

**FEDERALLY ENFORCEABLE STATE
OPERATING PERMIT (FESOP)
and ENHANCED NEW SOURCE REVIEW
OFFICE OF AIR MANAGEMENT**

**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 facilities listed in Section A (Source Summary) of this permit.

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 and 326 IAC 2-1-3.2, 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.: F105-8436-00030	
Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

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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 Management (OAM) and 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.

Responsible Official: Scott Eells
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Mailing Address: 6330 North Matthews Drive, P.O. Box 277, Ellettsville, Indiana 47429
SIC Code: 3841
County Location: Monroe
County Status: Attainment for all criteria pollutants
Source Status: Federally Enforceable State Operating Permit (FESOP)
Minor Source, under PSD Rules;
Major 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) six (6) ethylene oxide sterilization chambers, identified as S1 through S6, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one new (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one new (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01;
- (b) thirteen (13) aeration rooms, identified as HC1 through HC13, of which zero (0) to a maximum of six (6) can exhaust through one (1) new wet acid pre-scrubber and three (3) new dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) new 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:
 - (1) one (1) ethylene oxide/HCFC-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
 - (2) 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;
 - (3) 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) two (2) gluing operations in Departments 1 and 4, respectively, each using a maximum of 0.005 ounces per hour of adhesive, each exhausting through one (1) fume hood with one (1) stack, identified as E08 and S10, respectively;

- (e) two (2) buffing and grinding operations in Departments 1 and 4, respectively, with a dust collector controlling particulate matter emissions from both operations, exhausting through one (1) stack, identified as S11;
- (f) 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;
- (g) natural gas fired combustion sources with a total heat input of 11.3 MMBtu per hour;
- (h) vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;
- (i) application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings;
- (j) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment;
- (k) closed loop heating and cooling systems;
- (l) exposure chambers ("towers", "columns"), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge;
- (m) replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;
- (n) heat exchanger cleaning and repair;
- (o) TDMAC package prep operations, exhausting through one (1) stack, identified as S07;
- (p) fume hood operations, exhausting through one (1) stack, identified as E09; and
- (q) heat forming, taping, masking, and printing operations exhausting through various building exhausts.

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 Management (OAM) for a Federally Enforceable State Operating Permit (FESOP).

SECTION B GENERAL CONDITIONS

B.1 Permit No Defense [326 IAC 2-1-10] [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, any applicable definitions found in IC 13-11, 326 IAC 1-2, and 326 IAC 2-7 shall prevail.

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

This permit is issued for a fixed term of five (5) years from the effective date, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3.

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

- (a) All terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM.

- (b) Unless otherwise stated, terms and conditions of this permit, including any provisions to limit the source's potential to emit, are enforceable by the United States Environmental Protection Agency (U.S. EPA) and citizens under 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 Supplement and Provide Information [326 IAC 2-8-3(f)] [326 IAC 2-8-4(5)(E)]

- (a) The Permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall promptly submit such supplementary facts or corrected information to:

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

- (b) The Permittee shall furnish to IDEM, OAM, within a reasonable time, any information that IDEM, OAM, 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.

- (c) Upon request, the Permittee shall also furnish to IDEM, OAM, copies of records required to be kept by this permit. For information claimed to be confidential, the Permittee shall furnish such records to IDEM, OAM, along with a claim of confidentiality under 326 IAC 17. If requested by IDEM, OAM, or the U.S. EPA, the Permittee shall furnish such confidential records directly to the U.S. EPA along with a claim of confidentiality under 40 CFR 2, Subpart B.

Such confidentiality claims shall meet the requirements of 40 CFR 2, Subpart B (when submitting to U.S. EPA) and 326 IAC 17 (when submitting to IDEM, OAM).

B.9 Compliance Order Issuance [326 IAC 2-8-5(b)]

IDEM, OAM 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 Compliance with Permit Conditions [326 IAC 2-8-4(5)(A)] [326 IAC 2-8-4(5)(B)]

- (a) The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit constitutes a violation of the Clean Air Act and is grounds for:
- (1) Enforcement action;
 - (2) Permit termination, revocation and reissuance, or modification; and
 - (3) Denial of a permit renewal application.
- (b) 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.

B.11 Certification [326 IAC 2-8-3(d)] [326 IAC 2-8-4(3)(C)(i)] [326 IAC 2-8-5(1)]

- (a) Any application form, report, or compliance certification submitted under this permit shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, and any other certification required under this permit, 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, on the attached Certification Form, with each submittal.
- (c) A responsible official is defined at 326 IAC 2-7-1(34).

B.12 Annual Compliance Certification [326 IAC 2-8-5(a)(1)]

- (a) The Permittee shall annually certify that the source has complied with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. The certification 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 Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

and

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

- (b) The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAM, on or before the date it is due.
- (c) The annual compliance certification report shall include the following:
 - (1) The 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 compliance of the source, currently and over the reporting period consistent with 326 IAC 2-8-4(3); and
 - (5) Such other facts, as specified in Sections D of this permit, as IDEM, OAM, 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 "responsible official" as defined by 326 IAC 2-7-1(34).

B.13 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 prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days after issuance of this permit, including the following information on each:
 - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission units and associated emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions;
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.
- (b) The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that lack of proper maintenance does not cause or contribute to a violation of any limitation on emissions or potential to emit.
- (c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM.

B.14 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, OAM, 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 Management, 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 notice either in writing or facsimile, of the emergency to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Management
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 "responsible official" as defined by 326 IAC 2-7-1(33).

- (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) for sources subject to

this rule after the effective date of this rule. This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.

