Department of Environmental Protection

Jeb Bush
Governor

Central District
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

Colleen M. Castille
Secretary

E-CORRESPONDENCE
wmathis@isl-fl.com

Wes Mathis, Plant Manager
International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736

Re: Draft Air Construction Permit No.: 0694823-003-AC
DRAFT Title V Air Operation Permit No.: 0694823-004-AV
Sterilization Facility

Dear Mr. Mathis:

One copy of the combined notice, the DRAFT Air Construction Permit, and the DRAFT Title V Air Operation Permit for the Sterilization Facility, located at 217 Sampey Road, Groveland, Lake County, Florida, is enclosed. The permitting authority's "INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT" and the "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT" are also included.

An electronic version of the DRAFT Permit has been posted on the Division of Air Resources Management's world wide web site for the United States Environmental Protection Agency (USEPA) Region 4 office's review. The web site address is:

http://www.dep.state.fl.us/air/eproducts/ards/default.asp

The "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT" must be published as soon as possible upon receipt of this letter. Proof of publication, i.e., newspaper affidavit, must be provided to the permitting authority's office within 7 (seven) days of publication pursuant to Rule 62-110.106(5), F.A.C. Failure to publish the notice and provide proof of publication within the allotted time may result in the denial of the permit pursuant to Rule 62-110.106(11), F.A.C.

Please submit any written comments you wish to have considered concerning the permitting authority's proposed action to Alan Zahm P.E., at the above letterhead address. If you have any other questions, please contact Mr. Zahm at 407/893-3335.

Sincerely,

L.T. Kozlov, P.E.
Program Administrator
Air Resources Management

LTK/jt
Enclosures

In the Matter of an
Application for Permits by:

International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736
Wes Mathis, Plant Manager

DRAFT Air Construction Permit No.: 0694823-003-AC
DRAFT Title V Air Operation Permit No.: 0694823-004-AV
Sterilization Facility
Lake County

INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT

The Florida Department of Environmental Protection (permitting authority) gives notice of its intent to issue an Air Construction Permit and a DRAFT Title V Air Operation Permit (copies of DRAFT Air Construction Permit and Draft Title V Air Operation Permit attached) for the Title V source detailed in the application specified above, for the reasons stated below.

The applicant, International Sterilization Laboratory, applied on December 12, 2005, to the permitting authority for an Air Construction Permit and a Title V Air Operation Permit for the Sterilization Facility, located at 217 Sampey Road, Groveland, Lake County, Florida.

The permits will allow operation of the facility which includes four sterilization chambers and three aeration rooms used to sterilize medical equipment.

The permitting authority has permitting jurisdiction under the provisions of Chapter 403, Florida Statutes (F.S.), and Florida Administrative Code (F.A.C.) Chapters 62-4, 62-210, and 62-213. This source is not exempt from Title V permitting procedures. The permitting authority has determined that an Air Construction Permit and a Title V Air Operation Permit are required to commence or continue operations at the described facility.

The permitting authority intends to issue the Air Construction Permit and the Title V Air Operation Permit based on the belief that reasonable assurances have been provided to indicate that operation of the source will not adversely impact air quality, and the source will comply with all appropriate provisions of Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-256, 62-257, 62-281, 62-296, and 62-297, F.A.C.

Pursuant to Sections 403.815 and 403.0872, F.S., and Rules 62-103.150 and 62-210.350(3), F.A.C., you (the applicant) are required to publish at your own expense the enclosed "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT." The notice shall be published one time only as soon as possible in the legal advertisement section of a newspaper of general circulation in the area affected. For the purpose of these rules, "publication in a newspaper of general circulation in the area affected" means publication in a newspaper meeting the requirements of Sections 50.011 and 50.031, F.S., in the county where the activity is to take place. If you are uncertain that a newspaper meets these requirements, please contact the permitting authority at the address or telephone number listed below. The applicant shall provide proof of publication to the permitting authority's office, 3319 Maguire Boulevard, Suite 232, Orlando, Florida 32803, [Telephone: 407/894-7555, Fax: 407/897-5963] within 7 (seven) days of publication. Failure to publish the notice and provide proof of publication within the allotted time may result in the denial of the permit pursuant to Rule 62-110.106(5), F.A.C.

The permitting authority will issue the Air Construction Permit and the PROPOSED Title V Air Operation Permit, and subsequent FINAL Title V Air Operation Permit, in accordance with the conditions of the enclosed DRAFT Title V Air Operation Permit unless a response received in accordance with the following procedures results in a different decision or significant change of terms or conditions.

The permitting authority will accept written comments concerning the proposed Air Construction Permit issuance action for a period of 14 (fourteen) days from the date of publication of the "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT." Written comments should be provided to the permitting authority office. Any written comments filed shall be made available for public inspection. If written comments received result in a significant change in this DRAFT Air Construction Permit, the permitting authority shall issue a Revised DRAFT Air Construction Permit and require, if applicable, another Public Notice.

The permitting authority will accept written comments concerning the proposed Title V Air Operation Permit issuance action for a period of 30 (thirty) days from the date of publication of the "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT." Written comments should be provided to the permitting authority office. Any written comments filed shall be made available for public inspection. If written comments received result in a significant change in this DRAFT Title V Air Operation Permit, the permitting authority shall issue a Revised DRAFT Title V Air Operation Permit and require, if applicable, another Public Notice.

A person whose substantial interests are affected by the proposed permitting decision may petition for an administrative hearing in accordance with Sections 120.569 and 120.57, F.S. The petition must contain the information set forth below and must be filed (received) in the Office of General Counsel at 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, FL 32399-3000, Telephone: 850/245-2242, Fax: 850/245-2303. Petitions filed by the permit applicant or any of the parties listed below must be filed within 14 (fourteen) days of receipt of this notice of intent. Petitions filed by any persons other than those entitled to written notice under Section 120.60(3), F.S., must be filed within 14 (fourteen) days of publication of the public notice or within 14 (fourteen) days of receipt of this notice of intent, whichever occurs first. Under Section 120.60(3), F.S., however, any person who asked the permitting authority for notice of agency action may file a petition within 14 (fourteen) days of receipt of that notice, regardless of the date of publication. A petitioner shall mail a copy of the petition to the applicant at the address indicated above, at the time of filing. The failure of any person to file a petition within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57, F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention will be only at the approval of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205, F.A.C.

A petition that disputes the material facts on which the permitting authority's action is based must contain the following information:

(a) The name and address of each agency affected and each agency's file or identification number, if known;

(b) The name, address, and telephone number of the petitioner; the name, address and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how the petitioner's substantial interests will be affected by the agency determination;

(c) A statement of how and when each petitioner received notice of the agency action or proposed action;

(d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate;

(e) A concise statement of the ultimate facts alleged, as well as the rules and statutes which entitle the petitioner to relief;

(f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action; and,

(g) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the agency to take with respect to the agency's proposed action.

A petition that does not dispute the material facts upon which the permitting authority's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by Rule 28-106.301, F.A.C.

Because the administrative hearing process is designed to formulate final agency action, the filing of a petition means that the permitting authority's final action may be different from the position taken by it in this notice of intent. Persons whose substantial interests will be affected by any such final decision of the permitting authority on the application(s) have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

Mediation will not be available in this proceeding.

Finally, pursuant to 42 United States Code (U.S.C.) Section 7661d(b)(2), any person may petition the Administrator of the EPA within 60 (sixty) days of the expiration of the Administrator's 45 (forty-five) day review period as established at 42 U.S.C. Section 7661d(b)(1), to object to issuance of any permit revision. Any petition shall be based only on objections to the permit revision that were raised with reasonable specificity during the 30 (thirty) day public comment period provided in this notice, unless the petitioner demonstrates to the Administrator of the EPA that it was impracticable to raise such objections within the comment period or unless the grounds for such objection arose after the comment period. Filing of a petition with the Administrator of the EPA does not stay the effective date of any permit properly issued pursuant to the provisions of Chapter 62-213, F.A.C. Petitions filed with the Administrator of EPA must meet the requirements of 42 U.S.C. Section 7661d(b)(2) and must be filed with the Administrator of the EPA at: U.S. EPA, 401 M Street, S.W., Washington, D.C. 20460.

Executed in Orlando, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION

L.T. Kozlov, P.E.
Program Administrator
Air Resources Management

CERTIFICATE OF SERVICE

The undersigned duly designated deputy agency clerk hereby certifies that this INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT (including the combined PUBLIC NOTICE, DRAFT Air Construction Permit, and the DRAFT Title V Air Operation Permit) and all copies were sent by certified mail or electronically (with Received Receipt) before the close of business on 2/28/06 to the person(s) listed:

E-CORRESPONDENCE
wmathis@isl-fl.com

Wes Mathis, Plant Manager
International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736

In addition, the undersigned duly designated deputy agency clerk hereby certifies that copies of this INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT (including the combined PUBLIC NOTICE, DRAFT Air Construction Permit, and the DRAFT Title V Air Permit) were sent by U.S. mail or electronically (with Received Receipt) on the same date to the person(s) listed or as otherwise noted:

Robert A. Baker, P.E. **(baker@atlantic.net)**
Caroline Shine, FDEP
Al Linero **(alvaro.linero@dep.state.fl.us)**
Barbara Friday, BAR **[Barbara.Friday@dep.state.fl.us]** (for posting with Region 4, USEPA)

Clerk Stamp

FILED, on this date, pursuant to Section 120.52, F. S., with the designated Department Clerk, receipt of which is hereby acknowledged.

Dina Jones — Clerk
02/28/2006 — Date

PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT

Florida Department of Environmental Protection
Central District

DRAFT Air Construction Permit No.: 0694823-003-AC
DRAFT Title V Air Operation Permit No.: 0694823-004-AV

Sterilization Facility
Lake County

The Florida Department of Environmental Protection (permitting authority) gives notice of its intent to issue an Air Construction Permit and a Title V Air Operation Permit to International Sterilization Laboratory, for the Sterilization Facility, located at 217 Sampey Road, Groveland, Lake County, Florida. The applicant's name and address are: International Sterilization Laboratory, 217 Sampey Road, Groveland, FL 34736, Attention: Mr. Wes Mathis, Plant Manager.

Air Construction Permit No. 0694823-003-AC and Title V Air Operation Permit No. 0694823-004-AV will allow operation of the facility which includes four sterilization chambers and three aeration rooms used to sterilize medical equipment.

The permitting authority will issue the Air Construction Permit and the PROPOSED Title V Air Operation Permit and subsequent FINAL Title V Air Operation Permit, in accordance with the conditions of the DRAFT Air Construction Permit and the DRAFT Title V Air Operation Permit unless a response received in accordance with the following procedures results in a different decision or significant change of terms or conditions.

The permitting authority will accept written comments concerning the proposed Air Construction Permit issuance action for a period of 14 (fourteen) days from the date of publication of the "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT." Written comments should be provided to the permitting authority office. Any written comments filed shall be made available for public inspection. If written comments received result in a significant change in this DRAFT Air Construction Permit, the permitting authority shall issue a Revised DRAFT Air Construction Permit and require, if applicable, another Public Notice.

The permitting authority will accept written comments concerning the proposed Title V Air Operation Permit issuance action for a period of 30 (thirty) days from the date of publication of the "PUBLIC NOTICE OF INTENT TO ISSUE AN AIR CONSTRUCTION PERMIT AND A TITLE V AIR OPERATION PERMIT." Written comments should be provided to the permitting authority office. Any written comments filed shall be made available for public inspection. If written comments received result in a significant change in this DRAFT Title V Air Operation Permit, the permitting authority shall issue a Revised DRAFT Title V Air Operation Permit and require, if applicable, another Public Notice.

Written comments must be post-marked and all facsimile comments must be received by the close of business (5:00 pm), on or before the end of this 30-day period, by the Permitting Authority at the Florida Department of Environmental Protection, 3319 Maguire Blvd., Suite 232, Orlando, Florida 32803 (telephone: 407/894-7555; fax: 407/897-5963). As part of his or her comments, any person may also request that the Permitting Authority hold a public meeting on this permitting action. If the Permitting Authority determines there is sufficient interest for a public meeting, it will publish notice of the time, date, and location on the Department's official web site for notices at http://tlhora6.dep.state.fl.us/onw and in a newspaper of general circulation in the area affected by the permitting action. For additional information, contact the Permitting Authority at the above address or phone number. If written comments or comments received at a public meeting result in a significant change in this DRAFT Permit, the

Permitting Authority shall issue a Revised DRAFT Permit and require, if applicable, another Public Notice. All comments filed will be made available for public inspection.

A person whose substantial interests are affected by the proposed permitting decision may petition for an administrative hearing in accordance with Sections 120.569 and 120.57 of the Florida Statutes (F.S.). The petition must contain the information set forth below and must be filed (received) in the Office of General Counsel, 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, FL 32399-3000, Telephone: 850/245-2242, Fax: 850/245-2303. Petitions filed by any persons other than those entitled to written notice under Section 120.60(3), F.S., must be filed within 14 (fourteen) days of publication of the public notice or within 14 (fourteen) days of receipt of the notice of intent, whichever occurs first. Under Section 120.60(3), F.S., however, any person who asked the permitting authority for notice of agency action may file a petition within 14 (fourteen) days of receipt of that notice, regardless of the date of publication. A petitioner shall mail a copy of the petition to the applicant at the address indicated above, at the time of filing. The failure of any person to file a petition within the applicable time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57, F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention will be only at the approval of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205 of the Florida Administrative Code (F.A.C.).

A petition that disputes the material facts on which the permitting authority's action is based must contain the following information:

(a) The name and address of each agency affected and each agency's file or identification number, if known;

(b) The name, address and telephone number of the petitioner; name address and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how petitioner's substantial rights will be affected by the agency determination;

(c) A statement of how and when the petitioner received notice of the agency action or proposed action;

(d) A statement of all disputed issues of material fact. If there are none, the petition must so state;

(e) A concise statement of the ultimate facts alleged, as well as the rules and statutes which entitle petitioner to relief;

(f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action; and,

(g) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the agency to take with respect to the agency's proposed action.

A petition that does not dispute the material facts upon which the permitting authority's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by Rule 28-106.301, F.A.C.

Because the administrative hearing process is designed to formulate final agency action, the filing of a petition means that the permitting authority's final action may be different from the position taken by it in this notice of intent. Persons whose substantial interests will be affected by any such final decision of the permitting authority on the application(s) have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

Mediation is not available for this proceeding.

In addition to the above, pursuant to 42 United States Code (U.S.C.) Section 7661d(b)(2), any person may petition the Administrator of the EPA within 60 (sixty) days of the expiration of the Administrator's 45 (forty-five) day review period as established at 42 U.S.C. Section 7661d(b)(1), to object to issuance of any permit. Any petition shall be based only on objections to the permit that were raised with reasonable specificity during the 30 (thirty) day public comment period provided in this notice, unless the petitioner demonstrates to the Administrator of the EPA that it was impracticable to raise such objections within the comment period or unless the grounds for such objection arose after the

comment period. Filing of a petition with the Administrator of the EPA does not stay the effective date of any permit properly issued pursuant to the provisions of Chapter 62-213, F.A.C. Petitions filed with the Administrator of EPA must meet the requirements of 42 U.S.C. Section 7661d(b)(2) and must be filed with the Administrator of the EPA at U.S. EPA, 401 M. Street SW, Washington, D.C. 20460.

A complete project file is available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Permitting Authority:
Florida Department of Environmental Protection
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803
Telephone: 407/894-7555
Fax: 407/897-5963

The complete project file includes the DRAFT Air Construction Permit and DRAFT Title V Air Operation Permit, the application(s), and the information submitted by the responsible official, exclusive of confidential records under Section 403.111, F.S. Interested persons may contact Alan Zahm P.E., at the above address or call 407/893-3335 for additional information.

International Sterilization Laboratory
Sterilization Facility
Facility ID No.: 0694823
Lake County

Title V Air Operation Permit

DRAFT Permit No.: 0694823-004-AV

Permitting Authority:
Florida Department of Environmental Protection
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803
Telephone: 407/893-3334
Fax: 407/897-5963

DRAFT Title V Air Operation Permit No.: 0694823-004-AV

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Department of Environmental Protection

Central District
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

Jeb Bush
Governor

Colleen M. Castille
Secretary

Permittee:

International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736
Attention: Wes Mathis,
Plant Manager

DRAFT Permit No.: 0694823-004-AV
Facility ID No.: 0694823
SIC Nos.: 38
Project: Title V Air Operation Permit

This permit is for the operation of the International Sterilization Laboratory, Sterilization Facility. This facility is located at 217 Sampey Road, Groveland, Lake County; UTM Coordinates: Zone 17, 417.97 km East and 3159.55 km North; Latitude: 28° 37' 19" North and Longitude: 81° 50' 37" West.

Statement of Basis: This Title V air operation permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.) and Florida Administrative Code (F.A.C.) Chapters 62-4, 62-210, and 62-213. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents, attached hereto or on file with the permitting authority, in accordance with the terms and conditions of this permit.

Referenced attachments made a part of this permit:
Appendix I-1, LIST of INSIGNIFICANT EMISSION UNITS and/or ACTIVITIES
Appendix TV-5, TITLE V CONDITIONS
Appendix O, NESHAP Subpart O (includes NESHAP Subpart A, General Provisions)
Appendix CP, Compliance Plan

Effective Date:	**to be determined**
Renewal Application Due Date:	**December 30, 2010**
Expiration Date:	**June 30, 2011**

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION

L.T. Kozlov, P.E.
Program Administrator
Air Resources Management

LTK/jt

SPECIFIC CONDITIONS

Section I. Facility Information.

Subsection A. Facility Description.

This facility is a Sterilization Facility that includes four sterilization chambers and three aeration rooms. The four sterilizers are equipped with an acid scrubber that reduces ethylene oxide emissions by 99%. The three aeration rooms are equipped with a continuous emission monitor to ensure ethylene oxide emissions do not exceed 1 ppm.

Also included in this permit are miscellaneous insignificant emission units and/or activities

Based upon the Title V permit application received December 12, 2005, this facility is not a major source of hazardous air pollutants (HAPs).

Subsection B. Summary of Emissions Unit ID No(s). and Brief Description(s).

E.U. ID No./Brief Description

001 Four Sterilization Chambers and Three Aeration Rooms

Please reference the Permit No., Facility ID No., and appropriate Emissions Unit(s) ID No(s). on all correspondence, test report submittals, applications, etc.

Subsection C. Relevant Documents.

The documents listed below are not a part of this permit, however, are specifically related to this permitting action.

These documents are provided to the permittee for information purposes only:
Appendix A-1, Abbreviations, Acronyms, Citations, and Identification Numbers
Appendix H-1, Permit History/ID Number Changes

These documents are on file with permitting authority:
Combined Air Construction and Title V Permit Application received December 12, 2005.

SPECIFIC CONDITIONS

Section II. Facility-wide Conditions.

The following conditions apply facility-wide:

1. APPENDIX TV-5, TITLE V CONDITIONS is a part of this permit.

2. General Pollutant Emission Limiting Standards. Objectionable Odor Prohibited. The permittee shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
[Rule 62-296.320(2), F.A.C.]

3. General Particulate Emission Limiting Standards. General Visible Emissions Standard. Except for emissions units that are subject to a particulate matter or opacity limit set forth or established by rule and reflected by conditions in this permit, no person shall cause, let, permit, suffer or allow to be discharged into the atmosphere the emissions of air pollutants from any activity, the density of which is equal to or greater than that designated as Number 1 on the Ringelmann Chart (20 percent opacity). EPA Method 9 is the method of compliance pursuant to Rule 62-297, F.A.C.
[Rule 62-296.320(4)(b)1., F.A.C.]

4. Prevention of Accidental Releases (Section 112(r) of CAA).
a) The permittee shall submit its Risk Management Plan (RMP) to the Chemical Emergency Preparedness and Prevention Office (CEPPO) RMP Reporting Center when, and if, such requirement becomes applicable. Any Risk Management Plans, original submittals, revisions or updates to submittals, should be sent to:

RMP Reporting Center
Post Office Box 1515
Lanham-Seabrook, MD 20703-1515
Telephone: 301/429-5018

b) The permittee hall submit to the permitting authority Title V certification forms or a compliance schedule in accordance with Rule 62-213.440(2), F.A.C.
[40 CFR 68]

5. Insignificant Emissions Units and/or Activities. Appendix I-1, List of Insignificant Emissions Units and/or Activities, is a part of this permit.
[Rules 62-213.440(1), 62-213.430(6), and 62-4.040(1)(b), F.A.C.]

6. General Pollutant Emission Limiting Standards. Volatile Organic Compounds (VOC) Emissions or Organic Solvents (OS) Emissions. The permittee shall allow no person to store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds (VOC) or organic solvents (OS) without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the Department.

To comply, procedures to minimize pollutant emissions shall include the following:

SPECIFIC CONDITIONS

a) tightly cover or close all VOC containers when they are not in use,
b) tightly cover, where possible, all open troughs, basins, baths, tanks, etc. when they are not in use,
c) maintain all piping, valves, fittings, etc. in good operating condition,
d) prevent excessive air turbulence across exposed VOC's,
e) immediately confine and clean up VOC spills and make sure certain wastes are placed in closed containers for reuse, recycling or proper disposal.
[Rule 62-296.320(1)(a), F.A.C.]

7. Emissions of Unconfined Particulate Matter. Reasonable precautions to prevent emissions of unconfined particulate matter at this facility include:
a) Maintenance of paved areas as needed;
b) Regular mowing of grass and care of vegetation;
c) Limited access to plant property by unnecessary vehicles.
[Rule 62-296.320(4)(c), F.A.C.]

8. When appropriate, any recordings, monitoring, or reporting requirements that are time-specific shall be in accordance with the effective date of the permit, which defines day one.
[Rule 62-213.440, F.A.C.]

