



# 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](http://www.idem.IN.gov)

TO: Interested Parties / Applicant

DATE: January 5, 2010

RE: Schwarz Pharma USA, Inc. / 071 - 28749 - 00023

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

## Notice of Decision – Approval

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 326 IAC 2, this approval was effective immediately upon submittal of the application.

If you wish to challenge this decision, IC 4-21.5-3-7 requires 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 from 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-AM.dot12/3/07



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January 5, 2010

Mr. Dwight Howard  
Schwarz Pharma Manufacturing, Inc.  
1101 C Avenue West  
Seymour, IN 47274

Re: 071-28749-00023  
First Administrative Amendment to  
Part 70 Renewal No.: T 071-23273-00023

Dear Mr. Howard:

Schwarz Pharma Manufacturing, Inc. was issued a Part 70 Operating Permit Renewal on May 2, 2008 for a stationary batch pharmaceutical facility producing liquid, capsule, and tablet pharmaceuticals located at 1101 C Avenue West, Seymour Indiana 47274. A letter requesting changes to this permit was received on December 15, 2009. The source requested that the permit be updated to include the installation of one (1) new aqueous based Tablet Hi-Coater unit, equipped with a dust collector. Pursuant to 326 IAC 2-7-11(a)(8), this change to the permit qualifies as an administrative permit amendment, since it is a revision that incorporates an exempt unit pursuant to 326 IAC 2-1.1-3.

Pursuant to the provisions of 326 IAC 2-7-11, the permit is hereby administratively amended as follows with deleted language as ~~strikeouts~~ and new language **bolded**:

A.2 Emission Units and Pollution Control Equipment Summary  
[326 IAC 2-7-4(c)(3)][326 IAC 2-7-5(15)]

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

- .....
- (b) One (1) tablet manufacturing department, constructed in 1993, **modified in 2010**, consisting of the following:
- (1) One (1) granulation department consisting of various mixing and milling operations with drying operations performed by four (4) steam heated ovens. Particulate emissions from the mixing and milling operations are controlled by a dust collector, identified as EFDC1.
  - (2) One (1) tablet compression department consisting of tablet pressing and finishing equipment. Particulate emissions are controlled by two dust collectors, identified as V3 and V4.
  - (3) One (1) tablet coating department consisting of ~~three (3)~~ **four (4)** hi-coaters, equipped with ~~three (3)~~ **four (4)** dust collectors for particulate control, identified as DC04, DC05, and DC013 and **DC014**.

**SECTION D.2 EMISSIONS UNIT OPERATION CONDITIONS**

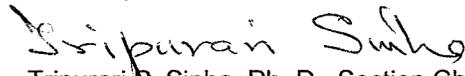
**Emissions Unit Description:**

- (b) One (1) tablet manufacturing department, constructed in 1993, **modified in 2010**, consisting of the following:
- (1) One (1) granulation department consisting of various mixing and milling operations with drying operations performed by four (4) steam heated ovens. Particulate emissions from the mixing and milling operations are controlled by a dust collector, identified as EFDC1.
  - (2) One (1) tablet compression department consisting of tablet pressing and finishing equipment. Particulate emissions are controlled by two dust collectors, identified as V3 and V4.
  - (3) One (1) tablet coating department consisting of ~~three (3)~~ **four (4)** hi-coaters, equipped with ~~three (3)~~ **four (4)** dust collectors for particulate control, identified as DC04, DC05, and DC013 and **DC014**.
- .....

All other conditions of the permit shall remain unchanged and in effect.

This decision is subject to the Indiana Administrative Orders and Procedures Act – IC 4-21.5-3-5. If you have any questions on this matter, please contact Heath Hartley, OAQ, 100 North Senate Avenue, MC 61-53, Room 1003, Indianapolis, Indiana, 46204-2251, or call at (800) 451-6027, and ask for Heath Hartley or extension (2-8217), or dial (317) 232-8217.

Sincerely,

  
Tripurari P. Sinha, Ph. D., Section Chief  
Permits Branch  
Office of Air Quality

Attachments:  
Updated Permit  
PTE Calculations

cc: File – Jackson County  
Jackson County Health Department  
U.S. EPA, Region V  
IDEM Southeast Regional Office  
Compliance and Enforcement Branch  
Permits Administration and Support Section

Mr. Jeff Siefert  
Schwarz Pharma Manufacturing, Inc.  
1101 C Avenue West  
Seymour, IN 47274

Ms. Brooke Myer  
August Mack Environmental  
1200 North Meridian Street, Suite 400  
Indianapolis, IN 46204



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## PART 70 OPERATING PERMIT RENEWAL OFFICE OF AIR QUALITY

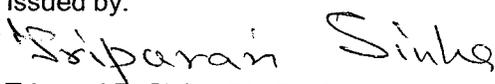
**Schwarz Pharma Manufacturing, Inc.  
1101 C Avenue West  
Seymour, Indiana 47274**

(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.

**The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. Noncompliance with any provision of this permit, except any provision specifically designated as not federally enforceable, constitutes a violation of the Clean Air Act. It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.**

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17. This permit also addresses certain new source review requirements for existing equipment and is intended to fulfill the new source review procedures pursuant to 326 IAC 2-7-10.5, applicable to those conditions

Operation Permit No.: T071-23273-00023	
Issued by/Original Signed By:  Alfred C. Dumauval Ph.D., Section Chief Permits Branch Office of Air Quality	Issuance Date: May 2, 2008  Expiration Date: May 2, 2013

First Administrative Amendment No.: 071-28749-00023	
Issued by:  Tripurari P. Sinha, Ph. D., Section Chief Permits Branch Office of Air Quality	Issuance Date:  January 5, 2010 Expiration Date: May 2, 2013

## TABLE OF CONTENTS

<b>A. SOURCE SUMMARY .....</b>	<b>5</b>
A.1 General Information [326 IAC 2-7-4(c)][326 IAC 2-7-5(15)][326 IAC 2-7-1(22)]	
A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]	
A.3 Specifically Regulated Insignificant Activities [326 IAC 2-7-1(21)][326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]	
A.4 Part 70 Permit Applicability [326 IAC 2-7-2]	
<b>B. GENERAL CONDITIONS .....</b>	<b>7</b>
B.1 Definitions [326 IAC 2-7-1]	
B.2 Permit Term [326 IAC 2-7-5(2)][326 IAC 2-1.1-9.5][326 IAC 2-7-4(a)(1)(D)] [IC 13-15-3-6(a)]	
B.3 Term of Conditions [326 IAC 2-1.1-9.5]	
B.4 Enforceability [326 IAC 2-7-7]	
B.5 Severability [326 IAC 2-7-5(5)]	
B.6 Property Rights or Exclusive Privilege [326 IAC 2-7-5(6)(D)]	
B.7 Duty to Provide Information [326 IAC 2-7-5(6)(E)]	
B.8 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]	
B.9 Annual Compliance Certification [326 IAC 2-7-6(5)]	
B.10 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)][326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]	
B.11 Emergency Provisions [326 IAC 2-7-16]	
B.12 Permit Shield [326 IAC 2-7-15][326 IAC 2-7-20][326 IAC 2-7-12]	
B.13 Prior Permits Superseded [326 IAC 2-1.1-9.5][326 IAC 2-7-10.5]	
B.14 Termination of Right to Operate [326 IAC 2-7-10][326 IAC 2-7-4(a)]	
B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-7-5(3)(C)(ii)]	
B.16 Permit Modification, Reopening, Revocation and Reissuance, or Termination [326 IAC 2-7-5(6)(C)][326 IAC 2-7-8(a)][326 IAC 2-7-9]	
B.17 Permit Renewal [326 IAC 2-7-3][326 IAC 2-7-4][326 IAC 2-7-8(e)]	
B.18 Permit Amendment or Modification [326 IAC 2-7-11][326 IAC 2-7-12]	
B.19 Permit Revision Under Economic Incentives and Other Programs [326 IAC 2-7-5(8)] [326 IAC 2-7-12(b)(2)]	
B.20 Operational Flexibility [326 IAC 2-7-20][326 IAC 2-7-10.5]	
B.21 Source Modification Requirement [326 IAC 2-7-10.5]	
B.22 Inspection and Entry [326 IAC 2-7-6][IC 13-14-2-2][IC 13-30-3-1][IC 13-17-3-2]	
B.23 Transfer of Ownership or Operational Control [326 IAC 2-7-11]	
B.24 Annual Fee Payment [326 IAC 2-7-19] [326 IAC 2-7-5(7)][326 IAC 2-1.1-7]	
B.25 Credible Evidence [326 IAC 2-7-5(3)][326 IAC 2-7-6][62 FR 8314] [326 IAC 1-1-6]	
<b>C. SOURCE OPERATION CONDITIONS.....</b>	<b>17</b>
<b>Emission Limitations and Standards [326 IAC 2-7-5(1)]</b>	
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 Opacity [326 IAC 5-1]	
C.3 Open Burning [326 IAC 4-1] [IC 13-17-9]	
C.4 Incineration [326 IAC 4-2] [326 IAC 9-1-2]	
C.5 Fugitive Dust Emissions [326 IAC 6-4]	
C.6 Stack Height [326 IAC 1-7]	
C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]	
<b>Testing Requirements [326 IAC 2-7-6(1)]</b>	
C.8 Performance Testing [326 IAC 3-6]	
<b>Compliance Requirements [326 IAC 2-1.1-11]</b>	
C.9 Compliance Requirements [326 IAC 2-1.1-11]	

**Compliance Monitoring Requirements [326 IAC 2-7-5(1)][326 IAC 2-7-6(1)]**

- C.10 Compliance Monitoring [326 IAC 2-7-5(3)][326 IAC 2-7-6(1)]
- C.11 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]
- C.12 Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)]  
[326 IAC 2-7-6(1)]

**Corrective Actions and Response Steps [326 IAC 2-7-5][326 IAC 2-7-6]**

- C.13 Emergency Reduction Plans [326 IAC 1-5-2] [326 IAC 1-5-3]
- C.14 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68]
- C.15 Response to Excursions or Exceedances [326 IAC 2-7-5] [326 IAC 2-7-6]
- C.16 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]  
[326 IAC 2-7-6]

**Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]**

- C.17 Emission Statement [326 IAC 2-7-5(3)(C)(iii)][326 IAC 2-7-5(7)][326 IAC 2-7-19(c)][326 IAC 2-6]
- C.18 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6]
- C.19 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11]

**Stratospheric Ozone Protection**

- C.20 Compliance with 40 CFR 82 and 326 IAC 22-1

**D.1. EMISSIONS UNIT OPERATION CONDITIONS..... 25**

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

- D.1.1 Particulate Emissions [326 IAC 6-2-4]
- D.1.2 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

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

- D.1.3 General Provisions Relating to New Source Performance Standards [326 IAC 12-1] [40 CFR Part 60, Subpart A]
- D.1.4 New Source Performance Standard for Small Industrial-Commercial-Institutional Steam Generating Units Requirements [40 CFR Part 60, Subpart Dc] [326 IAC 12]
- D.1.5 One Time Deadlines

**D.2. EMISSIONS UNIT OPERATION CONDITIONS..... 29**

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

- D.2.1 Particulate Emissions [326 IAC 6-3]
- D.2.2 Volatile Organic Compounds (VOC) [326 IAC 8-1-6]
- D.2.3 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

**Compliance Determination Requirements**

- D.2.4 Particulate Emissions

**Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]**

- D.2.5 Visible Emissions Notations
- D.2.6 Parametric Monitoring
- D.2.7 Broken or Failed Bag Detection
- D.2.8 Cyclone Failure Detection

**Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]**

- D.2.9 Record Keeping Requirements

**National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements [326 IAC 2-7-5(1)]**

- D.2.10 General Provisions Relating to National Emission Standards for Hazardous Air Pollutants (NESHAP) [326 IAC 12-1] [40 CFR Part 63, Subpart GGG]
- D.2.11 National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals

Production [40 CFR Part 63, Subpart GGG] [326 IAC 20-57]  
D.2.12 One Time Deadlines Relating to NESHAP Subpart GGG

**D.3. EMISSIONS UNIT OPERATION CONDITIONS ..... 58**

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

D.3.1 Particulate Emissions [326 IAC 6-3]

**Compliance Determination Requirements**

D.3.2 Particulate Emissions

**D.4. EMISSIONS UNIT OPERATION CONDITIONS ..... 60**

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

D.4.1 Volatile Organic Compounds (VOC) [326 IAC 8-3-2]

D.4.2 Volatile Organic Compounds (VOC) [326 IAC 8-3-5]

Certification ..... 62

Emergency Occurrence Report ..... 63

Quarterly Deviation and Compliance Monitoring Report ..... 65

## 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 through A.3 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 2-7-4(c)][326 IAC 2-7-5(15)][326 IAC 2-7-1(22)]

---

The Permittee owns and operates a stationary batch pharmaceutical facility producing liquid, capsule, and tablet pharmaceuticals.

Source Address:	1101 C Avenue West, Seymour, Indiana 47274
Mailing Address:	1101 C Avenue West, Seymour, Indiana 47274
General Source Phone Number:	812-523-3457
SIC Code:	2834
County Location:	Jackson
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Operating Permit Program Major Source, under PSD Major Source, Section 112 of the Clean Air Act Not in 1 of 28 Source Categories

### A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)][326 IAC 2-7-5(15)]

---

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

- (a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000. These units are considered affected facilities under 40 CFR 60, Subpart Dc.
- (b) One (1) tablet manufacturing department, constructed in 1993, modified in 2010, consisting of the following:
  - (1) One (1) granulation department consisting of various mixing and milling operations with drying operations performed by four (4) steam heated ovens. Particulate emissions from the mixing and milling operations are controlled by a dust collector, identified as EFDC1.
  - (2) One (1) tablet compression department consisting of tablet pressing and finishing equipment. Particulate emissions are controlled by two dust collectors, identified as V3 and V4.
  - (3) One (1) tablet coating department consisting of four (4) hi-coaters, equipped with four (4) dust collectors for particulate control, identified as DC04, DC05, DC013 and DC014.

The tablet manufacturing department is considered an affected facility under 40 CFR 63, Subpart GGG.

- (c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a dust collector for particulate control, identified as V5. The capsule manufacturing department is considered an affected facility under 40 CFR 63, Subpart GGG.

- (d) One (1) Phase IIIA production area, identified as emission unit EU-02. This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,300 pounds per batch (lbs/batch) of raw material and the particulate emissions are controlled by dust collector EFDC2. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with one (1) dust collector, identified as DC08. These units were constructed in 2000. The Phase IIIA production area is considered an affected facility under 40 CFR 63, Subpart GGG.
- (e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.
- (f) One (1) Colyte production area (identified as emission unit EU-01), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 328,300 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by dust collector DC011.

