



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
Toll Free (800) 451-6027
www.idem.IN.gov

TO: Interested Parties / Applicant

DATE: February 11, 2009

RE: Baxter Pharmaceutical / 105 - 27180 - 00040

FROM: Matthew Stuckey, Branch Chief
Permits Branch
Office of Air Quality

Notice of Decision: Approval - Effective Immediately

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 13-15-5-3, this permit is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3 and IC 13-15-6-1 require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Suite N 501E, Indianapolis, IN 46204, **within eighteen (18) calendar days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER.dot12/03/07



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
Toll Free (800) 451-6027
www.idem.IN.gov

Minor Source Operating Permit Renewal OFFICE OF AIR QUALITY

Baxter Pharmaceutical Solutions, LLC
927 South Curry Pike
Bloomington, Indiana 47403

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

This permit is issued to the above mentioned company under the provisions of 326 IAC 2-1.1, 326 IAC 2-6.1 and 40 CFR 52.780, with conditions listed on the attached pages.

Indiana statutes from IC 13 and rules from 326 IAC, quoted in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a MSOP under 326 IAC 2-6.1.

Operation Permit No.: M105-27180-00040	
Issued by:  Iryn Calilung, Section Chief Permits Branch Office of Air Quality	Issuance Date: February 11, 2009 Expiration Date: February 11, 2019

TABLE OF CONTENTS

A. SOURCE SUMMARY.....	4
A.1 General Information [326 IAC 2-5.1-3(c)][326 IAC 2-6.1-4(a)]	
A.2 Emission Units and Pollution Control Equipment Summary	
B. GENERAL CONDITIONS	6
B.1 Definitions [326 IAC 2-1.1-1]	
B.2 Permit Term [326 IAC 2-6.1-7(a)][326 IAC 2-1.1-9.5][IC 13-15-3-6(a)]	
B.3 Term of Conditions [326 IAC 2-1.1-9.5]	
B.4 Enforceability	
B.5 Severability	
B.6 Property Rights or Exclusive Privilege	
B.7 Duty to Provide Information	
B.8 Certification	
B.9 Annual Notification [326 IAC 2-6.1-5(a)(5)]	
B.10 Preventive Maintenance Plan [326 IAC 1-6-3]	
B.11 Prior Permits Superseded [326 IAC 2-1.1-9.5]	
B.12 Termination of Right to Operate [326 IAC 2-6.1-7(a)]	
B.13 Permit Renewal [326 IAC 2-6.1-7]	
B.14 Permit Amendment or Revision [326 IAC 2-5.1-3(e)(3)][326 IAC 2-6.1-6]	
B.15 Source Modification Requirement	
B.16 Inspection and Entry [326 IAC 2-5.1-3(e)(4)(B)][326 IAC 2-6.1-5(a)(4)][IC 13-14-2-2] [IC 13-17-3-2][IC 13-30-3-1]	
B.17 Transfer of Ownership or Operational Control [326 IAC 2-6.1-6]	
B.18 Annual Fee Payment [326 IAC 2-1.1-7]	
B.19 Credible Evidence [326 IAC 1-1-6]	
C. SOURCE OPERATION CONDITIONS	11
Emission Limitations and Standards [326 IAC 2-6.1-5(a)(1)]	
C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour [326 IAC 6-3-2]	
C.2 Permit Revocation [326 IAC 2-1.1-9]	
C.3 Opacity [326 IAC 5-1]	
C.4 Open Burning [326 IAC 4-1] [IC 13-17-9]	
C.5 Incineration [326 IAC 4-2] [326 IAC 9-1-2]	
C.6 Fugitive Dust Emissions [326 IAC 6-4]	
C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]	
Testing Requirements [326 IAC 2-6.1-5(a)(2)]	
C.8 Performance Testing [326 IAC 3-6]	
Compliance Requirements [326 IAC 2-1.1-11]	
C.9 Compliance Requirements [326 IAC 2-1.1-11]	
Compliance Monitoring Requirements [326 IAC 2-6.1-5(a)(2)]	
C.10 Compliance Monitoring [326 IAC 2-1.1-11]	
C.11 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]	
C.12 Instrument Specifications [326 IAC 2-1.1-11]	
Corrective Actions and Response Steps	
C.13 Response to Excursions or Exceedances	
C.14 Actions Related to Noncompliance Demonstrated by a Stack Test	

Record Keeping and Reporting Requirements [326 IAC 2-6.1-5(a)(2)]

- C.15 Malfunctions Report [326 IAC 1-6-2]
- C.16 General Record Keeping Requirements [326 IAC 2-6.1-5]
- C.17 General Reporting Requirements [326 IAC 2-1.1-11] [326 IAC 2-6.1-2]
[IC 13-14-1-13]

D.1. EMISSIONS UNIT OPERATION CONDITIONS - Pharmaceutical Manufacturing Units 17

Emission Limitations and Standards [326 IAC 2-7-5(1)]

- D.1.1 Preventive Maintenance Plan [326 IAC 1-6-3]

SECTION D.2 EMISSIONS UNIT OPERATION CONDITIONS - Combustion Units 18

Emission Limitations and Standards [326 IAC 2-7-5(1)]

- D.2.1 Particulate [326 IAC 6-2-4]
- D.2.2 Preventive Maintenance Plan [326 IAC 1-6-3]

SECTION E.1. EMISSIONS UNIT OPERATION CONDITIONS 20

New Source Performance Standards (NSPS) Requirement [326 IAC 2-7-5(1)]

- E.1.1 General Provisions Relating to New Source Performance Standards [326 IAC 12-1]
[40 CFR Part 60, Subpart A]
- E.1.2 New Source Performance Standards of Performance for Small Industrial-Commercial-
Institutional Steam Generating Units
[40 CFR 60, Subpart Dc] [326 IAC 12]

Certification 21
Annual Notification 22
Malfunction Report 23
Attachment A - NSPS Subpart Dc

SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 and A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-5.1-3(c)][326 IAC 2-6.1-4(a)]

The Permittee owns and operates a stationary third party pharmaceutical manufacturing operation.

Source Address:	927 South Curry Pike, Bloomington, Indiana 47403
Mailing Address:	927 South Curry Pike, Bloomington, Indiana 47403
General Source Phone Number:	812-333-0887
SIC Code:	2834
County Location:	Monroe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Minor Source Operating Permit Program Minor Source, under PSD and Emission Offset Rules Minor Source, Section 112 of the Clean Air Act Not 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary

This stationary source consists of the following emission units and pollution control devices:

- (a) One (1) pharmaceutical manufacturing operation consisting of:
- (1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour, with no add-on control.
 - (2) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging, with no add-on control.
 - (3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced, with no add-on control.
 - (4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping, with no add-on control.
 - (5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging, with no add-on control.
- (b) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as BR01 and BR02, located in Building A, both installed in 1990.
- (c) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as BR03 and BR04, located in Building A, both installed in 1990.

- (d) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as BR05, located in Building C, installed in 1999.

The natural gas tangential fired boiler (BR05) is subject to NSPS 40 CFR 60 Subpart Dc.
- (e) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as BR06 and BR07, located in Building C, both installed in 1999.
- (f) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BR09, located in Building F, installed prior to 2004 by previous owner, date unknown.
- (g) Three (3) natural gas-fired boilers (identified as BR11, BR12, and BR13), each with a maximum heat input capacity of 14.7 MMBtu per hour, all three installed in 2004.

The three (3) natural gas-fired boilers (BR11, BR12 and BR13) are subject to NSPS 40 CFR 60 Subpart Dc.
- (h) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.
- (i) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.
- (j) One (1) 6.43 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-1.1-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-1.1-1) shall prevail.

B.2 Permit Term [326 IAC 2-6.1-7(a)][326 IAC 2-1.1-9.5][IC 13-15-3-6(a)]

- (a) This permit, M105-27180-00040, is issued for a fixed term of ten (10) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date of this permit.
- (b) If IDEM, OAQ, upon receiving a timely and complete renewal permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, until the renewal permit has been issued or denied.

B.3 Term of Conditions [326 IAC 2-1.1-9.5]

Notwithstanding the permit term of a permit to construct, a permit to operate, or a permit modification, any condition established in a permit issued pursuant to a permitting program approved in the state implementation plan shall remain in effect until:

- (a) the condition is modified in a subsequent permit action pursuant to Title I of the Clean Air Act; or
- (b) the emission unit to which the condition pertains permanently ceases operation.

B.4 Enforceability

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.5 Severability

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Provide Information

- (a) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The submittal by the Permittee does require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1). Upon request, the Permittee shall also furnish to IDEM, OAQ copies of records required to be kept by this permit.
- (b) For information furnished by the Permittee to IDEM, OAQ, the Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Certification

- (a) Where specifically designated by this permit or required by an applicable requirement, any application form, report, or compliance certification submitted shall contain certification by an "authorized individual" of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- (b) One (1) certification shall be included, using the attached Certification Form, with each submittal requiring certification. One (1) certification may cover multiple forms in one (1) submittal.
- (c) An "authorized individual" is defined at 326 IAC 2-1.1-1(1).

B.9 Annual Notification [326 IAC 2-6.1-5(a)(5)]

- (a) An annual notification shall be submitted by an authorized individual to the Office of Air Quality stating whether or not the source is in operation and in compliance with the terms and conditions contained in this permit.
- (b) The annual notice shall be submitted in the format attached no later than March 1 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251
- (c) The notification shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

B.10 Preventive Maintenance Plan [326 IAC 1-6-3]

- (a) If required by specific condition(s) in Section D of this permit, the Permittee shall maintain and implement Preventive Maintenance Plans (PMPs) including the following information on each facility:
 - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.
- (b) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions or potential to emit. The PMPs do not require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

- (c) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.11 Prior Permits Superseded [326 IAC 2-1.1-9.5]

- (a) All terms and conditions of permits established prior to M105-27180-00040 and issued pursuant to permitting programs approved into the state implementation plan have been either:
 - (1) incorporated as originally stated,
 - (2) revised, or
 - (3) deleted.
- (b) All previous registrations and permits are superseded by this permit.

B.12 Termination of Right to Operate [326 IAC 2-6.1-7(a)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least one hundred twenty (120) days prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-6.1-7.

B.13 Permit Renewal [326 IAC 2-6.1-7]

- (a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ and shall include the information specified in 326 IAC 2-6.1-7. Such information shall be included in the application for each emission unit at this source. The renewal application does require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

- (b) A timely renewal application is one that is:
 - (1) Submitted at least one hundred twenty (120) days prior to the date of the expiration of this permit; and
 - (2) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.
- (c) If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-6.1 until IDEM, OAQ takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified in writing by IDEM, OAQ any additional information identified as being needed to process the application.

B.14 Permit Amendment or Revision [326 IAC 2-5.1-3(e)(3)][326 IAC 2-6.1-6]

(a) Permit amendments and revisions are governed by the requirements of 326 IAC 2-6.1-6 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application shall be certified by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee shall notify the OAQ within thirty (30) calendar days of implementing a notice-only change. [326 IAC 2-6.1-6(d)]

B.15 Source Modification Requirement

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2.

B.16 Inspection and Entry

[326 IAC 2-5.1-3(e)(4)(B)][326 IAC 2-6.1-5(a)(4)][IC 13-14-2-2][IC 13-17-3-2][IC 13-30-3-1]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a permitted source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

(c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;

(d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.17 Transfer of Ownership or Operational Control [326 IAC 2-6.1-6]

(a) The Permittee must comply with the requirements of 326 IAC 2-6.1-6 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

- (b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The application which shall be submitted by the Permittee does require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

- (c) The Permittee may implement notice-only changes addressed in the request for a notice-only change immediately upon submittal of the request. [326 IAC 2-6.1-6(d)(3)]

B.18 Annual Fee Payment [326 IAC 2-1.1-7]

- (a) The Permittee shall pay annual fees due within thirty (30) calendar days of receipt of a bill from IDEM, OAQ,.
- (b) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.19 Credible Evidence [326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

Emission Limitations and Standards [326 IAC 2-6.1-5(a)(1)]

C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Permit Revocation [326 IAC 2-1.1-9]

Pursuant to 326 IAC 2-1.1-9 (Revocation of Permits), this permit to operate may be revoked for any of the following causes:

- (a) Violation of any conditions of this permit.
- (b) Failure to disclose all the relevant facts, or misrepresentation in obtaining this permit.
- (c) Changes in regulatory requirements that mandate either a temporary or permanent reduction of discharge of contaminants. However, the amendment of appropriate sections of this permit shall not require revocation of this permit.
- (d) Noncompliance with orders issued pursuant to 326 IAC 1-5 (Episode Alert Levels) to reduce emissions during an air pollution episode.
- (e) For any cause which establishes in the judgment of IDEM, the fact that continuance of this permit is not consistent with purposes of this article.

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.4 Open Burning [326 IAC 4-1] [IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1.

C.5 Incineration [326 IAC 4-2] [326 IAC 9-1-2]

The Permittee shall not operate an incinerator or incinerate any waste or refuse except as provided in 326 IAC 4-2 and 326 IAC 9-1-2.

C.6 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions).