9. Annual Statement of Compliance. The annual statement of compliance pursuant to Rule 62-213.440(3)(a)2., F.A.C., shall be submitted to the air compliance section of this office and EPA within 60 (sixty) days after the end of the calendar year using DEP Form No. 62-213.900(7), F.A.C.
[Rules 62-213.440(3) and 62-213.900, F.A.C.]
{Permitting note: This condition implements the requirements of Rules 62-213.440(3)(a)2. &3., F.A.C. (see Condition 51 of APPENDIX TV-5, TITLE V CONDITIONS)}

10. The permittee shall submit all compliance related notifications and reports required of this permit to the following office:

Florida Department of Environmental Protection
3319 Maguire Blvd., Suite 232
Orlando, Florida 32803
Telephone: 407/893-3334; Fax: 407/897-5963

11. Any reports, data, notifications, certifications, and requests required to be sent to the United States Environmental Protection Agency, Region 4, should be sent to:

United States Environmental Protection Agency
Region 4
Air, Pesticides & Toxic Management Division
Air and EPCRA Enforcement Branch
Air Enforcement Section
61 Forsyth Street
Atlanta, Georgia 30303-8960
Telephone: 404/562-9155; Fax: 404/562-9163

SPECIFIC CONDITIONS

12. Certification by Responsible Official (RO). In addition to the professional engineering certification required for applications by Rule 62-4.050(3), F.A.C., any application form, report, compliance statement, compliance plan and compliance schedule submitted pursuant to Chapter 62-213, F.A.C., shall contain a certification signed by a responsible official that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete. Any responsible official who fails to submit any required information or who has submitted incorrect information shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary information or correct information.
[Rule 62.213.420(4), F.A.C.]

13. Annual Operating Report. A DEP Form No. 62-210.900(5), "Annual Operating Report for Air Pollutant Emitting Facility", including the Emissions Report, shall be completed for each calendar year, **on or before March 1** of the following year and submitted to the air compliance section of this office.
[Rule 62-210.370(3), F.A.C.]

SPECIFIC CONDITIONS

Section III. Emissions Unit(s) and Conditions.

Subsection A. This section addresses the following emissions unit(s).

E.U. ID No./ Brief Description

001 Four Sterilization Chambers and Three Aeration Rooms

The following conditions apply to the emissions unit(s) listed above:

Essential Potential to Emit (PTE) Parameters

A1. Capacity. The maximum facility-wide ethylene oxide usage rate is 60 tons per consecutive twelve month period.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-003-AC, and Title V application received 12/12/05]

A2. Hours of Operation. Continuous operation is allowed.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-003-AC, and Title V application received 12/12/05]

A3. No person shall circumvent any pollution control device or allow the emissions of air pollutants without the applicable air pollution control device operating properly.
[Rule 62-210.200, (PTE), F.A.C. and Rule 62-210.650, F.A.C.]

Emission Limitations and Standards

A4. The maximum facility wide combined volatile organic compound (VOC) emission rate is limited to no more than 4.0 tons per twelve consecutive months, combined HAP emissions are limited to no more than 4.0 tons per consecutive twelve months, and any individual HAP emission is limited to no more than 4.0 tons per consecutive twelve months, updated monthly, as requested by the applicant.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-003-AC, and Title V application received 12/12/05]

A5. Pursuant to 40CFR63.362(c), each owner or operator 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. Pursuant to 40CFR63.362(d), each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or at least 99 percent whichever is least stringent, from each aeration room vent.
[Rule 62-210.200, (PTE), F.A.C., construction permit 0694823-003-AC, and Title V application received 12/12/05]

SPECIFIC CONDITIONS

Recordkeeping and Reporting Requirements

A6. In order to demonstrate compliance with specific conditions number **A1.** and **A4.,** the permittee shall maintain a monthly log at the facility for a period of at least five years from the date the data is recorded. The log, at a minimum, shall contain the following:

Monthly
a) month
b) Consecutive 12 month total of:
- facility-wide ethylene oxide usage rate
- facility-wide VOC, combined HAPs and single HAP emission rates

[Rules 62-4.070(3) and 62-213.440(1)(b)2., F.A.C.]

Note: A consecutive 12 month total is equal to the total for the month in question plus the totals for the eleven months previous to the month in question. A consecutive 12-month total treats each month of the year as the end of a 12-month period. A 12-month total is not a year-to-date total. Facilities that have not been operating for 12 months should retain 12-month totals using whatever number of months of data are available until such a time as a consecutive 12 month total can be maintained each month.

A7. Pursuant to Consent Order OGC 06-0303, the facility must comply with the provisions of the compliance plan as set forth in this Title V operating permits Appendix CP.

NESHAP Conditions

A8. The sterilization chambers and aeration rooms are subject to 40 CFR Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities and 40 CFR Part 63, Subpart A, General Provisions.
[Rule 62-204.800(11)(b)9., F.A.C.; 40 CFR Part 63, Subpart A; and Title V permit 0694823-004-AV, Appendix O]

Appendix A-1, Abbreviations, Acronyms, Citations, and Identification Numbers

Abbreviations and Acronyms:

°F:	Degrees Fahrenheit
BACT:	Best Available Control Technology
CFR:	Code of Federal Regulations
DEP:	State of Florida, Department of Environmental Protection
DARM:	Division of Air Resource Management
EPA:	United States Environmental Protection Agency
F.A.C.:	Florida Administrative Code
F.S.:	Florida Statute
ISO:	International Standards Organization
LAT:	Latitude
LONG:	Longitude
MMBtu:	million British thermal units
MW:	Megawatt
ORIS:	Office of Regulatory Information Systems
SOA:	Specific Operating Agreement
UTM:	Universal Transverse Mercator

Citations:

The following examples illustrate the methods used in this permit to abbreviate and cite the references of rules, regulations, guidance memorandums, permit numbers, and ID numbers.

Code of Federal Regulations:

Example: **[40 CFR 60.334]**

Where:	40	reference to	Title 40
	CFR	reference to	Code of Federal Regulations
	60	reference to	Part 60
	60.334	reference to	Regulation 60.334

Florida Administrative Code (F.A.C.) Rules:

Example: **[Rule 62-213, F.A.C.]**

Where:	62	reference to	Title 62
	62-213	reference to	Chapter 62-213
	62-213.205	reference to	Rule 62-213.205, F.A.C.

ISO: International Standards Organization refers to those conditions at 288 degrees K, 60 percent relative humidity, and 101.3 kilopascals pressure.

Identification Numbers:

Facility Identification (ID) Number:

Example: Facility ID No.: 1050221

Where:

105 = 3-digit number code identifying the facility is located in Polk County
0221 = 4-digit number assigned by state database.

Permit Numbers:

Example: 1050221-002-AV, or
1050221-001-AC

Where:

AC = Air Construction Permit
AV = Air Operation Permit (Title V Source)
105 = 3-digit number code identifying the facility is located in Polk County
0221 = 4-digit number assigned by permit tracking database
001 or 002 = 3-digit sequential project number assigned by permit tracking database

Example: PSD-FL-185
PA95-01
AC53-208321

Where:

PSD = Prevention of Significant Deterioration Permit
PA = Power Plant Siting Act Permit
AC = old Air Construction Permit numbering

Appendix H-1, Permit History/ID Number Changes

International Sterilization Laboratory
Sterilization Facility

DRAFT Permit No.: 0694823-004-AV
Facility ID No.: 0694823

Permit History (for tracking purposes):

E.U. ID No.	Description	Permit No.	Issue Date	Expiration Date	Extended Date[1, 2]	Revised Date(s)
001	Sterilization Facility	0694823-003-AC	to be determined	to be determined		
001	Sterilization Facility	0694823-002-AG	16-Aug-02	16-Sept-07		
001	Sterilization Facility	0694823-001-AG	10-Nov-97	10-Oct-02		

Appendix I-1, List of Insignificant Emissions Units and/or Activities.

International Sterilization Laboratory
Sterilization Facility

DRAFT Title V Permit No. 0694823-004-AV
Facility ID No.: 0694823

The facilities, emissions units, or pollutant-emitting activities listed in Rule 62-210.300(3)(a), F.A.C., Categorical Exemptions, are exempt from the permitting requirements of Chapters 62-210 and 62-4, F.A.C.; provided, however, that exempt emissions units shall be subject to any applicable emission limiting standards and the emissions from exempt emissions units or activities shall be considered in determining the potential emissions of the facility containing such emissions units. Emissions units and pollutant-emitting activities exempt from permitting under Rule 62-210.300(3)(a), F.A.C., shall not be exempt from the permitting requirements of Chapter 62-213, F.A.C., if they are contained within a Title V source; however, such emissions units and activities shall be considered insignificant for Title V purposes provided they also meet the criteria of Rule 62-213.430(6)(b), F.A.C. No emissions unit shall be entitled to an exemption from permitting under Rule 62.210.300(3)(a), F.A.C., if its emissions, in combination with the emissions of other units and activities at the facility, would cause the facility to emit or have the potential to emit any pollutant in such amount as to make the facility a Title V source.

The below listed emissions units and/or activities are considered insignificant pursuant to Rule 62-213.430(6), F.A.C.

Brief Description of Emissions Units and/or Activities

1. Liquid Nitrogen Tank
2. Neutralization Tank for Liquid Scrubber
3. 3.0 MMBTU/hr natural gas fired Boiler (Hurtz)
4. 2.0 MMBTU/hr natural gas fired Boiler (Kewanee)

APPENDIX TV-5, TITLE V CONDITIONS (version dated 03/28/05)

[Note: This attachment includes "canned conditions" developed from the "Title V Core List."]

{Permitting note: APPENDIX TV-5, TITLE V CONDITIONS, is distributed to the permittee only. Other persons requesting copies of these conditions shall be provided one copy when requested or otherwise appropriate.}

Chapter 62-4, F.A.C.

1. **Not federally enforceable.** General Prohibition. Any stationary installation which will reasonably be expected to be a source of pollution shall not be operated, maintained, constructed, expanded, or modified without the appropriate and valid permits issued by the Department, unless the source is exempted by Department rule. The Department may issue a permit only after it receives reasonable assurance that the installation will not cause pollution in violation of any of the provisions of Chapter 403, F.S., or the rules promulgated thereunder. A permitted installation may only be operated, maintained, constructed, expanded or modified in a manner that is consistent with the terms of the permit.
[Rule 62-4.030, Florida Administrative Code (F.A.C.); Section 403.087, Florida Statute (F.S.)]

2. **Not federally enforceable.** Procedures to Obtain Permits and Other Authorizations; Applications.
(1) Any person desiring to obtain a permit from the Department shall apply on forms prescribed by the Department and shall submit such additional information as the Department by law may require.
(2) All applications and supporting documents shall be filed in quadruplicate with the Department.
(3) To ensure protection of public health, safety, and welfare, any construction, modification, or operation of an installation which may be a source of pollution, shall be in accordance with sound professional engineering practices pursuant to Chapter 471, F.S. All applications for a Department permit shall be certified by a professional engineer registered in the State of Florida except, when the application is for renewal of an air pollution operation permit at a non-Title V source as defined in Rule 62-210.200, F.A.C., or where professional engineering is not required by Chapter 471, F.S. Where required by Chapter 471 or 492, F.S., applicable portions of permit applications and supporting documents which are submitted to the Department for public record shall be signed and sealed by the professional(s) who prepared or approved them.
(4) Processing fees for air construction permits shall be in accordance with Rule 62-4.050(4), F.A.C.
(5)(a) To be considered by the Department, each application must be accompanied by the proper processing fee. The fee shall be paid by check, payable to the Department of Environmental Protection. The fee is non-refundable except as provided in Section 120.60, F.S., and in this section.
(b) When an application is received without the required fee, the Department shall acknowledge receipt of the application and shall immediately notify the applicant that the required fee was not received and advise the applicant of the correct fee. The Department shall take no further action until the correct fee is received. If a fee was received by the Department which is less than the amount required, the Department shall return the fee along with the written notification.
(c) Upon receipt of the proper application fee, the permit processing time requirements of Sections 120.60(2) and 403.0876, F.S., shall begin.
(d) If the applicant does not submit the required fee within ten days of receipt of written notification, the Department shall either return the unprocessed application or arrange with the applicant for the pick up of the application.
(e) If an applicant submits an application fee in excess of the required fee, the permit processing time requirements of Sections 120.60(2) and 403.0876, F.S., shall begin upon receipt, and the Department shall refund to the applicant the amount received in excess of the required fee.
(6) Any substantial modification to a complete application shall require an additional processing fee determined pursuant to the schedule set forth in Rule 62-4.050, F.A.C., and shall restart the time requirements of Sections 120.60 and 403.0876, F.S. For purposes of this subsection, the term "substantial modification" shall mean a modification which is reasonably expected to lead to substantially different environmental impacts which require a detailed review.
(7) Modifications to existing permits proposed by the permittee which require substantial changes in the existing permit or require substantial evaluation by the Department of potential impacts of the proposed modifications shall require the same fee as a new application for the same time duration except for modification under Chapter 62-45, F.A.C.
[Rule 62-4.050, F.A.C.]

APPENDIX O

Subpart O--Ethylene Oxide Emissions Standards for Sterilization Facilities (07/29/98)

Sec.
63.360 Applicability.
63.361 Definitions.
63.362 Standards.
63.363 Compliance and performance testing.
63.364 Monitoring requirements.
63.365 Test methods and procedures.
63.366 Reporting requirements.
63.367 Recordkeeping requirements.
§ 63.368 Implementation and enforcement.

Appendix A to Subpart O- General Provisions

§ 63.360 Applicability.

(a) All sterilization sources using 1 ton (see definitions) in sterilization or fumigation operations are subject to the emissions standards in § 63.362, except as specified in § 63.360(b) through (e) of this section. Owners or operators of sources using 1 ton (see definitions) subject to the provisions of this subpart must comply with the requirements of subpart A, according to the applicability of subpart A to such sources in Table 1.

(b) Sterilization sources using less than 1 ton (see definitions) are not subject to the emissions standards in § 63.362. The recordkeeping requirements of § 63.367(c) apply.

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

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

(e) This subpart does not apply to ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals.

(f) The permittee of a source using 1 ton (see definition) is subject to title V permitting requirements. If the source is not major or located at a major source, it may defer title V permitting requirements for five years. However, all sources shall submit title V permit applications by December 9, 2000, and all sources shall meet the compliance schedule called out in this Section.

(g) The permittee shall comply with the provisions of this subpart as follows:

(1) All sources subject to the emissions standards in § 63.362 with an initial startup date before 12/8/97, no later than 3 years after the effective date.

(2) All sources subject to the emissions standards in § 63.362 with an initial startup date after 12/8/97, immediately upon initial startup of the source.

(3) All sources using less than 10 tons that increase their ethylene oxide usage after 12/8/97 such that any vent becomes subject to the emissions standards in § 63.362, immediately upon becoming subject to the emissions standards.

(4) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date before December 6, 2000, no later than December 6, 2000.

(5) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 2000, immediately upon initial startup of the source.

(6) All aeration room vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2000, such that the aeration room vents become subject to the emissions standards in § 63.362, immediately upon becoming subject to the emission standards.

(7)-(10) Reserved

§ 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 of subpart A of 40 CFR part 63, or in this section. For the purposes of subpart O, if the same term is defined in subpart A and in this section, it shall have the meaning given in this section.

Aeration room means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Baseline temperature means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

Chamber exhaust vent means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Compliance date means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

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

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard:
(2) Fails to meet any term or condition that is adopted to implement an applicable requirement of this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or
(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown or malfunction, regardless of whether or not such failure is permitted by this subpart.

Effective date means the date of promulgation in the Federal Register notice.

Initial startup date means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Maximum ethylene glycol concentration means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Oxidation temperature means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Source(s) using less than 1 ton means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after [insert date 2 years after the date of publication in the Federal Register].

Source(s) using 1 ton means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after 12/6/96.

Source(s) using 1 to 10 tons means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after 12/6/96.

Source(s) using less than 10 tons means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after 12/6/96.

Source(s) using 10 tons means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after 12/6/96.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

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

Sterilization facility means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Sterilization operation means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

Thermal Oxidizer means all combustion devices except Flares.

§ 63.362 Standards.

(a) Each permittee of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in § 63.360(g). The standards of this section are summarized in Table 2.

TABLE 2. STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS

		EXISTING AND NEW SOURCES	
Source type		Sterilization Chamber Vent	Aeration Room Vent
Source size	<907 kg (<1 ton)	No controls required; minimal recordkeeping require	
	³907 kg and <9,070 kg (³1 ton and <10 tons)	99% emission reduction [see § 63.362(c)]	no control
	³9,070 kg (³10 tons)	99% emission reduction [see § 63.362(c)]	1 ppm maximum outlet concentration or 99% emission reduction [see § 63.362(d)]

[1]Affected sources may show compliance by manifolding emissions to a control device used to comply with § 63.362(c) or (d) or by reducing emissions by at least 99 percent.

(b) Applicability of emission limits. The emission limitations of § 63.362(c), (d), and (e) apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(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.

(d) Aeration room vent at sources using 10 tons. Each permittee of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

(e) Reserved

§ 63.363 Compliance and performance provisions.

(a) (1) The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).

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

(1) The owner or operator shall determine the efficiency of control devices used to comply with § 63.362(c) using the test methods and procedures in § 63.365(b)

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit either:

(i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(ii) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(3) For facilities with catalytic oxidizers, the operating limit consists of the recommended minimum oxidation temperature, provided by the oxidation unit manufacturer for an operating limit.

(4) Facilities with catalytic oxidizers shall comply with one of the following work practices:

(i) Once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in § 63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or

(ii) Once per year after the initial compliance test, analyze ethylene oxide concentration data from § 63.364(e) or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 after data analysis; or,

(iii) Every 5 years, beginning after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.

(c) The following procedures in paragraphs (c)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d), the aeration room vent standard:

(1) The owner or operator shall comply with either paragraph (b)(2) or (3) of this section.

(2) Determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with § 63.362(d) using the methods in § 63.365(c)(1); or

(3) Determine the efficiency of the control device to comply with § 63.362(d) using the methods and procedures in § 63.365(d)(2).

(d) Reserved

(e) For facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating 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(g), the owner or operator shall determine the site-specific operating parameters approved by the Administrator.

(f) A facility must demonstrate continuous compliance with each operating limit and work practice standard required under this section, except during periods of startup, shutdown, or malfunction, according to methods specified in § 63.364.

§ 63.364 Monitoring requirements.

(a) (1) The permittee of a source subject to emissions standards in § 63.362 shall comply with the monitoring requirements in § 63.8 of subpart A of 40 CFR part 63, according to the applicability in Table 1, and in this section.

(2) Each permittee of an ethylene oxide sterilization facility subject to these emissions standards 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.

(b) For sterilization facilities complying with § 63.363(b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

(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). Monitoring is required during a week only if the scrubber unit has been operated; or

(2) Measure and record once per week the level of the scrubber liquor in the recirculation 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.

(c) For sterilization facilities complying with § 63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with § 63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature day any instantaneous temperature recording falls below a minimum temperature.

(1)-(3) Reserved

(4) The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6 °C (±10 °F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year 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 temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(d) For sterilization facilities complying with § 63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Permitting authority using the methods and procedures in § 63.365(g).

(e) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in § 63.365(c)(1). The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a gas chromatograph consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, Appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 or section of PS 8 are required only on days when ethylene oxide emissions are vented to the control device.

(f) Reserved

§ 63.365 Test methods and procedures.

(a) Performance testing. The permittee of a source subject to the emissions standards in § 63.362 shall comply with the performance testing requirements in § 63.7 of subpart A of 40 CFR part 63, according to the applicability in Table 1, and in this section.

(b) 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) of this subpart, sterilization chamber vent standard.

(1) First evacuation of the sterilization chamber. This procedure shall be performed on an empty sterilization chamber, charged a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization cycle pressure and temperature).

(i) The amount of ethylene oxide loaded into the sterilizer (W_c) shall be determined by either:

(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) 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:

$$W_c = F_v \times t \times \%EO_v \times \left(\frac{MW}{SV}\right)$$

where:

W_c = weight of ethylene oxide charged, g (lb)

F_v = volumetric flow rate, liters per minute (L/min) corrected to 200°C and 101.325 kilopascals (kPa) (scf per minute [scfm] corrected to 680°F and 1 atmosphere of pressure [atm]); the flowrate must be constant during time (t)

t = time, min

$\%EO_V$ = volume fraction ethylene oxide

SV = standard volume, 24.05 liters per mole (L/mole) = 22.414 L/mole ideal gas law constant corrected to 200C and 101.325 kPa (385.32 scf per mole [scf/mole] = 359 scf/mole ideal gas law constant corrected to 680°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

(C) Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

$$W_c = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

P = chamber pressure, kPa (psia)
V = chamber volume, liters (L) (ft^3)
R = gas constant, 8.313 L*kPa/g-mole*(10.73 psia*ft^3/mole°R)
T = temperature, K (°R)

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

$$\%EO_v = W_{EO}/[W_{EO} + (W_x \times MW/MW_x)]$$

where:

W_{EO} = weight percent of ethylene oxide
W_x = weight percent of compound in the balance of the mixture
MW_x = molecular weight of compound in the balance gas mixture

(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:

$$W_r = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

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

(iii) Calculate the total mass of ethylene oxide at the inlet to the control device (W_i) by subtracting the residual mass (W_r) calculated in § 63.365(b)(1)(ii) of this subpart from the charged weight (W_c) calculated in § 63.365(b)(1)(i) of this subpart.

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

(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 Rootstype 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 [200°C and 101.325 kPa (680°F and 1 atm)] and determine the flow rate for the run as outlined in the test methods listed in this paragraph.

(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.

(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 volume.
(2) Calculate the mass of ethylene oxide by using the following equation:

$$W_o = C \times V \times \frac{MW}{SV} \times \frac{1}{10^6}$$

where:

W_o = Mass of ethylene oxide for each bag, g (lb)
C = concentration of ethylene oxide in ppmv
V = volume of gas exiting the control device corresponding to each bag sample corrected to standard conditions, L (ft^3)
$1/10^6$ = correction factor $L_{EO}/10^6\ L_{TOTAL\ GAS}$ ($ft^3_{EO}/10^6\ ft^3_{TOTAL\ GAS}$)

Sum the mass corresponding to each bag (W_b) used during the evacuation to calculate the total mass (W_o).

(iv) Calculate the efficiency by the equation in § 63.365(b)(1)(v) of this section.

(2) Collect a Tedlar bag (or equivalent collection device) sample at 1-minute intervals throughout the test cycle. (The first bag must be in place and sampling at t = 15 seconds. A fresh bag shall be in place and sampling exhaust gas at each 1-minute mark after time zero.) Collect enough sample gas in each bag to complete the analysis. Each bag sample shall be labelled with the sampling time and run number.

