April 2, 2026

MEMORANDUM

TO: Docket ID No. EPA-HQ-OAR-2019-0178

FROM: Brian Langloss, Physical Scientist, U.S. EPA

SUBJECT: Proposed changes to the Commercial Sterilization Facilities 2024 Final Rule

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The attachments to this memorandum, for the convenience of interested parties, present the proposed changes to performance specification (PS) 19, PS 19 Appendix A, and PS 19 Appendix B of 40 CFR 60 Appendix B, procedure 7 of 40 CFR 60 Appendix F, and 40 CFR 63 Subpart O provided in the final rule "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (89 FR 24090).

Attachment 1: PS 19 of 40 CFR 60 Appendix B regulatory text with proposed changes in redline/strikeout

Attachment 2: PS 19 Appendix A of 40 CFR 60 Appendix B regulatory text with proposed changes in redline/strikeout

Attachment 3: PS 19 Appendix B of 40 CFR 60 Appendix B regulatory text with proposed changes in redline/strikeout

Attachment 4: Procedure 7 of 40 CFR 60 Appendix F regulatory text with proposed changes in redline/strikeout

Attachment 5: 40 CFR 63 Subpart O regulatory text with proposed changes in redline/strikeout

Attachment 1:

PS 19 of 40 CFR 60 Appendix B regulatory text with proposed changes

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Title 40 → Chapter I → Subchapter C → Part 60→ Appendix B

Title 40: Protection of Environment
PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

Performance Specification 19-Performance Specifications and Test Procedures for Ethylene Oxide (ETO) Continuous Emission Monitoring Systems

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1.0 Scope and Application

1.1 Analyte. This performance specification (PS) is applicable for measuring gaseous concentrations of Ethylene Oxide (EtO), CAS: 775-21-8, on a continuous basis in the units of the applicable standard or in units that can be converted to units of the applicable standard(s) (*e.g.,* lbs/hr). This performance specification may be approved for the measurement of other pollutants and/or in other sectors by the Administrator on a case-by-case basis if not otherwise allowed or denied in an applicable subpart of the regulations.

1.2 Applicability.

1.2.1 This specification is used to evaluate the acceptability of EtO continuous emission monitoring systems (CEMS) at the time of installation or soon after and whenever specified in the regulations. The specification includes requirements for initial acceptance including instrument accuracy and stability assessments and use of audit samples if they are available.

1.2.2 The Administrator may require the operator, under section 114 of the Clean Air Act, to conduct CEMS performance evaluations at other times besides the initial test to evaluate the CEMS performance. See 40 CFR part 60, § 60.13(c) and § 63.8(e)(1).

1.2.3 A source that demonstrates their CEMS meets the criteria of this PS may use the system to continuously monitor gaseous EtO under any regulation or permit that requires compliance with this PS. If your CEMS reports the EtO concentration in the units of the applicable standard, no additional CEMS components are necessary. If your CEMS does not report concentrations in the units of the existing standard, then other CEMS (*i.e.,* oxygen) or CEMS components (*e.g.,* temperature, stack gas flow, moisture, and pressure) may be necessary to convert the units reported by your CEMS to the units of the standard.

1.2.4 These specification test results are intended to be valid for the life of the system. As a result, the EtO measurement system must be tested and operated in a configuration consistent with the configuration that will be used for ongoing continuous emissions monitoring.

1.2.5 Substantive changes to the system configuration require retesting according to this PS. Examples of such conditions include but are not limited to: major changes in dilution ratio (for dilution-based systems); changes in sample conditioning and transport, if used, such as filtering device design or materials; changes in probe design or configuration and changes in materials of construction. Changes consistent with instrument manufacturer upgrade that fall under manufacturer's certification do not require additional field verification. Manufacturer's upgrades (*e.g.,* changes to the quantification algorithm) require recertification by the manufacturer for those requirements allowed by this PS, including interference, and level of detection (LOD).

1.2.6 This specification is not designed to evaluate the ongoing CEMS performance, nor does it identify specific calibration techniques and auxiliary procedures to assess CEMS performance over an extended period of time. The requirements in Procedure 7 to Appendix F of this part are designed to provide a way to assess CEMS and CEMS components (if applicable) performance over an extended period of time. The source owner or operator is responsible to calibrate, maintain, and operate the CEMS properly.

2.0 Summary of Performance Specification

2.1 This specification covers the procedures that each EtO CEMS must meet during the performance evaluation test. Installation and measurement location specifications, data reduction procedures, and performance criteria are included.

2.2 The technology used to measure EtO must provide a distinct response and address any appropriate interference correction(s). It must accurately measure EtO in a representative sample of stack effluent.

2.3 The relative accuracy (RA) must be established against a reference method (RM) (*i.e.,* Method 320, or other alternative approved as a RM by the Administrator) on a case-by-case basis if not otherwise allowed or denied in an applicable subpart of the regulations.

2.4 A standard addition (SA) procedure using a reference standard is included in appendix A to this performance specification for use in verifying LOD. For extractive CEMS, where the SA is done by dynamic spiking (DS), the appendix A procedure is allowed as an option for assessing calibration drift and is also referenced by Procedure 7 of appendix F to this part for ongoing quality control tests.

3.0 Definitions

3.1 *Calibration drift* (CD) means the absolute value of the difference between the CEMS output response and an upscale reference gas or a zero-level gas, expressed as a percentage of the span value, when the CEMS is challenged after a stated period of operation during which no unscheduled adjustments, maintenance or repairs took place. For other parameters that are selectively measured by the CEMS (*e.g.,* temperature, velocity, pressure, flow rate) to measure in

the units of the applicable standard, use two analogous values (*e.g.,* Low: 0-20% of full scale, High: 50-100% of full scale).

3.2 *Calibration Span* means the calibrated portion of the measurement range as specified in the applicable regulation or another requirement. If the span is not specified in the applicable regulation or other requirement, then it must be a value approximately equivalent to three times the applicable emission standard. When the emission standard is expressed as mass emissions, use the average flow rate in the duct to calculate the concentration equivalent of the emission standard.

3.3 *Centroidal area* means a central area that is geometrically similar to the stack or duct cross section and is no greater than 10 percent of the stack or duct cross-sectional area.

3.4 *Continuous Emission Monitoring System* (CEMS) means the total equipment required to measure the pollutant concentration or emission rate continuously. The system generally consists of the following three major subsystems:

3.4.1 *Sample interface* means that portion of the CEMS used for one or more of the following: Sample acquisition, sample transport, sample conditioning, and protection of the monitor from the effects of the stack effluent.

3.4.2 *EtO analyzer* means that portion of the EtO CEMS that measures the total vapor phase EtO concentration and generates a proportional output.

3.4.3 *Data recorder* means that portion of the CEMS that provides a permanent electronic record of the analyzer output. The data recorder may record other pertinent data such as effluent flow rates, various instrument temperatures or abnormal CEMS operation. The data recorder may also include automatic data reduction capabilities and CEMS control capabilities.

3.5 *Diluent gas* means a major gaseous constituent in a gaseous pollutant mixture. For combustion sources, either carbon dioxide (CO_2) or oxygen (O_2) or a combination of these two gases are the major gaseous diluents of interest.

3.6 *Dynamic spiking (DS)* means the procedure where a known concentration of EtO gas is injected into the probe sample gas stream for extractive CEMS at a known flow rate to assess the performance of the measurement system in the presence of potential interference from the flue gas sample matrix.

3.7 *Flow Rate Sensor* means that portion of the CEMS that senses the volumetric flow rate and generates an output proportional to that flow rate. The flow rate sensor shall have provisions to check the CD for each flow rate parameter that it measures individually (*e.g.,* velocity, pressure).

3.8 *Independent measurement(s)* means the series of CEMS data values taken during sample gas analysis separated by two times the procedure specific response time (RT) of the CEMS.

3.9 *Interference* means a compound or material in the sample matrix other than EtO whose characteristics may bias the CEMS measurement (positively or negatively). The interference may not prevent the sample measurement but could increase the analytical uncertainty in the

measured EtO concentration through reaction with EtO or by changing the electronic signal generated during EtO measurement.

3.10 *Interference test* means the test to detect CEMS responses to interferences that are not adequately accounted for in the calibration procedure and may cause measurement bias.

3.11 *Level of detection (LOD)* means the lowest level of pollutant that the CEMS can detect in the presence of the source gas matrix interferents with 99 percent confidence.

3.12 *Measurement error (ME)* is the mean difference between the concentration measured by the CEMS and the known concentration of a reference gas standard, divided by the span, when the entire CEMS, including the sampling interface, is challenged.

3.13 *Reference gas standard* means the gas mixture containing EtO at a known concentration and produced and certified in accordance with "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards," September 1997, as amended August 25, 1999, EPA-600/R-97/121 or more recent updates. The tests for analyzer measurement error, calibration drift, and system bias require the use of calibration gas prepared according to this protocol. If a zero gas is used for the low-level gas, it must meet the requirements under the definition for "zero air material" in 40 CFR 72.2. Alternatively, if the "protocol" gas is not commercially available, you must use a reference gas that has been prepared according to the procedures in appendix B of this PS.

3.14 *Relative accuracy (RA)* means the absolute mean difference between the gas concentration, or the emission rate determined by the CEMS, and the value determined by the RM, plus the confidence coefficient of a series of nine test runs, divided by the average of the RM or the applicable emission standard.

3.15 *Response time (RT)* means the time it takes for the measurement system, while operating normally at its target sample flow rate, dilution ratio, or data collection rate to respond to a known step change in gas concentration, either from a low- or zero-level to a high-level gas concentration or from a high-level to a low or zero-level gas concentration, and to read 95 percent of the change to the stable instrument response. There may be several RTs for an instrument related to different functions or procedures (*e.g.,* DS, LOD, and ME).

3.16 *Span value* means an EtO concentration approximately equal to two times the concentration equivalent to the emission standard unless otherwise specified in the applicable regulation, permit or another requirement. Unless otherwise specified, the span may be rounded up to the nearest multiple of 5.

3.17 *Stable value* means the measure of two or more values that are statistically the same and indicate the absence of measurement system drift.

3.18 *Standard addition* means the addition of known amounts of EtO gas (either statically or dynamically) to the actual measurement path or measured sample gas stream.

3.19 *Zero gas* means a gas with an EtO concentration that is below the LOD of the measurement system.

4.0 Interferences

Sample gas interferences will vary depending on the instrument or technology used to make the measurement. Interferences must be evaluated through the interference test in this PS. Several compounds including carbon dioxide (CO_2), carbon monoxide (CO), methane (CH_4), and water (H_2O) are potential optical interferences with certain types of EtO monitoring technology.

Note: Interferences may be mitigated though the use of dilution systems, however this approach could also affect the sensitivity of the measurement.

5.0 Safety

The procedures required under this PS may involve hazardous materials, operations, and equipment. This PS may not address all the safety issues associated with these procedures. It is the responsibility of the user to establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. The CEMS user's manual and as well as cautions within and materials recommended by the RM should be consulted for specific precautions to be taken in regard to the relative accuracy testing.

6.0 Equipment and Supplies

The equipment and supplies are the same as in section 6 of PS 18, except replace HCl for EtO where appropriate. The following definitions are added and/or revised:

6.1 Moisture Measurement System. If correction of the measured EtO emissions for moisture is required, you must install, operate, maintain, and quality assure a continuous moisture monitoring system for measuring and recording the moisture content of the flue gases. The following continuous moisture monitoring systems are acceptable: Any optical measurement system validated according to Method 301 or section 13.0 of Method 320 in appendix A to part 63 of this chapter; a continuous moisture sensor; an oxygen analyzer (or analyzers) capable of measuring O_2 both on a wet basis and on a dry basis; or other continuous moisture measurement methods approved by the Administrator.

7.0 Reagents and Standards

7.1 Reference Gases means the gas mixture containing EtO at a known concentration and produced and certified in accordance with “EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R-12/531) or more recent updates. The tests for analyzer measurement error, calibration drift, and system bias require the use of calibration gas prepared according to this protocol. If a zero gas is used for the low-level gas, it must meet the requirements under the definition for “zero air material” in 40 CFR 72.2. Alternatively, if the “protocol” gas is not commercially available, you must use a reference gas that has been prepared according to the procedures in appendix B of this PS and meeting the requirements in section 12.2 of appendix B of this PS, if applicable.

7.2 Cylinder gas may be diluted for use in this specification, including measurement error testing. You must document the quantitative introduction of EtO standards into the system using Method 205, found in 40 CFR part 51, appendix M, or other procedure approved by the Administrator. The laboratory/field evaluations in Method 205 must be conducted at least quarterly and prior to any audit test (*e.g.,* CGA, RAA) required in QA Procedure 7 (40 CFR part 60, appendix F). Calibration must be conducted on an annual basis or whenever significant changes are made to the dilution system. In addition to the requirements in Method 205, when in use, you must document gas flow rates through each of the channels; if the dilution system records these values electronically, this is considered the documentation. For the purpose of this PS, cylinder gas should not be diluted beyond a dilution ratio of 500:1 using Method 205.

8.0 CEMS Measurement Location Specifications and Pretest Preparation

8.1 Prior to the start of your initial PS tests, you must ensure that the CEMS is installed according to the manufacturer's specifications and the requirements in this section.

8.2 CEMS Installation. Install the CEMS at an accessible location where the pollutant concentration or emission rate measurements are directly representative of the EtO emissions. If the units of the emission standard are expressed as a mass (*e.g.,* lb/hr), then the CEMS probe must also be located within 0.5 equivalent diameters of the flow sensor and the CEMS must be located (1) at least two equivalent diameters downstream from the nearest control device, the point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur and (2) at least a half equivalent diameter upstream from the effluent exhaust or control device. If the CEMS are to utilize time-sharing, the distance between each measurement point and the CEMS should be approximately the same. The CEMS need not be installed at the same location as the relative accuracy test location. If you fail the RA requirements in this specification due to the CEMS measurement location and a satisfactory correction technique cannot be established, the Administrator may require the CEMS to be relocated.

8.2.1 Single point sample gas extraction should be (1) no less than 1.0 m (3.3 ft.) from the stack or duct wall or (2) within the centroidal area of the stack or duct cross section.

8.2.2 CEMS and Data Recorder Scale Check. After CEMS installation, record and document the measurement range of the EtO CEMS. The CEMS operating range and the range of the data recording device must encompass all potential and expected EtO concentrations, including the concentration equivalent to the applicable emission limit and the span value.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization—Reserved

11.0 Performance Specification Test Procedure

After completing the CEMS installation, setup, and calibration, you must complete the PS test procedures in this section. You must perform the following procedures and meet the performance requirements for the initial demonstration of your CEMS:

a. Interference Test;

b. Level of Detection Determination;

c. Response Time Test;

d. Measurement Error Test;

e. Calibration Drift Test; and

f. Relative Accuracy Test.

g. If CEMS is to be time-shared, determine the response time to each measurement point, the sampling time at each measurement point, and the cycle time at each measurement point. The sampling time at each measurement point shall be at least 3 times as long as the system response time (RT), and the maximum number of measurement points shall not exceed the quotient, rounded down to the next whole number, of 15 minutes divided by the longest cycle time of the measurement point.

11.1 *Interference Test*

11.1.1 Prior to its initial use in the field, you must demonstrate that your monitoring system meets the performance requirements of the interference test in section 13.5 of this PS to verify that the candidate system measures EtO accurately in the presence of common interferences in emission matrices from commercial sterilizers. In the event this performance specification is applied in other emission sources, the interference test must evaluate any other predominant gases is the emission matrices of those sources.

11.1.2 Your interference test must be conducted in a controlled environment. The equipment you test for interference must include the combination of the analyzer, related analysis software, and any sample conditioning equipment (*e.g.,* dilution module, moisture removal equipment or other interferent scrubber) used to control interferents.

11.1.3 If you own multiple measurement systems with components of the same make and model numbers, you need only perform this interference test on one analyzer and associated interference conditioning equipment combination. You may also rely on an interference test conducted by the manufacturer or a continuous measurement system integrator on a system having components of the same make(s) and model(s) of the system that you use.

11.1.4 Perform the interference check using an EtO reference gas concentration of approximately ten times the LOD or at 50 parts per billion, whichever is greater.

11.1.5 Introduce the interference test gases listed in table 1 in section 17.0 of this PS to the analyzer/conditioning system separately or in any combination. The interference test gases need not be of reference gas quality.

11.1.6 The interference test must be performed by combining an EtO reference gas with each interference test gas (or gas mixture). You must measure the baseline EtO response, followed by the response after adding the interference test gas(es) while maintaining a constant EtO concentration. You must perform each interference gas injection and evaluation in triplicate.

Note: The baseline EtO gas may include interference gases at concentrations typical of ambient air (*e.g.,* 21 percent O_2, 400 parts per million (ppm) CO_2, 2 percent H_2O), but these concentrations must be brought to the concentrations listed in table 1 of this PS when their interference effects are being evaluated.

11.1.7 You should document the gas volume/rate, temperature, and pressure used to conduct the interference test. A gas blending system or manifold may be used.

11.1.8 Ensure the duration of each interference test is sufficient to condition the EtO measurement system surfaces before a stable measurement is obtained.

11.1.9 Measure the EtO response of the analyzer/sample conditioning system combination to the test gases in ppbv. Record the responses and determine the overall interference response using table 2 in section 17.0 of this PS.

11.1.10 For each interference gas (or mixture), calculate the mean difference (ΔMC_{avg}) between the measurement system responses with and without the interference test gas(es) using equation 1 in section 12.2 of this PS. Summarize the results following the format contained in table 2 in section 17.

11.1.11 Calculate the percent interference (I) for the gas runs using equation 2 in section 12.2 of this PS.

11.1.12 The total interference response (*i.e.,* the sum of the interference responses of all tested gaseous components) must not exceed the criteria set forth in section 13.5 of this PS.

11.2 Level of Detection Determination

11.2.1 You must determine the minimum amount of EtO that can be detected above the background in a representative gas matrix.

11.2.2 You must perform the LOD determination in a controlled environment such as a laboratory or manufacturer's facility.

11.2.3 You must add interference gases listed in table 1 of this PS to a constant concentration of EtO reference gas.

11.2.3.1 You may not use an effective reference EtO gas concentration greater than ten times the estimated instrument LOD.

11.2.3.2 Inject the EtO and interferents described in section 11.1.5 of this PS directly into the inlet to the analyzer, allow time for the value to stabilize and then collect measurement data for 15 minutes and average those results. Repeat this procedure to obtain a total of seven or more of these runs, purging the measurement system with ambient air between each run, to determine the LOD.

11.2.4 Calculate the standard deviation of the measured values and define the LOD as three times the standard deviation of these measurements.

11.2.5 You must verify the controlled environment LOD of section 11.2.2 of this PS for your CEMS during initial setup and field certification testing using the SA procedure in appendix A of this PS with the following exceptions:

11.2.5.1 You must make three independent SA measurements spiking the native source concentration by no more than five times the controlled environment LOD concentration determined in section 11.2.4.

11.2.5.2 You must perform the SA as a dynamic spike by passing the spiked source gas sample through all filters, scrubbers, conditioners, and other monitoring system components used during normal sampling, and as much of the sampling probe as practical.

11.2.5.3 The amount detected, or standard addition response (SAR), is based on the average difference of the native EtO concentration in the stack or duct relative to the native stack concentration plus the SA. You must be able to detect the effective spike addition (ESA) above the native EtO present in the stack gas matrix. The ESA is calculated using equation A7 in appendix A of this PS.

11.2.5.4 If the field verification of your system LOD does not demonstrate a SAR greater than or equal to your initial controlled environment LOD, you must increase the SA concentration incrementally and repeat the field verification procedure until the SAR is equal to or greater than LOD. The site-specific standard addition detection level (SADL) is equal to the standard addition needed to achieve the acceptable SAR, and the SADL replaces the controlled environment LOD. The SADL is calculated as the ESA using equation A7 in appendix A of this PS. As described in section 13.1 of this PS, the controlled environment LOD or the SADL that replaces a controlled environment LOD must be less than 20 percent of the applicable emission limit.

11.3 Response Time Determination. You must determine ME- and SA-RT.

11.3.1 For ME-RT, start the upscale RT determination by injecting zero gas into the measurement system as required by the procedures in section 11.4 of this PS. For the SA-RT start the upscale RT determination at native stack concentration of EtO. Allow the value to stabilize, which for the purpose of this PS is no change greater than 1.0 percent of span or 10 ppbv (whichever is greater) for 30 seconds.

11.3.2 When the CEMS output has stabilized, record the response in ppbv, record the time (hh:mm:ss), and immediately introduce an upscale (high level) or spike reference gas as required by the relevant (ME-RT or SA-RT) procedure. Record the time (hh:mm:ss) required for the measurement system to reach 95 percent of the change to the final stable value, the difference in these times is the upscale RT.

11.3.3 Reintroduce the zero gas for the ME-RT or stop the upscale gas flow for the SA-RT and immediately record the time (hh:mm:ss). Record the time (hh:mm:ss) required to reach within 95 percent of the previous stable response in 11.3.1 or 10 ppbv (whichever is greater); the difference in these times is the downscale RT.

Note: For CEMS that perform a series of operations (purge, blow back, sample integration, analyze, etc.), you must start adding reference or zero gas immediately after these procedures are complete.)

11.3.4 Repeat the entire procedure until you have three sets of data, then determine the mean upscale and mean downscale RTs for each relevant procedure (from each measurement point if the CEMS is time-sharing). Report the greater of the average upscale or average downscale RTs as the RT for the system.

11.4 Measurement Error (ME) Test

11.4.1 The measurement error test must be performed at the same time as the calibration drift test when the system is being placed in service. The measurement error test must be performed any time a substantive change (see section 1.2.5) has been made to the measurement system.

11.4.1.1 Introduce reference gases to the CEMS probe, prior to the sample conditioning and filtration system. You may use a gas dilution system meeting the requirement in section 7.2 of this PS.

11.4.1.2 Challenge the measurement system with a zero gas and at the three upscale EtO reference gas concentrations in the range shown in table 3 of this PS. You may introduce different reference gas concentrations in any order, but you must not introduce the same gas concentration twice in succession.

11.4.1.3 Introduce the calibration gas into the sampling probe with sufficient flow rate to replace the entire source gas sample and continue the gas flow until the response is stable, as evidenced when the difference between two consecutive measurements is within 1.0 percent of span or 5 ppbv (whichever is less). Record this value and inject the next calibration gas.

11.4.1.4 Make triplicate measurements for each reference gas for a total of twelve measurements.

11.4.1.5 At each reference gas concentration, determine the average of the three CEMS responses (MC_l). Calculate the ME using equation 3A in section 12.3.

11.4.1.6 For non-dilution systems, you may adjust the system to maintain the correct flow rate at the analyzer during the test, but you may not make adjustments for any other purpose. For dilution systems, you must operate the measurement system at the appropriate dilution ratio

during all system ME checks, and you may make only the adjustments necessary to maintain the proper ratio.

11.4.2 You may use table 5 in section 17.0 to record and report your ME test results.

11.4.3 If the ME specification in section 13.3 is not met for all four reference gas concentrations, take corrective action, and repeat the test until an acceptable 4-level ME test is achieved.

11.5 Seven-Day Calibration Drift (CD) Test

11.5.1 The CD Test Period. Prior to the start of the RA tests, you must perform a seven-day CD test. The purpose of the seven-day CD test is to verify the ability of the CEMS to maintain calibration for each of seven consecutive unit operating days as specified in section 11.5.5 of this PS.

11.5.2 The CD tests must be performed using the zero gas and high-level reference gas standards as defined in table 3 of this PS.

11.5.3 Conduct the CD test on each day during continuous operation of the CEMS and normal facility operations following the procedures in section 11.4 of this PS, except that the zero gas and high-level gas need only be introduced to the measurement system once each for the seven days.

11.5.4 If periodic automatic or manual adjustments are made to the CEMS zero and upscale response factor settings, conduct the CD test immediately before these adjustments.

Note: Automatic signal or mathematical processing of all measurement data to determine emission results may be performed throughout the entire CD process.

11.5.5 Determine the magnitude of the CD at approximately 24-hour intervals, for 7 consecutive unit operating days. The 7 consecutive unit operating days need not be 7 consecutive calendar days.

11.5.6 Record the CEMS response for single measurements of zero gas and high-level reference gas. You may use table 6 in section 17 of this PS to record and report the results of your 7-day CD test. Calculate the CD using equation 3B in section 12.3. Report the absolute value of the differences as a percentage of the span value.

11.5.7 The zero-level and high-level CD for each day must be less than 5.0 percent of the span value or an absolute difference of 10 ppbv, as specified in section 13.2 of this PS. You must meet this criterion for 7 consecutive operating days.

11.5.8 Dynamic Spiking Option for Seven-Day CD Test. You have the option to conduct a high-level dynamic spiking procedure for each of the 7 days in lieu of the high-level reference gas injection described in sections 11.5.2 and 11.5.3. If this option is selected, the daily zero CD check is still required.

11.5.8.1 To conduct each of the seven daily mid-level dynamic spikes, you must use the DS procedure described in appendix A of this PS using a single spike chosen to yield the range as indicated in table 3.

11.5.8.2 You must perform the dynamic spike procedure by passing the spiked source gas sample through all filters, scrubbers, conditioners, and other monitoring system components used during normal sampling, and as much of the sampling probe as practical.

11.5.8.3 Calculate the high-level CD as a percent of span using equation A6 of appendix A to this PS and calculate the zero-drift using equation 3B in section 12.3. Record and report the results as described in sections 11.5.6 and 11.5.7.

11.6 Relative Accuracy Test

11.6.1 Unless otherwise specified in an applicable regulation, use Method 320 as the RM for EtO measurement. Conduct the RM tests in such a way that they will yield results representative of the emissions from the source that can be compared to the CEMS data. You must collect gas samples that are at stack conditions (hot and wet), and you must traverse the stack or duct as required in section 11.6.3.

11.6.2 Conduct the diluent (if applicable), moisture (if needed), and pollutant measurements simultaneously. If the emission standard is expressed in a mass unit (*i.e.,* lb/hr) you must also determine the flow rate simultaneously with each test using Method 2, 2A, 2B, 2C or 2D in appendix A-1 to this part, as applicable.

