



Joseph E. Kernan
Governor

Lori F. Kaplan
Commissioner

October 14, 2004

100 North Senate Avenue
P.O. Box 6015
Indianapolis, Indiana 46206-6015
(317) 232-8603
(800) 451-6027
www.in.gov/idem

TO: Interested Parties / Applicant
RE: Cook, Inc / 105-15590-00030
FROM: Paul Dubenetzky
Chief, Permits Branch
Office of Air Quality

Notice of Decision: Approval - Effective Immediately

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

If you wish to challenge this decision, IC 4-21.5-3 and IC 13-15-6-1 require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) calendar days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

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

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

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

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

Enclosures
FNPER.dot 9/16/03



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

**Cook, Inc.
6330 North Matthews Drive
Ellettsville, Indiana 47429**

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

The Permittee must comply with all conditions of this permit. Noncompliance with any provision of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; and 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.

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.

Operation Permit No.: F105-15590-00030	
Issued by: Original Signed by Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: October 14, 2004 Expiration Date: October 14, 2009

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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 medical device manufacturing and sterilization operation.

Authorized individual:	President
Source Address:	6330 North Matthews Drive, Ellettsville, Indiana 47429
Mailing Address:	6330 North Matthews Drive, Ellettsville, Indiana 47429
General Source Phone:	812-876-7790
SIC Code:	3841
Source Location Status:	Monroe
Source Status:	Attainment for all criteria pollutants Federally Enforceable State Operating Permit (FESOP) Minor Source, under PSD Rules; Minor Source, Section 112 of the Clean Air Act

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) seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 will be constructed in 2004;
- (b) fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and
- (c) miscellaneous cleaning with isopropyl alcohol.

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) manual plastic tubing and metal wiring slip coating operation, consisting of five trays using a maximum total of 0.033 gallons of coating per hour, exhausting through one (1) stack, identified as E07;
- (b) the following storage containers:
 - A. one (1) ethylene oxide/HCF-124 mixture storage tank, identified as ST01, with a maximum storage capacity of 5,500 gallons, exhausting through one (1) stack, identified as ST01; or
 - B. four (4) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (1,600 pounds total). These are portable cylinders that will be connected to the sterilization process;

- C. eight (8) additional 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide to be stored on site;
- (c) three (3) liquor storage tanks, identified as Tanks A, B, and C, each with a working storage capacity of 5,870 gallons, all venting to the wet acid pre-scrubber, exhausting through one (1) stack, identified as HV01;
- (d) one (1) buffing and grinding operation, with a dust collector controlling particulate matter emissions, exhausting through one (1) stack, identified as S11; [326 IAC 6-3-2]
- (e) gluing, heat forming, tapering, marking and printing operations associated with manufacturing activities and product assembly, exhausting through building exhausts and one (1) stack, identified as S10;
- (f) natural gas fired combustion sources with a total heat input of 11.3 MMBtu per hour;
- (g) vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;
- (h) application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings;
- (i) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]
- (j) closed loop heating and cooling systems;
- (k) exposure chambers ("towers", "columns"), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge;
- (l) replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;
- (m) heat exchanger cleaning and repair;
- (n) TDMAC package prep operations, exhausting through one (1) stack, identified as S07;
- (o) heat forming, taping, masking, and printing operations exhausting through various building exhausts;
- (p) Catheter Impregnation Process with potential methanol emissions of less than 0.02 tons per year; and
- (q) Paclitaxel Treatment Process consisting of two (2) units with potential VOC emissions of less than 15 pounds per day.

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).

A.5 Prior Permits Superseded [326 IAC 2-1.1-9.5]

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

SECTION B GENERAL CONDITIONS

B.1 Permit No Defense [IC 13]

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.

B.2 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.3 Permit Term [326 IAC 2-8-4(2)][326 IAC 2-1.1-9.5]

This permit 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.

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 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.6 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.7 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.8 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 the "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.9 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.10 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.11 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 in letter form no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

- (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, IDEM, OAQ, may require to determine the compliance status of the source.

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

B.12 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) The Permittee shall implement the PMPs, including any required record keeping, as necessary to ensure that failure to implement a PMP does not cause or contribute to an exceedance of any limitation on emissions or potential to emit.
- (c) 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 PMP does not require the certification by the "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (d) 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.13 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 describes the following:
- (1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;
 - (2) The permitted facility was at the time being properly operated;
 - (3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;
 - (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone No.: 1-800-451-6027 (ask for Office of Air Quality, Compliance Section) or,
Telephone No.: 317-233-5674 (ask for Compliance Section)
Facsimile No.: 317-233-5967

- (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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

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 the "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) 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.14 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 Provision), 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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

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 need to be included in this report.

The Quarterly Deviation and Compliance Monitoring Report does require the certification by the "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.15 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 FESOP 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 the "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.16 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 the "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, P.O. Box 6015
Indianapolis, IN 46206-6015

- (b) Timely Submittal of Permit Renewal [326 IAC 2-8-3]
 - (1) A timely renewal application is one that is:
 - (A) Submitted at least nine (9) months prior to the date of the expiration of this permit; and
 - (B) 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.
 - (2) If IDEM, OAQ upon receiving a timely and complete 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.
- (c) Right to Operate After Application for Renewal [326 IAC 2-8-9]

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 needed to process the application.

B.17 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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

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

- (c) The Permittee may implement the administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]
- (d) No permit amendment or modification is required for the addition, operation or removal of a nonroad engine, as defined in 40 CFR 89.2.

B.18 Operational Flexibility [326 IAC 2-8-15][326 IAC 2-8-11.1]

- (a) The Permittee may make any change or changes at this source that are described in 326 IAC 2-8-15(b) through (d), without 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 emissions allowable under 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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

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 which document, on a rolling five (5) year basis, all such changes and emissions trading that are subject to 326 IAC 2-8-15(b) through (d) and makes such records available, upon reasonable request, to 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 increases and decreases in emissions in 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.19 Permit Revision 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.20 Inspection and Entry [326 IAC 2-8-5(a)(2)][IC 13-14-2-2][IC 13-17-3-2][IC 13-17-3-2][IC 13-30-3-1]

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

- (a) Enter upon the Permittee's premises where a 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.21 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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

The application which shall be submitted by the Permittee does require the certification by the "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.22 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 317-233-4320 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.23 Credible Evidence [326 IAC 2-8-4(3)][326 IAC 2-8-5][62 FR 8314]

Notwithstanding the conditions of this permit that state specific methods that may be used to demonstrate compliance with, or a violation of, applicable requirements, any person (including the Permittee) may also use other credible evidence to demonstrate compliance with, or a violation of, any term or condition of this permit.

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 [40 CFR 52 Subpart P][326 IAC 6-3-2]

- (1) Pursuant to 40 CFR 52 Subpart P, particulate matter emissions from any process not already regulated by 326 IAC 6-1 or any New Source Performance Standard, and which has a maximum process weight rate less than 100 pounds per hour shall not exceed 0.551 pounds per hour.
- (2) Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Overall Source Limit [326 IAC 2-8]

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.
 - (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) 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 that the source's potential to emit does not exceed the above specified limits.
- (c) 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(3)]

The Permittee shall not operate an incinerator or incinerate any waste or refuse except as provided in 326 IAC 4-2 and in 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 Operation of Equipment [326 IAC 2-8-5(a)(4)]

Except as otherwise provided by statute, rule or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment are in operation.