C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

- (a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.
- (b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:
- (1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or
- (2) If there is a change in the following:
- (A) Asbestos removal or demolition start date;
- (B) Removal or demolition contractor; or
- (C) Waste disposal site.
- (c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).
- (d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Asbestos Section, Office of Air Quality
100 North Senate Avenue
MC 61-52 IGCN 1003
Indianapolis, Indiana 46204-2251

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

- (e) Procedures for Asbestos Emission Control
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-1, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.

- (f) **Demolition and Renovation**
The Permittee shall thoroughly inspect the affected facility or part of the facility where the demolition or renovation will occur for the presence of asbestos pursuant to 40 CFR 61.145(a).
- (g) **Indiana Licensed Asbestos Inspector**
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Licensed Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos. The requirement to use an Indiana Licensed Asbestos inspector is not federally enforceable.

Testing Requirements [326 IAC 2-6.1-5(a)(2)]

C.8 Performance Testing [326 IAC 3-6]

- (a) All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this permit, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAQ.

A test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

- (b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ if the Permittee submits to IDEM, OAQ a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.9 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements by issuing an order under 326 IAC 2-1.1-11. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-6.1-5(a)(2)]

C.10 Compliance Monitoring [326 IAC 2-1.1-11]

Compliance with applicable requirements shall be documented as required by this permit. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. All monitoring and record keeping requirements not already legally required shall be implemented when operation begins.

C.11 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]

Any monitoring or testing required by Section D of this permit shall be performed according to the provisions of 326 IAC 3, 40 CFR 60, Appendix A, 40 CFR 60, Appendix B, 40 CFR 63, or other approved methods as specified in this permit.

C.12 Instrument Specifications [326 IAC 2-1.1-11]

- (a) When required by any condition of this permit, an analog instrument used to measure a parameter related to the operation of an air pollution control device shall have a scale such that the expected maximum reading for the normal range shall be no less than twenty percent (20%) of full scale.
- (b) The Permittee may request that the IDEM, OAQ approve the use of an instrument that does not meet the above specifications provided the Permittee can demonstrate that an alternative instrument specification will adequately ensure compliance with permit conditions requiring the measurement of the parameters.

Corrective Actions and Response Steps

C.13 Response to Excursions or Exceedances

- (a) Upon detecting an excursion or exceedance, the Permittee shall restore operation of the emissions unit (including any control device and associated capture system) to its normal or usual manner of operation as expeditiously as practicable in accordance with good air pollution control practices for minimizing emissions.
- (b) The response shall include minimizing the period of any startup, shutdown or malfunction and taking any necessary corrective actions to restore normal operation and prevent the likely recurrence of the cause of an excursion or exceedance (other than those caused by excused startup or shutdown conditions). Corrective actions may include, but are not limited to, the following:
 - (1) initial inspection and evaluation;
 - (2) recording that operations returned to normal without operator action (such as through response by a computerized distribution control system); or
 - (3) any necessary follow-up actions to return operation to within the indicator range, designated condition, or below the applicable emission limitation or standard, as applicable.
- (c) A determination of whether the Permittee has used acceptable procedures in response to an excursion or exceedance will be based on information available, which may include, but is not limited to, the following:
 - (1) monitoring results;
 - (2) review of operation and maintenance procedures and records; and/or

- (3) inspection of the control device, associated capture system, and the process.
- (d) Failure to take reasonable response steps shall be considered a deviation from the permit.
- (e) The Permittee shall maintain the following records:
 - (1) monitoring data;
 - (2) monitor performance data, if applicable; and
 - (3) corrective actions taken.

C.14 Actions Related to Noncompliance Demonstrated by a Stack Test

- (a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall take appropriate response actions. The Permittee shall submit a description of these response actions to IDEM, OAQ, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize excess emissions from the affected facility while the response actions are being implemented.
- (b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAQ that retesting in one hundred twenty (120) days is not practicable, IDEM, OAQ may extend the retesting deadline.
- (c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The response action documents submitted pursuant to this condition do require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Record Keeping and Reporting Requirements [326 IAC 2-6.1-5(a)(2)]

C.15 Malfunctions Report [326 IAC 1-6-2]

Pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunction):

- (a) A record of all malfunctions, including startups or shutdowns of any facility or emission control equipment, which result in violations of applicable air pollution control regulations or applicable emission limitations shall be kept and retained for a period of three (3) years and shall be made available to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) or appointed representative upon request.
- (b) When a malfunction of any facility or emission control equipment occurs which lasts more than one (1) hour, said condition shall be reported to OAQ, using the Malfunction Report Forms (2 pages). Notification shall be made by telephone or facsimile, as soon as practicable, but in no event later than four (4) daytime business hours after the beginning of said occurrence.
- (c) Failure to report a malfunction of any emission control equipment shall constitute a violation of 326 IAC 1-6, and any other applicable rules. Information of the scope and expected duration of the malfunction shall be provided, including the items specified in 326 IAC 1-6-2(a)(1) through (6).

- (d) Malfunction is defined as any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. [326 IAC 1-2-39]

C.16 General Record Keeping Requirements [326 IAC 2-6.1-5]

- (a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.
- (b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance or ninety (90) days of initial start-up, whichever is later.

C.17 General Reporting Requirements [326 IAC 2-1.1-11] [326 IAC 2-6.1-2] [IC 13-14-1-13]

- (a) Reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
- (b) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.
- (c) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (d) Reporting periods are based on calendar years, unless otherwise specified in this permit. For the purpose of this permit "calendar year" means the twelve (12) month period from January 1 to December 31 inclusive.

SECTION D.1 EMISSIONS UNIT OPERATION CONDITIONS

Emissions Unit Description:

- (a) One (1) pharmaceutical manufacturing operation consisting of:
- (1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour, with no add-on control.
 - (2) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging, with no add-on control.
 - (3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced, with no add-on control.
 - (4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping, with no add-on control.
 - (5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging, with no add-on control.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-6.1-5(a)(1)]

D.1.1 Preventive Maintenance Plan [326 IAC 1-6-3]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this equipment and any control devices.

SECTION D.2

EMISSIONS UNIT OPERATION CONDITIONS

Emissions Unit Description [326 IAC 2-7-5(15)]:

- (b) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as BR01 and BR02, located in Building A, both installed in 1990.
- (c) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as BR03 and BR04, located in Building A, both installed in 1990.
- (d) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as BR05, located in Building C, installed in 1999.

The natural gas tangential fired boiler (BR05) is subject to NSPS 40 CFR 60 Subpart Dc.

- (e) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as BR06 and BR07, located in Building C, both installed in 1999.
- (f) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BR09, located in Building F, installed prior to 2004 by previous owner, date unknown.
- (g) Three (3) natural gas-fired boilers (identified as BR11, BR12, and BR13), each with a maximum heat input capacity of 14.7 MMBtu per hour, all three installed in 2004.

The three (3) natural gas-fired boilers (BR11, BR12 and BR13) are subject to NSPS 40 CFR 60 Subpart Dc.
- (h) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.
- (i) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.
- (j) One (1) 6.43 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards

D.2.1 Particulate [326 IAC 6-2-4]

Pursuant to 326 IAC 6-2-4(a) (Particulate Emission Limitations for Sources of Indirect Heating), the particulate emissions from the natural gas-fired boilers, all constructed after September 21, 1983, shall not exceed the pounds per million British thermal units heat input limit as shown in the table below:

Emission Unit ID (Boilers)	Total Source Max Heat Input Capacity (MMBtu/hr)	Particulate Emission Limit (lb/MMBtu)
BR01, BR02, BRO3, BR04 AND BRO9	17.0	0.52
BR05, BR06 AND BR07	38.0	0.42
BR11, BR12 AND BR13	82.1	0.35

These limitations are based on the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Where Pt = Pounds of particulate matter emitted per million Btu (lb per MMBtu) heat input.
 Q = Total source maximum operating capacity rating in million Btu per hour heat input.

$$Q_1 = 7.33 + 7.33 + 1.08 + 1.08 + 0.45 = 17.27$$

$$Q_2 = Q_1 + 14.7 + 3.00 + 3.00 = 37.97$$

$$Q_3 = Q_2 + 14.7 + 14.7 + 14.7 = 82.07$$

D.2.2 Preventive Maintenance Plan [326 IAC 1-6-3]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this facility and its control device.

SECTION E.1 EMISSIONS UNIT OPERATION CONDITIONS

Emissions Unit Description:

- (d) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as BR05, located in Building C, installed in 1999.
- (g) Three (3) natural gas-fired boilers (identified as BR11, BR12, and BR13), each with a maximum heat input capacity of 14.7 MMBtu per hour, all three installed in 2004.

The natural gas tangential fired boiler (BR05) and the three (3) natural gas-fired boilers (BR11, BR12 and BR13) are subject to NSPS 40 CFR 60 Subpart Dc.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

New Source Performance Standards (NSPS) Requirements [326 IAC 2-7-5(1)]

E.1.1 General Provisions Relating to New Source Performance Standards [326 IAC 12-1] [40 CFR Part 60, Subpart A]

The provisions of 40 CFR 60, Subpart A - General Provisions, which are incorporated as 326 IAC 12-1, apply to this facility described in this section except when otherwise specified in 40 CFR 60, Subpart Dc.

- (a) Pursuant to 40 CFR 60.1, the Permittee shall comply with the provisions of 40 CFR Part 60 Subpart A – General Provisions, which are incorporated by reference as 326 IAC 12-1 for the pharmaceutical operation except as otherwise specified in 40 CFR Part 60, Subpart Dc.
- (b) Pursuant to 40 CFR 60.10, the Permittee shall submit all required notifications and reports to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

E.1.2 New Source Performance Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units [40 CFR 60, Subpart Dc] [326 IAC 12]

Pursuant to 40 CFR Part 60, Subpart Dc, the Permittee shall comply with the following provisions of 40 CFR Part 60, Subpart Dc (included as Attachment A), which are incorporated by reference as 326 IAC 12 for the natural gas tangential fired boiler (BR05) and the three (3) boilers identified as BR11, BR12 and BR13.

- 40 CFR 60.48c(g)
- 40 CFR 60.48c(i)
- 40 CFR 60.48c(a)

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY**

**MINOR SOURCE OPERATING PERMIT (MSOP)
CERTIFICATION**

Source Name: Baxter Pharmaceutical Solutions, LLC
Source Address: 927 South Curry Pike, Bloomington, Indiana 47403
Mailing Address: 927 South Curry Pike, Bloomington, Indiana 47403
MSOP No.: M105-27180-00040

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

- Annual Compliance Certification Letter
- Test Result (specify) _____
- Report (specify) _____
- Notification (specify) _____
- Affidavit (specify) _____
- Other (specify) _____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Date:

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH**

**MINOR SOURCE OPERATING PERMIT
ANNUAL NOTIFICATION**

This form should be used to comply with the notification requirements under 326 IAC 2-6.1-5(a)(5).

Company Name:	Baxter Pharmaceutical Solutions, LLC
Address:	927 South Curry Pike
City:	Bloomington, Indiana 47403
Phone #:	812-333-0887
MSOP #:	M105-27180-00040

I hereby certify that Baxter Pharmaceutical Solutions, LLC still in operation.

:

no longer in operation.

I hereby certify that Baxter Pharmaceutical Solutions, LLC in compliance with the requirements of MSOP M105-27180-00040.

:

not in compliance with the requirements of MSOP M105-27180-00040.

Authorized Individual (typed):
Title:
Signature:
Date:

If there are any conditions or requirements for which the source is not in compliance, provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be achieved.

Noncompliance:

MALFUNCTION REPORT

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR QUALITY FAX NUMBER: (317) 233-6865

This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

THIS FACILITY MEETS THE APPLICABILITY REQUIREMENTS BECAUSE IT HAS POTENTIAL TO EMIT 25 TONS/YEAR PARTICULATE MATTER ?____, 25 TONS/YEAR SULFUR DIOXIDE ?____, 25 TONS/YEAR NITROGEN OXIDES?____, 25 TONS/YEAR VOC ?____, 25 TONS/YEAR HYDROGEN SULFIDE ?____, 25 TONS/YEAR TOTAL REDUCED SULFUR ?____, 25 TONS/YEAR REDUCED SULFUR COMPOUNDS ?____, 25 TONS/YEAR FLUORIDES ?____, 100 TONS/YEAR CARBON MONOXIDE ?____, 10 TONS/YEAR ANY SINGLE HAZARDOUS AIR POLLUTANT ?____, 25 TONS/YEAR ANY COMBINATION HAZARDOUS AIR POLLUTANT ?____, 1 TON/YEAR LEAD OR LEAD COMPOUNDS MEASURED AS ELEMENTAL LEAD ?____, OR IS A SOURCE LISTED UNDER 326 IAC 2-5.1-3(2) ?____. EMISSIONS FROM MALFUNCTIONING CONTROL EQUIPMENT OR PROCESS EQUIPMENT CAUSED EMISSIONS IN EXCESS OF APPLICABLE LIMITATION _____.