11.6.3 Reference Method Measurement Location and Traverse Point(s) Selection.

11.6.3.1 Measurement Location. Select, as appropriate, an accessible RM measurement location at least two equivalent diameters downstream from the nearest control device, point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur, and at least one-half equivalent diameter upstream from the effluent exhaust or a control device. When pollutant concentration changes are due solely to diluent leakage (*e.g.,* air heater leakages) and pollutants and diluents are simultaneously measured at the same location, a half diameter may be used in lieu of two equivalent diameters. The equivalent duct diameter is calculated according to Method 1 in appendix A-1 to this part. The CEMS and RM sampling locations need not be the same.

11.6.3.2 Traverse Point Selection. Select traverse points that assure acquisition of representative RM samples over the stack or duct cross section according to one of the following options: (a) sample at twelve traverse points located according to section 11.3 of Method 1 in appendix A-1 to this part or (b) sample at the three traverse points at 16.7, 50.0, and 83.3 percent of the measurement line. Alternatively, you may conduct a stratification test following the procedures in sections 11.6.3.2.1 through 11.6.3.2.4 to justify sampling at a single point. Stratification testing must be conducted at the sampling location to be used for the RM measurements during the RA test and must be made during normal facility operating conditions. You must evaluate the

stratification by measuring the gas on the same moisture basis as the EtO CEMS (wet or dry). Stratification testing must be repeated for each RA test program to justify single point.

11.6.3.2.1 Use a probe of appropriate length to measure the EtO concentration, as described in this section, using 12 traverse points located according to section 11.3 of Method 1 in appendix A-1 to this part for a circular stack or nine points at the centroids of similarly shaped, equal area divisions of the cross section of a rectangular stack.

11.6.3.2.2 Calculate the mean measured concentration for all sampling points (MN_{avg}).

11.6.3.2.3 Calculate the percent stratification (S_t) of each traverse point using equation 5 in section 12.5.

11.6.3.2.4 The gas stream is considered to be unstratified and you may perform the RA testing at a single point that most closely matches the mean if the concentration at each traverse point differs from the mean measured concentration for all traverse points by no more than 5.0 percent of the mean concentration of EtO or 10 ppbv, whichever is less restrictive.

11.6.4 In order to correlate the CEMS and RM data properly, record the beginning and end of each RM run (including the time of day in hours, minutes, and seconds) using a clock synchronized with the CEMS clock used to create a permanent time record with the CEMS output.

11.6.5 You must conduct the RA test during representative process and control operating conditions or as specified in an applicable regulation, permit or subpart.

11.6.6 Conduct a minimum of nine RM test runs.

Note: More than nine RM test runs may be performed. If this option is chosen, up to three test run results may be excluded so long as the total number of test run results used to determine the CEMS RA is greater than or equal to nine. However, all data must be reported including the excluded test runs.

11.6.7 Analyze the results from the RM test runs using equations 6 through 11 in section 12.6. Calculate the RA between the CEMS results and the RM results.

11.7 Record Keeping and Reporting

11.7.1 Record the results of the CD test, the RT test, the ME test, and the RA test. Also keep records of the RM and CEMS field data, calculations, and reference gas certifications necessary to confirm that the performance of the CEMS met the performance specifications.

11.7.2 For systems that use Method 205 to prepare EtO reference gas standards, record results of Method 205 performance test field evaluation, reference gas certifications, and gas dilution system calibration.

11.7.3 Record the LOD and field verified SADL for the CEMS in ppbv.

11.7.4 Record the results of the interference test.

11.7.5 Report the results of all certification tests to the appropriate regulatory agency (or agencies), in hardcopy and/or electronic format, as required by the applicable regulation or permit.

12.0 Calculations and Data Analysis

12.1 Nomenclature.

C_i = Zero or EtO reference gas concentration used for test i (ppbv);

CC = Confidence coefficient (ppbv);

CD = Calibration drift (percent);

d_{avg} = Mean difference between CEMS response and the reference gas (ppbv);

d_i = Difference of CEMS response and the RM value (ppbv or units of emission standard, as applicable);

I = Total interference from major matrix stack gases (percent);

ΔMC_{avg} = Average of the 3 absolute values of the difference between the measured EtO calibration gas concentrations with and without interference from selected stack gases (ppbv);

MC_i = Measured EtO (or zero) reference gas concentration i (ppbv);

MC_i = Average of the measured EtO (or zero) reference gas concentration i (ppbv);

MC_{int} = Measured EtO concentration of the EtO reference gas plus the individual or combined interference gases (ppbv);

ME = Measurement error for CEMS (percent);

MN_{avg} = Average concentration at all sampling points (ppbv);

MN_{bi} = Measured native concentration bracketing each calibration check measurement (ppbv);

MN_i = Measured native concentration for test or run I (ppbv);

n = Number of measurements in an average value;

RA = Relative accuracy of CEMS compared to a RM (percent);

RM_{avg} = Mean measured RM value (ppbv) or units of the emission standard);

RM_i = RM concentration for test run i (ppbv or units of the emission standard);

S = Span value (ppmv);

S_d = Standard deviation of the differences (ppmv);

S_{ti} = Stratification at traverse point i (percent);

SADL = Standard addition detection level (ppmv);

$t_{0.975}$ = One-sided t-value at the 97.5th percentile obtained from table 4 in section 17.0 for n-1 measurements;

12.2 Calculate the difference between the measured EtO concentration with and without interferents for each interference gas (or mixture) for your CEMS as:

$$\Delta MC_{avg}=\frac{\sum_{i=1}^{3}|MC_i-MC_{int}|}{3} \quad \text{Eq. 1}$$

Calculate the total percent interference as:

$$I=\sum_{i=1}^{n}\frac{\Delta MC_{avg}}{\overline{MC_i}}x100 \quad \text{Eq. 2}$$

12.3 Calculate the ME or CD at Concentration i as:

$$ME=\frac{|C_i-\overline{MC_i}|}{S} \quad \text{Eq. 3A}$$

$$CD=\frac{|C_i-MC_i|}{S} \quad \text{Eq. 3B}$$

12.4 Calculate the average native concentration before and after each calibration check measurement as:

$$MN_{bi}=\frac{MN_i+MN_{i+1}}{2} \quad \text{Eq. 4}$$

12.5 Calculate the Percent Stratification at Each Traverse Point as:

$$S_{ti}=\frac{|MN_i-MN_{avg}|}{MN_{avg}} \quad \text{Eq. 5}$$

12.6 Calculate the RA Using RM and CEMS Data

12.6.1 Determine the CEMS final integrated average pollutant concentration or emission rate for each RM test period. Consider system RT, if important, and confirm that the results have been corrected to the same moisture, temperature, and diluent concentration basis, as applicable. If the emission standard is based on a mass emission (*i.e.,* lbs/hr), confirm the results have been calculated correctly.

12.6.3 Make a direct comparison of the average RM results and CEMS average value for identical test periods.

12.6.4 For each test run, calculate the arithmetic difference of the RM and CEMS results using equation 6.

$$d_i = RM_i - MN_i \quad \text{Eq. 6}$$

12.6.5 Calculate the standard deviation of the differences (S_d) of the CEMS measured results and RM results using equation 7.

$$S_d = \sqrt{\frac{\sum_i^n \left(d_i - \left(\sum_{i=1}^n d_i\right)\right)^2}{n-1}} \quad \text{Eq. 7}$$

12.6.6 Calculate the confidence coefficient (CC) for the RA test using equation 8.

$$CC = t_{0.975}\left(\frac{S_d}{(n^{1/2})}\right) \quad \text{Eq. 8}$$

12.6.7 Calculate the mean difference (d_{avg}) between the RM and CEMS values in the units of ppbv or of the emission standard using equation 9.

$$d_{avg} = \frac{1}{n}\sum_{i=1}^{n} d_i \quad \text{Eq. 9}$$

12.6.8 Calculate the average RM value using equation 10.

$$RM_{avg} = \frac{1}{n}\sum_{i=1}^{n} RM_i \quad \text{Eq. 10}$$

12.6.9 Calculate RA of the CEMS using equation 11.

$$RA = \left[\frac{(|d_{avg}| + CC)}{RM_{avg}}\right] x100 \quad \text{Eq. 11}$$

13.0 Method Performance

13.1 Level of Detection. You may not use a CEMS whose LOD or SADL is greater than 20 percent of the applicable regulatory limit or other action level for the intended use of the data. If the regulatory limit is not based on a concentration, document the calculated concentration equivalent.

13.2 Calibration Drift. The zero- and high-level calibration drift for the CEMS must not exceed 5.0 percent of the span value or an absolute difference of 10.0 ppbv for 7 consecutive operating days.

13.3 Measurement Error. The ME must be less than or equal to 5.0 percent of the span or an absolute difference of 10.0 ppbv value at the low-, mid-, and high-level reference gas concentrations.

13.4 Relative Accuracy. Unless otherwise specified in an applicable regulation or permit, the RA of the CEMS, whether calculated in units of EtO concentration or in units of the emission standard, must be less than or equal to 20.0 percent of the RM when RM_{avg} is used in the denominator of equation 11.

13.4.1 In cases where the RA is calculated on a concentration (ppmv) basis, if the average RM emission level for the test is less than 50 percent of the EtO concentration equivalent to the emission standard, you may substitute the EtO concentration equivalent to the standard in the denominator of equation 11 in place of RM_{avg}.

13.4.2 Similarly, if the RA is calculated in units of the emission standard and the EtO emission level measured by the RMs is less than 50 percent of the emission standard, you may substitute the emission standard in the denominator of equation 11 in place of RM_{avg}.

13.4.3 The alternative calculated RA in paragraph 13.4.1 or 13.4.2 must be less than or equal to 15.0 percent.

13.5 Interference Test.

13.5.1 The sum of the interference response(s) from equation 2 must not be greater than 2.5 percent of the calibration span or ±3.0 percent of the equivalent EtO concentration used for the interference test, whichever is less restrictive. The results are also acceptable if the sum of the interference response(s) does not exceed ten times the LOD or 30 ppbv.

14.0 Pollution Prevention—[Reserved]

15.0 Waste Management—[Reserved]

16.0 Bibliography

1. “Method 301—Field Validation of Pollutant Measurement Methods from Various Waste Media,” 40 CFR part 63, appendix A.

2. 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.

17.0 Tables, Diagrams, Flowcharts, and Validation Data

Table 1—Interference Test Gas Concentrations

Potential interferent gas[1]	Approximate concentration (balance N_2)
CO_2	1% ± 0.2% CO_2
CH_4	20 ± 5 ppm.
H_2O	5% ± 1% H_2O.[1]
N_2	Balance.[1]

[1] *Any of these specific gases can be tested at a lower level if the manufacturer has provided reliableness for limiting or scrubbing that gas to a specified level in CEMS field installations.*

Table 2—Example Interference Test Data Sheet

Date of Test	
Analyzer type	
Model Number	
Serial Number	
Span	
Test Organization	
Test Personnel	

Interference Gas or Combination	EtO Concentration (ppbv)	EtO Concentration w/ Interference (ppbv)	Absolute Difference (ppbv)	Average Absolute Difference (ppbv)

Table 3—Performance Specification Test Zero and Reference Gas Ranges

Test	Units	EtO Zero and Reference Gas Concentrations in Terms of Percent of Span[a]				Section
		Zero	Low Level	Mid-Level	High Level	
Calibration Drift	% Of Span	<LOD	NA		[b] 80-100	11.5
Measurement Error	% Of Span	NA	20-30	50-60	80-100	11.4

[a] *Reference gas concentration must be NIST traceable. (See section 7.1)*

[b] *High-level is required. For DS calibration drift option, choose a concentration that yields a value in this range at the analyzer.*

Table 4—Student's t-Values

n-1[a]	t-value	n-1[a]	t-value	n-1[a]	t-value
1	12.71	11	2.201	21	2.080
2	4.303	12	2.179	22	2.074
3	3.182	13	2.160	23	2.069
4	2.776	14	2.145	24	2.064
5	2.571	15	2.131	25	2.060
6	2.447	16	2.120	26	2.056
7	2.365	17	2.110	27	2.052
8	2.306	18	2.101	28	2.048
9	2.262	19	2.093	29	2.045
10	2.228	20	2.086	30	2.042

[a] *The value n is the number of independent pairs of measurements. Either discrete (independent) measurements in a single run or run averages can be used.*

Table 5 – Measurement Error Test Data

Source:			Date:		
CEMS:			Location:		
Serial Number:			Span:		
Run Number	Reference gas Value (ppbv)	CEMS Response (ppbv)	Difference – Low (ppbv)	Difference – Low (ppbv)	Difference – Low (ppbv)
1					
2					
3					
4					
5					
6					
7					
8					
9					
Mean Difference – ppbv					
Measurement Error - %					

Table 6 – Calibration Drift Test Data

Source/Location						
CEMS						
Instrument Serial Number						
Instrument Span						
Day	Date	Time	Reference Gas Value (ppbv)	CEMS Response (ppbv)	Difference (ppbv)	Percent of Span
Zero Gas						
1			0			
2			0			
3			0			
4			0			
5			0			
6			0			
7			0			
High-Level Gas						
1						
2						
3						
4						
5						
6						
7						

Attachment 2:

PS 19 Appendix A of 40 CFR 60 Appendix B regulatory text with proposed changes

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Title 40 → Chapter I → Subchapter C → Part 60→ Appendix B

Title 40: Protection of Environment
PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

PS-19 Appendix A Standard Addition Procedures

1.0 Scope and Application

1.1 This appendix A (appendix PS-19A) to Performance Specification 19 (PS-19) describes the procedure and performance requirements for standard addition (SA) as a quality check for ethylene oxide (EtO) continuous emission monitoring systems (CEMS).

1.2 This procedure must be used, as a level of detection (LOD) verification of all field-installed CEMS. Additionally, it is allowed by Procedure 7 in appendix F to this part as an alternative to upscale calibration drift (CD) tests, cylinder gas audits and relative accuracy audits (RAAs), and may be used for quality assurance purposes under other applicable regulations or permits that require EtO monitoring.

2.0 Summary of the Appendix for Standard Addition

As used here, SA is a gas phase method of standard additions (either static or dynamic) used to verify the accuracy of CEMS measurements in the presence of the sample matrix. For extractive CEMS, it consists of spiking a known quantity of EtO dynamically into the measurement system as an addition to the native EtO and the native source gas matrix.

3.0 Definitions

(See PS-19 and Procedure 7 of appendix F to this part for the Definitions Used in this appendix.)

4.0 Interferences

Interferences are discussed in PS-19, section 4.0.

5.0 Safety

The procedures required under this appendix may involve hazardous materials, operations, and equipment. This procedure may not address all of the safety problems associated with these procedures. You as the facility or operator must establish appropriate safety and health practices

and determine the applicable regulatory limitations prior to performing these procedures. As the CEMS user, you should consult instrument operation manuals, material safety data sheets, compressed gas safety requirements, and other Occupational Safety and Health Administration regulations for specific precautions to be taken.

6.0 Equipment and Supplies

An example of equipment and supplies is described in section 6 of PS-18.

7.0 Reagents and Standards

SA materials must meet the requirements defined for reference gases in section 7 of PS-19 to perform this procedure.

8.0 Standard Addition and Dynamic Spiking Procedure

The standard addition procedure consists of measuring the native source gas concentration, addition of reference gas, and measurement of the resulting SA elevated source gas concentration. EtO is spiked dynamically and thus, one must account for the dilution of sample gas from the addition of the EtO reference gas.

8.1 SA Concentration and Measurement Replicates.

8.1.1 You must inject EtO gas to create a measured concentration based on the requirements of the particular performance test (*e.g.,* LOD verification, CD).

8.1.2 Each dynamic spike (DS) or standard addition (SA) replicate consists of a measurement of the source emissions concentration of EtO (native stack concentration) with and without the addition of EtO. With a single CEMS, you must alternate the measurement of the native and SA-elevated source gas so that each measurement of SA-elevated source gas is immediately preceded and followed by a measurement of native stack gas. Introduce the SA gases in such a manner that the entire CEMS is challenged. Alternatively, you may use an independent continuous EtO monitor to measure the native source concentration before and after each standard addition as described in section 8.1.4.

8.1.3 Unless specified otherwise by an applicable rule, your SA-elevated concentration may not exceed 100 percent of span when the SA and native EtO concentration are combined.

8.1.4 As an alternative to making background measurements pre- and post-SA, you may use an independent continuous EtO monitor as a temporary unit to measure native stack EtO concentration while simultaneously using the CEMS to measure the SA-elevated source concentration. If you use an independent continuous EtO monitor you must make one concurrent background or native EtO measurement using both the installed CEMS and the independent continuous EtO monitor, immediately before the SA procedure in section 8.2 begins, to confirm that the independent monitoring system measures the same background concentration as the CEMS being qualified with this PS.

8.2 Dynamic Spiking Procedure.

8.2.1 Your EtO spike addition must not alter the total volumetric sample system flow rate or basic dilution ratio of your CEMS (if applicable).

8.2.2 Your spike gas flow rate must not contribute more than 10 percent of the total volumetric flow rate through the CEMS.

8.2.3 You must determine a dilution factor (DF) or relative concentration of EtO for each dynamic spike. Calibrated, NIST-traceable flow meters accurate to within 2.0 percent or highly accurate tracer gas measurements are required to make the necessary DF determinations at the accuracy required for this PS. Calibrated, NIST-traceable flow meters (*e.g.,* venturi, orifice) accurate to within 2.0 percent should be recertified against an NIST-traceable flow meter annually. Note: Since the spiking mass balance calculation is directly dependent on the accuracy of the DF determination, the accuracy of measurements required to determine the total volumetric gas flow rate, spike gas flow rate, or tracer gas standard addition concentration is critical to your ability to accurately perform the DS procedure and calculate the results.

8.2.4 You must monitor and record the total sampling system flow rate and sample dilution factor (DF) for the spiking and stack gas sampling systems to ensure they are known and do not change during the spiking procedure. Record all data on a data sheet similar to table A1 in section 13 of this appendix.

8.2.4.1 You may either measure the spike gas flow and the total flow with calibrated flow meters capable of NIST traceable accuracy to ±2.0 percent or calculate the flow using a stable tracer gas included in your spike gas standard.

8.2.4.2 If you use flow measurements to determine the spike dilution, then use equation A1 in section 11.2.1 of this appendix PS-19A to calculate the DF. Determination of the spike dilution requires measurement of EtO spike flow (Q_{spike}) and total flow through the CEM sampling system (Q_{probe}).

8.2.4.3 If your CEMS is capable of measuring an independent stable tracer gas, you may use a spike gas that includes the tracer to determine the DF using equation A2 or A3 (sections 11.2.2 and 11.2.3 of this appendix PS-19A) depending on whether the tracer gas is also present in the native source emissions.

8.2.4.4 For extractive CEMS, you must correct the background measurements of EtO for the dilution caused by the addition of the spike gas standard. For spiking systems that alternate between addition of EtO and zero gas at a constant DF, the background measurements between spikes will not be equal to the native source concentration.

8.2.5 Begin by collecting unspiked sample measurements of EtO. You must use the average of two unspiked sample measurements as your pre-spike background.

Note: Measurements should agree within 5.0 percent or three times the level of detection to avoid biasing the spike results.

8.2.5.1 Introduce the EtO gas spike into the permanent CEMS probe, upstream of the particulate filter or sample conditioning system and as close to the sampling inlet as practical.

8.2.5.2 Maintain the EtO gas spike for at least twice the DS response time of your CEMS or until the consecutive measurements agree within 5.0 percent. Collect two independent measurements of the native plus spiked EtO concentration.

8.2.5.3 Stop the flow of spike gas for at least twice the DS response time of your CEMS or until the consecutive measurements agree within 5.0 percent. Collect two independent measurements of the native EtO concentration.

8.2.6 Repeat the collection of sample measurements in section 8.2.5 until you have data for each spike concentration including a final set of unspiked sample measurements according to section 8.2.5.3.

8.2.7 Verify that the CEMS responded as expected for each spike gas injection, and that the data quality is not impacted by large shifts in the native source concentration. Discard and repeat any spike injections as necessary to generate a complete set of the required replicate spike measurements.

8.2.8 Calculate the standard addition response (SAR) for extractive CEMS, using equation A4 in section 11.2, of this appendix PS-19A.

8.2.9 If the DS results do not meet the specifications for the appropriate performance test in PS-19 or Procedure 7 of appendix F of this part, you must take corrective action and repeat the DS procedure.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization—Reserved

11.0 Calculations and Data Analysis

Calculate the SA response for each measurement and its associated native EtO measurement(s), using equations in this section. (Note: For cases where the emission standard is expressed in units of lb/hr or corrected to a specified O_2 or CO_2 concentration, an absolute accuracy specification based on a span at stack conditions may be calculated using the average concentration and applicable conversion factors. The appropriate procedures for use in cases where a percent removal standard is more restrictive than the emission standard is the same as in PS-2, sections 12 and 13, in this appendix.)

11.1 Nomenclature.

C_{spike} = Actual EtO reference gas concentration spiked (*e.g.,* bottle or reference gas concentration) ppmv;

$C_{tracer\ spiked}$ = Tracer gas concentration injected with spike gas (“reference concentration”) ppmv;

DF = Spiked gas dilution factor;

DSCD = Calibration drift determined using DS procedure (percent);

DSE = Dynamic spike error (ppmv);

ESA = Effective spike addition (ppmv);

MCSA = Measured SA-elevated source gas concentration (ppmv);

MC_{spiked} = Measured EtO reference gas concentration i (ppmv);

MC_{native} = Average measured concentration of the native EtO (ppmv);

$M_{native\ tracer}$ = Measured tracer gas concentration present in native effluent gas (ppmv);

$M_{spiked\ tracer}$ = Measured diluted tracer gas concentration in a spiked sample (ppmv);

Q_{spike} = Flow rate of the dynamic spike gas (Lpm);

Q_{probe} = Average total stack sample flow through the system (Lpm);

S = Span (ppmv);

SAR = Standard addition response (ppmv)

11.2 Calculating Dynamic Spike Response and Error.

11.2.1 If you determine your spike DF using spike gas and stack sample flow measurements, calculate the DF using equation A1:

$$DF=\frac{Q_{spike}}{Q_{probe}} \qquad \text{Eq. A1}$$

11.2.2 If you determine your spike DF using an independent stable tracer gas that is not present in the native source emissions, calculate the DF for DS using equation A2:

$$DF=\frac{M_{spiked\ tracer}}{C_{tracer\ spiked}} \qquad \text{Eq. A2}$$

11.2.3 If you determine your spike dilution factor using an independent stable tracer that is present in the native source emissions, calculate the dilution factor for dynamic spiking using equation A3:

$$DF=\frac{M_{spiked\ tracer} - M_{native\ tracer}}{C_{tracer\ spiked} - M_{native\ tracer}} \qquad \text{Eq. A3}$$

11.2.4 Calculate the SA response using equation A4:

$$SAR=MC_{spiked}-(1-DF)xMC_{native} \qquad \text{Eq. A4}$$

11.2.5 Calculate the DS error using equation A5.

$$DSE=MC_{spiked}-MC_{native}-DFx(C_{spike}-MC_{native}) \quad \text{Eq. A5}$$

11.2.6 Calculating CD using DS. When using the DS option for determining mid-level CD, calculate the CD as a percent of span using equation A6:

$$DCSD=\frac{|DSE|}{S} \quad \text{Eq. A6}$$

11.2.7 The effective spike addition (ESA) is the expected increase in the measured concentration as a result of injecting a spike. Calculate ESA using equation A7:

$$ESA=DF(C_{spike}-MC_{native}) \quad \text{Eq. A7}$$

12.0 Reserved

13.0 Tables and Figures

Table A1—Spike Data Sheet

Facility Name:	Date:	Time:
Unit(s) Tested:	Personnel:	
Analyzer Make and Mode		
Serial Number		
Calibration Span		

Q_{probe} (lpm)	Q_{spike} (lpm)	DF[1]	MC_{native}			Actual Value (ppb)		DSE (ppbv)
			Pre	Post	Avg.	C_{spike}[2]	MC_{spike}[3]	
							Average	
							SD	

[1] DF must be less than or equal to 10%

[2] Cspike = Actual EtO concentration of the spike gas, ppbv

[3] MCspiked = Measured EtO concentration of the spiked sample at the target level, ppbv

Attachment 3:

PS 19 Appendix B of 40 CFR 60 Appendix B regulatory text with proposed changes

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Title 40 → Chapter I → Subchapter C → Part 60→ Appendix B

Title 40: Protection of Environment
PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

PS-19 Appendix B Preparation and Certification of Ethylene Oxide Gas Standards

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1.0 Scope and Application

1.1 This appendix (appendix PS-19B) to Performance Specification 19 (PS-19) describes the procedure and performance criteria for the preparation and certification of EtO Gas Manufacturer Primary Standards (GMPS) and Gas Manufacturer Alternative Certified Standards (GMACS). These procedures are not specific to ethylene oxide and could be transferable to the preparation of gas standards for other pollutants regulated under 40 CFR parts 59, 60, 61, 63, and 65.

2.0 Summary of the Appendix

EPA requires the use of EPA Protocol gas standards for emissions monitoring. These gases are established following the EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R-12/531) otherwise referred in this appendix PS-19B as the EPA Traceability Protocol. The EPA Traceability Protocol requires the use of certified reference gas standards directly traceable to National Institute of Standards and Technology (NIST) or other recognized national metrology institute (NMI) reference gas standards. A NIST certified value is a value for which NIST has the highest confidence in that all known or suspected sources of bias and imprecision have been accounted for. Without NIST or other NMI reference gas standards, the necessary EPA Protocol gas standards cannot be prepared. An alternative approach is needed to establish a gas standard functionally equivalent to the EPA Protocol gas standard when NIST or NMI reference gas standard are not available. This appendix PS-19B is intended to provide procedures and performance criteria for the establishment of Gas Manufacturer Alternative Certified Standards (GMACS), the functional equivalent of EPA Protocol gas standards. GMACS and Gas Manufacturer Primary Standards (GMPS), the functional equivalent of the NIST or NMI reference gas standards. The GMPS are the reference gases used to establish the certified concentrations of the GMACs. The GMPS are established using a dual certification approach where the gravimetrically prepared reference value is confirmed using an independent measurement approach traceable to the International System of Units (SI) and references materials or devices.