C.8 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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification by the "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. The requirement to use an Indiana Accredited Asbestos inspector is not federally enforceable.

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

C.9 Performance Testing [326 IAC 3-6]

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

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

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require certification by the "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 the "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.10 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.11 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 upon issuance of this permit. If required by Section D, the Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment.

Unless otherwise specified in the approval for the new emissions unit, compliance monitoring for new emission units or emission units added through a permit revision shall be implemented when operation begins.

C.12 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.13 Pressure Gauge and Other Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-8-4(3)] [326 IAC 2-8-5(1)]

- (a) Whenever a condition in this permit requires the measurement of pressure drop across any part of the unit or its control device, the gauge employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent (" 2%) of full scale reading.
- (b) Whenever a condition in this permit requires the measurement of a temperature or flow rate, the instrument employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent (" 2%) of full scale reading.
- (c) The gas chromatograph techniques utilized to measure the outlet emissions from the three (3) dry bed reactors controlling aeration room exhaust will provide a precision of 5 percent relative standard deviation (RSD);
- (d) The Permittee may request the IDEM, OAQ approve the use of a pressure gauge or other instrument that does not meet the above specifications provided the Permittee can demonstrate an alternative pressure gauge or other instrument specification will adequately ensure compliance with permit conditions requiring the measurement of pressure drop or other parameters.

Corrective Actions and Response Steps [326 IAC 2-8-4] [326 IAC 2-8-5(a)(1)]

C.14 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.15 Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-8-4] [326 IAC 2-8-5]

(a) The Permittee is required to prepare a Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. A CRP shall be submitted to IDEM, OAQ upon request. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee, supplemented from time to time by the Permittee, maintained on site, and is comprised of:

- (1) Reasonable response steps that may be implemented in the event that a response step is needed pursuant to the requirements of Section D of this permit; and an expected time frame for taking reasonable response steps.
- (2) If, at any time, the Permittee takes reasonable response steps that are not set forth in the Permittee's current Compliance Response Plan and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan to include such response steps taken.

(b) For each compliance monitoring condition of this permit, reasonable response steps shall be taken when indicated by the provisions of that compliance monitoring condition as follows:

- (1) Reasonable response steps shall be taken as set forth in the Permittee's current Compliance Response Plan; or
- (2) If none of the reasonable response steps listed in the Compliance Response Plan is applicable or responsive to the excursion, the Permittee shall devise and implement additional response steps as expeditiously as practical. Taking such additional response steps shall not be considered a deviation from this permit so long as the Permittee documents such response steps in accordance with this condition.
- (3) If the Permittee determines that additional response steps would necessitate that the emissions unit or control device be shut down, and it will be ten (10) days or more until the unit or device will be shut down, then the Permittee shall promptly notify the IDEM, OAQ of the expected date of the shut down. The notification shall also include the status of the applicable compliance monitoring parameter with respect to normal, and the results of the response actions taken up to the time of notification.

(4) Failure to take reasonable response steps shall be considered a deviation from the permit.

(c) The Permittee is not required to take any further response steps for any of the following reasons:

- (1) A false reading occurs due to the malfunction of the monitoring equipment and prompt action was taken to correct the monitoring equipment.

- (2) The Permittee has determined that the compliance monitoring parameters established in the permit conditions are technically inappropriate, has previously submitted a request for an administrative amendment to the permit, and such request has not been denied.
- (3) An automatic measurement was taken when the process was not operating.
- (4) The process has already returned or is returning to operating within "normal" parameters and no response steps are required.
- (d) When implementing reasonable steps in response to a compliance monitoring condition, if the Permittee determines that an exceedance of an emission limitation has occurred, the Permittee shall report such deviations pursuant to Section B-Deviations from Permit Requirements and Conditions.
- (e) The Permittee shall record all instances when response steps are taken. In the event of an emergency, the provisions of 326 IAC 2-8-12 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.
- (f) Except as otherwise provided by a rule or provided specifically in Section D, all monitoring as required in Section D shall be performed when the emission unit is operating, except for time necessary to perform quality assurance and maintenance activities.

C.16 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 the "authorized individual" as defined by 326 IAC 2-1.1-1(1).

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

C.17 General Record Keeping Requirements [326 IAC 2-8-4(3)] [326 IAC 2-8-5]

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- (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.18 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 the "authorized individual" as defined by 326 IAC2-1.1-1(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, P. O. Box 6015
Indianapolis, Indiana 46206-6015
- (c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.
- (d) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by the "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.19 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) seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 will be constructed in 2004;
- (b) fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and
- (c) miscellaneous cleaning with isopropyl alcohol.

(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 Ethylene Oxide [40 CFR Part 63, Subpart O] [326 IAC 8-1-6]

- (a) Pursuant to 40 CFR 63.362, Subpart O, the sterilization operation is subject to the following conditions:
 - (1) The emission limitations of paragraphs (2) and (3) below apply during sterilization operation. The emission limitations do not apply during periods of malfunction.
 - (2) The Permittee shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.
 - (3) The Permittee shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99%, whichever is less stringent, from each aeration room vent.
- (b) The Permittee will comply with the requirements of this rule by using a primary wet acid scrubber to control sterilization chamber vents. The device will have a control efficiency of 99%. A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) or three (3) dry bed reactors alone, each configuration with a control efficiency of 99%, will be provided to control emissions from the fourteen (14) aeration rooms. In addition, in order to comply with the requirements of 326 IAC 8-1-6 (New Facilities, General Reduction Requirements), the Permittee will also use a single non-regenerable dry bed reactor with a control efficiency of 99% to control the seven (7) sterilization chamber exhaust vents.

Compliance with the requirements of 40 CFR 63.360 through 63.367, Subpart O will also satisfy the requirements of 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Compliance with the requirements of 40 CFR 63.360 through 63.367, Subpart O will also limit source-wide HAP emissions to less than 10 tons per year of any single HAP and less than 25 tons per year of any combination of HAPs and will satisfy the requirements of 326 IAC 2-8-4 included in condition D.1.2.

D.1.2 Hazardous Air Pollutants (HAPs) [326 IAC 2-8-4]

Pursuant to 326 IAC 2-8-4, the primary wet acid scrubber and the single non-regenerable dry bed reactor controlling the seven (7) ethylene oxide sterilization chambers and the three (3) dry bed reactors with or without the wet acid pre-scrubber controlling the fourteen (14) aeration rooms shall be in operation at all times when the sterilization process is emitting ethylene oxide and total ethylene oxide (a HAP) emissions shall not exceed 9.4 tons per year. Therefore, the requirements of 326 IAC 2-7 do not apply.

D.1.3 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 this facility and any control devices.

Compliance Determination Requirements

D.1.4 Ethylene Oxide [40 CFR Part 63, Subpart O]

- (a) Pursuant to 40 CFR 63.363(b), the following procedures shall be used to determine compliance with the emission limits stated in paragraph (a)(2) of condition D.1.1:
- (1) During the performance test required in 40 CFR 63.363(a), the Permittee was required to determine the efficiency of the control devices used to comply with paragraph (a)(2) of condition D.1.1 above using the test methods and procedures in 40 CFR 63.365(b). The Permittee was also required to determine the following:
 - (A) the maximum ethylene glycol concentration using the procedures described in 40 CFR 63.365(e)(1); or
 - (B) the maximum liquor tank level using the procedures described in 40 CFR 63.365(e)(2).