- (e) IDEM, OAM, 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, OAM, by telephone or facsimile of an emergency lasting more than one (1) hour in compliance 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.

B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-8-4(3)(C)(ii)]

- (a) Deviations from any permit requirements (for emergencies see Section B - Emergency 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 Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

within ten (10) calendar days from the date of the discovery of the deviation.

- (b) Written notification shall be submitted on the attached Emergency/Deviation Occurrence Reporting Form or its substantial equivalent.
- (c) Proper notice submittal under 326 IAC 2-7-16 satisfies the requirement of this subsection.

B.16 Permit Modification, Reopening, Revocation and Reissuance, or Termination
[326 IAC 2-8-4(5)(C)] [326 IAC 2-8-7(a)] [326 IAC 2-8-8]

- (a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a 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)]

- (b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAM 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, OAM, 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, OAM, at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAM, may provide a shorter time period in the case of an emergency. [326 IAC 2-8-8(c)]

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

- (a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAM 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).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Management
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, OAM, on or before the date it is due. [326 IAC 2-5-3]

B.18 Administrative Permit Amendment [326 IAC 2-8-10]

- (a) An administrative permit amendment is a FESOP revision that makes changes of the type specified under 326 IAC 2-8-10(a).
- (b) An administrative permit amendment may be made by IDEM, OAM, consistent with the procedures specified under 326 IAC 2-8-10(b).
- (c) The Permittee may implement the changes addressed in the request for an

administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.19 Minor Permit Modification [326 IAC 2-8-11(a)] [326 IAC 2-8-11(b)(1) and (2)]

- (a) A permit modification is any revision to this permit that cannot be accomplished as an administrative permit amendment under 326 IAC 2-8-10.
- (b) Minor modification of this permit shall follow the procedures specified under 326 IAC 2-7-12(b), except as provided by 326 IAC 2-8-11(c).
- (c) An application requesting the use of minor modification procedures shall meet the requirements of 326 IAC 2-8-3(c) and shall include the information required in 326 IAC 2-8-11(b)(3)(A) through (D).
- (d) The Permittee may make the change proposed in its minor permit modification application immediately after it files such application provided that the change has received any approval required by 326 IAC 2-1. After the Permittee makes the change allowed under minor permit modification procedures, and until IDEM, OAM takes any of the actions specified in 326 IAC 2-8-11(b)(5), the Permittee must comply with both the applicable requirements governing the change and the proposed permit terms and conditions. During this period, the Permittee need not comply with the existing permit terms and conditions it seeks to modify. If the Permittee fails to comply with its proposed permit terms and conditions during this time period, the existing permit terms and conditions it seeks to modify may be enforced against it. [326 IAC 2-8-11(b)(6)]

B.20 Significant Permit Modification [326 IAC 2-8-11(d)]

- (a) Significant modification procedures shall be used for applications requesting permit modifications that do not qualify as minor permit modifications or as administrative amendments.
- (b) Any significant change in existing monitoring permit terms or conditions and every relaxation of reporting or record keeping permit terms or conditions of this permit shall be considered significant.
- (c) Nothing in 326 IAC 2-8-11(d) shall be construed to preclude the Permittee from making changes consistent with 326 IAC 2-8 that would render existing permit compliance terms and conditions irrelevant.
- (d) Significant modifications of this permit shall meet all requirements of 326 IAC 2-8, including those for application, public participation, review by affected states, and review by U.S. EPA, as they apply to permit issuance and renewal.

B.21 Permit Revision Under Economic Incentives and Other Programs [326 IAC 2-8-11(b)(2)]

Notwithstanding 326 IAC 2-8-11(b)(1)(D)(i) and 326 IAC 2-8-11(c)(1), minor permit modification procedures may be used for modifications of this permit involving the use of economic incentives, marketable permits, emissions trading, and other similar approaches to the extent that such minor permit modification procedures are explicitly provided for in the applicable State Implementation Plan (SIP) or in applicable requirements promulgated by U.S. EPA.

B.22 Changes Under Section 502(b)(10) of the Clean Air Act [326 IAC 2-8-15(b)]

The Permittee may make Section 502(b)(10) of the Clean Air Act changes (this term is defined at 326 IAC 2-7-1(36)) without a permit revision, subject to the constraint of 326 IAC 2-8-15(a) and the following additional condition:

For each such change, the required written notification shall include a brief description of the change within the source, the date on which the change will occur, any change in emissions, and any permit term or condition that is no longer applicable as a result of the change.

B.23 Operational Flexibility [326 IAC 2-8-15]

(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 2-1 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 Management
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, OAM, in the notices specified in 326 IAC 2-8-15(b), (c)(1), and (d).

(b) For each such Section 502(b)(10) of the Clean Air Act change, the required written notification shall include the following:

- (1) A brief description of the change within the source;
- (2) The date on which the change will occur;
- (3) Any change in emissions; and
- (4) Any permit term or condition that is no longer applicable as a result of the

change.

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

- (c) Emission Trades [326 IAC 2-8-15(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).
- (d) 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, OAM or U.S. EPA is required.
- (e) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

B.24 Construction Permit Requirement [326 IAC 2]

Except as allowed by Indiana P.L. 130-1996 Section 12, as amended by P.L. 244-1997, modification, construction, or reconstruction shall be approved as required by and in accordance with 326 IAC 2.

B.25 Inspection and Entry [326 IAC 2-8-5(a)(2)]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, the Permittee shall allow IDEM, OAM, 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) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- (c) Inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;
- (d) Sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and
- (e) Utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.
[326 IAC 2-8-5(a)(4)]

B.26 Transfer of Ownership or Operation [326 IAC 2-1-6] [326 IAC 2-8-10]

Pursuant to 326 IAC 2-1-6 and 2-8-10:

- (a) In the event that ownership of this source is changed, the Permittee shall notify IDEM, OAM, Permits Branch, within thirty (30) days of the change. Notification shall include a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current Permittee and the new owner.