2.1 This appendix PS-19B is intended to be performance-based and allow specialty gas manufacturers (SGM) flexibility in the preparation and certification of GMPS and GMACS.

2.2 This appendix PS-19B is not intended to be a replacement for the EPA Protocol gases established according to the EPA Traceability Protocol when calibration gases that meet EPA Traceability Protocol requirements are available. When NIST or other recognized NMI reference gas standards are manufactured and readily available, those gases must be used.

2.3 This appendix PS-19B is reliant on the procedures included the EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R-12/531). Users of this appendix PS-19B for the preparation of GMPS and GMACS must be proficient with the preparation protocol cylinders using this standard.

Note: This appendix PS-19B does not require the user to participate in any protocol gas verification program.

2.4 Any alternatives to the procedures in this appendix PS-19B are subject to Administrator review under the alternative test method the authority to approve alternatives or changes to test methods specified in the General Provisions to 40 CFR parts 60, 61, and 63 (§§ 60.8(b)(2), 61.13(h)(1)(ii), and 63.7(e)(2)(ii)). Requests for alternative to the procedures must be submitted to the agency according to Guideline Document 22 (*https://www.epa.gov/system/files/documents/2022-09/gd-022r5.pdf*).

3.0 Definitions

3.1 *Certification* means a set of procedures and performance criteria used by a SGM to prepare and certify a GMPS and/or GMACS for commercial sale.

3.2 *Certified Reference Material or CRM* means a material that has been certified or verified by either NIST or other NMI (*e.g.,* VSL, NPL) and may be used for traceability purposes.

3.3 *Dual Method Certification* means a process in which the gravimetric value is independently confirmed by a measured value.

3.4 *EPA Protocol Gas* means a calibration or reference gas required for emissions monitoring directly traceable to NIST or other accepted NMI reference gas standards, prepared following the EPA Traceability Protocol

3.5 *EPA Traceable Protocol for Assay and Calibration Gas Standards or commonly referred to as the "EPA Traceability Protocol"* means the protocol that allows producers of these standards, users of gaseous standards, and other analytical laboratories to establish traceability of EPA Protocol Gases to gaseous reference standards produced by the National Institute of Standards and Technology (NIST).

3.6 *Gas Calibration Cylinder* means a refillable cylinder that meets the applicable DOT/TC specifications for high pressure cylinders. The cylinders shall be permanently stamped with a unique value.

3.7 *Gas Manufacturer Alternative Certified Standards or GMACS* means a gas that has been prepared according to this procedure and serves as a functional substitute for an EPA Protocol Gas where EPA Protocol gases are not available.

3.8 *Gas Manufacturer Intermediate Standard* means a gas reference standard made by a gas supplier and certified according to the U.S. EPA protocol rules for GMISs. For the purpose of this Appendix, GMISs may be assayed against a GMPS.

3.9 *Gas Manufacturer Primary Standards or GMPS* means a reference gas standard prepared and certified by the SGM that serves as a functional substitute for the reference gas standards established by, but not yet available from NIST or other accepted NMI and required by the EPA Traceability Protocol to produce EPA Protocol gases.

3.10 *Gravimetry* means the quantitative measurement of an analyte by weight.

3.11 *NIST* means the National Institute of Standards and Technology, located in Gaithersburg, Maryland.

3.12 *NIST Traceable Reference Material or NTRM* means is a reference material produced by a commercial supplier with a well-defined traceability linkage to NIST and named by NIST procedures, on a batch rather than individual basis. This linkage is established via criteria and protocols defined by NIST that are tailored to meet the needs of the metrological community to be served.

3.13 *Primary Reference Material or PRM* means a mixture composition that is verified against VSL's own primary standard gas mixtures to confirm the assigned value.

3.14 *Protocol Gas* means a calibration or reference gas required for emissions monitoring traceable to NIST or other accepted NMI, prepared following the EPA Traceability Protocol.

3.15 *Research Gas Mixture or RGM* means a reference material produced by a commercial supplier certified by NIST on an individual basis, often using non routine procedures, and may be used for traceability purposes.

3.16 *Specialty Gas Manufacturer or SGM* means an organization that prepares and certified gas calibration gas mixtures.

3.17 *International System of Units or SI* means the standards for international measurement and are comprised of length (meter), time (second), amount of substance (mole), electric current (ampere), temperature (kelvin), luminous intensity (candela), and mass (kilogram).

3.18 *Standard Reference Material or SRM* means a material or substance issued by NIST that meets NIST-specific certification criteria and is issues with that with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material.

3.19 *Uncertainty* means the expression of the statistical dispersion of the values attributed to a measured quantity. For the purpose of this appendix, uncertainty is calculated using the root sum

square of all uncertainty budget items associated with each procedure at k=2 (*i.e.,* approximately 95 confidence).

3.20 *VSL* means Van Swinden National Lab, located in Delft, Netherlands.

4.0 Interferences—Reserved

5.0 Safety

The procedures required under this appendix may involve hazardous materials, operations, and equipment. This procedure may not address all of the safety problems associated with these procedures. You as the facility or operator must establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. You should consult instrument operation manuals, material safety data sheets, compressed gas safety requirements, and other Occupational Safety and Health Administration regulations for specific precautions to be taken.

6.0 Equipment and Supplies

This procedure is not prescriptive on the type of equipment or the supplies necessary for the preparation of GMPS and GMACS gaseous cylinder standards, however SGM must use the appropriate equipment and supplies necessary to meet the uncertainty requirements in this appendix.

7.0 Reagents and Standards—Reserved

8.0 Procedures.

The exact procedures used will depend on the gas manufacturer and the physical characteristics of the compound being prepared as a gaseous calibration standard. Any procedure is deemed appropriate so long as the criteria in section 8.1 for GMPS and section 8.2 for GMACS are met.

8.1 *Preparation and Certification of the GMPS.*

The GMPS certified value is established using the dual certification approach. A candidate GMPS cylinder is prepared gravimetrically, and its established reference value is confirmed by an independent measurement traceable to SI units as well as other appropriate reference materials. The level of agreement between the gravimetric reference value and the SI-based independent measurements along with the average value and associated, combined, expanded uncertainties serve to establish the certified reference value. If high purity reference material is not readily available for a gravimetric preparation, a user may petition the Administrator for an alternative method for preparation of a GMPS.

The procedures for the gravimetric preparation, stability evaluation, and independent verification of GMPS must meet the criteria in this section following the procedures in 8.1(*a*) through (g).

(a) Raw Materials

(b) GMPS Gravimetric Cylinder Preparation/Creation

(c) GMPS Cylinder Independent Verification

(d) GMPS Cylinder Certification

(e) GMPS Cylinder Stability Testing

(f) GMPS Cylinder Expiration Period

(g) GMPS Documentation

8.1.1 Raw Materials. Raw materials used in the production of GMPS must be of high quality (*e.g.,* 99+% purity recommended). Additionally, because raw material purity is the largest component of uncertainty in gas gravimetry, SGMs must substantiate the purity of the raw material prior to use, either via (1) a validated certificate of analysis for the actual lot number purchased provided by the raw material vendor, or (2) a purity assay conducted by the SGM on the actual raw material to be used. The uncertainty of the raw material (U_r) assay must be included as one of the components of the total combined uncertainty for the mixture.

8.1.2 GMPS Gravimetric Cylinder Preparation/Creation. The GMPS standards shall be based on a gravimetric preparation. The gravimetric preparation shall yield an expected concentration for the target component, and with the required statistical controls in place to calculate the uncertainty of that concentration.

8.1.2.1 The scale used to generate the gravimetric reference standard must be independently calibrated over the range of target masses with ASTM E617-13 Class-1 weights on no less than a yearly basis. For such certifications, a high accuracy mass comparator (electronic or pendulum-type scale) is employed as the "scale." The resolution of the scale should be sufficient to be able to calculate the overall uncertainty of any concentration derived from these steps.

8.1.2.1.1 The scale used for the gravimetric operation must be independently calibrated and traceable to NIST standards with a defined uncertainty (u_t).

8.1.2.1.2 The scale calibration must be checked before the start of each new weighing operation (*i.e.,* the day of) with a weight in the appropriate range that also meets ASTM E617-13 Class-1 requirements.

8.1.2.1.3 All material and equipment associated with the gravimetric analysis shall have or apply a procedure to estimate the uncertainty of the measurement, including but not limited to the balance(s) used (u_{ca}) standard weight (u_w).

8.1.2.1.4 The assay purity and associated material uncertainty (u_r) of the assay for each component raw material and the balance gas must be known. This purity deviation is factored into the uncertainty of the mass of each material blended into the mixture.

8.1.2.1.5 The procedures below are minimum requirements and do not speak to all of the details an SRM would do to ensure the preparation of a high-accuracy gravimetric candidate GMPS, (*e.g.,* controls for external factors that would influence scale reading accuracy buoyancy effects,

moisture/dust adsorption on the cylinder surface, and errors caused by the location of the cylinder on the scale). The SGM should develop and follow and internal standard operation procedures (SOP) for the preparation of the candidate GMPS.

8.1.2.1.6 Record the Target cylinder identification number, blend date, and balance gas on the appropriate form (see figure B-1). Additionally, record the intended component(s) to be used in the preparation for this candidate GMPS, identifying the standard type, material name (*e.g.,* Ethylene Oxide), MW (g/mol), and purity (wt%).

8.1.2.1.7 Add the components to the candidate GMPS, recording the weight of each component added.

8.1.2.1.8 GMPS Gravimetric Uncertainty. Calculate and document the gravimetric concentration (GMPS-C_g) for each component of the candidate GMPS. You must also document the combined uncertainty, expressed as the root sum of the uncertainty budget items identified, for the candidate GMPS value (GMPS-C_{gu}). Gravimetric preparation uncertainty budget items include:

(a) The purity of the raw material and the balance gas;

(b) The measured accuracy of the (electronic) balance including consideration the uncertainty of the calibration weights, the calibration uncertainty, and its linearity;

(c) The repeatability of the balance readings including errors caused by the location of the cylinder on the balance;

(d) Balance Buoyancy effects;

(e) Effects of moisture adsorption and dust on the outer surface of the cylinder;

(f) Cylinder dilutions, if any, used to prepare target concentrations, including propagated uncertainties.

8.1.3 *GMPS Cylinder Independent Verification*. The certification of the candidate GMPS is based on independent measurements verifying the reference concentration of the gravimetrically prepared GMPS candidate. The independent verification must be based on a measurement approach traceable to the SI and may include the use of intrinsic NIST or accepted NMI reference materials to establish said traceability. Candidate independent verification measurement approaches include classical chemistry, spectroscopic approaches, as well as other instrumental approaches as long as adequate and appropriate SI traceability can be incorporated. The approach must be performed using NIST (or equivalent) traceable calibrations materials and using procedures that would allow the user to determine the overall uncertainty of the measurement. In some instances, a component may not be suitable to analysis using a classical approach, in those instances alternative approaches may be used do long as they (1) yield a concentration for the target component, (2) have a calculated uncertainty, (3) have traceability to the SI, and (4) documented conformity to the general metrological principles for primary methods outlined above.

8.1.3.1 *GMPS Independent Verification Measurement Uncertainty*. The cumulative uncertainty of the GMPS independent verification measurement approach is integral to the ability to assess the overall quality of the independent verification measurement. You must also document the combined uncertainty, expressed as the root sum of the uncertainty budget items identified. Ensure that all known or suspected sources of bias and imprecision have been accounted for. The following elements are examples of sources of measurement error that must be included in the overall uncertainty calculation for the GMPS independent verification measurement:

(a) The uncertainty of the certified reference solution (the traceability source);

(b) Any propagated uncertainties through serial dilutions;

(c) The errors in volumetric sampling of the candidate GMPS mixture;

(d) The uncertainty of the instrument calibration curve (least squares fit and residual);

(e) The bias or error associated with any measurement interferences;

(f) The repeatability of replicate aliquot injections from the same sample;

(g) The repeatability of replicate samples of the mixture;

(h) Any external factors influencing sampling or instrument accuracy;

(i) The uncertainty of measured volumetric gas flows;

(j) The bias or uncertainty associated with quantitative gas flow delivery;

(k) The error associated with instrumental measurement analyzers;

(l) Replicate measurement instrument error and precision.

8.1.4 GMPS Cylinder Certification. The candidate GMPS certified value is based on three factors:

(a) The relative agreement between the gravimetric reference value and the independent, measured value of the gravimetrically-prepared GMPS candidate;

(b) The combined, expanded uncertainty (k=2) of the gravimetric value and independently measured concentrations values;

(c) The average of the independently measured concentrations values.

8.1.4.1 GMPS Relative Agreement. Calculate the relative agreement according to equation B1, expressed as Relative Percent Difference (RPD) between the gravimetric concentration (GMPS-C_g) the independently measured concentrations (GMPS-C_a). The results of these two analyses must agree within 4.0 percent (%).

$$RPD = \frac{\text{GMPS-}C_g - \text{GMPS-}C_a}{\left(\frac{\text{GMPS-}C_g + \text{GMPS-}C_a}{2}\right)} \qquad \text{Eq. B1}$$

8.1.4.2 GMPS Combined, Expanded Uncertainty. Determine the individual uncertainties for the gravimetric approach (GMPS-C_{ug}) and the independent measurement verification approach (GMPS-C_{ua}) according to equation B2. Establish the GMPS combined, expanded uncertainty (GMPS-C_{uc}) as the root sum of the two individual uncertainties with a coverage factor k=2. The combined uncertainty must ≤5.0 percent (%). If these objectives are not met, the candidate GMPS is not acceptable, and must not be used.

$$\text{GMPS-}C_{ug} \text{ or GMPS-}C_{ua} = \sqrt{u_1^2 + u_2^2 + \cdots + u_i^2} \qquad \text{Eq. B2}$$

8.1.4.3 GMPS Certified Concentration Value. If the GMPS meets the Relative Agreement criteria in section 8.1.4.1 and the combined, expanded uncertainty criteria in section 8.1.4.2, the GMPS is valid. The GMPS certified value (GMPS-C_C) is based on the independently measurement concentration (GMPS-C_a). The certification date is the date of the last confirmatory measurement.

8.1.4.4 An SGM may propose to Administrator an alternative acceptance values for section 8.1.4.1 or 8.1.4.2 for those components that are unable to meet the documented criteria. These proposals must include sufficient documentation that the objectives are unreasonable for a given component and concentrations.

8.1.5 GMPS Cylinder Stability Testing. The SGM must test and document mixture stability of the GMPS to assure that the mixture stays within claimed accuracy bounds for the entire claimed expiration period. Alternatively, once a preparation process has been developed, the SGM can perform a stability study consisting not less than three cylinders prepared using the defined process and at the concentration(s) defined by the process. Once the stability study cylinders have demonstrated acceptable stability for the minimum expiration period (6-months), additional GMPS cylinders can be prepared under identical process conditions.

8.1.5.1 The SGM may select the sampling frequency based on the targeted expiration period, the gas consumed in the analysis and expected component behavior. Stability testing data must consist of at least:

(a) Five discrete samplings of the retained mixture for an expiration period of 6-months to 1-year;

(b) Ten discrete samplings for an expiration period of 1-3 years; and

(c) Twenty for any period greater than 3 years.

8.1.5.2 Stability testing must be conducted for each cylinder size/type and at a similar concentration as the candidate GMPS. Stability analyses must be performed using methods that assure consistent results can be achieved. If instrumental analysis using a gas standard is employed, use of a GMPS standard is highly recommended. In the absence of a certified GMPS, stability testing must be conducted using the same independent verification measurement procedures and methodology used in section 8.1.3, or using another known-to-be-stable gas standard containing the target component in a similar concentration range.

8.1.5.3 Stability testing data must not show any upward or downward trends that would cause the mixture to become out of specification prior to the claimed expiration period.

8.1.6 GMPS Cylinder Expiration Period. The expiration period for the GMPS mixture based must be based on the empirical stability test data. The expiration periods for reactive gases must not exceed the length of the stability test, however for non-reactive gases you may forecast an expiration period not to exceed two times the actual stability testing duration. The maximum expiration period for a GMPS is time span from the date of preparation to the date of the last/most recent stability study may not be less than 6-months. Provided that acceptable stability is observed, the maximum expiration period may be extended by retaining the stability study cylinders and performing additional analyses.

8.1.7 GMPS Documentation. You must document the preparation of the GMPS through the appropriate record keeping and document the certification of a GMPS. The information in section 8.1.7.1 and 8.1.7.2 must be maintained as a record by the SGM for the purpose of maintaining traceability and to verify the preparation. The information in section 8.1.7.3 must be documented and maintained by the SGM. This documentation and the records of the preparation and certification must be made available upon request by the appropriate delegated authority.

8.1.7.1 The following information for the gravimetric preparation information of the GMPS must be documented and maintained as a record. This record should include but is not limited to the: blend date, gravimetric concentration, gravimetric concentration uncertainties as a percentage and absolute, reference material information and purity, scale ID, scale accuracy, and calculated gravimetric uncertainties associated with material, balance, and environmental effects. You must include sufficient information that will allow a 3rd party to recalculate the prepared concentration and expanded uncertainties.

8.1.7.2 The following information for the analytical verification of the GMPS must be recorded and maintained as a record. This record should include the confirming methodology and any associated SOPs, confirming concentration(s), instrumentation used, calibration standards used and associated COAs, calibration curve data, replicate analysis calculated, and expanded uncertainties.

8.1.7.3 The following information must be documented for inclusion on the COA for the GMACS.

(a) Manufacturer's company name and address of the producing location

(b) Manufacturer's part number for the GMPS, lot number, and/or production record.

(c) Cylinder number, cylinder type, cylinder preparation ID, moisture dew point and cylinder pressure.

(d) Certification date and claimed expiration date.

(e) GMPS component(s) name, final certified concentration(s) (GMPS-C_c), and balance gas.

(f) Gravimetric value and uncertainty

(g)Verification value and uncertainty

(h) GMPS final certified value and uncertainty absolute as a percentage (GMPS-C_u)

8.2 Preparation and Certification of the GMACS. The preparation and certification of the candidate GMACS is also based on the independent verification of the gravimetrically prepared reference value. However, the independent verification utilizes the GMPS to perform the independent verification. This is accomplished by following the procedures in section 2.1 and 2.2 of the EPA Traceability Protocol, using the GMPS as the certified reference material. The measured value of the independent verification following the EPA Traceability Protocol procedures also establishes the certified reference value, providing the relative agreement performance criteria are met.

8.2.1 GMACS Gravimetric Cylinder Preparation/Creation. The gravimetric preparation of the GMACS is identical to the procedures used to gravimetrically prepare the GMPS. You must maintain the same information required for the gravimetric preparation of GMPS, as found in section 8.1.7.1 for GMACS, as a record.

8.2.2 GMACS Independent Verification and Certification. The candidate GMACS independent verification of the gravimetrically prepared reference value is contingent on the SGM following the procedures in sections 2.1 and 2.2 of the EPA Traceability Protocol. In addition, the EtO candidate GMACS certified reference value and associated expanded uncertainty is based on the EPA Traceability Protocol measured value. This is contingent upon the gravimetric and measured values meeting the relative agreement performance criteria established in section 8.1.4.1 and the uncertainty criteria established in section 8.1.4.2. Gas Manufacturers Intermediate Standards (GMIS) can be prepared by direct comparison to a GMPS that has been prepared and certified according to section 2.1.3.1 and 2.2 of the EPA Traceability Protocol. The tagged value of the GMACS must be based on the EPA Traceability Protocol measured value as long as the performance criteria in sections 12.1 and 12.2 are met.

8.2.3 GMACS Stability Testing. The SGM must test and document the stability of the GMACS to assure that the mixture stays within claimed certified bounds for the entire claimed expiration period. Use the procedures in section 8.1.5 to assess stability. The GMACS must also meet the requirements in section 2.1.5.2 of the EPA Traceability Protocol.

8.2.4 GMACS Expiration Date. The certification period of the GMACS shall be based on the documented stability tests of the GMPS in section 8.1.6. The expiration date shall be based on the certification date, plus the certification period plus one day. There is not a maximum period of expiration; however, expiration periods must not be less than six months.

8.2.5 GMACS Documentation You must document and maintain the same information required for the analytical verification of the GMPS, as found in section 8.1.7 for GMACS, as a record. The records of the preparation and certification must be made available upon request by the appropriate delegated authority.

8.2.6 GMACS Certificate of Analysis (COA). You must provide comprehensive documentation of the GMPS and GMACS development process in the form of a GMACS Certificate of

Analysis (COA) that accompanies each commercially distributed GMACS. As a minimum, the COA must contain the following information:

(a) Identification of the gas as a Gas Manufacturer Alternative Certified Standard;

(b) The cylinder number;

(c) The certified concentration of the GMACS;

(d) The combined expanded uncertainty (k=2) of the GMACS reference value (both absolute and relative);

(e) The expiration date;

(f) The reference materials or standards used (*i.e.,* GMPS and GMIS);

(g) The same information (cylinder number, certified concentration, uncertainties, expiration dates, etc. for these cylinders);

(h) The gravimetric and independent measured verification reference concentration values and associated uncertainties for each GMPS used;

(i) Associated measurement principles and uncertainties;

(j) Any additional information stipulated by the EPA Traceability Protocol;

(k) Any comments/special instructions.

The SGM GMACS provider is encouraged to include additional relevant information to the COA, as appropriate. An example GMACS COA can be found in section 16 of this appendix.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization

There is a myriad of instrumental and mechanical techniques used in the performance of this Appendix B. When reference methods are used, you must follow the calibration requirements of those methods and as defined in this appendix. For all other approaches, it is recommended to develop internal SOPs.

11.0 Calculations and Data Analysis—Reserved

12.0 Method Performance

12.1 GMPS/GMACS Relative Agreement. As part of the certification/verification procedures for the candidate GMPS and GMACS, the relative agreement between the gravimetrically prepared reference value and the independently measured verification value must agree within 4.0 percent (%).

12.2 GMACS/GMPS Uncertainty. Final certification of the GMPS and GMACS reference concentrations must meet the combined expanded uncertainty (k=2) of ≤5.0 percent (%).

13.0 Pollution Prevention—Reserved

14.0 Waste Management—Reserved

15.0 Bibliography

1. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, Office of Research and Development, National Risk Management Research Laboratory, May 2012, EPA 600/R-12/531. *https://www.epa.gov/air-research/epa-traceability-protocol-assay-and-certification-gaseous-calibration-standards*.

2. EPA Alternative Method 114, Approval of Alternative Method for preparation of HCl Gas Standards for PS-18 and Procedure 6, February 22, 2016, *https://www.epa.gov/sites/default/files/2020-08/documents/alt114.pdf*.

3. Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement, JCGM 100:2008, *https://www.bipm.org/documents/20126/2071204/JCGM_100_2008_E.pdf/cb0ef43f-baa5-11cf-3f85-4dcd86f77bd6*.

16.0 Tables and Figures

Figure B-1 Example Gravimetric Preparation Sheet for GMPS and GMACS

General Information

Project	Operator	Blend Date	Cylinder Number
Phase	Valve Connection	Blend Pressure	Headspace

Component Parameters

	Component 1	Component 2	Component 3	Component 4	Component 5
Material Name					
Material molecular weight (g/mol)					
Dilution Standard or Pure Cylinder Number					
Lot Number					
Dilution Standard Weight Concentration or Pure Weight % Assay (wt%)					
Dilution Standard Weight Accuracy, relative or +/- weight% uncertainty (wt%)					
Dilution Standard or Pure Weight (g)					
Mechanical Effects - u_m (g)					
Scale Capacity Selection (g)					
Scale Calibration Uncertainty - u_{cal} (g)					
Scale Accuracy - u_s (g)					
Weight Standard - u_w (g)					
Material Weight Added (g)					
Material Uncertainty - u_c (g)					
Total Weight Uncertainty (g)					
Additional Weight Uncertainty (g)					

Dilution Standard or Cross Contaminant Additions

Contributing Component #					
Weight Added (g)					
Uncertainty (g)					
Contributing Component #					
Weight Added (g)					
Uncertainty (g)					

Totals Calculations

Total Weight from all additions (g)					
Total moles					

Concentrations and Accuracy Calculations

Weight Concentration (%)					
Weight Accuracy Relative (%)					
Mole Concentration (%)					
Standard Uncertainty - u_s (%)					

Figure B-2 Apparatus for the assay of the GMACs

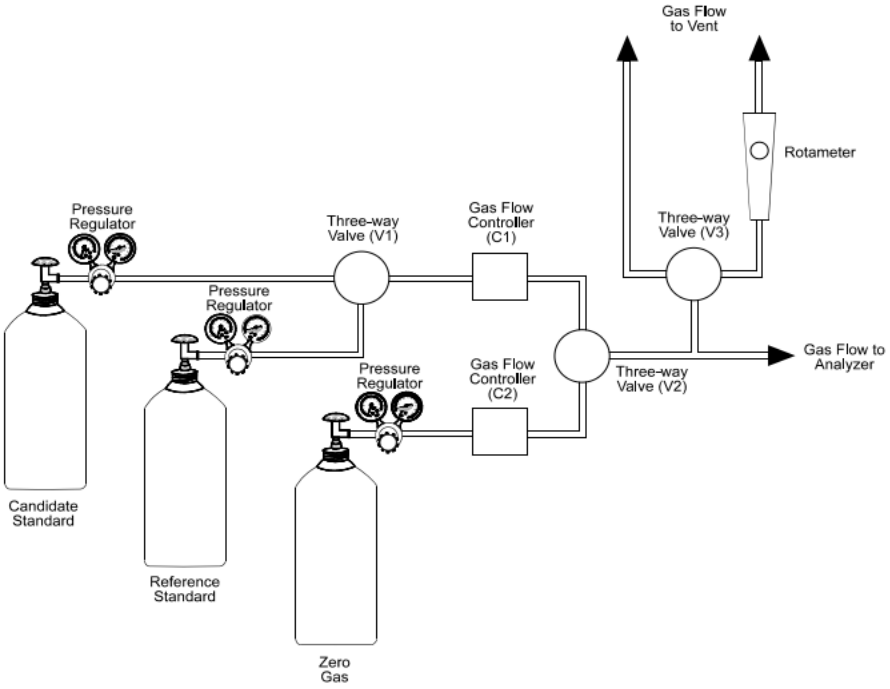

Figure B-3 Examples COA

Example Certificate of Analysis (COA) Ethylene Oxide Gas Manufacturer Alternative Certified Standard

Assay Laboratory		Customer Information
Company Name	Lot Number	Client Name
Company Address		Client Address
City, State, Zip Code		City, State, Zip Code

Product information

Composition	Certified Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %
Nitrogen	Balance		

Cylinder Number:	XXXXXXXXX	Certification Date:	X-XXX-XXXX
Cylinder Type:	XXXXXX	Prior Certification Date:	X-XXX-XXXX
Cylinder Pressure	XXXX	Expiration Date:	X-XXX-XXXX
Mixture Dew Point	XXXX	Part Number:	XXXXXXXXXXXX

Certification Data

Gravimetric Analysis

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Confirming Analysis

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Instrument Model/Analytical Principle
XXXXXXXXX/XXXXXXXXXXX

Reference Standard XXXXXXXXXXX

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Attachment 4:

Procedure 7 of 40 CFR 60 Appendix F regulatory text with proposed changes

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Title 40 → Chapter I → Subchapter C → Part 60→ Appendix F

Title 40: Protection of Environment
PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

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

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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 1 to section 1.0: 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

(f) 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 5.3, 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 with § 63.8(c) of this chapter, 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 11.5 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) of this chapter, 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

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

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 5.4 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 (CGA) or a Dynamic Spiking Audit (DSA) 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.