The Permittee conducted the initial performance test on June 3, 1999 and the control efficiency of the control devices used to comply with paragraph (a)(2) of condition D.1.1 was determined to be greater than 99% and the maximum liquor level in the sterilization scrubber recirculation tank was recorded at 114.0 inches above floor level.
 - (2) Pursuant to 40 CFR 63.364(b), the Permittee shall measure and record once per week the level of the scrubber liquor in the sterilization scrubber recirculation tank. The Permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.).
 - (3) Pursuant to 40 CFR 63.364(a), all monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system;
 - (4) Following the date on which the initial performance test was completed, which was June 3, 1999, operation of the primary wet acid scrubber with the liquor tank level in excess of the maximum liquor tank level of 114.0 inches above floor level shall constitute a violation of the sterilization chamber vent standard in paragraph (a)(2) of condition D.1.1 above.

- (b) Pursuant to 40 CFR 63.363(c), the following procedures shall be used to determine compliance with the emission limits stated in paragraph (a)(3) of condition D.1.1:
- (1) During the performance test required in 40 CFR 63.363(a), this sterilization source was required to determine either of the following:
 - (A) the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with paragraph (a)(3) of condition D.1.1) using the methods in 40 CFR 63.365(c)(1); or
 - (B) the combined efficiency of the control device used to comply with paragraph (a)(3) of condition D.1.1 above using the test methods and procedures in 40 CFR 63.365(d)(2).

The Permittee conducted the initial performance test on June 3, 1999 and the aeration room ethylene oxide emission control system averaged 99.6% removal efficiency.

- (2) Pursuant to 40 CFR 63.364(b), the Permittee shall measure and record once per week the level of the scrubber liquor in the aeration scrubber recirculation tank. The Permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.).
- (3) Pursuant to 40 CFR 63.364(a), all monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system;
- (4) Pursuant to 40 CFR 63.363(e), monitoring requirements for alternative control technologies, such as the dry bed reactor technology utilized by the Permittee, must be recommended by the Permittee to the Administrator (U.S. EPA). The Permittee submitted recommended operating parameters for the dry bed reactors to the U.S. EPA for review and approval. In Administrative Compliance Order (Non-Penalty) No. 05-2003-0335, issued by the U.S. EPA on April 7, 2003, the U.S. EPA approved the alternative monitoring plan. Pursuant to the plan and 40 CFR 63.364(d), the Permittee shall comply with the following:
 - (A) The outlet ethylene oxide emissions from the dry bed system controlling the aeration rooms will be measured and recorded on a weekly basis using bag sampling and analysis for residual ethylene oxide by gas chromatograph; and
 - (B) The maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached will be recorded for reference purposes only. (In time, this will provide a baseline to correlate dry bed control capability with respect to equivalent cycle loading.)
- (5) Following the date on which the initial performance test is completed, which was June 3, 1999, the Permittee shall comply with the following provisions:

- (A) operation of the source with a maximum ethylene oxide concentration in excess of the 1 ppmv ethylene oxide concentration limit shall constitute a violation of the aeration room vent standard in paragraph (a)(3) of condition D.1.1 above.
- (B) operation of the aeration room wet acid pre-scrubber with the liquor tank level in excess of the maximum liquor tank level of 103.5 inches above floor level shall constitute a violation of the aeration room vent standard in paragraph (a)(3) of condition D.1.1 above.

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

D.1.5 Monitoring

- (a) To demonstrate compliance with the control efficiency required in condition D.1.1(b) pursuant to 326 IAC 8-1-6 (New Facilities, General Reduction Requirements) for the single non-regenerable dry bed reactor controlling ethylene oxide emissions from the seven (7) sterilization chamber exhaust vents, the Permittee shall monitor and record the number of equivalent sterilization cycles performed while the bed is in service.
- (b) The Permittee shall keep a record of the number of sterilization cycles run for each sterilizer, convert this to equivalent cycles for a 512 ft³ sterilizer, and keep a daily running record of total equivalent cycles. Upon reaching 2,917 equivalent sterilization cycles, based on the manufacturer's guaranteed bed capacity of 360 pounds of ethylene oxide, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed material will have to be removed and replaced with fresh reactant.

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

D.1.6 Record Keeping Requirements

- (a) To document compliance with Conditions D.1.1, D.1.4, and D.1.5, the Permittee shall maintain records in accordance with (1) through (4) below. Records maintained for (1) and (2) shall be taken once weekly and records maintained for (3) shall be taken daily and shall be complete and sufficient to establish compliance with the ethylene oxide emission limits and/or control efficiency limits established in Condition D.1.1 and the monitoring requirements established in Conditions D.1.4 and D.1.5. Records maintained for (4) shall be taken daily and shall be used for reference purposes only. Records necessary to demonstrate compliance shall be available within 30 days of the end of each compliance period.
 - (1) The level of the scrubber liquor in the recirculation tank for each of the wet acid scrubbers for each week;
 - (2) The outlet ethylene oxide emissions from the dry bed system controlling the aeration rooms for each week;
 - (3) The number of equivalent sterilization cycles performed daily while the single non-regenerable dry bed reactor controlling chamber exhaust vents is in service; and
 - (4) The number of equivalent sterilization cycles performed daily while the three (3) dry bed reactors controlling aeration room exhaust are in service.
- (b) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

SECTION D.2

FACILITY OPERATION CONDITIONS

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

- (d) one (1) buffing and grinding operation, with a dust collector controlling particulate matter emissions, exhausting through one (1) stack, identified as S11; [326 IAC 6-3-2]
- (i) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]

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

Process Weight Activities

Emission Limitations and Standards [326 IAC 2-8-4(1)]

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

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

- (a) one (1) buffing and grinding operation, with a dust collector controlling particulate matter emissions, exhausting through one (1) stack, identified as S11; and
- (b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR QUALITY

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP) CERTIFICATION

Source Name: Cook, Inc.
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Mailing Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP No.: F105-15590-00030

**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
P.O. Box 6015
100 North Senate Avenue
Indianapolis, Indiana 46206-6015
Phone: 317-233-5674
Fax: 317-233-5967**

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

Source Name: Cook, Inc.
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Mailing Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP No.: F105-15590-00030

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 317-233-5674, ask for Compliance Section); and• The Permittee must submit notice in writing or by facsimile within two (2) working days (Facsimile Number: 317-233-5967), 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

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

Source Name: Cook, Inc.
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Mailing Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP No.: F105-15590-00030

Months: _____ to _____ Year: _____

Page 1 of 2

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

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.

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

Technical Support Document (TSD) for a Federally Enforceable State Operating Permit
(FESOP) Renewal

Source Background and Description

Source Name:	Cook, Inc.
Source Location:	6330 North Matthews Drive, Ellettsville, Indiana 47429
County:	Monroe
SIC Code:	3841
Operation Permit No.:	105-8436-00030
Operation Permit Issuance Date:	February 16, 1998
Permit Renewal No.:	105-15590-00030
Permit Reviewer:	Trish Earls/EVP

The Office of Air Quality (OAQ) has reviewed a FESOP renewal application from Cook, Inc. relating to the operation of a stationary medical device manufacturing and sterilization operation.

Permitted Emission Units and Pollution Control Equipment

The source consists of the following permitted emission units and pollution control devices:

- (a) seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 will be constructed in 2004;
- (b) fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and
- (c) miscellaneous cleaning with isopropyl alcohol.

