



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

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

TO: Interested Parties / Applicant
DATE: January 22, 2007
RE: Siemens Medical Solutions Diagnostics / 039-23901-00242
FROM: Nisha Sizemore
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, Room 1049, 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.dot 03/23/06



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We make Indiana a cleaner, healthier place to live.

Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

January 22, 2007

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Indianapolis, Indiana 46204-2251
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Mr. Thomas M. Lenz
Siemens Medical Solutions Diagnostics, Inc.
3400 Middlebury Street
Elkhart, Indiana 46516

Re: 039-23901-00242
Second Administrative Amendment to
FESOP No: F039-15752-00242

Dear Mr. Lenz:

Bayer Health Care LLC was issued a FESOP permit on November 3, 2005 for a stationary test strip impregnation source. A letter requesting a change in ownership, operational control and in the authorized individual was received on November 16, 2006. Pursuant to the provisions of 326 IAC 2-8-10 (a)(2) and (4), the permit is hereby administratively amended as follows:

1. The authorized individual was changed from Mr. Williams T. Loyd, Vice President, Global Manufacturing and Distribution for Bayer HealthCare Diabetes Care to Michael W. Kofeldt, Acting Plant Manager for Siemens Medical Solutions Diagnostics, Inc. The Plant Manager position meets the requirements of 326 IAC 2-1.1-1(1) as an authorized individual. The **bold faced language** is new language that has been added and ~~language with a line drawn through~~ is language that has been removed. The following changes were made to Sections A.1 of the permit:

A.1 General Information [326 IAC 2-8-3(b)]

The Permittee owns and operates a stationary test strip impregnation source.

Authorized individual: ~~Vice President, Manufacturing~~
Plant Manager

Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516

Mailing Address: ~~430 South Beiger Street, P.O. Box 2004, Mishawaka, Indiana 46546-2004~~
3400 Middlebury Street, Elkhart, Indiana 46516

General Source Phone: (574) 262-6136

SIC Code: 2835

County Location: Elkhart

Source Location Status: Nonattainment for the 8-hour Ozone Standard
Attainment for all other criteria pollutants

Source Status: Federally Enforceable State Operating Permit (FESOP)
Minor Source, under PSD and Emission Offset Rules
Minor Source, Section 112 of the Clean Air Act
Not in 1 of 28 Source Categories

2. Effective January 1, 2007, Siemens Medical Solutions Diagnostics, Inc. assumed ownership from Bayer Healthcare Diabetes Care of the source located at 3400 Middlebury Street, Elkhart, Indiana 46516. Operational control was also transferred on January 1, 2007 from Bayer HealthCare, LLC to Siemens Medical Solutions Diagnostics, Inc., who assumed responsibility for the compliance and reporting requirements. The mailing address was changed from 430 South Beiger Street, Mishawaka, Indiana 46544 to 3400 Middlebury Street, Elkhart, Indiana 46516.

As a courtesy, a complete updated copy of the permit has been provided.

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 Gary Freeman, of my staff, at 317-233-5334 or 1-800-451-6027, and ask for extension 3-5334.

Sincerely,

*Original document signed
by Iryn Calilung for*

Nisha Sizemore Chief
Permits Branch
Office of Air Quality

Attachments: Updated Permit

NS/gkf

cc: File – Elkhart County
Elkhart County Health Department
Air Compliance Section – Anthony Pelath
IDEM Northern Regional Office
Permit Review Section 4 - Gary Freeman
Billing, Licensing and Training Section
Compliance Data Section



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FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP) RENEWAL OFFICE OF AIR QUALITY

**Siemens Medical Solutions Diagnostics, Inc.
3400 Middlebury Street
Elkhart, Indiana 46516**

(herein known as the Permittee) is hereby authorized to construct and 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 provision of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. 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.

Indiana statutes from IC 13 and rules from 326 IAC, quoted in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a FESOP under 326 IAC 2-8.

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 2-8 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 2-8-11.1, applicable to those conditions.

Operation Permit No.: F039-15752-00242	
Issued by: Original signed by Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: November 3, 2005 Expiration Date: November 3, 2010
First Administrative Amendment No.: 039-22403-00242, issued January 31, 2006 First Significant Permit Revision No: 039-22998-00242, issued October 2, 2006	
Second Administrative Amendment No: 039-23901-00242	Pages Affected: All
<i>Original document signed by Iryn Calilung for</i> Issued by: Nisha Sizemore, Chief Permits Branch Office of Air Quality	Issuance Date: January 22, 2007 Expiration Date: November 3, 2010

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Stratospheric Ozone Protection

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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 2-8-3(b)]

The Permittee owns and operates a stationary test strip impregnation source.

Authorized individual: Plant Manager
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
General Source Phone: (574) 262-6136
SIC Code: 2835
County Location: Elkhart
Source Location Status: Nonattainment for the 8-hour Ozone Standard
Attainment for all other criteria pollutants
Source Status: Federally Enforceable State Operating Permit (FESOP)
Minor Source, under PSD and Emission Offset Rules
Minor 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 2-8-3(c)(3)]