5.1.3.3 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 11.5 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.

5.4.1 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.

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

5.4.3 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 5.4.

6.0 Calculations for CEMS Data Accuracy

6.1 RATA RA Calculation. Follow equations 6 through 11 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.

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

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.

$$\text{DSA Accuracy} = \frac{\sum_1^3 \left[\frac{|DSEi|}{S}\right]}{3} x100 \qquad \text{Eq. 7-3}$$

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.

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 [Reserved]

Attachment 5:

40 CFR 63 Subpart O regulatory text with proposed changes

Title 40 → Chapter I → Subchapter C → Part 63→ Subpart O

Title 40: Protection of Environment
PART 63— NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

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Contents

§63.360 Applicability.
§63.361 Definitions.
§63.362 Standards.
§63.363 Compliance and performance provisions.
§63.364 Monitoring requirements.
§63.365 Test methods and procedures.
§63.366 Reporting requirements.
§63.367 Recordkeeping requirements.
§63.368 Implementation and enforcement.
Table 1 to Subpart O of Part 63
Standards for SCVs
Table 2 to Subpart O of Part 63
Standards for ARVs
Table 3 to Subpart O of Part 63
Standards for CEVs
Table 4 to Subpart O of Part 63
Standards for Group 1 Room Air Emissions
Table 5 to Subpart O of Part 63
Standards for Group 2 Room Air Emissions
Table 6 to Subpart O of Part 63
Applicability of General Provisions to Subpart O
Appendix A to Subpart O of Part 63

Monitoring Provisions for EtO CEMS

Source: 89 FR 24172, April 5, 2024, unless otherwise noted.

§ 63.360 Applicability.

(a) You are subject to the requirements of this subpart if you own or operate a sterilization facility that has an affected source specified in paragraph (b) of this section. Table 6 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

(b) The affected sources subject to this subpart are:

(1) Each SCV at any sterilization facility;

(2) Each ARV at any sterilization facility;

(3) Each CEV at any sterilization facility;

(4) The collection of all Group 1 room air emissions at any sterilization facility; and

(5) The collection of all Group 2 room air emissions at any sterilization facility.

(c) An existing affected source is one the construction or reconstruction of which was commenced on or before April 13, 2023.

(d) A new affected source is one the construction or reconstruction of which is commenced after April 13, 2023.

(e) An SCV, ARV, or CEV is reconstructed if you meet the reconstruction criteria as defined in § 63.2, and if you commence reconstruction after April 13, 2023.

(f) This subpart does not apply to beehive fumigators.

(g) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(h) This subpart does not apply to EtO sterilization operations at stationary sources such as hospitals, doctor's offices, clinics, or other facilities whose primary purpose is to provide medical or dental services to humans or animals.

(i) If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart. Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart applicable to area sources.

(j) You must comply with the provisions of this subpart no later than the dates specified in paragraphs (j)(1) through (9) of this section:

(1) If you own or operate an existing affected source, you must comply with the applicable provisions of this subpart no later than the dates specified in tables 1 through 5 to this subpart, as applicable.

(2) If you own or operate a new affected source, and the initial startup of your affected source is on or before April 5, 2024, you must comply with the provisions of this subpart no later than April 5, 2024.

(3) If you own or operate a new affected source, and the initial startup is after April 5, 2024, you must comply with the provisions of this subpart upon startup of your affected source.

(4) If existing SCV, ARV, or CEV or parts of an existing collection of Group 1 or Group 2 room air emissions are replaced such that the replacement meets the definition of reconstruction in § 63.2 and the reconstruction commenced after April 13, 2023, then the existing affected source becomes a new affected source. The reconstructed source must comply with the requirements for a new affected source upon initial startup of the reconstructed source or by April 5, 2024, whichever is later.

(5) All existing SCVs at facilities that meet or exceed 1 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use after April 5, 2027, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(6) All existing SCVs at facilities that do not exceed 1 tpy of EtO use within any consecutive 12-month period after April 5, 2027, that increase their EtO use thereafter, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(7) All new SCVs at facilities that increase their EtO use over a year after startup such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(8) All existing ARVs at facilities that do not exceed 10 tpy of EtO use within any consecutive 12-month period after April 5, 2027, that increase their EtO use thereafter, such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(9) All new ARVs at facilities that increase their EtO use over a year after startup such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

§ 63.361 Definitions.

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§ 63.2 and 63.3, or in this section. For the purposes of this subpart, if the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section.

Acid-water scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquid to absorb and neutralize acid gases.

Aeration means, for the purposes of this rule, exposing sterilized material at elevated temperatures to drive EtO out of the material.

Aeration room means any vessel or room that is used to facilitate off-gassing of EtO at a sterilization facility. If a facility uses only combination sterilization units, for the purposes of this rule, there are no aeration rooms at the facility.

Aeration room vent (ARV) means the point(s) through which the evacuation of EtO-laden air from an aeration room occurs. For combination sterilization units, there is no ARV.

Catalytic oxidizer means a combustion device that uses a solid-phase catalyst to lower the temperature required to promote the oxidization and achieve adequate reduction of volatile organic compounds, as well as volatile hazardous air pollutants.

Chamber exhaust vent (CEV) means the point(s) through which EtO-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes. This may also be referred to as a "backvent" (or "back vent"). For combination sterilization units, there is no CEV.

Combination sterilization unit means any enclosed vessel in which both sterilization and aeration of the same product occur within the same vessel, *i.e.,* the vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by aeration of ethylene oxide.

Combined emission stream means when the emissions from more than one emission source are routed together using common ductwork prior to the control system.

Continuous monitoring system (CMS) means, for the purposes of this rule, the equipment necessary to continuously sample the regulated parameter specified in § 63.364 or § 63.365 of this subpart without interruption, evaluate the detector response at least once every 15 seconds, and compute and record the average value at least every 60 seconds, except during allowable periods of calibration and except as defined otherwise by the continuous emission monitoring system (CEMS) performance specifications (PS) in appendix B to part 60 of this chapter.

Control System Residence Time means the time elapsed from entrance of flow into the control system until gaseous materials exit the control system. For control systems with multiple

exhaust streams whereby the residence time may vary for the streams, the residence time for purposes of complying with this subpart means the longest residence time for any exhaust stream in use. If a peak shaver is used, it is part of the control system, and its residence time must be considered.

Deviation means any instance in which an owner or operator of an affected source, subject to this subpart:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation, parameter value, or best management practice; or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart or that is included in the operating permit for any facility required to obtain such a permit.

EtO dispensing means charging a sterilization chamber or chambers with EtO from non-cartridge storage media (*e.g.,* drums, cylinders) via the use of piping, lines, and other equipment. This includes injection rooms and post-injection handling of containers.

Gas/solid reactor means an add-on air pollution control device that uses a dry, solid-phase system to chemically convert EtO so that it becomes bound to the solid packing. This may also be referred to as a "dry bed reactor" or a "dry bed scrubber."

Group 1 room air emissions mean emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material.

Group 2 room air emissions mean emissions from post-aeration handling of sterilized material.

Indoor EtO storage means the storage of EtO within non-cartridge media (*e.g.,* drums, cylinders) inside a sterilization building. This definition does not include gas calibration cylinder storage of EtO that is used to evaluate the performance of an EtO CEMS at the facility.

Initial startup means the moment when an affected source subject to an emissions standard in § 63.362 first begins operation.

Injection room means any room where EtO is injected into containers (*e.g.,* bags, pouches) that are filled with product to be sterilized.

Maximum flue gas flow rate means the average of flue gas flow rate established as an operating parameter limit (OPL) during a performance test when the control device achieves the appropriate control of EtO emissions.

Maximum gas/solid reactor pressure drop means the average of pressure drop of the gas/solid reactor established as an OPL during a performance test when the gas/solid reactor achieves the appropriate control of EtO emissions.

Maximum gas/solid reactor outlet EtO concentration means the allowed maximum outlet EtO concentration determined during a performance test when the gas/solid reactor achieves the appropriate control of EtO emissions.

Maximum scrubber liquid pH means the average of the pH of the acid-water scrubber liquid established as an OPL during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum scrubber liquid inlet temperature means the average of the temperature measured and used to establish an OPL during a performance test when a scrubber achieves the appropriate control of EtO emissions.

Minimum scrubber liquid-to-gas (L/G) *ratio* means the average of the L/G ratio measured and used to establish an OPL during a performance test when a scrubber achieves the appropriate control of EtO emissions.

Minimum temperature at the inlet to the catalyst bed means the average of the temperature at the inlet to the catalyst bed established as an OPL during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum temperature difference across the catalyst bed means the average of the temperature difference across the catalyst bed established as an OPL during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum combustion chamber temperature means the average of the combustion chamber temperature established as an OPL during a performance test when the thermal oxidizer achieves the appropriate control of EtO emissions.

Natural draft opening (NDO) means any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct in which a fan is installed.

Operating day means any day that an affected source is engaged in a sterilization operation.

Peak shaver means a device that is used to reduce high EtO concentrations within an exhaust stream such that the downstream control device is not overwhelmed.

Post-aeration handling of sterilized material means the storage and transportation of material that has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility. Post-aeration handling of sterilized material ends when that vehicle is closed for the final time before leaving the facility. This definition does not include handling of material that has been both previously sterilized and not removed from aeration following re-sterilization.

Post-injection handling of containers means the storage and transportation of containers (*e.g.,* bags, pouches) that have been injected with EtO but have not been placed in a sterilization chamber.

Pre-aeration handling of sterilized material means the storage and transportation of material that has been removed from a sterilization chamber but has not been placed in an aeration room. If only combination sterilization units are used, and if material is not moved out of the vessel between sterilization and aeration, then emissions from this source do not exist. This does not include post-injection handling of containers.

Rolling sum means the weighted sum of all data, meeting QA/QC requirements or otherwise normalized, collected during the applicable rolling time period. The period of a rolling sum stipulates the frequency of data collection, summing, and reporting. As an example, to demonstrate compliance with a rolling 30-operating day sum emission reduction standard determined from hourly data, you must

(1) determine the total mass of ethylene oxide prior to control and following control for each operating day;

(2) then sum the current daily total mass prior to control with the previous 29 operating day total mass values and repeat the same process for the current daily total mass following control; and

(3) then divide the 30-operating day total mass emissions following control by the 30-operating day total mass prior to control and subtract the resulting value from one to obtain the 30-operating day emission reduction achieved.

Single-item sterilization means a process in which one or more items are placed in a container (*e.g.*, bags, pouches), EtO is injected into the container, and the sealed container is placed in a vessel to allow sterilization to occur.

Sterilization chamber means any enclosed vessel or room that is filled with EtO gas, or an EtO/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility. This does not include injection rooms.

Sterilization chamber vent (SCV) means the point (prior to the vacuum pump) through which the evacuation of EtO from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where EtO is used in the sterilization or fumigation of materials, including but not limited to facilities that engage in single-item sterilization.

Sterilization operation means any time when EtO is removed from the sterilization chamber through the SCV or the CEV, when EtO is removed from the aeration room through theARV, when EtO is stored within the building, when EtO is dispensed from a non-cartridge storage media (*e.g.,* drums, cylinders) to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration.

Thermal oxidizer means all combustion devices except flares.

Vacuum pump operation means the operation of vacuum pumps, excluding dry seal vacuum pumps, for the purpose of removing EtO from a sterilization chamber.

§ 63.362 Standards.

(a) *Compliance date*. If you own or operate an affected source, you must comply with the applicable requirement by the compliance date specified in § 63.360(j). The standards of this section are summarized in tables 1 through 5 to this subpart.

(b) *Applicability of standards*. The standards in paragraphs (c) through (k) of this section apply at all times. If using EtO CEMS to determine compliance with an applicable standard, this compliance demonstration is based on the previous 30-operating days of data. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraphs (c) through (g) and (i) of this section for each operating day, you must determine the total inlet mass to and outlet mass from the control system using the procedures laid out in § 63.364(f) and appendix A to this subpart, and you must maintain the emission limit based on the inlet mass and the applicable emission reduction standard. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraph (j) of this section, you must continuously comply with the requirements of that paragraph.

(c) *SCV*. You must comply with each applicable standard in table 1 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a SCV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(d) *ARV*. You must comply with each applicable standard in table 2 to this subpart, and you must meet each applicable requirement specified in § 63.363. If an ARV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(e) *CEV*. You must comply with each applicable standard in table 3 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a CEV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(f) *Group 1 room air emissions*. You must comply with the applicable standard in table 4 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 1 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(g) *Group 2 room air emissions*. You must comply with the applicable standard in table 5 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 2 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (h) of this section. If you comply by limiting the sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must meet the monitoring requirements specified in § 63.364(h).

(h) *Requirements for combined emission streams*. If you elect to demonstrate compliance using an EtO CEMS, when streams from two or more emission sources are combined, you must demonstrate compliance by either the approach specified in paragraph (h)(1) of this section or the approach specified in paragraph (h)(2) of this section in lieu of the applicable standards in paragraphs (c) through (g) of this section for the affected sources. The combined emission stream limit is based on a 30-operating day rolling sum. In order to elect to comply with a combined emission streams limit, you must use a CEMS on each exhaust stack at the facility to determine compliance. If you elect to not use a EtO CEMS, you must follow paragraph (h)(4) of this section.

(1) *Monitoring after emission streams are combined*. You must follow requirements of paragraphs (h)(1)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine the 30-operating day rolling sum of inlet mass to the control system. Then, the emission limitation is determined by applying the most stringent emission reduction standard to the 30-operating day rolling sum of the inlet mass. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.6% and 99%, respectively. Further suppose that the mass of uncontrolled EtO emissions from the combined stream is 5.0 lb during the 30-operating day period. Under this approach, the facility would need to apply an emission reduction of 99.6% to the combined stream, resulting in an emission limit of 0.020 lb for the 30-operating day period.

(i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 1 to this paragraph.

Equation 1 to paragraph (h)(1)(i)

$$CES_{Combined} = M_{30day} * (1 - Max(ER)) \quad \text{(Eq. 1)}$$

Where:
$CES_{Combined}$ = The combined emission stream limit based upon monitoring after the emission streams are combined, in pounds.
M_{30day} = The 30-operating day total mass sent to controls for the combined emission stream (*i.e.,* monitoring data at the inlet of the control system), as calculated using equation A-3 and determined in accordance with appendix A to this subpart. The term "M_{30day}" as used in this equation is equivalent to the term "E_{30day}" as designated in equation A-3.
Max(ER) = The most stringent emission reduction standard specified in tables 1 through 5 of this subpart applicable to any of the constituent streams, in decimal format.

(ii) The 30-operating day rolling sum of emissions for the combined emission stream (*i.e.,* monitoring data at the outlet of the control system) is calculated daily using equation A-3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as $E_{Combined}$. If the combined emission stream is split between two or more

control systems, further sum the 30-operating day rolling sum of emissions from each control system to obtain $E_{Combined}$.

(iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that $E_{Combined}$, as calculated in accordance with paragraph (h)(1)(ii) of this section, for each 30-operating day period is at or below $CES_{Combined}$, as calculated in paragraph (h)(1)(i) of this section.

(2) *Monitoring before emission streams are combined*. You must follow requirements of paragraphs (h)(2)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine the 30-operating day rolling sum of inlet mass to the control system for each component stream. Then, the emission limitation is determined by applying the applicable emission reduction standards to the 30-operating day rolling sum of each component stream and summing across the components. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.6% and 99%, respectively. Further suppose that during a 30-operating day period the mass of uncontrolled EtO emissions from the ARVs is 4.0 lb and the mass of uncontrolled EtO emissions from the CEVs is 1.0 lb. Under this approach, the facility would need to apply an emission reduction of 99.6% to the ARV stream and an emission reduction of 99% to the CEV stream, resulting in an emission limit of 0.026 lb for the 30-operating day period.

(i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 2 to this paragraph.

Equation 2 to paragraph (h)(2)(i)

$$CES_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \qquad \text{(Eq. 2)}$$

Where:
$CES_{Streams}$ = The combined emission stream limit based upon monitoring before the emission streams are combined, in pounds.
$M_{c,i}$ = The 30-operating day total mass sent to controls for each non-SCV constituent emission stream (*i.e.,* monitoring data at the inlet of the control system), as calculated using equation A-3 and determined in accordance with appendix A to this subpart. The term "$M_{c,i}$" as used in this equation is equivalent to the term "E_{30day}" as designated in equation A-3.
ER_i = The applicable emission reduction standard from tables 2 through 5 of this subpart, in decimal format, to each non-SCV constituent emission stream *i*.
i = Non-SCV constituent emission stream index.
n = Total number of non-SCV constituent emission streams.
$M_{c,j}$ = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 7 of § 63.364(f)(1)(i)(C)(*1*).
ER_j = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.
j = SCV emission stream index.
m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum emissions for the combined emission stream (*i.e.,* monitoring data at the outlet of the control system) is calculated daily using equation A-3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as $E_{Combined}$. If the combined emission stream is split between two or more control systems, then further sum the 30-operating day rolling sum emissions from each control system to obtain $E_{Combined}$.

(iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that $E_{Combined}$, as calculated in accordance with paragraph (h)(2)(ii) of this section, for each 30-operating day period is at or below $CES_{Streams}$, as calculated in paragraph (h)(2)(i) of this section.

(3) *Split room air emissions.* If room air emissions are both subject to an emission standard and split between two or more control systems, then these control systems must be treated as part of the same control system.

(4) *Parametric monitoring for combined streams.* If owners and operators comply with the combined emissions streams using performance test and parametric monitoring, you must demonstrate compliance as required in § 63.363(c) or (d) setting an OPL and use the applicable monitoring requirements in § 63.364(b) through (e).

(i) *Site-wide emission limitation*. If you elect to demonstrate compliance using an EtO CEMS, you may choose to comply with a site-wide emission limitation (SWEL) specified in this paragraph (j) in lieu of the applicable standards in paragraphs (c) through (g) of this section for the facility. The SWEL, which is calculated daily, is based on the previous 30 operating days of data. In order to elect to comply with a SWEL, you must utilize an EtO CEMS on each exhaust stack at the facility to determine compliance. The owner or operator may demonstrate compliance via one of the two SWEL approaches in lieu of the applicable standard(s) in paragraphs (c) through (g) of this section for the facility. If electing to comply with a SWEL, you must comply with paragraph (i)(3) of this section.

(1) *SWEL based upon facility EtO use*. If you elect to comply with a SWEL based upon facility EtO use, you must follow requirements of paragraphs (i)(1)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, you first determine the 30-operating day rolling sum of EtO use. The SWEL is determined by multiplying by 0.99 and then applying the required SCV percent emission reduction standard in table 1 to this subpart to the 30-operating day rolling sum of EtO usage. Then, for each CEMS at the outlet of the control systems at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 3 to this paragraph.

Equation 3 to paragraph (i)(1)(i)

$$SWEL_{Fac} = M_{Fac} * 0.99 * (1 - ER_{SCV}) \quad \text{(Eq. 3)}$$

Where:
$SWEL_{Fac}$ = SWEL based upon facility EtO use, in pounds.
M_{Fac} = Facility EtO use over the previous 30-operating days, in pounds, as determined in accordance with equation 8 of § 63.364(i)(2).
0.99 = Adjustment factor for EtO residual in sterilized product.
ER_{SCV} = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this paragraph.

Equation 4 to paragraph (i)(1)(ii)

$$E_{Fac} = \sum_{i=1}^{n} E_{o,i} \quad \text{(Eq. 4)}$$

Where:
E_{Fac} = The total emissions from the facility over the previous 30-operating days, in pounds.
$E_{o,i}$ = The 30-operating day rolling sum of emissions calculated at each exhaust stack, *i*, monitored by an EtO CEMS, as calculated using equation A-3 of appendix A to this subpart. The term "$E_{o,i}$" as used in this equation is equivalent to the term "E_{30day}" as designated in equation A-3.
i = Exhaust stack index
n = Total number of exhaust stacks

(iii) Compliance with the SWEL based upon facility EtO usage shall be determined by demonstrating that E_{Fac}, as calculated in accordance with paragraph (i)(1)(ii) of this section, for each 30-operating day period is at or below the $SWEL_{Fac}$, as calculated in paragraph (i)(1)(i) of this section.

(2) *SWEL based upon emissions streams*. If you elect to comply with a SWEL based upon emissions streams, you must follow requirements of paragraphs (i)(2)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, for each non-SCV affected source, you must determine the mass of EtO sent to controls and apply the applicable emission reduction standard. For each SCV affected source, you must determine the mass of EtO sent to controls as specified in § 63.364(f)(1)(i)(C)(*1*) and apply the applicable emission reduction standard. The SWEL is determined by summing across the result of this calculation for each affected source (both non-SCV and SCV). Then, for each CEMS at the outlet of the control system(s) at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 5 to this paragraph.

Equation 5 to paragraph (i)(2)(i)

$$SWEL_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \quad \text{(Eq. 5)}$$

Where:
$SWEL_{Streams}$ = SWEL based upon individual emissions streams, in pounds.
$M_{c,i}$ = The 30-operating day total mass sent to controls (*i.e.,* monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A-3 and determined in accordance with appendix A to this subpart. The term "$M_{c,i}$" as used in this equation is equivalent to the term "E_{30day}" as designated in equation A-3.
ER_i = The applicable emission reduction standard to each non-SCV emission stream, *i*, specified in tables 2 through 5 of this subpart, in decimal format.
i = Non-SCV emission streams index.
n = Total number of non-SCV emission streams.
$M_{c,j}$ = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 7 in § 63.364(f)(1)(i)(C)(*1*).
ER_j = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.
j = SCV emission stream index.
m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this section.

(iii) Compliance with the SWEL based upon emission streams shall be determined by demonstrating that E_{Fac}, as calculated in accordance with paragraph (i)(2)(ii) of this section, for each 30-operating day period is at or below $SWEL_{Streams}$, as calculated in paragraph (i)(2)(i) of this section.

(3) *Boundary*. The boundary for this approach includes all affected sources at the facility.

(j) *General duty*. At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

§ 63.363 Compliance and performance provisions.

(a) *Continuous compliance*. You must demonstrate continuous compliance by conducting annual performance tests using the performance testing requirements in § 63.7, according to the

applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365. You must also demonstrate continuous compliance with each operating parameter limit (OPL) required under this section according to the methods specified in § 63.364. If you have a deviation from the established OPL and corrective actions do not confirm the established OPL, a performance test must occur to establish a new OPL within 150 days. Alternatively, you may demonstrate continuous compliance with the applicable emission standard(s) using an EtO CEMS, including a shared EtO CEMS, installed and operated in accordance with the requirements of Performance Specification 19 (PS 19) in appendix B and Procedure 7 in appendix F to part 60 of this chapter.

(b) *Initial compliance demonstration for facility complying by annual performance testing*. If you own or operate an affected source that is subject to an emission standard in § 63.362, you must comply with paragraphs (b)(1) and (2) of this section:

(1) Conduct an initial compliance demonstration using the procedures listed in § 63.7 of this part according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365;

(2) Complete the initial compliance demonstration within 180 days after the compliance date for the affected source as determined in § 63.360(j).

(c) *Operating parameter limits for facility demonstrating continuous compliance using annual performance testing*. The procedures in paragraphs (c)(1) through (5) of this section may be used to determine compliance with the standard(s) under § 63.362(c) through (g) and to establish OPLs for each of the control devices, as applicable.

(1) You must determine the percent emission reduction of the control system used to comply with § 63.362(c) through (g) using the test methods and procedures in § 63.365(d).

(2) If an acid-water scrubber(s) is used to comply with a standard, then you must establish OPLs specified in paragraphs (c)(2)(i) through (iii).

(i) The minimum scrubber L/G ratio using the procedures described in § 63.365(e)(1)(i);

(ii) The maximum scrubber liquid temperature entering the scrubber column using the procedures described in § 63.365(e)(1)(ii); and

(iii) The maximum scrubber liquid pH using the procedures described in § 63.365(e)(1)(iii).

(3) If a thermal oxidizer(s) is used to comply with a standard, you must establish OPLs specified in paragraphs (c)(3)(i) and (ii).

(i) The minimum combustion chamber temperature using the procedures described in § 63.365(e)(2)(i); and

(ii) The maximum flue gas flow rate using the procedures described in § 63.365(e)(2)(ii).

(4) If a catalytic oxidizer(s) is used to comply with the standard, you must establish OPLs specified in paragraphs (c)(4)(i) through (iii).

(i) The minimum temperature at the inlet to the catalyst bed using the procedures described in § 63.365(e)(3)(ii);

(ii) The minimum temperature difference across the catalyst bed using the procedures described in § 63.365(e)(3)(iii); and

(iii) The maximum flue gas flow rate using the procedures described in § 63.365(e)(3)(iv).