Note: The seventh ethylene oxide sterilization chamber identified as S7 above is a new sterilization chamber being added to the source. Emissions from the sterilizer are exempt, therefore, it is being listed with the permitted emission units.

Unpermitted Emission Units and Pollution Control Equipment

There are no unpermitted emission units operating at this source during this review process.

Insignificant Activities

The source also consists of the following insignificant activities, as defined in 326 IAC 2-7-1(21):

- (a) one (1) manual plastic tubing and metal wiring slip coating operation, consisting of five trays using a maximum total of 0.033 gallons of coating per hour, exhausting through one (1) stack, identified as E07;

- (b) the following storage containers:
 - A. one (1) ethylene oxide/HCF-124 mixture storage tank, identified as ST01, with a maximum storage capacity of 5,500 gallons, exhausting through one (1) stack, identified as ST01; or
 - B. four (4) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (1,600 pounds total). These are portable cylinders that will be connected to the sterilization process;
 - C. eight (8) additional 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide to be stored on site;
- (c) three (3) liquor storage tanks, identified as Tanks A, B, and C, each with a working storage capacity of 5,870 gallons, all venting to the wet acid pre-scrubber, exhausting through one (1) stack, identified as HV01;
- (d) one (1) buffing and grinding operation, with a dust collector controlling particulate matter emissions, exhausting through one (1) stack, identified as S11;
- (e) gluing, heat forming, tapering, marking and printing operations associated with manufacturing activities and product assembly, exhausting through building exhausts and one (1) stack, identified as S10;
- (f) natural gas fired combustion sources with a total heat input of 11.3 MMBtu per hour;
- (g) vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;
- (h) application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings;
- (i) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment;
- (j) closed loop heating and cooling systems;
- (k) exposure chambers ("towers", "columns"), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge;
- (l) replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;
- (m) heat exchanger cleaning and repair;
- (n) TDMAC package prep operations, exhausting through one (1) stack, identified as S07;
- (o) heat forming, taping, masking, and printing operations exhausting through various building exhausts;
- (p) Catheter Impregnation Process with potential methanol emissions of less than 0.02 tons per year; and
- (q) Paclitaxel Treatment Process consisting of two (2) units with potential VOC emissions of less than 15 pounds per day.

Existing Approvals

The source has been operating under the previous FESOP 105-8436-00030 issued on February 16, 1998, and the following amendments and revisions:

- (a) AA105-10011-00030 issued on November 22, 1998.

All conditions from previous approvals were incorporated into this FESOP, except the following:

- (a) FESOP F105-8436-00030, issued on February 16, 1998

Conditions D.1.2 and D.1.3

D.1.2 Compliance Schedule

Pursuant to U.S. EPA rulemaking, the compliance date for Subpart O has been extended to and including December 8, 1998. Because of this, Cook, Inc. has submitted the following compliance schedule for the source:

- (a) Cook, Inc.'s existing production equipment, consisting of five (5) sterilizers and two (2) aeration rooms, is currently operating in compliance with applicable air pollution control requirements. Ethylene oxide emissions from sterilization chamber (vacuum) vents are controlled by a wet scrubbing system (by CHEMROX) that has a control efficiency of 96%. Since sterilization chamber vents account for 95% of total ethylene oxide usage at the facility, overall ethylene oxide emissions are therefore controlled by 91.2% ($0.95 * 0.96$). Current operations limit emissions well below major source levels for HAPs and VOCs. The CHEMROX system will continue to limit emissions from the current sterilizers until they are moved to the new facility or until temporary connections are made with the new wet scrubber.
- (b) The new emissions control system will be capable of satisfying the requirements of 40 CFR 63, Subpart O - Ethylene Oxide Emission Standards for Sterilization Facilities. It will be installed and ready for operation on or before February 16, 1998. Cook, Inc. has a phased construction schedule that will bring the new sterilizer (ID No. S3) on-line by March 30, 1998. At the time that this sterilizer is operational, all sterilization chamber vents and exhaust vents from the unit will be controlled by the new emissions control system. Approximately every six weeks thereafter, one of the existing sterilizers will be moved to the new building addition. Depending upon the sequence in which the sterilizers will be moved, temporary connections may be made with the new wet scrubber to allow it to function in place of the CHEMROX scrubber. This may be necessary to allow the CHEMROX scrubber to be removed so it does not interfere with moving some or all of the existing sterilizers to the new building addition. The phased shutdown and relocation of each sterilizer will continue until all sterilizers are permanently connected to the new emissions control system. It is important to note that, because the first phase of the project is the installation of the new emissions control system, all production equipment will be connected to the new Subpart O-compliant system upon being moved to the new building addition. Additionally, at no time in the moving/transition process will any sterilizer be operated without its chamber vents being controlled by either the CHEMROX scrubber or the new wet scrubber.
- (c) The first (of 13) aeration rooms will be installed and connected to the new emissions control system on or before June 22, 1998. Additional aeration rooms will be brought on-line and connected to the new emissions control system as time allows. By the time that the first seven (7) aeration rooms are brought on-line (and connected to the new emissions control system), the existing (uncontrolled) aeration rooms will be removed from service. All new equipment contemplated by the permit will be installed within 18 months of the permit's effective date.
- (d) The phased construction program, including the phased shutdown and relocation of existing sterilizers and the installation of the new aeration rooms and subsequent shutdown of the existing aeration rooms, is expected to be completed by mid-November, 1998. Therefore, all sources of ethylene oxide emissions will be controlled by the new emissions control system that meets the requirements of Subpart O, in advance of the December 8, 1998 Subpart O compliance deadline.

D.1.3 Removal of Equipment

The following currently unpermitted equipment will be taken out of service upon completion of the new building addition and the installation of the replacement equipment listed on page 23 of this permit:

- (a) one (1) ethylene oxide sterilization chamber, identified as S3, to be replaced by one (1) new ethylene oxide sterilization chamber, also identified as S3 (included in item (a) of equipment listed on page 23 of this permit);
- (b) two (2) aeration rooms, identified as HC1 and HC2, each exhausting through one (1) stack, identified as S03 and S02, respectively, to be replaced by thirteen (13) new aeration rooms, identified as HC1 through HC13 (see item (b) of equipment listed on page 23 of this permit); and
- (c) one (1) wet acid hydrolysis scrubber which exhausts through one (1) stack, identified as T01, to be replaced by one (1) new primary wet acid scrubber which exhausts through one (1) stack, identified as PS01.

Reason not incorporated:

All the new equipment and emissions control systems that were scheduled to be installed as required in the original FESOP have been installed and the emission units that were required to be removed upon completion of the building addition and the installation of the replacement equipment have been taken out of service and removed. Therefore, these conditions no longer apply.

- (b) All construction conditions from FESOP F105-8436-00030, issued on February 16, 1998.

Reason not incorporated: All facilities previously permitted have already been constructed; therefore, the construction conditions are no longer necessary as part of the operating permit.