A.3 Specifically Regulated Insignificant Activities  
[326 IAC 2-7-1(21)][326 IAC 2-7-4(c)][326 IAC 2-7-5(15)]

---

This stationary source also includes the following insignificant activities which are specifically regulated, as defined in 326 IAC 2-7-1(21):

- (a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed in 1998, including:
  - (1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4]; and
  - (2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4].
- (b) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of two (2) solid-dose weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as EFDC2. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3]. In addition, the weigh-up department consists of one (1) liquid solvent weigh-up room with drums, pneumatic pumps and scales, with emissions exhausted through (1) exhaust fan identified as EF 11-2 [326 IAC 8-1-6].
- (c) One (1) cold cleaner degreaser installed in 2006 with a fifteen gallon capacity [326 IAC 8-3].

A.4 Part 70 Permit Applicability [326 IAC 2-7-2]

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This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

- (a) It is a major source, as defined in 326 IAC 2-7-1(22);
- (b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

## **SECTION B GENERAL CONDITIONS**

### **B.1 Definitions [326 IAC 2-7-1]**

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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 2-7) shall prevail.

### **B.2 Permit Term [326 IAC 2-7-5(2)][326 IAC 2-1.1-9.5][326 IAC 2-7-4(a)(1)(D)][IC 13-15-3-6(a)]**

- (a) This permit, T071-23273-00023, is issued for a fixed term of five (5) 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, including any permit shield provided in 326 IAC 2-7-15, until the renewal permit has been issued or denied.

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

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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 [326 IAC 2-7-7]**

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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 [326 IAC 2-7-5(5)]**

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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 [326 IAC 2-7-5(6)(D)]**

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

### **B.7 Duty to Provide Information [326 IAC 2-7-5(6)(E)]**

- (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 the "responsible official" as defined by 326 IAC 2-7-1(34). 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 [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]**

- (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 the "responsible official" 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) A "responsible official" is defined at 326 IAC 2-7-1(34).

**B.9 Annual Compliance Certification [326 IAC 2-7-6(5)]**

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- (a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. All certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted no later than July 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, Indiana 46204-2251

and

United States Environmental Protection Agency, Region V  
Air and Radiation Division, Air Enforcement Branch - Indiana (AE-17J)  
77 West Jackson Boulevard  
Chicago, Illinois 60604-3590

- (b) The annual compliance certification report 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) The annual compliance certification report shall include the following:
  - (1) The appropriate identification of each term or condition of this permit that is the basis of the certification;
  - (2) The compliance status;
  - (3) Whether compliance was continuous or intermittent;
  - (4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-7-5(3); and
  - (5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ may require to determine the compliance status of the source.

The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

**B.10 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)][326 IAC 2-7-6(1) and (6)][326 IAC 1-6-3]**

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- (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 the "responsible official" as defined by 326 IAC 2-7-1(34).
- (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 Emergency Provisions [326 IAC 2-7-16]

- (a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation.
- (b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:
- (1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;
  - (2) The permitted facility was at the time being properly operated;
  - (3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;
  - (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality,  
Compliance Section), or  
Telephone Number: 317-233-0178 (ask for Compliance Section)  
Facsimile Number: 317-233-6865

- (5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

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

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-7-5(3)(C)(ii) and must contain the following:

- (A) A description of the emergency;
- (B) Any steps taken to mitigate the emissions; and
- (C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (6) The Permittee immediately took all reasonable steps to correct the emergency.
- (c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
- (d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.
- (e) The Permittee seeking to establish the occurrence of an emergency shall make records available upon request to ensure that failure to implement a PMP did not cause or contribute to an exceedance of any limitations on emissions. However, IDEM, OAQ may require that the Preventive Maintenance Plans required under 326 IAC 2-7-4(c)(9) be revised in response to an emergency.
- (f) Failure to notify IDEM, OAQ by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-7 and any other applicable rules.
- (g) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.
- (h) The Permittee shall include all emergencies in the Quarterly Deviation and Compliance Monitoring Report.

B.12 Permit Shield [326 IAC 2-7-15][326 IAC 2-7-20][326 IAC 2-7-12]

- (a) Pursuant to 326 IAC 2-7-15, the Permittee has been granted a permit shield. The permit shield provides that compliance with the conditions of this permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that either the applicable requirements are included and specifically identified in this permit or the permit contains an explicit determination or concise summary of a determination that other specifically identified requirements are not applicable. The Indiana statutes from IC 13 and rules from 326 IAC, referenced 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 Part 70 permit under 326 IAC 2-7 or for applicable requirements for which a permit shield has been granted.

This permit shield does not extend to applicable requirements which are promulgated after the date of issuance of this permit unless this permit has been modified to reflect such new requirements.

- (b) If, after issuance of this permit, it is determined that the permit is in nonconformance with an applicable requirement that applied to the source on the date of permit issuance, IDEM, OAQ, shall immediately take steps to reopen and revise this permit and issue a compliance order to the Permittee to ensure expeditious compliance with the applicable requirement until the permit is reissued. The permit shield shall continue in effect so long as the Permittee is in compliance with the compliance order.
- (c) No permit shield shall apply to any permit term or condition that is determined after issuance of this permit to have been based on erroneous information supplied in the permit application. Erroneous information means information that the Permittee knew to be false, or in the exercise of reasonable care should have been known to be false, at the time the information was submitted.
- (d) Nothing in 326 IAC 2-7-15 or in this permit shall alter or affect the following:
  - (1) The provisions of Section 303 of the Clean Air Act (emergency orders), including the authority of the U.S. EPA under Section 303 of the Clean Air Act;
  - (2) The liability of the Permittee for any violation of applicable requirements prior to or at the time of this permit's issuance;
  - (3) The applicable requirements of the acid rain program, consistent with Section 408(a) of the Clean Air Act; and
  - (4) The ability of U.S. EPA to obtain information from the Permittee under Section 114 of the Clean Air Act.
- (e) This permit shield is not applicable to any change made under 326 IAC 2-7-20(b)(2) (Sections 502(b)(10) of the Clean Air Act changes) and 326 IAC 2-7-20(c)(2) (trading based on State Implementation Plan (SIP) provisions).
- (f) This permit shield is not applicable to modifications eligible for group processing until after IDEM, OAQ, has issued the modifications. [326 IAC 2-7-12(c)(7)]
- (g) This permit shield is not applicable to minor Part 70 permit modifications until after IDEM, OAQ, has issued the modification. [326 IAC 2-7-12(b)(8)]

B.13 Prior Permits Superseded [326 IAC 2-1.1-9.5][326 IAC 2-7-10.5]

- (a) All terms and conditions of permits established prior to T071-23273-00023 and issued pursuant to permitting programs approved into the state implementation plan have been either:
  - (1) incorporated as originally stated,
  - (2) revised under 326 IAC 2-7-10.5, or
  - (3) deleted under 326 IAC 2-7-10.5.
- (b) Provided that all terms and conditions are accurately reflected in this combined permit, all previous registrations and permits are superseded by this combined new source review and part 70 operating permit.

B.14 Termination of Right to Operate [326 IAC 2-7-10][326 IAC 2-7-4(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 nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-7-3 and 326 IAC 2-7-4(a).

**B.15** Deviations from Permit Requirements and Conditions [326 IAC 2-7-5(3)(C)(ii)]

- (a) Deviations from any permit requirements (for emergencies see Section B - Emergency Provisions), the probable cause of such deviations, and any response steps or preventive measures taken shall be reported 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

using the attached Quarterly Deviation and Compliance Monitoring Report, or its equivalent. A deviation required to be reported pursuant to an applicable requirement that exists independent of this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report.

The Quarterly Deviation and Compliance Monitoring Report does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

**B.16** Permit Modification, Reopening, Revocation and Reissuance, or Termination [326 IAC 2-7-5(6)(C)][326 IAC 2-7-8(a)][326 IAC 2-7-9]

- (a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Part 70 Operating Permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-7-5(6)(C)] The notification by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ determines any of the following:
- (1) That this permit contains a material mistake.
  - (2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.
  - (3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-7-9(a)(3)]
- (c) Proceedings by IDEM, OAQ to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-7-9(b)]
- (d) The reopening and revision of this permit, under 326 IAC 2-7-9(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ may provide a shorter time period in the case of an emergency. [326 IAC 2-7-9(c)]

**B.17** Permit Renewal [326 IAC 2-7-3][326 IAC 2-7-4][326 IAC 2-7-8(e)]

- (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 2-7-4. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(40). The renewal application does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

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 nine (9) months 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 2-7 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.18 Permit Amendment or Modification [326 IAC 2-7-11][326 IAC 2-7-12]**

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- (a) Permit amendments and modifications are governed by the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 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 the "responsible official" as defined by 326 IAC 2-7-1(34).
- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

**B.19 Permit Revision Under Economic Incentives and Other Programs [326 IAC 2-7-5(8)][326 IAC 2-7-12(b)(2)]**

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- (a) No Part 70 permit revision shall be required under any approved economic incentives, marketable Part 70 permits, emissions trading, and other similar programs or processes for changes that are provided for in a Part 70 permit.
- (b) Notwithstanding 326 IAC 2-7-12(b)(1) and 326 IAC 2-7-12(c)(1), minor Part 70 permit modification procedures may be used for Part 70 modifications involving the use of economic incentives, marketable Part 70 permits, emissions trading, and other similar approaches to the extent that such minor Part 70 permit modification procedures are explicitly provided for in the applicable State Implementation Plan (SIP) or in applicable requirements promulgated or approved by the U.S. EPA.

B.20 Operational Flexibility [326 IAC 2-7-20][326 IAC 2-7-10.5]

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- (a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-7-20(b),(c), or (e) without a prior permit revision, if each of the following conditions is met:
- (1) The changes are not modifications under any provision of Title I of the Clean Air Act;
  - (2) Any preconstruction approval required by 326 IAC 2-7-10.5 has been obtained;
  - (3) The changes do not result in emissions which exceed the limitations provided in this permit (whether expressed herein as a rate of emissions or in terms of total emissions);
  - (4) The Permittee notifies the:  
  
Indiana Department of Environmental Management  
Permits Branch, Office of Air Quality  
100 North Senate Avenue  
MC 61-53 IGCN 1003  
Indianapolis, Indiana 46204-2251  
  
and  
  
United States Environmental Protection Agency, Region V  
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)  
77 West Jackson Boulevard  
Chicago, Illinois 60604-3590  
  
in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and
  - (5) The Permittee maintains records on-site, on a rolling five (5) year basis, which document all such changes and emission trades that are subject to 326 IAC 2-7-20(b),(c), or (e). The Permittee shall make such records available, upon reasonable request, for public review.  
  
Such records shall consist of all information required to be submitted to IDEM, OAQ in the notices specified in 326 IAC 2-7-20(b)(1), (c)(1), and (e)(2).
- (b) The Permittee may make Section 502(b)(10) of the Clean Air Act changes (this term is defined at 326 IAC 2-7-1(36)) without a permit revision, subject to the constraint of 326 IAC 2-7-20(a). For each such Section 502(b)(10) of the Clean Air Act change, the required written notification shall include the following:
- (1) A brief description of the change within the source;
  - (2) The date on which the change will occur;
  - (3) Any change in emissions; and
  - (4) Any permit term or condition that is no longer applicable as a result of the change.

The notification which shall be submitted is not considered an application form, report or compliance certification. Therefore, the notification by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (c) Emission Trades [326 IAC 2-7-20(c)]  
The Permittee may trade emissions increases and decreases at the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-7-20(c).
- (d) Alternative Operating Scenarios [326 IAC 2-7-20(d)]  
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-7-5(9). No prior notification of IDEM, OAQ, or U.S. EPA is required.
- (e) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

B.21 Source Modification Requirement [326 IAC 2-7-10.5]

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2 and 326 IAC 2-7-10.5.

B.22 Inspection and Entry [326 IAC 2-7-6][IC 13-14-2-2][IC 13-30-3-1][IC 13-17-3-2]

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 Part 70 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 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 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 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.23 Transfer of Ownership or Operational Control [326 IAC 2-7-11]

- (a) The Permittee must comply with the requirements of 326 IAC 2-7-11 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 the "responsible official" as defined by 326 IAC 2-7-1(34).

- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

B.24 Annual Fee Payment [326 IAC 2-7-19] [326 IAC 2-7-5(7)][326 IAC 2-1.1-7]

- (a) The Permittee shall pay annual fees to IDEM, OAQ within thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ the applicable fee is due April 1 of each year.
- (b) Except as provided in 326 IAC 2-7-19(e), failure to pay may result in administrative enforcement action or revocation of this permit.
- (c) 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.25 Credible Evidence [326 IAC 2-7-5(3)][326 IAC 2-7-6][62 FR 8314] [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 2-7-5(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 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.3 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. 326 IAC 4-1-3(a)(2)(A) and (B) are not federally enforceable.

#### C.4 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.5 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). 326 IAC 6-4-2(4) is not federally enforceable.

#### C.6 Stack Height [326 IAC 1-7]

The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted. The provisions of 326 IAC 1-7-1(3), 326 IAC 1-7-2, 326 IAC 1-7-3(c) and (d), 326 IAC 1-7-4, and 326 IAC 1-7-5(a), (b), and (d) are not federally enforceable.

#### 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 the "responsible official" as defined by 326 IAC 2-7-1(34).

- (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 Accredited 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 Accredited Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos. The requirement to use an Indiana Accredited Asbestos inspector is not federally enforceable.

### **Testing Requirements [326 IAC 2-7-6(1)]**

#### **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 the "responsible official" as defined by 326 IAC 2-7-1(34).

- (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 the "responsible official" as defined by 326 IAC 2-7-1(34).
- (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 2-7-5(1)][326 IAC 2-7-6(1)]**

##### C.10 Compliance Monitoring [326 IAC 2-7-5(3)][326 IAC 2-7-6(1)]

Unless otherwise specified in this permit, all monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance. If required by Section D, the Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

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

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a source modification 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] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

- (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 [326 IAC 2-7-5][326 IAC 2-7-6]**

C.13 Emergency Reduction Plans [326 IAC 1-5-2] [326 IAC 1-5-3]

Pursuant to 326 IAC 1-5-2 (Emergency Reduction Plans; Submission):

- (a) The Permittee prepared and submitted written emergency reduction plans (ERPs) consistent with safe operating procedures on September 3, 2002.
- (b) Upon direct notification by IDEM, OAQ, that a specific air pollution episode level is in effect, the Permittee shall immediately put into effect the actions stipulated in the approved ERP for the appropriate episode level. [326 IAC 1-5-3]

C.14 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68]

If a regulated substance, as defined in 40 CFR 68, is present at a source in more than a threshold quantity, the Permittee must comply with the applicable requirements of 40 CFR 68.

C.15 Response to Excursions or Exceedances [326 IAC 2-7-5] [326 IAC 2-7-6]

- (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.16 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5][326 IAC 2-7-6]**

- (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 the "responsible official" as defined by 326 IAC 2-7-1(34).

**Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]**

**C.17 Emission Statement [326 IAC 2-7-5(3)(C)(iii)][326 IAC 2-7-5(7)][326 IAC 2-7-19(c)][326 IAC 2-6]**

- (a) Pursuant to 326 IAC 2-6-3(a)(1), the Permittee shall submit by July 1 of each year an emission statement covering the previous calendar year. The emission statement shall contain, at a minimum, the information specified in 326 IAC 2-6-4(c) and shall meet the following requirements:
  - (1) Indicate estimated actual emissions of all pollutants listed in 326 IAC 2-6-4(a);
  - (2) Indicate estimated actual emissions of regulated pollutants as defined by 326 IAC 2-7-1(32) ("Regulated pollutant, which is used only for purposes of Section 19 of this rule") from the source, for purpose of fee assessment.

The statement must be submitted to:

Indiana Department of Environmental Management  
Technical Support and Modeling Section, Office of Air Quality  
100 North Senate Avenue  
MC 61-50 IGCN 1003  
Indianapolis, Indiana 46204-2251

The emission statement does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) The emission statement 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.18 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6] [326 IAC 2-2]

- (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.
- (c) If there is a "project" (as defined in 326 IAC 2-2-1(qq) and/or 326 IAC 2-3-1(II)) at an existing emissions unit, other than projects at a source with a Plantwide Applicability Limitation (PAL), which is not part of a "major modification" (as defined in 326 IAC 2-2-1(ee) and/or 326 IAC 2-3-1(z)) and the Permittee elects to utilize the "projected actual emissions" (as defined in 326 IAC 2-2-1(rr) and/or 326 IAC 2-3-1(mm)), the Permittee shall comply with following:
- (1) Before beginning actual construction of the "project" (as defined in 326 IAC 2-2-1(qq) and/or 326 IAC 2-3-1(II)) at an existing emissions unit, document and maintain the following records:
    - (A) A description of the project.
    - (B) Identification of any emissions unit whose emissions of a regulated new source review pollutant could be affected by the project.
    - (C) A description of the applicability test used to determine that the project is not a major modification for any regulated NSR pollutant, including:
      - (i) Baseline actual emissions;
      - (ii) Projected actual emissions;
      - (iii) Amount of emissions excluded under section 326 IAC 2-2-1(rr)(2)(A)(iii) and/or 326 IAC 2-3-1 (mm)(2)(A)(iii); and
      - (iv) An explanation for why the amount was excluded, and any netting calculations, if applicable.
  - (2) Monitor the emissions of any regulated NSR pollutant that could increase as a result of the project and that is emitted by any existing emissions unit identified in (1)(B) above; and
  - (3) Calculate and maintain a record of the annual emissions, in tons per year on a calendar year basis, for a period of five (5) years following resumption of regular operations after the change, or for a period of ten (10) years following resumption of regular operations after the change if the project increases the design capacity of or the potential to emit that regulated NSR pollutant at the emissions unit.

C.19 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11] [326 IAC 2-2]

- (a) The Permittee shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported. This report shall be submitted within thirty (30) days of the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (b) The report required in (a) of this condition and 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
- (c) 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.
- (d) 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 the "responsible official" as defined by 326 IAC 2-7-1(34).
- (e) 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.
- (f) If the Permittee is required to comply with the recordkeeping provisions of (c) in Section C - General Record Keeping Requirements for any "project" (as defined in 326 IAC 2-2-1 (qq) and/or 326 IAC 2-3-1 (ll)) at an existing emissions unit, and the project meets the following criteria, then the Permittee shall submit a report to IDEM, OAQ:
- (1) The annual emissions, in tons per year, from the project identified in (c)(1) in Section C- General Record Keeping Requirements exceed the baseline actual emissions, as documented and maintained under Section C- General Record Keeping Requirements (c)(1)(C)(i), by a significant amount, as defined in 326 IAC 2-2-1 (xx) and/or 326 IAC 2-3-1 (qq), for that regulated NSR pollutant, and
  - (2) The emissions differ from the preconstruction projection as documented and maintained under Section C - General Record Keeping Requirements (c)(1)(C)(ii).
- (g) The report for project at an existing emissions unit shall be submitted within sixty (60) days after the end of the year and contain the following:
- (1) The name, address, and telephone number of the major stationary source.
  - (2) The annual emissions calculated in accordance with (c)(2) and (3) in Section C - General Record Keeping Requirements.
  - (3) The emissions calculated under the actual-to-projected actual test stated in 326 IAC 2-2-2(d)(3) and/or 326 IAC 2-3-2(c)(3).

- (4) Any other information that the Permittee deems fit to include in this report.

Reports required in this part shall be submitted to:

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

- (h) The Permittee shall make the information required to be documented and maintained in accordance with (c) in Section C- General Record Keeping Requirements available for review upon a request for inspection by IDEM, OAQ. The general public may request this information from the IDEM, OAQ under 326 IAC 17.1.

### **Stratospheric Ozone Protection**

#### **C.20 Compliance with 40 CFR 82 and 326 IAC 22-1**

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Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with the standards for recycling and emissions reduction:

- (a) Persons opening appliances for maintenance, service, repair, or disposal must comply with the required practices pursuant to 40 CFR 82.156.
- (b) Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to 40 CFR 82.158.
- (c) Persons performing maintenance, service, repair, or disposal of appliances must be certified by an approved technician certification program pursuant to 40 CFR 82.161.

## SECTION D.1 EMISSIONS UNIT OPERATION CONDITIONS

### Emissions Unit Description:

- (a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000. These units are considered affected facilities under 40 CFR 60, Subpart Dc.

### Specifically Regulated Insignificant Activities:

- (a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed in 1998, including:
- (1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4]; and
  - (2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4].

(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 2-7-5(1)]

#### D.1.1 Particulate Emissions [326 IAC 6-2-4]

- (a) Pursuant to 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating), the particulate emissions from the two (2) 20.9 MMBtu per hour boilers shall be limited to 0.39 pounds per MMBtu heat input.
- (b) Pursuant to 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating), the particulate emissions from the 4.8 MMBtu per hour boiler and the 3.6 MMBtu per hour boiler shall be limited to 0.6 pounds per MMBtu heat input.

#### D.1.2 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for these facilities.

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

#### D.1.3 General Provisions Relating to New Source Performance Standards [326 IAC 12-1] [40 CFR Part 60, Subpart A]

- (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 20.9 MMBtu boilers 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 Branch, Office of Air Quality  
100 North Senate Avenue  
MC 61-53 IGCN 1003  
Indianapolis, Indiana 46204-2251

#### D.1.4 New Source Performance Standard for Small Industrial-Commercial-Institutional Steam Generating Units Requirements [40 CFR Part 60, Subpart Dc] [326 IAC 12]

Pursuant to 40 CFR Part 60, Subpart Dc, the Permittee shall comply with the provisions of 40 CFR 60, Subpart Dc (Standards of Performance for Small Industrial-Commercial-Institutional

Steam Generating Units), which are incorporated by reference as 326 IAC 12 for the two (2) 20.9 MMBtu per hour boilers as follows:

### **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.

#### **§ 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 hydrodesulfurization 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 SO<sub>2</sub> 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 SO<sub>2</sub> 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 SO<sub>2</sub> 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 SO<sub>2</sub> 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 SO<sub>2</sub>.

*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.

**§ 60.48c 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.

(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 SO<sub>2</sub> 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.

(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.

**D.1.5 One Time Deadlines Relating to NSPS Subpart Dc**

The Permittee shall comply with the following requirements by the dates listed below:

Requirement	Rule Citation	Affected Facility	Deadline
Notification of the date of construction commencement	40 CFR 60.7(a)(1)	Two (2) 20.9 MMBtu/hr boilers	No later than 30 days after commencement of construction
Notification of initial startup and Compliance Report	40 CFR 60.7(a)(3)	Two (2) 20.9 MMBtu/hr boilers	Within 15 days of startup

## SECTION D.2 EMISSIONS UNIT OPERATION CONDITIONS

### Emissions Unit Description:

(b) One (1) tablet manufacturing department, constructed in 1993, modified in 2010, consisting of the following:

(1) One (1) granulation department consisting of various mixing and milling operations with drying operations performed by four (4) steam heated ovens—Particulate emissions from the mixing and milling operations are controlled by a dust collector, identified as EFDC1.

(2) One (1) tablet compression department consisting of tablet pressing and finishing equipment. Particulate emissions are controlled by two dust collectors, identified as V3 and V4.

(3) One (1) tablet coating department consisting of four (4) hi-coaters, equipped with four (4) dust collectors for particulate control, identified as DC04, DC05, DC013 and DC014.

The tablet manufacturing department is considered an affected facility under 40 CFR 63, Subpart GGG.

(c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a cyclone dust collector for particulate control, identified as V5. The capsule manufacturing department is considered an affected facility under 40 CFR 63, Subpart GGG.

(d) One (1) Phase IIIA production area, identified as emission unit EU-02. This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,300 pounds per batch (lbs/batch) of raw material and the particulate emissions are controlled by dust collector EFDC2. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with one (1) dust collector, identified as DC08. These units were constructed in 2000. The Phase IIIA production area is considered an affected facility under 40 CFR 63, Subpart GGG.

(e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.

### Specifically Regulated Insignificant Activities:

(b) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of two (2) solid-dose weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as EFDC2. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3]. In addition, the weigh-up department consists of one (1) liquid solvent weigh-up room with drums, pneumatic pumps and scales, with emissions exhausted through (1) exhaust fan identified as EF 11-2 [326 IAC 8-1-6].

(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 2-7-5(1)]

#### D.2.1 Particulate Emissions [326 IAC 6-3]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the tablet and capsule manufacturing areas and the

weigh-up department shall be limited as follows:

Facility	Process Weight (lbs/hr)	Particulate Emission Limit (lbs/hour)
Tablet Manufacturing Department	442	1.49
Capsule Manufacturing Department	300	1.15
Weigh-up Department	740	2.11

The pounds per hour limitations were calculated with the following equation:

Interpolation of the data for process weight rates up to 60,000 pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour; and} \\ P = \text{process weight rate in tons per hour.}$$

#### D.2.2 Volatile Organic Compounds (VOC) [326 IAC 8-1-6]

Pursuant to 326 IAC 8-1-6, and CP 071-3874-00023 (issued January 25, 1995), the Permittee shall control VOC emissions from the tablet and capsule manufacturing department, Phase IIIA production area, the cleaning and sanitizing operations, and the liquid solvent weigh-up room, with a Best Available Control Technology (BACT), which has been determined to be the following:

Process Modifications:

- (a) For capsule manufacturing, the Permittee shall use flo-coaters for applying sustained release coatings for all products in which volatile organic compounds (VOCs) are used.
- (b) The capture and off-site disposal of VOC containing chemicals,
- (c) Solvent handling procedures (currently being conducted):
  - (1) Solvents are stored in sealed 55-gallon drums until utilized in the manufacturing process.
  - (2) The drums are kept sealed except when solvents are withdrawn.
  - (3) The solvents are extracted from the drums using a dedicated pump.
  - (4) If one half of the drum content is needed, the entire drum can be transported to the manufacturing area for disposing.
  - (5) If less than one half of the content of the drum is to be used, the needed portion is transported to the process area in a covered container.
  - (6) When the manufacturing process requires other chemicals to be dissolved in liquid, the process is conducted in covered vessels.
  - (7) The use of isopropanol in cleaning and sanitizing operations shall be minimized by using bleaches and other non-solvent sanitizers where appropriate.
- (d) The BACT shall be implemented such that:
  - (1) Implementation of the flo-coater shall reduce VOC emissions by 18%.
  - (2) The solvents shall be disposed off-site in accordance with the applicable hazardous waste rule found in 40 CFR part 260 to part 272, and shall reduce VOC emissions by 8%.
  - (3) The on-going solvent handling procedures shall reduce VOC emissions by 0.5%.

- (4) The minimization of isopropanol in cleaning and sanitizing operations shall reduce isopropanol emissions by 8%.

The implementation of this BACT shall result in a total VOC reduction of 34.5% from 1995 VOC emission levels.

**D.2.3 Preventive Maintenance Plan [326 IAC 2-7-5(13)]**

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

**Compliance Determination Requirements**

**D.2.4 Particulate Emissions**

- (a) In order to comply with Condition D.2.1, the dust collectors for particulate control shall be in operation and control emissions from the tablet and capsule manufacturing departments at all times that the tablet and capsule manufacturing departments are in operation.
- (b) In the event that bag failure is observed in a multi-compartment baghouse, if operations will continue for ten (10) days or more after the failure is observed before the failed units will be repaired or replaced, the Permittee shall promptly notify the IDEM, OAQ of the expected date the failed units will be repaired or replaced. The notification shall also include the status of the applicable compliance monitoring parameters with respect to normal, and the results of any response actions taken up to the time of notification.

**Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]**

**D.2.5 Visible Emissions Notations**

- (a) Daily visible emission notations of the tablet and capsule manufacturing departments stack exhaust shall be performed during normal daylight operations. A trained employee shall record whether emissions are normal or abnormal.
- (b) For processes operated continuously, "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time.
- (c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.
- (d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.
- (e) If abnormal emissions are observed, the Permittee shall take reasonable response steps in accordance with Section C - Response to Excursions or Exceedances. Failure to take response steps in accordance with Section C - Response to Excursions or Exceedances shall be considered a deviation from this permit.

**D.2.6 Parametric Monitoring**

The Permittee shall record the pressure drop across the baghouses used in conjunction with the tablet manufacturing department at least once per day when the tablet manufacturing department is in operation. When for any one reading, the pressure drop across the baghouse is outside the normal range of 0.2 and 5.0 inches of water or a range established during the latest stack test, the Permittee shall take reasonable response steps in accordance with Section C – Response to Excursions and Exceedances. A pressure reading that is outside the above mentioned range is not a deviation from this permit. Failure to take response steps in accordance with Section C - Response to Excursions or Exceedances, shall be considered a deviation from this permit.

The instrument used for determining the pressure shall comply with Section C - Instrument Specifications, of this permit, shall be subject to approval by IDEM, OAQ, and shall be calibrated in accordance with the manufacturer's specifications. The specifications shall be available on site with the Preventive Maintenance Plan.

#### D.2.7 Broken or Failed Bag Detection

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- (a) For a single compartment baghouses controlling emissions from a process operated continuously, a failed unit and the associated process shall be shut down immediately until the failed unit has been repaired or replaced. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).
- (b) For a single compartment baghouse controlling emissions from a batch process, the feed to the process shall be shut down immediately until the failed unit have been repaired or replaced. The emissions unit shall be shut down no later than the completion of the processing of the material in the line. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

Bag failure can be indicated by a significant drop in the baghouse's pressure reading with abnormal visible emissions, by an opacity violation, or by other means such as gas temperature, flow rate, air infiltration, leaks, dust traces or triboflows.