(5) If a gas/solid reactor(s) is used to comply with the standard, you must establish OPLs specified in paragraphs (c)(5)(i) and (ii):

(i) The maximum gas-solid reactor pressure drop using the procedures described in § 63.365(e)(4)(i); and

(ii) The maximum gas/solid reactor outlet EtO concentration using the procedures described in 63.365(e)(4)(ii).

(d) *Other control technology for facility demonstrating continuous compliance using annual performance testing*. If you are conducting a performance test using a control technology other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator information describing the design and operation of the air pollution control system, including recommendations for the parameters to be monitored that will demonstrate continuous compliance. Based on this information, the Administrator will determine the parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(e)(5), you must determine the site-specific OPL(s) for the operating parameters approved by the Administrator. You must submit the information at least sixty days before the performance test is scheduled to begin. The information on the control technology must include the five items listed in paragraphs (d)(1) through (5) of this section.

(1) Identification of the specific parameters you propose to use as additional OPLs;

(2) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(3) A discussion of how you will establish the upper and/or lower values which will establish the operating limits for these parameters;

(4) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(5) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

(e) *Initial compliance for Facilities that use EtO CEMS*. To demonstrate initial compliance with an emission standard using a CEMS that measures HAP concentrations directly (*i.e.,* an EtO CEMS), the initial performance test must consist of the first 30 operating days after the certification of the CEMS according to Performance Specification 19 in Appendix B to part 60 of this chapter. The initial compliance demonstration period must be completed on or before the date that compliance must be demonstrated (*i.e.,* 180 days after the applicable compliance date). You must follow the procedures in appendix A to this subpart.

(1) The CEMS performance test must demonstrate compliance with the applicable EtO standards in tables 1 through 5 to this subpart. Alternatively, the CEMS performance test may demonstrate compliance with § 63.362(h) or (i). You may time-share your CEMS among different measurement points provided that:

(i) The measurement points are approximately equidistant from the CEMS or the response times are approximately the same under the system design;

(ii) The sampling time at each measurement point is at least 3 times as long as the CEMS response time;

(iii) The CEMS completes at least one complete cycle of operation for each shared measurement point within a 15-minute period; and

(iv) The CEMS meets the other requirements of PS 19.

(2) You must collect hourly data from auxiliary monitoring systems during the CEMS performance test period, to convert the pollutant concentrations to pounds per hour.

(f) *Other emission streams*. If the emission stream does not consist only of an SCV(s), the procedures in paragraphs (f)(1) and (2) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d) through (g), as applicable:

(1) You must comply with paragraph (b) of this section, as applicable.

(2) If you are complying with a percent emission reduction standard as specified in tables 1 through 5 to this subpart and are demonstrating continuous compliance through annual performance testing, you must determine compliance with § 63.362(c) through (g), as applicable, using the test methods and procedures in § 63.365.

§ 63.364 Monitoring requirements.

(a) *General requirements*.

(1) If you own or operate an affected source subject to an emission standard in § 63.362, you must comply with the monitoring requirements in § 63.8, according to the applicability in table 6 to this subpart, and in this section.

(2) If you own or operate an affected source at a facility that is subject to an emission standard in § 63.362 and demonstrate initial and annual compliance using performance testing, you must monitor the applicable parameters specified in paragraphs (b), (c), (d), (e), (g), and (i) of this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(3) If you own or operate an affected source that is subject to an emission standard in § 63.362 and you choose to demonstrate initial and continuous complianceusing EtO CEMS, you must comply with paragraphs (f), (g), and (i) of this section.

(4) If you comply with Group 2 room air emissions at area sources, you must comply with paragraph (h) of this section or paragraphs (g) and (i) of this section.

(5) You must keep the written procedures required by § 63.8(d)(2) on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you must keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(6) *Monitoring Plan*. You must create a monitoring plan that details the monitoring approach (performance test and parametric monitoring, or EtO CEMS), the OPLs, and continuous monitoring parameters you will record. The OPL must be calculated after every performance test and monitoring parameters reset. These OPL and monitoring parameters must be updated and included in the quarterly compliance reports according to § 63.366(b) and (c). The monitoring plan will include a description of the device; test results collected in accordance with § 63.363(c) verifying the performance of the device for controlling EtO emissions to the atmosphere to the levels required by the applicable standards; the appropriate OPLs that will be monitored, identifying the ongoing QA procedures and performance specifications that will be conducted on the instruments; the frequency of conducting QA and performance checks; and the frequency of measuring and recording to establish continuous compliance with the standards.

(7) In the initial compliance report, you must detail the monitoring approach, the OPLs, and continuous monitoring parameters you will record. The OPL must be calculated after every performance test and monitoring parameters reset. These OPL and monitoring parameters must be updated and included in the quarterly compliance reports according to § 63.366(b) and (c).

(b) *Acid-water scrubbers*. If you are demonstrating compliance through annual performance testing and you vent through acid-water scrubber(s) you must establish OPLs specified in paragraphs (b)(1) through (3) of this section using procedures in § 63.365(e)(1). For continuous compliance, you must comply with paragraphs (b)(4) through (6) of this section:

(1) *Scrubber liquid-to-gas (L/G) ratio*. Scrubber L/G ratio is determined from the total scrubber liquid inlet flow rate and the exit gas flow rate. Determine the average scrubber L/G ratio during the performance test as the average of the test run averages.

(2) *Scrubber liquid inlet temperature*. The scrubber liquid inlet temperature may be measured at any point after the heat exchanger and prior to entering the top of the scrubber column. Determine the average scrubber liquid inlet temperature during the performance test as the average of the test run averages.

(3) *Scrubber liquid pH of the liquid in the reactant tank*. The scrubber liquid pH may be measured at any point between the discharge from the scrubber column and the inlet to the reactant tank. Determine the average scrubber liquid pH during the performance test as the average of the test run averages.

(4) Minimum scrubber L/G, equal to the average L/G ratio measured during the most recent performance test. Compliance with the minimum L/G ratio operating limit must be determined continuously on a 1-hour block basis. Use a liquid flow sensor and gas flow rate sensor that meets the requirements of paragraphs (b)(7)(i) and (ii) of this section, respectively.

(5) Maximum scrubber liquid inlet temperature, i.e., entering the scrubber column, equal to the average temperature measured during the most recent performance test. Compliance with the maximum scrubber liquid inlet temperature operating limit must be determined continuously on a 1-hour block basis. Use a temperature sensor that meets the requirement of paragraph (b)(7)(iii) of this section.

(6) Maximum scrubber liquid pH of the liquid in the reactant tank, equal to the average scrubber liquid pH measured during the most recent performance test. Compliance with the maximum scrubber liquid pH operating limit must be determined continuously on a 1-hour block basis. Use a pH sensor that meets the requirements of paragraph (b)(7)(iv) of this section.

(7) If you vent through an acid-water scrubber, you must install and operate the equipment described in paragraph (b)(7)(i) through (v).

(i) *Liquid flow sensor.* Determine total scrubber liquid inlet flow rate with a flow sensor with a minimum accuracy of at least ±5 percent over the normal range of flow measured, or 1.9 liters per minute (0.5 gallons per minute), whichever is greater.

(ii) *Gas flow sensor*. Determine exit gas flow rate from the scrubber with a flow sensor with a minimum accuracy of at least ±5 percent over the normal range of flow measured, or 280 liters per minute (10 cubic feet per minute), whichever is greater.

(iii) *Temperature sensor.* Use a temperature sensor with a minimum accuracy of at least ±1 percent over the normal range of temperature measured, expressed in degrees Celsius, or 2.8 degrees Celsius, whichever is greater. You must verify the accuracy of the temperature monitor twice each calendar year at least five months apart with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the

probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy of the temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(iv) *pH sensor*. Use a pH sensor with a minimum accuracy of ±0.2 pH units. A performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system must be conducted in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(v) A data acquisition system capable of collecting a value every 15 seconds and compute and record each 1-hour block average.

(c) *Oxidizers*. If you are demonstrating compliance through annual performance testing and you vent through thermal oxidizer(s), the requirements in paragraphs (c)(1), (3), and (4) apply. If you are demonstrating compliance through annual performance testing and you vent through catalytic oxidizer(s), the requirements in paragraphs (c)(2) through (4) apply.

(1) For thermal oxidizers, you must establish OPLs specified in paragraphs (c)(1)(i) and (ii) of this section using procedures in § 63.365(e)(2). For continuous compliance, you must comply with paragraphs (c)(1)(iii) and (iv) of this section when the affected source is engaged in a sterilization operation.

(i) *Combustion chamber temperature*. The chamber temperature must be determined in or immediately downstream of the firebox. Determine the average combustion chamber temperature during the performance test as the average of the test run averages.

(ii) *Flue gas flow rate*. Determine the average flue gas flow rate during the performance test as the average of the test run averages.

(iii) Minimum combustion chamber temperature, equal to the average combustion chamber temperature measured during the most recent performance test. Compliance with the minimum combustion chamber temperature operating limit must be determined continuously on a 1-hour block basis. Use a temperature sensor that meets the requirements of paragraph (b)(7)(iii) of this paragraph.

(iv) Maximum flue gas flow rate, equal to the average flue gas flow rate measured during the most recent performance test. Compliance with the maximum flue gas flow rate operating limit must be determined continuously on a 1-hour block basis. Use a gas flow rate sensor that meets the requirements in paragraph (b)(7)(ii) of this section.

(2) For catalytic oxidizers, you must establish OPLs specified in paragraphs (c)(2)(i) and (ii) of this section using procedures in § 63.365(e)(3). For continuous compliance, you must comply with paragraphs (c)(2)(iii) through (v) of this section when the catalytic oxidizer is in operation.

(i) Catalyst bed temperatures. The catalyst bed temperatures must be measured at the inlet and the outlet of the catalyst bed(s). Determine the average catalyst bed temperatures during the performance test as the average of the test run averages.

(ii) Flue gas flow rate. Determine the average flue gas flow rate during the performance test as the average of the test run averages.

(iii) Minimum temperature at the inlet to the catalyst bed, equal to the average temperature measured at the inlet to the catalyst bed measured during the most recent performance test. Compliance with the minimum inlet catalyst bed temperature operating limit must be determined continuously on a 1-hour block basis. Use a temperature sensor that meets the requirements of paragraph (b)(7)(iii) of this section.

(iv) Minimum temperature difference across the catalyst bed, equal to the average temperature difference across the catalyst bed measured during the most recent performance test. Compliance with the minimum temperature difference across the catalyst bed operating limit must be determined continuously on a 1-hour block basis. Use a temperature sensor that meets the requirements of paragraph (b)(7)(iii) of this section.

(v) Maximum flue gas flow rate, equal to the average flue gas flow rate measured during the most recent performance test. Compliance with the maximum flue gas flow rate operating limit must be determined continuously on a 1-hour block basis. Use a gas flow sensor that meets the requirements in paragraph (b)(7)(ii) of this section.

(3) If you vent through a thermal oxidizer or catalytic oxidizer you must install and operate the equipment described in paragraph (b)(7)(ii), (iii), and (v) of this section.

(4). You must maintain the thermal oxidizer and/or catalytic oxidizer in accordance with good combustion practices that ensure proper combustion. Good combustion practices include, but are not limited to, proper burner maintenance, proper burner alignment, proper fuel to air distribution and mixing, routine inspection, and preventative maintenance.(d) *Gas-solid reactors*. If you are demonstrating compliance through annual performance testing and you vent through gas/solid reactor(s), you must establish OPLs specified in paragraphs (d)(1) and (2).

(1) *Gas/solid reactor pressure drop.* Determine the average gas/solid reactor pressure drop as the average of the test runs. Monitor and record at least every 15 minutes the pressure drop. Monitoring is required when the gas/solid reactor is operating. All data collected during the operating hour must be used, even if the gas/solid reactor unit is not operating for a complete hour. You must maintain the 1-hour block average gas/solid reactor pressure drop below the applicable operating limit established during the most recent performance test. Use a pressure sensor with a minimum accuracy of ±5 percent over the normal operating range or 0.12 kilopascals, whichever is greater. A data acquisition system for the pressure drop monitor shall compute and record each 1-hour block average gas/solid reactor pressure drop value.

(2) *Gas/solid reactor outlet EtO concentration*. During the annual performance test, determine the average EtO concentration and flow rate at the inlet and outlet of the gas-solid reactor. If the gas-solid reactor is in series with another air pollution control device, measure at

the inlet of the initial device. Alternatively, if a gas-solid reactor is used to control emissions from a Group 1 or Group 2 room air emissions vent and you conduct room air monitoring required under FIFRA, you may use your highest 24-hour average room air concentration of EtO from the preceding year in lieu of the inlet concentration determined during the performance test.

(i) Calculate the estimated maximum outlet mass emission of EtO for the gas-solid reactor using Equation 1 of this paragraph.

Equation 1 to paragraph (d)(2)(i)

$$EM_{EtO} = \left(\frac{\text{RE x } Q_i \text{ x } 44.05 \text{ x } C_{EtO,i}}{385.1 \times 10^6}\right) \quad \text{(Eq. 1)}$$

Where:
EM_{EtO} = Estimated maximum emission rate at outlet of the gas/solid reactor, lb/hr
RE = Reduction efficiency standard of the emission source, percent
Q_i = average inlet volumetric flow per hour at standard conditions, dscf/hr
44.05 = molecular weight (MW) of EtO, lb/lb-mole
$C_{EtO,i}$ = inlet EtO concentration, ppmvd
385.1×10^6 = conversion factor, from ppmv at standard conditions to lb/cf

(ii) Determine the maximum outlet EtO concentration operating limit for the gas-solid reactor using Equation 2 of this paragraph.

Equation 2 to paragraph (d)(2)(ii)

$$OPL_{EtO} = \left(\frac{EM_{Et0} \text{ x } (385.1 \times 10^9)}{Q_o \text{ x } 44.05}\right) \quad \text{(Eq. 2)}$$

Where:

OPL_{EtO} = Outlet EtO concentration Operating Limit, ppbv.

EM_{EtO} = Estimated Maximum Emission Rate, lb/hr

385.1×10^9 = Conversion factor, from ppbv at standard conditions to lb/cf

Q_o = Average outlet volumetric flow per hour at standard conditions, dscf/hr

44.05 = Molecular weight (MW) of EtO, lb/lb-mole

(iii) You must maintain the concentration at the outlet of the gas-solid reactor below the EtO concentration limit, as monitored weekly at the outlet using one or more of the options in paragraph (d)(2)(iii)(A) through (D) of this section.

(A) Collect and analyze a sample according to section 8.2.1.5 of Method 18 to Appendix A of 40 CFR Part 60. You are not required to conduct the required recovery study in section

8.4.2 of the Method if the analysis is conducted within 24 hours of sampling.

(B) Collect and analyze a sample according to the procedures found in § 63.365(b).

(C) Monitor using an instrument that meets the requirements of Performance Specification 19 to Appendix B of 40 CFR Part 60.

(D) Stationary Indoor Monitoring using an instrument which meets the requirements of the Ethylene Oxide Interim Registration Review Decision (CASE 2275, January 2025) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

(e) *Performance testing, other control technology*. If you are complying with § 63.363(c) or (d) using annual performance testing and the use of a control device other than acid-water scrubbers, catalytic or thermal oxidizers, or gas/solid reactors, you must monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(e).

(f) *EtO CEMS configurations*. If you elect to use EtO CEMS to demonstrate compliance with an emission standard, you must install and operate an EtO CEMS on each outlet for the control system in accordance with the requirements of Appendix A to this subpart. You must also conduct monitoring for each inlet to the control system that is used to demonstrate compliance with the emission reduction standard in accordance with the requirements of Appendix A to this subpart, with the exception for SCV emission streams to the control system.

(1) *EtO CEMS inlet configuration*. The following caveats apply:

(i) *SCVs*. If you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to monitoring the inlet emission stream to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(A) Determine the mass ($M_{SCV,n}$) of EtO used for each charge and at each sterilization chamber used during the previous 30 days using the procedures in either paragraph (f)(1)(i)(A)(1) or (2) of this section.

(*1*) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 3 to this paragraph.

Equation 3 to paragraph (f)(1)(i)(A)(1)

$$M_{SCV,n} = M_{charge} \times \%EO_w \quad \text{(Eq. 3)}$$

Where:
$M_{SCV,n}$ = Theoretical total mass of EtO vented to controls per charge, g (lb)
M_{charge} = total mass of sterilizer gas charge, g (lb)

$\%EO_w$ = weight percent of EtO

(*2*) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Q_m) and duration of each sterilizer charge. Calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 4 to this paragraph.

Equation 4 to paragraph (f)(1)(i)(A)(2)

$$M_{SCV,n} = (Q_m \times T_n \times \%EO_v \times \frac{MW}{SV}) \quad \text{(Eq. 4)}$$

Where:
$M_{SCV,n}$ = theoretical total mass of EtO sent to controls per charge
Q_m = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))
T_n = time duration of each charge, min
$\%EO_v$ = volume fraction percent of EtO
n = number of EtO charges
MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))
SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(B) Determine the adjustment factor (f_{det}) using equation 5 to this paragraph. Determine the mass of EtO sent to controls from all non-SCV affected sources, *I*, using equation 6 to this paragraph. For facilities where not all Group 2 room air emissions are routed to a control device (i.e., Group 2 room air emissions at existing area sources), do not include those Group 2 room air emissions in *I*, and subtract 0.002 from this factor.

Equations 5 and 6 to paragraph (f)(1)(i)(B)

$$f_{det} = 0.99 - \frac{I}{M_{Fac}} \quad \text{(Eq. 5)}$$

Where:
f_{det} = Adjustment factor.
I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days
M_{Fac} = Facility EtO use over the previous 30-operating days, in pounds, as determined in accordance with equation 8 of § 63.364(i)(2)

$$I = \sum_{i=1}^{n} M_{c,i} \quad \text{(Eq. 6)}$$

Where:
I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days
$M_{c,i}$ = The 30-operating day total mass sent to controls (*i.e.,* monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A-3 and determined in

accordance with appendix A to this subpart. The term "$M_{c,i}$" as used in this equation is equivalent to the term "E_{30day}" as designated in equation A-3.
i = Non-SCV emission stream index.
n = Total number of non-SCV emission streams.

(C)

(*1*) Determine the mass rate of EtO sent to controls during the previous 30 days using equation 7 to this paragraph.

Equation 7 to paragraph (f)(1)(i)(C)(1)

$$M_{SCV} = f_{det} \text{ x } \sum_{i=1}^{n} M_{SCV,n} \qquad \text{(Eq. 7)}$$

Where:
M_{SCV} = Total mass of EtO sent to controls over the previous 30 operating days, g/hr (lb/hr)
f_{det} = Adjustment factor
$M_{SCV,n}$ = Theoretical mass of EtO sent to controls per charge per chamber, g (lb)
n = Total number of charges during the previous 30 operating days

(*2*) If both this approach is chosen and the SCV is (or SCVs are) combined with another emission stream, then the owner or operator cannot monitor the point after the combination occurs.

(ii) *Room air emissions*. If room air emissions are both subject to an emission standard and split between two or more control systems, then monitoring must be conducted for room air emissions before they are combined with other streams.

(2) *EtO CEMS on exhaust configurations*. Exhaust gases from the emission sources under this subpart exhaust to the atmosphere through a variety of different configurations, including but not limited to individual stacks, a common stack configuration, or a main stack plus a bypass stack. For the CEMS used to provide data under this subpart, the CMS installation requirements for these exhaust configurations are as follows:

(i) *Single unit-single stack configurations*. For an emission source that exhausts to the atmosphere through a single, dedicated stack, you shall either install the required CEMS in the stack or at a location in the ductwork downstream of all emissions control devices, where the pollutant and diluents concentrations are representative of the emissions that exit to the atmosphere.

(ii) *Unit utilizing common stack with other emission source(s)*. When an emission source utilizes a common stack with one or more other emission sources, but no emission sources not subject to this rule, you shall either:

(A) Install the required CEMS in the duct from each emission source, leading to the common stack; or

(B) Install the required CEMS in the common stack.

(iii) *Unit(s) utilizing common stack with non-commercial sterilization emission source(s).*

(A) When one or more emission sources shares a common stack with one or more emission sources not subject to this rule, you shall either:

(*1*) Install the required CEMS in the ducts from each emission source that is subject to this rule, leading to the common stack; or

(*2*) Install the required CEMS in the common stack and attribute all of the emissions measured at the common stack to the emission source(s).

(B) If you choose the common stack monitoring option:

(*1*) For each hour in which valid data are obtained for all parameters, you must calculate the pollutant emission rate; and

(*2*) You must assign the calculated pollutant emission rate to each of the units subject to the rule that share the common stack.

(iv) *Unit with multiple parallel control devices with multiple stacks.* If the exhaust gases from an emission source, which is configured such that emissions are controlled with multiple parallel control devices or multiple series of control devices are discharged to the atmosphere through more than one stack, you shall install the required CEMS in each of the multiple stacks. You shall calculate hourly, flow-weighted, average pollutant emission rates for the unit as follows:

(A) Calculate the pollutant emission rate at each stack or duct for each hour in which valid data are obtained for all parameters;

(B) Multiply each calculated hourly pollutant emission rate at each stack or duct by the corresponding hourly gas flow rate at that stack or duct;

(C) Sum the products determined under paragraph (f)(2)(iv)(B) of this section; and

(D) Divide the result obtained in paragraph (f)(2)(iv)(C) of this section by the total hourly gas flow rate for the unit, summed across all of the stacks or ducts.

(g) *Continuous flow rate monitoring system.* If you are required to operate a continuous flow rate monitoring system, you must:(1) *Continuous compliance - flow rate monitoring*. If you choose to demonstrate continuous compliance through volumetric flow rate monitoring, you must monitor and record at least every 15 minutes the volumetric flow rate using a flow rate monitoring system described in paragraph (g)(2) of this section. A data acquisition system for the flow rate monitoring system shall compute and record each 3-hour average flow rate value, rolled hourly. This must be done by first averaging the flow rate readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used.

Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average flow rate. You must maintain the 3-hour rolling average flow rate above the applicable operating limits established during the most recent compliance demonstration.

(2) *Continuous flow rate monitoring system*. You must install, operate, calibrate, and maintain instruments, according to the requirements in paragraphs (g)(3)(i) through (ix) of this section, for continuously measuring and recording the stack gas flow rate to allow determination of compliance with the minimum volumetric flow rate through the affected stack operating limit(s).

(i) You must install each sensor of the flow rate monitoring system in a location that provides representative measurement of the exhaust gas flow rate. The flow rate sensor is that portion of the system that senses the volumetric flow rate and generates an output proportional to that flow rate.

(ii) The flow rate monitoring system must be designed to measure the exhaust flow rate over a range that extends from a value of at least 20 percent less than the lowest expected exhaust flow rate to a value of at least 20 percent greater than the highest expected exhaust flow rate.

(iii) The flow rate monitoring system must be equipped with a data acquisition and recording system that is capable of recording values over the entire range specified in paragraph (g)(3)(ii) of this section.

(iv) The signal conditioner, wiring, power supply, and data acquisition and recording system for the flow rate monitoring system must be compatible with the output signal of the flow rate sensors used in the monitoring system.

(v) The flow rate monitoring system must be designed to complete a minimum of one cycle of operation for each successive 15-minute period.

(vi) The flow rate sensor must have provisions to determine the daily zero and upscale calibration drift (CD) (see sections 3.1 and 8.3 of Performance Specification 2 inof appendix B to Ppart 60 of this chapter for a discussion of CD).

(A) Conduct the CD tests at two reference signal levels, zero (*e.g.,* 0 to 20 percent of span) and upscale (*e.g.,* 50 to 70 percent of span).

(B) The absolute value of the difference between the flow monitor response and the reference signal must be equal to or less than 3 percent of the flow monitor span.

(vii) You must perform an initial relative accuracy test of the flow rate monitoring system according to section 8.2 of Performance Specification 6 of appendix B to part 60 of thethis chapter with the exceptions in paragraphs (g)(3)(vii)(A) and (B) of this section.

(A) The relative accuracy test is to evaluate the flow rate monitoring system alone rather than a continuous emission rate monitoring system.

(B) The relative accuracy of the flow rate monitoring system shall be no greater than 10 percent of the mean value of the reference method data.

(viii) You must verify the accuracy of the flow rate monitoring system at least once per year by repeating the relative accuracy test specified in paragraph (g)(3)(vii) of this section.

(ix) You must operate the flow rate monitoring system and record data during all periods of operation of the affected facility including periods of startup, shutdown, and malfunction.(g) *Sterilization chamber end-cycle EtO concentration*. As part of your monitoring plan, you must document your approach for determining the sterilization chamber end-cycle EtO concentration. If you choose a parametric approach you must meet the requirements in paragraph (g)(1) of this section and if you choose a direct measurement approach you must meet the requirements in paragraph (g)(2) of this section. Alternatively, you may petition the administrator for an alternative monitoring approach under § 63.8(f).

(1) If you choose a parametric approach for determining sterilization chamber end-cycle EtO concentrations you must document parameter(s) used in the calculation to determine EtO concentrations and the calculation(s) used to determine the chamber concentration. Any instrumentation used for parametric monitoring must also be identified in the monitoring plan and at a minimum this plan should include the following for each instrument:

(i) Parameter measured and measurement principle of the monitor.

(ii) Instrument name, model number, serial number, and range.

(iii) Manufacturer recommended operation practices, including daily operational check.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(2) If you choose a direct measurement approach for determining sterilization chamber end-cycle EtO concentrations you must document the procedures used for the operation of the instruments. Any instrument used for direct measurement of EtO must be identified in the monitoring plan and at a minimum this plan must include the following information:

(i) Instrument name, model number, serial number, and range.

(ii) Description of the measurement principle and any potential interferences.

(iii) If applicable, the description of the sampling condition system.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(h) *EtO usage*. If you own or operate a sterilization facility subject to the requirements of this subpart you must monitor and record on a daily basis the daily and 30-operating day EtO usage according to the requirements of this paragraph. Additionally, you must record EtO usage for each calendar month.

(1) Monitor and record on a daily basis, the daily total mass of ethylene oxide, in pounds, used at the facility. The daily total mass must be determined using the methodology specified in § 63.365(c)(1)(i) or (ii).

