

[67 FR 6994, Feb. 14, 2002]

APPENDIX TO SUBPART EEE OF PART
63—QUALITY ASSURANCE PROCEDURE
S FOR CONTINUOUS EMISSIONS
MONITORS USED FOR HAZARDOUS
WASTE COMBUSTORS

1. *Applicability and Principle*

1.1 *Applicability.* These quality assurance requirements are used to evaluate the effectiveness of quality control (QC) and quality assurance (QA) procedures and the quality of data produced by continuous emission monitoring systems (CEMS) that are used for determining compliance with the emission standards on a continuous basis as specified in the applicable regulation. The QA procedures specified by these requirements represent the minimum requirements necessary for the control and assessment of the quality of CEMS data used to demonstrate compliance with the emission standards provided under this subpart EEE of part 63. Owners and operators must meet these minimum requirements and are encouraged to develop and implement a more extensive QA program. These requirements supersede those found in part 60, Appendix F, of this chapter. Appendix F does not apply to hazardous waste-burning devices.

1.2 *Principle.* 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 a control loop. When the assessment function indicates that the data quality is inadequate, the source must immediately stop burning hazardous waste. The CEM data control effort must be increased until the data quality is acceptable before hazardous waste burning can resume.

a. In order to provide uniformity in the assessment and reporting of data quality, this procedure explicitly specifies the assessment methods for response drift and accuracy. The methods are based on procedures included in the applicable performance specifications provided in appendix B to part 60 of this chapter. These procedures also require the analysis of the EPA audit samples concurrent with certain reference method (RM) analyses as specified in the applicable RM's.

b. 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 each source owner or operator to develop a QC system that is most effective and efficient for the circumstances.

2. *Definitions*

2.1 *Continuous Emission Monitoring System (CEMS).* The total equipment required for the determination of a pollutant concentration. The system consists of the following major subsystems:

2.1.1 *Sample Interface.* That portion of the CEMS used for one or more of the following: sample acquisition, sample transport, and sample conditioning, or protection of the monitor from the effects of the stack effluent.

2.1.2 *Pollutant Analyzer.* That portion of the CEMS that senses the pollutant concentration and generates a proportional output.

2.1.3 *Diluent Analyzer.* That portion of the CEMS that senses the diluent gas (O₂) and generates an output proportional to the gas concentration.

2.1.4 *Data Recorder.* That portion of the CEMS that provides a permanent record of the analyzer output. The data recorder may provide automatic data reduction and CEMS control capabilities.

2.2 *Relative Accuracy (RA).* The absolute mean difference between the pollutant concentration determined by the CEMS and the value determined by the reference method (RM) plus the 2.5 percent error confidence coefficient of a series of test divided by the mean of the RM tests or the applicable emission limit.

2.3 *Calibration Drift (CD).* The difference in the CEMS output readings from the established reference value after a stated period of operation during which no unscheduled maintenance, repair, or adjustment took place.

2.4 *Zero Drift (ZD).* The difference in CEMS output readings at the zero pollutant level after a stated period of operation during which no unscheduled maintenance, repair, or adjustment took place.

2.5 *Calibration Standard.* Calibration standards produce a known and unchanging response when presented to the pollutant analyzer portion of the CEMS, and are used to calibrate the drift or response of the analyzer.

2.6 *Relative Accuracy Test Audit (RATA).* Comparison of CEMS measurements to reference method measurements in order to evaluate relative accuracy following procedures and specification given in the appropriate performance specification.

2.7 *Absolute Calibration Audit (ACA).* Equivalent to calibration error (CE) test defined in the appropriate performance specification using NIST traceable calibration standards to challenge the CEMS and assess accuracy.

2.8 *Rolling Average.* The average emissions, based on some (specified) time period, calculated every minute from a one-minute average of four measurements taken at 15-second intervals.

3. QA/QC Requirements

3.1 QC Requirements. a. Each owner or operator must develop and implement a QC program. At a minimum, each QC program must include written procedures describing in detail complete, step-by-step procedures and operations for the following activities.

1. Checks for component failures, leaks, and other abnormal conditions.
2. Calibration of CEMS.
3. CD determination and adjustment of CEMS.
4. Integration of CEMS with the automatic waste feed cutoff (AWFCO) system.
5. Preventive Maintenance of CEMS (including spare parts inventory).
6. Data recording, calculations, and reporting.
7. Checks of record keeping.
8. Accuracy audit procedures, including sampling and analysis methods.
9. Program of corrective action for malfunctioning CEMS.
10. Operator training and certification.
11. Maintaining and ensuring current certification or naming of cylinder gasses, metal solutions, and particulate samples used for audit and accuracy tests, daily checks, and calibrations.

b. Whenever excessive inaccuracies occur for two consecutive quarters, the current written procedures must be revised or the CEMS modified or replaced to correct the deficiency causing the excessive inaccuracies. These written procedures must be kept on record and available for inspection by the enforcement agency.

3.2 QA Requirements. Each source owner or operator must develop and implement a QA plan that includes, at a minimum, the following.