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

- (a) One (1) reagent strip coating/drying line, identified as Egan Impregnating Line and Tunnel Dryer, constructed in 1980, equipped with a natural gas-fired direct flame oxidizer, identified as TO-1, exhausting to stacks 5 and 5B, rated at twenty-three (23) million British thermal units per hour, capacity: twenty (20) feet of paper strips per minute.
- (b) One (1) reagent strip coating/drying line with two (2) dryers, identified as the Overly Impregnating Line and Dryers 1 and 2, constructed in 1982, equipped with one (1) natural gas-fired direct flame oxidizer, identified as TO-2, exhausting to stacks 6, 6B1 and 6B2, rated at 3.95 million British thermal units per hour, capacity: twenty (20) feet of paper strips per minute, total.
- (c) One (1) Chemical Synthesis Unit, formerly identified as Building 10, approved for construction in 2006, for the production of invitro diagnostic reagents, consisting of uncontrolled bench scale laboratory batch operations exhausting to various fume hoods and sweeps, a Stokes vacuum shelf dryer, and a steam jet vacuum system.
- (d) One (1) Organic Chemistry Production Lab, approved for construction in 2006, consisting of uncontrolled bench scale laboratory batch operations exhausting to various fume hoods and sweeps.
- (e) One (1) Protein Development Lab, formerly identified as Building 17, approved for construction in 2006, consisting of uncontrolled methanol cleaning operations exhausting to various fume hoods and sweeps.

A.3 Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-8-3(c)(3)(I)]

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

- (a) One (1) natural gas-fired boiler, identified as 1-1-1, constructed in 1980, exhausting to Vent 1a, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (b) One (1) natural gas-fired boiler, identified as 2-1-1, constructed in 1980, exhausting to Vent 1b, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (c) One (1) natural gas-fired boiler, identified as 3-1-1, constructed in 1982, exhausting to Vent 1c, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (d) One (1) natural gas-fired boiler, identified as 4-1-1, constructed in 1982, exhausting to Vent 1d, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (e) One (1) natural gas-fired emergency generator, identified as 11-1-1, constructed in 1980, equipped with a combustion vent, rated at 0.3415 million British thermal units per hour.
- (f) One (1) natural gas-fired emergency generator, identified as 12-1-1, constructed in 1980, equipped with a combustion vent, rated at 0.1024 million British thermal units per hour.
- (g) One (1) ethylene glycol usage facility, identified as F1-1, using a maximum of 1.0 ton of ethylene glycol per year.
- (h) Two (2) maintenance degreasers, using only non-VOC, non-HAP materials.
- (i) One (1) natural gas-fired emergency generator, identified as 13-1-1, to be installed in 2006, equipped with a combustion vent, rated at 0.222 million British thermal units per hour.

A.4 FESOP Applicability [326 IAC 2-8-2]

This stationary source, otherwise required to have a Part 70 permit as described in 326 IAC 2-7-2(a), has applied to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) to renew a Federally Enforceable State Operating Permit (FESOP).

SECTION B

GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-8-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2, and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-8-4(2)] [326 IAC 2-1.1-9.5] [IC 13-15-3-6(a)]

- (a) This permit, F039-15752-00242, 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 until the renewal permit has been issued or denied.

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

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

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

B.4 Enforceability [326 IAC 2-8-6]

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 2-8-4(4)]

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 2-8-4(5)(D)]

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

B.7 Duty to Provide Information [326 IAC 2-8-4(5)(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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1). Upon request, the Permittee shall also furnish to IDEM, OAQ copies of records required to be kept by this permit.
- (b) For information furnished by the Permittee to IDEM, OAQ, the Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U.S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Compliance Order Issuance [326 IAC 2-8-5(b)]

IDEM, OAQ may issue a compliance order to this Permittee upon discovery that this permit is in nonconformance with an applicable requirement. The order may require immediate compliance or contain a schedule for expeditious compliance with the applicable requirement.

B.9 Certification [326 IAC 2-8-3(d)] [326 IAC 2-8-4(3)(C)(i)] [326 IAC 2-8-5(1)]

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

B.10 Annual Compliance Certification [326 IAC 2-8-5(a)(1)]

- (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 April 15 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204-2251

- (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 2-8-4(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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

B.11 Preventive Maintenance Plan [326 IAC 1-6-3] [326 IAC 2-8-4(9)] [326 IAC 2-8-5(a)(1)]

- (a) If required by specific condition(s) in Section D of this permit, the Permittee shall maintain and implement Preventive Maintenance Plans (PMPs), including the following information on each facility:
- (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.
- (b) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions or potential to emit. The PMPs do not require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (c) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation, Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.12 Emergency Provisions [326 IAC 2-8-12]

- (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 except as provided in 326 IAC 2-8-12.
- (b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a health-based or 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 and the Northern Regional Office 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
Northern Regional Office phone: 574-245-4870, fax: 574-245-4877

- (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
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 2-8-4(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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

- (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 2-8-3(c)(6) 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 2-8 and any other applicable rules.
- (g) Operations may continue during an emergency only if the following conditions are met:
- (1) 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.
 - (2) If an emergency situation causes a deviation from a health-based limit, the Permittee may not continue to operate the affected emissions facilities unless:
 - (A) The Permittee immediately takes all reasonable steps to correct the emergency situation and to minimize emissions; and

- (B) Continued operation of the facilities is necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw material of substantial economic value.

Any operations shall continue no longer than the minimum time required to prevent the situations identified in (g)(2)(B) of this condition.

- (h) The Permittee shall include all emergencies in the Quarterly Deviation and Compliance Monitoring Report.

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

- (a) All terms and conditions of permits established prior to F039-15752-00242 and issued pursuant to permitting programs approved into the state implementation plan have been either:
- (1) incorporated as originally stated,
 - (2) revised, or
 - (3) deleted.
- (b) All previous registrations and permits are superseded by this permit.

B.14 Termination of Right to Operate [326 IAC 2-8-9] [326 IAC 2-8-3(h)]

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 2-8-3(h) and 326 IAC 2-8-9.

