

Facility ID: 0448011623 Issuance type: Final State Permit To Operate

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In addition to the terms and conditions, hyperlinks have been inserted into the document so you may more readily access the section of the document you wish to review.

Finally, the term language under "Part II" and before "A. Applicable Emissions Limitations..." has been added to aid in document conversion, and was not part of the original issued permit.

THIS IS NOT AN OFFICIAL VERSION OF THE PERMIT. SEE PAGE 1 FOR ADDITIONAL INFORMATION

Facility ID: 0448011623 Emissions Unit ID: P003 Issuance type: Final State Permit To Operate

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Part II - Special Terms and Conditions

This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

1. For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.
 - (a) None.
2. For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.
 - (a) None.

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P003 - ethylene oxide sterilization chamber with an acid-water scrubber for control	40 CFR 63, subpart O 40 CFR 63.362(a) and (c)	99% Reduction of ethylene oxide emissions from the sterilization chamber vent see section A.2.a. and B.1.
	40 CFR 63, subpart A 40 CFR 63.360(a)	see section A.2.b.
	OAC rule 3745-31-05(A)(3) PTI 04-962 issued on June 7, 1995, modified on August 9, 1995 and May 28, 2002.	0.11 pound per hour ethylene oxide; 0.48 ton per year ethylene oxide from the sterilization chamber vent see section A.2.c.

2. Additional Terms and Conditions

- (a) [63.360(f)]
If you are the permittee of a source subject to the provisions of this subpart, you are also subject to title V permitting requirements under 40 CFR parts 70 or 71, as applicable. Your title V permitting authority may defer your source from these permitting requirements until December 9, 2004, if your source is not a major source and is not located at a major source as defined under 40 CFR 63.2m 70.2 or 71.2, and is not otherwise required to obtain a title V permit. If you receive a deferral under this section, you must submit a title V permit application by December 9, 2005. You must continue to comply with the provisions of this subpart applicable to area sources, even if you receive a deferral from title V permitting requirements.
Permittees of sources using 1 ton (see definition in 40 CFR 63.361) subject to the provisions of subpart O must comply with the requirements of 40 CFR 63, subpart A, according to the applicability of this subpart in Table 1 of 40 CFR 63, subpart O. Some regulations from subpart A are incorporated in this permit.
The hourly and annual emission limitations were established for PTI purposes to reflect the potential to emit for this emissions unit with control of 99% efficiency. Therefore, it is not necessary to develop monitoring, record keeping and/or reporting requirements to ensure compliance with these limitations.

B. Operational Restrictions

1. [63.362] STANDARDS - 40 CFR 63, subpart O
[63.362(a)]
The permittee shall comply with these requirements on and after the compliance date specified in 40 CFR 63.360(g). The standards of this section are summarized in Table 1 of 40 CFR 63.362(a). For a source using 1 ton to 10 tons of ethylene oxide, the permittee shall have 99% emission reduction for the sterilizations chamber and no control is required for the aeration room vent.
[63.362(b)]
Applicability of emission limits. The emission limitations of 63.362(c) [see paragraph c. of this section], 40 CFR 63.362(d) and (e) apply during sterilization operation. The emission limitations do not apply during periods of malfunction.
[63.362(c)]
Sterilization chamber vent at sources using 1 ton: each permittee of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

C. Monitoring and/or Record Keeping Requirements

1. [63.364] - MONITORING REQUIREMENTS - 40 CFR 63, subpart O
i. [63.364(a)(1)]

The permittee of a source subject to emissions standards in 63.362 [see section B.] shall comply with the monitoring requirements in 63.8 [see section C. and 40 CFR 63.8 of subpart A], according to the applicability in Table 1 of 40 CFR 63.360, and in this section.

- ii. [63.364(a)(2)]
The permittee shall monitor the parameters specified in 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.