(2) Determine and record daily the 30-operating day rolling ethylene oxide usage rate using equation 8 to this paragraph.

Equation 8 to paragraph (h)(2)

$$M_{Fac} = \sum_{i=1}^{30} m_{Fac,i} \qquad \text{(Eq. 8)}$$

Where:
M_{Fac} = Facility EtO use over the previous 30 operating days, in pounds.
$m_{Fac,i}$ = Daily EtO use for operating day *i*, in pounds, as determined in accordance with paragraph (h)(1) of this section
i = Operating day index.

(3) Determine and record the total mass of EtO used in each calendar month.

§ 63.365 Test methods and procedures.

(a) *General —*

(1) *Performance testing – initial and annual*. If you own or operate an affected source that is subject to an emission standard in § 63.362 and you are demonstrating continuous compliance using parametric monitoring,you must comply with the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, using the methods in paragraph (b) or (c) of this section, following the applicable procedures for initial compliance and continuous compliance in paragraphs (d), (e), and (f) of this section.

(b) *Test methods for facility complying by annual performance testing*. You must use the following test methods to determine the average mass emissions of EtO in lb/hr at the inlet(s) of a control system ($M_{APCD,\,i}$) and/or outlet of a control system(s) or stack(s) ($E_{APCD,\,o}$).

(1) Exhaust gases from the affected emission sources under this subpart exhaust to the atmosphere through a variety of different configurations, including but not limited to individual stacks, a common stack, or a main stack plus a bypass stack. For performance testing under this subpart, the sampling requirements for these exhaust configurations are as follows:

(i) *Single affected emission source-single stack configurations*. For an affected emission source that exhausts to the atmosphere through a single, dedicated stack, you shall conduct

performance testing at locations upstream and downstream of the emissions control device(s), for %RE. If there are multiple inlets leading to the control device(s), you must sample the ductworks separately unless they are manifolded and then you may sample at a point downstream of the manifold and downstream of the control device, subject to that sampling point meeting the requirements of paragraph (b)(2) of this section.

(ii) *Affected Source utilizing common stack with other affected source(s)*. When an emission source utilizes a common stack with one or more other affected emission sources, you shall:

(A) Conduct performance testing upstream of the control device(s), for each affected source. If there are multiple inlets leading to the control device(s), you must sample the ductworks separately unless they are manifolded and then you may sample at a point upstream of the manifold, subject to that sampling point meeting the requirements of paragraph (b)(2) of this section.

(B) Conduct performance testing in the ductwork downstream of the control devices, leading to the common stack; or

(C) Conduct performance testing in the common stack.

(iii) *Affected Sources utilizing common stack with non-commercial sterilization emission source(s).*

(A) Conduct performance testing upstream of the control device(s) as detailed in paragraph (b)(1)(ii)(A) of this section.

(B) Conduct performance testing in the ductwork downstream of the control device(s), leading to the common stack; or

(C) Conduct performance testing in common stack and attribute all of the emissions measured at the common stack to the emission source(s).

(iv) *Affected Sources with multiple parallel control devices with multiple stacks.* If the exhaust gases from an emission source, which is configured such that emissions are controlled with multiple parallel control devices or multiple series of control devices are discharged to the atmosphere through more than one stack, you shall conduct performance testing in each of the multiple stacks.

(A) Conduct performance testing upstream of the control device(s) as detailed in paragraph (b)(1)(ii)(A) of this section.

(B) Conduct performance testing in the ductwork or stack downstream of the control device(s); or

(C) Conduct performance testing in the stack.

(2) Select the location of the sampling ports and the number of traverse points according to Method 1 of appendix A-1 to part 60 of this chapter. Alternatively, for ducts less than 0.3 meter (12 in.) in diameter, you may choose to locate sample ports according to Method 1A of appendix A-1 to part 60 of this chapter.

(3) Determine the flow rate through the control system exhaust(s) continuously during the test period according to either Methods 2, 2A, or 2C of appendix A-1 to part 60 of this chapter, as appropriate. If using Method 2, 2A, or 2C, you must complete velocity traverses immediately before and subsequently after each test run. If your test run is greater than 1 hour, you must also complete a velocity traverse at least every hour. Average the velocity collected during a test run and calculate volumetric flow as outlined in the appropriate method.

(4) Determine the oxygen and carbon dioxide concentration of the effluent according to Method 3A or 3B of appendix A-2 to part 60 of this chapter. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10-1981 (incorporated by reference, see § 63.14) may be used as an alternative to EPA Method 3B.

(5) Determine the moisture content of the stack gas according to Method 4 of appendix A-3 to part 60 of this chapter. Alternatively, you may use an on-line technique that has been validated using Method 301 of appendix A to this part.

(6) Determine the EtO concentration according to either paragraph (b)(6)(i) or (ii) of this section.

(i) Follow Method 320 of appendix A to this part and the following paragraphs (6)(i)(A) through (D).

(A) The instrumentation used for measurement must have the measurement range to properly quantify the EtO in the gas stream. Additionally, for outlet emission streams, the instrumentation must have a method detection limit an order of magnitude below concentration equivalent of the emission limit.

(B) Instrumentation used must be continuous in nature with an averaging time of one minute or less.

(C) Calibration Spectra and all other analyte spiking required in the method must use EtO gaseous cylinder standard(s) which meet the criteria found in Performance Specification 19 of appendix B to part 60 of this chapter.

(D) Other methods and materials may be used; however, these alternative test methods are subject to Administrator approval.

(ii) Alternatively, ASTM D6348-12 (Reapproved 2020), (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) The test plan preparation and implementation in the Annexes to ASTM D 6348-12 (R2020), Sections A1 through A8 are mandatory; and

(B) In ASTM D6348-12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). In order for the test data to be acceptable for a compound, %R must be 70% ≥ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using equation 1 to this paragraph:

Equation 1 to paragraph (b)(6)(ii)

Reported Results = ((Measured Concentration in Stack))/(%R) x 100.] (Eq. 1)

(7) Calculate the mass emission of EtO by using equations 2 and 3 to this paragraph:

Equations 2 and 3 to paragraph (b)(7)

$$M_{APCD,in} = \frac{C_{Eto,i} \text{ x } Q_i \text{ x } 44.05}{385.1 \text{ x } 10^6} \quad \text{(Eq. 2)}$$

$$E_{APCD,o} = \frac{C_{EtO,o} \text{ x } Q_o \text{ x } 44.05}{385.1 \text{ x } 10^9} \quad \text{(Eq. 3)}$$

Where:
$M_{APCD,in}$ = average inlet mass rate of EtO per hour, lb/hr
$C_{EtO,i}$ = inlet EtO concentration, ppmvd.
Q_i = average inlet volumetric flow per hour at standard conditions, dscf/hr
44.05 = molecular weight (MW) of EtO, lb/lb-mole
MW/385.1 × 10^6 = conversion factor, from ppmv at standard conditions to lb/cf
$E_{APCD,o}$ = average outlet mass rate of EtO per hour, lb/hr
$C_{EtO,o}$ = outlet EtO concentration, ppbvd.
Q_o = average outlet volumetric flow per hour at standard conditions, dscf/hr
MW/385.1 × 10^9 = conversion factor, from ppbv at standard conditions to lb/cf

(c) *Alternative approach for SCVs*. If you are using annual performance testing to demonstrate compliance with removal efficiency standards and you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to paragraph (b) of this section to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(1) Determine the mass ($M_{SCV,n}$) of EtO used for each charge and at each sterilization chamber used during the performance tests using the procedures in either paragraph (c)(1)(i) or (ii) of this section.

(i) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 4 to this paragraph.

Equation 4 to paragraph (c)(1)(i)

$$M_{SCV,n} = M_{charge} x \%EO_w \quad \text{(Eq. 4)}$$

Where:
$M_{SCV,n}$ = Theoretical total mass of EtO vented to controls per charge, g (lb)
M_{charge} = total mass of sterilizer gas charge, g (lb)
$\%EO_w$ = weight percent of EtO, in decimal format

(ii) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Q_m) and duration of each sterilizer charge. Calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 5 to this paragraph.

Equation 5 to paragraph (c)(1)(ii)

$$M_{SCV,n} = (Q_m \times T_n \times \%EO_v \times \frac{MW}{SV}) \quad \text{(Eq. 5)}$$

Where:
$M_{SCV,n}$ = Total mass of EtO sent to controls per charge
Q_m = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))
T_n = time duration of each charge, min
n = number of EtO charges
$\%EO_v$ = volume fraction percent of EtO, in decimal format
MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))
SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(2) Determine the mass rate of EtO sent to controls during the performance test using equation 6 to this paragraph.

Equation 6 to paragraph (c)(2)

$$M_{SCV} = \frac{\sum_{i=1}^{n} M_{SCV,n}}{T_t} x f_{default} \quad \text{(Eq. 6)}$$

Where:
M_{SCV} = Total mass of EtO sent to controls per hour, g/hr (lb/hr)
$M_{SCV,n}$ = Total mass of EtO sent to controls per charge per chamber, g (lb)
T_t = Total time of the performance test, hour
n = Total number of charges during testing period
$f_{default}$ = Portion of EtO use that is assumed to be routed to the control system (0.93 if aeration is conducted in separate vessel; 0.98 otherwise)

(d) *Compliance determination for annual performance testing*. Each compliance demonstration shall consist of three separate runs using the applicable methods in paragraph (b) and/or (c) of this section. To determine compliance with the relevant standard, arithmetic mean of the three runs must be used. These procedures must be performed over a run duration of at least 1 hour (for a total of three 1-hour runs), except for the SCV testing from this category, where each run shall consist of the entirety of the sterilizer chamber evacuation and subsequent washes. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent the entire range of normal operation, including operational conditions for maximum emissions if such emissions are not expected during maximum production. The owner or operator must also account for the control system residence time when conducting the performance test. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. The following procedures shall be used to demonstrate compliance with a removal efficiency standard. In addition to these procedures, the procedures in paragraph (e) of this section must be followed to establish the OPLs for each applicable emission control(s).

(1) You may determine the mass rate emissions of the stream prior to the control system and at the outlet of the control system using the test methods in paragraph (b) of this section. If the vent stream is comprised only of one or more SCVs, then you may use the procedures in paragraph (c) of this section for the mass rate emissions at the inlet.

(2) Calculate the total mass of EtO per hour that is routed to the control system by summing the mass of EtO per hour from each vent.

(3) Determine percent emission reduction (%ER) using the equation 7 to this paragraph:

Equation 7 to paragraph (d)(3)

$$\%ER = \frac{M_{APCD,i} - E_{APCD,o}}{M_{APCD,i}} \times 100 \qquad \text{(Eq. 7)}$$

Where:
% ER = percent emission reduction
$M_{APCD,i}$ = total mass of EtO per hour to the control device
$E_{APCD,o}$ = total mass of EtO per hour from the control device

(4) Repeat these procedures two additional times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control system.

(e) *Determination of operating parameter limits for control device(s)*. If you are using annual performance testing to demonstrate compliance with removal efficiency standards, and if you are not demonstrating continual compliance with the applicable standard(s) using an EtO CEMS, you must also determine the OPL(s) for each control device and then monitor the parameter(s) for each control device. The procedures in the following paragraphs shall be used to establish the OPLs to be continually monitored in § 63.364.

(1) *Acid-water scrubbers*. The procedures in paragraph (e)(1) of this section shall be used to determine the OPLs for acid-water scrubbers during the performance test.

(i) *Scrubber liquid-to-gas (L/G) ratio*. You must monitor and record the scrubber liquid inlet flow rate and the exit gas flow rate at least every 15 minutes during each test run. Establish the OPL of minimum scrubber L/G ratio by determining the total scrubber liquid inlet flow rate and the exit gas flow rate. Determine the average L/G during the performance test as the average of the test run averages.

(ii) *Scrubber liquid inlet temperature*. You must monitor and record the temperature at any point prior to entering the top of the scrubber column at least every 15 minutes during each test run. Establish the OPL of maximum scrubber liquid inlet temperature as the scrubber liquid inlet temperature averaged over three test runs.

(iii) *Scrubber liquid pH*. You must monitor and record the scrubber liquid pH at least every 15 minutes during each test run. Establish the OPL of maximum scrubber liquid pH as the liquid pH averaged over three test runs.

(2) *Thermal oxidizers*. The procedures in paragraph (e)(2) of this section shall be used to determine the OPLs for thermal oxidizers during the performance test.

(i) *Combustion chamber temperature.* You must monitor and record the combustion chamber temperature at least every 15 minutes during each test run. Establish the OPL of minimum combustion chamber temperature as the combustion chamber temperature averaged over three test runs.(ii) *Flue gas flow rate.* You must monitor and record the flue gas flow rate at least every 15 minutes during each test run. Establish the OPL of maximum flue gas flow rate as the flue gas flow rate averaged over three test runs.

(iii) Paragraphs (e)(2)(i) and (ii) of this section must be completed for each thermal oxidizer that is involved in the performance test.

(3) *Catalytic oxidizers*. The procedures in paragraph (e)(3) of this section shall be used to determine the OPLs for catalytic oxidizers during the performance test.

(i) Prior to the start of the performance test, you must check the catalyst bed for channeling, abrasion, and settling. If problems are found during the inspection, you must replace the catalyst bed or take other corrective action consistent with the manufacturer's recommendations.

(ii) *Temperature at the inlet to the catalyst bed.* You must monitor and record the temperature at the inlet to the catalyst bed at least every 15 minutes during each test run. Establish the OPL of minimum temperature at the inlet to the catalyst bed as the catalyst bed inlet temperature averaged over three test runs.

(iii) *Temperature difference across the catalyst bed.* You must monitor and record the temperatures at the inlet and outlet of the catalyst bed at least every 15 minutes during each test run. Establish the OPL of minimum temperature difference across the catalyst bed as the mean bed temperature difference averaged over three test runs.

(iv) *Flue gas flow rate.* You must monitor and record the flue gas flow rate at least every 15 minutes during each test run. Establish the OPL as the flue gas flow rate averaged over three test runs.

(v) Paragraphs (e)(3)(i) through (iv) of this section must be completed for each catalytic oxidizer that is involved in the performance test.

(4) *Gas/solid reactors*. The procedures in paragraph (e)(4) of this section shall be used to determine the OPLs for gas/solid reactors during the performance test.

(i) Gas/solid reactor *pressure drop.* You must monitor and record the pressure drop across the gas/solid reactor media beds at least every 15 minutes during each test run, Use the data collected during the most recent performance test to calculate the gas/solid reactor pressure measured. Establish the OPL of maximum gas/solid reactor pressure drop as the mean pressure difference averaged over three test runs.

(ii) *Gas/solid reactor outlet EtO concentraion*. You must monitor and record the inlet and outlet volumetric flow and inlet ethylene oxide concentration during the annual performance testing. Establish the maximum outlet EtO concentration using the procedures in § 63.364(d)(2).

(iii) Paragraphs (e)(4)(i) and (ii) of this section must be completed for each gas/solid reactor that is involved in the performance test.

(5) *Other control system*. If you seek to demonstrate compliance with a standard found at § 63.362 with a control device other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator the information requested under § 63.363(d). You must submit a monitoring plan that contains the following items: a description of the device; test results collected in accordance with § 63.363(d) verifying the performance of the device for controlling EtO emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored, identifying the ongoing QA procedures and performance specifications that will be conducted on the instruments; the frequency of conducting QA and performance checks; and the frequency of measuring and recording to establish continuous compliance with the standards. Your monitoring plan is subject to the Administrator's approval. Upon approval by the Administrator you must install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted in your monitoring plan. You must include in your monitoring plan proposed performance specifications and quality assurance procedures for your monitors. The

Administrator may request further information and shall approve appropriate test methods and procedures.

(6) *Application for alternative monitoring parameters*. You may submit an application to the Administrator under this paragraph for approval of alternative monitoring requirements and OPLs to document continuous compliance with the standards of this subpart, for acid-water scrubbers, catalytic oxidizers, thermal oxidizers, and gas-solid reactors. You must comply with the following procedures for application submitted under paragraph (e)(6) of this section:(i) *Timing of the application.* You must submit the application to the Administrator not later than submittal of the site-specific test plan.

(ii) *Content of the application.* You must include in the application:

(A) Data or information justifying your request for an alternative monitoring requirement;

(B) A description of the proposed alternative monitoring requirement, including the operating parameter to be monitored, the monitoring approach/technique (e.g., type of detector, monitoring location), the averaging period for the limit, and how the limit is to be calculated; and

(C) Data or information documenting that the alternative monitoring requirement would provide equivalent or better assurance of compliance with the relevant emission standard, or that it is the monitoring requirement that best assures compliance with the standard and that is technically and economically practicable.

§ 63.366 Reporting requirements.

(a) *General requirements*. The owner or operator of an affected source subject to the emissions standards in § 63.362 must fulfill all reporting requirements in § 63.10(a), (d), (e), and (f), according to the applicability in table 6 to this subpart. These reports will be made to the Administrator at the appropriate address identified in § 63.13 or submitted electronically.

(b) *Monitoring plan and initial compliance report submission*. You must submit a monitoring plan and an initial compliance report that provides summary, OPLs, monitoring system performance, and deviation information to the Administrator on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for one year, whichever date is later, and submit all subsequent reports using the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart and following the procedure specified in §63.9(k).The date report templates become available will be listed on the CEDRI website. Unless the Administrator or delegated state agency or other authority has approved a different schedule for submission of reports, the report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted.Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, along with information from any calibration tests in which the monitoring equipment is not in compliance with the method used for parameter monitoring device calibration or, if EtO CEMS are used, the Performance

Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the summary report shall include:

(1) The following information:

(i) Date that facility commenced construction or reconstruction;

(ii) Hours of commercial sterilization operation over the previous 12 months; and

(iii) Monthly EtO use, in tons, over the previous 36 months.

(iv) If you are electing to determine the mass of EtO sent to the control device from the SCV(s) via the procedure in § 63.364(f)(1)(i), you must report the daily EtO use from each applicable chamber for the previous 7 months.

(v) An indication on how you are demonstrating continuous compliance by conducting annual performance tests and continuous parametric monitoring, or by EtO CEMS.

(vi) An indication if you are required to comply with one or more combined emission stream limitations. If so, indicate the affected sources that are included in each combined emission stream limitation.

(vii) An indication if you are electing to comply with a site-wide emission limit. If you are electing to comply with a site-wide emission limit, report the daily EtO use over the previous 7 months.

(2) If your sterilization facility is demonstrating continuous compliance through annual performance testing, you must report the following:

(i) Control system ID;

(ii) Control device ID;

(iii) Control device type;

(iv) Recirculation tank ID if an acid-water scrubber is used to meet the emission standard;

(v) OPLs and continuous monitoring parameters recorded and reported and name of the performance test report used to calculate the OPLs; and

(vi) The ID(s) of the parametric monitoring equipment used to monitor each control system.

(3) You must report the following for each sterilization chamber at your facility:

(i) The sterilization chamber ID;

(ii) The ID of the control system that the SCV was routed to, if applicable;

(iii) The portion of SCV exhaust that was routed to the control system, if applicable;

(iv) The ID of the EtO CEMS that was used to monitor SCV emissions, if applicable;

(v) The portion of SCV exhaust that was monitored with the EtO CEMS, if applicable;

(vi) The ID of the control system that the CEV was routed to, if applicable;

(vii) The portion of CEV exhaust that was routed to the control system, if applicable;

(viii) The ID of the EtO CEMS that was used to monitor CEV emissions, if applicable;

(ix) The portion of CEV exhaust that was monitored with the EtO CEMS, if applicable;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the following for each room where there is the potential for EtO emissions:

(i) Room ID;

(ii) Documentation of the type of emissions occurring within the room, including aeration, EtO storage, EtO dispensing, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material;

(iii) The ID of the control system that the room air was routed to, if applicable;

(iv) The portion of room air that was routed to the control system, if applicable;

(v) The ID of the EtO CEMS that was used to monitor room air emissions, if applicable;

(vi) The portion of room air that was monitored with the EtO CEMS, if applicable;

(5) If an EtO CEMS was used to demonstrate continuous compliance with an emission standard for more than 30-operating days, you must report the following:

(i) The information specified in section 11 of appendix A to this subpart.

(ii) The affected sources that are included in each inlet that is being monitored with EtO CEMS;

(iii) The IDs of each inlet(s) to and outlet(s) from each control system.

(iv) The daily sum of EtO for each inlet, along with 30-operating day rolling sums.

(v) The daily sum of EtO emissions from each outlet of the control system, along with 30-operating day rolling sums.

(vi) For each day, calculate and report the daily mass emission limit that the control system must achieve based on the previous 30 days of data. For control systems with multiple emission streams, and complying with a combined emission stream limitation in § 63.362(h) or a SWEL in § 63.362(i), report the daily 30-operating day mass emission limit as determined in accordance with CES in § 63.362(i)(1)(i) and (i)(2)(i) or in accordance with SWEL in § 63.362(j)(1)(i) and (j)(2)(i), as applicable.

(vii) For each day, the mass of EtO emitted from the control system over the previous 30 operating days.

(6) If you are complying with the requirement to follow the best management practice to limit sterilization chamber end-cycle EtO concentration to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.364(i).

(7) If you own or operate an existing collection of Group 2 room air emissions at an area source facility, you must report the following for each room where there are Group 2 room air emissions:

(i) Room ID;

(ii) Number of room air changes per hour;

(iii) Room temperature, in degrees Celsius; and

(iv) EtO concentration, in ppmv dry basis (ppbvd).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility, you are not required to report the information in paragraph (b)(8) of this section if you meet the following requirements:

(i) You are complying with the best management practice to limit sterilization chamber end-cycle EtO concentration to 1 ppmv prior to opening the sterilization chamber door; and

(ii) The requirements of § 63.363 are met.

(9) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, duration, the cause (including unknown cause, if applicable), as applicable of each deviation and the corrective action taken. For each deviation, the report must include a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(c) *Quarterly compliance report submission*. You must submit compliance reports that provide summary, OPLs, monitoring system performance, and deviation information to the Administrator within 30 days following the end of each calendar quarter. Beginning on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for 1 year, whichever date is later, submit all subsequent reports using the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart and followi the procedure specified in §63.9(k). The date report templates become available will be listed on the CEDRI website. Unless the Administrator or delegated state agency or other authority has approved a different schedule for submission of reports, the report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted.Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, and information from any calibration tests in which the monitoring equipment is

not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. If there are any changes in the monitoring plan, this also needs to be included in the quarterly compliance report. In addition, the summary report shall include:

(1) The information listed in paragraphs (b)(1)(i) through (vi) of this section, with the exception that monthly EtO use, in tons, only needs to be reported for the previous 12 months;

(2) If your sterilization facility is demonstrating continuous compliance through annual performance testing, you must report the ID for any control system that has not operated since the end of the period covered by the previous compliance report. If a control system has commenced operation since end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(2)(i) through (v) of this section has changed for a control system that was included in the previous compliance report, you must report the information in paragraphs (b)(2)(i) through (v) of this section for those control systems;

(3) You must report the ID for any sterilization chamber that has not operated since the end of the period covered by the previous compliance report. If a sterilization chamber has commenced operation since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(3)(i) through (ix) of this section has changed for a sterilization chamber that was included in the previous compliance report, you must report the information in paragraphs (b)(3)(i) through (ix) of this section for those sterilization chambers;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the ID for any room where there has not been the potential for EtO emissions since the end of the period covered by the previous compliance report. If a room has had the potential for EtO emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(4)(i) through (vi) of this section has changed for a room where there is the potential for EtO emissions that was included in the previous compliance report, you must report the information in paragraphs (b)(4)(i) through (vi) of this section for those rooms;

(5) If an EtO CEMS was used to demonstrate continuous compliance, you must report the information specified in paragraphs (b)(5)(i) through (vii) of this section.

(6) If you are complying with the requirement to follow the best management practice to limit sterilization chamber end-cycle EtO concentration to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.364(h).

(7) If you own or operate an existing collection of Group 2 room air emissions at an area source facility, you must report the ID for any room where Group 2 room air emissions have ceased since end of the period covered by the previous compliance report. If a room has had Group 2 room air emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(7)(i) through (iv) of this section has changed for a room where there are Group 2 room air emissions that were included in the previous compliance report, you must report the information in paragraphs (b)(7)(i) through (iv) of this section for each room where there are Group 2 room air emissions.

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility, you are not required to report the information in paragraph (c)(7) of this section if you meet the requirements in paragraph (b)(8) of this section.

(9) Report the number of deviations to meet an applicable standard. For each instance, report the date, start and end time, duration, and the cause (including unknown cause, if applicable), as applicable of each deviation and the corrective action taken. For each deviation, the report must include a list of the affected sources or equipment, the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(d) *Construction and reconstruction application*. You must fulfill all requirements for construction or reconstruction of a major source facility in § 63.5, according to the applicability in table 6 to this subpart, and in this paragraph.

(1) *Applicability*.

(i) This paragraph (d) and § 63.5 implement the preconstruction review requirements of section 112(i)(1) for facilities subject to these emissions standards. In addition, this paragraph (d) and § 63.5 include other requirements for constructed and reconstructed facilities that are or become subject to these emissions standards.

(ii) After April 5, 2024, the requirements in this section and in § 63.5 apply to owners or operators who construct a new facility or reconstruct a facility subject to these emissions standards after April 5, 2024. New or reconstructed facilities subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (d)(2) and (3) of this section and § 63.5(d)(3) and (4) and (e).

(2) *Advance approval*. After April 5, 2024, no person may construct a new facility or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards, without obtaining advance written approval from the jurisdictional authority in accordance with the procedures specified in paragraph (d)(3) of this section and § 63.5(d)(3) and (4) and (e).

(3) *Application for approval of construction or reconstruction*. The provisions of paragraph (d)(3) of this section and § 63.5(d)(3) and (4) implement section 112(i)(1) of the Act.

(i) *General application requirements*.

(A) An owner or operator who is subject to the requirements of paragraph (d)(2) of this section shall submit to the Administrator an application for approval of the construction of a new facility subject to these emissions standards, the reconstruction of a facility subject to these emissions standards, or the reconstruction of a facility such that the facility becomes a facility subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (e)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(*1*) The applicant's name and address.

(*2*) A notification of intention to construct a new facility subject to these emissions standards or make any physical or operational change to a facility subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2.