B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-8-4(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
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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

- (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 2-8-4(5)(C)] [326 IAC 2-8-7(a)] [326 IAC 2-8-8]

- (a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Federally Enforceable State 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 2-8-4(5)(C)] The notification by the Permittee does require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (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 2-8-8(a)]
- (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 2-8-8(b)]
- (d) The reopening and revision of this permit, under 326 IAC 2-8-8(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 2-8-8(c)]

B.17 Permit Renewal [326 IAC 2-8-3(h)]

- (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 2-8-3. 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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- Request for renewal shall be submitted to:
- Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
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 2-8 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 Revision [326 IAC 2-8-10] [326 IAC 2-8-11.1]

- (a) Permit amendments and revisions are governed by the requirements of 326 IAC 2-8-10 or 326 IAC 2-8-11.1 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
Indianapolis, Indiana 46204-2251
- Any such application shall be certified by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.19 Operational Flexibility [326 IAC 2-8-15] [326 IAC 2-8-11.1]

- (a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-8-15(b) through (d) 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 approval required by 326 IAC 2-8-11.1 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
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 2-8-15(b) through (d). 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 2-8-15(b)(2), (c)(1), and (d).

- (b) Emission Trades [326 IAC 2-8-15(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 2-8-15(c).
- (c) Alternative Operating Scenarios [326 IAC 2-8-15(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 2-8-4(7). No prior notification of IDEM, OAQ or U.S. EPA is required.

B.20 Source Modification Requirement [326 IAC 2-8-11.1]

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2 and 326 IAC 2-8-11.1.

B.21 Inspection and Entry [326 IAC 2-8-5(a)(2)] [IC 13-14-2-2] [IC 13-17-3-2] [IC13-30-3-1]

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

- (a) Enter upon the Permittee's premises where a FESOP source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
- (b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- (c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;
- (d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and
- (e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.22 Transfer of Ownership or Operational Control [326 IAC 2-8-10]

- (a) The Permittee must comply with the requirements of 326 IAC 2-8-10 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
Indianapolis, Indiana 46204-2251

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

- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.23 Annual Fee Payment [326 IAC 2-7-19] [326 IAC 2-8-4(6)] [326 IAC 2-8-16] [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) 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.24 Credible Evidence [326 IAC 2-8-4(3)] [326 IAC 2-8-5] [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

Emissions Limitations and Standards [326 IAC 2-8-4(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 one hundred (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 Overall Source Limit [326 IAC 2-8] [326 IAC 2-2]

The purpose of this permit is to limit this source's potential to emit to less than major source levels for the purpose of Section 502(a) of the Clean Air Act.

(a) Pursuant to 326 IAC 2-8:

- (1) The potential to emit any regulated pollutant, except particulate matter (PM), from the entire source shall be limited to less than one-hundred (100) tons per twelve (12) consecutive month period. This limitation shall also satisfy 326 IAC 2-1.1-5 (Air quality requirements) and render the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration (PSD)) not applicable;
- (2) The potential to emit any individual hazardous air pollutant (HAP) from the entire source shall be limited to less than ten (10) tons per twelve (12) consecutive month period; and
- (3) The potential to emit any combination of HAPs from the entire source shall be limited to less than twenty-five (25) tons per twelve (12) consecutive month period.

(b) The potential to emit particulate matter (PM) from the entire source shall be limited to less than two hundred fifty (250) tons per twelve (12) consecutive month period. This limitation shall render the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration (PSD)) not applicable.

(c) This condition shall include all emission points at this source including those that are insignificant as defined in 326 IAC 2-7-1(21). The source shall be allowed to add insignificant activities not already listed in this permit, provided the source's potential to emit does not exceed the above specified limits.

(d) Section D of this permit contains independently enforceable provisions to satisfy this requirement.

C.3 Opacity [326 IAC 5-1]

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

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

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

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

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

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

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

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

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

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

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

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Asbestos Section, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204-2251

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

- (e) **Procedures for Asbestos Emission Control**
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-1, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.
- (f) **Demolition and Renovation**
The Permittee shall thoroughly inspect the affected facility or part of the facility where the demolition or renovation will occur for the presence of asbestos pursuant to 40 CFR 61.145(a).
- (g) **Indiana 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.

Testing Requirements [326 IAC 2-8-4(3)]

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

- (a) Compliance testing on new emissions units shall be conducted within 60 days after achieving maximum production rate, but no later than 180 days after initial start-up, if specified in Section D of this approval. 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
Indianapolis, Indiana 46204-2251

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

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

Compliance Requirements [326 IAC 2-1.1-11]

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

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

Compliance Monitoring Requirements [326 IAC 2-8-4] [326 IAC 2-8-5(a)(1)]

C.10 Compliance Monitoring [326 IAC 2-8-4(3)] [326 IAC 2-8-5(a)(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
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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a permit revision 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 2-8-4(3)] [326 IAC 2-8-5(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 2-8-4] [326 IAC 2-8-5(a)(1)]

C.13 Risk Management Plan [326 IAC 2-8-4] [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.14 Response to Excursions or Exceedances [326 IAC 2-8-4] [326 IAC 2-8-5]

- (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;
 - (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.15 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-8-4]
[326 IAC 2-8-5]

- (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 and twenty (120) days is not practicable, IDEM, OAQ may extend the retesting deadline.
- (c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

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

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)]

C.16 General Record Keeping Requirements [326 IAC 2-8-4(3)] [326 IAC 2-8-5]

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

C.17 General Reporting Requirements [326 IAC 2-8-4(3)(C)] [326 IAC 2-1.1-11]

- (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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (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
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 an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (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.