#### D.2.8 Cyclone Failure Detection

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In the event that cyclone failure has been observed:

Failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. The emissions unit shall be shut down no later than the completion of the processing of the material in the line. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

### **Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]**

#### D.2.9 Record Keeping Requirements

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- (a) To document compliance with Condition D.2.5, the Permittee shall maintain records of daily visible emission notations of the tablet and capsule manufacturing departments stack exhaust. The Permittee shall include in its daily record when a visible emission notation is not taken and the reason for the lack of visible emission notation (e.g. the process did not operate that day).
- (b) To document compliance with Condition D.2.6, the Permittee shall maintain daily records of the pressure drop. The Permittee shall include in its daily record when a pressure drop reading is not taken and the reason for the lack of a pressure drop reading (e.g. the process did not operate that day).
- (c) To document compliance with Condition D.2.2, the Permittee shall maintain monthly logs of information pertaining to the usage and handling of volatile organic solvents and the implementation of the flo-coaters.
- (d) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

### **National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements [326 IAC 2-7-5(1)]**

#### D.2.10 General Provisions Relating to National Emission Standards for Hazardous Air Pollutants (NESHAP) [326 IAC 12-1] [40 CFR Part 63, Subpart GGG]

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- (a) Pursuant to 40 CFR 63.1250(c), the Permittee shall comply with the provisions of 40 CFR

Part 63, Subpart A – General Provisions, which are incorporated by reference as 326 IAC 20-1-1, for the pharmaceutical manufacturing operations as specified in Table 1 of 40 CFR Part 63, Subpart GGG in accordance with schedule in 40 CFR 63, Subpart GGG.

- (b) Pursuant to 40 CFR 63.10, the Permittee shall submit all required notifications and reports to:

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

D.2.11 National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production [40 CFR Part 63, Subpart GGG] [326 IAC 20-57]

Pursuant to 40 CFR Part 63, Subpart GGG, the Permittee shall comply with the provisions of 40 CFR 63, Subpart GGG (National Emission Standards for Pharmaceuticals Production), which are incorporated by reference as 326 IAC 20-57, for the pharmaceutical manufacturing operations as follows.

**Subpart GGG—National Emission Standards for Pharmaceuticals Production**

**Source:** 63 FR 50326, Sept. 21, 1998, unless otherwise noted.

**§ 63.1250 Applicability.**

(a) *Definition of affected source.* (1) The affected source subject to this subpart consists of the pharmaceutical manufacturing operations as defined in §63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) (i) through (iii) of this section:

- (i) Manufacture a pharmaceutical product as defined in §63.1251;
- (ii) Are located at a plant site that is a major source as defined in section 112(a) of the Act; and
- (iii) Process, use, or produce HAP.

(2) Determination of the applicability of this subpart shall be reported as part of an operating permit application or as otherwise specified by the permitting authority.

(c) *General Provisions.* Table 1 of this subpart specifies and clarifies the provisions of subpart A of this part that apply to an owner or operator of an affected source subject to this subpart. The provisions of subpart A specified in Table 1 are the only provisions of subpart A that apply to an affected source subject to this subpart.

(f) *Compliance dates.* The compliance dates for affected sources are as follows:

(1) An owner or operator of an existing affected source must comply with the provisions of this subpart no later than October 21, 2002.

(g) *Applicability of this subpart except during periods of startup, shutdown, and malfunction.* (1) Each provision set forth in this subpart shall apply at all times except that emission limitations shall not apply during periods of: startup; shutdown; and malfunction, if the startup, shutdown, and malfunction precludes the ability of a particular emission point of an affected source to comply with one or more specific emission limitations to which it is subject and the owner or operator follows the provisions for periods of startup, shutdown, and malfunction, as specified in §§63.1259(a)(3) and 63.1260(i). Startup, shutdown, and malfunction are defined in §63.1251.

(2) The provisions set forth in §63.1255 of this subpart shall apply at all times except during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which §63.1255 of this subpart applies.

(3) The owner or operator shall not shut down items of equipment that are required or utilized for

compliance with the emissions limitations of this subpart during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations of this subpart applicable to such items of equipment. This paragraph does not apply if the item of equipment is malfunctioning, or if the owner or operator must shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof.

(4) During startups, shutdowns, and malfunctions when the emissions limitations of this subpart do not apply pursuant to paragraphs (g)(1) through (3) of this section, the owner or operator shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. For purposes of this paragraph, "excess emissions" means emissions in excess of those that would have occurred if there were no startup, shutdown, or malfunction and the owner or operator complied with the relevant provisions of this subpart. The measures to be taken shall be identified in the applicable startup, shutdown, and malfunction plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, monitoring, and/or changes in the manner of operation of the source. Back-up control devices are not required, but may be used if available.

(i) For the purposes of establishing whether a person is in violation of this subpart, nothing in this subpart shall preclude the use of any credible evidence or information relevant to whether a source would have been in compliance with applicable requirements.

[63 FR 50326, Sept. 21, 1998, as amended at 65 FR 52596, Aug. 29, 2000; 66 FR 40131, Aug. 2, 2001]

### **§ 63.1251 Definitions.**

Terms used in this subpart are defined in the Act, in subpart A of this part, or in this section. If the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section for the purposes of this subpart.

*Active ingredient* means any material that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. This term does not include food, food additives (except vitamins and other materials described by SIC code 2833 or 2834), color additives, cosmetics, in-vitro diagnostic substances, x-ray film, test indicator devices, and medical devices such as implants, artificial joints, surgical bandages, and stitching material.

*Actual HAP emissions* means the HAP emitted to the atmosphere from either uncontrolled or controlled emission points.

*Air pollution control device or Control device* means equipment installed on a process vent, storage tank, wastewater treatment exhaust stack, or combination thereof that reduces the mass of HAP emitted to the air. The equipment may consist of an individual device or a series of devices. Examples include, but are not limited to, incinerators, carbon adsorption units, condensers, flares, boilers, process heaters, and gas absorbers. Process condensers are not considered air pollution control devices or control devices.

*Annual average concentration*, as used in the wastewater provisions in §63.1256, means the total mass of partially soluble and/or soluble HAP compounds in a wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year, as determined according to the procedures specified in §63.1257(e)(1) (i) and (ii).

*Automated monitoring and recording system* means any means of measuring values of monitored parameters and creating a hard copy or computer record of the measured values that does not require manual reading of monitoring instruments and manual transcription of data values. Automated monitoring and recording systems include, but are not limited to, computerized systems and strip charts.

*Batch emission episode* means a discrete venting episode that may be associated with a single unit operation. A unit operation may have more than one batch emission episode. For example, a displacement of vapor resulting from the charging of a vessel with HAP will result in a discrete emission episode that will last through the duration of the charge and will have an average flowrate equal to the rate of the charge. If the vessel is then heated, there will also be another discrete emission episode resulting from the expulsion of expanded vapor. Both emission episodes may occur in the same vessel or unit operation. There are possibly other emission episodes that may occur from the vessel or other process equipment, depending on process operations.

*Batch operation or Batch process* means a noncontinuous operation involving intermittent or discontinuous feed into equipment, and, in general, involves the emptying of the equipment after the batch operation ceases and prior to beginning a new operation. Addition of raw material and withdrawal of product do not occur simultaneously in a batch operation.

*Bench-scale batch process* means a batch process (other than a research and development facility) that is capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product.

*Block* means a time period that comprises a single batch.

*Boiler* means any enclosed combustion device that extracts useful energy in the form of steam and is not an incinerator. Boiler also means any industrial furnace as defined in 40 CFR 260.10.

*Centralized combustion control device (CCCD)* means enclosed combustion devices that are used to control process vent emissions from non-dedicated PMPU's at a facility. Centralized combustion control devices may also be used to control emissions from source types including, but not limited to, storage tanks, waste management units, and equipment leaks.

*Cleaning operation* means routine rinsing, washing, or boil-off of equipment in batch operations between batches.

*Closed biological treatment process* means a tank or surface impoundment where biological treatment occurs and air emissions from the treatment process are routed to either a control device by means of a closed-vent system or by means of hard-piping. The tank or surface impoundment has a fixed roof, as defined in this section, or a floating flexible membrane cover that meets the requirements specified in §63.1256(c).

*Closed-loop system* means an enclosed system that returns process fluid to the process and is not vented to the atmosphere except through a closed-vent system.

*Closed-purge system* means a system or combination of system and portable containers, to capture purged liquids. Containers must be covered or closed when not being filled or emptied.

*Closed-vent system* means a system that is not open to the atmosphere and is composed of piping, ductwork, connections, and, if necessary, flow inducing devices that transport gas or vapor from an emission point to a control device.

*Combustion device* means an individual unit of equipment, such as a flare, incinerator, process heater, or boiler, used for the combustion of HAP vapors.

*Combustion device burner* means a device designed to mix and ignite fuel and air to provide a flame to heat and oxidize waste organic vapors in a combustion device.

*Connector* means flanged, screwed, or other joined fittings used to connect two pipe lines or a pipe line and a piece of equipment. A common connector is a flange. Joined fittings welded completely around the circumference of the interface are not considered connectors for the purpose of this regulation. For the purpose of reporting and recordkeeping, connector means joined fittings that are not inaccessible, ceramic, or ceramic-lined as described in §63.1255(b)(1)(vii) and §63.1255(f)(3).

*Construction* means the onsite fabrication, erection, or installation of an affected source or a PMPU. Addition of new equipment to a PMPU subject to existing source standards does not constitute construction, but it may constitute reconstruction of the affected source or PMPU if it satisfies the definition of reconstruction in this section.

*Consumption* means the quantity of all HAP raw materials entering a process in excess of the theoretical amount used as reactant, assuming 100 percent stoichiometric conversion. The raw materials include reactants, solvents, and any other additives. If a HAP is generated in the process as well as added as a raw material, consumption includes the quantity generated in the process.

*Container*, as used in the wastewater provisions, means any portable waste management unit that has a capacity greater than or equal to 0.1 m<sup>3</sup> in which a material is stored, transported, treated, or otherwise handled. Examples of containers are drums, barrels, tank trucks, barges, dumpsters, tank cars, dump

trucks, and ships.

*Continuous process* means a process where the inputs and outputs flow continuously throughout the duration of the process. Continuous processes are typically steady state.

*Continuous recorder* means a data recording device that either records an instantaneous data value at least once every 15 minutes or records 15-minute or more frequent block average values.

*Continuous seal* means a seal that forms a continuous closure that completely covers the space between the wall of the storage tank and the edge of the floating roof. A continuous seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

*Control device*, for purposes of this §63.1255, means any equipment used for recovering or oxidizing organic hazardous air pollutant vapors. Such equipment includes, but is not limited to, absorbers, carbon adsorbers, condensers, flares, boilers, and process heaters.

*Controlled HAP emissions* means the quantity of HAP discharged to the atmosphere from an air pollution control device.

*Cover*, as used in the wastewater provisions, means a device or system which is placed on or over a waste management unit containing wastewater or residuals so that the entire surface area is enclosed to minimize air emissions. A cover may have openings necessary for operation, inspection, and maintenance of the waste management unit such as access hatches, sampling ports, and gauge wells provided that each opening is closed when not in use. Examples of covers include a fixed roof installed on a wastewater tank, a lid installed on a container, and an air-supported enclosure installed over a waste management unit.

*Dedicated PMPU* means a PMPU that is composed of equipment that is used to manufacture the same product for a continuous period of 6 months or greater. The PMPU includes any shared storage tank(s) that are determined to belong to the PMPU according to the procedures in §63.1250(e).

*Dense gas system* means a conveyance system operated to limit oxygen levels below 12 percent.

*Double block and bleed system* means two block valves connected in series with a bleed valve or line that can vent the line between the two block valves.

*Duct work* means a conveyance system such as those commonly used for heating and ventilation systems. It is often made of sheet metal and often has sections connected by screws or crimping. Hard-piping is not ductwork.

*Enhanced biological treatment system or enhanced biological treatment process* means an aerated, thoroughly mixed treatment unit(s) that contains biomass suspended in water followed by a clarifier that removes biomass from the treated water and recycles recovered biomass to the aeration unit. The mixed liquor volatile suspended solids (biomass) is greater than 1 kilogram per cubic meter throughout each aeration unit. The biomass is suspended and aerated in the water of the aeration unit(s) by either submerged air flow or mechanical agitation. A thoroughly mixed treatment unit is a unit that is designed and operated to approach or achieve uniform biomass distribution and organic compound concentration throughout the aeration unit by quickly dispersing the recycled biomass and the wastewater entering the unit.

*Equipment*, for purposes of §63.1255, means each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in organic hazardous air pollutant service; and any control devices or closed-vent systems required by this subpart.

*Excipient* means any substance other than the active drug or product which has been appropriately evaluated for safety and is included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture; protect, support, or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

*External floating roof* means a pontoon-type or double-deck type cover that rests on the liquid surface in a storage tank or waste management unit with no fixed roof.

*Fill or filling* means the introduction of material into a storage tank or the introduction of a wastewater stream or residual into a waste management unit, but not necessarily to complete capacity.

*First attempt at repair* means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere.

*Fixed roof* means a cover that is mounted on a waste management unit or storage tank in a stationary manner and that does not move with fluctuations in liquid level.

*Floating roof* means a cover consisting of a double deck, pontoon single deck, internal floating cover or covered floating roof, which rests upon and is supported by the liquid being contained, and is equipped with a closure seal or seals to close the space between the roof edge and waste management unit or storage tank wall.

*Flow indicator* means a device which indicates whether gas flow is, or whether the valve position would allow gas flow to be, present in a line.

*Formulation* means the process of mixing, blending, or diluting one or more active or inert ingredients with one or more active or inert ingredients, without an intended chemical reaction, to obtain a pharmaceutical dosage form. Formulation operations include mixing, compounding, blending, and tablet coating.

*Group of processes* means all of the equipment associated with processes in a building, processing area, or facility-wide. For a dedicated process, a group of processes may consist of a single process.

*Halogen atoms* mean atoms of chlorine or fluorine.

*Halogenated compounds* means organic HAP compounds that contain halogen atoms.

*Halogenated vent stream or Halogenated stream* means a process, storage tank, or waste management unit vent determined to have a concentration of halogenated compounds of greater than 20 ppmv, as determined through process knowledge, test results using Method 18 of 40 CFR part 60, appendix A, or test results using any other test method that has been validated according to the procedures in Method 301 of appendix A of this part.

*Hard-piping* means piping or tubing that is manufactured and properly installed using good engineering judgment and standards, such as ANSI B31-3.

*Hydrogen halides and halogens* means hydrogen chloride (HCl), chlorine (Cl<sup>2</sup>), and hydrogen fluoride (HF).

*In gas/vapor service* means that a piece of equipment in organic hazardous air pollutant service contains a gas or vapor at operating conditions.

*In heavy liquid service* means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service or in light liquid service.

*In light liquid service* means that a piece of equipment in organic hazardous air pollutant service contains a liquid that meets the following conditions:

- (1) The vapor pressure of one or more of the organic compounds is greater than 0.3 kilopascals at 20 °C;
- (2) The total concentration of the pure organic compounds constituents having a vapor pressure greater than 0.3 kilopascals at 20 °C is equal to or greater than 20 percent by weight of the total process stream; and
- (3) The fluid is a liquid at operating conditions. (Note: Vapor pressures may be determined by the methods described in 40 CFR 60.485(e)(1).)