[63.364(b)]

For sterilization facilities complying with 63.363(b) [see section D.] or 40 CFR 63.363(d) through the use of an acid-water scrubber, the permittee shall either:

- i. [63.364(b)(1)]
Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in 63.365(e)(1) [see section E.] . Monitoring is required during a week only if the scrubber unit has been operated; or
 - ii. [63.364(b)(2)]
Measure and record once per week the level of the scrubber liquor in the recirculating tank. The permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a week only if the scrubber unit has been operated.
2. [63.367(a)] RECORDKEEPING REQUIREMENTS - 40 CFR 63, subpart O
The permittee of a source subject to 63.362 [see section E.] shall comply with the recordkeeping requirements in 63.10 (b) and (c) [see section C. and 40 CFR 63.10 of subpart A], according to the applicability in Table 1 of 40 CFR 63.360. All records required to be maintained by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.
3. [63.8] MONITORING REQUIREMENTS - 40 CFR 63, subpart A
[63.8(b)] Conduct of Monitoring
- i. [63.8(b)(1); (b)(1)(i) and (b)(1)(ii)]
Monitoring shall be conducted as set forth in this section and the relevant standard(s) unless the Administrator specifies or approves the use of minor changes in methodology for the specified monitoring requirements and procedures; or approves the use of alternatives to any monitoring requirements or procedures.
 - ii. [63.8(b)(2)]
 - (a) [63.8(b)(2)(i)]
When the effluents from a single affected source, or from two or more affected sources, are combined before being released to the atmosphere, the permittee shall install an applicable continuous monitoring system (CMS) on each effluent.
 - (b) [63.8(b)(2)(ii); (b)(2)(ii)(A) and (b)(2)(ii)(B)]
If the relevant standard is a mass emission standard and the effluent from one affected source is released to the atmosphere through more than one point, the permittee shall install an applicable CMS at each emission point unless the installation of fewer systems is approved by the Administrator; or provided for in a relevant standard (e.g., instead of requiring that a CMS be installed at each emission point before the effluents from those points are channeled to a common control device, the standard specifies that only one CMS is required to be installed at the vent of the control device).

[63.8(c)] Operation and Maintenance of Continuous Monitoring Systems

- i. [63.8(c)(1) and (c)(1)(iii)]
The permittee of an affected source shall maintain and operate each CMS as specified in this section, or in a relevant standard, and in a manner consistent with good air pollution control practices. The Administrator's determination of whether acceptable operation and maintenance procedures are being used will be based on information that may include, but is not limited to, review of operation and maintenance procedures, operation and maintenance records, manufacturing recommendations and specifications, and inspection of the CMS. Operation and maintenance procedures written by the CMS manufacturer and other guidance also can be used to maintain and operate each CMS.
- ii. [63.8(c)(2)]
All CMS shall be installed such that representative measurements of emissions or process parameters from the affected source are obtained. In addition, CEMS shall be located according to procedures contained in the applicable performance specification(s).
- iii. [63.8(c)(3)]
All CMS shall be installed, operational, and the data verified as specified in the relevant standard either prior to or in conjunction with conducting performance tests under 63.7 [see section E. and 40 CFR 63.7 of subpart A]. Verification of operational status shall, at a minimum, include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

[63.8(e)] Performance Evaluation of Continuous Monitoring Systems

- i. [63.8(e)(1)]
General. When required by a relevant standard, and at any other time the Administrator may require under section 114 of the Act, the permittee of an affected source being monitored shall conduct a performance evaluation of the CMS. Such performance evaluation shall be conducted according to the applicable specifications and procedures described in this section or in the relevant standard.
- ii. [63.8(e)(2)]
Notification of performance evaluation. The permittee shall notify the Administrator in writing of the date of the performance evaluation simultaneously with the notification of the performance test date required under 40 CFR 63.7(b) or at least 60 days prior to the date the performance evaluation is scheduled to begin if no performance test is required.

iii. [63.8(e)(4)]

Conduct of performance evaluation and performance evaluation dates. The permittee of an affected source shall conduct a performance evaluation of a required CMS during any performance test required under 63.7 [see section E. and 40 CFR 63.7 of subpart A] in accordance with the applicable performance specification as specified in the relevant standard. Notwithstanding the requirement in the previous sentence, if the permittee of an affected source elects to submit COMS data for compliance with a relevant opacity emission standard as provided under 40 CFR 63.6(h)(7), he/she shall conduct a performance evaluation of the COMS as specified in the relevant standard, before the performance test required under 63.7 [see section E. and 40 CFR 63.7 of subpart A] is conducted in time to submit the results of the performance evaluation as specified in 40 CFR 63.8(e)(5)(ii). If a performance test is not required, or the requirement for a performance test has been waived under 40 CFR 63.6(h), the permittee of an affected source shall conduct the performance evaluation not later than 180 days after the appropriate compliance date for the affected source, as specified in 40 CFR 63.7(a), or as otherwise specified in the relevant standard.