- (b) The written notification shall be sufficient to transfer the permit to the new owner by an administrative amendment pursuant to 326 IAC 2-8-10.
- (c) IDEM, OAM shall reserve the right to issue a new permit.

B.27 Annual Fee Payment [326 IAC 2-8-4(6)] [326 IAC 2-8-16]

- (a) The Permittee shall pay annual fees to IDEM, OAM, within thirty (30) calendar days of receipt of a billing, or in a time period consistent with the fee schedule established in 326 IAC 2-8-16.
- (b) Failure to pay may result in administrative enforcement action or revocation of this permit.
- (c) If the Permittee does not receive a bill from IDEM, OAM, thirty (30) calendar days before the due date, the Permittee shall call the following telephone numbers: 1-800-451-6027 or 317-233-0425 (ask for OAM, Technical Support and Modeling Section), to determine the appropriate permit fee. The applicable fee is due April 1 of each year.

B.28 Enhanced New Source Review [326 IAC 2]

The requirements of the construction permit rules in 326 IAC 2 are satisfied by this permit for any previously unpermitted facilities and such facilities to be constructed within eighteen (18) months after the date of issuance of this permit, as listed in Sections A.2 and A.3.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

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

C.1 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 from the entire source shall be limited to less than one-hundred (100) tons per three hundred sixty-five (365) consecutive day period. This limitation shall also make the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration (PSD)) not applicable;
 - (2) The potential to emit any individual hazardous air pollutant (HAP) from the entire source shall be limited to less than ten (10) tons per three hundred sixty-five (365) consecutive day 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 three hundred sixty-five (365) consecutive day 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(20). 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.2 Opacity [326 IAC 5-1]

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

- (a) Visible emissions shall not exceed an average of forty percent (40%) opacity in twenty-four (24) consecutive readings as determined by 326 IAC 5-1-4,
- (b) Visible emissions shall not exceed sixty percent (60%) opacity for more than a cumulative total of fifteen (15) minutes (sixty (60) readings) in a six (6) hour period.

C.3 Open Burning [326 IAC 4-1] [IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1. 326 IAC 4-1-3(a)(2)(A) and (B) are not federally enforceable.

C.4 Incineration [326 IAC 4-2] [326 IAC 9-1-2(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.5 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would

violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

C.6 Operation of Equipment [326 IAC 2-8-5(a)(4)]

All air pollution control equipment listed in this permit shall be operated at all times that the emission unit vented to the control equipment is in operation, as described in Section D of this permit.

**C.7 Asbestos Abatement Projects - Accreditation [326 IAC 14-10] [326 IAC 18-1]
[40 CFR 61, Subpart M]**

Prior to the commencement of any demolition or renovation activities, the Permittee shall use an Indiana accredited asbestos inspector to inspect thoroughly the affected facility or part of the facility where the demolition or renovation operation will occur for the presence of asbestos, including Category I and Category II nonfriable asbestos containing material. The requirement that the inspector must be Indiana accredited is not federally enforceable.

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

C.8 Performance Testing [326 IAC 3-2.1]

(a) All testing shall be performed according to the provisions of 326 IAC 3-2.1 (Source Sampling Procedures), except as provided elsewhere in this permit, utilizing methods approved by IDEM, OAM.

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 Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days before the intended test date.

(b) All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the Commissioner, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.

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

C.9 Compliance Monitoring [326 IAC 2-8-4(3)] [326 IAC 2-8-5(a)(1)]

Compliance with applicable requirements shall be documented as required by this permit. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment no more than ninety (90) days after receipt of this permit. If due to circumstances beyond its control, this schedule cannot be met, the Permittee shall notify:

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

in writing no more than ninety (90) days after receipt of this permit, with full justification of the reasons for inability to meet this date and a schedule which it expects to meet. If a denial of the request is not received before the monitoring is fully implemented, the schedule shall be deemed approved.

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

C.10 Maintenance of Monitoring Equipment [326 IAC 2-8-4(3)(A)(iii)]

- (a) In the event that a breakdown of the monitoring equipment occurs, a record shall be made of the times and reasons of the breakdown and efforts made to correct the problem. To the extent practicable, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less frequent than required in Section D of this permit until such time as the monitoring equipment is back in operation. In the case of continuous monitoring, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less than one (1) hour, or at intervals determined to be practicable, until such time as the continuous monitor is back in operation.
- (b) The Permittee shall install, calibrate, quality assure, maintain, and operate all necessary monitors and related equipment. In addition, prompt corrective action shall be initiated whenever indicated.

C.11 Monitoring Methods [326 IAC 3]

Any monitoring or testing performed to meet the requirements of this permit shall be performed, according to the provisions of 326 IAC 3, or 40 CFR 60, Appendix A, or other approved methods as specified in this permit.

C.12 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18-1] [40 CFR 61.140]

- (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
 - (3) 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 Management

100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

- (e) **Procedures for Asbestos Emission Control**
The Permittee shall comply with the emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-4 emission control requirements are mandatory 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) **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 that the inspector be accredited is federally enforceable.