Stratospheric Ozone Protection

C.18 Compliance with 40 CFR 82 and 326 IAC 22-1

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

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

- (a) One (1) reagent strip coating/drying line, identified as Egan Impregnating Line and Tunnel Dryer, constructed in 1980, equipped with a natural gas-fired direct flame oxidizer, identified as TO-1, exhausting to stacks 5 and 5B, rated at twenty-three (23) million British thermal units per hour, capacity: twenty (20) feet of paper strips per minute.
- (b) One (1) reagent strip coating/drying line with two (2) dryers, identified as the Overly Impregnating Line and Dryers 1 and 2, constructed in 1982, equipped with one (1) natural gas-fired direct flame oxidizer, identified as TO-2, exhausting to stacks 6, 6B1 and 6B2, rated at 3.95 million British thermal units per hour, capacity: twenty (20) feet of paper strips per minute, total. Operation of TO-2 is optional and is not used to demonstrate compliance with any applicable requirement.
- (c) One (1) Chemical Synthesis Unit, formerly identified as Building 10, approved for construction in 2006, for the production of invitro diagnostic reagents, consisting of uncontrolled bench scale laboratory batch operations exhausting to various fume hoods and sweeps, a Stokes vacuum shelf dryer, and a steam jet vacuum system.
- (d) One (1) Organic Chemistry Production Lab, approved for construction in 2006, consisting of uncontrolled bench scale laboratory batch operations exhausting to various fume hoods and sweeps.
- (e) One (1) Protein Development Lab, formerly identified as Building 17, approved for construction in 2006, consisting of uncontrolled methanol cleaning operations exhausting to various fume hoods and sweeps.

(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 2-8-4(1)]

D.1.1 Volatile Organic Compound (VOC) Content Limitations [326 IAC 8-2-5]

The two (2) reagent strip coating/drying lines are only subject to this condition when using coatings as defined by 326 IAC 8-1-0.5(c). Pursuant to 326 IAC 8-2-5, the Permittee shall not cause, allow, or permit the discharge into the atmosphere of any volatile organic compounds in excess of thirty-five hundredths (0.35) kilograms per liter of coating (two and nine-tenths (2.9) pounds per gallon) excluding water, from each of the two (2) reagent strip coating/drying lines, when performing paper coating.

D.1.2 Volatile Organic Compound (VOC) and Hazardous Air Pollutants (HAP) Limitations [326 IAC 2-8-4] [326 IAC 2-3] [326 IAC 2-4.1]

- (a) The total potential to emit VOC from the two (2) reagent strip coating/drying lines, the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein Development Lab shall not exceed 93.17 tons per twelve (12) consecutive month period with compliance determined at the end of each month.

Compliance with this limit, combined with the potential VOC emissions from all other emission units at this source, will limit the source-wide total potential to emit VOC to less than 100 tons per 12 consecutive month period. Therefore, compliance with this limit renders the requirements of 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-3 (Emission Offset) not applicable.

- (b) The potential to emit each individual HAP from the two (2) reagent strip coating/drying lines, the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein

Development Lab shall be limited to less than 8.0 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month. Compliance with this limit, combined with the potential HAP emissions from all other emission units at this source, shall limit the potential to emit each individual HAP to less than 10 tons per year from the entire source. Therefore, compliance with this limit renders the requirements of 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-4.1 (Major Source of Hazardous Air Pollutants) not applicable.

- (c) The potential to emit any combination of HAPs from the two (2) reagent strip coating/drying lines, the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein Development Lab shall not exceed 22.78 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month. Compliance with this limit, combined with the potential HAP emissions from all other emission units at this source, shall limit the potential to emit any combination of HAPs to less than 25 tons per year from the entire source. Therefore, compliance with this limit renders the requirements of 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-4.1 (Major Source of Hazardous Air Pollutants) not applicable.

D.1.3 Volatile Organic Compound (VOC) Limitations [326 IAC 8-1-6]

Each of the three (3) dryers at the two (2) reagent strip coating/drying lines are subject to this condition only when not using coatings as defined by 326 IAC 8-1-0.5(c). Pursuant to F 039-5362-00242, issued on March 25, 1998, and Amendment 039-10502, issued on May 14, 1999, the potential to emit VOC from each of the three (3) dryers at the two (2) reagent strip coating/drying lines shall not exceed 24.0 tons per twelve (12) consecutive month period with compliance determined at the end of each month.

Compliance with these limits renders the requirements of 326 IAC 8-1-6 (New facilities; General reduction requirements) not applicable.

D.1.4 Volatile Organic Compound (VOC) Limitations [326 IAC 8-5-3]

- (a) The potential to emit VOC from the Chemical Synthesis Unit shall be limited to less than 15.0 pounds per day with compliance determined at the end of each day.
- (b) The potential to emit VOC from the Organic Chemistry Production Lab shall be limited to less than 15.0 pounds per day with compliance determined at the end of each day.

Compliance with these limits renders the requirements of 326 IAC 8-5-3 (Volatile Organic Compounds, Synthetic Pharmaceutical Manufacturing Operations) not applicable.

D.1.5 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for these facilities and TO-1.

Compliance Determination Requirements

D.1.6 Volatile Organic Compounds (VOC)

- (a) Operation of TO-1 is optional. Credit for emissions reductions shall only be taken when TO-1 is operating and controlling emissions from the Egan Impregnating Line.
- (b) Operation of TO-2 is optional. Operating TO-2 for compliance with any emissions limitations or standards in the permit is not permitted under this approval and shall require prior IDEM, OAQ, approval. No credit for emissions reductions shall be taken when TO-2 is operating and controlling emissions from the Overly Impregnating Line.