4. [63.10] RECORDKEEPING REQUIREMENTS - 40 CFR 63, subpart A

[63.10(b)(1)]

The permittee shall maintain files of all information (including all reports and notifications) required by this part recorded in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent 2 years of data shall be retained on site. The remaining 3 years of data may be retained off site. Such files may be maintained on microfilm, on a computer, on computer floppy disks, on magnetic tape disks, or on microfiche.

[63.10(b)(2); (2)(ii) and (2)(xiv)]

The permittee of an affected source subject to the provisions of this part shall maintain relevant records for such source of the occurrence and duration of each malfunction of the air pollution control equipment and all documentation supporting initial notifications and notifications of compliance status under 63.9 [see section D. and 40 CFR 63.9].

D. Reporting Requirements

1. [63.366(a)] REPORTING REQUIREMENTS - 40 CFR 63, subpart O

The permittee of a source subject to the emissions standards in 63.362 [see section B.] shall fulfill all reporting requirements in 40 CFR 63.10(a), (d), (e) and (f) of subpart A, according to the applicability in Table 1 of 40 CFR 63.360. These reports will be made to the Administrator at the appropriate address identified in 40 CFR 63.13 of subpart A.

[63.366(a)(1)]

Reports required by 40 CFR 63, subpart A and this section may be sent by U.S. mail, fax, or by another courier.

- i. [63.366(a)(1)(i)]
Submittals sent by U.S. mail shall be postmarked on or before the specified date.
- ii. [63.366(a)(1)(ii)]
Submittals sent by other methods shall be received by the Administrator on or before the specified date.

[63.366(a)(2)]

If acceptable to both the Administrator and the permittee of a source, reports may be submitted on electronic media.

[63.366(a)(3)]

Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per 40 CFR 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see 40 CFR 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in 40 CFR 63.10(c)(5) through (13), as applicable in Table 1 of 40 CFR 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

2. [63.366(c)] REPORTING REQUIREMENTS - 40 CFR 63, subpart O

Notification requirements. The permittee of each source subject to the emissions standards in 63.362 [see section E.] shall fulfill all notification requirements in 63.9 [see section D. and 40 CFR 63.9 of subpart A], according to the applicability in Table 1 of 40 CFR 63.360, and in this paragraph.

[63.366(c)(1)]

Initial Notifications

- i. (a) [63.366(c)(1)(i)(A)]
If a source that otherwise would be subject to these emissions standards subsequently increases its use of ethylene oxide within any consecutive 12-month period after December 6, 1996, such that the source becomes subject to other requirements, such source shall be subject to the notification requirements of 40 CFR 63.9 of subpart A.
- (b) [63.366(c)(1)(i)(B)]

Sources subject to these emissions standards may use the application for approval of construction or reconstruction under 40 CFR 63.366(b)(3)(ii) and 40 CFR 63.5(d)(3) of subpart A, respectively, if relevant to fulfill the initial notification requirements.

3. [63.8(e)(5)(i)] REPORTING PERFORMANCE EVALUATION RESULTS - 40 CFR 63, subpart A
The permittee shall furnish the Administrator a copy of a written report of the results of the performance evaluation simultaneously with the results of the performance test required under 63.7 [see section D. and 40 CFR 63.7 of subpart A] or within 60 days of completion of the performance evaluation if no test is required, unless otherwise specified in a relevant standard. The Administrator may request that the permittee submit the raw data from a performance evaluation in the report of the performance evaluation results.
4. [63.9(h)] NOTIFICATION OF COMPLIANCE STATUS - 40 CFR 63, subpart A
[63.9(h)(1)]
The requirements of 63.9(h)(2) through (h)(4) [see section D. and 40 CFR 63.9(h)(2) through (h)(4)] apply when an affected source becomes subject to a relevant standard.
[63.9(h)(2)]
 - i. [63.9(h)(2)(i); and (h)(2)(i)(A) through (G)]
Before a permit has been issued to the permittee of an affected source, and each time a notification of compliance status is required under this part, the permittee of such source shall submit to the Administrator and Toledo Division of Environmental Services, a notification of compliance status, signed by the responsible official who shall certify its accuracy, attesting to whether the source has complied with the relevant standard. The notification shall list:
 - (a) The methods that were used to determine compliance;
 - (b) The results of any performance tests, opacity or visible emission observations, continuous monitoring system (CMS) performance evaluations, and/or other monitoring procedures or methods that were conducted;
 - (c) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods;
 - (d) The type and quantity of hazardous air pollutants emitted by the source (or surrogate pollutants if specified in the relevant standard), reported in units and averaging times and in accordance with the test methods specified in the relevant standard;
 - (e) An analysis demonstrating whether the affected source is a major source or an area source (using the emissions data generated for this notification);
 - (f) A description of the air pollution control equipment (or method) for each emission point, including each control device (or method) for each hazardous air pollutant and the control efficiency (percent) for each control device (or method); and
 - (g) A statement by the permittee of the affected existing, new, or reconstructed source as to whether the source has complied with the relevant standard or other requirements.