(*3*) The address (*i.e.,* physical location) or proposed address of the facility.

(*4*) An identification of the relevant standard that is the basis of the application.

(*5*) The expected commencement date of the construction or reconstruction.

(*6*) The expected completion date of the construction or reconstruction.

(*7*) The anticipated date of (initial) startup of the facility.

(*8*) The type and quantity of hazardous air pollutants emitted by the facility, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the facility reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.

(*9*) Other information as specified in paragraph (d)(3)(ii) of this section and § 63.5(d)(3).

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (d)(3)(i)(B)(*8*) and (d)(3)(ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (e)(2) of this section.

(ii) *Application for approval of construction*. Each application for approval of construction shall include, in addition to the information required in paragraph (paragraph (d)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the facility subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (d)(3) of this section shall submit the actual control efficiencies as specified in paragraph (d)(3)(i)(C) of this section.

(4) *Approval of construction or reconstruction based on prior jurisdictional authority preconstruction review*.

(i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (d)(2) and (3) of this section and § 63.5(d)(3) and (4) if the owner or operator of a new or reconstructed facility who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed facility subject to these emissions standards has undergone a preconstruction review and approval process in the jurisdictional authority in which the facility is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the facility will meet these emissions standards as proposed, if the facility is properly built and operated;

(B) In making its finding, the jurisdictional authority has considered factors substantially equivalent to those specified in § 63.5(e)(1).

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (d)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in § 63.5. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(e) *Notification requirements*. The owner or operator of an affected source subject to an emissions standard in § 63.362 shall fulfill all notification requirements in § 63.9, according to the applicability in table 6 to this subpart, and in this paragraph (e).

(1) *Initial notifications*.

(i) If you own or operate an affected source subject to an emissions standard in § 63.362, you may use the application for approval of construction or reconstruction under paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed major source facility subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (d)(3) of this section and § 63.5(d)(3) and (4) shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new facility subject to these emissions standards, reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (d)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked no later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the facility, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the facility, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, an owner or operator who intends to construct a new major source facility subject to these emissions standards or reconstruct a major source facility subject to these emissions standards, or reconstruct a facility such that it becomes a major source facility subject to these emissions standards, shall notify the delegated authority in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred

before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (d)(3) of this section and § 63.5(d)(3) and (4). For major source facilities subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.9.

(2) If an owner or operator of a facility subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, in place of the actual emissions data or control efficiencies required in paragraphs (d)(3)(i)(B)(*8*) and (d)(3)(ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) If you own or operate an affected source subject to an emissions standard in § 63.362, you must also include the amount of EtO used at the facility during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3). For new sterilization facilities subject to this subpart, the amount of EtO used at the facility shall be an estimate of expected use during the first consecutive 12-month period of operation.

(4) Beginning October 7, 2024, you must submit all subsequent Notification of Compliance Status reports in PDF format to the EPA following the procedure specified in § 63.9(k), except any medium submitted through mail must be sent to the attention of the Commercial Sterilization Sector Lead.

(f) *Performance test submission*. Beginning on June 4, 2024, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in §63.9(k). Submit the data in a file format generated using the EPA's Electronic Reporting Tool (ERT). Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) accompanied by the other information required by §63.7(g)(2) in PDF format.

(g) *Performance evaluation submission*. If you demonstration compliance using EtO CEMS, beginning on [**DATE 60 DAYS AFTER PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER**], within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in §63.9(k). The results must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website accompanied by the other information required by §63.7(g)(2) in PDF format.

§ 63.367 Recordkeeping requirements.

(a) If you own or operate an affected source subject to § 63.362, you must comply with the recordkeeping requirements in § 63.10(a) through (c), according to the applicability in table 6

to this subpart, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection.

(b) You must maintain the previous five years of records specified in § 63.366(b) and (c), as applicable.

(c) You must maintain the previous five years of records for compliance tests and associated data analysis, as applicable.

(d) Any records required to be maintained by this subpart that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

(e) If you are using an EtO CEMS to demonstrate continuous compliance, you must maintain the previous five years of records for all required certification and QA tests.

(f) For each deviation from an emission limit, operating limit, or best management practice, you must keep a record of the information specified in paragraphs (f)(1) through (5) of this section. The records shall be maintained as specified in § 63.10(b)(1).

(1) The occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment.

(2) In the event that an affected unit does not meet an applicable standard, record the number of deviations. For each deviation, record the date, time, cause, and duration of each deviation.

(3) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(4) Record actions taken to minimize emissions in accordance with § 63.362(k) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.(g) If you are using continuous parametric monitoring to demonstrate continuous compliance, you must maintain the electronic records of the output from the continuous parametric monitors and data system, all calibrations, maintenance logs, and corrective actions as specified in § 63.10(b)(1), (b)(2)(iii), (b)(2)(vi) through (xiv), (b)(3) and (c).

§ 63.368 Implementation and enforcement.

(a) This subpart can be implemented and enforced by the U.S. EPA or a delegated authority such as the applicable State, local, or Tribal agency. If the U.S. EPA Administrator has delegated authority to a State, local, or Tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. Contact the applicable U.S. EPA

Regional Office to find out whether implementation and enforcement of this subpart are delegated to a State, local, or Tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or Tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of U.S. EPA and cannot be transferred to the State, local, or Tribal agency.

(c) The authorities that cannot be delegated to State, local, or Tribal agencies are as specified in paragraphs (c)(1) through (5) of this section.

(1) Approval of alternatives to the requirements in §§ 63.360 and 63.362.

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f), as defined in § 63.90, and as required in this subpart.

(3) Approval of major alternatives to monitoring under § 63.8(f), as defined in § 63.90, and as required in this subpart.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f), as defined in § 63.90, and as required in this subpart.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

Table 1 to Subpart O of Part 63—Standards for SCVs

As required in § 63.362(c), for each SCV, you must meet the applicable standard in the following table:

For each…	For which…	You must…	You must comply with the standard…
1. Existing SCV	a. Facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99 percent[1]	Until April 5, 2027.
		ii. Continuously reduce EtO emissions by 99.9 percent[2 3]	No later than April 5, 2027.
	b. Facility EtO use is at least 1 tpy but less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent[1]	Until April 5, 2027.
		ii. Continuously reduce EtO emissions by 99.8 percent[2 3]	No later than April 5, 2027.

	c. Facility EtO use is less than 1 tpy	i. Continuously reduce EtO emissions by 99 percent[2] [4]	No later than April 5, 2027.
2. New SCV			
	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99.9 percent[2] [5]	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is at least 1 tpy but less than 10 tpy	i. Continuously reduce EtO emissions by 99.8 percent[2] [5]	No later than April 5, 2024.
	c. Initial startup is on or before April 5, 2024, and facility EtO use is less than 1 tpy	i. Continuously reduce EtO emissions by 99 percent[2] [6]	No later than April 5, 2024.
	d. Initial startup is after April 5, 2024, and facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99.9 percent[2] [5]	Upon startup of the source.
	e. Initial startup is after April 5, 2024, and facility EtO use is at least 1 tpy but less than 10 tpy	i. Continuously reduce EtO emissions by 99.8 percent[2] [5]	Upon startup of the source.
	f. Initial startup is after April 5, 2024, and facility EtO use is less than 1 tpy	i. Continuously reduce EtO emissions by 99 percent[2] [6]	Upon startup of the source.

[1] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.

[2] If using EtO CEMS to determine compliance, this standard is based on the previous 30 operating days of data.

[3] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 5, 2026.

[4] The standard applies if the facility has used less than 1 tpy of EtO within all consecutive 12-month periods after April 5, 2026.

[5] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.

[6] The standard applies if the facility is not expected to meet or exceed 1 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 1 tpy of EtO within all consecutive 12-month periods after startup.

Table 2 to Subpart O of Part 63—Standards for ARVs

As required in § 63.362(d), for each ARV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing ARV	a. Facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99 percent[1]	Until April 5, 2027.
		ii. Continuously reduce EtO emissions by 99.6 percent[2] [3]	No later than April 5, 2027.
	b. Facility EtO use is less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent[2] [4]	No later than April 5, 2027.
2. New ARV	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99.6 percent[2] [5]	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024 and facility EtO use is less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent[2] [6]	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99.6 percent[2] [5]	Upon startup of the source.
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent[2] [6]	Upon startup of the source.

[1] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.

[2] If using CEMS to determine compliance, this standard is based on the previous 30 operating days of data.

[3] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 5, 2026.

[4] The standard applies if the facility has used less than 10 tpy of EtO within all consecutive 12-month periods after April 5, 2026.

[5] *The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.*

[6] *The standard applies if the facility is not expected to meet or exceed 10 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 10 tpy of EtO within all consecutive 12-month periods after startup.*

Table 3 to Subpart O of Part 63—Standards for CEVs

As required in § 63.362(e), for each CEV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing CEV at a major source facility	a. Not applicable	i. Continuously reduce EtO emissions by 99.94 percent[1]	No later than April 5, 2027.
2. Existing CEV at an area source facility	a. Not applicable	i. Continuously reduce EtO emissions by 99 percent[1]	No later than April 5, 2027.
3. New CEV at a major source facility	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 99.94 percent[1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 99.94 percent[1]	Upon startup of the source.
4. New CEV at an area source facility	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 99 percent[1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 99 percent[1]	Upon startup of the source.

[1] *If using CEMS to determine compliance, this standard is based on the previous 30 operating days of data.*

Table 4 to Subpart O of Part 63—Standards for Group 1 Room Air Emissions

As required in § 63.362(f), for your collection of Group 1 room air emissions at each facility, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the requirement(s) . . .
1. Existing collection of Group 1 room air emissions at a major source facility	a. Not applicable	i. Continuously reduce EtO emissions by 97 percent[1]	No later than April 5, 2027.
2. Existing collection of Group 1 room air emissions at an area source facility	a. Not applicable	i. Continuously reduce EtO emissions by 80 percent[1]	No later than April 5, 2027.
3. New collection of Group 1 room air emissions at a major source facility	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 97 percent[1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 97 percent[1]	Upon startup of the source.
4. New collection of Group 1 room air emissions at an area source facility	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 80 percent[14]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 80 percent[1]	Upon startup of the source.

[1] *If using CEMS to determine compliance, this standard is based on the previous 30 operating days of data.*

Table 5 to Subpart O of Part 63—Standards for Group 2 Room Air Emissions

As required in § 63.362(g), for your collection of Group 2 room air emissions, you must meet the applicable standard in the following table:

For each…	For which…	You must…	You must comply with the requirement(s) . . .
1. Existing collection of Group 2 room air emissions at a major source facility	a. Not applicable	i. Continuously reduce EtO emissions by 86 percent[1]	No later than April 5, 2027.
2. Existing collection of Group 2 room air emissions at an area source facility	a. Not applicable	i. Lower the sterilization chamber end-cycle EtO concentration to 1 ppm before the chamber can be opened. Or ii. Continuously reduce EtO emissions by 80 percent[1]	No later than April 5, 2027
3. New collection of Group 2 room air emissions at a major source facility	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 86 percent[1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 86 percent[1]	Upon startup of the source.
4. New collection of Group 2 room air emissions at an area source facility	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 80 percent[1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024	i. Also, ii. Continuously reduce EtO emissions by 80 percent[1]	Upon startup of the source.

[1] *This standard is based on the previous 30 operating days of data.*

Table 6 to Subpart O of Part 63—Applicability of General Provisions to This Subpart

As specified in § 63.360, the parts of the General Provisions that apply to you are shown in the following table:

Citation	Subject	Applies to subpart O
§ 63.1(a)(1)	Applicability	Yes, additional terms defined in §63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.1(a)(2)-(3)		Yes
§ 63.1(a)(4)		Yes. Subpart O clarifies the applicability of each paragraph in subpart A to facilities subject to subpart O.
§ 63.1(a)(5)	[Reserved]	No
§ 63.1(a)(6)-(8)		Yes
§ 63.1(a)(9)	[Reserved]	
§ 63.1(a)(10)-(14)		Yes
§ 63.1(b)(1)-(2)		Yes
§ 63.1(b)(3)		No.
§ 63.1(c)(1)		No. Subpart O clarifies the applicability of each paragraph in subpart A to facilities subject to subpart O in this table.
§ 63.1(c)(2)		Yes
§ 63.1(c)(3)	[Reserved]	No
§ 63.1(c)(4)		Yes
§ 63.1(c)(5)		No. § 63.360 specifies applicability.
§ 63.1(c)(6)		Yes

Citation	Subject	Applies to subpart O
§ 63.1(d)	[Reserved]	No
§ 63.1(e)		Yes
§ 63.2	Definitions	Yes, additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.3	Units and abbreviations	Yes, other units used in subpart O are defined in the text of subpart O.
§ 63.4(a)(1)-(3)	Prohibited activities	Yes
§ 63.5(a)	Construction/ Reconstruction	No. § 63.366(d)(1) contains applicability requirements for constructed or reconstructed facilities.
§ 63.5(b)(1)		Yes
§ 63.5(b)(2)	[Reserved]	
§ 63.5(b)(3)		No. See § 63.366(d)(2).
§ 63.5(b)(4)-(6)		Yes
§ 63.5(c)	[Reserved]	
§ 63.5(d)(1)-(2)		No. See § 63.366(d)(3).
§ 63.5(d)(3)-(4)		Yes
§ 63.5(e)		Yes
§ 63.5(f)(1)-(2)		No. See § 63.366(d)(4).
§ 63.6(a)	Applicability	Yes
§ 63.6(b)-(c)		No. § 63.360(j) specifies compliance dates for facilities.
§ 63.6(d)	[Reserved]	
§ 63.6(e)(1)(i)		No.

Citation	Subject	Applies to subpart O
§ 63.6(e)(1)(ii)	Requirement to correct malfunctions ASAP	No.
§ 63.6(e)(1)(iii)		Yes
§ 63.6(e)(2)	[Reserved]	No
§ 63.6(e)(3)	SSM Plan Requirements	No.
§ 63.6(f)(1)	SSM exemption	No.
§ 63.6(f)(2)(i)	Methods for Determining Compliance	Yes
§ 63.6(f)(2)(ii)		No. § 63.363 specifies parameters for determining compliance.
§ 63.6(f)(2)(iii)-(iv)		Yes
§ 63.6(f)(2)(v)		No
§ 63.6(f)(3)		Yes
§ 63.6(g)	Alternative Standard	Yes
§ 63.6(h)	Compliance with opacity and visible emission standards	No. Subpart O does not contain any opacity or visible emission standards.
§ 63.6(i)(1)-(14), and (16)	Compliance Extension	Yes.
§ 63.6(j)	Presidential Compliance Exemption	Yes.
§ 63.7(a)	Applicability and Performance Test Dates	Yes
§ 63.7(b)	Notification of Performance Test	Yes
§ 63.7(c)	Quality Assurance/Test Plan	Yes
§ 63.7(d)	Testing Facilities	Yes

Citation	Subject	Applies to subpart O
§ 63.7(e)(1)	SSM exemption	No.
§ 63.7(e)(2)-(4)	Conduct of Performance Tests	Yes. § 63.365 also contains test methods specific to facilities subject to the emissions standards.
§ 63.7(f)	Alternative Test Method	Yes
§ 63.7(g)	Performance Test Data Analysis	Yes, except this subpart specifies how and when the performance test and performance evaluation results are reported.
§ 63.7(h)	Waiver of Tests	Yes
§ 63.8(a)(1)	Applicability of Monitoring Requirements	Yes
§ 63.8(a)(2)	Performance Specifications	Yes
§ 63.8(a)(3)	[Reserved]	No
§ 63.8(a)(4)	Monitoring with Flares	Yes
§ 63.8(b)(1)	Monitoring	Yes
§ 63.8(b)(2)-(3)	Multiple Effluents and Multiple Monitoring Systems	Yes
§ 63.8(c)(1)(i)	General duty to minimize emissions and CMS operation.	No.
§ 63.8(c)(1)(ii)		No. A startup, shutdown, and malfunction plan is not required for these standards.
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS	No.
§ 63.8(c)(2)-(3)		Yes
§ 63.8(c)(4)-(5)		No. Frequency of monitoring measurements is provided in §

Citation	Subject	Applies to subpart O
		63.363; opacity monitors are not required for these standards.
§ 63.8(c)(6)		No. Performance specifications are contained in § 63.365.
§ 63.8(c)(7)(i)(A)-(B)		No. Performance specifications are contained in § 63.365.
§ 63.8(c)(7)(i)(C)		No. Opacity monitors are not required for these standards.
§ 63.8(c)(7)(ii)		No. Performance specifications are contained in § 63.365.
§ 63.8(c)(8)		No
§ 63.8(d)(1)-(2)		Yes.
§ 63.8(d)(3)	Written procedures for CMS	No.
§ 63.8(e)(1)	CMS Performance Evaluation	Yes, but only applies for CEMS, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.8(e)(2)		Yes
§ 63.8(e)(3)		Yes
§ 63.8(e)(4)		Yes
§ 63.8(e)(5)(i)		Yes
§ 63.8(e)(5)(ii)		No. Opacity monitors are not required for these standards.
§ 63.8(f)(1)-(5)		Yes
§ 63.8(f)(6)		No
§ 63.8(g)(1)		Yes
§ 63.8(g)(2)		No

Citation	Subject	Applies to subpart O
§ 63.8(g)(3)-(5)		Yes
§ 63.9(a)	Notification requirements	Yes.
§ 63.9(b)(1)-(i)		Yes.
§ 63.9(b)(1)(ii)-(iii)	Initial Notifications	No. § 63.366(e)(1)(i) contains language for facilities that increase usage such that the source becomes subject to the emissions standards.
§ 63.9(b)(2)-(3)	Initial Notifications	Yes. § 63.366(e)(3) contains additional information to be included in the initial notification for existing and new facilities.
§ 63.9(b)(4)-(5)	Initial Notifications	No. § 63.366(e)(1)(ii) and (iii) contains requirements for new or reconstructed facilities subject to the emissions standards.
§ 63.9(c)	Request for Compliance Extension	Yes
§ 63.9(d)	Notification of Special Compliance Requirements for New Sources	No
§ 63.9(e)	Notification of Performance Test	Yes
§ 63.9(f)	Notification of VE/Opacity Test	No. Opacity monitors are not required for these standards.
§ 63.9(g)(1)	Additional Notifications When Using CMS	Yes
§ 63.9(g)(2)-(3)	Additional Notifications When Using CMS	No. Opacity monitors and relative accuracy testing are not required for these standards.
§ 63.9(h)(1)-(3)	Notification of Compliance Status	Yes, except § 63.9(h)(5) does not apply because § 63.366(e)(2)

Citation	Subject	Applies to subpart O
		instructs facilities to submit actual data.
§ 63.9(i)	Adjustment of Submittal Deadlines	Yes
§ 63.9(j)	Change in previous information	Yes
§ 63.9(k)	Electronic reporting procedures	Yes
§ 63.10(a)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(1)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(2)(i)	Recordkeeping for startup and shutdown	No. See 63.367(f) for recordkeeping requirements.
§ 63.10(b)(2)(ii)	Recordkeeping for SSM and failures to meet standards	No. See 63.367(f) for recordkeeping requirements.
§ 63.10(b)(2)(iii)	Records related to maintenance of air pollution control equipment	Yes.
§ 63.10(b)(2)(iv)-(v)	Actions taken to minimize emissions during SSM	No.
§ 63.10(b)(2)(vi)	CMS Records	Yes.
§ 63.10(b)(2)(vii)-(ix)	Records	Yes.
§ 63.10(b)(2)(x)-(xi)	CMS Records	Yes.
§ 63.10(b)(2)(xii)	Records	Yes.
§ 63.10(b)(2)(xiii)	Records	Yes.
§ 63.10(b)(2)(xiv)	Records	Yes.
§ 63.10(b)(3)	Records	Yes.

Citation	Subject	Applies to subpart O
§ 63.10(c)(1)-(14)	Records	Yes.
§ 63.10(c)(15)	Use of SSM Plan	No.
§ 63.10(d)(1)	General Reporting Requirements	Yes.
§ 63.10(d)(2)	Report of Performance Test Results	No. This subpart specifies how and when the performance test results are reported.
§ 63.10(d)(3)	Reporting Opacity or VE Observations	No. Subpart O does not contain opacity or visible emissions standards.
§ 63.10(d)(4)	Progress Reports	Yes.
§ 63.10(d)(5)	SSM Reports	No. See § 63.366 for malfunction reporting requirements.
§ 63.10(e)(1)	Additional CEMS Reports	Yes.
§ 63.10(e)(2)(i)	Additional CMS Reports	Yes, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.10(e)(2)(ii)	Additional COMS Reports	No. Opacity monitors are not required for these standards.
§ 63.10(e)(3)(i)-(iv)	Reports	Yes.
§ 63.10(e)(3)(v)	Excess Emissions Reports	No. § 63.366(b) and (c) specify contents and submittal dates for excess emissions and monitoring system performance reports.
§ 63.10(e)(3)(vi)-(viii)	Excess Emissions Report and Summary Report	Yes.
§ 63.10(e)(4)	Reporting COMS data	No. Opacity monitors are not required for these standards.
§ 63.10(f)	Waiver for Recordkeeping/Reporting	Yes.

Citation	Subject	Applies to subpart O
§ 63.11	Control device requirements for flares and work practice requirements for equipment leaks	Yes.
§ 63.12	Delegation	Yes.
§ 63.13	Addresses	Yes.
§ 63.14	Incorporation by Reference	Yes.
§ 63.15	Availability of Information	Yes.

Appendix A to Subpart O of Part 63—Monitoring Provisions for EtO CEMS

1. Applicability

These monitoring provisions apply to the measurement of EtO emissions from commercial sterilization facilities, using CEMS. The CEMS must be capable of measuring EtO in lb/hr.

2. Monitoring of EtO Emissions

2.1 *Monitoring System Installation Requirements*. Install EtO CEMS and any additional monitoring systems needed to convert pollutant concentrations to lb/hr in accordance with § 63.365 and Performance Specification 19 (PS 19) of appendix B to part 60 of this chapter.

2.2 *Primary and Backup Monitoring Systems*. In the electronic monitoring plan described in section 10.1.1.2.1 of this appendix, you must designate a primary EtO CEMS. The primary EtO CEMS must be used to report hourly EtO concentration values when the system is able to provide quality-assured data, *i.e.,* when the system is "in control". However, to increase data availability in the event of a primary monitoring system outage, you may install, operate, maintain, and calibrate backup monitoring systems, as follows:

2.2.1 *Redundant Backup Systems*. A redundant backup monitoring system is a separate EtO CEMS with its own probe, sample interface, and analyzer. A redundant backup system is one that is permanently installed at the unit or stack location and is kept on "hot standby" in case the primary monitoring system is unable to provide quality-assured data. A redundant backup system must be represented as a unique monitoring system in the electronic monitoring plan. Each redundant backup monitoring system must be certified according to the applicable provisions in section 3 of this appendix and must meet the applicable on-going QA requirements in section 5 of this appendix.

2.2.2 *Non-redundant Backup Monitoring Systems*. A non-redundant backup monitoring system is a separate EtO CEMS that has been certified at a particular unit or stack location but is not

permanently installed at that location. Rather, the system is kept on "cold standby" and may be reinstalled in the event of a primary monitoring system outage. A nonredundant backup monitoring system must be represented as a unique monitoring system in the electronic monitoring plan. Non-redundant backup EtO CEMS must complete the same certification tests as the primary monitoring system, with one exception. The 7-day calibration error test is not required for a non-redundant backup EtO CEMS. Except as otherwise provided in section 2.2.4.4 of this appendix, a non-redundant backup monitoring system may only be used for 720 hours per year at a particular unit or stack location.

2.2.3 *Temporary Like-kind Replacement Analyzers*. When a primary EtO analyzer needs repair or maintenance, you may temporarily install a like-kind replacement analyzer, to minimize data loss. Except as otherwise provided in section 2.2.4.4 of this appendix, a temporary like-kind replacement analyzer may only be used for 720 hours per year at a particular unit or stack location. The analyzer must be represented as a component of the primary EtO CEMS and must be assigned a 3-character component ID number, beginning with the prefix "LK".

2.2.4 *Quality Assurance Requirements for Non-redundant Backup Monitoring Systems and Temporary Like-kind Replacement Analyzers*. To quality-assure the data from non-redundant backup EtO monitoring systems and temporary like-kind replacement EtO analyzers, the following provisions apply:

2.2.4.1 When a certified non-redundant backup EtO CEMS or a temporary like-kind replacement EtO analyzer is brought into service, a calibration error test and a linearity check must be performed and passed. A single point system integrity check is also required.

2.2.4.2 Each non-redundant backup EtO CEMS or temporary like-kind replacement EtO analyzer shall comply with all required daily, weekly, and quarterly quality-assurance test requirements in section 5 of this appendix, for as long as the system or analyzer remains in service.

2.2.4.3 For the routine, on-going quality-assurance of a non-redundant backup EtO monitoring system, a relative accuracy test audit (RATA) must be performed and passed at least once every 8 calendar quarters at the unit or stack location(s) where the system will be used. RATA test runs must be at least 21 minutes in length.

2.2.4.4 To use a non-redundant backup EtO monitoring system or a temporary like-kind replacement analyzer for more than 720 hours per year at a particular unit or stack location, a RATA must first be performed and passed at that location.

2.3 Monitoring System Equipment, Supplies, Definitions, and General Operation.

The following provisions apply:

2.3.1 PS 19, sections 3.0, 6.0, and 11.0 of appendix B to part 60 of this chapter.

3. Initial Certification Procedures

The initial certification procedures for the EtO CEMS used to provide data under this subpart are as follows:

3.1 Your EtO CEMS must be certified according to PS 19, section(s) 13.

3.2 Any additional stack gas flow rate monitoring system(s) needed to express pollutant concentrations in lb/hr must be certified according to § 63.364(g)(2) of this chapter.

4. Recertification Procedures

Whenever the owner or operator makes a replacement, modification, or change to a certified CEMS that may significantly affect the ability of the system to accurately measure or record pollutant gas concentrations or stack gas flow rates, the owner or operator shall recertify the monitoring system. Furthermore, whenever the owner or operator makes a replacement, modification, or change to the flue gas handling system or the unit operation that may significantly change the concentration or flow profile, the owner or operator shall recertify the monitoring system. The same tests performed for the initial certification of the monitoring system shall be repeated for recertification, unless otherwise specified by the Administrator. Examples of changes that require recertification include: Replacement of a gas analyzer; complete monitoring system replacement, and changing the location or orientation of the sampling probe.