THIS MALFUNCTION RESULTED IN A VIOLATION OF: 326 IAC _____ OR, PERMIT CONDITION # _____ AND/OR PERMIT LIMIT OF _____

THIS INCIDENT MEETS THE DEFINITION OF "MALFUNCTION" AS LISTED ON REVERSE SIDE ? Y N

THIS MALFUNCTION IS OR WILL BE LONGER THAN THE ONE (1) HOUR REPORTING REQUIREMENT ? Y N

COMPANY: _____ PHONE NO. () _____
LOCATION: (CITY AND COUNTY) _____
PERMIT NO. _____ AFS PLANT ID: _____ AFS POINT ID: _____ INSP: _____
CONTROL/PROCESS DEVICE WHICH MALFUNCTIONED AND REASON: _____

DATE/TIME MALFUNCTION STARTED: ____/____/20____ _____ AM / PM

ESTIMATED HOURS OF OPERATION WITH MALFUNCTION CONDITION: _____

DATE/TIME CONTROL EQUIPMENT BACK-IN SERVICE ____/____/20____ _____ AM/PM

TYPE OF POLLUTANTS EMITTED: TSP, PM-10, SO2, VOC, OTHER: _____

ESTIMATED AMOUNT OF POLLUTANT EMITTED DURING MALFUNCTION: _____

MEASURES TAKEN TO MINIMIZE EMISSIONS: _____

REASONS WHY FACILITY CANNOT BE SHUTDOWN DURING REPAIRS:

CONTINUED OPERATION REQUIRED TO PROVIDE ESSENTIAL* SERVICES: _____
CONTINUED OPERATION NECESSARY TO PREVENT INJURY TO PERSONS: _____
CONTINUED OPERATION NECESSARY TO PREVENT SEVERE DAMAGE TO EQUIPMENT: _____
INTERIM CONTROL MEASURES: (IF APPLICABLE) _____

MALFUNCTION REPORTED BY: _____ TITLE: _____
(SIGNATURE IF FAXED)

MALFUNCTION RECORDED BY: _____ DATE: _____ TIME: _____

*SEE PAGE 2

Please note - This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

326 IAC 1-6-1 Applicability of rule

Sec. 1. This rule applies to the owner or operator of any facility required to obtain a permit under 326 IAC 2-5.1 or 326 IAC 2-6.1.

326 IAC 1-2-39 "Malfunction" definition

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner.

***Essential services** are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

If this item is checked on the front, please explain rationale:

**Indiana Department of Environmental Management
Office of Air Quality**

Technical Support Document (TSD) for a Minor Source Operating Permit Renewal

Source Background and Description

Source Name:	Baxter Pharmaceutical Solutions, LLC
Source Location:	927 South Curry Pike, Bloomington, Indiana 47403
County:	Monroe
SIC Code:	2834
Permit Renewal No.:	105-27180-00040
Permit Reviewer:	Janet Mobley

The Office of Air Quality (OAQ) has reviewed the operating permit renewal application from Baxter Pharmaceutical Solutions, LLC relating to the operation of a third party pharmaceutical manufacturing operation.

History

On November 26, 2008, Baxter Pharmaceutical Solutions, LLC submitted an application to the OAQ requesting to renew its operating permit. Pharmaceutical Solutions, LLC was issued a MSOP Permit on March 5, 2004.

Permitted Emission Units and Pollution Control Equipment

- (a) One (1) pharmaceutical manufacturing operation consisting of:
 - (1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour, with no add-on control.
 - (2) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging, with no add-on control.
 - (3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced, with no add-on control.
 - (4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping, with no add-on control.
 - (5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging, with no add-on control.
- (b) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as BR01 and BR02, located in Building A, both installed in 1990.
- (c) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as BR03 and BR04, located in Building A, both installed in 1990.

- (d) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as BR05, located in Building C, installed in 1999.

The natural gas tangential fired boiler (BR05) is subject to NSPS 40 CFR 60 Subpart Dc.
- (e) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as BR06 and BR07, located in Building C, both installed in 1999.
- (f) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BR09, located in Building F, installed prior to 2004 by previous owner, date unknown.
- (g) Three (3) natural gas-fired boilers (identified as BR11, BR12, and BR13), each with a maximum heat input capacity of 14.7 MMBtu per hour, all three installed in 2004.

The three (3) natural gas-fired boilers (BR11, BR12 and BR13) are subject to NSPS 40 CFR 60 Subpart Dc.
- (h) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.
- (i) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.
- (j) One (1) 6.43 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.

Emission Units and Pollution Control Equipment Constructed and/or Operated without a Permit

The source had no emission units that were constructed and/or operating without a permit.

Emission Units and Pollution Control Equipment Removed From the Source

The final packing process, consisting of packaging the capped vials and syringes in containers in preparation for shipping, located in Building B, was removed from the source during the review process.

Existing Approvals

Since the issuance of the MSOP (105-16441-00040) on March 5, 2004, the source has constructed or has been operating under the following approvals as well:

- (a) Minor Permit Revision No. (105-19185-00040) issued on August 27, 2004; and
- (b) Notice Only Change No. (105-14671-00040) issued on May 18, 2007.

All terms and conditions of previous permits issued pursuant to permitting programs approved into the state implementation plan have been either incorporated as originally stated, revised, or deleted by this permit. All previous registrations and permits are superseded by this permit.

Enforcement Issue

There are no enforcement actions pending.

Emission Calculations

See Appendix A of this document for detailed emission calculations.

County Attainment Status

The source is located in Monroe County.

Pollutant	Designation
SO ₂	Better than national standards.
CO	Unclassifiable or attainment effective November 15, 1990.
O ₃	Unclassifiable or attainment effective June 15, 2004, for the 8-hour ozone standard. ¹
PM ₁₀	Unclassifiable effective November 15, 1990.
NO ₂	Cannot be classified or better than national standards.
Pb	Not designated.
¹ Unclassifiable or attainment effective October 18, 2000, for the 1-hour ozone standard which was revoked effective June 15, 2005. Unclassifiable or attainment effective April 5, 2005, for PM2.5.	

(a) Ozone Standards

- (1) On October 25, 2006, the Indiana Air Pollution Control Board finalized a rule revision to 326 IAC 1-4-1 revoking the one-hour ozone standard in Indiana.
- (2) On September 6, 2007, the Indiana Air Pollution Control Board finalized a temporary emergency rule to re-designate Allen, Clark, Elkhart, Floyd, LaPorte, and St. Joseph as attainment for the 8-hour ozone standard.
- (3) On November 9, 2007, the Indiana Air Pollution Control Board finalized a temporary emergency rule to re-designate Boone, Clark, Elkhart, Floyd, LaPorte, Hamilton, Hancock, Hendricks, Johnson, Madison, Marion, Morgan, Shelby, and St. Joseph as attainment for the 8-hour ozone standard.
- (4) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NOx emissions are considered when evaluating the rule applicability relating to ozone. Monroe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

- (b) Monroe County has been classified as attainment for PM2.5. On May 8, 2008, U.S. EPA promulgated the requirements for Prevention of Significant Deterioration (PSD) for PM2.5 emissions, and the effective date of these rules was July 15th, 2008. Indiana has three years from the publication of these rules to revise its PSD rules, 326 IAC 2-2, to include those requirements. The May 8, 2008 rule revisions require IDEM to regulate PM10 emissions as a surrogate for PM2.5 emissions until 326 IAC 2-2 is revised.

(c) Other Criteria Pollutants

Monroe County has been classified as attainment or unclassifiable in Indiana for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

- (d) Fugitive Emissions
 Since this type of operation is not one of the twenty-eight (28) listed source categories under 326 IAC 2-2 or 326 IAC 2-3, fugitive emissions are not counted toward the determination of PSD and Emission Offset applicability.

Unrestricted Potential Emissions

Appendix A of this TSD reflects the unrestricted potential emissions of the source.

- (a) The potential to emit (as defined in 326 IAC 2-7-1(29)) of all criteria pollutants is still less than 100 tons per year. The source is not subject to the provisions of 326 IAC 2-7. Therefore, the source will be issued an MSOP Renewal.
- (b) The potential to emit (as defined in 326 IAC 2-7-1(29)) of any single HAP is less than ten (10) tons per year and/or the potential to emit (as defined in 326 IAC 2-7-1(29)) of a combination of HAPs is less than twenty-five (25) tons per year.
- (c) Since this type of operation is not one of the twenty-eight (28) listed source categories under 326 IAC 2-7, fugitive emissions are not counted toward the determination of Part 70 applicability.

Potential to Emit After Issuance

The table below summarizes the potential to emit, reflecting all limits of the emission units. Any control equipment is considered enforceable only after issuance of this MSOP and only to the extent that the effect of the control equipment is made practically enforceable in the permit.

Process/ Emission Unit	Potential To Emit (tons/year)							
	PM	PM ₁₀	PM _{2.5}	SO ₂	NO _x	VOC	CO	HAPs
Pharmaceutical Manufacturing Process	0.00	0.00	0.00	0.00	0.00	22.15	0.00	0.00
Natural Gas Boilers - Units ID# - BR01, BR02, BR03, BR04, BR05, BR06, BR07, BR09	0.32	1.26	1.26	0.10	16.60	0.91	14.00	0.30
Natural Gas Boilers Unit ID# BR11, BR12 and BR13	0.37	1.47	1.47	0.12	19.30	1.06	16.20	0.35
Natural Gas Emergency Generator GN01	0.02	0.02	0.02	0.07	0.02	0.00	0.01	negl.
No. 2 Fuel fired Emergency Generators Units GN02 and GN05	0.04	0.04	0.04	0.23	0.41	0.01	0.10	negl.
Total Emissions	0.75	2.79	2.79	0.52	36.33	24.13	30.31	<10/25
TV Major	-	100	100	100	100	100	100	10/25
PSD Major	250	250	250	250	250	250	250	-

- (a) This existing stationary source is not major for PSD because the emissions of each criteria pollutant are less than two hundred fifty (<250) tons per year, and it is one of the twenty-eight (28) listed source categories.

- (b) Fugitive Emissions
Since this type of operation is not one of the twenty-eight (28) listed source categories under 326 IAC 2-2 or 326 IAC 2-3, fugitive emissions are not counted toward the determination of PSD and Emission Offset applicability.

Federal Rule Applicability

The requirements of 40 CFR Part 64, Compliance Assurance Monitoring, are not included in this permit. This source is operating as a MSOP. Therefore, the requirements of 40 CFR 64, Compliance Assurance Monitoring, are not applicable to this source.

NSPS/NESHAPs

- (a) The natural gas tangential fired boiler (BR05) and the three (3) boilers identified as BR11, BR12 and BR13 are subject to the requirements of the New Source Performance Standard, 40 CFR 60, Subpart Dc - Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units, which is incorporated by reference as 326 IAC 12. These boilers were constructed after June 9, 1989, and each have a heat input capacity greater than 10 MMBtu per hour and less than 100 MMBtu per hour. However, these boilers are subject to the reporting requirements in 40 CFR 60.48c, because they burn natural gas only. As per the reporting requirements, the source must maintain daily records of the amount of natural gas combusted.

Nonapplicable portions of the NSPS will not be included in the permit. These units are subject to the following portion of Subpart Dc.

40 CFR 60.48c(g)
40 CFR 60.48c(i)
40 CFR 60.48c(a)

- (b) The requirements of 40 CFR 60, Subparts VV, (Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry) III, (Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry Air Oxidation Processes) NNN, (Standards of Performance for Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry Distillation Operations) and RRR (Standards of Performance for Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry Reactor Processes) are still not applicable to this source. The source is not engaged in the manufacture of synthetic organic chemicals as defined by these standards. The source does not produce as an intermediate, final product, co-product or by-product, a chemical listed in 40 CFR 60.480, 40 CFR 60.117, 40 CFR 60.707 or 40 CFR 60.667.
- (c) There are no National Emission Standards for Hazardous Air Pollutants (NESHAP) (326 IAC 14, 326 IAC 20 and 40 CFR Part 63) included in this permit renewal.

State Rule Applicability - Entire Source

326 IAC 2-2 (Prevention of Significant Deterioration (PSD))

This source was constructed in 2004 and is not in 1 of 28 source categories. The potential to emit of all criteria pollutants before control were less than 250 tons per year. Therefore, the requirements of 326 IAC 2-2 are not applicable.

326 IAC 2-6 (Emission Reporting)

This source is located in Monroe County and the potential to emit of each criteria pollutant is less than one hundred (100) tons per year. Therefore, 326 IAC 2-6 does not apply.

326 IAC 5-1 (Opacity Limitations)

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in the permit:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

326 IAC 2-4.1 (Major Source of Hazardous Air Pollutants (HAP))

This source was constructed in 2004. The potential to emit HAPs from this source has never exceeded 10 tons per year for a single HAP and 25 tons per year for any combination of HAPs. Therefore, the requirements of 326 IAC 2-4.1 are not applicable.

State Rule Applicability - Pharmaceutical Manufacturing Operation

326 IAC 8-1-6 (New Facilities: General Reduction Requirements)

326 IAC 8-1-6 does not apply to the mixing and formulation and the vial or syringe preparation processes because the estimated VOC PTE does not have the potential to emit twenty-five (25) tons or more per year of VOC. Therefore, the requirements of 326 IAC 8-1-6 are not applicable.

326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations)

The requirements of 326 IAC 8-5-3 do not apply to the equipment at this source because the source does not have any reactors, distillation units dryers, storage of volatile organic compounds, transfer of volatile organic compounds (VOC), extraction equipment, filters, crystallizers and centrifuges that generate VOCs. The source is not subject to the requirements of 326 IAC 8-5-3, because no chemical synthesis occurs at the source. Therefore, the requirements of 326 IAC 8-5-3 are not applicable.