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

C.13 Risk Management Plan [326 IAC 2-8-4] [40 CFR 68.215]

If a regulated substance, subject to 40 CFR 68, is present in more than the threshold quantity that is subject to 40 CFR 68, 40 CFR 68 is an applicable requirement, and the Permittee shall:

- (a) **Submit:**
- (1) A compliance schedule for meeting the requirements of 40 CFR 68 by the date provided in 40 CFR 68.10(a); or
 - (2) As part of the compliance certification submitted under 326 IAC 2-8-5(a)(1), a certification statement that the source is in compliance with all the requirements of 40 CFR 68, including the registration and submission of a Risk Management Plan (RMP); and
 - (3) A verification to IDEM, OAM that a RMP or a revised plan was prepared and submitted as required by 40 CFR 68.
- (b) Provide annual certification to IDEM, OAM that the Risk Management Plan is being properly implemented.

C.14 Compliance Monitoring Plan - Failure to Take Corrective Action [326 IAC 2-8-4(3)]

-
- (a) The Permittee is required to implement a compliance monitoring plan to ensure that reasonable information is available to evaluate its continuous compliance with applicable requirements. This compliance monitoring plan is comprised of:
- (1) This condition;
 - (2) The Compliance Determination Requirements in Section D of this permit;
 - (3) The Compliance Monitoring Requirements in Section D of this permit;
 - (4) The Record Keeping and Reporting Requirements in Section C (Monitoring Data Availability, General Record Keeping Requirements, and General Reporting Requirements) and in Section D of this permit; and
 - (5) A Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. CRP's shall be submitted to IDEM, OAM upon request and shall

be subject to review and approval by IDEM, OAM. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee and maintained on site, and is comprised of :

- (A) Response steps that will be implemented in the event that compliance related information indicates that a response step is needed pursuant to the requirements of Section D of this permit; and
 - (B) A time schedule for taking such response steps including a schedule for devising additional response steps for situations that may not have been predicted.
- (b) For each compliance monitoring condition of this permit, appropriate response steps shall be taken when indicated by the provisions of that compliance monitoring condition. Failure to perform the actions detailed in the compliance monitoring conditions or failure to take the response steps within the time prescribed in the Compliance Response Plan, shall constitute a violation of the permit unless taking the response steps set forth in the Compliance Response Plan would be unreasonable.
- (c) After investigating the reason for the excursion, the Permittee is excused from taking further response steps for any of the following reasons:
- (1) The monitoring equipment malfunctioned, giving a false reading. This shall be an excuse from taking further response steps providing that 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 or;
 - (3) An automatic measurement was taken when the process was not operating; or
 - (4) The process has already returned to operating within "normal" parameters and no response steps are required.
- (d) Records shall be kept of all instances in which the compliance related information was not met and of all response steps taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

C.15 Actions Related to Noncompliance Demonstrated by a Stack Test

- (a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall take appropriate corrective actions. The Permittee shall submit a description of these corrective actions to IDEM, OAM, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. IDEM, OAM shall notify the Permittee within thirty (30) days, if the corrective actions taken are deficient. The Permittee shall submit a description of additional corrective actions taken to IDEM, OAM within thirty (30) days of receipt of the notice of deficiency. IDEM, OAM reserves the authority to use enforcement activities to resolve noncompliant stack tests.
- (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,

OAM that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAM may extend the retesting deadline. Failure of the second test to demonstrate compliance with the appropriate permit conditions may be grounds for immediate revocation of the permit to operate the affected facility.

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

C.16 Monitoring Data Availability

- (a) With the exception of performance tests conducted in accordance with Section C-Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this permit shall be performed at all times the equipment is operating at normal representative conditions.
- (b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this permit is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this permit.
- (c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.
- (d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.
- (e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.
- (f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements in (a) above.

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

- (a) Records of all required monitoring data and support information 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 kept at the source location and available within one (1) hour upon verbal request of an IDEM, OAM representative, for a minimum of three (3) years. They may be stored elsewhere for the remaining two (2) years providing they are made available within thirty (30) days after written request.
- (b) Records of required monitoring information shall include, where applicable:
 - (1) The date, place, and time of sampling or measurements;
 - (2) The dates analyses were performed;
 - (3) The company or entity performing the analyses;
 - (4) The analytic techniques or methods used;
 - (5) The results of such analyses; and
 - (6) The operating conditions existing at the time of sampling or

measurement.

- (c) Support information shall include, where applicable:
 - (1) Copies of all reports required by this permit;
 - (2) All original strip chart recordings for continuous monitoring instrumentation;
 - (3) All calibration and maintenance records;
 - (4) Records of preventive maintenance shall be sufficient to demonstrate that improper maintenance did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this permit, and whether a deviation from a permit condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.
- (d) 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)]

- (a) To affirm that the source has met all the requirements stated in this permit, the source shall submit a Quarterly Compliance Report. Any deviation from the requirements and the date(s) of each deviation must be reported.
- (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 Management
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, OAM on or before the date it is due.
- (d) Unless otherwise specified in this permit, any quarterly report shall be submitted within thirty (30) days of the end of the reporting period.
- (e) All instances of deviations must be clearly identified in such reports. A reportable deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit or a rule. It does not include:
 - (1) An excursion from compliance monitoring parameters as identified in Section D of this permit unless tied to an applicable rule or limit; or
 - (2) An emergency as defined in 326 IAC 2-7-1(12); or

- (3) Failure to implement elements of the Preventive Maintenance Plan unless lack of maintenance has caused or contributed to a deviation.
- (4) Failure to make or record information required by the compliance monitoring provisions of Section D unless such failure exceeds 5% of the required data in any calendar quarter.

A Permittee's failure to take the appropriate response step when an excursion of a compliance monitoring parameter has occurred or failure to monitor or record the required compliance monitoring is a deviation.

- (f) Any corrective actions or response steps taken as a result of each deviation must be clearly identified in such reports.
- (g) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period.