D.1.7 VOC and HAPs Emissions

- (a) Compliance with Conditions D.1.2(a) shall be determined within 30 days of the end of each month. For a particular month, this shall be based on the total volatile organic compound emitted for that month added to the previous eleven (11)-month total VOC emitted so as to arrive at VOC emissions for the most recent twelve (12) consecutive month period. The VOC emissions for a month can be arrived at using the following equation:

$$\begin{aligned} \text{Total VOC emitted} &= [(\text{VOC usage in the Egan Impregnating Line while TO-1 is operating}) \times \\ & \quad ((100 - \% \text{ overall control efficiency from the most recent valid stack test} \\ & \quad \text{that demonstrates compliance with limits in Conditions D.1.2 and} \\ & \quad \text{D.1.3})/100)] \\ & \quad + [\text{VOC usage in the Egan Impregnating Line while TO-1 is not operating}] \\ & \quad + [\text{VOC usage in the Overly Impregnating Line}] \\ & \quad + [\text{VOC usage in the Chemical Synthesis Unit}] \\ & \quad + [\text{VOC usage in the Organic Chemistry Production Lab}] \\ & \quad + [\text{VOC usage in the Protein Development Lab}] \end{aligned}$$

- (b) Compliance with Condition D.1.2(b) shall be determined within 30 days of the end of each month. For a particular month, this shall be based on the amount of each individual HAP emitted for that month added to the previous eleven (11)-month total emitted of that HAP so as to arrive at individual HAP emissions for the most recent twelve (12) consecutive month period. The individual HAP emissions for a month can be arrived at using the following equation:

$$\begin{aligned} \text{Individual HAP emitted} &= [(\text{individual HAP usage in the Egan Impregnating Line while TO-1 is} \\ & \quad \text{operating}) \times ((100 - \% \text{ overall control efficiency from the most recent} \\ & \quad \text{valid stack test that demonstrates compliance with limits in Conditions} \\ & \quad \text{D.1.2 and D.1.3})/100)] \\ & \quad + [\text{individual HAP usage in the Egan Impregnating Line while TO-1 is not} \\ & \quad \text{operating}] \\ & \quad + [\text{individual HAP usage in the Overly Impregnating Line}] \\ & \quad + [\text{individual HAP usage in the Chemical Synthesis Unit}] \\ & \quad + [\text{individual HAP usage in the Organic Chemistry Production Lab}] \\ & \quad + [\text{individual HAP usage in the Protein Development Lab}] \end{aligned}$$

- (c) Compliance with Condition D.1.2(c) shall be determined within 30 days of the end of each month. For a particular month, this shall be based on the total HAPs emitted for that month added to the previous eleven (11)-month total HAPs emitted so as to arrive at total HAP emissions for the most recent twelve (12) consecutive month period. The total HAP emissions for a month can be arrived at using the following equation:

$$\begin{aligned} \text{Total HAPs emitted} &= [(\text{total HAPs usage in the Egan Impregnating Line while TO-1 is} \\ & \quad \text{operating}) \times ((100 - \% \text{ overall control efficiency from the most recent} \\ & \quad \text{valid stack test that demonstrates compliance with limits in Conditions} \\ & \quad \text{D.1.2 and D.1.3})/100)] \\ & \quad + [\text{total HAPs usage in the Egan Impregnating Line while TO-1 is not} \\ & \quad \text{operating}] \\ & \quad + [\text{total HAPs usage in the Overly Impregnating Line}] \\ & \quad + [\text{total HAPs usage in The Chemical Synthesis Unit}] \\ & \quad + [\text{total HAPs usage in The Organic Chemistry Production Lab}] \\ & \quad + [\text{total HAPs usage in The Protein Development Lab}] \end{aligned}$$

- (d) Compliance with Condition D.1.3 shall be determined within 30 days of the end of each month. For a particular month, this shall be based on the total volatile organic compound emitted for that month added to the previous eleven (11)-month total VOC emitted so as to arrive at VOC emissions for the most recent twelve (12) consecutive month period. The VOC emissions for a month can be arrived at using the following equation:

Each of the two (2) dryers at the Overly Impregnating Line:
VOC emitted = VOC usage

Tunnel Dryer at the Egan Impregnating Line:
VOC emitted = [(VOC usage while TO-1 is operating) x ((100 - % overall control efficiency from the most recent valid stack test that demonstrates compliance with limits in Conditions D.1.2 and D.1.3)/100)]
+ [VOC usage while TO-1 is not operating]

- (e) Compliance with Condition D.1.4 shall be determined within 30 days of the end of each month. The VOC emissions for each day can be arrived at using the following equation for VOC usage:

The Chemical Synthesis Unit:
VOC emitted = [VOC usage]

The Organic Chemistry Production Lab:
VOC emitted = [VOC usage]

D.1.8 Volatile Organic Compounds (VOC) and Hazardous Air Pollutants (HAP) [326 IAC 8-1-2] [326 IAC 8-1-4]

Compliance with the VOC content and VOC and HAP emission limitations contained in Conditions D.1.1, D.1.2(a), D.1.3, and D.1.4 shall be determined pursuant to 326 IAC 8-1-4(a)(3) and 326 IAC 8-1-2(a) by using formula information from the manufacturers or by obtaining copies of the "as supplied" and "as applied" VOC data sheets for all coatings, as defined by 326 IAC 8-1-0.5. IDEM, OAQ reserves the authority to determine compliance using Method 24 in conjunction with the analytical procedures specified in 326 IAC 8-1-4.