State Rule Applicability – Natural Gas-fired Boilers

326 IAC 6-2-4(a) (Particulate Emission Limitations for Sources of Indirect Heating)

Pursuant to 326 IAC 6-2-4(a) (Particulate Emission Limitations for Sources of Indirect Heating), the particulate emissions from the natural gas-fired boilers, all constructed after September 21, 1983, shall not exceed the pounds per million British thermal units heat input limit as shown below:

Emission Unit ID (Boilers)	Total Source Max Heat Input Capacity (MMBtu/hr)	Particulate Emission Limit (lb/MMBtu)
BR01, BR02, BRO3, BR04 AND BRO9	17.0	0.52
BR05, BR06 AND BR07	38.0	0.42
BR11, BR12 AND BR13	82.1	0.35

These limitations are based on the following equation:

$$P_t = \frac{1.09}{Q^{0.26}}$$

Where P_t = Pounds of particulate matter emitted per million Btu (lb per MMBtu) heat input.
 Q = Total source maximum operating capacity rating in million Btu per hour heat input.

Boilers installed 1990 and prior to 1990 $Q_1 = 7.33 + 7.33 + 1.08 + 1.08 + 0.45 = 17.27$

Boilers installed prior to 1999 $Q_2 = Q_1 + 14.7 + 3.00 + 3.00 = 37.97$

Boilers installed 2004 and prior $Q_3 = Q_2 + 14.7 + 14.7 + 14.7 = 82.07$

Compliance Determination and Monitoring Requirements

Permits issued under 326 IAC 2-6 are required to ensure that sources can demonstrate compliance with all applicable state and federal rules on a continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a continuous demonstration. When this occurs, IDEM, OAQ, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-6. As a result, Compliance Determination Requirements are included in the permit. The Compliance Determination Requirements in Section D of the permit are those conditions that are found directly within state and federal rules and the violation of which serves as grounds for enforcement action.

If the Compliance Determination Requirements are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also in Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance monitoring requirements applicable to this source are as follows:

There are no compliance monitoring requirements.

Recommendation

The staff recommends to the Commissioner that the MSOP Renewal be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on November 26, 2008.

Conclusion

The operation of this third party pharmaceutical manufacturing operation shall be subject to the conditions of the MSOP Renewal No. M105-27180-00040.

Summary Emissions

Appendix A: Emission Calculations

Company Name: Baxter Pharmaceutical Solutions, LLC
 Address: 927 South Curry Pike, Bloomington, Indiana 47403
 Permit Number: M105-27180-00040
 Reviewer: Janet Mobley
 Date: December 2, 2008

POTENTIAL TO EMIT BEFORE CONTROLS

Emission Units	PM	PM10	PM 2.5	SO2	NOx	VOC	CO	HAPs
Pharmaceutical Manufacturing Process	0.00	0.00	0.00	0.00	0.00	22.15	0.00	0.00
Natural Gas Boilers ID#'s - BR01, BR02, BRO3, BR04, BR05, BRO6, BR07 and BR09	0.32	1.26	1.26	0.10	16.60	0.91	14.00	0.30
Natural Gas Boilers ID# - BR11, BR12 and BR13	0.37	1.47	1.47	0.12	19.30	1.06	16.20	0.35
Natural Gas Emergency Generator GN01	0.02	0.02	0.02	0.07	0.02	0.00	0.01	negl.
No.2 Fuel Fired Internal Combustion Emergency Generator GN02, No.2 Fuel Fired Emergency Generator GN05	0.04	0.04	0.04	0.23	0.41	0.01	0.10	negl.
TOTAL	0.75	2.79	2.79	0.52	36.33	24.13	30.31	<10/25

VOC PTE FOR PHARMACEUTICAL OPERATIONS

Appendix A: Emission Calculations

Company Name: Baxter Pharmaceutical Solutions, LLC
Address: 927 South Curry Pike, Bloomington, Indiana 47403
Permit Number: M105-27180-00040
Reviewer: Janet Mobley
Date: December 2, 2008

(1) Mixing and Formulation Process

VOC	Max. Rate (lb/hr)	Emissions (tons/yr)
Phenol	0.002	0.01
Benzyl Alcohol	0.273	0.85
Ethanol	0.106	0.33
Metacresol	0.007	0.02
TOTAL		1.21

(3) Vial/Syringe Preparation Process

VOC	Max. Rate (lb/hr)	Emissions (tons/yr)
Isopropyl Alcohol	6.71	20.94

TOTAL VOC PTE FOR THE PHARMACEUTICAL OPERATION	22.15
---	--------------

Methodology:

VOC = Maximum Rate lb/hr * 6240 hr/yr * 1/2000 ton/lb = tons/yr

This is a batch operation, thus PTE is determined using the maximum batch operation time of 6240 hours of operation instead of 8670 hours.

Notes: The (2) Product Filtration Process, (4) Filling Process and (5) Capping Process are determined to be ancillary processes with no emissions associated with the affected equipment.

**Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100**

**(Units ID # BR01, BR02, BR03, BR04, BR05, BR06, BR07 and BR09)
Company Name: Baxter Pharmaceutical Solutions, LLC
Address City IN Zip: 927 South Curry Pike, Bloomington, Indiana 47403
Permit Number: M105-27180-0040
Reviewer: Janet Mobley
Date: December 2, 2008**

Heat Input Capacity
MMBtu/hr

Potential Throughput
MMCF/yr

38.0

332.5

	Pollutant					
	PM*	PM10*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	0.6	100 **see below	5.5	84
Potential Emission in tons/yr	0.32	1.26	0.10	16.6	0.91	14.0

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.

**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

Methodology

All emission factors are based on normal firing.

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03

Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,000 MMBtu

Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton

See next page for HAPs emissions calculations.

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100 (Units ID # BR01,02,03,04,05,06, 07 and 09
HAPs Emissions

Company Name: Baxter Pharmaceutical Solutions, LLC
Address City IN Zip: 927 South Curry Pike, Bloomington, Indiana 47403
Permit Number: M105-27180-00040
Reviewer: Janet Mobley
Date: December 2, 2008

HAPs - Organics					
Emission Factor in lb/MMcf	Benzene 2.1E-03	Dichlorobenzene 1.2E-03	Formaldehyde 7.5E-02	Hexane 1.8E+00	Toluene 3.4E-03
Potential Emission in tons/yr	3.491E-04	1.995E-04	1.247E-02	2.992E-01	5.652E-04

HAPs - Metals					
Emission Factor in lb/MMcf	Lead 5.0E-04	Cadmium 1.1E-03	Chromium 1.4E-03	Manganese 3.8E-04	Nickel 2.1E-03
Potential Emission in tons/yr	8.312E-05	1.829E-04	2.327E-04	6.317E-05	3.491E-04

Methodology is the same as previous page.

The five highest organic and metal HAPs emission factors are provided above.
 Additional HAPs emission factors are available in AP-42, Chapter 1.4.

**Appendix A: Emission Calculations
 Natural Gas Combustion Only
 (Three (3) Boilers) (UNITS BR11, BR12 and BR13)**

**Company Name: Baxter Pharmaceutical Solutions, LLC
 Address: 927 South Curry Pike, Bloomington, Indiana 47403
 MSOP: M105-27180-00040
 Reviewer: Janet Mobley
 Date: December 2, 2008**

Heat Input Capacity
 MMBtu/hour

Potential Throughput
 MMCF/year

44.1 (3 units only)

386.3

Pollutant

	* PM	* PM10	SO ₂	** NO _x	VOC	CO
Emission Factor (lb/MMCF)	1.9	7.6	0.6	100	5.5	84.0
Potential To Emit (tons/year)	0.37	1.47	0.12	19.3	1.06	16.2

*PM and PM10 emission factors are filterable and condensable PM and PM10 combined.

**Emission factors for NO_x (Uncontrolled) = 100 lb/MMCF

Emission factors from AP-42, Chapter 1.4, Tables 1.4-1, 1.4-2, and 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03 (July, 1998).

All Emission factors are based on normal firing.

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

METHODOLOGY

Potential throughput (MMCF/year) = Heat input capacity (MMBtu/hour) * 8760 hours/year * 1 MMCF/1000 MMBtu

PTE (tons/year) = Potential throughput (MMCF/year) * Emission factor (lb/MMCF) * 1 ton/2000 lbs

See next page for HAPs emissions calculations.

**Appendix A: Emission Calculations
Natural Gas Combustion Only
(Three (3) Boilers)(Units BR11, BR12 and BR13)**

Company Name: Baxter Pharmaceutical Solutions, LLC
Address: 927 South Curry Pike, Bloomington, Indiana 47403
MSOP: M105-27180-00040
Reviewer: Janet Mobley
Date: December 2, 2008

HAPs - Organics

Emission Factor (lb/MMCF)	Benzene 2.1E-03	Dichlorobenzene 1.2E-03	Formaldehyde 7.5E-02	Hexane 1.8E+00	Toluene 3.4E-03
Potential To Emit (tons/year)	4.056E-04	2.318E-04	1.449E-02	3.477E-01	6.567E-04

HAPs - Metals

Emission Factor (lb/MMCF)	Lead 5.0E-04	Cadmium 1.1E-03	Chromium 1.4E-03	Manganese 3.8E-04	Nickel 2.1E-03
Potential To Emit (tons/year)	9.658E-05	2.125E-04	2.704E-04	7.340E-05	4.056E-04

Methodology is the same as previous page.

The five highest organic and metal HAPs emission factors provided above are from AP-42, Chapter 1.4, Table 1-4.2, 1.4-3 and 1.4-4 (July, 1998). Additional HAPs emission factors are available in AP-42, Chapter 1.4.

Appendix A: Emissions Calculations
Emergency Generator(s) operated at 500 hours per year
(< 100 MMBtu/hr)
#1 and #2 Fuel Oil

(Unit GN01)
Company Name: Baxter Pharmaceutical Solutions, LLC
Address City IN Zip: 927 South Curry Pike, Bloomington, Indiana 47403
Permit Number: M105-27180-00040
Reviewer: Janet Mobley
Date: December 2, 2008

Criteria Pollutants

Weight % Sulfur, S = 0.5 %

Emission Unit	Number of Units	Unit Heat Input Capacity (MMBtu/hr)	Combined Total Heat Input Capacity (MMBtu/hr)	Potential Throughput (kgals/year)	Emission Factor (lb/kgal)				
					PM*	SO2 (142xS)	NOx	VOC	CO
Emergency Generator GN-01	1	2.47	0.56	2.00	0.00	0.07	0.02	0.000	0.01
Totals	1		0.56		0.00	0.07	0.02	0.000	0.01

Hazardous Air Pollutants (HAPs)

Emission Unit	Number of Units	Unit Heat Input Capacity (MMBtu/hr)	Combined Total Heat Input Capacity (MMBtu/hr)	Emission Factor (lb/MMBtu)									
				As	Be	Cd	Cr	Pb	Mn	Hg	Ni	Se	
Emergency Generator GN-01	1	2.47	0.56	5.6E-07	4.2E-07	4.2E-07	4.2E-07	1.3E-06	8.4E-07	4.2E-07	4.2E-07	2.1E-06	
Totals	1		0.56	5.6E-07	4.2E-07	4.2E-07	4.2E-07	1.3E-06	8.4E-07	4.2E-07	4.2E-07	2.1E-06	

Methodology

Potential Throughput at 500 hrs/yr = [Combined Total Heat Input Capacity (MMBtu/hr)] x 500 hrs/yr x 1kgal/1000 gal x 1 gal/0.140 MM Btu

Potential to Emit for Criteria Pollutants (tons/yr) = [Potential Throughput (kgals/ yr)] x [Emission Factor (lb/kgal)] /2,000 lb/ton

Potential to Emit for HAPs (tons/year) = [Potential Throughput (MMBtu/hr)] x [Emission Factor (lb/MMBtu)] x 500 hrs/yr / 2,000 lb/ton

where:

1 gallon of No. 2 Fuel Oil has a heating value of 0.14 MMBtu

Emission Factors for Criteria Pollutants are from AP 42, Tables 1.3-1, 1.3-2, and 1.3-3 (SCC 1-03-005-01/02/03) Supplement E 9/98 (see errata file)

*PM emission factor is filterable PM only. Condensable PM emission factor is 1.3 lb/kgal.

No data was available in AP-42 for organic HAPs.

Abbreviations

PM = Particulate Matter	VOC - Volatile Organic Compounds	As = Arsenic	Cr = Chromium	Hg = Mercury
SO2 = Sulfur Dioxide	CO = Carbon Monoxide	Be = Beryllium	Pb = Lead	Ni = Nickel
NOx = Nitrous Oxides		Cd = Cadmium	Mn = Manganese	Se = Selenium

**Appendix A: Emission Calculations
Two (2) Emergency Generator using No. 2 Fuel Oil
(Units GN02 and GN05)**

**Company Name: Baxter Pharmaceutical Solutions, LLC
Address: 927 South Curry Pike, Bloomington, Indiana 47403
MSOP: M105-27180-00040
Reviewer: Janet Mobley
Date: December 2, 2008**

Heat Input Capacity
MMBtu/hour

12.02

Potential Throughput
kgals/year

41.5

S = Weight % Sulfur

0.078

	Pollutant				
	PM/PM10*	SO ₂	NO _x	VOC	CO
Emission Factor (lb/kgal)	2.0	11.1 (142.0 S)	20.0	0.34	5.0
Potential To Emit (tons/year)	0.04	0.23	0.41	0.007	0.10

*PM emission factor is filterable PM only. Condensable PM emission factor is 1.3 lb/kgal. Assume all PM emissions are equal to PM10.