ii. [63.9(h)(2)(ii)]

The notification shall be sent before the close of business on the 60th day following the completion of the relevant compliance demonstration activity specified in the relevant standard (unless a different reporting period is specified in a relevant standard, in which case the letter shall be sent before the close of business on the day the report of the relevant testing or monitoring results is required to be delivered or postmarked). For example, the notification shall be sent before close of business on the 60th (or other required) day following completion of the initial performance test and again before the close of business on the 60th (or other required) day following the completion of any subsequent required performance test.

[63.9(h)(3)]

After a permit has been issued to the permittee of an affected source, the permittee of such source shall comply with all requirements for compliance status reports contained in the source's permit, including reports required under this part. After a permit has been issued to the permittee of an affected source, and each time a notification of compliance status is required under this part, the permittee of such source shall submit the notification of compliance status to the appropriate permitting authority following completion of the relevant compliance demonstration activity specified in the relevant standard.

[63.9(i)]

Change in information already provided: any change in the information already provided under this section shall be provided to the Administrator in writing within 15 calendar days after the change.

5. [63.10] REPORTING REQUIREMENTS - 40 CFR 63, subpart A
[63.10(a)(4)(ii)]
After a State has been delegated the authority to implement and enforce recordkeeping and reporting requirements established under this part, the permittee of an affected source in such State subject to such requirements shall submit reports to the delegated State authority (which may be the same as the permitting authority). In addition, if the delegated (permitting) authority is the State, the permittee shall send a copy of each report submitted to the State to the appropriate Regional Office of the EPA, as specified in 40 CFR 63.10(a)(4)(i). The Regional Office may waive this requirement for any reports at its discretion.
[63.10(a)(5)]
If the permittee in a State with delegated authority is required to submit periodic reports under this part to the State, and if the State has an established timeline for the submission of periodic reports that is consistent with the reporting frequency(ies) specified for such source under this part, the permittee may change the dates by which periodic reports under this part shall be submitted (without changing the frequency of reporting) to be consistent with the State's schedule by mutual agreement between the permittee and the State. For each relevant standard established pursuant to section 112 of the Act, the allowance in the previous sentence applies in each State beginning 1 year after the affected source's compliance date for that standard. Procedures governing the implementation of this provision are specified in 63.9(i) [see section D.].

E. **Testing Requirements**

1. [63.363(b)] COMPLIANCE AND PERFORMANCE PROVISIONS - 40 CFR 63, subpart O

The procedures in 63.363(b)(1) through (3) [see paragraphs a. through c. of this section] shall be used to determine initial compliance with the emission limits under 63.362(c) [see section B.], the sterilization chamber vent standard and to establish operating limits for the control devices:

[63.363(b)(1)]
The permittee shall determine the efficiency of control devices used to comply with 63.362(c) [see section B.] using the test methods and procedures in 63.365(b) [see section E.].

[63.363(b)(2)]
For facilities with acid-water scrubbers, the permittee shall establish as an operating limit either:

 - i. [63.363(b)(2)(i)]
The maximum ethylene glycol concentration using the procedures described in 63.365(e)(1) [see section E.]; or
 - ii. [63.363(b)(2)(ii)]
The maximum liquor tank level using the procedures described in 63.365(e)(2) [see section E.].
2. [63.363(f)] COMPLIANCE AND PERFORMANCE PROVISIONS - 40 CFR 63, subpart O

A facility must demonstrate continuous compliance with each operating limit and work practice standard required under this section, except during periods of startup, shutdown, and malfunction, according to the methods specified in 63.364 [see section C.].
3. [63.365(a)] - TEST METHODS AND PROCEDURES - 40 CFR 63, subpart O

Performance testing. The permittee of a source subject to the emissions standards in 63.362 [see section B.] shall comply with the performance testing requirements in 63.7 [see section E. and 40 CFR 63, subpart A], according to the applicability in Table 1 of 40 CFR 63.360, and in this section.
4. [63.365(b)] - TEST METHODS AND PROCEDURES - 40 CFR 63, subpart O

Efficiency at the sterilization chamber vent. The following procedures shall be used to determine the efficiency of all types of control devices used to comply with 63.362(c) [see section A.II.], sterilization chamber vent standard.