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

- (a) six (6) ethylene oxide sterilization chambers, identified as S1 through S6, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one new (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one new (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01;
- (b) thirteen (13) aeration rooms, identified as HC1 through HC13, of which zero (0) to a maximum of six (6) can exhaust through one (1) new wet acid pre-scrubber and three (3) new dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) new dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and
- (c) miscellaneous cleaning with isopropyl alcohol.

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 63.360 through 63.367, Subpart O, the sterilization operation, which uses 10 tons or more of ethylene oxide in any consecutive 12-month period, is subject to the following conditions:
 - (1) The emission limitations of paragraphs (2), (3), and (4) below apply during sterilization operation. The emission limitations do not apply during periods of malfunction.
 - (2) This sterilization source shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent immediately upon initial startup of each facility listed in Section D.1.
 - (3) 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 percent, whichever is less stringent, from each aeration room vent immediately upon initial startup of each facility listed in Section D.1.
 - (4) This sterilization source shall either reduce ethylene oxide emissions to the atmosphere by manifolded emissions from each chamber exhaust vent to a control device used to comply with paragraphs (2) or (3) above or shall reduce ethylene oxide emissions by at least 99 percent from each chamber exhaust vent (without manifolded) immediately upon initial startup of each facility listed in Section D.1.
 - (5) Pursuant to 40 CFR 63.363(a), the owner or operator of this sterilization source 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.
- (b) This source will comply with the requirements of this rule immediately upon initial startup

of each facility listed in Section D.1 by using a primary wet acid scrubber with a control efficiency of 99% to control the six (6) sterilization chamber vents, and a single non-regenerable dry bed reactor with a control efficiency of 99% to control the six (6) sterilization chamber exhaust vents and a wet acid pre-scrubber with three (3) dry bed reactors (in parallel) with a control efficiency of 99% to control emissions from the thirteen (13) aeration rooms.

- (c) The following procedures shall be used to determine compliance with the emission limits stated in paragraph (2) of section (a) above:
- (1) During the performance test required in paragraph (5) of section (a) above, this sterilization source shall determine the efficiency of the control devices used to comply with paragraph (2) of section (a) above using the test methods and procedures in 40 CFR 63.365(b)(1). The source shall also 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).
 - (2) Following the date on which the initial performance test is completed, operation of the source with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the sterilization chamber vent standard in paragraph (2) of section (a) above.
- (d) The following procedures shall be used to determine compliance with the emission limits stated in paragraph (3) of section (a) above:
- (1) During the performance test required in paragraph (5) of section (a) 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 (3) of section (a) 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 (3) of section (a) above using the test methods and procedures in 40 CFR 63.365(d)(1).

The source shall also determine the following:

- (iii) the maximum ethylene glycol concentration using the procedures described in 40 CFR 63.365(e)(1); or
- (iv) the maximum liquor level using the procedures described in 40 CFR 63.365(e)(2); and

NOTE: Since the wet acid pre-scrubber that initially treats aeration room exhaust is hydraulically connected with the primary wet acid scrubber, the monitoring parameter that is ultimately selected for the primary wet acid scrubber will also be used for the pre-scrubber.

- (v) the maximum number of equivalent sterilization cycles that can be run

until the manufacturer's recommended (and guaranteed) bed capacity is reached.

- (2) Following the date on which the initial performance test is completed, this sterilization source shall comply with either of the following provisions:
 - (i) for sources continuously measuring the ethylene oxide concentration emitted from the aeration room (after any control device), operation of the source with a 3-hour average 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 (3) of section (a) above; or
 - (ii) the following:
 - (a) for all other sources, operation of the source with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the aeration room vent standard in paragraph (3) of section (a) above, and
 - (b) operation of the source with the dry bed reactors beyond the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached, shall constitute a violation of the aeration room vent standard in paragraph (3) of section (a), above.
- (e) The following procedures shall be used to determine compliance with the emission limits stated in paragraph (4) of section (a) above:
 - (1) During the performance test required in paragraph (5) of section (a) above using the methods approved in 40 CFR 63.365(g), this sterilization source shall determine the following for the dry bed reactor:
 - (a) the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached, and
 - (b) dry bed reactor performance.
 - (2) Following the date on which the initial performance test is completed, operation of the source with a dry bed reactor beyond the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached shall constitute a violation of the sterilization chamber exhaust vent standard in paragraph (4) of section (a), 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).

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.

D.1.4 Preventive Maintenance Plan [326 IAC 2-8-3(c)(6)]

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.1.5 Testing Requirements [326 IAC 2-8-5(1)]

- (a) Testing shall be performed 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 by June 8, 1999. The owner or operator shall conduct an initial performance test using the procedures listed in 326 IAC 3-2.1 and 40 CFR 63.7 of Subpart A, whichever is more stringent, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. During the performance test, the owner or operator shall determine the efficiency of the control devices and the site-specific operating parameters for the wet acid scrubbers and the dry bed reactors.

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

D.1.6 Monitoring

- (a) The primary wet acid scrubber controlling sterilization chamber exhaust and the wet acid pre-scrubber controlling aeration room exhaust have applicable compliance monitoring conditions as specified below:
 - (1) Pursuant to 40 CFR 63.364(a), this source 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;

- (2) Pursuant to 40 CFR 63.364(b), the source shall either:
- i) sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of scrubber liquor using the test methods and procedures in Part 63.365(e)(1). Such sampling is required during a given week only if the scrubber unit has been operated; or
 - ii) measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator 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 scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks will be determined during the initial performance test as required by 40 CFR 63.363, Subpart O. The parameter which more accurately reflects site-specific needs in accordance with 40 CFR 63.363 (b) will ultimately be the monitored parameter.

