

1.1.1 This procedure specifies the minimum QA requirements necessary for the control and assessment of the quality of CEMS data submitted to the Environmental Protection Agency (EPA) or a delegated authority. If you are responsible for one or more CEMS used for EtO compliance monitoring you must meet these minimum requirements and you are encouraged to develop and implement a more extensive QA program or to continue such programs where they already exist.

1.1.2 Data collected as a result of QA and quality control (QC) measures required in this procedure are to be submitted to the EPA or the delegated authority in accordance with the applicable regulation or permit. These data are to be used by both the delegated authority and you, as the CEMS operator, in assessing the effectiveness of the CEMS QC and QA procedures in the maintenance of acceptable CEMS operation and valid emission data.

1.2 Principle

1.2.1 The QA procedures consist of two distinct and equally important functions. One function is the assessment of the quality of the CEMS data by estimating accuracy. The other function is the control and improvement of the quality of the CEMS data by implementing QC

policies and corrective actions. These two functions form an iterative control loop. When the assessment function indicates that the data quality is inadequate, the control effort must be increased until the data quality is acceptable. In order to provide uniformity in the assessment and reporting of data quality, this procedure specifies the assessment procedures to evaluate response drift and accuracy. The procedures specified are based on Performance Specification 19 (PS-19) in appendix B to this part.

NOTE: Because the control and corrective action function encompasses a variety of policies, specifications, standards and corrective measures, this procedure treats QC requirements in general terms to allow you, as source owner or operator to develop the most effective and efficient QC system for your circumstances.

2.0 Definitions

See PS-19 in appendix B to this part for the primary definitions used in this Procedure.

3.0 QC Requirements

3.1 You, as a source owner or operator, must develop and implement a QC program. At a minimum, each QC program must include written procedures and/or manufacturer's information which should describe in detail, complete, step-by-step procedures and operations for each of the following activities: (a) Calibration Drift (CD) checks of CEMS; (b) CD determination and adjustment of CEMS; (c) Routine and preventative maintenance of CEMS (including spare parts inventory); (d) Data recording, calculations, and reporting; (e) Accuracy audit procedures for CEMS including reference method(s); and (h) Program of corrective action for malfunctioning CEMS.

3.2 These written procedures must be kept on site and available for inspection by the delegated authority. As described in section 5.4, whenever excessive inaccuracies occur for two

consecutive quarters, you must revise the current written procedures, or modify or replace the CEMS to correct the deficiency causing the excessive inaccuracies.

4.0 Daily Data Quality Requirements and Measurement Standardization Procedures

4.1 CD Assessment. An upscale gas, used to meet a requirement in this section must be a gas meeting the requirements in section 7.1 of PS-19 of appendix B to this part.

4.1.1 CD Requirement. Consistent with §§60.13(d) and 63.8(c), you, as source owners or operators of CEMS must check, record, and quantify the CD at two levels, using a zero gas and high-level gas at least once daily (approximately every 24 hours). Perform the CD check in accordance with the procedure in the applicable performance specification (e.g., section 11.3 of PS-19 in appendix B to this part). The daily zero- and high-level CD must not exceed two times the drift limits specified in the applicable performance specification (e.g., section 13.2 of PS-19 in appendix B to this part.)

4.1.2 Recording Requirement for CD Corrective action. Corrective actions taken to bring a CEMS back in control after exceeding a CD limit must be recorded and reported with the associated CEMS data. Reporting of a corrective action must include the unadjusted concentration measured prior to resetting the calibration and the adjusted value after resetting the calibration to bring the CEMS back into control.

4.1.3 Dynamic Spiking Option for high-level CD. You have the option to conduct a daily dynamic spiking procedure found in section 11.5.8 of PS-19 of appendix B to this part in lieu of the daily high-level CD check. If this option is selected, the daily zero CD check is still required.

4.1.4 Out of Control Criteria for Excessive CD. Consistent with §63.8(c)(7)(i)(A), an EtO CEMS is out of control if the zero or high-level CD exceeds two times the applicable CD specification in the applicable performance specification or in the relevant standard. When a

CEMS is out of control, you as owner or operator of the affected source must take the necessary corrective actions and repeat the tests that caused the system to go out of control (in this case, the failed CD check) until the applicable performance requirements are met.