Note: Emission factors are from AP-42, Tables 1.3-1, 1.3-2, and 1.3-3 (SCC 1-03-005-01/02/03) Supplement E 9/98.

1 gallon of No. 2 Fuel Oil has a heating value of 144,905 Btu per gallon.

METHODOLOGY

Potential Throughput (kgals/year) = Heat Input Capacity (MMBtu/hr) * 500 hours/year * 1 kgal/1000 gal * 1 gal/0.144905 MMBtu

Potential To Emit (tons/year) = Potential Throughput (MMCF/year) * Emission Factor (lb/kgal) * 1 ton//2000 lbs

* As defined in the September 6, 1995 memorandum from John S. Seitz of US EPA on the subject of "Calculating Potential to Emit for Emergency Generators", an emergency generator's sole function is to provide back-up power when power from the local utility is interrupted. The only circumstances under which an emergency generator would operate when utility power is available are during operator training or brief maintenance checks. The generator's potential to emit is based on an operating time of 500 hours per year as set forth in the EPA memo.

See next page for HAPs emissions calculations.

**Appendix A: Emission Calculations
Two (2) Emergency Generator using No. 2 Fuel Oil
(Units GN02 and GN05)**

**Company Name: Baxter Pharmaceutical Solutions, LLC
Address: 927 South Curry Pike, Bloomington, Indiana 47403
MSOP: M105-27180-00040
Reviewer: Janet Mobley
Date: December 2, 2008**

HAPs - Metals

Emission Factor (lb/MMBtu)	Arsenic 4.0E-06	Beryllium 3.0E-06	Cadmium 3.0E-06	Chromium 3.0E-06	Lead 9.0E-06
Potential To Emit (tons/year)	2.11E-04	1.58E-04	1.58E-04	1.58E-04	4.74E-04

HAPs - Metals (continued)

Emission Factor (lb/MMBtu)	Mercury 3.0E-06	Mangamese 6.0E-06	Nickel 3.0E-06	Selenium 1.5E-05
Potential To Emit (tons/year)	1.58E-04	3.16E-04	1.58E-04	7.90E-04

No data was available in AP-42 for organic HAPs.

METHODOLOGY

Potential To Emit (tons/year) = Heat Input Capacity (MMBtu/hr) * Emission Factor (lb/MMBtu) * 8760 hours/year * 1 ton/2000lb

Attachment A

**Baxter Pharmaceutical Solutions LLC
927 South Curry Pike
Bloomington, Indiana 47403**

Permit No. M105-27180-00040

Subpart Dc—Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units

Source: 72 FR 32759, June 13, 2007, unless otherwise noted.

§ 60.40c Applicability and delegation of authority.

(a) Except as provided in paragraph (d) of this section, the affected facility to which this subpart applies is each steam generating unit for which construction, modification, or reconstruction is commenced after June 9, 1989 and that has a maximum design heat input capacity of 29 megawatts (MW) (100 million British thermal units per hour (MMBtu/hr)) or less, but greater than or equal to 2.9 MW (10 MMBtu/hr).

(b) In delegating implementation and enforcement authority to a State under section 111(c) of the Clean Air Act, §60.48c(a)(4) shall be retained by the Administrator and not transferred to a State.

(c) Steam generating units that meet the applicability requirements in paragraph (a) of this section are not subject to the sulfur dioxide (SO₂) or particulate matter (PM) emission limits, performance testing requirements, or monitoring requirements under this subpart (§§60.42c, 60.43c, 60.44c, 60.45c, 60.46c, or 60.47c) during periods of combustion research, as defined in §60.41c.

(d) Any temporary change to an existing steam generating unit for the purpose of conducting combustion research is not considered a modification under §60.14.

(e) Heat recovery steam generators that are associated with combined cycle gas turbines and meet the applicability requirements of subpart GG or KKKK of this part are not subject to this subpart. This subpart will continue to apply to all other heat recovery steam generators that are capable of combusting more than or equal to 2.9 MW (10 MMBtu/hr) heat input of fossil fuel but less than or equal to 29 MW (100 MMBtu/hr) heat input of fossil fuel. If the heat recovery steam generator is subject to this subpart, only emissions resulting from combustion of fuels in the steam generating unit are subject to this subpart. (The gas turbine emissions are subject to subpart GG or KKKK, as applicable, of this part).

(f) Any facility covered by subpart AAAA of this part is not covered by this subpart.

(g) Any facility covered by an EPA approved State or Federal section 111(d)/129 plan implementing subpart BBBB of this part is not covered by this subpart.

§ 60.41c Definitions.

As used in this subpart, all terms not defined herein shall have the meaning given them in the Clean Air Act and in subpart A of this part.

Annual capacity factor means the ratio between the actual heat input to a steam generating unit from an individual fuel or combination of fuels during a period of 12 consecutive calendar months and the potential heat input to the steam generating unit from all fuels had the steam generating unit been operated for 8,760 hours during that 12-month period at the maximum design heat input capacity. In the case of steam generating units that are rented or leased, the actual heat input shall be determined based on the combined heat input from all operations of the affected facility during a period of 12 consecutive calendar months.

Coal means all solid fuels classified as anthracite, bituminous, subbituminous, or lignite by the American Society of Testing and Materials in ASTM D388 (incorporated by reference, see §60.17), coal refuse, and petroleum coke. Coal-derived synthetic fuels derived from coal for the purposes of creating useful heat, including but not limited to solvent refined coal, gasified coal, coal-oil mixtures, and coal-water mixtures, are also included in this definition for the purposes of this subpart.

Coal refuse means any by-product of coal mining or coal cleaning operations with an ash content greater than 50 percent (by weight) and a heating value less than 13,900 kilojoules per kilogram (kJ/kg) (6,000 Btu per pound (Btu/lb) on a dry basis.

Cogeneration steam generating unit means a steam generating unit that simultaneously produces both electrical (or mechanical) and thermal energy from the same primary energy source.

Combined cycle system means a system in which a separate source (such as a stationary gas turbine, internal combustion engine, or kiln) provides exhaust gas to a steam generating unit.

Combustion research means the experimental firing of any fuel or combination of fuels in a steam generating unit for the purpose of conducting research and development of more efficient combustion or more effective prevention or control of air pollutant emissions from combustion, provided that, during these periods of research and development, the heat generated is not used for any purpose other than preheating combustion air for use by that steam generating unit (*i.e.* , the heat generated is released to the atmosphere without being used for space heating, process heating, driving pumps, preheating combustion air for other units, generating electricity, or any other purpose).

Conventional technology means wet flue gas desulfurization technology, dry flue gas desulfurization technology, atmospheric fluidized bed combustion technology, and oil hydrosulfurization technology.

Distillate oil means fuel oil that complies with the specifications for fuel oil numbers 1 or 2, as defined by the American Society for Testing and Materials in ASTM D396 (incorporated by reference, see §60.17).

Dry flue gas desulfurization technology means a SO₂ control system that is located between the steam generating unit and the exhaust vent or stack, and that removes sulfur oxides from the combustion gases of the steam generating unit by contacting the combustion gases with an alkaline reagent and water, whether introduced separately or as a premixed slurry or solution and forming a dry powder material. This definition includes devices where the dry powder material is subsequently converted to another form. Alkaline reagents used in dry flue gas desulfurization systems include, but are not limited to, lime and sodium compounds.

Duct burner means a device that combusts fuel and that is placed in the exhaust duct from another source (such as a stationary gas turbine, internal combustion engine, kiln, etc.) to allow the firing of additional fuel to heat the exhaust gases before the exhaust gases enter a steam generating unit.

Emerging technology means any SO₂ control system that is not defined as a conventional technology under this section, and for which the owner or operator of the affected facility has received approval from the Administrator to operate as an emerging technology under §60.48c(a)(4).

Federally enforceable means all limitations and conditions that are enforceable by the Administrator, including the requirements of 40 CFR parts 60 and 61, requirements within any applicable State implementation plan, and any permit requirements established under 40 CFR 52.21 or under 40 CFR 51.18 and 51.24.

Fluidized bed combustion technology means a device wherein fuel is distributed onto a bed (or series of beds) of limestone aggregate (or other sorbent materials) for combustion; and these materials are forced upward in the device by the flow of combustion air and the gaseous products of combustion. Fluidized bed combustion technology includes, but is not limited to, bubbling bed units and circulating bed units.

Fuel pretreatment means a process that removes a portion of the sulfur in a fuel before combustion of the fuel in a steam generating unit.

Heat input means heat derived from combustion of fuel in a steam generating unit and does not include the heat derived from preheated combustion air, recirculated flue gases, or exhaust gases from other sources (such as stationary gas turbines, internal combustion engines, and kilns).

Heat transfer medium means any material that is used to transfer heat from one point to another point.

Maximum design heat input capacity means the ability of a steam generating unit to combust a stated maximum amount of fuel (or combination of fuels) on a steady state basis as determined by the physical design and characteristics of the steam generating unit.

Natural gas means: (1) A naturally occurring mixture of hydrocarbon and nonhydrocarbon gases found in geologic formations beneath the earth's surface, of which the principal constituent is methane; or (2) liquefied petroleum (LP) gas, as defined by the American Society for Testing and Materials in ASTM D1835 (incorporated by reference, see §60.17).

Noncontinental area means the State of Hawaii, the Virgin Islands, Guam, American Samoa, the Commonwealth of Puerto Rico, or the Northern Mariana Islands.

Oil means crude oil or petroleum, or a liquid fuel derived from crude oil or petroleum, including distillate oil and residual oil.

Potential sulfur dioxide emission rate means the theoretical SO₂ emissions (nanograms per joule (ng/J) or lb/MMBtu heat input) that would result from combusting fuel in an uncleaned state and without using emission control systems.

Process heater means a device that is primarily used to heat a material to initiate or promote a chemical reaction in which the material participates as a reactant or catalyst.

Residual oil means crude oil, fuel oil that does not comply with the specifications under the definition of distillate oil, and all fuel oil numbers 4, 5, and 6, as defined by the American Society for Testing and Materials in ASTM D396 (incorporated by reference, see §60.17).

Steam generating unit means a device that combusts any fuel and produces steam or heats water or any other heat transfer medium. This term includes any duct burner that combusts fuel and is part of a combined cycle system. This term does not include process heaters as defined in this subpart.

Steam generating unit operating day means a 24-hour period between 12:00 midnight and the following midnight during which any fuel is combusted at any time in the steam generating unit. It is not necessary for fuel to be combusted continuously for the entire 24-hour period.

Wet flue gas desulfurization technology means an SO₂ control system that is located between the steam generating unit and the exhaust vent or stack, and that removes sulfur oxides from the combustion gases of the steam generating unit by contacting the combustion gases with an alkaline slurry or solution and forming a liquid material. This definition includes devices where the liquid material is subsequently converted to another form. Alkaline reagents used in wet flue gas desulfurization systems include, but are not limited to, lime, limestone, and sodium compounds.

Wet scrubber system means any emission control device that mixes an aqueous stream or slurry with the exhaust gases from a steam generating unit to control emissions of PM or SO₂.

Wood means wood, wood residue, bark, or any derivative fuel or residue thereof, in any form, including but not limited to sawdust, sanderdust, wood chips, scraps, slabs, millings, shavings, and processed pellets made from wood or other forest residues.

§ 60.42c Standard for sulfur dioxide (SO₂).

(a) Except as provided in paragraphs (b), (c), and (e) of this section, on and after the date on which the performance test is completed or required to be completed under §60.8, whichever date comes first, the owner or operator of an affected facility that combusts only coal shall neither: cause to be discharged into the atmosphere from the affected facility any gases that contain SO₂ in excess of 87 ng/J (0.20 lb/MMBtu)

heat input or 10 percent (0.10) of the potential SO₂emission rate (90 percent reduction), nor cause to be discharged into the atmosphere from the affected facility any gases that contain SO₂in excess of 520 ng/J (1.2 lb/MMBtu) heat input. If coal is combusted with other fuels, the affected facility shall neither: cause to be discharged into the atmosphere from the affected facility any gases that contain SO₂in excess of 87 ng/J (0.20 lb/MMBtu) heat input or 10 percent (0.10) of the potential SO₂emission rate (90 percent reduction), nor cause to be discharged into the atmosphere from the affected facility any gases that contain SO₂in excess of the emission limit is determined pursuant to paragraph (e)(2) of this section.

(b) Except as provided in paragraphs (c) and (e) of this section, on and after the date on which the performance test is completed or required to be completed under §60.8, whichever date comes first, the owner or operator of an affected facility that:

(1) Combusts only coal refuse alone in a fluidized bed combustion steam generating unit shall neither:

(i) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂in excess of 87 ng/J (0.20 lb/MMBtu) heat input or 20 percent (0.20) of the potential SO₂emission rate (80 percent reduction); nor

(ii) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂in excess of SO₂in excess of 520 ng/J (1.2 lb/MMBtu) heat input. If coal is fired with coal refuse, the affected facility subject to paragraph (a) of this section. If oil or any other fuel (except coal) is fired with coal refuse, the affected facility is subject to the 87 ng/J (0.20 lb/MMBtu) heat input SO₂emissions limit or the 90 percent SO₂reduction requirement specified in paragraph (a) of this section and the emission limit is determined pursuant to paragraph (e)(2) of this section.