Enforcement Issue

- (a) IDEM is aware that monitoring of the aeration rooms' dry bed reactors meets the definition of "major change to monitoring" under the NESHAP delegation of authorities, and major changes to monitoring methods can not be delegated to the States. So the provisions IDEM put into FESOP No. F105-8436-00030, issued to Cook, Inc. on February 16, 1998, for dry bed monitoring were not an approved alternative monitoring plan under the NESHAP, 40 CFR 63, Subpart O. Since it was Cook, Inc.'s understanding that those FESOP provisions were all they needed, the U.S. EPA and IDEM believe Cook acted in good faith, and this was resolved through an Administrative Compliance Order (Non-Penalty) No. 05-2003-0335, issued by the U.S. EPA on April 7, 2003, where it was not stated that they were in violation of the rule. Also, the U.S. EPA did not issue a Finding of Violation. Through the Administrative Order, Cook, Inc. did send the U.S. EPA an alternative monitoring plan, which was approved.
- (b) Issuance of the Administrative Compliance Order by the U.S. EPA referenced above has resolved this matter with IDEM. The alternative monitoring requirements in this proposed permit will satisfy the requirements of the NESHAP, 40 CFR 63, Subpart O.

Recommendation

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

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

An administratively complete FESOP renewal application for the purposes of this review was received on May 2, 2002. Additional information was received on February 17, 2004. There was no notice of completeness letter mailed to the source.

Emission Calculations

See Appendix A of this document for detailed emission calculations (7 pages).

Unrestricted Potential Emissions

This table reflects the unrestricted potential emissions of the source, excluding the emission limits that were contained in the previous FESOP.

Pollutant	Unrestricted Potential Emissions (tons/yr)
PM	0.23
PM-10	0.52
SO ₂	0.03
VOC	49.91
CO	4.17
NO _x	4.97

HAPs	Unrestricted Potential Emissions (tons/yr)
Ethylene Oxide	Greater than 10
Methanol	Less than 10
Methylene Chloride	Less than 10
Toluene	Less than 10
Hexane	Less than 10
TCE	Less than 10
Total	Greater than 25

- (a) The unrestricted potential emissions of any single HAP is equal to or greater than ten (10) tons per year and the unrestricted potential emissions of a combination of HAPs is equal to or greater than twenty-five (25) tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7. The source will be issued a FESOP because the source will limit its emissions below the Title V levels.
- (b) Fugitive Emissions
Since this type of operation is not one of the twenty-eight (28) listed source categories under 326 IAC 2-2 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive particulate matter (PM) and volatile organic compound (VOC) emissions are not counted toward determination of PSD and Emission Offset applicability.

Potential to Emit After Issuance

The source has opted to remain a FESOP source. The table below summarizes the potential to emit, reflecting all limits of the emission units. Any control equipment is considered enforceable only after issuance of this FESOP and only to the extent that the effect of the control equipment is made practically enforceable in the permit. Since the source has not constructed any new emission units, the source's potential to emit is based on the emission units included in the original FESOP.

Process/emission unit	Potential To Emit (tons/year)							
	PM	PM-10	SO ₂	VOC	CO	NO _x	Single HAP	Total HAPs
Sterilization*	-	-	-	9.40	-	-	9.40	9.40
Misc. cleaning with IPA	-	-	-	9.47	-	-	-	-
Insignificant Activities**	0.23	0.52	0.03	2.64	4.17	4.97	0.09	0.27
Total Emissions	0.23	0.52	0.03	21.51	4.17	4.97	9.40	9.67

*Note: Ethylene oxide is the only pollutant emitted from the sterilization operation. VOC emissions from the sterilization operation represent ethylene oxide as a VOC. Therefore, the 9.4 ton limit on ethylene oxide as the worst case single HAP to comply with 326 IAC 2-8-4 (FESOP) is reflected in the VOC limited potential to emit.

** Emissions from insignificant natural gas combustion units were updated based on the most recent emission factors from U.S. EPA's AP-42.

County Attainment Status

The source is located in Monroe County.

Pollutant	Status
PM-10	Attainment
SO ₂	Attainment
NO ₂	Attainment
1-hour Ozone	Attainment
8-hour Ozone	Attainment
CO	Attainment
Lead	Attainment

- (a) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC emissions and NOx are considered when evaluating the rule applicability relating to ozone. Monroe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC emissions and NOx were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability for the source section.
- (b) Monroe County has been classified as attainment or unclassifiable in Indiana for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability for the source section.
- (c) Fugitive Emissions
 Since this type of operation is not one of the 28 listed source categories under 326 IAC 2-2 or 2-3 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive particulate matter (PM) and volatile organic compound (VOC) emissions are not counted toward determination of PSD and Emission Offset applicability.

Source Status

Existing Source FESOP Definition (emissions after controls, based on 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Emissions (tons/yr)
PM	0.74
PM-10	0.74
SO ₂	0.03
VOC	21.5
CO	1.04
NO _x	4.97
Single HAP	9.40
Combination HAPs	9.58

- (a) This existing source is **not** a major stationary source because no attainment regulated pollutant is emitted at a rate of 250 tons per year or greater and it is not in one of the 28 listed source categories.

Federal Rule Applicability

- (a) There are no New Source Performance Standards (NSPS) (326 IAC 12 and 40 CFR Part 60) applicable to this source.
- (b) The requirements of the New Source Performance Standard, 326 IAC 12, (40 CFR 60.110b, Subpart Kb) are not included in the permit for the one (1) 5,500 gallon ethylene oxide/HCFC-124 mixture storage tank (ST01) and the three (3) 5,870 gallon liquor storage tanks (Tanks A, B, and C) because the maximum storage capacity of each tank is less than 75 cubic meters.
- (c) The sterilization operation at this source is subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP), 326 IAC 14, (40 CFR 63.360 through 63.367, Subpart O). Although the source has not used more than 10 tons of ethylene oxide per year since issuance of FESOP F105-8436-00030, issued on February 16, 1998, it is a source that used 10 tons or more of ethylene oxide in any consecutive 12-month period after December 6, 1996. Therefore, it is subject to the emission standards for sources using 10 tons or more of ethylene oxide per consecutive 12-month period. The compliance date for Subpart O for this source was December 8, 1998.
- (1) Pursuant to 40 CFR 63.362, Subpart O, the sterilization operation is subject to the following conditions:
- (a) The emission limitations of paragraphs (b) and (c) below apply during sterilization operation. The emission limitations do not apply during periods of malfunction.
- (b) This sterilization source shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.
- (c) This sterilization source shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99%, whichever is less stringent, from each aeration room vent.

- (d) Pursuant to 40 CFR 63.363(a), the Permittee shall conduct an initial performance test using the procedures listed in 40 CFR 63.7 of Subpart A, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. The performance test shall be completed within 180 days after the Subpart O compliance date. Performance testing for this source was performed on June 3 and 4, 1999, and showed the source to be in compliance with the emission limitations included above. Therefore, this requirement was not included in the FESOP renewal.
- (2) The Permittee will comply with the requirements of this rule by using a primary wet acid scrubber to control sterilization chamber vents. The device will have a control efficiency of 99%. A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) or three (3) dry bed reactors alone, each configuration with a control efficiency of 99%, will be provided to control emissions from the fourteen (14) aeration rooms.
- (3) Pursuant to 40 CFR 63.363(b), the following procedures shall be used to determine compliance with the emission limits stated in paragraph (b) of section (1) above:
- (a) During the performance test required in paragraph (d) of section (1) above, the Permittee was required to determine the efficiency of the control devices used to comply with paragraph (b) of section (1) above using the test methods and procedures in 40 CFR 63.365(b)(1). The Permittee was also required to determine the following:
- (i) the maximum ethylene glycol concentration using the procedures described in 40 CFR 63.365(e)(1); or
- (ii) the maximum liquor tank level using the procedures described in 40 CFR 63.365(e)(2).