D.1.9 Testing Requirements [326 IAC 2-8-5(a)(1), (4)] [326 IAC 2-1.1-11]

The Permittee shall conduct a performance test to verify VOC control efficiency as per Conditions D.1.2 and D.1.3 for TO-1 utilizing methods as approved by the Commissioner. This test shall be repeated at least once every five years from the date of the most recent valid compliance demonstration. Testing shall be conducted in accordance with Section C - Performance Testing.

Compliance Monitoring Requirements [326 IAC 2-8-4] [326 IAC 2-8-5(a)]

D.1.10 Thermal Oxidizer Temperature

- (a) A continuous monitoring system shall be calibrated, maintained, and operated on TO-1 for measuring operating temperature when the Egan Impregnating Line and TO-1 are both in operation. For the purposes of this condition, continuous shall mean no less often than once per minute. The output of this system shall be recorded as a 3-hour average or an average for the total run time, whichever is shorter.
- (b) The Permittee shall determine the required 3-hour average temperature from the most recent valid stack test that demonstrates compliance with limits in the permit, as approved by IDEM.
- (c) On and after the date the approved stack test results are available, the Permittee shall take appropriate response steps in accordance with Section C - Response to Excursions or Exceedances whenever the 3-hour average temperature of the thermal oxidizer is below the 3-hour average temperature as observed during the compliant stack test.

A 3-hour average temperature that is below the 3-hour average temperature as observed during the compliant stack test 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.

D.1.11 Parametric Monitoring

- (a) The Permittee shall determine fan amperage or duct pressure of TO-1 from the most recent valid stack test that demonstrates compliance with limits in Conditions D.1.2 and D.1.3, as approved by IDEM.
- (b) The duct vacuum or fan amperage shall be observed at least once per day when the Egan Impregnating Line and TO-1 are both in operation. When for any one reading, the duct vacuum or fan amperage is less than that established in most recent compliant stack test, the Permittee shall take reasonable response steps in accordance with Section C - Response to Excursions or Exceedances. A reading that is less than that established in the most recent compliant stack test 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.

Record Keeping Requirements [326 IAC 2-8-4(3)] [326 IAC 2-8-16]

D.1.12 Record Keeping Requirements

- (a) To document compliance with Condition D.1.1, the Permittee shall maintain records in accordance with (1) through (4) below. Records maintained for (1) through (4) shall be taken as stated below and shall be complete and sufficient to establish compliance with the VOC content limitations established in Condition D.1.1.
 - (1) The VOC content of each coating material and solvent used at the coating/drying lines less water.
 - (2) The individual and total HAP content of each coating material and solvent used at the coating/drying lines.
 - (3) The amount of coating materials and solvents used at the coating/drying lines on a monthly basis.
 - (A) Records shall include formulation data and material safety data sheets (MSDS) necessary to verify the type and amount used.
 - (B) Solvent usage records shall differentiate between those added to coatings/materials and those used as cleanup solvents.
 - (C) Records for the Egan Impregnating Line shall differentiate between materials used when TO-1 is operating and those used when TO-1 is not operating.
 - (D) Records shall indicate whether each material is considered a coating pursuant to 326 IAC 8-1-0.5(c).
 - (4) The monthly cleanup solvent usage.
- (b) To document compliance with Conditions D.1.2 and D.1.3, the Permittee shall maintain records in accordance with (1) through (6) below. Records maintained for (1) through (6) shall be taken as stated below and shall be complete and sufficient to establish compliance with the VOC and HAPs emissions limits established in Conditions D.1.2 and D.1.3.

- (1) For the Egan Impregnating Line and Tunnel Dryer:
 - (A) The total individual HAP usage for each month when operating TO-1 and the total individual HAP usage for each month when TO-1 is not operating.
 - (B) The total HAPs usage for each month when operating TO-1 and the total HAPs usage for each month when TO-1 is not operating.
 - (C) The total VOC usage (including cleanup solvents) for each month when operating TO-1 and the total VOC usage for each month when TO-1 is not operating.
- (2) For the Overly Impregnating Line and Dryer 1, the Overly Impregnating Line and Dryer 2, individually:
 - (A) The total individual HAP usage for each month for each operation.
 - (B) The total HAPs usage for each month for each operation.
 - (C) The total VOC usage (including cleanup solvents) for each month for each operation.
- (3) For the Chemical Synthesis Unit and the Organic Chemistry Production Lab, individually:
 - (A) The total individual HAP usage for each month for each operation.
 - (B) The total HAPs usage for each month for each operation.
 - (C) The total VOC usage for each month for each operation.
- (4) For the Protein Development Lab:
 - (A) The total individual HAP usage (including cleanup solvents) for each month for each operation.
 - (B) The total HAPs usage (including cleanup solvents) for each month for each operation.
 - (C) The total VOC usage (including cleanup solvents) for each month for each operation.
- (5) For the two (2) reagent strip coating/drying lines (Egan Impregnating Line and Tunnel Dryer and Overly Impregnating Line and Dryers 1 and 2), the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein Development Lab, combined:
 - (A) The total individual HAP emissions for each month.
 - (B) The total HAPs emissions for each month.
 - (C) The total VOC emissions for each month.
- (6) The continuous temperature records (on a 3-hour average basis) for TO-1 when operating and the 3-hour average temperature used to demonstrate compliance during the most recent compliant stack test.