(i) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection. (Syringe samples should be analyzed within 4 hours.)

(ii) Plot a concentration versus time curve using the average concentration, in ppmv, determined in each bag sample. Prepare another graph of volumetric flow rate versus time. Calculate the mass flow at each 1-minute interval point by selecting the concentration (C) and volumetric flow rate corrected to standard conditions (F_v) at each 1-min point.

(iii) Use the following equation to determine the mass flow rate of ethylene oxide exiting the control device:

$$W_t = C \times F_v \times \frac{MW}{SV} \times \frac{1}{10^6}$$

where:

W_t = mass flow rate of ethylene oxide

(iv) Plot a curve of mass flow rate versus time and integrate for total mass of ethylene oxide for the control device outlet (W_o).

(v) Calculate efficiency by the equations in § 63.365(b)(1)(v) and (vi) of this section.

(C) **Reserved**

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

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(vi) Repeat the procedures in §§ 63.365(b)(1)(i) through (v) of this subpart, three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(2) **Reserved**

(i) the direct interface sampling and analysis procedure described in Method 18, section 7.2, may be used to continuously monitor ethylene oxide concentration at the inlet and outlet of the control device using a GC/FID or GC/PID; this procedure may be used only if a vent may be sampled and analyzed by the GC/FID or GC/PID once per minute for the duration of the last cycle.

(A) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(B) Follow the procedures in § 63.365(b)(1)(iv)(B)(2)(ii) through (iv) of this section.

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

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(D) Repeat the procedures in §§ 63.365(b)(2)(i)(A) through (C) of this subpart, three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(ii) The Tedlar bag sampling procedure in section 7.1 of Method 18, may be used to collect samples of inlet and exhaust gas for the duration of the last cycle.

(A) Continuously sample a slipstream of the control device inlet and outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(B) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(C) Follow the procedures in § 63.365(b)(1)(iv)(B)(2)(b) through (d) of this section.

(D) Determine control device efficiency (% Eff) using the equation in § 63.365(b)(2)(i)(C).

(E) Repeat the procedures in §§ 63.365(b)(2)(ii)(A) through (D) of this subpart three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(iii) In the event that the outlet concentration from the control device is below the detection limit for ethylene oxide for determining the efficiency in § 63.365(b)(2)(i)(C) or (ii)(D), the permittee shall assume the control device is meeting the standard in § 63.362(e)(1) or (2) if the inlet ethylene oxide concentration is at or below approximately 50 ppmv.

(c) Concentration determination. The following procedures shall be used to determine the ethylene oxide concentration.

1. *Parameter monitoring*. For determining the ethylene oxide concentration required in § 63.364(e), 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 section 2.4 and 3 of PS-8.
2. *Initial Compliance*. For determining the ethylene oxide concentration required in § 63.363(c)(2), the procedures outlined in Method 18 or Method 25A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate a report Method 25A instrument results using ethylene oxide at the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration form the control device.

(d) Efficiency determination at the aeration room vent (not manifolded). The following procedures shall be used to determine the efficiency of a control device used to comply with § 63.362(d), the aeration room vent standard.

(1) Aeration room vent. For determining the efficiency of aeration room vent control devices, either of the following test methods [(i) or (ii)] may be used:

(i) the direct interface sampling and analysis procedure described in Method 18, section 7.2, may be used to continuously monitor ethylene oxide concentration at the inlet and outlet of the control device using a GC/FID or GC/PID; this procedure may be used only if a vent may be sampled and analyzed by the GC/FID or GC/PID once every 5 minutes throughout a 1-hour test run.

(A) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(B) Follow the procedures in § 63.365(b)(1)(iv)(B)(2)(b) through (d) of this section.

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

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(D) Repeat the procedures in §§ 63.365(d)(1)(i)(A) through (C) of this subpart three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(ii) The Tedlar bag sampling procedure in section 7.1 of Method 18, may be used to collect samples of inlet and exhaust gas throughout a 1-hour test run.

(A) Continuously sample a slipstream of the control device inlet and outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(B) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(C) Follow the procedures in § 63.365(b)(1)(iv)(B)(2)(b) through (d) of this section.

(D) Determine control device efficiency (% Eff) using the equation in § 63.365(d)(1)(i)(C).

(E) Repeat the procedures in §§ 63.365(d)(1)(ii)(A) through (D) of this subpart, three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(2) Chamber exhaust vent (not manifolded). For determining the efficiency of non-manifolded chamber exhaust vent control devices, either of the following test methods [(i) or (ii)] may be used:

(i) The direct interface sampling and analysis procedures described in Method 18, section 7.2 or 7.3, may be used to continuously monitor ethylene oxide concentration at the inlet and outlet of the control device using a GC/FID or GC/PID; these procedures may be used only if a vent may be sampled and analyzed by the GC/FID or GC/PID once per minute for the duration of each cycle when the chamber exhaust vent is operated.

(A) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(B) Follow the procedures in § 63.365(b)(1)(iv)(B)(2)(b) through (d) of this section.

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

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(D) Repeat the procedures in §§ 63.365(d)(2)(i)(A) through (C) of this subpart three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(ii) The Tedlar bag sampling procedure in section 7.1 of Method 18, may be used to collect samples of inlet and exhaust gas for the duration of each cycle when the chamber exhaust vent is operated.

(A) Continuously sample a slipstream of the control device inlet and outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(B) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(C) Follow the procedures in § 63.365(b)(1)(iv)(B)(2)(b) through (d) of this section.

(D) Determine control device efficiency (% Eff) using the equation in § 63.365(d)(2)(i)(C).

(E) Repeat the procedures in §§ 63.365(d)(2)(ii)(A) through (D) of this subpart three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(iii) In the event that the outlet concentration from the control device is below the detection limit for ethylene oxide for determining the efficiency in § 63.365(b)(2)(i)(C) or (ii)(D), the permittee shall assume the control device is meeting the standard in § 63.362(e)(1) or (2) if the inlet ethylene oxide concentration is at or below approximately 50 ppmv.

(e) 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), (d), or (e) for acid-water scrubbers and to monitor the parameters as established in § 63.364(b).

(1) Ethylene glycol concentration. For determining the ethylene glycol concentration, the facility 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 § 63.14) shall be used to determine the ethylene glycol concentration.

(2) Scrubber liquor tank level. For determining the scrubber liquor tank level, the sterilization facility permittee shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.

(f) Reserved

(g) An permittee of a sterilization facility seeking to demonstrate compliance with the standards found at § 63.362(c), (d), or (e) of this subpart with a control device other than an acid-water scrubber or catalytic or thermal oxidation unit shall provide to the Permitting authority the

information requested under § 63.363(f). The permittee shall submit (1) a description of the device, (2) test results collected in accordance with § 63.363(f) verifying the performance of the device for controlling ethylene oxide emissions to the atmosphere to the levels required by the applicable standards, (3) the appropriate operating parameters that will be monitored, and (4) the frequency of measuring and recording to establish continuous compliance with the standards. The monitoring plan submitted identifying the compliance monitoring is subject to the Permitting authority's approval. The permittee of the sterilization facility shall install, calibrate, operate, and maintain the monitor(s) approved by the Permitting authority based on the information submitted by the permittee. The permittee shall include in the information submitted to the Permitting authority proposed performance specifications and quality assurance procedures for their monitors. The Permitting authority may request further information and shall approve appropriate test methods and procedures.

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the requirements of § 63.363 or § 63.364, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Administrator may request further information and will specify appropriate test methods and procedures.

§ 63.366 Reporting requirements.

(a) The permittee of a source subject to the emissions standards in § 63.362 shall fulfill all reporting requirements in §§ 63.10(a), (d), (e), and (f) of subpart A of 40 CFR part 63, according to the applicability in Table 1. These reports will be made to the Permitting authority at the appropriate address identified in § 63.13 of subpart A.

(1) Reports required by subpart A and this section may be sent by U.S. mail, fax, or by another courier.

(i) Submittals sent by U.S. mail shall be postmarked on or before the specified date.

(ii) Submittals sent by other methods shall be received by the Permitting authority on or before the specified date.

(2) If acceptable to both the Permitting authority and the permittee of a source, reports may be submitted on electronic media.

(3) Content and submittal dates for excess emissions and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per § 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 § 63.10(e)(3)(i) through (iv) for applicability]. Written reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13) as applicable in Table 1 of § 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.

(b) Construction and Reconstruction. The permittee of each source using 10 tons shall fulfill all requirements for construction or reconstruction of a source in § 63.5 of subpart A, according to the applicability in Table 1, and in this paragraph.

(1) Applicability.

(i) This paragraph and § 63.5 of subpart A implement the preconstruction review requirements of section 112(i)(1) for sources subject to these emissions standards. In addition, this section and § 63.5 of subpart A include other requirements for constructed and reconstructed sources that are or become subject to these emissions standards.

(ii) After the effective date, the requirements in this section and in § 63.5 of subpart A apply to owners or operators who construct a new source or reconstruct a source subject to these emissions standards after 12/6/94. New or reconstructed sources subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in § 63.366(b)(2) and (3) of this subsection and § 63.5(d)(3) and (4) and (e) of subpart A.

(2) After the effective date, whether or not an approved permit program is effective in the State in which a source is (or would be) located, no person may construct a new source or reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards, without obtaining advance written approval from the Permitting authority in accordance with the procedures specified in § 63.366(b)(3) of this subsection and § 63.5(d)(3) and (4) and (e) of subpart A.

(3) Application for approval of construction or reconstruction. The provisions of this subparagraph and § 63.5(d)(3) and (4) implement section 112(i)(1) of the Act.

(i) General application requirements.

(A) An permittee who is subject to the requirements of § 63.366(b)(2) of this subsection shall submit to the Permitting authority an application for approval of the construction of a new source subject to these emissions standards, the reconstruction of a source subject to these emissions standards, or the reconstruction of a source such that the source becomes a source 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 § 63.366(c)(1)(iii) of this subpart. The permittee 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 Permitting authority 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 source subject to these emissions standards or make any physical or operational change to a source subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2 of subpart A.

(3) The address (i.e., physical location) or proposed address of the source.

(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 source.

(8) The type and quantity of hazardous air pollutants emitted by the source, 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 source reported in units and averaging times specified. The permittee 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 § 63.366(b)(3)(ii) of this section and § 63.5(d)(3) of subpart A.

(C) An permittee who submits estimates or preliminary information in place of the actual emissions data and analysis required in § 63.366(b)(3)(i)(B)(8) and (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 § 63.366(c)(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 § 63.366(b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source 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 permittee who submits approximations of control efficiencies under this subparagraph shall submit the actual control efficiencies as specified in § 63.366(b)(3)(i)(C) of this section.

(4) Approval of construction or reconstruction based on prior State preconstruction review.

(i) The Permitting authority may approve an application for construction or reconstruction specified in § 63.366(b)(2) and (3) of this section and § 63.5(d)(3) and (4) of subpart A if the permittee of a new or reconstructed source who is subject to such requirement demonstrates to the Permitting authority's satisfaction that the following conditions have been (or will be) met:

(A) The permittee of the new or reconstructed source subject to these emissions standards has undergone a preconstruction review and approval process in the State in which the source is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the source will meet these emissions standards as proposed, if the source is properly built and operated;

(B) In making its finding, the State has considered factors substantially equivalent to those specified in § 63.5(e)(1) of subpart A.

(ii) The permittee shall submit to the Permitting authority the request for approval of construction or reconstruction no later than the application deadline specified in § 63.366(b)(3)(i) of this section. The permittee shall include in the request information sufficient for the Permitting authority's determination. The Permitting authority will evaluate the permittee's request in accordance with the procedures specified in § 63.5 of subpart A. The Permitting authority may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(c) Notification requirements. The permittee of each source subject to the emissions standards in § 63.362 shall fulfill all notification requirements in § 63.9 of subpart A, according to the applicability in Table 1, and in this paragraph.

(1) Initial Notifications

(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 12/6/96 such that the source becomes subject to these emissions standards or other requirements, such source shall be subject to the notification requirements of § 63.9 of subpart A.

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

(ii) The permittee of a new or reconstructed source 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 § 63.366(b)(3) of this section and § 63.5(d)(3) and (4) of subpart A shall provide the following information in writing to the Permitting authority:

(A) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in § 63.366(b)(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 commence before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked not 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 source, 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 source, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the State in which a source subject to these emissions standards is (or would be) located, an permittee who intends to construct a new source subject to these emissions standards or reconstruct a source subject to these emissions standards, or reconstruct a source such that it becomes a source subject to these emissions standards, shall notify the Permitting 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 § 63.366(b)(3) of this section and § 63.5(d)(3) and (4) of subpart A. For sources 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 of subpart A.

(2) If an permittee of a source subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in § 63.366(b)(3)(ii) of this section and § 63.5(d)(3) of subpart A, respectively, in place of the actual emissions data or control efficiencies required in paragraphs § 63.366(b)(3)(i)(B)(8) and (ii) of this section, the permittee 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) The permittee of any existing sterilization facility subject to this subpart shall also include the amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3) of subpart A of 40 CFR part 63. For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

§ 63.367 Recordkeeping requirements

(a) The owner or operator of a source subject to the emissions standards in § 63.362 shall comply with the recordkeeping requirements in §§ 63.10(b) and (c), according to the applicability in Table 1, 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 easily be accessed are suitable for inspection. The most recent two years of records shall be retained onsite or shall be accessible to an inspector onsite. The records of the proceeding 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 strip, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to § 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to an emissions standard in § 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to the emissions standards in § 63.362).

(d) The owners or operators complying with § 63.363(b)(4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof if replacement.

§ 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 if implementation and enforcement of this subpart is 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 (4) of this section.

(1) Approval of alternatives to the requirements in Sec. Sec. 63.360 and 63.362.

(2) Approval of major alternatives to test methods under Sec. 63.7(e)(2)(ii) and (f), as defined in Sec. 63.90, and as required in this subpart.

(3) Approval of major alternatives to monitoring under Sec.63.8(f), as defined in Sec. 63.90, and as required in this subpart.

(4) Approval of major alternatives to recordkeeping and reporting under Sec. 63.10(f), as defined in Sec. 63.90, and as required in this subpart.

Appendix A to Supbart O- General Provisions

§ 63.1 Applicability.

(a) *General. Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.*

(1) Terms used throughout this part are defined in § 63.2 or in the Clean Air Act (Act) as amended in 1990, except that individual subparts of this part may include specific definitions in addition to or that supersede definitions in § 63.2.

(2) This part contains national emission standards for hazardous air pollutants (NESHAP) established pursuant to section 112 of the Act as amended November 15, 1990. These standards
regulate specific categories of stationary sources that emit (or have the potential to emit) one or more hazardous air pollutants listed in this part pursuant to section 112(b) of the Act. This section
explains the applicability of such standards to sources affected by them. The standards in this part are independent of NESHAP contained in 40 CFR part 61. The NESHAP in part 61 promulgated
by signature of the Permitting authority before November 15, 1990 (i.e., the date of enactment of the Clean Air Act Amendments of 1990) remain in effect until they are amended, if appropriate, and added to this part.

(3) No emission standard or other requirement established under this part shall be interpreted, construed, or applied to diminish or replace the requirements of a more stringent emission limitation or other applicable requirement established by the Administrator pursuant to other authority of the Act (section 111, part C or D or any other authority of this Act), or a

standard issued under State authority. The Administrator may specify in a specific standard under this part that facilities subject to other provisions under the Act need only comply with the provisions of that standard.

(4) (i) Each relevant standard in this part 63 must identify explicitly whether each provision in this subpart A is or is not included in such relevant standard.

(ii) If a relevant part 63 standard incorporates the requirements of 40 CFR part 60, part 61, or other part 63 standards, the relevant part 63 standard must identify explicitly the applicability of each corresponding part 60,part 61, or other part 63 subpart A (General) Provision.

(iii) The General Provisions in this Subpart A do not apply to regulations developed pursuant to section112(r) of the amended Act., unless otherwise specified in those regulations. *Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O.*

(5) [Reserved]

(6) To obtain the most current list of categories of sources to be regulated under section 112 of the Act, or to obtain the most recent regulation promulgation schedule established pursuant to section 112(e) of the Act, contact the Office of the Director, Emission Standards Division, Office of Air Quality Planning and Standards, U.S. EPA (MD–13), Research Triangle Park, North Carolina 27711.

(7) Reserved

(8) Reserved

(9) [Reserved]

(10) For the purposes of this part, time periods specified in days shall be measured in calendar days, even if the word ''calendar'' is absent, unless otherwise specified in an applicable requirement.

(11) For the purposes of this part, if an explicit postmark deadline is not specified in an applicable requirement for the submittal of a notification, application, test plan, report, or other written communication to the Permitting authority, the permittee shall postmark the submittal on or before the number of days specified in the applicable requirement. For example, if a notification must be submitted 15 days before a particular event is scheduled to take place, the notification shall be postmarked on or before 15 days preceding the event; likewise, if a notification must be submitted 15 days after a particular event takes place, the notification shall be postmarked on or before 15 days following the end of the event. The use of reliable non-Government mail carriers that provide indications of verifiable delivery of information required to be submitted to the Permitting authority, similar to the postmark provided by the U.S. Postal Service, or alternative means of delivery agreed to by the permitting authority, is acceptable. *§ 63.366(a) of subpart O also allows report submissions via fax and on electronic media.*

(12) Notwithstanding time periods or postmark deadlines specified in this part for the submittal of information to the Permitting authority by a permittee, or the review of such information by the Permitting authority, such time periods or deadlines may be changed by mutual agreement between the permittee and the Permitting authority. Procedures governing the implementation of this provision are specified in § 63.9(i).

(13) Reserved

(14) Reserved

(b) *Initial applicability determination for this part.*

(1) The provisions of this part apply to the permittee of any stationary source that -

(i) Emits or has the potential to emit any hazardous air pollutant listed in or pursuant to section 112(b) of the Act; and

(ii) Is subject to any standard, limitation, prohibition, or other federally enforceable requirement established pursuant to this part.

(2) Reserved

(3) *§ 63.367 clarifies the applicability of recordkeeping requirements for sources that determine they are not subject to the emissions standards.*

(c) *Applicability of this part after a relevant standard has been set under this part.*

(1) If a relevant standard has been established under this part, the owner or operator of an affected source must comply with the provisions of that standard and of this subpart as provided in paragraph (a)(4) of this section. *Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O in this table.*

(2) If a relevant standard has been established under this part, the permittee of an affected source may be required to obtain a title V permit from the permitting authority in the State in which the source is located. Emission standards promulgated in this part for area sources will specify whether -

(1) (i) Except as provided in § 63.10(b)(3), if a relevant standard has been established under this part, the owner or operator of an affected source may be required to obtain a title V permit from a permitting authority in the State in which the source is located. Emission standards promulgated in this part for area sources pursuant to section 112(c)(3) of the Act will specify whether –

(i) States will have the option to exclude area sources affected by that standard from the requirement to obtain a title V permit (i.e., the standard will exempt the category of area sources altogether from the permitting requirement);

(ii) States will have the option to defer permitting of area sources in that category until the Administrator takes rulemaking action to determine applicability of the permitting requirements; or

(iii) If a standard fails to specify what the permitting requirements will be for area sources affected by such a standard, then area sources that are subject to the standard will be subject to the requirement to obtain a title V permit without any deferral. *Subpart O also specifies which sources are required to obtain a Title V permit in § 63.360.*

(3) [Reserved]

(4) Reserved

(5) *§ 63.360 specifies applicability.*

(d) [Reserved]

(e) If the Administrator promulgates an emission standard under section 112(d) or (h) of the Act that is applicable to a source subject to an emission limitation by permit established under section 112(j) of the Act, and the requirements under the section 112(j) emission limitation are substantially as effective as the promulgated emission standard, the owner or operator may request the permitting authority to revise the source's title V permit to reflect that the emission limitation in the permit satisfies the requirements of the promulgated emission standard. The process by which the permitting authority determines whether the section 112(j) emission

limitation is substantially as effective as the promulgated emission standard must include, consistent with part 70 or 71 of this chapter, the opportunity for full public, EPA, and affected State review (including the opportunity for EPA's objection) prior to the permit revision being finalized. A negative determination by the permitting authority constitutes final action for purposes of review and appeal under the applicable title V operating permit program.

§ 63.2 Definitions.

The terms used in this part are defined in the Act or in this section as follows:

Act means the Clean Air Act (42 U.S.C. 7401 et seq., as amended by Pub. L. 101–549, 104 Stat. 2399).

Actual emissions is defined in subpart D of this part for the purpose of granting a compliance extension for an early reduction of hazardous air pollutants.

Permitting authority means the Permitting authority of the United States Environmental Protection Agency or his or her authorized representative (e.g., a State that has been delegated the authority to implement the provisions of this part).

Affected source, for the purposes of this part, means the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a section 112(c) source category or subcategory for which a section 112(d) standard or other relevant standard is established pursuant to section 112 of the Act. Each relevant standard will define the "affected source," as defined in this paragraph unless a different definition is warranted based on a published justification as to why this definition would result in significant administrative, practical, or implementation problems and why the different definition would resolve those problems. The term "affected source," as used in this part, is separate and distinct from any other use of that term in EPA regulations such as those implementing title IV of the Act. Affected source may be defined differently for part 63 than affected facility and stationary source in parts 60 and 61, respectively. This definition of "affected source," and the procedures for adopting an alternative definition of "affected source," shall apply to each section 112(d) standard for which the initial proposed rule is signed by the Administrator after June 30, 2002.

Alternative emission limitation means conditions established pursuant to sections 112(i)(5) or 112(i)(6) of the Act by the Permitting authority or by a State with an approved permit program.

Alternative emission standard means an alternative means of emission limitation that, after notice and opportunity for public comment, has been demonstrated by a permittee to the Permitting authority's satisfaction to achieve a reduction in emissions of any air pollutant at least equivalent to the reduction in emissions of such pollutant achieved under a relevant design, equipment, work practice, or operational emission standard, or combination thereof, established under this part pursuant to section 112(h) of the Act.