*In liquid service* means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service.

*In organic hazardous air pollutant or in organic HAP service* means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAP's as determined according to the provisions of §63.180(d). The provisions of §63.180(d) also specify how to determine that a piece of equipment is not in organic HAP service.

*In vacuum service* means that equipment is operating at an internal pressure which is at least 5 kilopascals below ambient pressure.

*In-situ sampling systems* means nonextractive samplers or in-line samplers.

*Individual drain system* means the stationary system used to convey wastewater streams or residuals to a waste management unit. The term includes hard piping; all process drains and junction boxes; and associated sewer lines, other junction boxes, manholes, sumps, and lift stations conveying wastewater streams or residuals. A segregated stormwater sewer system, which is a drain and collection system designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition.

*Initial startup* means the first time a new or reconstructed source begins production. Initial startup does not include operation solely for testing equipment. Initial startup does not include subsequent start ups (as defined in this section) of processes following malfunctions or process shutdowns.

*Internal floating roof* means a cover that rests or floats on the liquid surface (but not necessarily in complete contact with it) inside a storage tank or waste management unit that has a permanently affixed roof.

*Instrumentation system* means a group of equipment components used to condition and convey a sample of the process fluid to analyzers and instruments for the purpose of determining process operating conditions (e.g., composition, pressure, flow, etc.). Valves and connectors are the predominant type of equipment used in instrumentation systems; however, other types of equipment may also be included in these systems. Only valves nominally 0.5 inches and smaller, and connectors nominally 0.75 inches and smaller in diameter are considered instrumentation systems for the purposes of this subpart. Valves greater than nominally 0.5 inches and connectors greater than nominally 0.75 inches associated with instrumentation systems are not considered part of instrumentation systems and must be monitored individually.

*Isolated intermediate* means a product of a process. An isolated intermediate is usually a product of a chemical synthesis, fermentation, or biological extraction process; several different isolated intermediates may be produced in the manufacture of a finished dosage form of a drug. Precursors, active ingredients, or finished dosage forms are considered isolated intermediates. An isolated intermediate is stored before subsequent processing. Storage occurs at any time the intermediate is placed in equipment used solely for storage, such as drums, totes, day tanks, and storage tanks. The storage of an isolated intermediate marks the end of a process.

*Junction box* means a manhole or access point to a wastewater sewer system line or a lift station.

*Large control device* means a control device that controls total HAP emissions of greater than or equal to 10 tons/yr, before control.

*Liquid-mounted seal* means a foam- or liquid-filled seal mounted in contact with the liquid between the wall of the storage tank or waste management unit and the floating roof. The seal is mounted continuously around the tank or unit.

*Liquids dripping* means any visible leakage from the seal including dripping, spraying, misting, clouding, and ice formation. Indications of liquid dripping include puddling or new stains that are indicative of an existing evaporated drip.

*Maintenance wastewater* means wastewater generated by the draining of process fluid from components in the pharmaceutical manufacturing process unit into an individual drain system in preparation for or during maintenance activities. Maintenance wastewater can be generated during planned and unplanned shutdowns and during periods not associated with a shutdown. Examples of activities that can generate maintenance wastewater include descaling of heat exchanger tubing bundles, cleaning of distillation column traps, draining of pumps into an individual drain system, and draining of portions of the pharmaceutical manufacturing process unit for repair. Wastewater from cleaning operations is not considered maintenance wastewater.

*Malfunction* means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, emissions monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable

standard to be exceeded. Failures that are caused all or in part by poor maintenance or careless operation are not malfunctions.

*Maximum true vapor pressure* means the equilibrium partial pressure exerted by the total organic HAP in the stored or transferred liquid at the temperature equal to the highest calendar-month average of the liquid storage or transferred temperature for liquids stored or transferred above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for liquids stored or transferred at the ambient temperature, as determined:

- (1) In accordance with methods described in Chapter 19.2 of the American Petroleum Institute's Manual of Petroleum Measurement Standards, Evaporative Loss From Floating-Roof Tanks (incorporated by reference as specified in §63.14); or
- (2) As obtained from standard reference texts; or
- (3) As determined by the American Society for Testing and Materials Method D2879-97, Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isotenoscope (incorporated by reference as specified in §63.14); or
- (4) Any other method approved by the Administrator.

*Metallic shoe seal or mechanical shoe seal* means metal sheets that are held vertically against the wall of the storage tank by springs, weighted levers, or other mechanisms and connected to the floating roof by braces or other means. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof.

*Nondedicated formulation operations* means equipment used to formulate numerous products.

*Nondedicated recovery device(s)* means a recovery device that receives material from more than one PMPU.

*Nonrepairable* means that it is technically infeasible to repair a piece of equipment from which a leak has been detected without a process shutdown.

*Open biological treatment process* means a biological treatment process that is not a closed biological treatment process as defined in this section.

*Open-ended valve or line* means any valve, except pressure relief valves, having one side of the valve seat in contact with process fluid and one side open to atmosphere, either directly or through open piping.

*Operating scenario* for the purposes of reporting and recordkeeping, means any specific operation of a PMPU and includes for each process:

- (1) A description of the process and the type of process equipment used;
- (2) An identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and storage tanks;
- (3) The applicable control requirements of this subpart, including the level of required control, and for vents, the level of control for each vent;
- (4) The control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device;
- (5) The process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s);
- (6) The applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device;
- (7) Calculations and engineering analyses required to demonstrate compliance; and
- (8) For reporting purposes, a change to any of these elements not previously reported, except for paragraph (5) of this definition, shall constitute a new operating scenario.

*Partially soluble HAP* means a HAP listed in Table 2 of this subpart.

*Pharmaceutical manufacturing operations* means the facilitywide collection of PMPU and any other equipment such as heat exchanger systems, wastewater and waste management units, or cooling towers that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

*Pharmaceutical manufacturing process unit (PMPU)* means the process, as defined in this subpart, and any associated storage tanks, equipment identified in §63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

*Pharmaceutical product* means any of the following materials, excluding any material that is a nonreactive solvent, excipient, binder, or filler, or any material that is produced in a chemical manufacturing process unit that is subject to the requirements of subparts F and G of this part 63:

- (1) Any material described by the standard industrial classification (SIC) code 2833 or 2834; or
- (2) Any material whose manufacturing process is described by North American Industrial Classification System (NAICS) code 325411 or 325412; or
- (3) A finished dosage form of a drug, for example, a tablet, capsule, solution, etc.; or
- (4) Any active ingredient or precursor that is produced at a facility whose primary manufacturing operations are described by SIC code 2833 or 2834; or
- (5) At a facility whose primary operations are not described by SIC code 2833 or 2834, any material whose primary use is as an active ingredient or precursor.

*Plant site* means all contiguous or adjoining property that is under common control, including properties that are separated only by a road or other public right-of-way. Common control includes properties that are owned, leased, or operated by the same entity, parent entity, subsidiary, or any combination thereof.

*Point of determination (POD)* means the point where a wastewater stream exits the process, storage tank, or last recovery device. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, the discharge point from the process equipment or storage tank is a POD. If water streams are routed to a recovery device, the discharge from the recovery device is a POD. There can be more than 1 POD per process or PMPU.

*Precursor* means a material that is manufactured to undergo further chemical change or processing to ultimately manufacture an active ingredient or finished dosage form of a drug. This term does not include commodity chemicals produced by the synthetic organic chemical manufacturing industry.

*Pressure release* means the emission of materials resulting from the system pressure being greater than the set pressure of the pressure relief device. This release can be one release or a series of releases over a short time period due to a malfunction in the process.

*Pressure relief device or valve* means a safety device used to prevent operating pressures from exceeding the maximum allowable working pressure of the process equipment. A common pressure relief device is a spring-loaded pressure relief valve. Devices that are actuated either by a pressure of less than or equal to 2.5 psig or by a vacuum are not pressure relief devices.

*Primary use* means 50 percent or more of a material is used for a particular purpose.

*Process* means all equipment which collectively function to produce a pharmaceutical product or isolated intermediate (which is also a pharmaceutical product). A process may consist of one or more unit operations. For the purposes of this subpart, process includes any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product or isolated intermediate. Cleaning operations conducted are considered part of the process. Nondedicated solvent recovery operations located within a contiguous area within the affected source are considered single processes. A storage tank that is used to accumulate used solvent from multiple batches of a single process for purposes of solvent recovery does not represent the end of the process. Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Quality assurance and quality control laboratories are not considered part of any process. Ancillary

activities are not considered a process or part of any process. Ancillary activities include boilers and incinerators (not used to comply with the provisions of §63.1253, §63.1254, or §63.1256(h)), chillers and refrigeration systems, and other equipment and activities that are not directly involved ( *i.e.*, they operate within a closed system and materials are not combined with process fluids) in the processing of raw materials or the manufacturing of a pharmaceutical product.

*Process condenser* means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition.

*Process shutdown* means a work practice or operational procedure that stops production from a process or part of a process during which it is technically feasible to clear process material from a process or part of a process consistent with safety constraints and during which repairs can be effected. An unscheduled work practice or operational procedure that stops production from a process or part of a process for less than 24 hours is not a process shutdown. An unscheduled work practice or operational procedure that would stop production from a process or part of a process for a shorter period of time than would be required to clear the process or part of the process of materials and start up the process, and would result in greater emissions than delay of repair of leaking components until the next scheduled process shutdown, is not a process shutdown. The use of spare equipment and technically feasible bypassing of equipment without stopping production are not process shutdowns.

*Process tank* means a tank that is used to collect material discharged from a feedstock storage tank or unit operation and to transfer this material to another unit operation within the process or to a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks. Product storage tanks are considered process tanks and are part of the PMPU that produce the stored material. For the purposes of this subpart, vents from process tanks are considered process vents.

*Process vent* means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge that no HAP are present in the emission stream or using an engineering assessment as discussed in §63.1257(d)(2)(ii), test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 of appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under §63.1253, vents on wastewater emission sources regulated under §63.1256, or pieces of equipment regulated under §63.1255.

*Production-indexed HAP consumption factor* is the result of dividing the annual consumption of total HAP by the annual production rate, per process.

*Production-indexed volatile organic compound (VOC) consumption factor* is the result of dividing the annual consumption of total VOC by the annual production rate, per process.

*Publicly owned treatment works (POTW)* means any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature as defined in section 212(2)(A) of the Clean Water Act, as amended [33 U.S.C. §1292(2)(A)]. A POTW includes the treatment works, intercepting sewers, outfall sewers, sewage collection systems, pumping, power, and other equipment. The POTW is defined at 40 CFR 403.3(o).

*Reactor* means a device or vessel in which one or more chemicals or reactants, other than air, are combined or decomposed in such a way that their molecular structures are altered and one or more new organic compounds are formed.

*Reconstruction*, as used in §63.1250(b), shall have the meaning given in §63.2, except that "affected or

previously unaffected stationary source” shall mean either “affected facility” or “PMPU.” As used in §63.1254(a)(3)(ii)(A)( 3 ), reconstruction shall have the meaning given in §63.2, except that “source” shall mean “control device.”

*Recovery device*, as used in the wastewater provisions, means an individual unit of equipment used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use, reuse, or for sale for fuel value, use or reuse. Examples of equipment that may be recovery devices include organic removal devices such as decanters, strippers, or thin-film evaporation units. To be a recovery device, a decanter and any other equipment based on the operating principle of gravity separation must receive only two-phase liquid streams.

*Repaired* means that equipment:

(1) Is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable paragraphs of §63.1255, and;

(2) Is, unless otherwise specified in applicable provisions of §63.1255, monitored as specified in §63.180(b) and (c) as appropriate, to verify that emissions from the equipment are below the applicable leak definition.

*Research and development facility* means any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically trained personnel, and is not engaged in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

*Residual* means any HAP-containing liquid or solid material that is removed from a wastewater stream by a waste management unit or treatment process that does not destroy organics (nondestructive unit). Examples of residuals from nondestructive waste management units are: the organic layer and bottom residue removed by a decanter or organic-water separator and the overheads from a steam stripper or air stripper. Examples of materials which are not residuals are: silt; mud; leaves; bottoms from a steam stripper or air stripper; and sludges, ash, or other materials removed from wastewater being treated by destructive devices such as biological treatment units and incinerators.

*Safety device* means a closure device such as a pressure relief valve, frangible disc, fusible plug, or any other type of device which functions exclusively to prevent physical damage or permanent deformation to a unit or its air emission control equipment by venting gases or vapors directly to the atmosphere during unsafe conditions resulting from an unplanned, accidental, or emergency event. For the purposes of this subpart, a safety device is not used for routine venting of gases or vapors from the vapor headspace underneath a cover such as during filling of the unit or to adjust the pressure in this vapor headspace in response to normal daily diurnal ambient temperature fluctuations. A safety device is designed to remain in a closed position during normal operations and open only when the internal pressure, or another relevant parameter, exceeds the device threshold setting applicable to the air emission control equipment as determined by the owner or operator based on manufacturer recommendations, applicable regulations, fire protection and prevention codes, standard engineering codes and practices, or other requirements for the safe handling of flammable, combustible, explosive, reactive, or hazardous materials.

*Sampling connection system* means an assembly of equipment within a process unit used during periods of representative operation to take samples of the process fluid. Equipment used to take nonroutine grab samples is not considered a sampling connection system.

*Sensor* means a device that measures a physical quantity or the change in a physical quantity, such as temperature, pressure, flow rate, pH, or liquid level.

*Set pressure* means the pressure at which a properly operating pressure relief device begins to open to relieve atypical process system operating pressure.

*Sewer line* means a lateral, trunk line, branch line, or other conduit including, but not limited to, grates, trenches, etc., used to convey wastewater streams or residuals to a downstream waste management unit.

*Shutdown* means the cessation of operation of a continuous process for any purpose. Shutdown also means the cessation of a batch process or any related individual piece of equipment required or used to comply with this subpart as a result of a malfunction or for replacement of equipment, repair, or any other

purpose not excluded from this definition. Shutdown also applies to emptying and degassing storage vessels. Shutdown does not apply to cessation of a batch process at the end of a campaign, for routine maintenance, for rinsing or washing of equipment between batches, or other routine operations.

*Single-seal system* means a floating roof having one continuous seal that completely covers the space between the wall of the storage tank and the edge of the floating roof. This seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

*Small control device* means a control device that controls total HAP emissions of less than 10 tons/yr, before control.

*Soluble HAP* means a HAP listed in Table 3 of this subpart.

*Standard batch* means a batch process operated within a range of operating conditions that are documented in an operating scenario. Emissions from a standard batch are based on the operating conditions that result in highest emissions. The standard batch defines the uncontrolled and controlled emissions for each emission episode defined under the operating scenario.