1. QA responsibilities (including maintaining records, preparing reports, reviewing reports).
2. Schedules for the daily checks, periodic audits, and preventive maintenance.
3. Check lists and data sheets.
4. Preventive maintenance procedures.
5. Description of the media, format, and location of all records and reports.
6. Provisions for a review of the CEMS data at least once a year. Based on the results of the review, the owner or operator must revise or update the QA plan, if necessary.

4. CD and ZD Assessment and Daily System Audit

4.1 *CD and ZD Requirement.* Owners and operators must check, record, and quantify the ZD and the CD at least once daily (ap-

proximately 24 hours) in accordance with the method prescribed by the manufacturer. The CEMS calibration must, at a minimum, be adjusted whenever the daily ZD or CD exceeds the limits in the Performance Specifications. If, on any given ZD and/or CD check the ZD and/or CD exceed(s) two times the limits in the Performance Specifications, or if the cumulative adjustment to the ZD and/or CD (see Section 4.2) exceed(s) three times the limits in the Performance Specifications, hazardous waste burning must immediately cease and the CEMS must be serviced and recalibrated. Hazardous waste burning cannot resume until the owner or operator documents that the CEMS is in compliance with the Performance Specifications by carrying out an ACA.

4.2 *Recording Requirements for Automatic ZD and CD Adjusting Monitors.* Monitors that automatically adjust the data to the corrected calibration values must record the unadjusted concentration measurement prior to resetting the calibration, if performed, or record the amount of the adjustment.

4.3 *Daily System Audit.* The audit must include a review of the calibration check data, an inspection of the recording system, an inspection of the control panel warning lights, and an inspection of the sample transport and interface system (e.g., flowmeters, filters, etc.) as appropriate.

4.4 *Data Recording and Reporting.* All measurements from the CEMS must be retained in the operating record for at least 5 years.

5. Performance Evaluation for CO, O₂, and HC CEMS

Carbon Monoxide (CO), Oxygen (O₂), and Hydrocarbon (HC) CEMS. An Absolute Calibration Audit (ACA) must be conducted quarterly, and a Relative Accuracy Test Audit (RATA) (if applicable, see sections 5.1 and 5.2) must be conducted yearly. An Interference Response Tests must be performed whenever an ACA or a RATA is conducted. When a performance test is also required under §63.1207 to document compliance with emission standards, the RATA must coincide with the performance test. The audits must be conducted as follows.

5.1 *Relative Accuracy Test Audit (RATA).* This requirement applies to O₂ and CO CEMS. The RATA must be conducted at least yearly. Conduct the RATA as described in the RA test procedure (or alternate procedures section) described in the applicable Performance Specifications. In addition, analyze the appropriate performance audit samples received from the EPA as described in the applicable sampling methods.

5.2 *Absolute Calibration Audit (ACA).* The ACA must be conducted at least quarterly except in a quarter when a RATA (if applicable, see section 5.1) is conducted instead.

Conduct an ACA as described in the calibration error (CE) test procedure described in the applicable Performance Specifications.

5.3 *Interference Response Test.* The interference response test must be conducted whenever an ACA or RATA is conducted. Conduct an interference response test as described in the applicable Performance Specifications.

5.4 *Excessive Audit Inaccuracy.* If the RA from the RATA or the CE from the ACA exceeds the criteria in the applicable Performance Specifications, hazardous waste burning must cease immediately. Hazardous waste burning cannot resume until the owner or operator takes corrective measures and audit the CEMS with a RATA to document that the CEMS is operating within the specifications.

6. Other Requirements

6.1 *Performance Specifications.* CEMS used by owners and operators of HWCs must comply with the following performance specifications in appendix B to part 60 of this chapter:

TABLE I: PERFORMANCE SPECIFICATIONS FOR CEMS

CEMS	Performance specification
Carbon monoxide	4B
Oxygen	4B
Total hydrocarbons	8A

6.2 *Downtime due to Calibration.* Facilities may continue to burn hazardous waste for a maximum of 20 minutes while calibrating the CEMS. If all CEMS are calibrated at once, the facility must have twenty minutes to calibrate all the CEMS. If CEMS are calibrated individually, the facility must have twenty minutes to calibrate each CEMS. If the CEMS are calibrated individually, other CEMS must be operational while the individual CEMS is being calibrated.

6.3 Span of the CEMS.

6.3.1 *CO CEMS.* The CO CEM must have two ranges, a low range with a span of 200 ppmv and a high range with a span of 3000 ppmv at an oxygen correction factor of 1. A one-range CEM may be used, but it must meet the performance specifications for the low range in the specified span of the low range.

6.3.2 *O₂ CEMS.* The O₂ CEM must have a span of 25 percent. The span may be higher than 25 percent if the O₂ concentration at the sampling point is greater than 25 percent.

6.3.3 *HC CEMS.* The HC CEM must have a span of 100 ppmv, expressed as propane, at an oxygen correction factor of 1.

6.3.4 *CEMS Span Values.* When the Oxygen Correction Factor is Greater than 2. When an owner or operator installs a CEMS at a location of high ambient air dilution, *i.e.*, where the maximum oxygen correction factor as determined by the permitting agency is greater than 2, the owner or operator must install a CEM with a lower span(s), proportionate to the larger oxygen correction factor, than those specified above.