The control efficiency of the control devices used to comply with paragraph (b) of section (1) was determined to be greater than 99% and the maximum liquor level in the sterilization scrubber recirculation tank was recorded at 114.0 inches above floor level during the initial performance test.

- (b) Pursuant to 40 CFR 364(b), the Permittee shall either:
- (i) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in 40 CFR 63.365(e)(1); or
- (ii) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The Permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.).

The Permittee has chosen to monitor the level of the scrubber liquor in the recirculation tank once per week for the primary wet acid scrubber controlling the sterilization chamber vents.

(c) Following the date on which the initial performance test is completed, which was June 3, 1999, operation of the source with the liquor tank level in excess of the maximum liquor tank level of 114.0 inches above floor level shall constitute a violation of the sterilization chamber vent standard in paragraph (b) of section (1) above.

(4) Pursuant to 40 CFR 63.363(c), the following procedures shall be used to determine compliance with the emission limits stated in paragraph (c) of section (1) above:

(a) During the performance test required in paragraph (d) of section (1) above, this sterilization source shall determine either of the following:

- (i) the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with paragraph (c) of section (1) above) using the methods in 40 CFR 63.365(c)(1); or
- (ii) the combined efficiency of the control device used to comply with paragraph (c) of section (1) above using the test methods and procedures in 40 CFR 63.365(d)(2).

During the initial performance test, the aeration room ethylene oxide emission control system averaged 99.6% removal efficiency.

(b) Pursuant to 40 CFR 364(b), the Permittee shall either:

- (i) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in 40 CFR 63.365(e)(1); or
- (ii) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The Permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.).

The maximum liquor level in the aeration scrubber recirculation tank was recorded at 103.5 inches above floor level during the initial performance test. This is the parameter that the source has chosen to monitor for the wet acid pre-scrubber controlling the aeration room vents.

(c) While the NESHAP provides explicit guidance for monitoring wet scrubbers and catalytic oxidizers, pursuant to 40 CFR 63.363(e), monitoring requirements for alternative control technologies, such as the dry bed reactor technology utilized by Cook, Inc. at this source, must be recommended by the owner or operator to the Administrator (U.S. EPA). Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test.

Cook, Inc. submitted recommended operating parameters for the dry bed reactors to the U.S. EPA for review and approval. In Administrative Compliance Order (Non-Penalty) No. 05-2003-0335, issued by the U.S. EPA on April 7, 2003, the U.S. EPA approved the alternative monitoring plan. Pursuant to the plan and 40 CFR 364(d), the Permittee shall comply with the following:

- (i) The outlet emissions from the dry bed system controlling the aeration rooms will be measured and recorded on a weekly basis using bag sampling and analysis for residual ethylene oxide by gas chromatograph; and
 - (ii) The maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached will be recorded for reference purposes only. (In time, this will provide a baseline to correlate dry bed control capability with respect to equivalent cycle loading.)
- (d) Following the date on which the initial performance test is completed, which was June 3, 1999, the Permittee shall comply with the following provisions:
- (i) operation of the source with a maximum ethylene oxide concentration in excess of the 1 ppmv ethylene oxide concentration limit shall constitute a violation of the aeration room vent standard in paragraph (c) of section (1) above.
 - (ii) operation of the source with the liquor tank level in excess of the maximum liquor tank level of 103.5 inches above floor level shall constitute a violation of the aeration room vent standard in paragraph (c) of section (1) above.

Compliance with the requirements of 40 CFR 63.360 through 63.367, Subpart O will also satisfy the requirements of 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Note that the emission limitations for the sterilization chamber exhaust vents, which were included in the original FESOP were removed from the NESHAP in the Federal Register notice dated November 2, 2001. Therefore, these emission limitations have been removed from the permit. However, since the requirement to operate the dry bed reactor controlling the emissions from the sterilization chamber exhaust vents in the original FESOP was also part of the requirements to satisfy 326 IAC 8-1-6 (New Facilities, General Reduction Requirements), the source is still required to operate the dry bed reactor controlling emissions from the sterilization chamber exhaust vents to comply with 326 IAC 8-1-6 (New Facilities, General Reduction Requirements) and 326 IAC 2-8-4 (FESOP).

- (d) The valves, connectors, and pressure relief seal associated with the sterilization process are not subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP), 326 IAC 14, (40 CFR 61, Subpart V), "National Emission Standard for Equipment Leaks (Fugitive Emission Sources). This rule applies to equipment that is in volatile hazardous air pollutant (VHAP) service. A VHAP is defined as a substance regulated under 40 CFR Part 61 for which a standard for equipment leaks of the substance has been proposed and promulgated. Ethylene oxide is not a VHAP pursuant to this definition because it is not regulated under 40 CFR Part 61, and no standards for equipment leaks of this substance has been proposed or promulgated. Therefore, the sterilization operation is not subject to the provisions of 40 CFR 61, Subpart V.

State Rule Applicability – Entire Source

326 IAC 1-6-3 (Preventive Maintenance Plan)

The source has submitted a Preventive Maintenance Plan (PMP) on February 17, 2004.

326 IAC 2-6 (Emission Reporting)

Since this source is complying with 326 IAC 2-8 (FESOP) and is not required to have an operating permit under 326 IAC 2-7, Part 70 Permit Program, this source is not subject to 326 IAC 2-6 (Emission Reporting).

326 IAC 5-1 (Opacity Limitations)

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

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

326 IAC 2-8-4 (FESOP)

This source is subject to 326 IAC 2-8-4 (FESOP). Pursuant to this rule, the primary wet acid scrubber and the single non-regenerable dry bed reactor controlling the seven (7) ethylene oxide sterilization chambers and the three (3) dry bed reactors with or without the wet acid pre-scrubber controlling the fourteen (14) aeration rooms shall be in operation at all times when the sterilization process is emitting ethylene oxide and total ethylene oxide (a HAP) emissions shall not exceed 9.4 tons per year. Therefore, the requirements of 326 IAC 2-7 do not apply.

State Rule Applicability – Individual Facilities

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

The operation of the sterilization process will emit less than 10 tons per year of a single HAP or 25 tons per year of a combination of HAPs. Therefore, 326 IAC 2-4.1 does not apply.

326 IAC 6-3-2 (Process Operations)

The surface coating operations at this source are not subject to this rule because they use less than 5 gallons per day of coating and are exempt from the rule.

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

- (a) one (1) buffing and grinding operation, with a dust collector controlling particulate matter emissions, exhausting through one (1) stack, identified as S11; and
- (b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment.

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

The sterilization process is subject to the provisions of 326 IAC 8-1-6. This rule requires all facilities constructed after January 1, 1980, which have potential VOC emission rates of 25 or more tons per year, and which are not otherwise regulated by other provisions of 326 IAC 8, to reduce VOC emissions using Best Available Control Technology (BACT). Potential emissions of VOC from the sterilization process represent ethylene oxide as a VOC and are greater than 25 tons per year, therefore, the sterilization process is subject to 326 IAC 8-1-6.