[63.365(b)(1)]
First evacuation of the sterilization chamber. These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

 - i. [63.365(b)(1)(i)]
The amount of ethylene oxide loaded into the sterilizer (Wc) shall be determined by either:
 - (a) [63.365(b)(1)(i)(A)]
Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 45 g (0.1 lb). Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas.
 - (b) [63.365(b)(1)(i)(B)]
Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to convert flow rate to weight of ethylene oxide:

$$Wc = Fv \times t \times \%EOv \times (MW/SV)$$

where:
Wc=weight of ethylene oxide charged, g (lb)

Fv=volumetric flow rate, liters per minute (L/min) corrected to 20 degrees C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 degrees F and 1 atmosphere of pressure (atm)); the flowrate must be constant during time (t)

t=time, min

%EOv=volume fraction ethylene oxide

SV=standard volume, 24.05 liters per mole (L/mole)=22.414 L/mole ideal gas law constant corrected to 20 degrees C and 101.325 kPa (385.32 scf per mole (scf/mole)=359 scf/mole ideal gas law constant corrected to 68 degrees F and 1 atm).

MW=molecular weight of ethylene oxide, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole)), or
 - i. [63.365(b)(1)(i)] (cont.)
 - (c) [63.365(b)(1)(i)(C)]
Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

$$Wc = (MW \times \%EOv \times P \times V) / (R \times T)$$

where:
P=chamber pressure, kPa (psia)

V=chamber volume, liters (L) (ft3)

R=gas constant, 8.313 L kPa/g-mole (10.73 psia ft3/mole degree R)

T=temperature, K (degrees R)

NOTE: If the ethylene oxide concentration is in weight percent, use the following equation to calculate mole fraction:

$$\%Eov = Weo / (Weo + (Wx \times (MW / SV)))$$

where:

Weo=weight percent of ethylene oxide

Wx=weight percent of compound in the balance of the mixture

MWx=molecular weight of compound in the balance gas mixture

SV=standard volume, 24.05 liters per mole (L/mole)=22.414 L/mole ideal gas law constant corrected to 20 degrees C and 101.325 kPa (385.32 scf per mole (scf/mole)=359 scf/mole ideal gas law constant corrected to 68 degrees F and 1 atm).

ii. [63.365(b)(1)(ii)]

The residual mass of ethylene oxide in the sterilizer shall be determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

$$Wr = (MW \times \%Eov \times P \times V) / (R + T)$$

where:

Wr=weight of ethylene oxide remaining in chamber (after the first evacuation), in g (lb)

iii. [63.365(b)(1)(iii)]

Calculate the total mass of ethylene oxide at the inlet to the control device (Wi) by subtracting the residual mass (Wr) calculated in 63.365(b)(1)(ii) [see paragraph a.ii. of this section] from the charged weight (Wc) calculated in 63.365(b)(1)(i) [see paragraph a.i. (c) of this section].

iv. [63.365(b)(1)(iv)]

The mass of ethylene oxide emitted from the control device outlet (Wo) shall be calculated by continuously monitoring the flow rate and concentration using the following procedure.

(a) [63.365(b)(1)(iv)(A)]

Measure the flow rate through the control device exhaust continuously during the first evacuation using the procedure found in 40 CFR part 60, appendix A, Test Methods 2, 2A, 2C or 2D, as appropriate. (Method 2D (using orifice plates or Rootstye meters) is recommended for measuring flow rates from sterilizer control devices.) Record the flow rate at 1-minute intervals throughout the test cycle, taking the first reading within 15 seconds after time zero. Time zero is defined as the moment when the pressure in the sterilizer is released. Correct the flow to standard conditions (20 degrees C and 101.325 kPa (68 degrees F and 1 atm)) and determine the flow rate for the run as outlined in the test methods listed in 63.365(b) [see section E.].