4.1.5 Additional Quality Assurance for Data Above Span. This procedure must be used when required by an applicable regulation and may be used when significant data above span are being collected. Furthermore, the terms of this procedure do not apply to the extent that alternate terms are otherwise specified in an applicable rule or permit.

4.1.5.1 Any time the average measured concentration of EtO exceeds 200 percent of the span value for two consecutive one-hour averages, conduct the following 'above span' CEMS response check.

4.1.5.1.1 Within a period of 24 hours (before or after) of the 'above span' period, introduce a higher, 'above span' EtO reference gas standard to the CEMS. Use 'above span' reference gas that meets the requirements of section 7.0 of PS-19 in appendix B to this part and target a concentration level between 75 and 125 percent of the highest hourly concentration measured during the period of measurements above span or 5 ppmv whichever is greater.

4.1.5.1.2 Introduce the reference gas at the probe for extractive CEMS.

4.1.5.1.3 At no time may the 'above span' concentration exceed the analyzer full-scale range.

4.1.5.2 Record and report the results of this procedure as you would for a daily calibration. The 'above span' response check is successful if the value measured by the CEMS is within 20 percent of the certified value of the reference gas.

4.1.5.3 If the 'above span' response check is conducted during the period when measured emissions are above span and there is a failure to collect at least one data point in an hour due to

the response check duration, then determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour.

4.1.5.4 In the event that the 'above span' response check is not successful (i.e., the CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the 'above span' response check for reporting based on the CEMS response to the reference gas as shown in Eq. 7-1:

Eq. 7-1

$$\text{Normalized stack gas result} = \frac{\text{Certified reference gas value}}{\text{Measured value of reference gas}} \times \text{Measured stack gas result}$$

4.2 Out of Control Period Duration for Daily Assessments. The beginning of the out-of-control period is the hour in which the owner or operator conducts a daily performance check (e.g., calibration drift) that indicates an exceedance of the performance requirements established under this procedure. The end of the out-of-control period is the completion of daily assessment of the same type following corrective actions, which shows that the applicable performance requirements have been met.

4.3 CEMS Data Status During Out-of-Control Period. During the period the CEMS is out-of-control, the CEMS data may not be used in calculating compliance with an emissions limit nor be counted towards meeting minimum data availability as required and described in the applicable regulation or permit.

5.0 Data Accuracy Assessment

You must audit your CEMS for the accuracy of EtO measurement on a regular basis at

the frequency described in this section, unless otherwise specified in an applicable regulation or permit. Quarterly audits are performed at least once each calendar quarter. Successive quarterly audits, to the extent practicable, shall occur no closer than 2 months apart. Annual audits are performed at least once every four consecutive calendar quarters.

5.1 Concentration Accuracy Auditing Requirements. Unless otherwise specified in an applicable regulation or permit, you must audit the EtO measurement accuracy of each CEMS at least once each calendar quarter, except in the case where the affected facility is off-line (does not operate). In that case, the audit must be performed as soon as is practicable in the quarter in which the unit recommences operation. Successive quarterly audits must, to the extent practicable, be performed no less than 2 months apart. The accuracy audits shall be conducted as follows:

5.1.1 Relative Accuracy Test Audit (RATA). A RATA must be conducted at least once every four calendar quarters, except as otherwise noted in sections 5.1.5 or 5.5 of this procedure. Perform the RATA as described in section 11.6 of PS-19 in appendix B to this part. If the EtO concentration measured by the RM during a RATA (in ppmv or other units of the standard) is less than or equal to 20 percent of the concentration equivalent to the applicable emission standard, you must perform a Cylinder Gas Audit (CGA) or a Dynamic Spike Audit (DSA) for at least one subsequent (one of the following three) quarterly accuracy audits.

5.1.2 Quarterly Relative Accuracy Audit (RAA). A quarterly RAA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three quarters in succession. To conduct an RAA, follow the test procedures in section 11.6 of PS-19 in appendix B to this part, except that only three test runs are required. The difference between the mean of the RM values and the mean of the CEMS responses relative to the mean of the

values (or alternatively the emission standard) is used to assess the accuracy of the CEMS.

Calculate the RAA results as described in section 6.2. As an alternative to an RAA, a cylinder gas audit or a dynamic spiking audit may be conducted.

5.1.3 Cylinder Gas Audit. A quarterly CGA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three consecutive quarters. To perform a CGA, challenge the CEMS with a zero-level and two upscale level audit gases of known concentrations within the following ranges:

Audit point	Audit range
1 (Mid-Level)	50 to 60% of span value.
2 (High-Level)	80 to 100% of span value.