- (c) To document compliance with Condition D.1.4, the Permittee shall maintain the following records for the Chemical Synthesis Unit and the Organic Chemistry Production Lab. These records shall be taken as stated below and shall be complete and sufficient to establish compliance with the VOC emissions limits established in Condition D.1.4.
 - (1) The total VOC usage for each day for each operation.
- (d) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.1.13 Reporting Requirements

A quarterly summary of the information to document compliance with Conditions D.1.2, D.1.3, and D.1.4 shall be submitted to the addresses listed in Section C - General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

SECTION D.2

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]: Insignificant Activities

- (a) One (1) natural gas-fired boiler, identified as 1-1-1, constructed in 1980, exhausting to Vent 1a, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (b) One (1) natural gas-fired boiler, identified as 2-1-1, constructed in 1980, exhausting to Vent 1b, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (c) One (1) natural gas-fired boiler, identified as 3-1-1, constructed in 1982, exhausting to Vent 1c, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (d) One (1) natural gas-fired boiler, identified as 4-1-1, constructed in 1982, exhausting to Vent 1d, rated at 6.7 million British thermal units per hour. [326 IAC 6-2-3]
- (e) One (1) natural gas-fired emergency generator, identified as 11-1-1, constructed in 1980, equipped with a combustion vent, rated at 0.3415 million British thermal units per hour.
- (f) One (1) natural gas-fired emergency generator, identified as 12-1-1, constructed in 1980, equipped with a combustion vent, rated at 0.1024 million British thermal units per hour.
- (g) One (1) ethylene glycol usage facility, identified as F1-1, using a maximum of 1.0 ton of ethylene glycol per year.
- (h) Two (2) maintenance degreasers, using only non-VOC, non-HAP materials.
- (i) One (1) natural gas-fired emergency generator, identified as 13-1-1, to be installed in 2006, equipped with a combustion vent, rated at 0.222 million British thermal units per hour.

(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 2-8-4(1)]

D.2.1 Particulate [326 IAC 6-2-3]

- (a) Pursuant to 326 IAC 6-2-3 (Particulate Emission Limitations for Sources of Indirect Heating) the PM emissions from each of the four (4) boilers shall be limited to 0.6 pounds per million British thermal units heat input.
- (b) Pursuant to 326 IAC 6-2-3 (e) (Particulate Emission Limitations for Sources of Indirect Heating: emission limitations for facilities specified in 326 IAC 6-2-1 (b)), particulate emissions from any facility used for indirect heating purposes which has 250 mmBtu/hr heat input or less and which began operation after June 8, 1972, shall in no case exceed 0.6 lb/mmBtu heat input.

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

**FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
CERTIFICATION**

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242

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

Please check what document is being certified:

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

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

Signature:

Printed Name:

Title/Position:

Date:

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

**FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
EMERGENCY OCCURRENCE REPORT**

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242

This form consists of 2 pages

Page 1 of 2

- | |
|---|
| <input type="checkbox"/> This is an emergency as defined in 326 IAC 2-7-1(12) <ul style="list-style-type: none">• 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 Describe:
Type of Pollutants Emitted: TSP, PM-10, SO ₂ , VOC, NO _x , 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**

FESOP Quarterly Report

Source Name: Siemens Medical Solutions Diagnostics, Inc.
 Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
 Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
 FESOP No.: F 039-15752-00242
 Facility: The two (2) reagent strip coating/drying lines (Egan Impregnating Line and Tunnel Dryer and Overly Impregnating Line and Dryers 1 and 2), the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein Development Lab
 Parameter: VOC Emissions
 Limit: 93.17 tons per twelve (12) consecutive month period, with compliance determined at the end of each month.

Total VOC emitted = [(VOC usage in the Egan Impregnating Line while the TO-1 is operating) x ((100 - % overall control efficiency from the most recent valid stack test that demonstrates compliance with limits in Conditions D.1.2 and D.1.3)/100)]
 + [VOC usage in the Egan Impregnating Line while TO-1 is not operating]
 + [VOC input at the Overly Impregnating Line]
 + [VOC usage in the Chemical Synthesis Unit]
 + [VOC usage in the Organic Chemistry Production Lab]
 + [VOC usage in the Protein Development Lab]

YEAR: _____

Month	VOC Emissions (tons)	VOC Emissions (tons)	VOC Emissions (tons)
	This Month	Previous 11 Months	12 Month Total

- No deviation occurred in this quarter.
- Deviation/s occurred in this quarter.
 Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
 OFFICE OF AIR QUALITY
 COMPLIANCE DATA SECTION**

FESOP Quarterly Report

Source Name: Siemens Medical Solutions Diagnostics, Inc.
 Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
 Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
 FESOP No.: F 039-15752-00242
 Facilities: Two (2) reagent strip coating/drying lines (Egan Impregnating Line and Tunnel Dryer and Overly Impregnating Line and Dryers 1 and 2), the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein Development Lab
 Parameter: Worst-case individual HAP emissions
 Limit: Less than 8.0 tons per twelve (12) consecutive month period, with compliance determined at the end of each month.