- (b) Pursuant to 40 CFR 63.363(f) and information provided by Cook, Inc., the single non-regenerable dry bed reactor controlling chamber exhaust vents has applicable compliance monitoring conditions as specified below:
- 1) Monitor and record the number of equivalent sterilization cycles performed while the bed is in service. The source will need to 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 5,350 equivalent sterilization cycles, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed will have to be changed out.

The initial performance test as required by 40 CFR 63.363, Subpart O will be used to verify dry bed reactor performance, the accuracy of the model, and the final number of equivalent sterilization cycles that will be used for compliance monitoring.

- (c) Pursuant to 40 CFR 63.363(f) and information provided by Cook, Inc., the three (3) dry bed reactors controlling aeration room exhaust have applicable compliance monitoring conditions as specified below:
- 1) Monitor and record the number of equivalent sterilization cycles performed while the beds are in service. The source will need to 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 6,330 equivalent sterilization cycles, the performance of the dry bed reactors is assumed to drop below 99% removal efficiency and the beds will have to be changed out.

The initial performance test as required by 40 CFR 63.363, Subpart O will be used to verify dry bed reactor performance, the accuracy of the model, and the final number of equivalent sterilization cycles that will be used for compliance monitoring.

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

D.1.7 Record Keeping Requirements

- (a) To document compliance with Condition D.1.1, the Permittee shall maintain records in

accordance with (1) or (2) and (3) below. Records maintained for (1) or (2) shall be taken once weekly and records maintained for (3) shall be taken once daily and all records shall be complete and sufficient to establish compliance with the ethylene oxide control efficiency limits established in Condition D.1.1.

- (1) the ethylene glycol concentration of the scrubber liquor for each of the wet acid scrubbers; or
 - (2) the level of the scrubber liquor in the recirculation tank for each of the wet acid scrubbers; and
 - (3) the number of equivalent sterilization cycles performed while the single non-regenerable dry bed reactor controlling chamber exhaust vents and 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 CONSTRUCTION CONDITIONS

- (a) construction/installation of two (2) ethylene oxide sterilization chambers, identified as S3 and S6, and relocation of four (4) ethylene oxide sterilization chambers, identified as S1, S2, S4, and S5, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) new primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one (1) new single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01; and
- (b) thirteen (13) aeration rooms, identified as HC1 through HC13, all exhausting through one (1) new wet acid pre-scrubber and three (3) new dry bed reactors (in parallel), exhausting through one (1) stack, identified as HV01.

THIS SECTION OF THE PERMIT IS BEING ISSUED UNDER THE PROVISIONS OF 326 IAC 2-1 AND 40 CFR 52.780, WITH CONDITIONS LISTED BELOW.

Construction Conditions [326 IAC 2-1-3.2]

General Construction Conditions

D.2.1 This permit to construct does not relieve the permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

Effective Date of the Permit

D.2.2 Pursuant to IC 13-15-5-3, this section of this permit becomes effective upon its issuance.

D.2.3 Pursuant to 326 IAC 2-1-9(b) (Revocation of Permits), IDEM, OAM may revoke this section of the approved permit if construction is not commenced within eighteen (18) months after receipt of this permit or if construction is suspended for a continuous period of one (1) year or more.

D.2.4 All requirements of these construction conditions shall remain in effect unless modified in a manner consistent with procedures established for modifications of construction permits pursuant to 326 IAC 2 (Permit Review Rules).

First Time Operation Permit

D.2.5 This document shall also become the first-time operation permit for the facilities under this section of this permit, pursuant to 326 IAC 2-1-4 (Operating Permits) when, prior to start of

operation, the following requirements are met:

- (a) The attached affidavit of construction shall be submitted to:

Indiana Department of Environmental Management
Permit Administration & Development Section, Office of Air Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

verifying that the facilities were constructed as proposed in the application. The facilities covered in this section of this permit may begin operating on the date the Affidavit of Construction is postmarked or hand delivered to IDEM.

- (b) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
- (c) The permittee shall receive an Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section and attach it to this permit.

Operation Conditions

See Section D.1 for Operation Conditions

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

**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, P.O. Box 277, Ellettsville, Indiana 47429
FESOP No.: F105-8436-00030

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:

- 9 Annual Compliance Certification Letter
- 9 Emergency/Deviation Occurrence Reporting Form
- 9 Test Result (specify) _____
- 9 Report (specify) _____
- 9 Notification (specify) _____
- 9 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 MANAGEMENT
COMPLIANCE DATA SECTION
P.O. Box 6015
100 North Senate Avenue
Indianapolis, Indiana 46206-6015
Phone: 317-233-5967
Fax: 317-233-6865**

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

Source Name: Cook, Inc.
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Mailing Address: 6330 North Matthews Drive, P.O. Box 277, Ellettsville, Indiana 47429
FESOP No.: F105-8436-00030

This form consists of 2 pages

Page 1 of 2

Check either No. 1 or No.2
9 1. This is an emergency as defined in 326 IAC 2-7-1(12) CThe Permittee must notify the Office of Air Management (OAM), within four (4) business hours (1-800-451-6027 or 317-233-5674, ask for Compliance Section); and CThe Permittee must submit notice in writing or by facsimile within two (2) days (Facsimile Number: 317-233-5967), and follow the other requirements of 326 IAC 2-7-16
9 2. This is a deviation, reportable per 326 IAC 2-7-5(3)(c) CThe Permittee must submit notice in writing within ten (10) calendar days

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/Deviation:
Describe the cause of the Emergency/Deviation:

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

Page 2 of 2

Date/Time Emergency/Deviation started:
Date/Time Emergency/Deviation was corrected:
Was the facility being properly operated at the time of the emergency/deviation? 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/deviation:
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: _____

Attach a signed certification to complete this report.