Alternative test method means any method of sampling and analyzing for an air pollutant that is not a test method in this chapter and that has been demonstrated to the Permitting authority's satisfaction, using Method 301 in Appendix A of this part, to produce results adequate for the Permitting authority's determination that it may be used in place of a test method specified in this part.

Approved permit program means a State permit program approved by the Permitting authority as meeting the requirements of part 70 of this chapter or a Federal permit program established in this chapter pursuant to title V of the Act (42 U.S.C. 7661).

Area source means any stationary source of hazardous air pollutants that is not a major source as defined in this part.

Commenced means, with respect to construction or reconstruction of an affected source, that an owner or operator has undertaken a continuous program of construction or reconstruction or that an owner or operator has entered into a contractual obligation to undertake and complete, within a reasonable time, a continuous program of construction or reconstruction.

Compliance date means the date by which an affected source is required to be in compliance with a relevant standard, limitation, prohibition, or any federally enforceable requirement established by the Permitting authority (or a State with an approved permit program) pursuant to section 112 of the Act.

Compliance schedule means:

(1) In the case of an affected source that is in compliance with all applicable requirements established under this part, a statement that the source will continue to comply with such requirements; or

(2) In the case of an affected source that is required to comply with applicable requirements by a future date, a statement that the source will meet such requirements on a timely basis and, if required by an applicable requirement, a detailed schedule of the dates by which each step toward compliance will be reached; or

(3) In the case of an affected source not in compliance with all applicable requirements established under this part, a schedule of remedial measures, including an enforceable sequence of
actions or operations with milestones and a schedule for the submission of certified progress reports, where applicable, leading to compliance with a relevant standard, limitation, prohibition, or any federally enforceable requirement established pursuant to section 112 of the Act for which the affected source is not in compliance. This compliance schedule shall resemble and be at least as
stringent as that contained in any judicial consent decree or administrative order to which the source is subject. Any such schedule of compliance shall be supplemental to, and shall not sanction non-compliance with, the applicable requirements on which it is based.

Construction means the on-site fabrication, erection, or installation of an affected source. Construction does not include the removal of all equipment comprising an affected source from an existing location and reinstallation of such equipment at a new location. The owner or operator of an existing affected source that is relocated may elect not to reinstall minor ancillary equipment including, but not limited to, piping, ductwork, and valves. However, removal and reinstallation of an affected source will be construed as reconstruction if it satisfies the criteria for reconstruction as defined in this section. The costs of replacing minor ancillary equipment must be considered in determining whether the existing affected source is reconstructed.

Continuous emission monitoring system (CEMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this part, used to sample, condition (if applicable), analyze, and provide a record of emissions.

Continuous monitoring system (CMS) is a comprehensive term that may include, but is not limited to, continuous emission monitoring systems, continuous opacity monitoring systems, continuous parameter monitoring systems, or other manual or automatic monitoring that is used for demonstrating compliance with an applicable regulation on a continuous basis as defined by the regulation.

Continuous opacity monitoring system (COMS) means a continuous monitoring system that measures the opacity of emissions.

Continuous parameter monitoring system means the total equipment that may be required to meet the data acquisition and availability requirements of this part, used to sample, condition (if applicable), analyze, and provide a record of process or control system parameters.

Effective date means:

(1) With regard to an emission standard established under this part, the date of promulgation in the FEDERAL REGISTER of such standard; or

(2) With regard to an alternative emission limitation or equivalent emission limitation determined by the Administrator (or a State with an approved permit program), the date that the alternative emission limitation or equivalent emission limitation becomes effective according to the provisions of this part.

Emission standard means a national standard, limitation, prohibition, or other regulation promulgated in a subpart of this part pursuant to sections 112(d), 112(h), or 112(f) of the Act.

Emissions averaging is a way to comply with the emission limitations specified in a relevant standard, whereby an affected source, if allowed under a subpart of this part, may create emission credits by reducing emissions from specific points to a level below that required by the relevant standard, and those credits are used to offset emissions from points that are not controlled to the level required by the relevant standard.

EPA means the United States Environmental Protection Agency.

Equivalent emission limitation means any maximum achievable control technology emission limitation or requirements which are applicable to a major source of hazardous air pollutants and are adopted by the Administrator (or a State with an approved permit program) on a case-by-case basis, pursuant to section 112(g) or (j) of the Act.

Excess emissions and continuous monitoring system performance report is a report that must be submitted periodically by an affected source in order to provide data on its compliance with relevant emission limits, operating parameters, and the performance of its continuous parameter monitoring systems.

Existing source means any affected source that is not a new source.

Federally enforceable means all limitations and conditions that are enforceable by the Permitting authority and citizens under the Act or that are enforceable under other statutes administered by the Permitting authority. Examples of federally enforceable limitations and conditions include, but are not limited to:

(1) Emission standards, alternative emission standards, alternative emission limitations, and equivalent emission limitations established pursuant to section 112 of the Act as amended in 1990;

(2) New source performance standards established pursuant to section 111 of the Act, and
emission standards established pursuant to section 112 of the Act before it was amended in 1990;

(3) All terms and conditions in a title V permit, including any provisions that limit a source's potential to emit, unless expressly designated as not federally enforceable;

(4) Limitations and conditions that are part of an approved State Implementation Plan (SIP) or a Federal Implementation Plan (FIP);

(5) Limitations and conditions that are part of a Federal construction permit issued under 40 CFR 52.21 or any construction permit issued under regulations approved by the EPA in accordance with 40 CFR part 51;

(6) Limitations and conditions that are part of an operating permit where the permit and the permitting program pursuant to which it was issued meet all of the following criteria:

(i) The operating permit program has been submitted to and approved by EPA into a State implementation plan (SIP) under section 110 of the CAA;

(ii) The SIP imposes a legal obligation that operating permit holders adhere to the terms and limitations of such permits and provides that permits which do not conform to the operating permit program requirements and the requirements of EPA's underlying regulations may be deemed not "federally enforceable" by EPA;

(iii) The operating permit program requires that all emission limitations, controls, and other requirements imposed by such permits will be at least as stringent as any other applicable limitations and requirements contained in the SIP or enforceable under the SIP, and that the program may not issue permits that waive, or make less stringent, any limitations or requirements contained in or issued pursuant to the SIP, or that are otherwise "federally enforceable";

(iv) The limitations, controls, and requirements in the permit in question are permanent, quantifiable, and otherwise enforceable as a practical matter; and

(v) The permit in question was issued only after adequate and timely notice and opportunity for comment for EPA and the public.

(7) Limitations and conditions in a State rule or program that has been approved by the EPA under subpart E of this part for the purposes of implementing and enforcing section 112; and

(8) Individual consent agreements that the EPA has legal authority to create.

Fixed capital cost means the capital needed to provide all the depreciable components of an existing source.

Fugitive emissions means those emissions from a stationary source that could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening. Under section 112 of the Act, all fugitive emissions are to be considered in determining whether a stationary source is a major source.

Hazardous air pollutant means any air pollutant listed in or pursuant to section 112(b) of the Act.

Issuance of a part 70 permit will occur, if the State is the permitting authority, in accordance with the requirements of part 70 of this chapter and the applicable, approved State permit program. When the EPA is the permitting authority, issuance of a title V permit occurs immediately after the EPA takes final action on the final permit.

Major source means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants, unless the Permitting authority establishes a lesser quantity, or in the case of radionuclides, different criteria from those specified in this sentence.

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable standard to be exceeded. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.

Monitoring means the collection and use of measurement data or other information to control the operation of a process or pollution control device or to verify a work practice

standard relative to assuring compliance with applicable requirements. Monitoring is composed of four elements:

(1) Indicator(s) of performance -- the parameter or parameters you measure or observe for demonstrating proper operation of the pollution control measures or compliance with the applicable emissions limitation or standard. Indicators of performance may include direct or predicted emissions measurements (including opacity), operational parametric values that correspond to process or control device (and capture system) efficiencies or emissions rates, and recorded findings of inspection of work practice activities, materials tracking, or design characteristics. Indicators may be expressed as a single maximum or minimum value, a function of process variables (for example, within a range of pressure drops), a particular operational or work practice status (for example, a damper position, completion of a waste recovery task, materials tracking), or an interdependency between two or among more than two variables.

(2) Measurement techniques -- the means by which you gather and record information of or about the indicators of performance. The components of the measurement technique include the detector type, location and installation specifications, inspection procedures, and quality assurance and quality control measures. Examples of measurement techniques include continuous emission monitoring systems, continuous opacity monitoring systems, continuous parametric monitoring systems, and manual inspections that include making records of process conditions or work practices.

(3) Monitoring frequency -- the number of times you obtain and record monitoring data over a specified time interval. Examples of monitoring frequencies include at least four points equally spaced for each hour for continuous emissions or parametric monitoring systems, at least every 10 seconds for continuous opacity monitoring systems, and at least once per operating day (or week, month, etc.) for work practice or design inspections.

(4) Averaging time -- the period over which you average and use data to verify proper operation of the pollution control approach or compliance with the emissions limitation or standard. Examples of averaging time include a 3-hour average in units of the emissions limitation, a 30-day rolling average emissions value, a daily average of a control device operational parametric range, and an instantaneous alarm.

New affected source means the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a section 112(c) source category or subcategory that is subject to a section 112(d) or other relevant standard for new sources. This definition of "new affected source," and the criteria to be utilized in implementing it, shall apply to each section 112(d) standard for which the initial proposed rule is signed by the Administrator after June 30, 2002. Each relevant standard will define the term "new affected source," which will be the same as the "affected source" unless a different collection is warranted based on consideration of factors including:

(1) Emission reduction impacts of controlling individual sources versus groups of sources;

(2) Cost effectiveness of controlling individual equipment;

(3) Flexibility to accommodate common control strategies;

(4) Cost/benefits of emissions averaging;

(5) Incentives for pollution prevention;

(6) Feasibility and cost of controlling processes that share common equipment (e.g., product recovery devices);

(7) Feasibility and cost of monitoring; and

(8) Other relevant factors.

New source means any affected source the construction or reconstruction of which is commenced after the Administrator first proposes a relevant emission standard under this part establishing an emission standard applicable to such source.

One-hour period, unless otherwise defined in an applicable subpart, means any 60-minute period commencing on the hour.

Opacity means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background. For continuous opacity monitoring systems, opacity means the fraction of incident light that is attenuated by an optical medium.

Permittee means any person who owns, leases, operates, controls, or supervises a stationary source.

Performance audit means a procedure to analyze blind samples, the content of which is known by the Permitting authority, simultaneously with the analysis of performance test samples in order to provide a measure of test data quality.

Performance evaluation means the conduct of relative accuracy testing, calibration error testing, and other measurements used in validating the continuous monitoring system data.

Performance test means the collection of data resulting from the execution of a test method (usually three emission test runs) used to demonstrate compliance with a relevant emission standard as specified in the performance test section of the relevant standard.

Permit modification means a change to a title V permit as defined in regulations codified in this chapter to implement title V of the Act (42 U.S.C. 7661).

Permit program means a comprehensive State operating permit system established pursuant to title V of the Act (42 U.S.C. 7661) and regulations codified in part 70 of this chapter and applicable State regulations, or a comprehensive Federal operating permit system established pursuant to title V of the Act and regulations codified in this chapter.

Permit revision means any permit modification or administrative permit amendment to a title V permit as defined in regulations codified in this chapter to implement title V of the Act (42 U.S.C. 7661).

Permitting authority means:

(1) The State air pollution control agency, local agency, other State agency, or other agency authorized by the Permitting authority to carry out a permit program under part 70 of this chapter; or

(2) The Permitting authority, in the case of EPA-implemented permit programs under title V of the Act (42 U.S.C. 7661).

Potential to emit means the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the stationary source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable.

Reconstruction means the replacement of components of an affected or a previously unaffected stationary source to such an extent that:

(1) The fixed capital cost of the new components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source; and

(2) It is technologically and economically feasible for the reconstructed source to meet the relevant standard(s) established by the Permitting authority (or a State) pursuant to section

112 of the Act. Upon reconstruction, an affected source, or a stationary source that becomes an affected source, is subject to relevant standards for new sources, including compliance dates, irrespective of any change in emissions of hazardous air pollutants from that source.

Regulation promulgation schedule means the schedule for the promulgation of emission standards under this part, established by the Permitting authority pursuant to section 112(e) of the Act and published in the FEDERAL REGISTER.

Relevant standard means:

(1) An emission standard;

(2) An alternative emission standard;

(3) An alternative emission limitation; or

(4) An equivalent emission limitation established pursuant to section 112 of the Act that applies to the collection of equipment, activities, or both regulated by such standard or limitation. A relevant standard may include or consist of a design, equipment, work practice, or operational requirement, or other measure, process, method, system, or technique (including prohibition of emissions) that the Administrator (or a State) establishes for new or existing sources to which such standard or limitation applies. Every relevant standard established pursuant to section 112 of the Act includes subpart A of this part, as provided by § 63.1(a)(4), and all applicable appendices of this part or of other parts of this chapter that are referenced in that standard.

Responsible official means one of the following:

(1) For a corporation: A president, secretary, treasurer, or vice president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if
the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(ii) The delegation of authority to such representative is approved in advance by the Permitting authority.

(2) For a partnership or sole proprietorship: a general partner or the proprietor, respectively.

(3) For a municipality, State, Federal, or other public agency: either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Permitting authority of the EPA).

(4) For affected sources (as defined in this part) applying for or subject to a title V permit: ''responsible official'' shall have the same meaning as defined in part 70 or Federal title V regulations in this chapter (42 U.S.C. 7661), whichever is applicable.

Run means one of a series of emission or other measurements needed to determine emissions for a representative operating period or cycle as specified in this part.

Shutdown means the cessation of operation of an affected source or portion of an affected source for any purpose.

Six-minute period means, with respect to opacity determinations, any one of the 10 equal parts of a 1-hour period.

The following are from Subpart O definitions:

<u>Source(s) using less than 1 ton</u> means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

<u>Source(s) using 1 ton</u> means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after 12/6/96.

<u>Source(s) using 1 to 10 tons</u> means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after 12/6/96.

<u>Source(s) using less than 10 tons</u> means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after 12/6/96.

<u>Source(s) using 10 tons</u> means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after 12/6/96.

Standard conditions means a temperature of 293 °K (68° F) and a pressure of 101.3 kilopascals (29.92 in. Hg).

Startup means the setting in operation of an affected source for any purpose.

State means all non-Federal authorities, including local agencies, interstate associations, and State-wide programs, that have delegated authority to implement:

(1) The provisions of this part and/or

(2) the permit program established under part 70 of this chapter. The term State shall have its conventional meaning where clear from the context.

Stationary source means any building, structure, facility, or installation which emits or may emit any air pollutant.

Test method means the validated procedure for sampling, preparing, and analyzing for an air pollutant specified in a relevant standard as the performance test procedure. The test method may include methods described in an appendix of this chapter, test methods incorporated by reference in this part, or methods validated for an application through procedures in Method 301 of appendix A of this part.

Title V permit means any permit issued, renewed, or revised pursuant to Federal or State regulations established to implement title V of the Act (42 U.S.C. 7661). A title V permit issued by a State permitting authority is called a part 70 permit in this part.

Visible emission means the observation of an emission of opacity or optical density above the threshold of vision.

Working day means any day on which Federal Government offices (or State government offices for a State that has obtained delegation under section 112(l)) are open for normal business. Saturdays, Sundays, and official Federal (or where delegated, State) holidays are not working days.

§ 63.3 Units and abbreviations.

Used in this part are abbreviations and symbols of units of measure. These are defined as follows:

(a) System International (SI) units of measure:

A = ampere
g = gram
Hz = hertz
J = joule

°K = degree Kelvin
kg = kilogram
l = liter
m = meter
m^3 = cubic meter
mg = milligram = 10^{-3} gram
ml = milliliter = 10^{-3} liter
mm = millimeter = 10^{-3} meter
Mg = megagram = 10^{6} gram = metric ton
MJ = megajoule
mol = mole
N = newton
ng = nanogram = 10^{-9} gram
nm = nanometer = 10^{-9} meter
Pa = pascal
s = second
V = volt
W = watt
Ω = ohm
μg = microgram = 10^{-6} gram
μl = microliter = 10^{-6} liter

(b) Other units of measure:

Btu = British thermal unit
°C = degree Celsius (centigrade)
cal = calorie
cfm = cubic feet per minute
cc = cubic centimeter
cu ft = cubic feet
d = day
dcf = dry cubic feet
dcm = dry cubic meter
dscf = dry cubic feet at standard conditions
dscm = dry cubic meter at standard conditions
eq = equivalent
°F = degree Fahrenheit
ft = feet
ft^2 = square feet
ft^3 = cubic feet
gal = gallon
gr = grain
g-eq = gram equivalent
g-mole = gram mole
hr = hour
in. = inch
in. H_2O = inches of water
K = 1,000

kcal = kilocalorie
lb = pound
lpm = liter per minute
meq = milliequivalent
min = minute
MW = molecular weight
oz = ounces
ppb = parts per billion
ppbw = parts per billion by weight
ppbv = parts per billion by volume
ppm = parts per million
ppmw = parts per million by weight
ppmv = parts per million by volume
psia = pounds per square inch absolute
psig = pounds per square inch gage
°R = degree Rankine
scf = cubic feet at standard conditions
scfh = cubic feet at standard conditions per hour
scm = cubic meter at standard conditions
scmm= cubic meter at standard conditions per minute
sec = second
sq ft = square feet
std = at standard conditions
v/v = volume per volume
yd^2 = square yards
yr = year

(c) Miscellaneous:
act = actual
avg = average
I.D. = inside diameter
M = molar
N = normal
O.D. = outside diameter
% = percent

§ 63.4 Prohibited activities and circumvention.

(a) *Prohibited activities.*

(1) No owner or operator subject to the provisions of this part must operate any affected source in violation of the requirements of this part. Affected sources subject to and in compliance with either an extension of compliance or an exemption from compliance are not in violation of the requirements of this part. An extension of compliance can be granted by the Administrator under this part; by a State with an approved permit program; or by the President under section 112(i)(4) of the Act.

(2) No owner or operator subject to the provisions of this part shall fail to keep records, notify, report, or revise reports as required under this part.

(3) [Reserved]
(4) [Reserved]
(5) [Reserved]

(b) *Circumvention.* No owner or operator subject to the provisions of this part shall build, erect, install, or use any article, machine, equipment, or process to conceal an emission that would otherwise constitute noncompliance with a relevant standard. Such concealment includes, but is not limited to

(1) The use of diluents to achieve compliance with a relevant standard based on the concentration of a pollutant in the effluent discharged to the atmosphere;

(2) The use of gaseous diluents to achieve compliance with a relevant standard for visible emissions; and

(3) [Reserved]

(c) *Severability.* Notwithstanding any requirement incorporated into a title V permit obtained by an owner or operator subject to the provisions of this part, the provisions of this part are federally enforceable.

§ 63.5 Preconstruction review and notification requirements.

(a) *Applicability. § 63.366(b)(1) contains applicability requirements for constructed or reconstructed sources.*

(b) *Requirements for existing, newly constructed, and reconstructed sources.*

(1) A new affected source for which construction commences after proposal of a relevant standard is subject to relevant standards for new affected sources, including compliance dates. An affected source for which reconstruction commences after proposal of a relevant standard is subject to relevant standards for new sources, including compliance dates, irrespective of any change in emissions of hazardous air pollutants from that source. *This paragraph does not apply to sources using 1 to 10 tons in Subpart O.*

(2) [Reserved]

(3) *See § 63.366(b)(2)*

(4) After the effective date of any relevant standard promulgated by the Administrator under this part, an owner or operator who constructs a new affected source that is not major-emitting or reconstructs an affected source that is not major-emitting that is subject to such standard, or reconstructs a source such that the source becomes an affected source subject to the standard, must notify the Administrator of the intended construction or reconstruction. The notification must be submitted in accordance with the procedures in § 63.9(b). *This paragraph does not apply to sources using 1 to 10 tons in Subpart O.*

(5) Reserved

(6) After the effective date of any relevant standard promulgated by the Administrator under this part, equipment added (or a process change) to an affected source that is within the scope of the definition of affected source under the relevant standard must be considered part of the affected source and subject to all provisions of the relevant standard established for that affected source. *This paragrapgh does not apply to sources using 1 to 10 tons in Subpart O.*

(c) [Reserved]

(d) *Application for approval of construction or reconstruction.* The provisions of this paragraph implement section 112(i)(1) of the Act. *This paragrapgh does not apply to sources using 1 to 10 tons in Subpart O.*

(1) & (2) *See § 63.366(b)(3).*

(3) *Application for approval of reconstruction.* Each application for approval of reconstruction shall include, in addition to the information required in paragraph (d)(1)(ii) of this section - (i) A brief description of the affected source and the components that are to be replaced;

(ii) A description of present and proposed emission control systems (i.e., equipment or methods). 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;

(iii) An estimate of the fixed capital cost of the replacements and of constructing a comparable entirely new source;

(iv) The estimated life of the affected source after the replacements; and

(v) A discussion of any economic or technical limitations the source may have in complying with relevant standards or other requirements after the proposed replacements. The discussion shall be sufficiently detailed to demonstrate to the Permitting authority's satisfaction that the technical or economic limitations affect the source's ability to comply with the relevant standard and how they do so.

(vi) If in the application for approval of reconstruction the owner or operator designates the affected source as a reconstructed source and declares that there are no economic or technical limitations to prevent the source from complying with all relevant standards or other requirements, the owner or operator need not submit the information required in paragraphs (d)(3)(iii) through (d)(3)(v) of this section.

(4) *Additional information.* The Permitting authority may request additional relevant information after the submittal of an application for approval of construction or reconstruction. *This paragrapgh does not apply to sources using 1 to 10 tons in Subpart O.*

(e) *Approval of construction or reconstruction. This section does not apply to sources using 1 to 10 tons in Subpart O.*

(1) (i) If the Permitting authority determines that, if properly constructed, or reconstructed, and operated, a new or existing source for which an application under paragraph (d) of this section was submitted will not cause emissions in violation of the relevant standard(s) and any other federally enforceable requirements, the Permitting authority will approve the construction or reconstruction.