Individual HAP emitted = [(individual HAP usage in the Egan Impregnating Line while TO-1 is operating) x ((100 - % overall control efficiency from the most recent valid stack test that demonstrates compliance with limits in Conditions D.1.2 and D.1.3)/100)]
 + [individual HAP usage in the Egan Impregnating Line while TO-1 is not operating]
 + [individual HAP usage in the Overly Impregnating Line]
 + [individual HAP usage in the Chemical Synthesis Unit]
 + [individual HAP usage in the Organic Chemistry Production Lab]
 + [individual HAP usage in the Protein Development Lab]

YEAR: _____

Month	Worst-case Individual HAP Emissions (tons)	Worst-case Individual HAP Emissions (tons)	Worst-case Individual HAP Emissions (tons)
	This Month	Previous 11 Months	12 Month Total

- No deviation occurred in this quarter.
- Deviation/s occurred in this quarter.
 Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
 OFFICE OF AIR QUALITY
 COMPLIANCE DATA SECTION**

FESOP Quarterly Report

Source Name: Siemens Medical Solutions Diagnostics, Inc.
 Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
 Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
 FESOP No.: F 039-15752-00242
 Facilities: Two (2) reagent strip coating/drying lines (Egan Impregnating Line and Tunnel Dryer and Overly Impregnating Line and Dryers 1 and 2), the Chemical Synthesis Unit, the Organic Chemistry Production Lab, and the Protein Development Lab
 Parameter: Total HAPs emissions
 Limit: 22.78 tons per twelve (12) consecutive month period, with compliance determined at the end of each month.

Total HAPs emitted = [(total HAPs usage in the Egan Impregnating Line while TO-1 is operating) x ((100 - % overall control efficiency from the most recent valid stack test that demonstrates compliance with limits in Conditions D.1.2 and D.1.3)/100)]
 + [total HAPs usage in the Egan Impregnating Line while TO-1 is not operating]
 + [total HAPs usage in the Overly Impregnating Line]
 + [total HAPs usage in The Chemical Synthesis Unit]
 + [total HAPs usage in The Organic Chemistry Production Lab]
 + [total HAPs usage in The Protein Development Lab]

YEAR: _____

Month	Total HAPs Emissions (tons)	Total HAPs Emissions (tons)	Total HAPs Emissions (tons)
	This Month	Previous 11 Months	12 Month Total

- No deviation occurred in this quarter.
- Deviation/s occurred in this quarter.
 Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

FESOP Quarterly Report

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242
Facility: Egan Impregnating Line and Tunnel Dryer
Parameter: VOC Emissions
Limit: 24.0 tons per twelve (12) consecutive month period, with compliance determined at the end of each month.

VOC emitted = [(VOC usage while TO-1 is operating) x ((100 - % overall control efficiency from the most recent valid stack test that demonstrates compliance with limits in Conditions D.1.2 and D.1.3)/100)]
+ [VOC usage while TO-1 is not operating]

YEAR: _____

Month	VOC Emissions (tons)	VOC Emissions (tons)	VOC Emissions (tons)
	This Month	Previous 11 Months	12 Month Total

- No deviation occurred in this quarter.
- Deviation/s occurred in this quarter.
Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

FESOP Quarterly Report

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242
Facility: Overly Impregnating Line and Dryer 1
Parameter: VOC Emissions
Limit: 24.0 tons per twelve (12) consecutive month period, with compliance determined at the end of each month.

VOC emitted = VOC usage

YEAR: _____

Month	VOC Emissions (tons)	VOC Emissions (tons)	VOC Emissions (tons)
	This Month	Previous 11 Months	12 Month Total

- No deviation occurred in this quarter.
- Deviation/s occurred in this quarter.
Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

FESOP Quarterly Report

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242
Facility: Overly Impregnating Line and Dryer 2
Parameter: VOC Emissions
Limit: 24.0 tons per twelve (12) consecutive month period, with compliance determined at the end of each month.

VOC emitted = VOC usage

YEAR: _____

Month	VOC Emissions (tons)	VOC Emissions (tons)	VOC Emissions (tons)
	This Month	Previous 11 Months	12 Month Total

- No deviation occurred in this quarter.
- Deviation/s occurred in this quarter.
Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

FESOP Emission Report
(Submit Report Quarterly)

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242
Facility: The Chemical Synthesis Unit
Parameter: VOC Emissions
Limit: Less than 15.0 pounds per day, with compliance determined at the end of each day.

VOC emitted = [VOC usage]

Month: _____ Year: _____

Day	VOC Emissions per day	Day	VOC Emissions per day
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16			

- No deviation occurred in this month.
- Deviation/s occurred in this month.
Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

FESOP Emission Report
(Submit Report Quarterly)

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242
Facility: The Organic Chemistry Production Lab
Parameter: VOC Emissions
Limit: Less than 15.0 pounds per day, with compliance determined at the end of each day.

VOC emitted = [VOC usage]

Month: _____ Year: _____

Day	VOC Emissions per day	Day	VOC Emissions per day
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16			

- No deviation occurred in this month.
 Deviation/s occurred in this month.
Deviation has been reported on: _____

Submitted by: _____

Title / Position: _____

Signature: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

**FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT**

Source Name: Siemens Medical Solutions Diagnostics, Inc.
Source Address: 3400 Middlebury Street, Elkhart, Indiana 46516
Mailing Address: 3400 Middlebury Street, Elkhart, Indiana 46516
FESOP No.: F 039-15752-00242

Months: _____ to _____ Year: _____

Page 1 of 2

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".

NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.

THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD

Permit Requirement (specify permit condition #)

Date of Deviation:

Duration of Deviation:

Number of Deviations:

Probable Cause of Deviation:

Response Steps Taken:

Permit Requirement (specify permit condition #)

Date of Deviation:

Duration of Deviation:

Number of Deviations:

Probable Cause of Deviation:

Response Steps Taken:

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

Form Completed by: _____

Title / Position: _____

Date: _____

Phone: _____

Attach a signed certification to complete this report.