(2) Combusts only coal and that uses an emerging technology for the control of SO₂emissions shall neither:

(i) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂in excess of 50 percent (0.50) of the potential SO₂emission rate (50 percent reduction); nor

(ii) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂in excess of 260 ng/J (0.60 lb/MMBtu) heat input. If coal is combusted with other fuels, the affected facility is subject to the 50 percent SO₂reduction requirement specified in this paragraph and the emission limit determined pursuant to paragraph (e)(2) of this section.

(c) On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that combusts coal, alone or in combination with any other fuel, and is listed in paragraphs (c)(1), (2), (3), or (4) of this section shall cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂in excess of the emission limit determined pursuant to paragraph (e)(2) of this section. Percent reduction requirements are not applicable to affected facilities under paragraphs (c)(1), (2), (3), or (4).

(1) Affected facilities that have a heat input capacity of 22 MW (75 MMBtu/hr) or less.

(2) Affected facilities that have an annual capacity for coal of 55 percent (0.55) or less and are subject to a federally enforceable requirement limiting operation of the affected facility to an annual capacity factor for coal of 55 percent (0.55) or less.

(3) Affected facilities located in a noncontinental area.

(4) Affected facilities that combust coal in a duct burner as part of a combined cycle system where 30 percent (0.30) or less of the heat entering the steam generating unit is from combustion of coal in the duct burner and 70 percent (0.70) or more of the heat entering the steam generating unit is from exhaust gases entering the duct burner.

(d) On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that combusts oil shall

cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂ in excess of 215 ng/J (0.50 lb/MMBtu) heat input; or, as an alternative, no owner or operator of an affected facility that combusts oil shall combust oil in the affected facility that contains greater than 0.5 weight percent sulfur. The percent reduction requirements are not applicable to affected facilities under this paragraph.

(e) On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that combusts coal, oil, or coal and oil with any other fuel shall cause to be discharged into the atmosphere from that affected facility any gases that contain SO₂ in excess of the following:

(1) The percent of potential SO₂ emission rate or numerical SO₂ emission rate required under paragraph (a) or (b)(2) of this section, as applicable, for any affected facility that

(i) Combusts coal in combination with any other fuel;

(ii) Has a heat input capacity greater than 22 MW (75 MMBtu/hr); and

(iii) Has an annual capacity factor for coal greater than 55 percent (0.55); and

(2) The emission limit determined according to the following formula for any affected facility that combusts coal, oil, or coal and oil with any other fuel:

$$E_s = \frac{(K_a H_a + K_b H_b + K_c H_c)}{(H_a + H_b + H_c)}$$

Where:

E_s = SO₂ emission limit, expressed in ng/J or lb/MMBtu heat input;

K_a = 520 ng/J (1.2 lb/MMBtu);

K_b = 260 ng/J (0.60 lb/MMBtu);

K_c = 215 ng/J (0.50 lb/MMBtu);

H_a = Heat input from the combustion of coal, except coal combusted in an affected facility subject to paragraph (b)(2) of this section, in Joules (J) [MMBtu];

H_b = Heat input from the combustion of coal in an affected facility subject to paragraph (b)(2) of this section, in J (MMBtu); and

H_cK_aH_b = Heat input from the combustion of oil, in J (MMBtu).

(f) Reduction in the potential SO₂ emission rate through fuel pretreatment is not credited toward the percent reduction requirement under paragraph (b)(2) of this section unless:

(1) Fuel pretreatment results in a 50 percent (0.50) or greater reduction in the potential SO₂ emission rate; and

(2) Emissions from the pretreated fuel (without either combustion or post-combustion SO₂ control) are equal to or less than the emission limits specified under paragraph (b)(2) of this section.

(g) Except as provided in paragraph (h) of this section, compliance with the percent reduction requirements, fuel oil sulfur limits, and emission limits of this section shall be determined on a 30-day rolling average basis.

(h) For affected facilities listed under paragraphs (h)(1), (2), or (3) of this section, compliance with the emission limits or fuel oil sulfur limits under this section may be determined based on a certification from the fuel supplier, as described under §60.48c(f), as applicable.

(1) Distillate oil-fired affected facilities with heat input capacities between 2.9 and 29 MW (10 and 100 MMBtu/hr).

(2) Residual oil-fired affected facilities with heat input capacities between 2.9 and 8.7 MW (10 and 30 MMBtu/hr).

(3) Coal-fired facilities with heat input capacities between 2.9 and 8.7 MW (10 and 30 MMBtu/hr).

(i) The SO₂ emission limits, fuel oil sulfur limits, and percent reduction requirements under this section apply at all times, including periods of startup, shutdown, and malfunction.

(j) Only the heat input supplied to the affected facility from the combustion of coal and oil is counted under this section. No credit is provided for the heat input to the affected facility from wood or other fuels or for heat derived from exhaust gases from other sources, such as stationary gas turbines, internal combustion engines, and kilns.

§ 60.43c Standard for particulate matter (PM).

(a) On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that commenced construction, reconstruction, or modification on or before February 28, 2005, that combusts coal or combusts mixtures of coal with other fuels and has a heat input capacity of 8.7 MW (30 MMBtu/hr) or greater, shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in excess of the following emission limits:

(1) 22 ng/J (0.051 lb/MMBtu) heat input if the affected facility combusts only coal, or combusts coal with other fuels and has an annual capacity factor for the other fuels of 10 percent (0.10) or less.

(2) 43 ng/J (0.10 lb/MMBtu) heat input if the affected facility combusts coal with other fuels, has an annual capacity factor for the other fuels greater than 10 percent (0.10), and is subject to a federally enforceable requirement limiting operation of the affected facility to an annual capacity factor greater than 10 percent (0.10) for fuels other than coal.

(b) On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that commenced construction, reconstruction, or modification on or before February 28, 2005, that combusts wood or combusts mixtures of wood with other fuels (except coal) and has a heat input capacity of 8.7 MW (30 MMBtu/hr) or greater, shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in excess of the following emissions limits:

(1) 43 ng/J (0.10 lb/MMBtu) heat input if the affected facility has an annual capacity factor for wood greater than 30 percent (0.30); or

(2) 130 ng/J (0.30 lb/MMBtu) heat input if the affected facility has an annual capacity factor for wood of 30 percent (0.30) or less and is subject to a federally enforceable requirement limiting operation of the affected facility to an annual capacity factor for wood of 30 percent (0.30) or less.

(c) On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that combusts coal,

wood, or oil and has a heat input capacity of 8.7 MW (30 MMBtu/hr) or greater shall cause to be discharged into the atmosphere from that affected facility any gases that exhibit greater than 20 percent opacity (6-minute average), except for one 6-minute period per hour of not more than 27 percent opacity.

(d) The PM and opacity standards under this section apply at all times, except during periods of startup, shutdown, or malfunction.

(e)(1) On and after the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that commences construction, reconstruction, or modification after February 28, 2005, and that combusts coal, oil, wood, a mixture of these fuels, or a mixture of these fuels with any other fuels and has a heat input capacity of 8.7 MW (30 MMBtu/hr) or greater shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in excess of 13 ng/J (0.030 lb/MMBtu) heat input, except as provided in paragraphs (e)(2), (e)(3), and (e)(4) of this section.

(2) As an alternative to meeting the requirements of paragraph (e)(1) of this section, the owner or operator of an affected facility for which modification commenced after February 28, 2005, may elect to meet the requirements of this paragraph. On and after the date on which the initial performance test is completed or required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that commences modification after February 28, 2005 shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in excess of both:

(i) 22 ng/J (0.051 lb/MMBtu) heat input derived from the combustion of coal, oil, wood, a mixture of these fuels, or a mixture of these fuels with any other fuels; and

(ii) 0.2 percent of the combustion concentration (99.8 percent reduction) when combusting coal, oil, wood, a mixture of these fuels, or a mixture of these fuels with any other fuels.

(3) On and after the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility that commences modification after February 28, 2005, and that combusts over 30 percent wood (by heat input) on an annual basis and has a heat input capacity of 8.7 MW (30 MMBtu/hr) or greater shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in excess of 43 ng/J (0.10 lb/MMBtu) heat input.

(4) On and after the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, an owner or operator of an affected facility that commences construction, reconstruction, or modification after February 28, 2005, and that combusts only oil that contains no more than 0.50 weight percent sulfur or a mixture of 0.50 weight percent sulfur oil with other fuels not subject to a PM standard under §60.43c and not using a post-combustion technology (except a wet scrubber) to reduce PM or SO₂ emissions is not subject to the PM limit in this section.

§ 60.44c Compliance and performance test methods and procedures for sulfur dioxide.

(a) Except as provided in paragraphs (g) and (h) of this section and §60.8(b), performance tests required under §60.8 shall be conducted following the procedures specified in paragraphs (b), (c), (d), (e), and (f) of this section, as applicable. Section 60.8(f) does not apply to this section. The 30-day notice required in §60.8(d) applies only to the initial performance test unless otherwise specified by the Administrator.

(b) The initial performance test required under §60.8 shall be conducted over 30 consecutive operating days of the steam generating unit. Compliance with the percent reduction requirements and SO₂ emission limits under §60.42c shall be determined using a 30-day average. The first operating day included in the initial performance test shall be scheduled within 30 days after achieving the maximum production rate at which the affect facility will be operated, but not later than 180 days after the initial startup of the facility. The steam generating unit load during the 30-day period does not have to be the maximum design heat input capacity, but must be representative of future operating conditions.

(c) After the initial performance test required under paragraph (b) of this section and §60.8, compliance with the percent reduction requirements and SO₂emission limits under §60.42c is based on the average percent reduction and the average SO₂emission rates for 30 consecutive steam generating unit operating days. A separate performance test is completed at the end of each steam generating unit operating day, and a new 30-day average percent reduction and SO₂emission rate are calculated to show compliance with the standard.

(d) If only coal, only oil, or a mixture of coal and oil is combusted in an affected facility, the procedures in Method 19 of appendix A of this part are used to determine the hourly SO₂emission rate (E_{ho}) and the 30-day average SO₂emission rate (E_{ao}). The hourly averages used to compute the 30-day averages are obtained from the CEMS. Method 19 of appendix A of this part shall be used to calculate E_{ao}when using daily fuel sampling or Method 6B of appendix A of this part.

(e) If coal, oil, or coal and oil are combusted with other fuels:

(1) An adjusted E_{ho}(E_{ho0}) is used in Equation 19–19 of Method 19 of appendix A of this part to compute the adjusted E_{ao}(E_{ao0}). The E_{ho0} is computed using the following formula:

$$E_{ho0} = \frac{E_{ho} - E_w(1 - X_k)}{X_k}$$

Where:

E_{ho0} = Adjusted E_{ho}, ng/J (lb/MMBtu);

E_{ho}= Hourly SO₂emission rate, ng/J (lb/MMBtu);

E_w= SO₂concentration in fuels other than coal and oil combusted in the affected facility, as determined by fuel sampling and analysis procedures in Method 9 of appendix A of this part, ng/J (lb/MMBtu). The value E_wfor each fuel lot is used for each hourly average during the time that the lot is being combusted. The owner or operator does not have to measure E_wif the owner or operator elects to assume E_w= 0.

X_k= Fraction of the total heat input from fuel combustion derived from coal and oil, as determined by applicable procedures in Method 19 of appendix A of this part.

(2) The owner or operator of an affected facility that qualifies under the provisions of §60.42c(c) or (d) (where percent reduction is not required) does not have to measure the parameters E_wor X_kif the owner or operator of the affected facility elects to measure emission rates of the coal or oil using the fuel sampling and analysis procedures under Method 19 of appendix A of this part.

(f) Affected facilities subject to the percent reduction requirements under §60.42c(a) or (b) shall determine compliance with the SO₂emission limits under §60.42c pursuant to paragraphs (d) or (e) of this section, and shall determine compliance with the percent reduction requirements using the following procedures:

(1) If only coal is combusted, the percent of potential SO₂emission rate is computed using the following formula:

$$\%P_r = 100 \left(1 - \frac{\%R_z}{100} \right) \left(1 - \frac{\%R_f}{100} \right)$$

Where:

%P_s= Potential SO₂emission rate, in percent;

%R_g= SO₂removal efficiency of the control device as determined by Method 19 of appendix A of this part, in percent; and

%R_f= SO₂removal efficiency of fuel pretreatment as determined by Method 19 of appendix A of this part, in percent.

(2) If coal, oil, or coal and oil are combusted with other fuels, the same procedures required in paragraph (f)(1) of this section are used, except as provided for in the following:

(i) To compute the %P_s, an adjusted %R_g(%R_{g,o}) is computed from E_{ao} from paragraph (e)(1) of this section and an adjusted average SO₂inlet rate (E_{ai,o}) using the following formula:

$$\%R_{g,o} = 100 \left(1 - \frac{E_{ao}}{E_{ai}} \right)$$

Where:

%R_{g,o} = Adjusted %R_g, in percent;

E_{ao} = Adjusted E_{ao}, ng/J (lb/MMBtu); and

E_{ai,o} = Adjusted average SO₂inlet rate, ng/J (lb/MMBtu).