5.1.3.1 Inject each of the three audit gases (zero and two upscale) three times each for a total of nine injections. Inject the gases so that the entire measurement system is challenged. Do not inject the same gas concentration twice in succession.

5.1.3.2 Use EtO audit gases that meet the requirements of section 7 of PS-19 in appendix B to this part.

5.2.3.3 Calculate results as described in section 6.3.

5.1.4 Dynamic Spiking Audit. A quarterly DSA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three quarters in succession.

5.1.4.1 To conduct a DSA, you must challenge the entire EtO CEMS with a zero gas in accordance with the procedure in section 11.8 of PS-19 in appendix B of this part. You must also

conduct the DS procedure as described in appendix A to PS-19 of appendix B to this part. You must conduct three spike injections with each of two upscale level audit gases. The upscale level gases must meet the requirements of section 7 of PS-19 in appendix B to this part and must be chosen to yield concentrations at the analyzer of 50 to 60 percent of span and 80 to 100 percent of span. Do not inject the same spike gas concentration twice in succession.

5.1.4.2 Calculate results as described in section 6.4. To determine CEMS accuracy, you must calculate the dynamic spiking error (DSE) for each of the two upscale audit gases using Equation A5 in appendix A to PS-19 and Equation 7-3 in section 6.4 of this Procedure.

5.1.5 Other Alternative Quarterly Audits. Other alternative audit procedures, as approved by the Administrator, may be used for three of four calendar quarters.

5.2 Out of Control Criteria for Excessive Audit Inaccuracy. If the results of the RATA, RAA, CGA, or DSA do not meet the applicable performance criteria in section 5.2.4, the CEMS is out-of-control. If the CEMS is out-of-control, take necessary corrective action to eliminate the problem. Following corrective action, the CEMS must pass a test of the same type that resulted in the out-of-control period to determine if the CEMS is operating within the specifications (e.g., a RATA must always follow an out-of-control period resulting from a RATA).

5.2.1 If the audit results show the CEMS to be out-of-control, you must report both the results of the audit showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

5.2.2 Out-Of-Control Period Duration for Excessive Audit Inaccuracy. The beginning of the out-of-control period is the time corresponding to the completion of the sampling for the failed RATA, RAA, CGA or DSA. The end of the out-of-control period is the time corresponding to the completion of the sampling of the subsequent successful audit.

5.2.3 CEMS Data Status During Out-Of-Control Period. During the period the CEMS is out-of- control, the CEMS data may not be used in calculating emission compliance nor be counted towards meeting minimum data availability as required and described in the applicable regulation or permit.

5.2.4 Criteria for Excessive Quarterly and Yearly Audit Inaccuracy. Unless specified otherwise in the applicable regulation or permit, the criteria for excessive inaccuracy are:

5.2.4.1 For the RATA, the CEMS must meet the RA specifications in section 13.4 of PS-19 in appendix B to this part.

5.2.4.2 For the CGA, the accuracy must not exceed 10.0 percent of the span value at the zero gas and the mid- and high-level reference gas concentrations.

5.2.4.3 For the RAA, the RA must not exceed 20.0 percent of the RM_{avg} as calculated using Equation 7-2 in section 6.2 of this procedure whether calculated in units of EtO concentration or in units of the emission standard. In cases where the RA is calculated on a concentration (ppbv) basis, if the average EtO concentration measured by the RM during the test is less than 75 percent of the EtO concentration equivalent to the applicable standard, you may substitute the equivalent emission standard value (in ppbw) in the denominator of Equation 7-2 in the place of RM_{avg} and the result of this alternative calculation of RA must not exceed 15.0 percent.

5.2.4.4 For DSA, the accuracy must not exceed 5.0 percent of the span value at the zero gas and the mid- and high-level reference gas concentrations or 20.0 percent of the applicable emission standard, whichever is greater.

5.3 Criteria for Acceptable QC Procedures. Repeated excessive inaccuracies (i.e., out-of-control conditions resulting from the quarterly or yearly audits) indicate that the QC procedures

are inadequate or that the CEMS is incapable of providing quality data. Therefore, whenever excessive inaccuracies occur for two consecutive quarters, you must revise the QC procedures (see section 3.0) or modify or replace the CEMS.