*Startup* means the setting in operation of a continuous process unit for any purpose; the first time a new or reconstructed batch process unit begins production; for new equipment added, including equipment used to comply with this subpart, the first time the equipment is put into operation; or, for the introduction of a new product/process, the first time the product or process is run in equipment. For batch process units, startup does not apply to the first time the equipment is put into operation at the start of a campaign to produce a product that has been produced in the past, after a shutdown for maintenance, or when the equipment is put into operation as part of a batch within a campaign. As used in §63.1255, startup means the setting in operation of a piece of equipment or a control device that is subject to this subpart.

*Storage tank* means a tank or other vessel that is used to store organic liquids that contain one or more HAP as raw material feedstocks. Storage tank also means a tank or other vessel in a tank farm that receives and accumulates used solvent from multiple batches of a process or processes for purposes of solvent recovery. The following are not considered storage tanks for the purposes of this subpart:

- (1) Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships;
- (2) Pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere;
- (3) Vessels storing organic liquids that contain HAP only as impurities;
- (4) Wastewater storage tanks; and
- (5) Process tanks (including product tanks and isolated intermediate tanks).

*Supplemental gases* are any gaseous streams that are not defined as process vents, or closed-vent systems from wastewater management and treatment units, storage tanks, or equipment components and that contain less than 50 ppmv TOC, as determined through process knowledge, that are introduced into vent streams or manifolds. Air required to operate combustion device burner(s) is not considered supplemental gas.

*Surface impoundment* means a waste management unit which is a natural topographic depression, manmade excavation, or diked area formed primarily of earthen materials (although it may be lined with manmade materials), which is designed to hold an accumulation of liquid wastes or waste containing free liquids. A surface impoundment is used for the purpose of treating, storing, or disposing of wastewater or residuals, and is not an injection well. Examples of surface impoundments are equalization, settling, and aeration pits, ponds, and lagoons.

*System flowrate* means the flowrate of gas entering the control device.

*Total organic compounds (TOC)* means those compounds measured according to the procedures of Method 18 or Method 25A, 40 CFR part 60, appendix A.

*Treatment process* means a specific technique that removes or destroys the organics in a wastewater or residual stream such as a steam stripping unit, thin-film evaporation unit, waste incinerator, biological treatment unit, or any other process applied to wastewater streams or residuals to comply with §63.1256.

Most treatment processes are conducted in tanks. Treatment processes are a subset of waste management units.

*Uncontrolled HAP emissions* means a gas stream containing HAP which has exited the process (or process condenser, if any), but which has not yet been introduced into an air pollution control device to reduce the mass of HAP in the stream. If the process vent is not routed to an air pollution control device, uncontrolled emissions are those HAP emissions released to the atmosphere.

*Unit operation* means those processing steps that occur within distinct equipment that are used, among other things, to prepare reactants, facilitate reactions, separate and purify products, and recycle materials. Equipment used for these purposes includes but is not limited to reactors, distillation columns, extraction columns, absorbers, decanters, dryers, condensers, and filtration equipment.

*Vapor-mounted seal* means a continuous seal that completely covers the annular space between the wall of the storage tank or waste management unit and the edge of the floating roof and is mounted such that there is a vapor space between the stored liquid and the bottom of the seal.

*Volatile organic compounds (VOC)* means those materials defined in 40 CFR 51.100.

*Waste management unit* means the equipment, structure(s), and or devices used to convey, store, treat, or dispose of wastewater streams or residuals. Examples of waste management units include wastewater tanks, air flotation units, surface impoundments, containers, oil-water or organic-water separators, individual drain systems, biological wastewater treatment units, waste incinerators, and organic removal devices such as steam and air stripper units, and thin film evaporation units. If such equipment is used for recovery then it is part of a pharmaceutical process and is not a waste management unit.

*Wastewater* means any portion of an individual wastewater stream or any aggregation of wastewater streams.

*Wastewater stream* means water that is discarded from a PMPU through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr. The following are not considered wastewater streams for the purposes of this subpart:

- (1) Stormwater from segregated sewers;
- (2) Water from fire-fighting and deluge systems, including testing of such systems;
- (3) Spills;
- (4) Water from safety showers;
- (5) Samples of a size not greater than reasonably necessary for the method of analysis that is used;
- (6) Equipment leaks;
- (7) Wastewater drips from procedures such as disconnecting hoses after clearing lines; and
- (8) Noncontact cooling water.

*Wastewater tank* means a stationary waste management unit that is designed to contain an accumulation of wastewater or residuals and is constructed primarily of nonearthen materials (e.g., wood, concrete, steel, plastic) which provide structural support. Wastewater tanks used for flow equalization are included in this definition.

*Water seal controls* means a seal pot, p-leg trap, or other type of trap filled with water (e.g., flooded sewers that maintain water levels adequate to prevent air flow through the system) that creates a water barrier between the sewer line and the atmosphere. The water level of the seal must be maintained in the vertical leg of a drain in order to be considered a water seal.

[63 FR 50326, Sept. 21, 1998, as amended at 65 FR 52598, Aug. 29, 2000; 71 FR 20459, Apr. 20, 2006]

### **§ 63.1257 Test methods and compliance procedures.**

- (a) *General.* Except as specified in paragraph (a)(5) of this section, the procedures specified in

paragraphs (c), (d), (e), and (f) of this section are required to demonstrate initial compliance with §§63.1253, 63.1254, 63.1256, and 63.1252(e), respectively. The provisions in paragraphs (a) (2) through (3) apply to performance tests that are specified in paragraphs (c), (d), and (e) of this section. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in §§63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of this section are used to comply with the outlet concentration requirements specified in §§63.1253(c), 63.1254(a)(2)(i) and (a)(3)(ii)(B), 63.1254(b)(i) and 63.1256(h)(2).

(b) *Test methods.* When testing is conducted to measure emissions from an affected source, the test methods specified in paragraphs (b)(1) through (10) of this section shall be used.

(1) EPA Method 1 or 1A of appendix A of part 60 is used for sample and velocity traverses.

(2) EPA Method 2, 2A, 2C, or 2D of appendix A of part 60 is used for velocity and volumetric flow rates.

(3) EPA Method 3 of appendix A of part 60 is used for gas analysis.

(4) EPA Method 4 of appendix A of part 60 is used for stack gas moisture.

(5) [Reserved]

(6) The following methods are specified for concentration measurements:

(i) Method 18 may be used to determine HAP concentration in any control device efficiency determination.

(8) *Testing and compliance determination conditions for batch processes.* Testing of emissions on equipment where the flow of gaseous emissions is intermittent (batch operations) shall be conducted as specified in paragraphs (b)(8)(i) through (iii) of this section.

(i) Except as provided in paragraph (b)(9) of this section for condensers, testing shall be conducted at absolute worst-case conditions or hypothetical worst-case conditions. Gas stream volumetric flow rates shall be measured at 15-minute intervals. The HAP or TOC concentration shall be determined from samples collected in an integrated sample over the duration of the test, or from grab samples collected simultaneously with the flow rate measurements (every 15 minutes). If an integrated sample is collected for laboratory analysis, the sampling rate shall be adjusted proportionally to reflect variations in flow rate. The absolute worst-case or hypothetical worst-case conditions shall be characterized by the criteria presented in paragraphs (b)(8)(i)(A) and (B) of this section. In all cases, a site-specific plan shall be submitted to the Administrator for approval prior to testing in accordance with §63.7(c) and §63.1260(l). The test plan shall include the emission profile described in paragraph (b)(8)(ii) of this section.

(A) Absolute worst-case conditions are defined by the criteria presented in paragraph (b)(8)(i)(A)( 1 ) or ( 2 ) of this section if the maximum load is the most challenging condition for the control device. Otherwise, absolute worst-case conditions are defined by the conditions in paragraph (b)(8)(i)(A)( 3 ) of this section. The owner or operator must consider all relevant factors, including load and compound-specific characteristics in defining absolute worst-case conditions.

( 1 ) The period in which the inlet to the control device will contain at least 50 percent of the maximum HAP load (in lb) capable of being vented to the control device over any 8 hour period. An emission profile as described in paragraph (b)(8)(ii)(A) of this section shall be used to identify the 8-hour period that includes the maximum projected HAP load.

( 2 ) A 1-hour period of time in which the inlet to the control device will contain the highest HAP mass loading rate, in lb/hr, capable of being vented to the control device. An emission profile as described in paragraph (b)(8)(ii)(A) of this section shall be used to identify the 1-hour period of maximum HAP loading.

( 3 ) The period of time when the HAP loading or stream composition (including non-HAP) is most challenging for the control device. These conditions include, but are not limited to the following:

( i ) Periods when the stream contains the highest combined VOC and HAP load, in lb/hr, described by the emission profiles in paragraph (b)(8)(ii) of this section;

( ii ) Periods when the streams contain HAP constituents that approach limits of solubility for scrubbing media;

( iii ) Periods when the streams contain HAP constituents that approach limits of adsorptivity for carbon adsorption systems.

(B) Hypothetical worst-case conditions are simulated test conditions that, at a minimum, contain the highest hourly HAP load of emissions that would be predicted to be vented to the control device from the emissions profile described in paragraph (b)(8)(ii)(B) or (C) of this section.

(ii) *Emissions profile.* The owner or operator may choose to perform tests only during those periods of the worst-case conditions that the owner or operator selects to control as part of achieving the required emission reduction. The owner or operator must develop an emission profile for the vent to the control device that describes the characteristics of the vent stream at the inlet to the control device under worst case conditions. The emission profile shall be developed based on any one of the procedures described in (b)(8)(ii)(A) through (C) of this section, as required by paragraph (b)(8)(i).

(A) *Emission profile by process.* The emission profile must consider all emission episodes that could contribute to the vent stack for a period of time that is sufficient to include all processes venting to the stack and shall consider production scheduling. The profile shall describe the HAP load to the device that equals the highest sum of emissions from the episodes that can vent to the control device in any given hour. Emissions per episode shall be calculated using the procedures specified in paragraph (d)(2) of this section. Emissions per episode shall be divided by the duration of the episode only if the duration of the episode is longer than 1 hour.

(B) *Emission profile by equipment.* The emission profile must consist of emissions that meet or exceed the highest emissions, in lb/hr, that would be expected under actual processing conditions. The profile shall describe equipment configurations used to generate the emission events, volatility of materials processed in the equipment, and the rationale used to identify and characterize the emission events. The emissions may be based on using a compound more volatile than compounds actually used in the process(es), and the emissions may be generated from all equipment in the process(es) or only selected equipment.

(C) *Emission profile by capture and control device limitation.* The emission profile shall consider the capture and control system limitations and the highest emissions, in lb/hr, that can be routed to the control device, based on maximum flowrate and concentrations possible because of limitations on conveyance and control equipment (e.g., fans, LEL alarms and safety bypasses).

(iii) Three runs, at a minimum of 1 hour each and a maximum of 8 hours each, are required for performance testing. Each run must occur over the same worst-case conditions, as defined in paragraph (b)(8)(i) of this section.

#### **§ 63.1258 Monitoring Requirements.**

(a) The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in this section. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the control device design shall be used to establish the operating parameter level.

#### **§ 63.1259 Recordkeeping requirements.**

(a) *Requirements of subpart A of this part.* The owner or operator of an affected source shall comply with the recordkeeping requirements in subpart A of this part as specified in Table 1 of this subpart and in paragraphs (a)(1) through (5) of this section.

(1) *Data retention.* Each owner or operator of an affected source shall keep copies of all records and reports required by this subpart for at least 5 years, as specified in §63.10(b)(1).

(2) *Records of applicability determinations.* The owner or operator of a stationary source that is not subject to this subpart shall keep a record of the applicability determination, as specified in §63.10(b)(3).

(3) *Startup, shutdown, and malfunction plan.* The owner or operator of an affected source shall develop a written startup, shutdown, and malfunction plan as specified in §63.6(e)(3). This plan shall describe, in detail, procedures for operating and maintaining the affected source during periods of startup, shutdown, and malfunction and a program for corrective action for malfunctioning process, air pollution control, and

monitoring equipment used to comply with this subpart. The owner or operator of an affected source shall keep the current and superseded versions of this plan onsite, as specified in §63.6(e)(3)(v). The owner or operator shall keep the startup, shutdown, and malfunction records specified in paragraphs (a)(3)(i) through (iii) of this section. Reports related to the plan shall be submitted as specified in §63.1260(i).

(i) The owner or operator shall record the occurrence and duration of each malfunction of the process operations or of air pollution control equipment used to comply with this subpart, as specified in §63.6(e)(3)(iii).

(ii) The owner or operator shall record the occurrence and duration of each malfunction of continuous monitoring systems used to comply with this subpart.

(iii) For each startup, shutdown, or malfunction, the owner or operator shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown, and malfunction plan were followed, as specified in §63.6(e)(3)(iii); alternatively, the owner or operator shall record any actions taken that are not consistent with the plan, as specified in §63.6(e)(3)(iv).

(5) *Application for approval of construction or reconstruction.* For new affected sources, each owner or operator shall comply with the provisions in §63.5 regarding construction and reconstruction, excluding the provisions specified in §63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii).

(c) *Records of operating scenarios.* The owner or operator of an affected source shall keep records of each operating scenario which demonstrates compliance with this subpart.

[63 FR 50326, Sept. 21, 1998, as amended at 65 FR 52613, Aug. 29, 2000; 66 FR 40135, Aug. 2, 2001; 70 FR 25670, May 13, 2005; 71 FR 20459, Apr. 20, 2006]

#### **§ 63.1260 Reporting requirements.**

(a) The owner or operator of an affected source shall comply with the reporting requirements of paragraphs (b) through (l) of this section. Applicable reporting requirements of §§63.9 and 63.10 are also summarized in Table 1 of this subpart.

(b) *Initial notification.* The owner or operator shall submit the applicable initial notification in accordance with §63.9(b) or (d).

(c) *Application for approval of construction or reconstruction.* An owner or operator who is subject to §63.5(b)(3) shall submit to the Administrator an application for approval of the construction of a new major affected source, the reconstruction of a major affected source, or the reconstruction of a major source such that the source becomes a major affected source subject to the standards. The application shall be prepared in accordance with §63.5(d).

(f) *Notification of Compliance Status report.* The Notification of Compliance Status report required under §63.9 shall be submitted no later than 150 days after the compliance date and shall include:

(1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.

(2) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.

(3) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.

(4) Listing of all operating scenarios.

(g) *Periodic reports.* An owner or operator shall prepare Periodic reports in accordance with paragraphs (g)(1) and (2) of this section and submit them to the Administrator.

(1) *Submittal schedule.* Except as provided in paragraphs (g)(1)(i), (ii), and (iii) of this section, an owner or operator shall submit Periodic reports semiannually. The first report shall be submitted no later than 240 days after the Notification of Compliance Status is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status is due. Each subsequent Periodic report shall cover the 6-

month period following the preceding period.