(ii) To compute E_{ai,o}, an adjusted hourly SO₂inlet rate (E_{hi,o}) is used. The E_{hi,o} is computed using the following formula:

$$E_{hi,o} = \frac{E_{hi} - E_w(1 - X_k)}{X_k}$$

Where:

E_{hi,o} = Adjusted E_{hi}, ng/J (lb/MMBtu);

E_{hi}= Hourly SO₂inlet rate, ng/J (lb/MMBtu);

E_w= SO₂concentration in fuels other than coal and oil combusted in the affected facility, as determined by fuel sampling and analysis procedures in Method 19 of appendix A of this part, ng/J (lb/MMBtu). The value E_wfor each fuel lot is used for each hourly average during the time that the lot is being combusted. The owner or operator does not have to measure E_wif the owner or operator elects to assume E_w= 0; and

X_k= Fraction of the total heat input from fuel combustion derived from coal and oil, as determined by applicable procedures in Method 19 of appendix A of this part.

(g) For oil-fired affected facilities where the owner or operator seeks to demonstrate compliance with the fuel oil sulfur limits under §60.42c based on shipment fuel sampling, the initial performance test shall consist of sampling and analyzing the oil in the initial tank of oil to be fired in the steam generating unit to demonstrate that the oil contains 0.5 weight percent sulfur or less. Thereafter, the owner or operator of the affected facility

shall sample the oil in the fuel tank after each new shipment of oil is received, as described under §60.46c(d)(2).

(h) For affected facilities subject to §60.42c(h)(1), (2), or (3) where the owner or operator seeks to demonstrate compliance with the SO₂ standards based on fuel supplier certification, the performance test shall consist of the certification, the certification from the fuel supplier, as described under §60.48c(f), as applicable.

(i) The owner or operator of an affected facility seeking to demonstrate compliance with the SO₂ standards under §60.42c(c)(2) shall demonstrate the maximum design heat input capacity of the steam generating unit by operating the steam generating unit at this capacity for 24 hours. This demonstration shall be made during the initial performance test, and a subsequent demonstration may be requested at any other time. If the demonstrated 24-hour average firing rate for the affected facility is less than the maximum design heat input capacity stated by the manufacturer of the affected facility, the demonstrated 24-hour average firing rate shall be used to determine the annual capacity factor for the affected facility; otherwise, the maximum design heat input capacity provided by the manufacturer shall be used.

(j) The owner or operator of an affected facility shall use all valid SO₂ emissions data in calculating %P_s and E_{h_o} under paragraphs (d), (e), or (f) of this section, as applicable, whether or not the minimum emissions data requirements under §60.46c(f) are achieved. All valid emissions data, including valid data collected during periods of startup, shutdown, and malfunction, shall be used in calculating %P_s or E_{h_o} pursuant to paragraphs (d), (e), or (f) of this section, as applicable.

§ 60.45c Compliance and performance test methods and procedures for particulate matter.

(a) The owner or operator of an affected facility subject to the PM and/or opacity standards under §60.43c shall conduct an initial performance test as required under §60.8, and shall conduct subsequent performance tests as requested by the Administrator, to determine compliance with the standards using the following procedures and reference methods, except as specified in paragraph (c) of this section.

(1) Method 1 of appendix A of this part shall be used to select the sampling site and the number of traverse sampling points.

(2) Method 3 of appendix A of this part shall be used for gas analysis when applying Method 5, 5B, or 17 of appendix A of this part.

(3) Method 5, 5B, or 17 of appendix A of this part shall be used to measure the concentration of PM as follows:

(i) Method 5 of appendix A of this part may be used only at affected facilities without wet scrubber systems.

(ii) Method 17 of appendix A of this part may be used at affected facilities with or without wet scrubber systems provided the stack gas temperature does not exceed a temperature of 160 °C (320 °F). The procedures of Sections 8.1 and 11.1 of Method 5B of appendix A of this part may be used in Method 17 of appendix A of this part only if Method 17 of appendix A of this part is used in conjunction with a wet scrubber system. Method 17 of appendix A of this part shall not be used in conjunction with a wet scrubber system if the effluent is saturated or laden with water droplets.

(iii) Method 5B of appendix A of this part may be used in conjunction with a wet scrubber system.

(4) The sampling time for each run shall be at least 120 minutes and the minimum sampling volume shall be 1.7 dry standard cubic meters (dscm) [60 dry standard cubic feet (dscf)] except that smaller sampling times or volumes may be approved by the Administrator when necessitated by process variables or other factors.

(5) For Method 5 or 5B of appendix A of this part, the temperature of the sample gas in the probe and filter holder shall be monitored and maintained at 160 ± 14 °C (320 ± 25 °F).

(6) For determination of PM emissions, an oxygen (O₂) or carbon dioxide (CO₂) measurement shall be obtained simultaneously with each run of Method 5, 5B, or 17 of appendix A of this part by traversing the duct at the same sampling location.

(7) For each run using Method 5, 5B, or 17 of appendix A of this part, the emission rates expressed in ng/J (lb/MMBtu) heat input shall be determined using:

(i) The O₂ or CO₂ measurements and PM measurements obtained under this section, (ii) The dry basis F factor, and

(iii) The dry basis emission rate calculation procedure contained in Method 19 of appendix A of this part.

(8) Method 9 of appendix A of this part (6-minute average of 24 observations) shall be used for determining the opacity of stack emissions.

(b) The owner or operator of an affected facility seeking to demonstrate compliance with the PM standards under §60.43c(b)(2) shall demonstrate the maximum design heat input capacity of the steam generating unit by operating the steam generating unit at this capacity for 24 hours. This demonstration shall be made during the initial performance test, and a subsequent demonstration may be requested at any other time. If the demonstrated 24-hour average firing rate for the affected facility is less than the maximum design heat input capacity stated by the manufacturer of the affected facility, the demonstrated 24-hour average firing rate shall be used to determine the annual capacity factor for the affected facility; otherwise, the maximum design heat input capacity provided by the manufacturer shall be used.

(c) In place of PM testing with EPA Reference Method 5, 5B, or 17 of appendix A of this part, an owner or operator may elect to install, calibrate, maintain, and operate a CEMS for monitoring PM emissions discharged to the atmosphere and record the output of the system. The owner or operator of an affected facility who elects to continuously monitor PM emissions instead of conducting performance testing using EPA Method 5, 5B, or 17 of appendix A of this part shall install, calibrate, maintain, and operate a CEMS and shall comply with the requirements specified in paragraphs (c)(1) through (c)(13) of this section.

(1) Notify the Administrator 1 month before starting use of the system.

(2) Notify the Administrator 1 month before stopping use of the system.

(3) The monitor shall be installed, evaluated, and operated in accordance with §60.13 of subpart A of this part.

(4) The initial performance evaluation shall be completed no later than 180 days after the date of initial startup of the affected facility, as specified under §60.8 of subpart A of this part or within 180 days of notification to the Administrator of use of CEMS if the owner or operator was previously determining compliance by Method 5, 5B, or 17 of appendix A of this part performance tests, whichever is later.

(5) The owner or operator of an affected facility shall conduct an initial performance test for PM emissions as required under §60.8 of subpart A of this part. Compliance with the PM emission limit shall be determined by using the CEMS specified in paragraph (d) of this section to measure PM and calculating a 24-hour block arithmetic average emission concentration using EPA Reference Method 19 of appendix A of this part, section 4.1.

(6) Compliance with the PM emission limit shall be determined based on the 24-hour daily (block) average of the hourly arithmetic average emission concentrations using CEMS outlet data.

(7) At a minimum, valid CEMS hourly averages shall be obtained as specified in paragraph (d)(7)(i) of this section for 75 percent of the total operating hours per 30-day rolling average.

(i) At least two data points per hour shall be used to calculate each 1-hour arithmetic average.

(ii) [Reserved]

(8) The 1-hour arithmetic averages required under paragraph (d)(7) of this section shall be expressed in ng/J or lb/MMBtu heat input and shall be used to calculate the boiler operating day daily arithmetic average emission concentrations. The 1-hour arithmetic averages shall be calculated using the data points required under §60.13(e)(2) of subpart A of this part.

(9) All valid CEMS data shall be used in calculating average emission concentrations even if the minimum CEMS data requirements of paragraph (d)(7) of this section are not met.

(10) The CEMS shall be operated according to Performance Specification 11 in appendix B of this part.

(11) During the correlation testing runs of the CEMS required by Performance Specification 11 in appendix B of this part, PM and O₂(or CO₂) data shall be collected concurrently (or within a 30- to 60-minute period) by both the continuous emission monitors and the test methods specified in paragraph (d)(7)(i) of this section.

(i) For PM, EPA Reference Method 5, 5B, or 17 of appendix A of this part shall be used.

(ii) For O₂(or CO₂), EPA reference Method 3, 3A, or 3B of appendix A of this part, as applicable shall be used.

(12) Quarterly accuracy determinations and daily calibration drift tests shall be performed in accordance with procedure 2 in appendix F of this part. Relative Response Audit's must be performed annually and Response Correlation Audits must be performed every 3 years.

(13) When PM emissions data are not obtained because of CEMS breakdowns, repairs, calibration checks, and zero and span adjustments, emissions data shall be obtained by using other monitoring systems as approved by the Administrator or EPA Reference Method 19 of appendix A of this part to provide, as necessary, valid emissions data for a minimum of 75 percent of total operating hours on a 30-day rolling average.

(d) The owner or operator of an affected facility seeking to demonstrate compliance under §60.43c(e)(4) shall follow the applicable procedures under §60.48c(f). For residual oil-fired affected facilities, fuel supplier certifications are only allowed for facilities with heat input capacities between 2.9 and 8.7 MW (10 to 30 MMBtu/hr).

§ 60.46c Emission monitoring for sulfur dioxide.

(a) Except as provided in paragraphs (d) and (e) of this section, the owner or operator of an affected facility subject to the SO₂emission limits under §60.42c shall install, calibrate, maintain, and operate a CEMS for measuring SO₂concentrations and either O₂or CO₂concentrations at the outlet of the SO₂control device (or the outlet of the steam generating unit if no SO₂control device is used), and shall record the output of the system. The owner or operator of an affected facility subject to the percent reduction requirements under §60.42c shall measure SO₂concentrations and either O₂or CO₂concentrations at both the inlet and outlet of the SO₂control device.

(b) The 1-hour average SO₂emission rates measured by a CEMS shall be expressed in ng/J or lb/MMBtu heat input and shall be used to calculate the average emission rates under §60.42c. Each 1-hour average SO₂emission rate must be based on at least 30 minutes of operation, and shall be calculated using the data points required under §60.13(h)(2). Hourly SO₂emission rates are not calculated if the affected facility is

operated less than 30 minutes in a 1-hour period and are not counted toward determination of a steam generating unit operating day.

(c) The procedures under §60.13 shall be followed for installation, evaluation, and operation of the CEMS.

(1) All CEMS shall be operated in accordance with the applicable procedures under Performance Specifications 1, 2, and 3 of appendix B of this part.

(2) Quarterly accuracy determinations and daily calibration drift tests shall be performed in accordance with Procedure 1 of appendix F of this part.

(3) For affected facilities subject to the percent reduction requirements under §60.42c, the span value of the SO₂CEMS at the inlet to the SO₂control device shall be 125 percent of the maximum estimated hourly potential SO₂emission rate of the fuel combusted, and the span value of the SO₂CEMS at the outlet from the SO₂control device shall be 50 percent of the maximum estimated hourly potential SO₂emission rate of the fuel combusted.

(4) For affected facilities that are not subject to the percent reduction requirements of §60.42c, the span value of the SO₂CEMS at the outlet from the SO₂control device (or outlet of the steam generating unit if no SO₂control device is used) shall be 125 percent of the maximum estimated hourly potential SO₂emission rate of the fuel combusted.

(d) As an alternative to operating a CEMS at the inlet to the SO₂control device (or outlet of the steam generating unit if no SO₂control device is used) as required under paragraph (a) of this section, an owner or operator may elect to determine the average SO₂emission rate by sampling the fuel prior to combustion. As an alternative to operating a CEMS at the outlet from the SO₂control device (or outlet of the steam generating unit if no SO₂control device is used) as required under paragraph (a) of this section, an owner or operator may elect to determine the average SO₂emission rate by using Method 6B of appendix A of this part. Fuel sampling shall be conducted pursuant to either paragraph (d)(1) or (d)(2) of this section. Method 6B of appendix A of this part shall be conducted pursuant to paragraph (d)(3) of this section.

(1) For affected facilities combusting coal or oil, coal or oil samples shall be collected daily in an as-fired condition at the inlet to the steam generating unit and analyzed for sulfur content and heat content according to the Method 19 of appendix A of this part. Method 19 of appendix A of this part provides procedures for converting these measurements into the format to be used in calculating the average SO₂input rate.