(ii) In addition, in the case of reconstruction, the Permitting authority's determination under this paragraph will be based on:

(A) The fixed capital cost of the replacements in comparison to the fixed capital cost that would be required to construct a comparable entirely new source;

(B) The estimated life of the source after the re-placements compared to the life of a comparable entirely new source;

(C) The extent to which the components being replaced cause or contribute to the emissions from the source; and

(D) Any economic or technical limitations on compliance with relevant standards that are inherent in the proposed replacements.

(2) (i) The Permitting authority will notify the permittee in writing of approval or intention to deny approval of construction or reconstruction within 60 calendar days after receipt of sufficient information to evaluate an application submitted under paragraph (d) of this section. The 60-day approval or denial period will begin after the permittee has been notified in writing that his/her application is complete. The Permitting authority will notify the permittee in writing of the status of his/her application, that is, whether the application contains sufficient information to make a determination, within 30 calendar days after receipt of the original application and within 30 calendar days after receipt of any supplementary information that is submitted.

(ii) When notifying the permittee that his/her application is not complete, the Permitting authority will specify the information needed to complete the application and provide notice of opportunity for the applicant to present, in writing, within 30 calendar days after he/she is notified of the incomplete application, additional information or arguments to the Permitting authority to enable further action on the application.

(3) Before denying any application for approval of construction or reconstruction, the Permitting authority will notify the applicant of the Permitting authority's intention to issue the denial together with -

(i) Notice of the information and findings on which the intended denial is based; and

(ii) Notice of opportunity for the applicant to present, in writing, within 30 calendar days after he/she is notified of the intended denial, additional information or arguments to the Permitting authority to enable further action on the application.

(4) A final determination to deny any application for approval will be in writing and will specify the grounds on which the denial is based. The final determination will be made within 60 calendar days of presentation of additional information or arguments (if the application is complete), or within 60 calendar days after the final date specified for presentation if no presentation is made.

(5) Neither the submission of an application for approval nor the Permitting authority's approval of construction or reconstruction shall -

(i) Relieve a permittee of legal responsibility for compliance with any applicable provisions of this part or with any other applicable Federal, State, or local requirement; or

(ii) Prevent the Permitting authority from implementing or enforcing this part or taking any other action under the Act.

(f) *Approval of construction or reconstruction based on prior State preconstruction review. See § 63.366(b)(4).*

§ 63.6 Compliance with standards and maintenance requirements.

(a) *Applicability.*

(1) The requirements in this section apply to the owner or operator of affected sources for which any relevant standard has been established pursuant to section 112 of the Act and the applicability of such requirements is set out in accordance with § 63.1(a)(4) unless --

(i) The Permitting authority (or a State with an approved permit program) has granted an extension of compliance consistent with paragraph (i) of this section; or

(ii) The President has granted an exemption from compliance with any relevant standard in accordance with section 112(i)(4) of the Act.

(2) *§ 63.360 specifies applicability.*

(b) *Compliance dates for new and reconstructed sources.* & (c) *Compliance dates for existing sources. § 63.360(g) specifies compliance dates for sources*

(d) [Reserved]

(e) *Operation and maintenance requirements. Subpart O does not contain any operation and maintenance plan requirements.*

(f) *Compliance with nonopacity emission standards -*

(1) *Applicability. § 63.362(b) specifies when the standards apply*

(2) *Methods for determining compliance.*

(i) The Permitting authority will determine compliance with nonopacity emission standards in this part based on the results of performance tests conducted according to the procedures in § 63.7, unless otherwise specified in an applicable subpart of this part.

(ii) *§ 63.363 specifies parameters for determining compliance.*

(iii) If an affected source conducts performance testing at startup to obtain an operating permit in the State in which the source is located, the results of such testing may be used to demonstrate compliance with a relevant standard if -

(A) The performance test was conducted within a reasonable amount of time before an initial performance test is required to be conducted under the relevant standard;

(B) The performance test was conducted under representative operating conditions for the source;

(C) The performance test was conducted and the resulting data were reduced using EPA-approved test methods and procedures, as specified in § 63.7(e) of this subpart; and

(D) The performance test was appropriately quality-assured, as specified in § 63.7(c).

(iv) The Permitting authority will determine compliance with design, equipment, work practice, or operational emission standards in this part by review of records, inspection of the source, and other procedures specified in applicable subparts of this part.

(v) *This section does not apply to EO sources.*

(3) *Finding of compliance.* The Administrator will make a finding concerning an affected source's compliance with a non-opacity emission standard, as specified in paragraphs (f)(1) and (2) of this section, upon obtaining all the compliance information required by the relevant standard (including the written reports of performance test results, monitoring results, and other information, if applicable), and information available to the Administrator pursuant to paragraph (e)(1)(i) of this section.

(g) *Use of an alternative nonopacity emission standard.*

(1) If, in the Permitting authority's judgment, a permittee of an affected source has established that an alternative means of emission limitation will achieve a reduction in emissions of
a hazardous air pollutant from an affected source at least equivalent to the reduction in emissions of that pollutant from that source achieved under any design, equipment, work practice, or operational emission standard, or combination thereof, established under this part pursuant to section 112(h) of the Act, the Permitting authority will publish in the FEDERAL REGISTER a notice permitting the use of the alternative emission standard for purposes of compliance with the promulgated standard. Any FEDERAL REGISTER notice under this paragraph shall be published only after the public is notified and given the opportunity to comment. Such notice will restrict the permission to the stationary source(s) or category(ies) of sources from which the alternative emission standard will achieve equivalent emission reductions. The Permitting authority will condition permission in such notice on requirements to assure the proper operation and maintenance of equipment and practices required for compliance with the alternative emission standard and other requirements, including appropriate quality assurance and quality control requirements, that are deemed necessary.

(2) A permittee requesting permission under this paragraph shall, unless otherwise specified in an applicable subpart, submit a proposed test plan or the results of testing and monitoring in accordance with § 63.7 and § 63.8, a description of the procedures followed in testing or monitoring, and a description of pertinent conditions during testing or monitoring. Any testing or monitoring conducted to request permission to use an alternative nonopacity emission standard shall be appropriately quality assured and quality controlled, as specified in § 63.7 and § 63.8.

(3) The Permitting authority may establish general procedures in an applicable subpart that accomplish the requirements of paragraphs (g)(1) and (g)(2) of this section.

(h) *Compliance with opacity and visible emission standards - Subpart O does not contain any opacity or visible emission standards.*

(i) *Extension of compliance with emission standards.*

(1) Until an extension of compliance has been granted by the Permitting authority (or a State with an approved permit program) under this paragraph, the permittee of an affected source subject to the requirements of this section shall comply with all applicable requirements of this part.

(2) *Extension of compliance for early reductions and other reductions*

(i) *Early reductions*. Pursuant to section 112(i)(5) of the Act, if the owner or operator of an existing source demonstrates that the source has achieved a reduction in emissions of hazardous air pollutants in accordance with the provisions of subpart D of this part, the Permitting authority (or the State with an approved permit program) will grant the permittee an extension of compliance with specific requirements of this part, as specified in subpart D.

(ii) *Other reductions*. Pursuant to section 112(i)(6) of the Act, if the permittee of an existing source has installed best available control technology (BACT) (as defined in section 169(3) of the Act) or technology required to meet a lowest achievable emission rate (LAER) (as defined in section 171 of the Act) prior to the promulgation of an emission standard in this part applicable to such source and the same pollutant (or stream of pollutants) controlled pursuant to the BACT or LAER installation, the Permitting authority will grant the permittee an extension of

compliance with such emission standard that will apply until the date 5 years after the date on which such installation was achieved, as determined by the Permitting authority.

(3) *Request for extension of compliance*. Paragraphs (i)(4) through (i)(7) of this section concern requests for an extension of compliance with a relevant standard under this part (except requests for an extension of compliance under paragraph (i)(2)(i) of this section will be handled through procedures specified in subpart D of this part).

(4) (i) (A) The permittee of an existing source who is unable to comply with a relevant standard established under this part pursuant to section 112(d) of the Act may request that the Permitting authority (or a State, when the State has an approved part 70 permit program and the source is required to obtain a part 70 permit under that program, or a State, when the State has been delegated the authority to implement and enforce the emission standard for that source) grant an extension allowing the source up to 1 additional year to comply with the standard, if such additional period is necessary for the installation of controls. An additional extension of up to 3 years may be added for mining waste operations, if the 1-year extension of compliance is insufficient to dry and cover mining waste in order to reduce emissions of any hazardous air pollutant. The permittee of an affected source who has requested an extension of compliance under this paragraph and who is otherwise required to obtain a title V permit shall apply for such permit or apply to have the source's title V permit revised to incorporate the conditions of the extension of compliance. The conditions of an extension of compliance granted under this paragraph will be incorporated into the affected source's title V permit according to the provisions of part 70 or Federal title V regulations in this chapter (42 U.S.C. 7661), whichever are applicable.

(B) Any request under this paragraph for an extension of compliance with a relevant standard must be submitted in writing to the appropriate authority no later than 120 days prior to the affected source's compliance date (as specified in paragraphs (b) and (c) of this section), except as provided for in paragraph (i)(4)(i)(C) of this section. Nonfrivolous requests submitted under this paragraph will stay the applicability of the rule as to the emission points in question until such time as the request is granted or denied. A denial will be effective as of the date of denial. Emission standards established under this part may specify alternative dates for the submittal of requests for an extension of compliance if alternatives are appropriate for the source categories affected by those standards.

(C) An owner or operator may submit a compliance extension request after the date specified in paragraph (i)(4)(i)(B) of this section provided the need for the compliance extension arose after that date, and before the otherwise applicable compliance date and the need arose due to circumstances beyond reasonable control of the owner or operator. This request must include, in addition to the information required in paragraph (i)(6)(i) of this section, a statement of the reasons additional time is needed and the date when the owner or operator first learned of the problems. Nonfrivolous requests submitted under this paragraph will stay the applicability of the rule as to the emission points in question until such time as the request is granted or denied. A denial will be effective as of the original compliance date.

(ii) The owner or operator of an existing source unable to comply with a relevant standard established under this part pursuant to section 112(f) of the Act may request that the Administrator grant an extension allowing the source up to 2 years after the standard's effective date to comply with the standard. The Administrator may grant such an extension if he/she finds that such additional period is necessary for the installation of controls and that steps will be taken during the period of the extension to assure that the health of persons will be protected from imminent endangerment. Any request for an extension of compliance with a relevant standard

(B) Under paragraph (i)(5), specify any additional conditions that the Permitting authority deems necessary to assure the proper operation and maintenance of the installed controls during the extension period.

(11) The permittee of an existing source that has been granted an extension of compliance under paragraph (i)(10) of this section may be required to submit to the Permitting authority (or the State with an approved permit program) progress reports indicating whether the steps toward compliance outlined in the compliance schedule have been reached. The contents of the progress reports and the dates by which they shall be submitted will be specified in the written extension of compliance granted under paragraph (i)(10) of this section.

(12) (i) The Administrator (or the State with an approved permit program) will notify the owner or operator in writing of approval or intention to deny approval of a request for an extension of compliance within 30 calendar days after receipt of sufficient information to evaluate a request submitted under paragraph (i)(4)(i) or (i)(5) of this section. The Administrator (or the State) will notify the owner or operator in writing of the status of his/her application, that is, whether the application contains sufficient information to make a determination, within 30 calendar days after receipt of the original application and within 30 calendar days after receipt of any supplementary information that is submitted. The 30-day approval or denial period will begin after the owner or operator has been notified in writing that his/her application is complete.

(ii) When notifying the permittee that his/her application is not complete, the Permitting authority will specify the information needed to complete the application and provide notice of opportunity for the applicant to present, in writing, within 30 calendar days after he/she is notified of the incomplete application, additional information or arguments to the Permitting authority to enable further action on the application.

(iii) Before denying any request for an extension of compliance, the Permitting authority (or the State with an approved permit program) will notify the permittee in writing of the Permitting authority's (or the State's) intention to issue the denial, together with -

(A) Notice of the information and findings on which the intended denial is based; and

(B) Notice of opportunity for the permittee to present in writing, within 15 calendar days after he/she is notified of the intended denial, additional information or arguments to the Permitting authority (or the State) before further action on the request.

(iv) The Permitting authority's final determination to deny any request for an extension will be in writing and will set forth the specific grounds on which the denial is based. The final determination will be made within 30 calendar days after presentation of additional information or argument (if the application is complete), or within 30 calendar days after the final date specified for the presentation if no presentation is made.

(13) (i) The Permitting authority will notify the permittee in writing of approval or intention to deny approval of a request for an extension of compliance within 30 calendar days after receipt of sufficient information to evaluate a request submitted under paragraph (i)(4)(ii) of this section. The 30-day approval or denial period will begin after the permittee has been notified in writing that his/her application is complete. The Permitting authority (or the State) will notify the permittee in writing of the status of his/her application, that is, whether the application contains sufficient information to make a determination, within 15 calendar days after receipt of the original application and within 15 calendar days after receipt of any supplementary information that is submitted.

(ii) When notifying the permittee that his/her application is not complete, the Permitting authority will specify the information needed to complete the application and provide

notice of opportunity for the applicant to present, in writing, within 15 calendar days after he/she is notified of the incomplete application, additional information or arguments to the Permitting authority to enable further action on the application.

(iii) Before denying any request for an extension of compliance, the Permitting authority will notify the permittee in writing of the Permitting authority's intention to issue the denial, together with -

(A) Notice of the information and findings on which the intended denial is based; and

(B) Notice of opportunity for the permittee to present in writing, within 15 calendar days after he/she is notified of the intended denial, additional information or arguments to the Permitting authority before further action on the request.

(iv) A final determination to deny any request for an extension will be in writing and will set forth the specific grounds on which the denial is based. The final determination will be made within 30 calendar days after presentation of additional information or argument (if the application is complete), or within 30 calendar days after the final date specified for the presentation if no presentation is made.

(14) The Administrator (or the State with an approved permit program) may terminate an extension of compliance at an earlier date than specified if any specification under paragraph (i)(10)(iii) or (iv) of this section is not met. Upon a determination to terminate, the Administrator will notify, in writing, the owner or operator of the Administrator's determination to terminate, together with:

(i) Notice of the reason for termination; and

(ii) Notice of opportunity for the owner or operator to present in writing, within 15 calendar days after he/she is notified of the determination to terminate, additional information or arguments to the Administrator before further action on the termination.

(iii) A final determination to terminate an extension of compliance will be in writing and will set forth the specific grounds on which the termination is based. The final determination will be made within 30 calendar days after presentation of additional information or arguments, or within 30 calendar days after the final date specified for the presentation if no presentation is made.

(15) [Reserved]

(16) The granting of an extension under this section shall not abrogate the Permitting authority's authority under section 114 of the Act.

(j) *Exemption from compliance with emission standards.* The President may exempt any stationary source from compliance with any relevant standard established pursuant to section 112 of the Act for a period of not more than 2 years if the President determines that the technology to implement such standard is not available and that it is in the national security interests of the United States to do so. An exemption under this paragraph may be extended for 1 or more additional periods, each period not to exceed 2 years.

§ 63.7 Performance testing requirements.

(a) *Applicability and performance test dates.*

(1) The applicability of this section is set out in § 63.1(a)(4).

(2) *§ 63.365(a)(2) specifies performance test dates.*

(3) The Permitting authority may require a permittee to conduct performance tests at the affected source at any other time when the action is authorized by section 114 of the Act.

(b) *Notification of performance test.*

(1) The owner or operator of an affected source must notify the Administrator in writing of his or her intention to conduct a performance test at least 60 calendar days before the performance test is initially scheduled to begin to allow the Administrator, upon request, to review an approve the site-specific test plan required under paragraph (c) of this section and to have an observer present during the test.

(2) In the event the owner or operator is unable to conduct the performance test on the date specified in the notification requirement specified in paragraph (b)(1) of this section due to unforeseeable circumstances beyond his or her control, the owner or operator must notify the Administrator as soon as practicable and without delay 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 owner or operator 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.

(c) *Quality assurance program. This section does not apply to sources using 1 to 10 tons in Subpart O.*

(1) The results of the quality assurance program required in this paragraph will be considered by the Permitting authority when he/she determines the validity of a performance test.

(2) (i) ***Submission of site-specific test plan.*** Before conducting a required performance test, the permittee of an affected source shall develop and, if requested by the Permitting authority, shall submit a site-specific test plan to the Permitting authority for approval. The test plan shall include a test program summary, the test schedule, data quality objectives, and both an internal and external quality assurance (QA) program. Data quality objectives are the pretest expectations of precision, accuracy, and completeness of data.

(ii) The internal QA program shall include, at a minimum, the activities planned by routine operators and analysts to provide an assessment of test data precision; an example of internal QA is the sampling and analysis of replicate samples.

(iii) The external QA program shall include, at a minimum, application of plans for a test method performance audit (PA) during the performance test. The PA's consist of blind audit samples provided by the Permitting authority and analyzed during the performance test in order to provide a measure of test data bias. The external QA program may also include systems audits that include the opportunity for on-site evaluation by the Permitting authority of instrument calibration, data validation, sample logging, and documentation of quality control data and field maintenance activities.

(iv) The permittee of an affected source shall submit the site-specific test plan to the Permitting authority upon the Permitting authority's request at least 60 calendar days before the performance test is scheduled to take place, that is, simultaneously with the notification of intention to conduct a performance test required under paragraph (b) of this section, or on a mutually agreed upon date.

(v) The Permitting authority may request additional relevant information after the submittal of a site-specific test plan.

(3) *Approval of site-specific test plan.*

(i) The Permitting authority will notify the permittee of approval or intention to deny approval of the site-specific test plan (if review of the site-specific test plan is requested) within 30 calendar days after receipt of the original plan and within 30 calendar days after receipt of any supplementary information that is submitted under paragraph (c)(3)(i)(B) of this section. Before disapproving any site-specific test plan, the Permitting authority will notify the applicant of the Permitting authority's intention to disapprove the plan together with -

(A) Notice of the information and findings on which the intended disapproval is based; and

(B) Notice of opportunity for the permittee to present, within 30 calendar days after he/she is notified of the intended disapproval, additional information to the Permitting authority before final action on the plan.

(ii) In the event that the Permitting authority fails to approve or disapprove the site-specific test plan within the time period specified in paragraph (c)(3)(i) of this section, the following conditions shall apply:

(A) If the owner or operator intends to demonstrate compliance using the test method(s) specified in the relevant standard or with only minor changes to those tests methods (see paragraph (e)(2)(i) of this section), the owner or operator must conduct the performance test within the time specified in this section using the specified method(s);

(B) If the owner or operator intends to demonstrate compliance by using an alternative to any test method specified in the relevant standard, the owner or operator is authorized to conduct the performance test using an alternative test method after the Administrator approves the use of the alternative method when the Administrator approves the site-specific test plan (if review of the site-specific test plan is requested) or after the alternative method is approved (see paragraph (f) of this section). However, the owner or operator is authorized to conduct the performance test using an alternative method in the absence of notification of approval 45 days after submission of the site-specific test plan or request to use an alternative method. The owner or operator is authorized to conduct the performance test within 60 calendar days after he/she is authorized to demonstrate compliance using an alternative test method. Notwithstanding the requirements in the preceding three sentences, the owner or operator may proceed to conduct the performance test as required in this section (without the Administrator's prior approval of the site-specific test plan) if he/she subsequently chooses to use the specified testing and monitoring methods instead of an alternative.

(iii) Neither the submission of a site-specific test plan for approval, nor the Permitting authority's approval or disapproval of a plan, nor the Permitting authority's failure to approve or disapprove a plan in a timely manner shall -

(A) Relieve a permittee of legal responsibility for compliance with any applicable provisions of this part or with any other applicable Federal, State, or local requirement; or

(B) Prevent the Permitting authority from implementing or enforcing this part or taking any other action under the Act.

(4) (i) *Performance test method audit program.* The owner or operator must analyze performance audit (PA) samples during each performance test. The owner or operator must request performance audit materials 30 days prior to the test date. Audit materials including cylinder audit gases may be obtained by contacting the appropriate EPA Regional Office or the responsible enforcement authority.

(ii) The Permitting authority will have sole discretion to require any subsequent remedial actions of the permittee based on the PA results.

(iii) If the Permitting authority fails to provide required PA materials to a permittee of an affected source in time to analyze the PA samples during a performance test, the requirement to conduct a PA under this paragraph shall be waived for such source for that performance test. Waiver under this paragraph of the requirement to conduct a PA for a particular performance test does not constitute a waiver of the requirement to conduct a PA for future required performance tests.

(d) *Performance testing facilities. This section does not apply to sources using 1 to 10 tons in Subpart O.*
If required to do performance testing, the permittee ofeach new source and, at the request of the Permitting authority, the permittee of each existingsource, shall provide performance testing facilities as follows:

(1) Sampling ports adequate for test methods applicable to such source. This includes:

(i) Constructing the air pollution control system such that volumetric flow rates and pollutant emission rates can be accurately determined by applicable test methods and procedures; and

(ii) Providing a stack or duct free of cyclonic flow during performance tests, as demonstrated by applicable test methods and procedures;

(2) Safe sampling platform(s);

(3) Safe access to sampling platform(s);

(4) Utilities for sampling and testing equipment; and

(5) Any other facilities that the Permitting authority deems necessary for safe and adequate testing of a source.

(e) *Conduct of performance tests.*
§ 63.365 also contains test methods specific to sources subject to the emissions standards.

(1) Performance tests shall be conducted under such conditions as the Permitting authority specifies to the permittee based on representative performance (i.e., performance based on normal operating conditions) of the affected source. Operations during periods of startup, shutdown, and malfunction shall not constitute representative conditions for the purpose of a performance test, nor shall emissions in excess of the level of the relevant standard during periods of startup, shutdown, and malfunction be considered a violation of the relevant standard unless otherwise specified in the relevant standard or a determination of noncompliance is made under § 63.6(e). Upon request, the permittee shall make available to the Permitting authority such records as may be necessary to determine the conditions of performance tests.