(i) When the Administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source; or

(ii) Quarterly reports shall be submitted when the source experiences an exceedance of a temperature limit monitored according to the provisions of §63.1258(b)(1)(iii) or an exceedance of the outlet concentration monitored according to the provisions of §63.1258(b)(1)(x) or (b)(5). Once an affected source reports quarterly, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If an owner or operator submits a request to reduce the frequency of reporting, the provisions in §63.10(e)(3)(ii) and (iii) shall apply, except that the phrase "excess emissions and continuous monitoring system performance report and/or summary report" shall mean "Periodic report" for the purposes of this section.

(iii) When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted.

(2) *Content of Periodic report.* The owner or operator shall include the information in paragraphs (g)(2)(i) through (vii) of this section, as applicable.

(i) Each Periodic report must include the information in §63.10(e)(3)(vi)(A) through (I) and (K) through (M). For each continuous monitoring system, the Periodic report must also include the information in §63.10(e)(3)(vi)(J).

(ii) If the total duration of excess emissions, parameter exceedances, or excursions for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total continuous monitoring system downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, the Periodic report must include the information in paragraphs (g)(2)(ii)(A) through (D) of this section.

(A) Monitoring data, including 15-minute monitoring values as well as daily average values of monitored parameters, for all operating days when the average values were outside the ranges established in the Notification of Compliance Status report or operating permit.

(B) Duration of excursions, as defined in §63.1258(b)(7).

(C) Operating logs and operating scenarios for all operating scenarios for all operating days when the values are outside the levels established in the Notification of Compliance Status report or operating permit.

(D) When a continuous monitoring system is used, the information required in §63.10(c)(5) through (13).

(iii) For each inspection conducted in accordance with §63.1258(h)(2) or (3) during which a leak is detected, the records specified in §63.1259(i)(7) must be included in the next Periodic report.

(iv) For each vapor collection system or closed vent system with a bypass line subject to §63.1252(b)(1), records required under §63.1259(i)(6)(i) of all periods when the vent stream is diverted from the control device through a bypass line. For each vapor collection system or closed vent system with a bypass line subject to §63.1252(b)(2), records required under §63.1259(i)(6)(ii) of all periods in which the seal mechanism is broken, the bypass valve position has changed, or the key to unlock the bypass line valve was checked out.

(v) The information in paragraphs (g)(2)(v)(A) through (D) of this section shall be stated in the Periodic report, when applicable.

(A) No excess emissions.

(B) No exceedances of a parameter.

(C) No excursions.

(D) No continuous monitoring system has been inoperative, out of control, repaired, or adjusted.

(vii) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each new operating scenario, the owner or operator shall provide verification that the

operating conditions for any associated control or treatment device have not been exceeded, and that any required calculations and engineering analyses have been performed. For the initial Periodic report, each operating scenario for each process operated since the due date of the Notification of Compliance Status Report shall be submitted.

(h) *Notification of process change.* (1) Except as specified in paragraph (h)(2) of this section, whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, the owner or operator shall submit the information specified in paragraphs (h)(1)(i) through (iv) of this section with the next Periodic report required under paragraph (g) of this section.

(i) A brief description of the process change.

(ii) A description of any modifications to standard procedures or quality assurance procedures.

(iii) Revisions to any of the information reported in the original Notification of Compliance Status Report under paragraph (f) of this section.

(iv) Information required by the Notification of Compliance Status Report under paragraph (f) of this section for changes involving the addition of processes or equipment.

(2) An owner or operator must submit a report 60 days before the scheduled implementation date of either of the following:

(i) Any change in the activity covered by the Precompliance report.

(ii) A change in the status of a control device from small to large.

(i) *Reports of startup, shutdown, and malfunction.* An owner or operator shall prepare startup, shutdown, and malfunction reports as specified in paragraphs (i)(1) and (2) of this section.

(1) If actions taken by an owner or operator during a startup, shutdown, or malfunction of an affected source (including actions to correct a malfunction) are consistent with the procedures specified in the source's startup, shutdown, and malfunction plan, the owner or operator shall state this fact in a startup, shutdown, or malfunction report. The report shall also include the information specified in §63.1259(a)(3)(i) and (ii) and shall contain the name, title, and signature of the owner or operator or other responsible official who is certifying its accuracy. For the purposes of this subpart, the startup, shutdown, and malfunction reports shall be submitted on the same schedule as the periodic reports required under paragraph (g) of this section instead of the schedule specified in §63.10(d)(5)(i). Reports are only required if a startup, shutdown, or malfunction occurred during the reporting period.

(2) Any time an owner or operator takes an action that is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, the owner or operator shall submit immediate startup, shutdown, and malfunction reports as specified in §63.10(d)(5)(ii).

(l) *Notification of performance test and test plan.* The owner or operator of an affected source shall notify the Administrator of the planned date of a performance test at least 60 days before the test in accordance with §63.7(b). The owner or operator also must submit the test plan required by §63.7(c) and the emission profile required by 63.1257(b)(8)(ii) with the notification of the performance test.

(m) *Request for extension of compliance.* An owner or operator may submit to the Administrator a request for an extension of compliance in accordance with §63.1250(f)(4).

[63 FR 50326, Sept. 21, 1998, as amended at 65 FR 52614, Aug. 29, 2000; 66 FR 40135, Aug. 2, 2001]

### **§ 63.1261 Implementation and enforcement.**

(a) This subpart can be implemented and enforced by the U.S. EPA, or a delegated authority such as the applicable State, local, or Tribal agency. If the U.S. EPA Administrator has delegated authority to a State, local, or Tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. Contact the applicable U.S. EPA Regional Office to find out if implementation and enforcement of this subpart is delegated to a State, local, or Tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or Tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained

by the Administrator of U.S. EPA and cannot be transferred to the State, local, or Tribal agency.

(c) The authorities that cannot be delegated to State, local, or Tribal agencies are as specified in paragraphs (c)(1) through (4) of this section.

(1) Approval of alternatives to the requirements in §§63.1250 and 63.1252 through 63.1256. Where these standards reference another subpart, the cited provisions will be delegated according to the delegation provisions of the referenced subpart.

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

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

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

[68 FR 37356, June 23, 2003]

**Table 1 to Subpart GGG of Part 63—General Provisions Applicability to Subpart GGG**

<b>General provisions reference</b>	<b>Summary of requirements</b>	<b>Applies to subpart GGG</b>	<b>Comments</b>
63.1(a)(1)	General applicability of the General Provisions	Yes	Additional terms defined in §63.1251; when overlap between subparts A and GGG of this part, subpart GGG takes precedence.
63.1(a)(2–7)		Yes	
63.1(a)(8)		No	Discusses state programs.
63.1(a)(9–14)		Yes	
63.1(b)(1)	Initial applicability determination	Yes	Subpart GGG clarifies the applicability in §63.1250.
63.1(b)(2)	Title V operating permit—see part 70	Yes	All major affected sources are required to obtain a title V permit.
63.1(b)(3)	Record of the applicability determination	Yes	All affected sources are subject to subpart GGG according to the applicability definition of subpart GGG.
63.1(c)(1)	Applicability after standards are set	Yes	Subpart GGG clarifies the applicability of each paragraph of subpart A to sources subject to subpart GGG.
63.1(c)(2)	Title V permit requirement	No	All major affected sources are required to obtain a title V permit. Area sources are not subject to subpart GGG.
63.1(c)(3)	Reserved		

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.1(c)(4)	Requirements for existing source that obtains an extension of compliance	Yes	
§63.1(c)(5)	Notification requirements for an area source that increases HAP emissions to major source levels	Yes	
63.1(d)	[Reserved]	NA	
63.1(e)	Applicability of permit program before a relevant standard has been set	Yes	
63.2	Definitions.	Yes	Additional terms defined in §63.1251; when overlap between subparts A and GGG of this part occurs, subpart GGG takes precedence.
63.3	Units and abbreviations.	Yes	Other units used in subpart GGG are defined in that subpart.
63.4	Prohibited activities.	Yes	
63.5(a)	Construction and reconstruction— applicability	Yes	Except replace the terms “source” and “stationary source” with “affected source”.
63.5(b)(1)	Upon construction, relevant standards for new sources	Yes	
63.5(b)(2)	[Reserved]	NA	
63.5(b)(3)	New construction/reconstruction	Yes	Except for changes and additions authorized under §52.2454 of this title. However, the requirement to submit the Precompliance report at least 90 days before the compliance date still applies.
63.5(b)(4)	Construction/reconstruction notification	Yes	
63.5(b)(5)	Construction/reconstruction compliance	Yes	
63.5(b)(6)	Equipment addition or process change	Yes	
63.5(c)	[Reserved]	NA	

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.5(d)	Application for approval of construction/reconstruction	Yes	Except for certain provisions identified in 63.1259(a)(5)
§63.5(e)	Construction/reconstruction approval	Yes	
63.5(f)	Construction/reconstruction approval based on prior State review.	Yes	Except replace “source” with “affected source”.
63.6(a)(1)	Compliance with standards and maintenance requirements	Yes	
63.6(a)(2)	Requirements for area source that increases emissions to become major	Yes	
63.6(b)(1–2)	Compliance dates for new and reconstructed sources	No	Subpart GGG specifies compliance dates.
63.6(b)(3–6)	Compliance dates for area sources that become major sources	Yes	
63.6 (b)(7)	Compliance dates for new sources resulting from new unaffected area sources becoming subject to standards	No	Subpart GGG specifies NS applicability and compliance dates
63.6(c)	Compliance dates for existing sources	Yes	Except replace “source” with “affected source”. Subpart GGG specifies compliance dates.
63.6(e)	Operation and maintenance requirements	Yes	Startup, Shutdown, Malfunction Plan requirements specifically include malfunction process, control and monitoring equipment.
63.6(f)–(g)	Compliance with nonopacity and alternative nonopacity emission standards	Yes	Except that subpart GGG specifies performance test conditions.
63.6(h)	Opacity and visible emission standards	No	Subpart GGG does not contain any opacity or visible emission standards.
§63.6(i)(1) through (7)	Requests for compliance extensions	No	§63.1250(f)(6) specifies provisions for compliance extensions.
§63.6(i)(8) through (14)	Approval of compliance extensions	Yes	Except references to §63.6(i)(4) through (6) mean §63.1250(f)(6).
63.6(j)	Exemption from compliance with	Yes	

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
	emission standards		
63.7(a)(1)	Performance testing requirements	Yes	Subpart GGG also specifies required testing and compliance procedures.
63.7(a)(2)(i)–(ix)		Yes	Except substitute “150 days” instead of “180 days.”
63.7(a)(3)		Yes	
63.7(b)(1)	Notification of performance test	Yes	
63.7(b)(2)	Notification of delay in conducting a scheduled performance test	Yes	
63.7(c)	Quality assurance program	Yes	Except that the test plan must be submitted with the notification of the performance test.
63.7(d)	Performance testing facilities.	Yes	Except replace “source” with “affected source”.
63.7(e)	Conduct of performance tests.	Yes	Subpart GGG also contains test methods and procedures specific to pharmaceutical sources.
63.7(f)	Use of alternative test method	Yes	
63.7(g)	Data analysis, recordkeeping, and reporting	Yes	
63.7(h)	Waiver of performance tests	Yes	
63.8(a)	Monitoring requirements	Yes	See §63.1258.
63.8(b)(1)	Conduct of monitoring	Yes	
63.8(b)(2)	CMS and combined effluents	No	§63.1258 of subpart GGG provides specific CMS requirements.
63.8(b)(3)–(c)(4)	CMS requirements	Yes	§63.1259 also specifies recordkeeping for CMS.
63.8(c)(5)	COMS operation requirements	No	
63.8 (c)(6)–(8)	CMS calibration and malfunction provisions	No	Calibration procedures are provided in §63.1258.

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.8(d)	CMS quality control program	Yes	
63.8(e)(1)	Performance evaluations of CMS	Yes	
63.8(e)(2)	Notification of performance evaluation	Yes	
63.8(e)(3–4)	CMS requirements/alternatives	Yes	
§63.8(e)(5)(i)	Reporting performance evaluation results	Yes	See §63.1260(a).
63.1260 (a).			
63.8(e)(5)(ii)	Results of COMS performance evaluation	No	Subpart GGG does not contain any opacity or visible emission standards.
63.8(f)–(g)	Alternative monitoring method/reduction of monitoring data	Yes	
63.9(a)–(d)	Notification requirements— Applicability and general information	Yes	§63.1260 (b) also specifies initial notification requirement.
63.9(e)	Notification of performance test	Yes	§63.1260 (l) also specifies notification requirement for performance test.
63.9(f)	Notification of opacity and visible emissions observations	No	Subpart GGG does not contain any opacity or visible emission standards.
63.9(g)(1)	Additional notification requirements for sources with CMS	Yes	§63.1260 (d) also specifies notification requirement for performance evaluation.
63.9(g)(2)	Notification of compliance with opacity emission standard	No	Subpart GGG does not contain any opacity or visible emission standards.
63.9(g)(3)	Notification that criterion to continue use of alternative to relative accuracy testing has been exceeded	Yes	§63.1260 (d) also specifies notification requirement for performance evaluation.
63.9(h)	Notification of compliance status	Yes	Specified in §63.1260(f). Due 150 days after compliance date.
63.9(i)	Adjustment to time periods or postmark deadlines for submittal and review of required communications	Yes	
63.9(j)	Change in information provided	No	Subpart GGG specifies procedures for

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
			notification of changes.
63.10(a)	Recordkeeping requirements	Yes	
63.1259.			
63.10(b)(1)	Records retention	Yes	Also stated in §63.1259.
63.10(b)(2)	Information and documentation to support notifications	No	Subpart GGG specifies recordkeeping requirements.
63.10(b)(3)	Records retention for sources not subject to relevant standard	Yes	Also stated in §63.1259 (a)(2).
63.10(c)–(d)(2)	Other recordkeeping and reporting provisions	Yes	Also stated in §63.1259 (a)(4).
63.10(d)(3)	Reporting results of opacity or visible emissions observations	No	Subpart GGG does not include any opacity or visible emission standards.
63.10(d)(4-5)	Other recordkeeping and reporting provisions	Yes	
63.10(e)	Additional CMS reporting requirements	Yes	
63.10(f)	Waiver of recordkeeping or reporting requirements.	Yes	
63.11	Control device requirements for flares	Yes	
63.12	State authority and delegations	Yes	See §63.1261.
63.13	Addresses of State air pollution control agencies	Yes	
63.14	Incorporations by reference	Yes	
63.15	Availability of information and confidentiality	Yes	

[63 FR 50326, Sept. 21, 1998, as amended at 65 FR 52614, Aug. 29, 2000; 66 FR 40136, Aug. 2, 2001]

**Table 2 to Subpart GGG of Part 63—Partially Soluble HAP**

1,1,1-Trichloroethane (methyl chloroform)	Chloroform
1,1,2,2-Tetrachloroethane	Chloromethane
1,1,2-Trichloroethane	Chloroprene
1,1-Dichloroethylene (vinylidene chloride)	Cumene
1,2-Dibromoethane	Dichloroethyl ether
1,2-Dichloroethane (ethylene dichloride)	Dinitrophenol
1,2-Dichloropropane	Epichlorohydrin
1,3-Dichloropropene	Ethyl acrylate
2,4,5-Trichlorophenol	Ethylbenzene
2-Butanone (mek)	Ethylene oxide
1,4-Dichlorobenzene	Hexachlorobenzene
2-Nitropropane	Hexachlorobutadiene
4-Methyl-2-pentanone (MIBK)	Hexachloroethane
Acetaldehyde	Methyl methacrylate
Acrolein	Methyl-t-butyl ether
Acrylonitrile	Methylene chloride
Allyl chloride	N,N-dimethylaniline
Benzene	Propionaldehyde
Benzyl chloride	Propylene oxide
Biphenyl	Styrene
Bromoform (tribromomethane)	Tetrachloroethene (perchloroethylene)
Bromomethane	Tetrachloromethane (carbon tetrachloride)
Butadiene	Toluene

Carbon disulfide	Trichlorobenzene (1,2,4-)
Chlorobenzene	Trichloroethylene
Chloroethane (ethyl chloride)	Trimethylpentane
Vinyl acetate	Xylene (p)
Vinyl chloride	N-hexane
Xylene (m)	
Xylene (o)	

[66 FR 40136, Aug. 2, 2001]

**Table 3 to Subpart GGG of Part 63—Soluble HAP**

Compound
1,1-Dimethylhydrazine.
1,4-Dioxane.
Acetonitrile.
Acetophenone.
Diethyl sulfate.
Dimethyl sulfate.
Dinitrotoluene.
Ethylene glycol dimethyl ether.
Ethylene glycol monobutyl ether acetate.
Ethylene glycol monomethyl ether acetate.
Isophorone.
Methanol (methyl alcohol).
Nitrobenzene.
Toluidene.
Triethylamine.