(b) [63.365(b)(1)(iv)(B)]

Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A, respectively), shall be used to measure the concentration of ethylene oxide.

(i) [63.365(b)(1)(iv)(B)(1)]

Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

(ii) [63.365(b)(1)(iv)(B)(2)]

Calculate the mass of ethylene oxide by using the equation found in 40 CFR 63.365(b)(1)(iv)(B)(2).

(iii) [63.365(b)(1)(iv)(B)(3)]

Calculate the efficiency by the equation in 63.365(b)(1)(v) [see paragraph a.v. of this section].

v. [63.365(b)(1)(v)]

Determine control device efficiency (% Eff) using the following equation:

$$\%Eff = ((Wi - Wo) / Wo) \times 100$$

where:

%Eff = percent efficiency

Wi = mass flow rate into the control device

Wo = mass flow rate out of the control device

vi. [63.365(b)(1)(vi)]

Repeat the procedures in 63.365(b)(1)(i) through (v) [see paragraphs a.i. through a.v. of this section] three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

5. [63.365(c) and (c)(1)] - TEST METHODS AND PROCEDURES - 40 CFR 63, subpart O
Concentration determination. The following procedures shall be used to determine the ethylene oxide concentration.

Parameter monitoring. For determining the ethylene oxide concentration required in 63.364(e) [see section A.III.], follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS-8.

6. [63.365(e)] - TEST METHODS AND PROCEDURES - 40 CFR 63, subpart O
Determination of baseline parameters for acid-water scrubbers. The procedures in this paragraph shall be used to determine the monitored parameters established in 63.363(b) [see section E.] for acid-water scrubbers and to monitor the parameters as established in 63.364(b) [see section C.].

[63.365(e)(1)]

Ethylene glycol concentration. For determining the ethylene glycol concentration, the permittee shall establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; the sampling and analysis procedures in ASTM D 3695-88, Standard Test Method for Volatile Alcohols in Water By Direct Aqueous-Injection Gas Chromatography, (incorporated by reference--see 40 CFR 63.14) shall be used to determine the ethylene glycol concentration.

[63.365(e)(2)]

Scrubber liquor tank level. For determining the scrubber liquor tank level, the sterilization facility owner or operator shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.

7. [63.7] PERFORMANCE TESTING REQUIREMENTS - 40 CFR 63, subpart A

[63.7(a)(3)]

The Administrator may require the permittee to conduct performance tests at the affected source at any other time when the action is authorized by section 114 of the Act.

[63.7(b)] Notification of Performance Test

i. [63.7(b)(1)]

The permittee of an affected source shall notify the Administrator and Toledo Division of Environmental Services in writing of his or her intention to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin to allow the Administrator, upon request, to review and approve the site-specific test plan required under 40 CFR 63.7(c) and to have an observer present during the test. Observation of the performance test by the Administrator is optional.

ii. [63.7(b)(2)]

In the event the permittee is unable to conduct the performance test on the date specified in the notification requirement specified in 63.7(b)(1) [see paragraph b.i. of this section], due to unforeseeable circumstances beyond his or her control, the permittee shall notify the Administrator within 5 days prior to the scheduled performance test date and specify the date when the performance test is rescheduled. This notification of delay in conducting the performance test shall not relieve the permittee of legal responsibility for compliance with any other applicable provisions of this part or with any other applicable Federal, State, or local requirement, nor will it prevent the Administrator from implementing or enforcing this part or taking any other action under the Act.

[63.7(g)(3)]

For a minimum of 5 years after a performance test is conducted, the permittee shall retain and make available, upon request, for inspection by the Administrator the records or results of such performance test and other data needed to determine emissions from an affected source.

8. Compliance with the emission limitation(s) in sections A.1 and A.2 of these terms and conditions shall be determined in accordance with the following method(s):

Emission Limitation:

0.11 lb/hr ethylene oxide

Applicable Compliance Method:

If required, compliance shall be demonstrated based upon the emission testing procedures specified in Method 18 or 25A of 40 CFR Part 60, Appendix A.

Emission Limitation:

0.48 tons per year of ethylene oxide

Applicable Compliance Method:

Compliance shall be demonstrated by multiplying the hourly allowable ethylene oxide emission limitation by the maximum annual hours of operation (8760 hrs), and then dividing by 2000 lbs/ton.

F. **Miscellaneous Requirements**

1. None