(2) Performance tests shall be conducted and data shall be reduced in accordance with the test methods and procedures set forth in this section, in each relevant standard, and, if required, in applicable appendices of parts 51, 60, 61, and 63 of this chapter unless the Permitting authority -

(i) Specifies or approves, in specific cases, the use of a test method with minor changes in methodology (see definition in § 63.90(a)). Such changes may be approved in conjunction with approval of the site-specific test plan (see paragraph (c) of this section); or

(ii) Approves the use of an intermediate or major change or alternative to a test method (see definitions in § 63.90(a)), the results of which the Administrator has determined to be adequate for indicating whether a specific affected source is in compliance; or

(iii) Approves shorter sampling times or smaller sample volumes when necessitated by process variables or other factors; or

(iv) Waives the requirement for performance tests because the permittee of an affected source has demonstrated by other means to the Permitting authority's satisfaction that the affected source is in compliance with the relevant standard.

(3) *This section does not apply to sources using 1 to 10 tons in Subpart O.* Unless otherwise specified in a relevant standard or test method, each performance test shall consist of three separate runs using the applicable test method. Each run shall be conducted for the time and under the conditions specified in the relevant standard. For the purpose of determining compliance with a relevant standard, the arithmetic mean of the results of the three runs shall apply. Upon receiving approval from the Permitting authority, results of a test run may be replaced with results of an additional test run in the event that:

(i) A sample is accidentally lost after the testing team leaves the site; or

(ii) Conditions occur in which one of the three runs must be discontinued because of forced shutdown; or

(iii) Extreme meteorological conditions occur; or

(iv) Other circumstances occur that are beyond the permittee's control.

(4) Nothing in paragraphs (e)(1) through (e)(3) of this section shall be construed to abrogate the Permitting authority's authority to require testing under section 114 of the Act.

(f) *Use of an alternative test method* -

(1) *General.* Until authorized to use an intermediate or major change or alternative to a test method, the owner or operator of an affected source remains subject to the requirements of this section and the relevant standard.

(2) The permittee of an affected source required to do performance testing by a relevant standard may use an alternative test method from that specified in the standard provided that the permittee -

(i) Notifies the Administrator of his or her intention to use an alternative test method at least 60 days before the performance test is scheduled to begin;

(ii) Uses Method 301 in appendix A of this part to validate the alternative test method. This may include the use of specific procedures of Method 301 if use of such procedures are sufficient to validate the alternative test method; and

(iii) Submits the results of the Method 301 validation process along with the notification of intention and the justification for not using the specified test method. The permittee may submit the information required in this paragraph well in advance of the deadline specified in paragraph (f)(2)(i) of this section to ensure a timely review by the Permitting authority in order to meet the performance test date specified in this section or the relevant standard.

(3) The Administrator will determine whether the owner or operator's validation of the proposed alternative test method is adequate and issue an approval or disapproval of the alternative test method. If the owner or operator intends to demonstrate compliance by using an alternative to any test method specified in the relevant standard, the owner or operator is authorized to conduct the performance test using an alternative test method after the Administrator approves the use of the alternative method. However, the owner or operator is authorized to conduct the performance test using an alternative method in the absence of notification of approval/disapproval 45 days after submission of the request to use an alternative method and the request satisfies the requirements in paragraph (f)(2) of this section. The owner or operator is authorized to conduct the performance test within 60 calendar days after he/she is authorized to demonstrate compliance using an alternative test method. Notwithstanding the

requirements in the preceding three sentences, the owner or operator may proceed to conduct the performance test as required in this section (without the Administrator's prior approval of the site-specific test plan) if he/she subsequently chooses to use the specified testing and monitoring methods instead of an alternative.

(4) If the Permitting authority finds reasonable grounds to dispute the results obtained by an alternative test method for the purposes of demonstrating compliance with a relevant standard, the Permitting authority may require the use of a test method specified in a relevant standard.

(5) If the permittee uses an alternative test method for an affected source during a required performance test, the permittee of such source shall continue to use the alternative test method for subsequent performance tests at that affected source until he or she receives approval from the Permitting authority to use another test method as allowed under § 63.7(f).

(6) Neither the validation and approval process nor the failure to validate an alternative test method shall abrogate the permittee's responsibility to comply with the requirements of this part.

(g) *Data analysis, recordkeeping, and reporting.*

(1) Unless otherwise specified in a relevant standard or test method, or as otherwise approved by the Permitting authority in writing, results of a performance test shall include the analysis of samples, determination of emissions, and raw data. A performance test is "completed" when field sample collection is terminated. The permittee of an affected source shall report the results of the performance test to the Permitting authority before the, close of business on the 60th day following the completion of the performance test, unless specified otherwise in a relevant standard or as approved otherwise in writing by the Permitting authority (see § 63.9(i)). The results of the performance test shall be submitted as part of the notification of compliance status required under § 63.9(h). Before a title V permit has been issued to the permittee of an affected source, the permittee shall send the results of the performance test to the Permitting authority. After a title V permit has been issued to the permittee of an affected source, the permittee shall send the results of the performance test to the appropriate permitting authority.

(2) [Reserved]

(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 Permitting authority the records or results of such performance test and other data needed to determine emissions from an affected source.

(h) *Waiver of performance tests.*

(1) Until a waiver of a performance testing requirement has been granted by the Permitting authority under this paragraph, the permittee of an affected source remains subject to the requirements of this section.

(2) Individual performance tests may be waived upon written application to the Permitting authority if, in the Permitting authority's judgment, the source is meeting the relevant standard(s) on a continuous basis, or the source is being operated under an extension of compliance, or the permittee has requested an extension of compliance and the Permitting authority is still considering that request.

(3) Request to waive a performance test.

(i) If a request is made for an extension of compliance under § 63.6(i), the application for a waiver of an initial performance test shall accompany the information

required for the request for an extension of compliance. If no extension of compliance is requested
or if the permittee has requested an extension of compliance and the Permitting authority is still considering that request, the application for a waiver of an initial performance test shall be submitted at least 60 days before the performance test if the site-specific test plan under paragraph
(c) of this section is not submitted.

(ii) If an application for a waiver of a subsequent performance test is made, the application may accompany any required compliance progress report, compliance status report, or excess emissions and continuous monitoring system performance report [such as those required under § 63.6(I), § 63.9(h), and § 63.10(e) or specified in a relevant standard or in the source's title V permit], but it shall be submitted at least 60 days before the performance test if the site-specific test plan required under paragraph (c) of this section is not submitted.

(iii) Any application for a waiver of a performance test shall include information justifying the permittee's request for a waiver, such as the technical or economic infeasibility, or the impracticality, of the affected source performing the required test.

(4) Approval of request to waive performance test. The Permitting authority will approve or deny a request for a waiver of a performance test made under paragraph (h)(3) of this section when he/she -

(i) Approves or denies an extension of compliance under § 63.6(i)(8); or

(ii) Approves or disapproves a site-specific test plan under § 63.7(c)(3); or

(iii) Makes a determination of compliance following the submission of a required compliance status report or excess emissions and continuous monitoring systems performance report; or

(iv) Makes a determination of suitable progress towards compliance following the submission of a compliance progress report, whichever is applicable.

(5) Approval of any waiver granted under this section shall not abrogate the Permitting authority's authority under the Act or in any way prohibit the Permitting authority from later canceling the waiver. The cancellation will be made only after notice is given to the permittee of the affected source.

§ 63.8 Monitoring requirements.

(a) *Applicability.*

(1) The applicability of this section is set out in § 63.1(a)(4).

(2) For the purposes of this part, all CMS required under relevant standards shall be subject to the provisions of this section upon promulgation of performance specifications for CMS as specified in the relevant standard or otherwise by the Permitting authority.

(3) [Reserved]

(4) Additional monitoring requirements for control devices used to comply with provisions in relevant standards of this part are specified in § 63.11.

(b) *Conduct of monitoring.*

(1) Monitoring shall be conducted as set forth in this section and the relevant standard(s) unless the Permitting authority -

(i) Specifies or approves the use of minor changes in methodology for the specified monitoring requirements and procedures (see § 63.90(a) for definition); or

(ii) Approves the use of an intermediate or major change or alternative to any monitoring requirements or procedures (see § 63.90(a) for definition).

(iii) Owners or operators with flares subject to § 63.11(b) are not subject to the requirements of this section unless otherwise specified in the relevant standard.

(2) (i) When the emissions from two or more affected sources are combined before being released to the atmosphere, the owner or operator may install an applicable CMS for each emission stream or for the combined emissions streams, provided the monitoring is sufficient to demonstrate compliance with the relevant standard.

(ii) If the relevant standard is a mass emission standard and the emissions from one affected source are released to the atmosphere through more than one point, the owner or operator must install an applicable CMS at each emission point unless the installation of fewer systems is –

(A) Approved by the Administrator; or

(B) 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).

(3) When more than one CMS is used to measure the emissions from one affected source (e.g., multiple breechings, multiple outlets), the permittee shall report the results as required for each CMS. However, when one CMS is used as a backup to another CMS, the permittee shall report the results from the CMS used to meet the monitoring requirements of this part. If both such CMS are used during a particular reporting period to meet the monitoring requirements of this part, then the permittee shall report the results from each CMS for the relevant compliance period.

(c) Operation and maintenance of continuous monitoring systems.

(1) 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.

(i) & (ii) *A startup, shutdown, and malfunction plan is not required for these standards.*

(iii) The owner or operator of an affected source must develop and implement a written startup, shutdown, and malfunction plan for CMS as specified in § 63.6(e)(3).

(2) (i) All CMS must be installed such that representative measures of emissions or process parameters from the affected source are obtained. In addition, CEMS must be located according to procedures contained in the applicable performance specification(s).

(ii) Unless the individual subpart states otherwise, the owner or operator must ensure the read out (that portion of the CMS that provides a visual display or record), or other indication of operation, from any CMS required for compliance with the emission standard is readily accessible on site for operational control or inspection by the operator of the equipment

(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. 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.

(4)-(5) *Frequency of monitoring measurements is provided in § 63.364; opacity monitors are not required for these standards.*

(6) *Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.*

(7) (i) A CMS is out of control if -

(A) & (B) *Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.*

(C) *Opacity monitors are not required for these standards.*

(ii) *Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.*

(8) *This paragraph does not apply to Subpart O sources.*

(d) *Quality control program.*

This section does not apply to sources using one to 10 tons.

(1) The results of the quality control program required in this paragraph will be considered by the Administrator when he/she determines the validity of monitoring data.

(2) The permittee of an affected source that is required to use a CMS and is subject to the monitoring requirements of this section and a relevant standard shall develop and implement a CMS quality control program. As part of the quality control program, the permittee shall develop and submit to the Permitting authority for approval upon request a site-specific performance evaluation test plan for the CMS performance evaluation required in paragraph (e)(3)(i) of this section, according to the procedures specified in paragraph (e). In addition, each quality control program shall include, at a minimum, a written protocol that describes procedures for each of the following operations:

(i) Initial and any subsequent calibration of the CMS;

(ii) Determination and adjustment of the calibration drift of the CMS;

(iii) Preventive maintenance of the CMS, including spare parts inventory;

(iv) Data recording, calculations, and reporting;

(v) Accuracy audit procedures, including sampling and analysis methods; and

(vi) Program of corrective action for a malfunctioning CMS.

(3) The permittee shall keep these written procedures 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 Permitting authority. If the performance evaluation plan is revised, the permittee shall keep previous (i.e., superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Permitting authority, for a period of 5 years after each revision to the plan. Where relevant, e.g., program of corrective action for a malfunctioning CMS, these written procedures may be incorporated as part of the affected source's startup, shutdown, and malfunction plan to avoid duplication of planning and recordkeeping efforts.

(e) *Performance evaluation of continuous monitoring systems -*

(1) *General.* When required by a relevant standard, and at any other time the Permitting authority 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.

(2) *Notification of performance evaluation.* The permittee shall notify the Permitting authority in writing of the date of the performance evaluation simultaneously with the notification of the performance test date required under § 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.

(3)

This section does not apply to sources using one to 10 tons.

(i) *Submission of site-specific performance evaluation test plan.* Before conducting a required CMS performance evaluation, the permittee of an affected source shall develop and submit a site-specific performance evaluation test plan to the Permitting authority for approval upon request. The performance evaluation test plan shall include the evaluation program objectives, an evaluation program summary, the performance evaluation schedule, data quality objectives, and both an internal and external QA program. Data quality objectives are the pre-evaluation expectations of precision, accuracy, and completeness of data.

(ii) The internal QA program shall include, at a minimum, the activities planned by routine operators and analysts to provide an assessment of CMS performance. The external QA program shall include, at a minimum, systems audits that include the opportunity for on-site evaluation by the Permitting authority of instrument calibration, data validation, sample logging, and documentation of quality control data and field maintenance activities.

(iii) The permittee of an affected source shall submit the site-specific performance evaluation test plan to the Permitting authority (if requested) at least 60 days before the performance test or performance evaluation is scheduled to begin, or on a mutually agreed upon date, and review and approval of the performance evaluation test plan by the Permitting authority will occur with the review and approval of the site-specific test plan (if review of the site-specific test plan is requested).

(iv) The Permitting authority may request additional relevant information after the submittal of a site-specific performance evaluation test plan.

(v) In the event that the Permitting authority fails to approve or disapprove the site-specific performance evaluation test plan within the time period specified in § 63.7(c)(3), the following conditions shall apply:

(A) If the permittee intends to demonstrate compliance using the monitoring method(s) specified in the relevant standard, the permittee shall conduct the performance evaluation within the time specified in this subpart using the specified method(s);

(B) If the permittee intends to demonstrate compliance by using an alternative to a monitoring method specified in the relevant standard, the permittee shall refrain from conducting the performance evaluation until the Permitting authority approves the use of the alternative method. If the Permitting authority does not approve the use of the alternative method within 30 days before the performance evaluation is scheduled to begin, the performance evaluation deadlines specified in paragraph (e)(4) of this section may be extended such that the permittee shall conduct the performance evaluation within 60 calendar days after the Permitting authority approves the use of the alternative method. Notwithstanding the requirements in the preceding two sentences, the permittee may proceed to conduct the performance evaluation as required in this section (without the Permitting authority's prior approval of the site-specific performance evaluation test plan) if he/she subsequently chooses to use the specified monitoring method(s) instead of an alternative.

(vi) Neither the submission of a site-specific performance evaluation test plan for approval, nor the Permitting authority's approval or disapproval of a plan, nor the Permitting authority' failure to approve or disapprove a plan in a timely manner shall -

(A) Relieve a permittee of legal responsibility for compliance with any applicable provisions of this part or with any other applicable Federal, State, or local requirement; or

(B) Prevent the Permitting authority from implementing or enforcing this part or taking any other action under the Act.

(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 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 § 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 is conducted in time to submit the results of the performance evaluation as specified in paragraph (e)(5)(ii) of this section. If a performance test is not required, or the requirement for a performance test has been waived under § 63.7(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 § 63.7(a), or as otherwise specified in the relevant standard.

(5) *Reporting performance evaluation results.*

(i) The permittee shall furnish the Permitting authority 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 or within 60 days of completion of the performance evaluation if no test is required, unless otherwise specified in a relevant standard. The Permitting authority may request that the permittee submit the raw data from a performance evaluation in the report of the performance evaluation results.

(ii) *Opacity monitors are not required for these standards.*

(f) *Use of an alternative monitoring method -*

(1) *General.* Until permission to use an alternative monitoring procedure (minor, intermediate, or major changes; see definition in § 63.90(a)) has been granted by the Administrator under this paragraph (f)(1), the owner or operator of an affected source remains subject to the requirements of this section and the relevant standard.

(2) After receipt and consideration of written application, the Permitting authority may approve alternatives to any monitoring methods or procedures of this part including, but not limited to, the following:

(i) Alternative monitoring requirements when installation of a CMS specified by a relevant standard would not provide accurate measurements due to liquid water or other interferences caused by substances within the effluent gases;

(ii) Alternative monitoring requirements when the affected source is infrequently operated;

(iii) Alternative monitoring requirements to accommodate CEMS that require additional measurements to correct for stack moisture conditions;

(iv) Alternative locations for installing CMS when the permittee can demonstrate that installation at alternate locations will enable accurate and representative measurements;

(v) Alternate methods for converting pollutant concentration measurements to units of the relevant standard;

(vi) Alternate procedures for performing daily checks of zero (low-level) and high-level drift that do not involve use of high-level gases or test cells;

(vii) Alternatives to the American Society for Testing and Materials (ASTM) test methods or sampling procedures specified by any relevant standard;

(viii) Alternative CMS that do not meet the design or performance requirements in this part, but adequately demonstrate a definite and consistent relationship between their measurements and the measurements of opacity by a system complying with the requirements as specified in the relevant standard. The Permitting authority may require that such demonstration be performed for each affected source; or

(ix) Alternative monitoring requirements when the effluent from a single affected source or the combined effluent from two or more affected sources is released to the atmosphere through more than one point.

(3) If the Permitting authority finds reasonable grounds to dispute the results obtained by an alternative monitoring method, requirement, or procedure, the Permitting authority may require the use of a method, requirement, or procedure specified in this section or in the relevant standard. If the results of the specified and alternative method, requirement, or procedure do not agree, the results obtained by the specified method, requirement, or procedure shall prevail.

(4) (i) *Request to use alternative monitoring procedure.* An owner or operator who wishes to use an alternative monitoring procedure must submit an application to the Administrator as described in paragraph (f)(4)(ii) of this section. The application may be submitted at any time provided that the monitoring procedure is not the performance test method used to demonstrate compliance with a relevant standard or other requirement. If the alternative monitoring procedure will serve as the performance test method that is to be used to demonstrate compliance with a relevant standard, the application must be submitted at least 60 days before the performance evaluation is scheduled to begin and must meet the requirements for an alternative test method under § 63.7(f).

(ii) The application must contain a description of the proposed alternative monitoring system which addresses the four elements contained in the definition of monitoring in § 63.2 and a performance evaluation test plan, if required, as specified in paragraph (e)(3) of this section. In addition, the application must include information justifying the owner or operator's request for an alternative monitoring method, such as the technical or economic infeasibility, or the impracticality, of the affected source using the required method.

(iii) The owner or operator may submit the information required in this paragraph well in advance of the submittal dates specified in paragraph (f)(4)(i) above to ensure a timely review by the Administrator in order to meet the compliance demonstration date specified in this section or the relevant standard.

(iv) Application for minor changes to monitoring procedures, as specified in paragraph (b)(1) of this section, may be made in the site-specific performance evaluation plan.

(5) *Approval of request to use alternative monitoring procedure.*

(i) The Administrator will notify the owner or operator of approval or intention to deny approval of the request to use an alternative monitoring method within 30 calendar days after receipt of the original request and within 30 calendar days after receipt of any supplementary information that is submitted. If a request for a minor change is made in conjunction with site-specific performance evaluation plan, then approval of the plan will constitute approval of the minor change. Before disapproving any request to use an alternative monitoring method, the Administrator will notify the applicant of the Administrator's intention to disapprove the request together with --

(A) Notice of the information and findings on which the intended disapproval is based; and

(B) Notice of opportunity for the permittee to present additional information to the Permitting authority before final action on the request. At the time the Permitting authority notifies the applicant of his or her intention to disapprove the request, the Permitting authority will specify how much time the permittee will have after being notified of the intended disapproval to submit the additional information.

(ii) The Permitting authority may establish general procedures and criteria in a relevant standard to accomplish the requirements of paragraph (f)(5)(i) of this section.

(iii) If the Permitting authority approves the use of an alternative monitoring method for an affected source under paragraph (f)(5)(i) of this section, the permittee of such source shall continue to use the alternative monitoring method until he or she receives approval from the Permitting authority to use another monitoring method as allowed by § 63.8(f).

(6) *This section does not apply to Subpart O sources.*

(g) *Reduction of monitoring data.*

(1) The owner or operator of each CMS must reduce the monitoring data as specified in paragraphs (g)(1) through (5) of this section.

(2) *This section does not apply to Subpart O sources.*

(3) The data may be recorded in reduced or nonreduced form (e.g., ppm pollutant and percent O_2 or ng/J of pollutant).

(4) All emission data shall be converted into units of the relevant standard for reporting purposes using the conversion procedures specified in that standard. After conversion into units of the relevant standard, the data may be rounded to the same number of significant digits as used in that standard to specify the emission limit (e.g., rounded to the nearest 1 percent opacity).

(5) Monitoring data recorded during periods of unavoidable CMS breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, and zero (low-level) and high-level adjustments must not be included in any data average computed under this part. For the owner or operator complying with the requirements of § 63.10(b)(2)(vii)(A) or (B), data averages must include any data recorded during periods of monitor breakdown or malfunction.

§ 63.9 Notification requirements.

(a) *Applicability and general information.*

(1) The applicability of this section is set out in § 63.1(a)(4).

(2) For affected sources that have been granted an extension of compliance under subpart D of this part, the requirements of this section do not apply to those sources while they are operating under such compliance extensions.

(3) If any State requires a notice that contains all the information required in a notification listed in this section, the permittee may send the Permitting authority a copy of the notice sent to the State to satisfy the requirements of this section for that notification.

(4) (i) Before a State has been delegated the authority to implement and enforce notification requirements established under this part, the permittee of an affected source in such State subject to such requirements shall submit notifications to the appropriate Regional Office of the EPA (to the attention of the Director of the Division indicated in the list of the EPA Regional Offices in § 63.13).

(ii) After a State has been delegated the authority to implement and enforce notification requirements established under this part, the permittee of an affected source in such State subject to such requirements shall submit notifications 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 notification submitted to the State to the appropriate Regional Office of the EPA, as specified in paragraph (a)(4)(i) of this section. The Regional Office may waive this requirement for any notifications at its discretion.

(b) *Initial notifications.*

(1) (i) The requirements of this paragraph apply to the permittee of an affected source when such source becomes subject to a relevant standard.

(i) & (ii) *§ 63.366(c)(1)(i) contains language for sources that increase usage such that the source becomes subject to the emissions standards.*

(2) *§ 63.366(c)(3) contains additional information to be included in the initial report for existing and new sources.* The permittee of an affected source that has an initial startup before the effective date of a relevant standard under this part shall notify the Permitting authority in writing that the source is subject to the relevant standard. The notification, which shall be submitted not later than 120 calendar days after the effective date of the relevant standard (or within 120 calendar days after the source becomes subject to the relevant standard), shall provide the following information:

(i) The name and address of the permittee;

(ii) The address (i.e., physical location) of the affected source;

(iii) An identification of the relevant standard, or other requirement, that is the basis of the notification and the source's compliance date;

(iv)) A brief description of the nature, size, design, and method of operation of the source and an identification of the types of emission points within the affected source subject to the relevant standard and types of hazardous air pollutants emitted; and

(v) A statement of whether the affected source is a major source or an area source.