[66 FR 40137, Aug. 2, 2001]

D.2.12 One Time Deadlines Relating to NESHAP Subpart GGG

The Permittee shall comply with the following requirements by the dates listed below:

Requirement	Rule Citation	Affected Facility	Deadline
Initial Notification	40 CFR 63.9(b)	Pharmaceutical manufacturing operations	No later than 120 days after the effective date
Notification of Compliance Status Report	40 CFR 63.9	Pharmaceutical manufacturing operations	No later than 150 days after compliance date

### SECTION D.3 EMISSIONS UNIT OPERATION CONDITIONS

#### Emissions Unit Description:

- (f) One (1) Colyte production area (identified as emission unit EU-01), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 328,300 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by dust collector DC011.

(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 2-7-5(1)]

##### D.3.1 Particulate Emissions [326 IAC 6-3]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the Colyte production area shall be limited as follows:

Facility	Process Weight (lbs/hr)	Particulate Emission Limit (lbs/hour)
Colyte Manufacturing Department	2,174	4.34

The pounds per hour limitation was calculated with the following equation:

Interpolation of the data for process weight rates up to 60,000 pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67}$$

where E = rate of emission in pounds per hour; and  
P = process weight rate in tons per hour.

#### Compliance Determination Requirements

##### D.3.2 Particulate Emissions

- (a) In order to comply with Condition D.3.1, the dust collector for particulate control shall be in operation and control emissions from the Colyte production area at all times that the Colyte production area is in operation.
- (b) In the event that bag failure is observed in a multi-compartment baghouse, if operations will continue for ten (10) days or more after the failure is observed before the failed units will be repaired or replaced, the Permittee shall promptly notify the IDEM, OAQ of the expected date the failed units will be repaired or replaced. The notification shall also include the status of the applicable compliance monitoring parameters with respect to normal, and the results of any response actions taken up to the time of notification.

## SECTION D.4

## EMISSIONS UNIT OPERATIONS CONDITIONS

### Specifically Regulated Insignificant Activities:

- (c) One (1) cold cleaner degreaser installed in 2006 with a fifteen gallon capacity [326 IAC 8-3].

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

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

#### D.4.1 Volatile Organic Compounds (VOC) [326 IAC 8-3-2]

Pursuant to 326 IAC 8-3-2 (Cold Cleaner Operations), for cold cleaning operations constructed after January 1, 1980, the Permittee shall:

- (a) Equip the cleaner with a cover;
- (b) Equip the cleaner with a facility for draining cleaned parts;
- (c) Close the degreaser cover whenever parts are not being handled in the cleaner;
- (d) Drain cleaned parts for at least fifteen (15) seconds or until dripping ceases;
- (e) Provide a permanent, conspicuous label summarizing the operation requirements;
- (f) Store waste solvent only in covered containers and not dispose of waste solvent or transfer it to another party, in such a manner that greater than twenty percent (20%) of the waste solvent (by weight) can evaporate into the atmosphere.

#### D.4.2 Volatile Organic Compounds (VOC) [326 IAC 8-3-5]

- (a) Pursuant to 326 IAC 8-3-5(a) (Cold Cleaner Degreaser Operation and Control), for cold cleaner degreaser operations without remote solvent reservoirs constructed after July 1, 1990, the Permittee shall ensure that the following control equipment requirements are met:

- (1) Equip the degreaser with a cover. The cover must be designed so that it can be easily operated with one (1) hand if:
  - (A) The solvent volatility is greater than two (2) kiloPascals (fifteen (15) millimeters of mercury or three-tenths (0.3) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100°F));
  - (B) The solvent is agitated; or
  - (C) The solvent is heated.
- (2) Equip the degreaser with a facility for draining cleaned articles. If the solvent volatility is greater than four and three-tenths (4.3) kiloPascals (thirty-two (32) millimeters of mercury or six-tenths (0.6) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100°F)), then the drainage facility must be internal such that articles are enclosed under the cover while draining. The drainage facility may be external for applications where an internal type cannot fit into the cleaning system.
- (3) Provide a permanent, conspicuous label which lists the operating requirements outlined in subsection (b).

- (4) The solvent spray, if used, must be a solid, fluid stream and shall be applied at a pressure which does not cause excessive splashing.
  - (5) Equip the degreaser with one (1) of the following control devices if the solvent volatility is greater than four and three-tenths (4.3) kiloPascals (thirty-two (32) millimeters of mercury or six-tenths (0.6) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100°F)), or if the solvent is heated to a temperature greater than forty-eight and nine-tenths degrees Celsius (48.9°C) (one hundred twenty degrees Fahrenheit (120°F)):
    - (A) A freeboard that attains a freeboard ratio of seventy-five hundredths (0.75) or greater.
    - (B) A water cover when solvent is used is insoluble in, and heavier than, water.
    - (C) Other systems of demonstrated equivalent control such as a refrigerated chiller or carbon adsorption. Such systems shall be submitted to the U.S. EPA as a SIP revision.
- (b) Pursuant to 326 IAC 8-3-5(b) (Cold Cleaner Degreaser Operation and Control), the owner or operator of a cold cleaning facility construction of which commenced after July 1, 1990, shall ensure that the following operating requirements are met:
- (1) Close the cover whenever articles are not being handled in the degreaser.
  - (2) Drain cleaned articles for at least fifteen (15) seconds or until dripping ceases.
  - (3) Store waste solvent only in covered containers and prohibit the disposal or transfer of waste solvent in any manner in which greater than twenty percent (20%) of the waste solvent by weight could evaporate.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR QUALITY  
PART 70 OPERATING PERMIT  
CERTIFICATION**

Source Name: Schwarz Pharma Manufacturing, Inc.  
Source Address: 1101 C Avenue West, Seymour, Indiana 47274  
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274  
Part 70 Permit No.: T071-23273-00023

**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:

Phone:

Date:

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR QUALITY  
COMPLIANCE BRANCH  
100 North Senate Avenue  
MC 61-53 IGCN 1003  
Indianapolis, Indiana 46204-2251  
Phone: 317-233-0178  
Fax: 317-233-6865**

**PART 70 OPERATING PERMIT  
EMERGENCY OCCURRENCE REPORT**

Source Name: Schwarz Pharma Manufacturing, Inc.  
Source Address: 1101 C Avenue West, Seymour, Indiana 47274  
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274  
Part 70 Permit No.: T071-23273-00023

**This form consists of 2 pages**

**Page 1 of 2**

- This is an emergency as defined in 326 IAC 2-7-1(12)
- The Permittee must notify the Office of Air Quality (OAQ), within four (4) business hours (1-800-451-6027 or 317-233-0178, ask for Compliance Section); and
  - The Permittee must submit notice in writing or by facsimile within two (2) working days (Facsimile Number: 317-233-6865), and follow the other requirements of 326 IAC 2-7-16.

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A

**Page 2 of 2**

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency?    Y    N
Type of Pollutants Emitted: TSP, PM-10, SO <sub>2</sub> , VOC, NO <sub>x</sub> , CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by: \_\_\_\_\_

Title / Position: \_\_\_\_\_

Date: \_\_\_\_\_

Phone: \_\_\_\_\_

A certification is not required for this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR QUALITY  
COMPLIANCE DATA SECTION  
PART 70 OPERATING PERMIT  
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT**

Source Name: Schwarz Pharma Manufacturing, Inc.  
Source Address: 1101 C Avenue West, Seymour, Indiana 47274  
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274  
Part 70 Permit No.: T071-23273-00023

**Months: \_\_\_\_\_ to \_\_\_\_\_ Year: \_\_\_\_\_**

Page 1 of 2

<p>This report shall be submitted quarterly based on a calendar year. Any deviation from the requirements, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. A deviation required to be reported pursuant to an applicable requirement that exists independent of the permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".</p>	
<p><input type="checkbox"/> NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.</p>	
<p><input type="checkbox"/> THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD</p>	
<p><b>Permit Requirement</b> (specify permit condition #)</p>	
<p><b>Date of Deviation:</b></p>	<p><b>Duration of Deviation:</b></p>
<p><b>Number of Deviations:</b></p>	
<p><b>Probable Cause of Deviation:</b></p>	
<p><b>Response Steps Taken:</b></p>	
<p><b>Permit Requirement</b> (specify permit condition #)</p>	
<p><b>Date of Deviation:</b></p>	<p><b>Duration of Deviation:</b></p>
<p><b>Number of Deviations:</b></p>	
<p><b>Probable Cause of Deviation:</b></p>	
<p><b>Response Steps Taken:</b></p>	

<b>Permit Requirement (specify permit condition #)</b>	
<b>Date of Deviation:</b>	<b>Duration of Deviation:</b>
<b>Number of Deviations:</b>	
<b>Probable Cause of Deviation:</b>	
<b>Response Steps Taken:</b>	
<b>Permit Requirement (specify permit condition #)</b>	
<b>Date of Deviation:</b>	<b>Duration of Deviation:</b>
<b>Number of Deviations:</b>	
<b>Probable Cause of Deviation:</b>	
<b>Response Steps Taken:</b>	
<b>Permit Requirement (specify permit condition #)</b>	
<b>Date of Deviation:</b>	<b>Duration of Deviation:</b>
<b>Number of Deviations:</b>	
<b>Probable Cause of Deviation:</b>	
<b>Response Steps Taken:</b>	

Form Completed by: \_\_\_\_\_

Title / Position: \_\_\_\_\_

Date: \_\_\_\_\_

Phone: \_\_\_\_\_

Attach a signed certification to complete this report.

**Appendix A: Emission Calculations**  
**Particulate Emissions from Tablet Hi-Coater**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Address City IN Zip:** 1101 C Avenue West, Seymour, IN 47274  
**Permit:** 071-28749-00023

Process	Throughput lb/hr	Throughput tons/year	Emission Factor* lb PM / ton material	PTE Before Controls PM/PM <sub>10</sub> tons/year	Control efficiency, pct.	PTE After Controls PM/PM <sub>10</sub> tons/year
Aqueous based Tablet Hi-Coater with dust collector DC014	30	130	5	0.3	99.9%	0.0003

Process	Max Batch / Month	Max Batch / Size (kg)	Throughput kg/month
DC014	28	350	9800

\*This emission factor is from AP-42 (4th Edition), Chapter 6.4-6 for grain handling and was used in the original TV Operating Permit 071-7162-00023.



# 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](http://www.idem.IN.gov)

## SENT VIA U.S. MAIL: CONFIRMED DELIVERY AND SIGNATURE REQUESTED

**TO:** Dwight Howard  
Schwarz Pharma USA, Inc.  
1101 C Avenue West  
Seymour, IN 47274

**DATE:** January 5, 2010

**FROM:** Matt Stuckey, Branch Chief  
Permits Branch  
Office of Air Quality

**SUBJECT:** Final Decision  
Title V - Administrative Amendment  
071 - 28749 - 00023

Enclosed is the final decision and supporting materials for the air permit application referenced above. Please note that this packet contains the original, signed, permit documents.

The final decision is being sent to you because our records indicate that you are the contact person for this application. However, if you are not the appropriate person within your company to receive this document, please forward it to the correct person.

A copy of the final decision and supporting materials has also been sent via standard mail to:  
Jeff Siefert, VP of Ops  
August Mack Environmental  
OAQ Permits Branch Interested Parties List

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178, or toll-free at 1-800-451-6027 (ext. 3-0178), and ask to speak to the permit reviewer who prepared the permit. If you think you have received this document in error, please contact Joanne Smiddie-Brush of my staff at 1-800-451-6027 (ext 3-0185), or via e-mail at [jbrush@idem.IN.gov](mailto:jbrush@idem.IN.gov).

Final Applicant Cover letter.dot 11/30/07

# Mail Code 61-53

IDEM Staff	LPOGOST 1/5/2010 Schwarz Pharma USA, Inc. 071 - 28749 - 00023 (/final)		AFFIX STAMP HERE IF USED AS CERTIFICATE OF MAILING	
Name and address of Sender		Indiana Department of Environmental Management Office of Air Quality – Permits Branch 100 N. Senate Indianapolis, IN 46204	Type of Mail:  <b>CERTIFICATE OF MAILING ONLY</b>	

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											Remarks
1		Dwight Howard Schwarz Pharma USA, Inc. 1101 C Avenue West Seymour IN 47274 (Source CAATS) Via confirmed delivery									
2		Jeff Siefert VP of Ops Schwarz Pharma USA, Inc. 1101 C Avenue West Seymour IN 47274 (RO CAATS)									
3		Jackson County Commissioner Jackson County Courthouse Brownstown IN 47220 (Local Official)									
4		Mr. Randy Brown Plumbers & Steam Fitters Union, Local 136 2300 St. Joe Industrial Park Dr Evansville IN 47720 (Affected Party)									
5		Mr. Tome Earnhart 3960 N. CR 300 W. North Vernon IN 47265 (Affected Party)									
6		Seymour City Council and Mayors Office 301 North Chestnut Street Seymour IN 47274 (Local Official)									
7		Jackson County Health Department 801 West 2nd Street Seymour IN 47274-2711 (Health Department)									
8		August Mack Environmental, Inc. 1200 N. Meridian Street Ste #400 Indianapolis IN 46204 (Consultant)									
9											
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