(2) As an alternative fuel sampling procedure for affected facilities combusting oil, oil samples may be collected from the fuel tank for each steam generating unit immediately after the fuel tank is filled and before any oil is combusted. The owner or operator of the affected facility shall analyze the oil sample to determine the sulfur content of the oil. If a partially empty fuel tank is refilled, a new sample and analysis of the fuel in the tank would be required upon filling. Results of the fuel analysis taken after each new shipment of oil is received shall be used as the daily value when calculating the 30-day rolling average until the next shipment is received. If the fuel analysis shows that the sulfur content in the fuel tank is greater than 0.5 weight percent sulfur, the owner or operator shall ensure that the sulfur content of subsequent oil shipments is low enough to cause the 30-day rolling average sulfur content to be 0.5 weight percent sulfur or less.

(3) Method 6B of appendix A of this part may be used in lieu of CEMS to measure SO₂at the inlet or outlet of the SO₂control system. An initial stratification test is required to verify the adequacy of the Method 6B of appendix A of this part sampling location. The stratification test shall consist of three paired runs of a suitable SO₂and CO₂measurement train operated at the candidate location and a second similar train operated according to the procedures in §3.2 and the applicable procedures in section 7 of Performance Specification 2 of appendix B of this part. Method 6B of appendix A of this part, Method 6A of appendix A of this part, or a combination of Methods 6 and 3 of appendix A of this part or Methods 6C and 3A of appendix A of this part are suitable measurement techniques. If Method 6B of appendix A of this part is used for the second train, sampling time and timer operation may be adjusted for the stratification test as long as an adequate sample volume is collected; however, both sampling trains are to be operated similarly. For the location to be adequate for Method 6B of appendix A of this part 24-hour tests, the mean of the absolute difference between the three paired runs must be less than 10 percent (0.10).

(e) The monitoring requirements of paragraphs (a) and (d) of this section shall not apply to affected facilities subject to §60.42c(h) (1), (2), or (3) where the owner or operator of the affected facility seeks to demonstrate compliance with the SO₂ standards based on fuel supplier certification, as described under §60.48c(f), as applicable.

(f) The owner or operator of an affected facility operating a CEMS pursuant to paragraph (a) of this section, or conducting as-fired fuel sampling pursuant to paragraph (d)(1) of this section, shall obtain emission data for at least 75 percent of the operating hours in at least 22 out of 30 successive steam generating unit operating days. If this minimum data requirement is not met with a single monitoring system, the owner or operator of the affected facility shall supplement the emission data with data collected with other monitoring systems as approved by the Administrator.

§ 60.47c Emission monitoring for particulate matter.

(a) Except as provided in paragraphs (c), (d), (e), and (f) of this section, the owner or operator of an affected facility combusting coal, oil, or wood that is subject to the opacity standards under §60.43c shall install, calibrate, maintain, and operate a COMS for measuring the opacity of the emissions discharged to the atmosphere and record the output of the system.

(b) All COMS for measuring opacity shall be operated in accordance with the applicable procedures under Performance Specification 1 of appendix B of this part. The span value of the opacity COMS shall be between 60 and 80 percent.

(c) Affected facilities that burn only distillate oil that contains no more than 0.5 weight percent sulfur and/or liquid or gaseous fuels with potential sulfur dioxide emission rates of 26 ng/J (0.06 lb/MMBtu) heat input or less and that do not use a post-combustion technology to reduce SO₂ or PM emissions are not required to operate a CEMS for measuring opacity if they follow the applicable procedures under §60.48c(f).

(d) Owners or operators complying with the PM emission limit by using a PM CEMS monitor instead of monitoring opacity must calibrate, maintain, and operate a CEMS, and record the output of the system, for PM emissions discharged to the atmosphere as specified in §60.45c(d). The CEMS specified in paragraph §60.45c(d) shall be operated and data recorded during all periods of operation of the affected facility except for CEMS breakdowns and repairs. Data is recorded during calibration checks, and zero and span adjustments.

(e) An affected facility that does not use post-combustion technology (except a wet scrubber) for reducing PM, SO₂, or carbon monoxide (CO) emissions, burns only gaseous fuels or fuel oils that contain less than or equal to 0.5 weight percent sulfur, and is operated such that emissions of CO to the atmosphere from the affected facility are maintained at levels less than or equal to 0.15 lb/MMBtu on a boiler operating day average basis is not required to operate a COMS for measuring opacity. Owners and operators of affected facilities electing to comply with this paragraph must demonstrate compliance according to the procedures specified in paragraphs (e)(1) through (4) of this section.

(1) You must monitor CO emissions using a CEMS according to the procedures specified in paragraphs (e)(1)(i) through (iv) of this section.

(i) The CO CEMS must be installed, certified, maintained, and operated according to the provisions in §60.58b(i)(3) of subpart Eb of this part.

(ii) Each 1-hour CO emissions average is calculated using the data points generated by the CO CEMS expressed in parts per million by volume corrected to 3 percent oxygen (dry basis).

(iii) At a minimum, valid 1-hour CO emissions averages must be obtained for at least 90 percent of the operating hours on a 30-day rolling average basis. At least two data points per hour must be used to calculate each 1-hour average.

(iv) Quarterly accuracy determinations and daily calibration drift tests for the CO CEMS must be performed in accordance with procedure 1 in appendix F of this part.

(2) You must calculate the 1-hour average CO emissions levels for each steam generating unit operating day by multiplying the average hourly CO output concentration measured by the CO CEMS times the corresponding average hourly flue gas flow rate and divided by the corresponding average hourly heat input to the affected source. The 24-hour average CO emission level is determined by calculating the arithmetic average of the hourly CO emission levels computed for each steam generating unit operating day.

(3) You must evaluate the preceding 24-hour average CO emission level each steam generating unit operating day excluding periods of affected source startup, shutdown, or malfunction. If the 24-hour average CO emission level is greater than 0.15 lb/MMBtu, you must initiate investigation of the relevant equipment and control systems within 24 hours of the first discovery of the high emission incident and, take the appropriate corrective action as soon as practicable to adjust control settings or repair equipment to reduce the 24-hour average CO emission level to 0.15 lb/MMBtu or less.

(4) You must record the CO measurements and calculations performed according to paragraph (e) of this section and any corrective actions taken. The record of corrective action taken must include the date and time during which the 24-hour average CO emission level was greater than 0.15 lb/MMBtu, and the date, time, and description of the corrective action.

(f) An affected facility that burns only gaseous fuels or fuel oils that contain less than or equal to 0.5 weight percent sulfur and operates according to a written site-specific monitoring plan approved by the appropriate delegated permitting authority is not required to operate a COMS for measuring opacity. This monitoring plan must include procedures and criteria for establishing and monitoring specific parameters for the affected facility indicative of compliance with the opacity standard.

§ 60.48c Reporting and recordkeeping requirements.

(a) The owner or operator of each affected facility shall submit notification of the date of construction or reconstruction and actual startup, as provided by §60.7 of this part. This notification shall include:

(1) The design heat input capacity of the affected facility and identification of fuels to be combusted in the affected facility.

(2) If applicable, a copy of any federally enforceable requirement that limits the annual capacity factor for any fuel or mixture of fuels under §60.42c, or §60.43c.

(3) The annual capacity factor at which the owner or operator anticipates operating the affected facility based on all fuels fired and based on each individual fuel fired.

(4) Notification if an emerging technology will be used for controlling SO₂ emissions. The Administrator will examine the description of the control device and will determine whether the technology qualifies as an emerging technology. In making this determination, the Administrator may require the owner or operator of the affected facility to submit additional information concerning the control device. The affected facility is subject to the provisions of §60.42c(a) or (b)(1), unless and until this determination is made by the Administrator.

(b) The owner or operator of each affected facility subject to the SO₂ emission limits of §60.42c, or the PM or opacity limits of §60.43c, shall submit to the Administrator the performance test data from the initial and any subsequent performance tests and, if applicable, the performance evaluation of the CEMS and/or COMS using the applicable performance specifications in appendix B of this part.

(c) The owner or operator of each coal-fired, oil-fired, or wood-fired affected facility subject to the opacity limits under §60.43c(c) shall submit excess emission reports for any excess emissions from the affected facility that occur during the reporting period.

(d) The owner or operator of each affected facility subject to the SO₂ emission limits, fuel oil sulfur limits, or percent reduction requirements under §60.42c shall submit reports to the Administrator.

(e) The owner or operator of each affected facility subject to the SO₂ emission limits, fuel oil sulfur limits, or percent reduction requirements under §60.42c shall keep records and submit reports as required under paragraph (d) of this section, including the following information, as applicable.

(1) Calendar dates covered in the reporting period.

(2) Each 30-day average SO₂ emission rate (ng/J or lb/MMBtu), or 30-day average sulfur content (weight percent), calculated during the reporting period, ending with the last 30-day period; reasons for any noncompliance with the emission standards; and a description of corrective actions taken.

(3) Each 30-day average percent of potential SO₂ emission rate calculated during the reporting period, ending with the last 30-day period; reasons for any noncompliance with the emission standards; and a description of the corrective actions taken.

(4) Identification of any steam generating unit operating days for which SO₂ or diluent (O₂ or CO₂) data have not been obtained by an approved method for at least 75 percent of the operating hours; justification for not obtaining sufficient data; and a description of corrective actions taken.

(5) Identification of any times when emissions data have been excluded from the calculation of average emission rates; justification for excluding data; and a description of corrective actions taken if data have been excluded for periods other than those during which coal or oil were not combusted in the steam generating unit.

(6) Identification of the F factor used in calculations, method of determination, and type of fuel combusted.

(7) Identification of whether averages have been obtained based on CEMS rather than manual sampling methods.

(8) If a CEMS is used, identification of any times when the pollutant concentration exceeded the full span of the CEMS.

(9) If a CEMS is used, description of any modifications to the CEMS that could affect the ability of the CEMS to comply with Performance Specifications 2 or 3 of appendix B of this part.

(10) If a CEMS is used, results of daily CEMS drift tests and quarterly accuracy assessments as required under appendix F, Procedure 1 of this part.

(11) If fuel supplier certification is used to demonstrate compliance, records of fuel supplier certification is used to demonstrate compliance, records of fuel supplier certification as described under paragraph (f)(1), (2), (3), or (4) of this section, as applicable. In addition to records of fuel supplier certifications, the report shall include a certified statement signed by the owner or operator of the affected facility that the records of fuel supplier certifications submitted represent all of the fuel combusted during the reporting period.

(f) Fuel supplier certification shall include the following information:

(1) For distillate oil:

(i) The name of the oil supplier;

(ii) A statement from the oil supplier that the oil complies with the specifications under the definition of distillate oil in §60.41c; and

(iii) The sulfur content of the oil.

(2) For residual oil:

(i) The name of the oil supplier;

(ii) The location of the oil when the sample was drawn for analysis to determine the sulfur content of the oil, specifically including whether the oil was sampled as delivered to the affected facility, or whether the sample was drawn from oil in storage at the oil supplier's or oil refiner's facility, or other location;

(iii) The sulfur content of the oil from which the shipment came (or of the shipment itself); and

(iv) The method used to determine the sulfur content of the oil.

(3) For coal:

(i) The name of the coal supplier;

(ii) The location of the coal when the sample was collected for analysis to determine the properties of the coal, specifically including whether the coal was sampled as delivered to the affected facility or whether the sample was collected from coal in storage at the mine, at a coal preparation plant, at a coal supplier's facility, or at another location. The certification shall include the name of the coal mine (and coal seam), coal storage facility, or coal preparation plant (where the sample was collected);

(iii) The results of the analysis of the coal from which the shipment came (or of the shipment itself) including the sulfur content, moisture content, ash content, and heat content; and

(iv) The methods used to determine the properties of the coal.

(4) For other fuels:

(i) The name of the supplier of the fuel;

(ii) The potential sulfur emissions rate of the fuel in ng/J heat input; and

(iii) The method used to determine the potential sulfur emissions rate of the fuel.

(g)(1) Except as provided under paragraphs (g)(2) and (g)(3) of this section, the owner or operator of each affected facility shall record and maintain records of the amount of each fuel combusted during each operating day.

(2) As an alternative to meeting the requirements of paragraph (g)(1) of this section, the owner or operator of an affected facility that combusts only natural gas, wood, fuels using fuel certification in §60.48c(f) to demonstrate compliance with the SO₂ standard, fuels not subject to an emissions standard (excluding opacity), or a mixture of these fuels may elect to record and maintain records of the amount of each fuel combusted during each calendar month.

(3) As an alternative to meeting the requirements of paragraph (g)(1) of this section, the owner or operator of an affected facility or multiple affected facilities located on a contiguous property unit where the only fuels combusted in any steam generating unit (including steam generating units not subject to this subpart) at that property are natural gas, wood, distillate oil meeting the most current requirements in §60.42C to use fuel certification to demonstrate compliance with the SO₂ standard, and/or fuels, excluding coal and residual oil, not subject to an emissions standard (excluding opacity) may elect to record and maintain records of the total amount of each steam generating unit fuel delivered to that property during each calendar month.

(h) The owner or operator of each affected facility subject to a federally enforceable requirement limiting the annual capacity factor for any fuel or mixture of fuels under §60.42c or §60.43c shall calculate the annual capacity factor individually for each fuel combusted. The annual capacity factor is determined on a 12-month rolling average basis with a new annual capacity factor calculated at the end of the calendar month.

(i) All records required under this section shall be maintained by the owner or operator of the affected facility for a period of two years following the date of such record.

(j) The reporting period for the reports required under this subpart is each six-month period. All reports shall be submitted to the Administrator and shall be postmarked by the 30th day following the end of the reporting period.