5.4 Criteria for Optional QA Test Frequency. If all the quality criteria are met in sections 4 and 5 of this procedure, the CEMS is in-control.

5.5.1 Unless otherwise specified in an applicable rule or permit, if the CEMS is in-control and if your source emits ≤ 75 percent of the EtO emission limit for each averaging period as specified in the relevant standard for eight consecutive quarters that include a minimum of two RATAs, you may revise your auditing procedures to use CGA, RAA or DSA each quarter for seven subsequent quarters following a RATA.

5.5.2 You must perform at least one RATA that meets the acceptance criteria every 2 years.

5.5.3 If you fail a RATA, RAA, CGA, or DSA, then the audit schedule in section 5.2 must be followed until the audit results meet the criteria in section 5.3.4 to start requalifying for the optional QA test frequency in section 5.5.

6.0 Calculations for CEMS Data Accuracy

6.1 RATA RA Calculation. Follow Equations 9 through 14 in section 12 of PS-19 in appendix B to this part to calculate the RA for the RATA. The RATA must be calculated either in units of the applicable emission standard or in concentration units (ppbv).

6.2 RAA Accuracy Calculation. Use Equation 7-2 to calculate the accuracy for the RAA. The RA may be calculated in concentration units (ppmv) or in the units of the applicable emission standard.

$$RA = \frac{MN_{avg} - RM_{avg}}{RM_{avg}} \times 100 \quad \text{Eq. 7-2}$$

Where:

RA = Accuracy of the CEMS (percent)

MN_{avg} = Average measured CEMS response during the audit in units of applicable standard or appropriate concentration.

RM_{avg} = Average reference method value in units of applicable standard or appropriate concentration.

6.3 CGA Accuracy Calculation. For each gas concentration, determine the average of the three CEMS responses and subtract the average response from the audit gas value. For extractive CEMS, calculate the ME at each gas level using Equation 3A in section 12.3 of PS-19 of appendix B to this part.

6.4 DSA Accuracy Calculation. DSA accuracy is calculated as a percent of span. To calculate the DSA accuracy for each upscale spike concentration, first calculate the DSE using Equation A5 in appendix A of PS-19 in appendix B to this part. Then use Equation 7-3 to calculate the average DSA accuracy for each upscale spike concentration. To calculate DSA accuracy at the zero level, use equation 3A in section 12.3 of PS-19 in appendix B to this part.

$$\text{DSA Accuracy} = \frac{\sum_1^3 \left[\frac{|DSE_i|}{S} \right]}{3} \times 100 \quad \text{Eq. 7-3}$$

7.0 Reporting Requirements

At the reporting interval specified in the applicable regulation or permit, report for each CEMS the quarterly and annual accuracy audit results from section 6 and the daily assessment results from section 4. Unless otherwise specified in the applicable regulation or permit, include all data sheets, calculations, CEMS data records (i.e., charts, records of CEMS responses), reference gas certifications and reference method results necessary to confirm that the performance of the CEMS met the performance specifications.

7.1 Unless otherwise specified in the applicable regulations or permit, report the daily assessments (CD and beam intensity) and accuracy audit information at the interval for emissions reporting required under the applicable regulations or permits.

7.1.1 At a minimum, the daily assessments and accuracy audit information reporting must contain the following information:

- a. Company name and address.
- b. Identification and location of monitors in the CEMS.
- c. Manufacturer and model number of each monitor in the CEMS.
- d. Assessment of CEMS data accuracy and date of assessment as determined by a RATA, RAA, CGA or DSA described in section 5 including:
 - i. The RA for the RATA;
 - ii. The accuracy for the CGA, RAA, or DSA;
 - iii. The RM results, the reference gas certified values;
 - iv. The CEMS responses;
 - v. The calculation results as defined in section 6; and
 - vi. Results from the performance audit samples described in section 5 and the applicable RMs.

e. Summary of all out-of-control periods including corrective actions taken when CEMS was determined out-of-control, as described in sections 4 and 5. 7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report

both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

8.0 Bibliography

1. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, U.S. Environmental Protection Agency office of Research and Development, EPA/600/R-12/531, May 2012.

2. Method 205, “Verification of Gas Dilution Systems for Field Instrument Calibrations,” 40 CFR part 51, appendix M.

9.0 Tables, Diagrams, Flowcharts [Reserved]