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

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

Source Name: Cook, Inc.
 Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
 Mailing Address: 6330 North Matthews Drive, P.O. Box 277, Ellettsville, Indiana 47429
 FESOP No.: F105-8436-00030

Months: _____ **to** _____ **Year:** _____

This report is an affirmation that the source has met all the requirements stated in this permit. This report shall be submitted quarterly. Any deviation from the requirements and the date(s) of each deviation must be reported. Additional pages may be attached if necessary. This form can be supplemented by attaching the Emergency/Deviation Occurrence Report. If no deviations occurred, please specify zero in the column marked "No Deviations".

LIST EACH COMPLIANCE REQUIREMENT EXISTING FOR THIS SOURCE:

Requirement (eg. Permit Condition D.1.3)	Number of Deviations	Date of each Deviations	No Deviations

Form Completed By: _____
 Title/Position: _____
 Date: _____
 Phone: _____

Attach a signed certification to complete this report.

Indiana Department of Environmental Management Office of Air Management

Technical Support Document (TSD) for a Federally Enforceable State Operating Permit (FESOP) and Enhanced New Source Review (ENSR)

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.: F105-8436-00030
Permit Reviewer: Trish Earls/EVP

The Office of Air Management (OAM) has reviewed a Federally Enforceable State Operating Permit (FESOP) application from Cook, Inc. relating to the operation of a medical device manufacturing and sterilization operation.

Permitted Emission Units and Pollution Control Equipment

There are no permitted facilities operating at this source during this review process.

Unpermitted Emission Units and Pollution Control Equipment

The existing source consists of the following unpermitted facilities/units:

- (a) five (4) ethylene oxide sterilization chambers, identified as S1, S2, S3, S4, and S5, each using Oxyfume 2000 for sterilization, with all sterilization chamber vacuum vents exhausting to one (1) existing wet acid scrubber which, in turn, exhausts through one (1) stack, identified as T01. All sterilization chamber exhaust back vents are uncontrolled and exhaust through one (1) stack, identified as S01;
- (b) miscellaneous cleaning with isopropyl alcohol; and
- (c) two (2) aeration rooms, identified as HC1 and HC2, each exhausting through one (1) dedicated stack, identified as S03 and S02, respectively.

Emission Units and Pollution Control Equipment Under Enhanced New Source Review (ENSR)

The application also includes information relating to the construction and operation of a new building addition to this medical device manufacturing and sterilization operation, including the following equipment:

- (a) two (2) ethylene oxide sterilization chambers, identified as S3 and S6, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, both exhausting to one (1) new primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one (1) new single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01; and

- (b) thirteen (13) aeration rooms, identified as HC1 through HC13, of which zero (0) to a maximum of six (6) can exhaust through one (1) new wet acid pre-scrubber and three (3) new dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) new dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01.

The following currently unpermitted equipment will be taken out of service upon completion of the new building addition and the installation of replacement equipment being reviewed under ENSR:

- (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 (see item (a) of equipment to be reviewed under ENSR);
- (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) aeration rooms, identified as HC1 through HC13 (see item (b) of equipment to be reviewed under ENSR); 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.

The following unpermitted equipment will be relocated to the new building addition upon completion of its construction:

- (a) four (4) ethylene oxide sterilization chambers, identified as S1, S2, S4, and S5, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization. These sterilizers will exhaust to one (1) new primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and one (1) new single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

Insignificant Activities

The source also consists of the following insignificant activities, as defined in 326 IAC 2-7-1(20):

- (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:
 - (1) 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
 - (2) four (4) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (1,600 pounds total);
- (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) two (2) gluing operations in Departments 1 and 4, respectively, each using a maximum of 0.005 ounces per hour of adhesive, each exhausting through one (1) fume hood with one (1) stack, identified as E08 and S10, respectively;
- (e) two (2) buffing and grinding operations in Departments 1 and 4, respectively, with a dust collector controlling particulate matter emissions from both operations, exhausting through one (1) stack, identified as S11;

- (f) 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;
- (g) natural gas fired combustion sources with a total heat input of 11.3 MMBtu per hour;
- (h) vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;
- (i) application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings;
- (j) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment;
- (k) closed loop heating and cooling systems;
- (l) exposure chambers ("towers", "columns"), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge;
- (m) replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;
- (n) heat exchanger cleaning and repair;
- (o) TDMAC package prep operations, exhausting through one (1) stack, identified as S07;
- (p) fume hood operations, exhausting through one (1) stack, identified as E09; and
- (q) heat forming, taping, masking, and printing operations exhausting through various building exhausts.

Enforcement Issue

- (a) IDEM is aware that the following equipment has been constructed and operated prior to receipt of the proper permit:
 - (1) five (4) ethylene oxide sterilization chambers, identified as S1, S2, S3, S4, and S5, each using Oxyfume 2000 for sterilization, with all sterilization chamber vacuum vents exhausting to one (1) existing wet acid scrubber which, in turn, exhausts through one (1) stack, identified as T01. All sterilization chamber exhaust back vents are uncontrolled and exhaust through one (1) stack, identified as S01;
 - (2) miscellaneous cleaning with isopropyl alcohol; and
 - (3) two (2) aeration rooms, identified as HC1 and HC2, each exhausting through one (1) dedicated stack, identified as S03 and S02, respectively.
- (b) IDEM is reviewing this matter and will take appropriate action. This proposed permit will also satisfy the requirements of the construction permit rules.