(3) [Reserved]

(4) & (5) *§ 63.366(c)(1)(ii) and (iii) contains requirements for new or reconstructed sources subject to the emissions standards.*

(c) *Request for extension of compliance.* If the permittee of an affected source cannot comply with a relevant standard by the applicable compliance date for that source, or if the permittee has installed BACT or technology to meet LAER consistent with § 63.6(i)(5) of this subpart, he/she may submit to the Permitting authority (or the State with an approved permit program) a request for an extension of compliance as specified in § 63.6(i)(4) through § 63.6(i)(6).

(d) *Notification that source is subject to special compliance requirements.* This paragraph not applicable to Subpart O sources.

(e) *Notification of performance test.* The permittee of an affected source shall notify the Permitting authority 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 Permitting authority to review and approve the site-specific test plan required under § 63.7(c), if requested by the Permitting authority, and to have an observer present during the test.

(f) *Notification of opacity and visible emission observations.* The permittee of an affected source shall notify the Permitting authority in writing of the anticipated date for conducting the opacity or
visible emission observations specified in § 63.6(h)(5), if such observations are required for the source by a relevant standard. The notification shall be submitted with the notification of the performance test date, as specified in paragraph (e) of this section, or if no performance test is required or visibility or other conditions prevent the opacity or visible emission observations from being conducted concurrently with the initial performance test required under § 63.7, the permittee shall deliver or postmark the notification not less than 30 days before the opacity or visible emission observations are scheduled to take place.

(g) *Additional notification requirements for sources with continuous monitoring systems.* The permittee of an affected source required to use a CMS by a relevant standard shall furnish the Permitting authority written notification as follows:

(1) A notification of the date the CMS performance evaluation under § 63.8(e) is scheduled to begin, submitted simultaneously with the notification of the performance test date required under § 63.7(b). If no performance test is required, or if the requirement to conduct a performance test has been waived for an affected source under § 63.7(h), the permittee shall notify the Permitting authority in writing of the date of the performance evaluation at least 60 calendar days before the evaluation is scheduled to begin;

(2) & (3) Opacity monitors and relative accuracy testing are not required for these standards.

(h) *Notification of compliance status.*

(1) The requirements of paragraphs (h)(2) through (h)(4)of this section apply when an affected source becomes subject to a relevant standard.

(2) (i) Before a title V 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 Permitting authority 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) If the relevant standard applies to both major and area sources, an analysis demonstrating whether the affected source is a major 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 owner or operator of the affected existing, new, or reconstructed source as to whether the source has complied with the relevant standard or other requirements.

(ii) The notification must 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 the standard, in which case the letter must 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. If no performance test is required but opacity or visible emission observations are required to demonstrate compliance with an opacity or visible emission standard under this part, the notification of compliance status shall be sent before close of business on the 30th day following the completion of opacity or visible emission observations. Notifications may be combined as long as the due date requirement for each notification is met.

(3) After a title V 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 title V permit, including reports required under this part. After a title V 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.

(4) [Reserved]

(5) *§ 63.366(c)(2) instructs sources to submit actual data.*

(6) Advice on a notification of compliance status may be obtained from the Permitting authority.

(i) *Adjustment to time periods or postmark deadlines for submittal and review of required communications.*

(1) (i) Until an adjustment of a time period or postmark deadline has been approved by the Permitting authority under paragraphs (i)(2) and (i)(3) of this section, the permittee of an affected source remains strictly subject to the requirements of this part.

(ii) A permittee shall request the adjustment provided for in paragraphs (i)(2) and (i)(3) of this section each time he or she wishes to change an applicable time period or postmark deadline specified in this part.

(2) Notwithstanding time periods or postmark deadlines specified in this part for the submittal of information to the Permitting authority by a permittee, or the review of such information by the Permitting authority, such time periods or deadlines may be changed by mutual agreement between the permittee and the Permitting authority. A permittee who wishes to request a change in a time period or postmark deadline for a particular requirement shall request the adjustment in writing as soon as practicable before the subject activity is required to take place. The permittee shall include in the request whatever information he or she considers useful to convince the Permitting authority that an adjustment is warranted.

(3) If, in the Permitting authority's judgment, a permittee's request for an adjustment to a particular time period or postmark deadline is warranted, the Permitting authority will approve the adjustment. The Permitting authority will notify the permittee in writing of approval or disapproval of the request for an adjustment within 15 calendar days of receiving sufficient information to evaluate the request.

(4) If the Permitting authority is unable to meet a specified deadline, he or she will notify the permittee of any significant delay and inform the permittee of the amended schedule.

(j) *Change in information already provided.* Any change in the information already provided under this section shall be provided to the Permitting authority in writing within 15 calendar days after the change.

§ 63.10 Recordkeeping and reporting requirements.

(a) *Applicability and general information.*

(1) The applicability of this section is set out in § 63.1(a)(4).

(2) For affected sources that have been granted an extension of compliance under subpart D of this part, the requirements of this section do not apply to those sources while they are operating under such compliance extensions.

(3) If any State requires a report that contains all the information required in a report listed in this section, a permittee may send the Permitting authority a copy of the report sent to the State to satisfy the requirements of this section for that report.

(4) (i) Before 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 appropriate Regional Office of the EPA (to the attention of the Director of the Division indicated in the list of the EPA Regional Offices in § 63.13).

(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 paragraph (a)(4)(i) of this section. The Regional Office may waive this requirement for any reports at its discretion.

(5) If a permittee of an affected source 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).

(6) If a permittee supervises one or more stationary sources affected by more than one standard established pursuant to section 112 of the Act, he/she may arrange by mutual agreement

between the permittee and the Permitting authority (or the State permitting authority) a common schedule on which periodic reports required for each source shall be submitted throughout the year. The allowance in the previous sentence applies in each State beginning 1 year after the latest compliance date for any relevant standard established pursuant to section 112 of the Act for any such affected source(s). Procedures governing the implementation of this provision are specified in § 63.9(i).

(7) If a permittee supervises one or more stationary sources affected by standards established pursuant to section 112 of the Act (as amended November 15, 1990) and standards set under part 60, part 61, or both such parts of this chapter, he/she may arrange by mutual agreement between the permittee and the Permitting authority (or the State permitting authority) a common schedule on which periodic reports required by each relevant (i.e., applicable) standard shall be submitted throughout the year. The allowance in the previous sentence applies in each State beginning 1 year after the stationary source is required to be in compliance with the relevant section 112 standard, or 1 year after the stationary source is required to be in compliance with the applicable part 60 or part 61 standard, whichever is latest. Procedures governing the implementation of this provision are specified in § 63.9(i).

(b) *General recordkeeping requirements.*

(1) The permittee of an affected source subject to the provisions of this part 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.

(2) The permittee of an affected source subject to the provisions of this part shall maintain relevant records for such source of -

(i) *Not applicable due to batch nature of the industry.*

(ii) The occurrence and duration of each malfunction of the required air pollution control and monitoring equipment;

(iii) *Not applicable to Subpart O sources.*

(iv) & (v) *A startup, shutdown, and malfunction plan is not required for these standards.*

(vi) Each period during which a CMS is malfunctioning or inoperative (including out-of-control periods);

(vii) All required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, 15-minute averages of CMS data, raw performance testing measurements, and raw performance evaluation measurements, that support data that the source is required to re-port);

(viii) All results of performance tests, CMS performance evaluations, and opacity and visible emission observations;

(ix) All measurements as may be necessary to determine the conditions of performance tests and performance evaluations;

(x) All CMS calibration checks;

(xi) All adjustments and maintenance performed on CMS;

(xii) Any information demonstrating whether a source is meeting the requirements for a waiver of recordkeeping or reporting requirements under this part, if the source has been granted a waiver under paragraph (f) of this section;

(A) This paragraph applies to owners or operators required to install a continuous emissions monitoring system (CEMS) where the CEMS installed is automated, and where the calculated data averages do not exclude periods of CEMS breakdown or malfunction. An automated CEMS records and reduces the measured data to the form of the pollutant emission standard through the use of a computerized data acquisition system. In lieu of maintaining a file of all CEMS subhourly measurements as required under paragraph (b)(2)(vii) of this section, the owner or operator shall retain the most recent consecutive three averaging periods of subhourly measurements and a file that contains a hard copy of the data acquisition system algorithm used to reduce the measured data into the reportable form of the standard.

(B) This paragraph applies to owners or operators required to install a CEMS where the measured data is manually reduced to obtain the reportable form of the standard, and where the calculated data averages do not exclude periods of CEMS breakdown or malfunction. In lieu of maintaining a file of all CEMS subhourly measurements as required under paragraph (b)(2)(vii) of this sections, the owner or operator shall retain all subhourly measurements for the most recent reporting period. The subhourly measurements shall be retained for 120 days from the date of the most recent summary or excess emission report submitted to the Administrator.

(C) The Administrator or delegated authority, upon notification to the source, may require the owner or operator to maintain all measurements as required by paragraph (b)(2)(vii), if the administrator or the delegated authority determines these records are required to more accurately assess the compliance status of the affected source.

(xiii) *Not applicable to Subpart O sources.*

(xiv) All documentation supporting initial notifications and notifications of compliance status under § 63.9.

(3) *§ 63.367(b) and (c) contains applicability determination requirements.*

(c) *Additional recordkeeping requirements for sources with continuous monitoring systems.* In addition to complying with the requirements specified in paragraphs (b)(1) and (b)(2) of this section, the permittee of an affected source required to install a CMS by a relevant standard shall maintain records for such source of -

(1) All required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods);

(2)–(4) [Reserved]

(5) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks;

(6) *Not applicable to Subpart O sources.*

(7) *Not applicable due to batch nature of the industry.*

(8) The specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances, as defined in the relevant standard(s), that occurs during periods other than startups, shutdowns, and malfunctions of the affected source;

(9) [Reserved]

(10) The nature and cause of any malfunction (if known);

(11) The corrective action taken or preventive measures adopted;

(12) The nature of the repairs or adjustments to the CMS that was inoperative or out of control;

(13) The total process operating time during the reporting period; and

(14) All procedures that are part of a quality control program developed and implemented for CMS under § 63.8(d). *This section does not apply to sources using 1 to 10 tons in Subpart O.*

(15) *A startup, shutdown, and malfunction plan is not required for these standards.*

(d) *General reporting requirements.*

(1) Not-withstanding the requirements in this paragraph or paragraph (e) of this section, the permittee of an affected source subject to reporting requirements under this part shall submit reports to the Permitting authority in accordance with the reporting requirements in the relevant standard(s).

(2) *Reporting results of performance tests.* Before a title V permit has been issued to the permittee of an affected source, the permittee shall report the results of any performance test under § 63.7 to the Permitting authority. After a title V permit has been issued to the permittee of an affected source, the permittee shall report the results of a required performance test to the appropriate permitting authority. The permittee of an affected source shall report the results of the performance test to the Permitting authority (or the State with an approved permit program) before the close of business on the 60th day following the completion of the performance test, unless specified otherwise in a relevant standard or as approved otherwise in writing by the Permitting authority. The results of the performance test shall be submitted as part of the notification of compliance status required under § 63.9(h).

(3) *Reporting results of opacity or visible emission observations. Subpart O does not contain opacity or visible emissions standards.*

(4) *Progress reports.* The permittee of an affected source who is required to submit progress reports as a condition of receiving an extension of compliance under § 63.6(i) shall submit such reports to the Permitting authority (or the State with an approved permit program) by the dates specified in the written extension of compliance.

(5) *A startup, shutdown, and malfunction plan is not required for these standards.*

(e) *Additional reporting requirements for sources with continuous monitoring systems -*

(1) *General.* When more than one CEMS is used to measure the emissions from one affected source (e.g., multiple breechings, multiple outlets), the permittee shall report the results as required for each CEMS.

(2) Reporting results of continuous monitoring system performance evaluations.

(i) The permittee of an affected source required to install a CMS by a relevant standard shall furnish the Permitting authority a copy of a written report of the results of the CMS performance evaluation, as required under § 63.8(e), simultaneously with the results of the performance test required under § 63.7, unless otherwise specified in the relevant standard.

(ii) *Opacity monitors are not required for these standards.*

(3) *Excess emissions and continuous monitoring system performance report and summary report.*

(i) Excess emissions and parameter monitoring exceedances are defined in relevant standards. The permittee of an affected source required to install a CMS by a relevant standard shall submit an excess emissions and continuous monitoring system performance report and/or a summary report to the Permitting authority semiannually, except when -

(A) More frequent reporting is specifically required by a relevant standard;

(B) The Permitting authority determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the source; or

(C) The CMS data are to be used directly for compliance determination and the source experienced excess emissions, in which case quarterly reports shall be submitted. Once a source reports excess emissions, the source shall follow a quarterly reporting format until a request to reduce reporting frequency under paragraph (e)(3)(ii) of this section is approved.

(ii) Request to reduce frequency of excess emissions and continuous monitoring system performance reports. Notwithstanding the frequency of reporting requirements specified in paragraph (e)(3)(i) of this section, a permittee who is required by a relevant standard to submit excess emissions and continuous monitoring system performance (and summary) reports on a quarterly (or more frequent) basis may reduce the frequency of reporting for that standard to semiannual if the following conditions are met:

(A) For 1 full year (e.g., 4 quarterly or 12 monthly reporting periods) the affected source's excess emissions and continuous monitoring system performance reports continually demonstrate that the source is in compliance with the relevant standard;

(B) The permittee continues to comply with all recordkeeping and monitoring requirements specified in this subpart and the relevant standard; and

(C) The Permitting authority does not object to a reduced frequency of reporting for the affected source, as provided in paragraph (e)(3)(iii) of this section.

(iii) The frequency of reporting of excess emissions and continuous monitoring system performance (and summary) reports required to comply with a relevant standard may be reduced only after the permittee notifies the Permitting authority in writing of his or her intention to make such a change and the Permitting authority does not object to the intended change. In deciding whether to approve a reduced frequency of reporting, the Permitting authority may review information concerning the source's entire previous performance history during the 5-year recordkeeping period prior to the intended change, including performance test results, monitoring data, and evaluations of a permittee's conformance with operation and maintenance requirements. Such information may be used by the Permitting authority to make a judgment about the source's potential for noncompliance in the future. If the Permitting authority disapproves the permittee's request to reduce the frequency of reporting, the Permitting authority will notify the permittee in writing within 45 days after receiving notice of the permittee's intention. The notification from the Permitting authority to the permittee will specify the grounds on which the disapproval is based. In the absence of a notice of disapproval within 45 days, approval is automatically granted.

(iv) As soon as CMS data indicate that the source is not in compliance with any emission limitation or operating parameter specified in the relevant standard, the frequency of reporting shall revert to the frequency specified in the relevant standard, and the permittee shall submit an excess emissions and continuous monitoring system performance (and summary) report for the noncomplying emission points at the next appropriate reporting period following the noncomplying event. After demonstrating ongoing compliance with the relevant standard for another full year, the permittee may again request approval from the Permitting authority to reduce the frequency of reporting for that standard, as provided for in paragraphs (e)(3)(ii) and (e)(3)(iii) of this section.

(v) *Content and submittal dates for excess emissions and monitoring system performance reports.* § 63.366(a)(3) specifies contents and submittal dates for excess emissions and monitoring system performance reports.

(vi) *Summary report.* As required under paragraphs (e)(3)(vii) and (e)(3)(viii) of this section, one summary report shall be submitted for the hazardous air pollutants monitored at each affected source (unless the relevant standard specifies that more than one summary report is required, e.g., one summary report for each hazardous air pollutant monitored). The summary report shall be entitled ''Summary Report - Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance'' and shall contain the following information:

(A) The company name and address of the affected source;

(B) An identification of each hazardous air pollutant monitored at the affected source;

(C) The beginning and ending dates of the reporting period;

(D) A brief description of the process units;

(E) The emission and operating parameter limitations specified in the relevant standard(s);

(F) The monitoring equipment manufacturer(s) and model number(s);

(G) The date of the latest CMS certification or audit;

(H) The total operating time of the affected source during the reporting period;

(I) An emission data summary (or similar summary if the permittee monitors control system parameters), including the total duration of excess emissions during the reporting period (recorded in minutes for opacity and hours for gases), the total duration of excess emissions expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control equipment problems, process problems, other known causes, and other unknown causes;

(J) A CMS performance summary (or similar summary if the permittee monitors control system parameters), including the total CMS downtime during the reporting period (recorded in minutes for opacity and hours for gases), the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, quality assurance/quality control calibrations, other known causes, and other unknown causes;

(K) A description of any changes in CMS, processes, or controls since the last reporting period;

(L) The name, title, and signature of the responsible official who is certifying the accuracy of the report; and

(M) The date of the report.

(vii) If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Permitting authority.

(viii) If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total CMS downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, both the summary report and the excess emissions and continuous monitoring system performance report shall be submitted.

(4) *Opacity monitors are not required for these standards.*

(f) *Waiver of recordkeeping or reporting requirements.*

(1) Until a waiver of a recordkeeping or reporting requirement has been granted by the Permitting authority under this paragraph, the permittee of an affected source remains subject to the requirements of this section.

(2) Recordkeeping or reporting requirements may be waived upon written application to the Permitting authority if, in the Permitting authority's judgment, the affected source is achieving the relevant standard(s), or the source is operating under an extension of compliance, or the permittee has requested an extension of compliance and the Permitting authority is still considering that request.

(3) If an application for a waiver of record-keeping or reporting is made, the application shall accompany the request for an extension of compliance under § 63.6(i), any required compliance progress report or compliance status report required under this part (such as under § 63.6(i) and § 63.9(h)) or in the source's title V permit, or an excess emissions and continuous monitoring system performance report required under paragraph (e) of this section, whichever is applicable. The application shall include whatever information the permittee considers useful to convince the Permitting authority that a waiver of recordkeeping or reporting is warranted.

(4) The Permitting authority will approve or deny a request for a waiver of recordkeeping or reporting requirements under this paragraph when he/she -

(i) Approves or denies an extension of compliance; or

(ii) Makes a determination of compliance following the submission of a required compliance status report or excess emissions and continuous monitoring systems performance report; or

(iii) Makes a determination of suitable progress towards compliance following the submission of a compliance progress report, whichever is applicable.

(5) A waiver of any recordkeeping or reporting requirement granted under this paragraph may be conditioned on other recordkeeping or reporting requirements deemed necessary by the Permitting authority.

(6) Approval of any waiver granted under this section shall not abrogate the Permitting authority's authority under the Act or in any way prohibit the Permitting authority from later canceling the waiver. The cancellation will be made only after notice is given to the permittee of the affected source.

§ 63.11 Control device requirements.

(a) *Applicability.* The applicability of this section is set out in Sec. 63.1(a)(4).

(b) Flares.

(1) Owners or operators using flares to comply with the provisions of this part shall monitor these control devices to assure that they are operated and maintained in conformance with

their designs. Applicable subparts will provide provisions stating how owners or operators using flares shall monitor these control devices.

(2) Flares shall be steam-assisted, air-assisted, or non-assisted.

(3) Flares shall be operated at all times when emissions may be vented to them.

(4) Flares shall be designed for and operated with no visible emissions, except for periods not to exceed a total of 5 minutes during any 2 consecutive hours. Test Method 22 in appendix A of part 60 of this chapter shall be used to determine the compliance of flares with the visible emission provisions of this part. The observation period is 2 hours and shall be used according to Method 22.

(5) Flares shall be operated with a flame present at all times. The presence of a flare pilot flame shall be monitored using a thermocouple or any other equivalent device to detect the presence of a flame.

(6) An owner/operator has the choice of adhering to the heat content specifications in paragraph (b)(6)(ii) of this section, and the maximum tip velocity specifications in paragraph (b)(7) or (b)(8) of this section, or adhering to the requirements in paragraph (b)(6)(i) of this section.

(i) (A) Flares shall be used that have a diameter of 3 inches or greater, are nonassisted, have a hydrogen content of 8.0 percent (by volume) or greater, and are designed for and operated with an exit velocity less than 37.2 m/sec (122 ft/sec) and less than the velocity V_{max}, as determined by the following equation:

$$V_{max} = (X_{H2} - K_1) * K_2$$

Where:

V_{max} = Maximum permitted velocity, m/sec.

K_1 = Constant, 6.0 volume-percent hydrogen.

K_2 = Constant, 3.9 (m/sec)/volume-percent hydrogen.

X_{H2} = The volume-percent of hydrogen, on a wet basis, as calculated by using the American Society for Testing and Materials (ASTM) Method D1946-77. (Incorporated by reference as specified in § 63.14).

(B) The actual exit velocity of a flare shall be determined by the method specified in paragraph (b)(7)(i) of this section.

(ii) Flares shall be used only with the net heating value of the gas being combusted at 11.2 MJ/scm (300 Btu/scf) or greater if the flare is steam-assisted or air-assisted; or with the net heating value of the gas being combusted at 7.45 MJ/scm (200 Btu/scf) or greater if the flare is non-assisted. The net heating value of the gas being combusted in a flare shall be calculated using the following equation:

$$H_T = K \sum_{i=1}^{n} C_i H_i$$

Where:

H_T = Net heating value of the sample, MJ/scm; where the net enthalpy per mole of offgas is

based on combustion at 25 °C and 760 mm Hg, but the standard temperature for determining the volume corresponding to one mole is 20 °C.

K = Constant = 1.740×10^{-7} (1/ppmv)(g-mole/scm)(MJ/kcal); where the standard temperature for (g-mole/scm) is 20 °C.

C_i = Concentration of sample component i in ppmv on a wet basis, as measured for organics by Test Method 18 and measured for hydrogen and carbon monoxide by American Society for Testing and Materials (ASTM) D1946–77 or 90 (Reapproved 1994) (incorporated by reference as specified in § 63.14).

H_i = Net heat of combustion of sample component i, kcal/g-mole at 25 °C and 760 mm Hg. The heats of combustion may be determined using ASTM D2382–76 or 88 or D4809-95. (incorporated by reference as specified in § 63.14) if published values are not available or cannot be calculated.

n = Number of sample components.