5. On-Going Quality Assurance Requirements

On-going QA test requirements for EtO CEMS must be implemented as follows:

5.1 The quality assurance/quality control procedures in Procedure 7 of appendix F to part 60 of this chapter shall apply.

5.2 Diluent gas and moisture monitoring systems must meet the applicable ongoing QA test requirements of PS-19. Stack gas flow rate must meet the QA requirements in § 63.364(g)(2) of this chapter.

5.2.1 *Out-of-Control Periods*. A EtO CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The EtO CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.2.2 *Grace Periods*. For the purposes of this appendix, a “grace period” is defined as a specified number of unit or stack operating hours after the deadline for a required QA test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.2.2.1 For the flow rate monitoring systems described in section 3.2 of this appendix, a 720 unit or stack operating hour grace period is available for RATAs.

5.2.2.2 For the purposes of this appendix, if the deadline for a required gas audit or RATA of a EtO CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.2.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit; or

5.2.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.2.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.2.2.3.1 For the gas audit of an EtO CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit is required for that quarter.

5.2.2.3.2 For the RATA of an EtO CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

5.3 *Data Validation*.

5.3.1 *Out-of-Control Periods*. An EtO CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The EtO CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.3.2 *Grace Periods*. For the purposes of this appendix, a "grace period" is defined as a specified number of unit or stack operating hours after the deadline for a required quality-assurance test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.3.2.1 For stack gas flow rate monitoring systems, a 720 unit or stack operating hour grace period is available for RATAs.

5.3.2.2 For the purposes of this appendix, if the deadline for a required gas audit/data accuracy assessment or RATA of an EtO CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.3.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit or other quarterly data accuracy assessment; or

5.3.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.3.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.3.2.3.1 For the gas audit or other quarterly data accuracy assessment of an EtO CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit/data accuracy assessment is required for that quarter.

5.3.2.3.2 For the RATA of an EtO CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

6. Missing Data Requirements

For the purposes of this appendix, the owner or operator of an affected unit shall not substitute for missing data from EtO CEMS. Any process operating hour for which quality-assured EtO concentration data are not obtained is counted as an hour of monitoring system downtime.

7. Bias Adjustment

Bias adjustment of hourly emissions data from an EtO CEMS is not required.

8. QA/QC Program Requirements

The owner or operator shall develop and implement a quality assurance/quality control (QA/QC) program for the EtO CEMS that are used to provide data under this subpart. At a minimum, the program shall include a written plan that describes in detail (or that refers to separate documents containing) complete, step-by-step procedures and operations for the most important QA/QC activities. Electronic storage of the QA/QC plan is permissible, provided that the information can be made available in hard copy to auditors and inspectors. The QA/QC program requirements for stack gas flow rate monitoring systems are specified in § 63.364(g)(2) of this chapter.

8.1 *General Requirements for EtO CEMS*.

8.1.1 *Preventive Maintenance*. Keep a written record of procedures needed to maintain the EtO CEMS in proper operating condition and a schedule for those procedures. This shall, at a minimum, include procedures specified by the manufacturers of the equipment and, if applicable, additional or alternate procedures developed for the equipment.

8.1.2 *Recordkeeping and Reporting*. Keep a written record describing procedures that will be used to implement the recordkeeping and reporting requirements of this appendix.

8.1.3 *Maintenance Records*. Keep a record of all testing, maintenance, or repair activities performed on any EtO CEMS in a location and format suitable for inspection. A maintenance log may be used for this purpose. The following records should be maintained: Date, time, and description of any testing, adjustment, repair, replacement, or preventive maintenance action performed on any monitoring system and records of any corrective actions associated with a monitor outage period. Additionally, any adjustment that may significantly affect a system's ability to accurately measure emissions data must be recorded and a written explanation of the procedures used to make the adjustment(s) shall be kept.

8.2 *Specific Requirements for EtO CEMS*. The following requirements are specific to EtO CEMS:

8.2.1 Keep a written record of the procedures used for each type of QA test required for each EtO CEMS. Explain how the results of each type of QA test are calculated and evaluated.

8.2.2 Explain how each component of the EtO CEMS will be adjusted to provide correct responses to calibration gases after routine maintenance, repairs, or corrective actions.

8.2.3 EtO emissions data must be collected over at least 90 percent of the process operating time. Periods associated with normal quality assurance activities, such as daily calibrations, do not count as periods of data unavailability. Periods of out-of-control monitor operation or when the EtO CEMS is unable to provide quality-assured data, such as those periods associated with monitor or data acquisition and handling system failure, are periods of data unavailability.

9. Data Reduction and Calculations

9.1 Design and operate the EtO CEMS to complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute period.

9.2 Reduce the EtO concentration data to hourly averages in accordance with § 60.13(h)(2) of this chapter.

9.3 Convert each hourly average EtO concentration to an EtO mass emission rate (lb/hr) using an equation that has the general form of equation A-1 of this appendix:

$$E_{ho} = KC_hQ_h \qquad \text{(Eq. A-1)}$$

Where:
E_{ho} = EtO mass emission rate for the hour, lb/hr
K = Units conversion constant, 1.144E-10 lb/scf-ppbv,
C_h = Hourly average EtO concentration, ppbv,
Q_h = Stack gas volumetric flow rate for the hour, scfh.

(Note: Use unadjusted flow rate values; bias adjustment is not required.)

9.4 Use equation A-2 of this appendix to calculate the daily total EtO emissions. Report each daily total to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and CEV subject to 99.9% and 99.94% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation.

$$E_{day} = \sum_{h=1}^{24} (E_{ho} * 1\ hr) \qquad \text{Equation A-2}$$

Where:
E_{day} = Total daily EtO emissions, lb.

E_{ho} = Hourly EtO emission rate for unit or stack sampling hour "h" in the averaging period, from equation A-1 of this appendix, lb/hr.

9.5 Use equation A-3 of this appendix to calculate the 30-operating day rolling total EtO emissions. Report each 30-operating day rolling total to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and CEV subject to 99.9% and 99.94% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation.

$$E_{30day} = \sum_{i=1}^{30} E_{day,i} \qquad \text{Equation A-3}$$

Where:
E_{30day} = Total EtO emissions during the 30-operating day, lb.
$E_{day,i}$ = Total daily EtO emissions, in lbs, for each operating day i from equation A-2 of this appendix, lb.
i = Operating day index.

10. Recordkeeping Requirements

10.1 For each EtO CEMS installed at an affected source, and for any other monitoring system(s) needed to convert pollutant concentrations to units of the applicable emissions limit, the owner or operator must maintain a file of all measurements, data, reports, and other information required by this appendix in a form suitable for inspection, for 5 years from the date of each record, in accordance with § 63.367. The file shall contain the information in sections 10.1.1 through 10.1.5 of this section.

10.1.1 *Monitoring Plan Records*. For each affected source or group of sources monitored at a common stack, the owner or operator shall prepare and maintain a monitoring plan for the EtO CEMS and any other monitoring system(s) (*i.e.,* flow rate, diluent gas, or moisture systems) needed to convert pollutant concentrations to units of the applicable emission standard. The monitoring plan shall contain essential information on the CMS and shall explain how the data derived from these systems ensure that all EtO emissions from the unit or stack are monitored and reported.

10.1.1.1 *Updates*. Whenever the owner or operator makes a replacement, modification, or change in a certified continuous EtO monitoring system that is used to provide data under this subpart (including a change in the automated data acquisition and handling system or the flue gas handling system) that affects information reported in the monitoring plan (*e.g.,* a change to a serial number for a component of a monitoring system), the owner or operator shall update the monitoring plan.

10.1.1.2 *Contents of the Monitoring Plan*. For EtO CEMS, the monitoring plan shall contain the applicable electronic and hard copy information in sections 10.1.1.2.1 and 10.1.1.2.2 of this appendix. For diluent gas and moisture monitoring systems, the monitoring plan shall include the

electronic and hard copy information required for those systems under § 63.366(b) of this chapter. The electronic monitoring plan shall be submitted using CEDRI.

10.1.1.2.1 *Electronic*. Record the unit or stack ID number(s); monitoring location(s); the EtO monitoring methodology used (*i.e.,* CEMS); EtO monitoring system information, including, but not limited to: unique system and component ID numbers; the make, model, and serial number of the monitoring equipment; the sample acquisition method; formulas used to calculate emissions; monitor span and range information (if applicable).

10.1.1.2.2 *Hard Copy*. Keep records of the following: schematics and/or blueprints showing the location of the monitoring system(s) and test ports; data flow diagrams; test protocols; monitor span and range calculations (if applicable); miscellaneous technical justifications.

10.1.2 *EtO Emissions Records*. For EtO CEMS, the owner or operator must record the following information for each unit or stack operating hour:

10.1.2.1 The date and hour;

10.1.2.2 Monitoring system and component identification codes, as provided in the electronic monitoring plan, for each hour in which the CEMS provides a quality-assured value of EtO concentration (as applicable);

10.1.2.3 The pollutant concentration, for each hour in which a quality-assured value is obtained. Record the data in parts per billion by volume (ppbv), with one leading non-zero digit and one decimal place, expressed in scientific notation. Use the following rounding convention: If the digit immediately following the first decimal place is 5 or greater, round the first decimal place upward (increase it by one); if the digit immediately following the first decimal place is 4 or less, leave the first decimal place unchanged.

10.1.2.4 A special code, indicating whether or not a quality-assured EtO concentration value is obtained for the hour. This code may be entered manually when a temporary like-kind replacement EtO analyzer is used for reporting; and

10.1.2.5 Determination of Monitor data availability.

10.1.2.5.1 Following initial certification of the required EtO monitoring system, the owner or operator shall begin calculating the percent monitor data availability as described in section 10.1.2.5.1.1 of this appendix, and shall record and report the percent monitor data availability for each monitored parameter. The percent monitor data availability shall be calculated for each monitored parameter at each unit or stack location, as follows:

10.1.2.5.1.1 Prior to completion of 8,760 unit or stack operating hours following initial certification, the owner or operator shall use Equation A-4 of this appendix to calculate, hourly, percent monitor data availability.

$$\text{Percent monitor data availability} = \frac{\text{Total unit operating hours for which quality-assured data were recorded since certification}}{\text{Total unit operating hours since certification}} \times 100$$

Equation A-4

10.1.2.5.1.2 Upon completion of 8,760 unit (or stack) operating hours following initial certification and thereafter, the owner or operator shall, use Equation A-5 of this appendix to calculate hourly, percent monitor data availability.

$$\text{Percent monitor data availability} = \frac{\text{Total unit operating hours for which quality-assured data were recorded during previous 8,760 unit operating hours}}{8{,}760} \times 100$$

Equation A-5

10.1.2.5.1.3 When calculating percent monitor data availability using Equation A-4 or A-5 of this appendix, the owner or operator shall include all unit operating hours, and all monitor operating hours for which quality-assured data were recorded by a certified primary monitor, a certified redundant or non-redundant backup monitor or a reference method for that unit.

10.1.2.5.2 The monitor data availability shall be calculated for each hour during each missing data period. The owner or operator shall record the percent monitor data availability for each hour of each missing data period.

10.1.3 *Stack Gas Volumetric Flow Rate Records*.

10.1.3.1 Hourly measurements of stack gas volumetric flow rate during unit operation are required to demonstrate compliance with EtO emission standards.

10.1.3.2 Use a flow rate monitor that meets the requirements of § 63.364(g)(1) and (2) of this chapter to record the required data. You must keep hourly flow rate records.

10.1.4 *EtO Emission Rate Records*. Record the following information for each affected unit or common stack:

10.1.4.1 The date and hour;

10.1.4.2 The hourly EtO emissions rate (lb/hr), for each hour in which valid values of EtO concentration and stack gas volumetric flow rate are obtained for the hour. Report each emission rate to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and CEV subject to 99.9% and 99.94% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation. Use the following rounding convention: If the digit immediately following the first decimal place is 5 or greater, round the first decimal place upward (increase it by one); if the digit immediately following the first decimal place is 4 or less, leave the first decimal place unchanged;

10.1.4.3 A code indicating that the EtO emission rate was not calculated for the hour, if valid data for EtO concentration and/or any of the other necessary parameters are not obtained for the hour. For the purposes of this appendix, the substitute data values for stack gas flow rate are not considered to be valid data.

10.1.5 *Certification and Quality Assurance Test Records*. For the EtO CEMS used to provide data under this subpart at each affected unit (or group of units monitored at a common stack), record the following information for all required certification, recertification, diagnostic, and quality-assurance tests:

10.1.5.1 EtO CEMS.

10.1.5.1.1 For each required 7-day and daily calibration drift (CD) test or daily calibration error test (including daily calibration transfer standard tests) of the EtO CEMS, record the test date(s) and time(s), reference gas value(s), monitor response(s), and calculated calibration drift or calibration error value(s). If you use the dynamic spiking option for the mid-level calibration drift check under PS 19 of appendix B to part 60 of this chapter, you must also record the measured concentration of the native EtO in the flue gas before and after the spike and the spiked gas dilution factor.

10.1.5.1.2 For each required RATA of an EtO CEMS, record the beginning and ending date and time of each test run, the reference method(s) used, and the reference method and EtO CEMS run values. Keep records of stratification tests performed (if any), all of the raw field data, relevant process operating data, and all of the calculations used to determine the relative accuracy.

10.1.5.1.3 For each required measurement error (ME) test of an EtO monitor, record the date and time of each gas injection, the reference gas concentration (low, mid, or high) and the monitor response for each of the three injections at each of the three levels. Also record the average monitor response and the ME at each gas level and the related calculations.

10.1.5.1.4 For each required level of detection (LOD) test of an EtO monitor performed in a controlled environment, record the test date, the concentrations of the reference gas and interference gases, the results of the seven (or more) consecutive measurements of EtO, the standard deviation, and the LOD value. For each required LOD test performed in the field, record the test date, the three measurements of the native source EtO concentration, the results of the three independent standard addition (SA) measurements known as standard addition response (SAR), the effective spike addition gas concentration, the resulting standard addition detection level (SADL) value and all related calculations. For extractive CEMS performing the SA using dynamic spiking, you must record the spiked gas dilution factor.

10.1.5.1.5 For each required ME/level of detection response time test of an EtO monitor, record the test date, the native EtO concentration of the flue gas, the reference gas value, the stable reference gas readings, the upscale/downscale start and end times, and the results of the upscale and downscale stages of the test.

10.1.5.1.6 For each required interference test of an EtO monitor, record (or obtain from the analyzer manufacturer records of): The date of the test; the gas volume/rate, temperature, and

pressure used to conduct the test; the EtO concentration of the reference gas used; the concentrations of the interference test gases; the baseline EtO responses for each interferent combination spiked; and the total percent interference as a function of span or EtO concentration.

10.1.5.1.7 For each quarterly relative accuracy audit (RAA) of an EtO monitor, record the beginning and ending date and time of each test run, the reference method used, the EtO concentrations measured by the reference method and CEMS for each test run, the average concentrations measured by the reference method and the CEMS, and the calculated relative accuracy. Keep records of the raw field data, relevant process operating data, and the calculations used to determine the relative accuracy.

10.1.5.1.8 For each quarterly cylinder gas audit (CGA) of an EtO monitor, record the date and time of each injection, and the reference gas concentration (zero, mid, or high) and the monitor response for each injection. Also record the average monitor response and the calculated ME at each gas level.

10.1.5.1.9 For each quarterly dynamic spiking audit (DSA) of an EtO monitor, record the date and time of the zero gas injection and each spike injection, the results of the zero gas injection, the gas concentrations (mid and high) and the dilution factors and the monitor response for each of the six upscale injections as well as the corresponding native EtO concentrations measured before and after each injection. Also record the average dynamic spiking error for each of the upscale gases, the calculated average DSA Accuracy at each upscale gas concentration, and all calculations leading to the DSA Accuracy.

10.1.5.2 *Additional Monitoring Systems*. For the stack gas flow rate monitoring systems described in section 3.2 of this appendix, you must keep records of all certification, recertification, diagnostic, and on-going quality-assurance tests of these systems, as specified in § 63.364(g)(2) of this chapter.

11. Reporting Requirements

11.1 *General Reporting Provisions*. The owner or operator shall comply with the following requirements for reporting EtO emissions from each affected unit (or group of units monitored at a common stack):

11.1.1 Notifications, in accordance with section 11.2 of this appendix;

11.1.2 Monitoring plan reporting, in accordance with section 11.3 of this appendix;

11.1.3 Certification, recertification, and QA test submittals, in accordance with section 11.4 of this appendix; and

11.1.4 Electronic quarterly report submittals, in accordance with section 11.5 of this appendix.

11.2 *Notifications*. The owner or operator shall provide notifications for each affected unit (or group of units monitored at a common stack) in accordance with § 63.366.

11.3 *Monitoring Plan Reporting*. For each affected unit (or group of units monitored at a common stack) using EtO CEMS, the owner or operator shall make electronic and hard copy monitoring plan submittals as follows:

11.3.1 For a sterilization facility that begins reporting hourly EtO concentrations with a previously certified CEMS, submit the monitoring plan information in section 10.1.1.2 of this appendix prior to or concurrent with the first required quarterly emissions report. For a new sterilization facility, submit the information in section 10.1.1.2 of this appendix at least 21 days prior to the start of initial certification testing of the CEMS. Also submit the monitoring plan information in §63.364(a)(6) of this chapterpertaining to any required flow rate monitoring systems within the applicable timeframe specified in this section, if the required records are not already in place.

11.3.2 Update the monitoring plan when required, as provided in section 10.1.1.1 of this appendix. An electronic monitoring plan information update must be submitted either prior to or concurrent with the quarterly report for the calendar quarter in which the update is required.

11.3.3 All electronic monitoring plan submittals and updates shall be made to the Administrator using CEDRI. Hard copy portions of the monitoring plan shall be kept on record according to section 10.1 of this appendix.

11.4 *Certification, Recertification, and Quality-Assurance Test Reporting Requirements*. Use CEDRI to submit the results of all required certification, recertification, quality-assurance, and diagnostic tests of the monitoring systems required under this appendix electronically. Submit the test results concurrent with the quarterly electronic emissions report. However, for RATAs of the EtO monitor, if this is not possible, you have up to 60 days after the test completion date to submit the test results; in this case, you may claim provisional status for the emissions data affected by the test, starting from the date and hour in which the test was completed and continuing until the date and hour in which the test results are submitted. If the test is successful, the status of the data in that time period changes from provisional to quality-assured, and no further action is required. However, if the test is unsuccessful, the provisional data must be invalidated and resubmission of the affected emission report(s) is required.

11.4.1 For each daily CD (or calibration error) assessment (including daily calibration transfer standard tests), and for each seven-day calibration drift (CD) test of an EtO monitor, report:

11.4.1.1 Facility ID information;

11.4.1.2 The monitoring component ID;

11.4.1.3 The instrument span and span scale;

11.4.1.4 For each gas injection, the date and time, the calibration gas level (zero or high-level), the reference gas value (ppbv), and the monitor response (ppbv);

11.4.1.5 A flag to indicate whether dynamic spiking was used for the high-level value;

11.4.1.6 Calibration drift (percent of span or reference gas, as applicable);

11.4.1.7 When using the dynamic spiking option, the measured concentration of native EtO before and after each mid-level spike and the spiked gas dilution factor; and

11.4.1.8 Reason for test.

11.4.2 For each RATA of an EtO CEMS, report:

11.4.2.1 Facility ID information;

11.4.2.2 Monitoring system ID number;

11.4.2.3 Type of test (*i.e.,* initial or annual RATA);

11.4.2.4 Reason for test;

11.4.2.5 The reference method used;

11.4.2.6 Starting and ending date and time for each test run;

11.4.2.7 Units of measure;

11.4.2.8 The measured reference method and CEMS values for each test run, on a consistent moisture basis, in appropriate units of measure;

11.4.2.9 Flags to indicate which test runs were used in the calculations;

11.4.2.10 Arithmetic mean of the CEMS values, of the reference method values, and of their differences;

11.4.2.11 Standard deviation, using equation 7 in section 12.6 of PS 19 in appendix B to part 60 of this chapter;

11.4.2.12 Confidence coefficient, using equation 8 in section 12.6 of PS 19 in appendix B to part 60 of this chapter;

11.4.2.13 t-value; and

11.4.2.14 Relative accuracy calculated using equation 11 in section 12.6 of PS 19 in appendix B to part 60 of this chapter.

11.4.3 For each ME test of an EtO monitor, report:

11.4.3.1 Facility ID information;

11.4.3.2 Monitoring component ID;

11.4.3.3 Instrument span and span scale;

11.4.3.4 For each gas injection, the date and time, the calibration gas level (zero, low, mid, or high), the reference gas value in ppbv and the monitor response.

11.4.3.5 For extractive CEMS, the mean reference value and mean of measured values at each reference gas level (ppbv).

11.4.3.6 ME at each reference gas level; and

11.4.3.7 Reason for test.

11.4.4 For each interference test of an EtO monitoring system, report:

11.4.4.1 Facility ID information;

11.4.4.2 Date of test;

11.4.4.3 Monitoring system ID;

11.4.4.4 Results of the test (pass or fail);

11.4.4.5 Reason for test; and

11.4.4.6 A flag to indicate whether the test was performed: On this particular monitoring system; on one of multiple systems of the same type; or by the manufacturer on a system with components of the same make and model(s) as this system.

11.4.5 For each LOD test of an EtO monitor, report:

11.4.5.1 Facility ID information;

11.4.5.2 Date of test;

11.4.5.3 Reason for test;

11.4.5.4 Monitoring system ID;

11.4.5.5 A code to indicate whether the test was done in a controlled environment or in the field;

11.4.5.6 EtO reference gas concentration;

11.4.5.7 EtO responses with interference gas (seven repetitions);

11.4.5.8 Standard deviation of EtO responses;

11.4.5.9 Effective spike addition gas concentrations;

11.4.5.10 EtO concentration measured without spike;

11.4.5.11 EtO concentration measured with spike;

11.4.5.12 Dilution factor for spike;

11.4.5.13 The controlled environment LOD value (ppbv or ppbv-meters);

11.4.5.14 The field determined SADL (in ppbv or ppbv-meters); and

11.4.5.15 Result of LOD/SADL test (pass/fail).

11.4.6 For each ME or LOD response time test of an EtO monitor, report:

11.4.6.1 Facility ID information;

11.4.6.2 Date of test;

11.4.6.3 Monitoring component ID;

11.4.6.4 The higher of the upscale or downscale tests, in minutes; and

11.4.6.5 Reason for test.

11.4.7 For each quarterly RAA of an EtO monitor, report:

11.4.7.1 Facility ID information;

11.4.7.2 Monitoring system ID;

11.4.7.3 Begin and end time of each test run;

11.4.7.4 The reference method used;

11.4.7.5 The reference method and CEMS values for each test run, including the units of measure;

11.4.7.6 The mean reference method and CEMS values for the three test runs;

11.4.7.7 The calculated relative accuracy, percent; and

11.4.7.8 Reason for test.

11.4.8 For each quarterly cylinder gas audit of an EtO monitor, report:

11.4.8.1 Facility ID information;

11.4.8.2 Monitoring component ID;

11.4.8.3 Instrument span and span scale;

11.4.8.4 For each gas injection, the date and time, the reference gas level (zero, mid, or high), the reference gas value in ppbv, and the monitor response.

11.4.8.5 For extractive CEMS, the mean reference gas value and mean monitor response at each reference gas level (ppbv).

11.4.8.6 ME at each reference gas level; and

11.4.8.7 Reason for test.

11.4.9 For each quarterly DSA of an EtO monitor, report:

11.4.9.1 Facility ID information;

11.4.9.2 Monitoring component ID;

11.4.9.3 Instrument span and span scale;

11.4.9.4 For the zero gas injection, the date and time, and the monitor response (Note: The zero gas injection from a calibration drift check performed on the same day as the upscale spikes may be used for this purpose.);

11.4.9.5 Zero spike error;

11.4.9.6 For the upscale gas spiking, the date and time of each spike, the reference gas level (mid- or high-), the reference gas value (ppbv), the dilution factor, the native EtO concentrations before and after each spike, and the monitor response for each gas spike;

11.4.9.7 Upscale spike error;

11.4.9.8 DSA at the zero level and at each upscale gas level; and

11.4.9.9 Reason for test.

11.5 *Quarterly Reports*.

11.5.1 The owner or operator of any affected unit shall use CEDRI to submit electronic quarterly reports to the Administrator in an XML format specified by the Administrator, for each affected unit (or group of units monitored at a common stack). If the certified EtO CEMS is used for the initial compliance demonstration, EtO emissions reporting shall begin with the first operating hour of the 30-operating day compliance demonstration period. Otherwise, EtO emissions reporting shall begin with the first operating hour after successfully completing all required certification tests of the CEMS.

11.5.2 The electronic reports must be submitted within 30 days following the end of each calendar quarter, except for units that have been placed in long-term cold storage.

11.5.3 Each electronic quarterly report shall include the following information:

11.5.3.1 The date of report generation;

11.5.3.2 Facility identification information;

11.5.3.3 The information in sections 10.1.2 through 10.1.4 of this appendix, as applicable to the type(s) of monitoring system(s) used to measure the pollutant concentrations and other necessary parameters; and

11.5.3.4 The results of all daily calibrations (including calibration transfer standard tests) of the EtO monitor and the quarterly RAA, CGA and DSA of an EtO monitor, as described in section 10.1.5.1.1 and 10.1.5.1.7 through 10.1.5.1.9 of this appendix as applicable.

11.5.4 *Compliance Certification*. Based on reasonable inquiry of those persons with primary responsibility for ensuring that all EtO emissions from the affected unit(s) have been correctly and fully monitored, the owner or operator shall submit a compliance certification in support of each electronic quarterly emissions monitoring report. The compliance certification shall include

a statement by a responsible official with that official's name, title, and signature, certifying that, to the best of his or her knowledge, the report is true, accurate, and complete.