6.3.5 *Use of Alternative Spans.* Owner or operators may request approval to use alternative spans and ranges to those specified. Alternate spans must be approved in writing in advance by the Administrator. In considering approval of alternative spans and ranges, the Administrator will consider that measurements beyond the span will be recorded as values at the maximum span for purposes of calculating rolling averages.

6.3.6 *Documentation of Span Values.* The span value must be documented by the CEMS manufacturer with laboratory data.

6.4.1 *Moisture Correction.* Method 4 of appendix A, part 60 of this chapter, must be used to determine moisture content of the stack gasses.

6.4.2 *Oxygen Correction Factor.* Measured pollutant levels must be corrected for the amount of oxygen in the stack according to the following formula:

$$P_c = P_m \times 14 / (E - Y)$$

Where:

P_c = concentration of the pollutant or standard corrected to 7 percent oxygen, dry basis;

P_m = measured concentration of the pollutant, dry basis;

E = volume fraction of oxygen in the combustion air fed into the device, on a dry basis (normally 21 percent or 0.21 if only air is fed);

Y = measured fraction of oxygen on a dry basis at the sampling point.

The oxygen correction factor is:

$$OCF = 14 / (E - Y)$$

6.4.3 *Temperature Correction.* Correction values for temperature are obtainable from standard reference materials.

6.5 *Rolling Average.* A rolling average is the arithmetic average of all one-minute averages over the averaging period.

6.5.1 *One-Minute Average for CO and HHC CEMS.* One-minute averages are the arithmetic average of the four most recent 15-second observations and must be calculated using the following equation:

$$\bar{c} = \sum_{i=1}^4 \frac{c_i}{4}$$

Where:

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\bar{c} = the one minute average

c_i = a fifteen-second observation from the CEM

Fifteen second observations must not be rounded or smoothed. Fifteen-second observations may be disregarded only as a result of a failure in the CEMS and allowed in the source's quality assurance plan at the time of the CEMS failure. One-minute averages must not be rounded, smoothed, or disregarded.

6.5.2 Ten Minute Rolling Average Equation. The ten minute rolling average must be calculated using the following equation:

$$C_{RA} = \sum_{i=1}^{10} \frac{\bar{c}_i}{10}$$

Where:

C_{RA} = The concentration of the standard, expressed as a rolling average

\bar{c}_i = a one minute average

6.5.3 *Hourly Rolling Average Equation for CO and THC CEMS and Operating Parameter Limits.* The rolling average, based on a specific number integer of hours, must be calculated using the following equation:

$$C_{RA} = \sum_{i=1}^{60} \frac{\bar{c}_i}{60}$$

Where:

C_{RA} = The concentration of the standard, expressed as a rolling average

\bar{c}_i = a one minute average

6.5.4 Averaging Periods for CEMS other than CO and THC. The averaging period for CEMS other than CO and THC CEMS must be calculated as a rolling average of all one-hour values over the averaging period. An hourly average is comprised of 4 measurements taken at equally spaced time intervals, or at most every 15 minutes. Fewer than 4 measurements might be available within an hour for reasons such as facility downtime or CEMS calibration. If at least two measurements (30 minutes of data) are available, an hourly average must be calculated. The n -hour rolling average is calculated by averaging the n most recent hourly averages.

6.6 Units of the Standards for the Purposes of Recording and Reporting Emissions. Emissions must be recorded and reported expressed after correcting for oxygen, temperature, and moisture. Emissions must be reported in metric, but may also be reported in the English system of units, at 7 percent oxygen, 20 °C, and on a dry basis.

6.7 Rounding and Significant Figures. Emissions must be rounded to two significant figures using ASTM procedure E-29-90

or its successor. Rounding must be avoided prior to rounding for the reported value.

7. Bibliography

1. 40 CFR part 60, appendix F, "Quality Assurance Procedures: Procedure 1. Quality Assurance Requirements for Gas continuous Emission Monitoring Systems Used For Compliance Determination".

[64 FR 53038, Sept. 30, 1999, as amended at 65 FR 42301, July 10, 2000]

Subpart FFF [Reserved]

Subpart GGG—National Emission Standards for Pharmaceuticals Production

SOURCE: 63 FR 50326, Sept. 21, 1998, unless otherwise noted.

§ 63.1250 Applicability.

(a) *Definition of affected source.* (1) The affected source subject to this subpart consists of the pharmaceutical manufacturing operations as defined in § 63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) (i) through (iii) of this section:

(i) Manufacture a pharmaceutical product as defined in § 63.1251;

(ii) Are located at a plant site that is a major source as defined in section 112(a) of the Act; and

(iii) Process, use, or produce HAP.

(2) Determination of the applicability of this subpart shall be reported as part of an operating permit application or as otherwise specified by the permitting authority.

(b) *New source applicability.* A new affected source subject to this subpart and to which the requirements for new sources apply is: An affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction; or a pharmaceutical manufacturing process unit (PMPU) dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any