The control technology used to comply with the requirements of 40 CFR 60.360 through 60.367, which apply to the sterilization process, as well as the dry bed reactor controlling emissions from the sterilization chamber exhaust, will control VOC (ethylene oxide) emissions from the sterilization operation to 0.38 tons per year. Since the requirement to operate the dry bed reactor controlling the emissions from the sterilization chamber exhaust vents in the original FESOP was also part of the requirements to satisfy 326 IAC 8-1-6 (New Facilities, General Reduction Requirements), the source is still required to operate the dry bed reactor controlling emissions from the sterilization chamber exhaust vents as well as the primary wet acid scrubber, the wet acid pre-scrubber, and three (3) dry bed reactors (in parallel) to comply with 326 IAC 8-1-6 (New Facilities, General Reduction Requirements). Pursuant to FESOP F105-8436-00030, issued on February 16, 1998, this control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operation.

The following insignificant activities are not subject to the requirements of 326 IAC 8-1-6 because potential VOC emissions are less than 25 tons per year:

- (a) one (1) manual plastic tubing and metal wiring slip coating operation, consisting of five trays using a maximum total of 0.033 gallons of coating per hour, exhausting through one (1) stack, identified as E07;
- (b) gluing, heat forming, tapering, marking and printing operations associated with manufacturing activities and product assembly, exhausting through building exhausts and one (1) stack, identified as S10;
- (c) TDMAC package prep operations, exhausting through one (1) stack, identified as S07; and
- (d) heat forming, taping, masking, and printing operations exhausting through various building exhausts.

326 IAC 8-2-9 (Miscellaneous Metal Coating)

The metal wiring slip coating operation, constructed in 1986, is not subject to the requirements of 326 IAC 8-2-9 because potential VOC emissions are less than 25 tons per year.

326 IAC 14-8 (Emission Standards for Equipment Leaks (Fugitive Emission Sources))

The sterilization process is not subject to the requirements of 326 IAC 14-8. This rule incorporates the provisions of 40 CFR Part 61, Subpart V, Emission Standards for Equipment Leaks (Fugitive Emission Sources). Ethylene oxide is not a VHAP pursuant to the rule definition because it is not regulated under 40 CFR Part 61, and no standards for equipment leaks of this substance has been proposed or promulgated. Therefore, the sterilization operation is not subject to the provisions of 326 IAC 14-8.

Testing Requirements

This source performed initial stack testing on the primary wet acid scrubber and the single non-regenerable dry bed reactor controlling the sterilization chamber ethylene oxide emissions and the wet acid pre-scrubber and the three (3) dry bed reactors controlling the aeration room ethylene oxide emissions on June 3rd and 4th, 1999 as required in the original FESOP. The stack testing indicated that the source was in compliance with the NESHAP, 40 CFR 63, Subpart O.

Since the site-specific operational parameters for the wet scrubbers obtained from the initial stack testing will be monitored weekly and the ethylene oxide emissions from the dry bed reactors controlling the aeration room vent will be measured and recorded weekly, testing is not required to be repeated to demonstrate compliance at this time.

Compliance Requirements

Permits issued under 326 IAC 2-8 are required to ensure that sources can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAQ in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-8-4. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within state and federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also in Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period. The compliance monitoring requirements applicable to this source are as follows:

1. The the primary wet acid scrubber controlling the sterilization chamber vents, and the wet acid pre-scrubber and three (3) dry bed reactors controlling the aeration room vents have applicable compliance monitoring conditions as specified below:
 - (a) Pursuant to 40 CFR 63.364(a), the Permittee shall monitor the parameters specified in 40 CFR 63.364(b) listed below. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system;
 - (b) The Permittee shall measure and record once per week the level of the scrubber liquor in the recirculation tank of the primary wet acid scrubber controlling sterilization chamber vents and the wet acid pre-scrubber controlling aeration room vents. The Permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e. a marker on the tank wall, a dipstick, a magnetic indicator, etc.).
 - (c) Pursuant to 40 CFR 63.363(f) and information provided by Cook, Inc. in the alternative monitoring plan, the three (3) dry bed reactors controlling aeration room exhaust have applicable compliance monitoring conditions as specified below:

- (1) The outlet emissions from the dry bed system will be measured and recorded on a weekly basis. A "grab" sample will be taken in a bag from the outlet of the dry bed reactor system once each week, and analyzed with the Cook, Inc. area monitoring gas chromatograph unit. The gas chromatograph techniques utilized will provide a precision of 5 percent relative standard deviation (RSD);
- (2) The maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached shall be monitored to track total loadings for reference purposes only. Draeger tubes may also be used to track total loadings for reference purposes only.

These monitoring conditions are necessary because the primary wet acid scrubber controlling sterilization chamber vents, and the wet acid pre-scrubber and three (3) dry bed reactors controlling aeration room vents must operate properly to ensure compliance with 40 CFR 63, Subpart O, 326 IAC 8-1-6 (New Facilities, General Reduction Requirements) and 326 IAC 2-8 (FESOP).

2. The the single non-regenerable dry bed reactor controlling the sterilization chamber exhaust vents has applicable compliance monitoring conditions as specified below:
 - (a) To demonstrate compliance with the control efficiency required pursuant to 326 IAC 8-1-6 (New Facilities, General Reduction Requirements) for the single non-regenerable dry bed reactor controlling ethylene oxide emissions from the seven (7) sterilization chamber exhaust vents, the Permittee shall monitor and record the number of equivalent sterilization cycles performed while the bed is in service.
 - (b) The Permittee shall keep a record of the number of sterilization cycles run for each sterilizer, convert this to equivalent cycles for a 512 ft³ sterilizer, and keep a daily running record of total equivalent cycles. Upon reaching 2,917 equivalent sterilization cycles, based on the manufacturer's guaranteed bed capacity of 360 pounds of ethylene oxide, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed material will have to be removed and replaced with fresh reactant.

These monitoring conditions are necessary because the single non-regenerable dry bed reactor controlling the sterilization chamber exhaust vents must operate properly to ensure compliance with 326 IAC 8-1-6 (New Facilities, General Reduction Requirements) and 326 IAC 2-8 (FESOP).

Conclusion

The operation of this stationary medical device manufacturing and sterilization operation shall be subject to the conditions of the FESOP 105-15590-00030.

Appendix A: Emission Calculations

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47.
FESOP: F105-15590
Pit ID: 105-00030
Reviewer: Trish Earls

Total Potential To Emit (tons/year)			
Emissions Generating Activity			
Pollutant	Sterilization	Miscellaneous Cleaning with IPA	Insignificant Activities*
PM	0.00	0.00	0.23
PM10	0.00	0.00	0.52
SO2	0.00	0.00	0.03
NOx	0.00	0.00	4.97
VOC	37.80	9.47	2.64
CO	0.00	0.00	4.17
total HAPs	37.80	0.00	0.27
worst case single HAP (Ethylene oxide)	37	0.00	(TCE) 0.09
Total emissions based on rated capacities at 8,760 hours/year.			
*Insignificant Activity Emissions represent emissions from surface coating, var package prep and printing, and from natural gas combustion.			
**For the purposes of determining Title V applicability, PM10 (not PM) is the r			
Limited Potential To Emit (tons/year)			
Emissions Generating Activity			
Pollutant	Sterilization	Miscellaneous Cleaning with IPA	Insignificant Activities*
PM	0.00	0.00	0.23
PM10	0.00	0.00	0.52
SO2	0.00	0.00	0.03
NOx	0.00	0.00	4.97
VOC	0.38	9.47	2.64
CO	0.00	0.00	4.17
total HAPs	0.38	0.00	0.27
worst case single HAP (ethylene oxide)	0.38	0.00	(TCE) 0.09
Total emissions based on rated capacities at 8,760 hours/year with control.			
*Insignificant Activity Emissions represent emissions from surface coating, var package prep and printing, and from natural gas combustion.			
**For the purposes of determining Title V applicability, PM10 (not PM) is the r			

