
40 C.F.R. § 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) *Initial compliance report submission.* You must submit an initial compliance report that provides summary, 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, to the EPA via CEDRI, which can be accessed through the EPA's Central Data Exchange (CDX) (<https://cdx.epa.gov/>). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (<https://www.epa.gov/electronic-reporting-air-emissions/cedri>) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the extensible markup language (XML) schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. 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 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. In addition, the summary report shall include:

- (1) The following information:
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- (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 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.
- (vi) 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 periodic performance testing, you must report the following:

- (i) Control system ID;
- (ii) Control device ID;
- (iii) Control device type; and
- (iv) Recirculation tank ID if an acid-water scrubber is used to meet the emission standard and you elect to comply with the maximum scrubber liquor height limit;

(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 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(i) or a SWEL in § 63.362(j), 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 with § 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 any portion of your facility is required to be operated with PTE, you must report the following:
- (i) If you are choosing to demonstrate continuous compliance through the use of volumetric flow rate monitoring, you must report the 3-hr rolling average, rolled hourly volumetric flow from each outlet where air from the PTE is sent, in cubic feet per second.
 - (ii) If you are choosing to demonstrate continuous compliance through use of differential pressure monitoring, you must report the 3-hr rolling average, rolled hourly pressure differential reading, in inches water.

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