(7) (i) Steam-assisted and nonassisted flares shall be designed for and operated with an exit velocity less than 18.3 m/sec (60 ft/sec), except as provided in paragraphs (b)(7)(ii) and (b)(7)(iii) of this section. The actual exit velocity of a flare shall be determined by dividing by the volumetric flow rate of gas being combusted (in units of emission standard temperature and pressure), as determined by Test Method 2, 2A, 2C, or 2D in appendix A to 40 CFR part 60 of this chapter, as appropriate, by the unobstructed (free) cross-sectional area of the flare tip.

(ii) Steam-assisted and nonassisted flares designed for and operated with an exit velocity, as determined by the method specified in paragraph (b)(7)(i) of this section, equal to or greater than 18.3 m/sec (60 ft/sec) but less than 122 m/sec (400 ft/sec), are allowed if the net heating value of the gas being combusted is greater than 37.3 MJ/scm (1,000 Btu/scf).

(iii) Steam-assisted and nonassisted flares designed for and operated with an exit velocity, as determined by the method specified in paragraph (b)(7)(i) of this section, less than the velocity V_{max}, as determined by the method specified in this paragraph, but less than 122 m/sec (400 ft/sec) are allowed. The maximum permitted velocity, V_{max}, for flares complying with this paragraph shall be determined by the following equation:

$$\mathrm{Log}_{10}(V_{max})=(H_T+28.8)/31.7$$

Where:

V_{max} = Maximum permitted velocity, m/sec.

28.8 = Constant.

31.7 = Constant.

H_T = The net heating value as determined in paragraph (b)(6)(ii) of this section.

(8) Air-assisted flares shall be designed and operated with an exit velocity less than the velocity V_{max}. The maximum permitted velocity, V_{max}, for air-assisted flares shall be determined by the following equation:

$$V_{max} = 8.71 + 0.708(H_T)$$

Where:

V_{max} = Maximum permitted velocity, m/sec.

8.71 = Constant.

0.708 = Constant.

H_T = The net heating value as determined in paragraph (b)(6) of this section.

§ 63.12 State authority and delegations.

(a) The provisions of this part shall not be construed in any manner to preclude any State or political subdivision thereof from -

(1) Adopting and enforcing any standard, limitation, prohibition, or other regulation applicable to an affected source subject to the requirements of this part, provided that such standard, limitation, prohibition, or regulation is not less stringent than any requirement applicable to such source established under this part;

(2) Requiring the permittee of an affected source to obtain permits, licenses, or approvals prior to initiating construction, reconstruction, modification, or operation of such source; or

(3) Requiring emission reductions in excess of those specified in subpart D of this part as a condition for granting the extension of compliance authorized by section 112(i)(5) of the Act.

(b) (1) Section 112(l) of the Act directs the Permitting authority to delegate to each State, when appropriate, the authority to implement and enforce standards and other requirements pursuant to section 112 for stationary sources located in that State. Because of the unique nature of radioactive material, delegation of authority to implement and enforce standards that control radionuclides may require separate approval.

(2) Subpart E of this part establishes procedures consistent with section 112(l) for the approval of State rules or programs to implement and enforce applicable Federal rules promulgated under the authority of section 112. Subpart E also establishes procedures for the review and withdrawal of section 112 implementation and enforcement authorities granted through a section 112(l) approval.

(c) All information required to be submitted to the EPA under this part also shall be submitted to the appropriate State agency of any State to which authority has been delegated under section 112(l) of the Act, provided that each specific delegation may exempt sources from a certain Federal or State reporting requirement. The Permitting authority may permit all or some of the information to be submitted to the appropriate State agency only, instead of to the EPA and the State agency.

§ 63.13 Addresses of State air pollution control agencies and EPA Regional Offices.

(a) All requests, reports, applications, submittals, and other communications to the Permitting authority pursuant to this part shall be submitted to the appropriate Regional Office of the U.S. Environmental Protection Agency indicated as follows:

EPA Region IV; Director; Air, Pesticides and Toxics, Management Division; Atlanta Federal Center, 61 Forsyth Street; Atlanta, GA 30303.

(b) All information required to be submitted to the Permitting authority under this part also shall be submitted to the appropriate State agency of any State to which authority has been delegated under section 112(l) of the Act. The permittee of an affected source may contact the appropriate EPA Regional Office for the mailing addresses for those States whose delegation requests have been approved.

(c) If any State requires a submittal that contains all the information required in an application, notification, request, report, statement, or other communication required in this part, an owner or operator may send the appropriate Regional Office of the EPA a copy of that submittal to satisfy the requirements of this part for that communication.

§ 63.14 Incorporations by reference.

(a) The materials listed in this section are incorporated by reference in the corresponding sections noted. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval, and notice of any change in these materials will be published in the Federal Register. The materials are available for purchase at the corresponding addresses noted below, and all are available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC, at the Air and Radiation Docket and Information Center, U.S. EPA, 401 M St., SW., Washington, DC, and at the EPA Library (MD-35), U.S. EPA, Research Triangle Park, North Carolina.

(b) The following materials are available for purchase from at least one of the following addresses: American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, Post Office Box C700, West Conshohocken, PA 19428-2959; or ProQuest, 300 North Zeeb Road, Ann Arbor, MI 48106.

(1) ASTM D523-89, Standard Test Method for Specular Gloss, IBR approved for § 63.782.

(2) ASTM D1193-77, 91, Standard Specification for Reagent Water, IBR approved for Appendix A: Method 306, Sections 7.1.1 and 7.4.2.

(3) ASTM D1331-89, Standard Test Methods for Surface and Interfacial Tension of Solutions of Surface Active Agents, IBR approved for Appendix A: Method 306B, Sections 6.2, 11.1, and 12.2.2.

(4) ASTM D1475-90, Standard Test Method for Density of Paint, Varnish Lacquer, and Related Products, IBR approved for § 63.788, Appendix A.

(5) ASTM D1946-77, 90, 94, Standard Method for Analysis of Reformed Gas by Gas Chromatography, IBR approved for § 63.11(b)(6).

(6) ASTM D2369-93, 95, Standard Test Method for Volatile Content of Coatings, IBR approved for § 63.788, Appendix A.

(7) ASTM D2382-76, 88, Heat of Combustion of Hydrocarbon Fuels by Bomb Calorimeter (High-Precision Method), IBR approved for § 63.11(b)(6).

(8) ASTM D2879-83, 96, Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope, IBR approved for § 63.111 of Subpart G.

(9) ASTM D3257-93, Standard Test Methods for Aromatics in Mineral Spirits by Gas Chromatography, IBR approved for § 63.786(b).

(10) ASTM 3695-88, Standard Test Method for Volatile Alcohols in Water by Direct Aqueous-Injection Gas Chromatography, IBR approved for § 63.365(e)(1) of Subpart O.

(11) ASTM D3792-91, Standard Method for Water Content of Water-Reducible Paints by Direct Injection into a Gas Chromatograph, IBR approved for § 63.788, Appendix A.

(12) ASTM D3912-80, Standard Test Method for Chemical Resistance of Coatings Used in Light-Water Nuclear Power Plants, IBR approved for § 63.782.

(13) ASTM D4017-90, 96a, Standard Test Method for Water in Paints and Paint Materials by the Karl Fischer Titration Method, IBR approved for § 63.788, Appendix A.

(14) ASTM D4082-89, Standard Test Method for Effects of Gamma Radiation on Coatings for Use in Light-Water Nuclear Power Plants, IBR approved for § 63.782.

(15) ASTM D4256-89, 94, Standard Test Method for Determination of the Decontaminability of Coatings Used in Light-Water Nuclear Power Plants, IBR approved for § 63.782.

(16) ASTM D4809-95, Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter (Precision Method), IBR approved for § 63.11(b)(6).

(17) ASTM E180-93, Standard Practice for Determining the Precision of ASTM Methods for Analysis and Testing of Industrial Chemicals, IBR approved for § 63.786(b).

(18) ASTM E260-91, 96, General Practice for Packed Column Gas Chromatography, IBR approved for §§ 63.750(b)(2) and 63.786(b)(5).

(19) Reserved

(20) Reserved

(21) ASTM D2099-00, Standard Test Method for Dynamic Water Resistance of Shoe Upper Leather by the Maeser Water Penetration Tester, IBR approved for § 63.5350.

(24) ASTM D2697-86(1998) (Reapproved 1998), Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings, IBR approved for §§63.4141(b)(1), 63.4741(b)(1), 63.4941(b)(1), and 63.5160(c).

(25) ASTM D6093-97, Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer, IBR approved for §§63.4141(b)(1), 63.4741(b)(1), 63.4941(b)(1), and 63.5160(c).

(26) ASTM D1475-98, Standard Test Method for Density of Liquid Coatings, Inks, and Related Products, IBR approved for §§ 63.4141(b)(3) and 63.4141(c).

(27) ASTM D 6522-00, Standard Test Method for Determination of Nitrogen Oxides, Carbon Monoxide and Oxygen concentrations in Emissions from Natural Gas Fired Reciprocating Engines, Combustion Turbines, Boilers, and Process heaters Using Portable Analyzers, IBR approved for Sec. 63.9307(c)(2).

(28) [Reserved]

(29) ASTM D6420-99, Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography-Mass Spectrometry, IBR approved for §§ 63.5799 and 63.5850.

(c) The materials listed below are available for purchase from the American Petroleum Institute (API), 1220 L Street, NW., Washington, DC 20005.

(1) API Publication 2517, Evaporative Loss from External Floating-Roof Tanks, Third Edition, February 1989, IBR approved for § 63.111 of subpart G of this part.

(2) API Publication 2518, Evaporative Loss from Fixed-roof Tanks, Second Edition, October 1991, IBR approved for § 63.150(g)(3)(i)(C) of subpart G of this part.

(3) API Manual of Petroleum Measurement Specifications (MPMS) Chapter 19.2, Evaporative Loss From Floating-Roof Tanks (formerly API Publications 2517 and 2519), First Edition, April 1997, IBR approved for § 63.1251 of subpart GGG of this part.

(d) *State and Local Requirements.* The materials listed below are available at the Air and Radiation Docket and Information Center, U.S. EPA, 401 M St., SW., Washington, DC.

(1) *California Regulatory Requirements Applicable to the Air Toxics Program,* January 5, 1999, IBR approved for § 63.99(a)(5)(ii) of subpart E of this part.

(2) New Jersey's *Toxic Catastrophe Prevention Act Program,* (July 20, 1998), Incorporation By Reference approved for § 63.99 (a)(30)(i) of subpart E of this part.

(3) (i) Letter of June 7, 1999 to the U.S. Environmental Protection Agency Region 3 from the Delaware Department of Natural Resources and Environmental Control requesting formal full delegation to take over primary responsibility for implementation and enforcement of the Chemical Accident Prevention Program under Section 112(r) of the Clean Air Act Amendments of 1990.

(ii) Delaware Department of Natural Resources and Environmental Control, Division of Air and Waste Management, Accidental Release Prevention Regulation, sections 1 through 5 and sections 7 through 14, effective January 11, 1999, IBR approved for § 63.99(a)(8)(i) of subpart E of this part.

(iii) State of Delaware Regulations Governing the Control of Air Pollution (October 2000), IBR approved for § 63.99(a)(8)(ii)-(v) of subpart E of this part.

(e) The materials listed below are available for purchase from the National Institute of Standards and Technology, Springfield, VA 22161, (800) 553-6847.

(1) Handbook 44, Specificiations, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices 1998, IBR approved for § 63.1303(e)(3).

(2) [Reserved]

(f) The following material is available from the National Council of the Paper Industry for Air and Stream Improvement, Inc. (NCASI), P. O. Box 133318, Research Triangle Park, NC 27709-3318 or at http://www.ncasi.org: NCASI Method DI/MEOH-94.02, Methanol in Process Liquids GC/FID (Gas Chromatography/Flame Ionization Detection), August 1998, Methods Manual, NCASI, Research Triangle Park, NC, IBR approved for § 63.457(c)(3)(ii) of subpart S of this part.

(g) The materials listed below are available for purchase from AOAC International, Customer Services, Suite 400, 2200 Wilson Boulevard, Arlington, Virginia, 22201-3301, Telephone (703) 522-3032, Fax (703) 522-5468.

(1) AOAC Official Method 978.01 Phosphorus (Total) in Fertilizers, Automated Method, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(2) AOAC Official Method 969.02 Phosphorus (Total) in Fertilizers, Alkalimetric Quinolinium Molybdophosphate Method, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(3) AOAC Official Method 962.02 Phosphorus (Total) in Fertilizers, Gravimetric Quinolinium Molybdophosphate Method, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(4) AOAC Official Method 957.02 Phosphorus (Total) in Fertilizers, Preparation of Sample Solution, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(5) AOAC Official Method 929.01 Sampling of Solid Fertilizers, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(6) AOAC Official Method 929.02 Preparation of Fertilizer Sample, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(7) AOAC Official Method 958.01 Phosphorus (Total) in Fertilizers, Spectrophotometric Molybdovanadophosphate Method, Sixteenth edition, 1995, IBR approved for § 63.626(d)(3)(vi).

(h) The materials listed below are available for purchase from The Association of Florida Phosphate Chemists, P.O. Box 1645, Bartow, Florida, 33830, Book of Methods Used and Adopted By The Association of Florida Phosphate Chemists, Seventh Edition 1991, IBR.

(1) Section IX, Methods of Analysis for Phosphate Rock, No. 1 Preparation of Sample, IBR approved for § 63.606(c)(3)(ii) and § 63.626(c)(3)(ii).

(2) Section IX, Methods of Analysis for Phosphate Rock, No. 3 Phosphorus -- P2O5 or Ca3(PO4)2, Method A-Volumetric Method, IBR approved for § 63.606(c)(3)(ii) and § 63.626(c)(3)(ii).

(3) Section IX, Methods of Analysis for Phosphate Rock, No. 3 Phosphorus-P2O5 or Ca3(PO4)2, Method B -- Gravimetric Quimociac Method, IBR approved for § 63.606(c)(3)(ii) and § 63.626(c)(3)(ii).

(4) Section IX, Methods of Analysis For Phosphate Rock, No. 3 Phosphorus-P2O5 or Ca3(PO4)2, Method C -- Spectrophotometric Method, IBR approved for § 63.606(c)(3)(ii) and § 63.626(c)(3)(ii).

(5) Section XI, Methods of Analysis for Phosphoric Acid, Superphosphate, Triple Superphosphate, and Ammonium Phosphates, No. 3 Total Phosphorus-P2O5, Method A -- Volumetric Method, IBR approved for § 63.606(c)(3)(ii), § 63.626(c)(3)(ii), and § 63.626(d)(3)(v).

(6) Section XI, Methods of Analysis for Phosphoric Acid, Superphosphate, Triple Superphosphate, and Ammonium Phosphates, No. 3 Total Phosphorus-P2O5, Method B -- Gravimetric Quimociac Method, IBR approved for § 63.606(c)(3)(ii), § 63.626(c)(3)(ii), and § 63.626(d)(3)(v).

(7) Section XI, Methods of Analysis for Phosphoric Acid, Superphosphate, Triple Superphosphate, and Ammonium Phosphates, No. 3 Total Phosphorus-P2O5, Method C -- Spectrophotometric Method, IBR approved for § 63.606(c)(3)(ii), § 63.626(c)(3)(ii), and § 63.626(d)(3)(v).

(i) The following materials are available for purchase from at least one of the following addresses: ASME International, Orders/Inquiries, P.O. Box 2900, Fairfield, NJ 07007-2900; or Global Engineering Documents, Sales Department, 15 Inverness Way East, Englewood, CO 80112.

(1) ASME standard number QHO-1-1994, ``Standard for the Qualification and Certification of Hazardous Waste Incinerator Operators," IBR approved for Sec. 63.1206(c)(6)(iii).

(2) ASME standard number QHO-1a-1996 Addenda to QHO-1-1994, ``Standard for the Qualification and Certification of Hazardous Waste Incinerator Operators," IBR approved for Sec. 63.1206(c)(6)(iii).

(3) ANSI/ASME PTC 19.10-1981, ``Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus]," IBR approved for Sec. Sec. 63.865(b), 63.3360(e)(1)(iii), 63.4166(a)(3), 63.4362(a)(3), 63.4766(a)(3), 63.4965(a)(3), 63.5160(d)(1)(iii), 63.9307(c)(2), and 63.9323(a)(3).

(j) [Reserved]

(k) The following material may be obtained from U.S. EPA, Office of Solid Waste (5305W), 1200 Pennsylvania Avenue, NW., Washington, DC 20460:

(1) Method 9071B, ``n-Hexane Extractable Material(HEM) for Sludge, Sediment, and Solid Samples," (Revision 2, April 1998) as published in EPA Publication SW-846: ``Test Methods for Evaluating Solid Waste, Physical/Chemical Methods." The incorporation by reference of Method 9071B is approved for Section 63.7824(e) of Subpart FFFFF of this part.

§ 63.15 Availability of information and confidentiality.

(a) *Availability of information.*

(1) With the exception of information protected through part 2 of this chapter, all reports, records, and other information collected by the Permitting authority under this part are available to the public. In addition, a copy of each permit application, compliance plan (including the schedule of compliance), notification of compliance status, excess emissions and continuous monitoring systems performance report, and title V permit is available to the public, consistent with protections recognized in section 503(e) of the Act.

(2) The availability to the public of information provided to or otherwise obtained by the Permitting authority under this part shall be governed by part 2 of this chapter.

(b) *Confidentiality.*

(1) If a permittee is required to submit information entitled to protection from disclosure under section 114(c) of the Act, the permittee may submit such information separately. The requirements of section 114(c) shall apply to such information.

(2) The contents of a title V permit shall not be entitled to protection under section 114(c) of the Act; however, information submitted as part of an application for a title V permit may be entitled to protection from disclosure.

Appendix CP - Compliance Plan

International Sterilization Laboratory

Sterilization Facility - 0694823

To Meet 40 CFR 63, Subpart O

This compliance schedule has been prepared in accordance with Rule 62-213.440(2) and is to become part of International Sterilization Laboratory's Title V permit for the Sterilization Facility. The schedule provides a list of milestones to be achieved on no less than a semiannual basis until compliance is achieved and demonstrated to the Department.

International Sterilization Laboratory will notify the Department in writing, within 15 days after the date specified for completion of each milestone, to include the achievement of compliance, of progress achieved, requirements met, requirements not met, corrective measures adopted and an explanation of any measures not met by the completion date for the milestone or for compliance. All reports will be accompanied by a certification, signed by a responsible official, in accordance with subsection 62-213.420(4), F. A. C.

International Sterilization Laboratory recognizes that compliance with the implementation schedule for future system expansions is a requirement of the Title V permit, and that failure to comply with the implementation schedule will be considered a violation of the conditions of this permit. Should unforeseen events occur that impact this schedule, the company recognizes the need to modify the permit as required to incorporate an amended schedule.

A form has been prepared and attached to assist International Sterilization Laboratory in their notification to the Department for meeting the specified milestones of the compliance schedule.

Milestone No.	Milestone Description	Completion or Submission no later than:
1	Install, calibrate, and conduct performance testing of continuous monitor and recorder to measure and record hourly ethylene oxide concentration at the outlet to the atmosphere, in accordance with 40 CFR Part 63, Subpart O, Section 63.364(e).	March 31, 2006
2	Submit results of Milestone #1 to the Department's Central District.	April 30, 2006
3	Perform compliance testing of the facility's aeration rooms in accordance with 40 CFR Part 63, Subpart O, Sections 63.363(a)(1), (c)(2) and (c)(3).	March 31, 2006
4	Submit results of Milestone #3 to the Department's Central District.	April 30, 2006
5	The responsible official shall notify the Department in writing of the date and time of milestones #1 and 3 test dates.	At least 15 days prior to conducting the tests

NOTIFICATION OF MILESTONE COMPLETION

International Sterilization Laboratory
Sterilization Facility - 0694823
To Meet 40 CFR 63, Subpart O

Date:_____

To: Program Administrator
Air Resources Department
Department of Environmental Protection
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

International Sterilization Laboratory is notifying the Department of a completion of a schedule milestone as required by the Sterilization Facility's Title V Permit No. _____, Specific Condition No._____ in accordance with Rule 62-213.440(2).

1. Milestone Number Completed: _____
2. Milestone Description: _____
3. Actual Achievement Date: _____
4. Discussion of Milestone Achieved:

_____

_____

5. Met Required Milestone Completion or Submission Date? (circle one): Yes No
6. **If No, Reasons for Not Meeting Milestone Date:**

_____

_____

_____

_____

7. Corrective Measures Adopted if Milestone Date Not Met:

_____

_____

_____

RESPONSIBLE OFFICIAL CERTIFICATION

I, the undersigned, am a responsible official (Title V air permit application or responsible official notification form on file with the Department) of the Title V source for which this document is being submitted. With respect to all matters concerning the requirements of this Title V permit, I hereby certify, based on the information and belief formed after reasonable inquiry, that the statements made and data contained in this document are true, accurate, and complete.

_____ _____
(Signature of Title V Source Responsible Official) (Date)

Name:_____ Title:_____

STATEMENT OF BASIS

International Sterilization Laboratory
Sterilization Facility
Facility ID No.: 0694823
Lake County

DRAFT Title V Air Operation Permit No.: 0694823-004-AV

This Title V air operation permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.), and Florida Administrative Code (F.A.C.) Chapters 62-4, 62-210, and 62-213. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents, attached hereto or on file with the permitting authority, in accordance with the terms and conditions of this permit.

The permittee may operate the Sterilization Facility that includes four sterilization chambers and three aeration rooms. The four sterilizers are equipped with an acid scrubber that reduces ethylene oxide emissions by 99%. The three aeration rooms are equipped with a continuous emission monitor to ensure ethylene oxide emissions do not exceed 1 ppm. The applicant has requested a VOC and HAP limit of 4.0 tons/year. The facility is subject to 40CFR63, Subpart O and will comply with the subpart and maintain records to show compliance. The Title V permit will also include a compliance plan as proposed by the applicant.

Based on the initial Title V permit application received December 12, 2005, this facility is a minor source of hazardous air pollutants (HAPs). Also included in this permit are miscellaneous insignificant emission units and/or activities.