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TOTAL
0.23
0.52
0.03
4.97
49.91
4.17
38.07
ethylene oxide) 37.80

ious assembly operat

regulated pollutant i

TOTAL
0.23
0.52
0.03
4.97
12.49
4.17
0.65
ethylene oxide) 0.38

ious assembly operat

regulated pollutant i

**Appendix A: Potential Emission Calculations
Source Wide Ethylene Oxide (EO) Emissions by Facility**

Company Name: Cook Inc.
Address City IN Zip:
FESOP: F105-15590
Plt ID: 105-00030
Reviewer: Trish Earls

Source	Stack Vent Identification #	Fraction of EO Usage	Maximum Uncontrolled Emissions (lb/yr) See Note 1	Control Efficiency (%)	Maximum Controlled Emissions (lbs/yr)
Sterilization Chamber (Vacuum) Vents	PS01	0.9500	72,000.0	99.00%	720
Sterilization Chamber Exhaust Vents (Back vents)	SV01	0.0035	260.0	99.00%	2.6
Product Transfer	SV01	0.0021	1.6	0.0	1.5600
Aeration	HV01	0.0444	3,340.0	99.00%	33.4
All	-	1.00	75,601.56	-	757.56
Tons/Year	-	-	37.80	-	0.38

Notes 1. Potential Emissions = Fraction of Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]

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Appendix A: Emission Calculations VOC and Particulate From Surface Coating and Miscellaneous Cleaning Operations

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP: F105-15590
Plt ID: 105-00030
Reviewer: Trish Earls

State Potential Emissions (uncontrolled):																
Material (as applied)	Process	Density (Lb/Gal)	Weight % Volatile (H2O& Organics)	Weight % Water	Weight % Organics	Volume % Water	Volume % Non-Vol (solids)	Maximum Gal of Mat. (gal/hr)	Pounds VOC per gallon of coating less water	Pounds VOC per gallon of coating	Potential VOC pounds per hour	Potential VOC pounds per day	Potential VOC tons per year	Particulate Potential ton/yr	lb VOC /gal solids	Transfer Efficiency
Surface Coating																
(Confidential)	Plastic Tubing & Metal Wiring								7.7	7.66	0.25	6.07	1.11	0.00	197.90	100.00%
(Confidential)	Plastic Tubing								6.5	6.51	0.21	5.16	0.94	0.00	N/A	100.00%
Miscellaneous Cleaning																
(Confidential)	Miscellaneous Cleaning								6.5	6.51	2.16	51.87	9.47	0.00	N/A	100.00%
Total State Potential Emissions:											2.63	63.09	11.51	0.00		
Federal Potential Emissions (controlled):																
										Control Efficiency:		Controlled VOC lbs per Hour	Controlled VOC lbs per Day	Controlled VOC tons per Year	Controlled PM tons/yr	
										VOC	PM					
Total Federal Potential Emissions:										0.00%	0.00%	2.63	63.09	11.51	0.00	

Note:
Shaded boxes indicate information is confidential.

Methodology:
Pounds of VOC per Gallon Coating less Water = (Density (lb/gal) * Weight % Organics) / (1-Volume % water)
Pounds of VOC per Gallon Coating = (Density (lb/gal) * Weight % Organics)
Potential VOC Pounds per Hour = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr)
Potential VOC Pounds per Day = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (24 hr/day)
Potential VOC Tons per Year = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (8760 hr/yr) * (1 ton/2000 lbs)
Particulate Potential Tons per Year = (units/hour) * (gal/unit) * (lbs/gal) * (1- Weight % Volatiles) * (1-Transfer efficiency) *(8760 hrs/yr) *(1 ton/2000 lbs)
Pounds VOC per Gallon of Solids = (Density (lbs/gal) * Weight % organics) / (Volume % solids) * Transfer Efficiency
Total = Worst Coating + Sum of all solvents used
Controlled emission rate = uncontrolled emission rate * (1 - control efficiency)

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Appendix A: Emission Calculations Uncontrolled Surface Coating HAP Emissions - Potential to Emit

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP: F105-15590
Pit ID: 105-00030
Reviewer: Trish Earls

Potential To Emit							
Material	Process	Density (lb/gal)	Maximum Gal of Mat. (gal/hr)	Weight % Methanol	Weight % MIBK	Methanol Emissions (tons/yr)	MIBK Emissions (tons/yr)
(Confidential)	Plastic Tubing & Metal Wiring					0.01	0.00
(Confidential)	Plastic Tubing					0.00	0.00
						0.01	0.00
							0.01

Note:

Shaded boxes indicate information is confidential.

Methodology:

HAPs emission rate (tons/yr) = density (lb/gal) * (gal/unit) * (units/hour) * weight % HAP * % Flash Off * (8,760 hrs/yr) * (1 ton/2,000 lb)

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

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP: F105-15590
Pit ID: 105-00030
Reviewer: Trish Earls

Heat Input Capacity
MMBtu/hr

11.3

Potential Throughput
MMCF/yr

99.4

Heat Input Capacity includes:

Insignificant natural gas fired combustion units with a total heat input of 11.3 MMBtu/hr.

Emission Factor in lb/MMCF	Pollutant					
	PM*	PM10*	SO2	NOx	VOC	CO
	1.9	7.6	0.6	100.0 **see below	5.5	84.0
Potential Emission in tons/yr	0.09	0.38	0.03	4.97	0.27	4.17

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

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

Methodology

All emission factors are based on normal firing.

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

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

Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03 (SUPPLEMENT D 3/98)

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

See page 6 for HAPs emissions calculations.

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

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP: F105-15590
Pit ID: 105-00030
Reviewer: Trish Earls

HAPs - Organics					
Emission Factor in lb/MMcf	Benzene 2.1E-03	Dichlorobenzene 1.2E-03	Formaldehyde 7.5E-02	Hexane 1.8E+00	Toluene 3.4E-03
Potential Emission in tons/yr	1.044E-04	5.963E-05	3.727E-03	8.944E-02	1.689E-04

HAPs - Metals						
Emission Factor in lb/MMcf	Lead 5.0E-04	Cadmium 1.1E-03	Chromium 1.4E-03	Manganese 3.8E-04	Nickel 2.1E-03	Total
Potential Emission in tons/yr	2.485E-05	5.466E-05	6.957E-05	1.888E-05	1.044E-04	0.09

Methodology is the same as page 5.

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

**Appendix A: Emission Calculations
Other Insignificant Activities**

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47404
FESOP: F105-15590
Plt ID: 105-00030
Reviewer: Trish Earls

Total Potential To Emit (tons/year)			
Emissions Generating Activity			
Pollutant	Assembly Operations	Package Prep	Marking, Printing
PM	0.14	0.00	0.00
PM10	0.14	0.00	0.00
SO2	0.00	0.00	0.00
NOx	0.00	0.00	0.00
VOC	0.11	0.18	0.03
CO	0.00	0.00	0.00
total HAPs	0.00	0.17	0.00
worst case single HAP	0.00	(TCE) 0.09	0.00
Total emissions based on rated capacities at 8,760 hours/year and are based on the original FESOP application (F105-8436-00030).			

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TOTAL
0.14
0.14
0.00
0.00
0.32
0.00
0.17
(TCE) 0.09
information provided