Recommendation

The staff recommends to the Commissioner that the FESOP 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.

The proposed FESOP satisfies the requirements of the construction permit rules in 326 IAC 2 for any previously unpermitted facilities and such facilities to be constructed within eighteen (18) months after the date of issuance of this proposed permit.

An administratively complete FESOP application for the purposes of this review was received on April 7, 1997. Additional information was received on July 9, 1997, and September 2, 1997.

Emissions Calculations

See Appendix A: Emissions Calculations for detailed calculations (6 pages). The ethylene oxide emission calculations submitted by the applicant have been verified and found to be accurate and correct. These calculations are provided in Appendix A, page 2 of 6, of this document.

Potential Emissions

Pursuant to 326 IAC 1-2-55, Potential Emissions are defined as “emissions of any one (1) pollutant which would be emitted from a facility, if that facility were operated without the use of pollution control equipment unless such control equipment is necessary for the facility to produce its normal product or is integral to the normal operation of the facility.”

Pollutant	Potential Emissions (tons/year)
PM	0.74
PM-10	0.74
SO ₂	0.03
VOC	49.10
CO	1.04
NO _x	4.97

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

HAP	Potential Emissions (tons/year)
Ethylene Oxide	37.00
Methanol	0.01
Methylene Chloride	0.008
Toluene	0.001
Hexane	0.07
1,1,1 Trichloroethane	0.09
TOTAL	37.18

See attached spreadsheets for detailed calculations (6 pages).

- (a) The potential emissions (as defined in Indiana Rule) of any single HAP is equal to or greater than ten (10) tons per year and the potential emissions (as defined in Indiana Rule) of a combination HAPs is greater than or equal to twenty-five (25) tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.
- (b) This source, otherwise required to obtain a Title V permit, has agreed to accept a permit with federally enforceable limits that restrict its PTE to below the Title V emission levels. Therefore, this source will be issued a Federally Enforceable State Operating Permit (FESOP), pursuant to 326 IAC 2-8.

Limited Potential To Emit

- (a) The source has accepted a limit on potential to emit of 9.4 tons per year for any single HAP. Limiting the potential to emit of any single HAP to 9.4 tons per year automatically limits the potential to emit of any combination of HAPs to less than 24 tons per year. Ethylene oxide (a HAP) emissions from the sterilization operation are controlled to 1.22 tons per year for a source wide total HAP emission rate of 1.40 tons per year, including control.

- (b) The table below summarizes the total limited potential to emit of the significant and insignificant emission units.

Process/ facility	Limited Potential to Emit (tons/year)							
	PM	PM-10	SO ₂	VOC*	CO	NO _x	Worst Case Single HAP	Total HAPs
Sterilization	0.00	0.00	0.00	9.40	0.00	0.00	9.40	9.40
Misc. Cleaning with IPA	0.00	0.00	0.00	9.47	0.00	0.00	0.00	0.00
Insignificant Activities	0.74	0.74	0.03	2.63	1.04	4.97	0.09	0.18
Total Emissions	0.74	0.74	0.03	21.5	1.04	4.97	9.40	9.58

*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 is reflected in the VOC limited potential to emit.

Attached Tables A through B summarize the permit conditions and requirements.

County Attainment Status

The source is located in Monroe County.

Pollutant	Status
TSP	attainment
PM-10	attainment
SO ₂	attainment
NO ₂	attainment
Ozone	attainment
CO	attainment
Lead	attainment

- (a) Volatile organic compounds (VOC) and oxides of nitrogen are precursors for the formation of ozone. Therefore, VOC and NO_x emissions are considered when evaluating the rule applicability relating to the ozone standards. Monroe County has been designated as attainment or unclassifiable for ozone.

Federal Rule Applicability

- (a) There are no New Source Performance Standards (326 IAC 12) applicable to this source.
- (b) The sterilization operation, which uses 10 tons or more of ethylene oxide in any consecutive 12-month period, 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). Pursuant to U.S. EPA rulemaking, the compliance date for Subpart O has been extended to and including December 8, 1998.

- (1) Pursuant to 40 CFR 63.360 through 63.367, Subpart O, the sterilization operation is subject to the following conditions by the Subpart O compliance date:
 - (a) The emission limitations of paragraphs (b), (c), and (d) 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 percent, whichever is less stringent, from each aeration room vent.
 - (d) This sterilization source shall either reduce ethylene oxide emissions to the atmosphere by manifolded emissions from each chamber exhaust vent to a control device used to comply with paragraphs (b) or (c) above or shall reduce ethylene oxide emissions by at least 99 percent from each chamber exhaust vent (without manifolded).
 - (e) Pursuant to 40 CFR 63.363(a), the owner or operator of this sterilization source 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.
- (2) This source will comply with the requirements of this rule as each piece of equipment being reviewed under the ENSR process is brought on-line by using a primary wet acid scrubber to control sterilization chamber vents and single non-regenerable dry bed reactor to control sterilization chamber exhaust vents. Each device will have a control efficiency of 99%. A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) with a combined control efficiency of 99% will be provided to control emissions from the thirteen (13) aeration rooms.
- (3) 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 (e) of section (1) above, this sterilization source shall 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 source shall also 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).
- (b) Following the date on which the initial performance test is completed, operation of the source with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the sterilization chamber vent standard in paragraph (b) of section (1) above.
- (4) 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 (e) 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)(1).

The source shall also determine the following:

- (iii) the maximum ethylene glycol concentration using the procedures described in 40 CFR 63.365(e)(1); or
 - (iv) the maximum liquor level using the procedures described in 40 CFR 63.365(e)(2); and
- NOTE: Since the wet acid pre-scrubber that initially treats aeration room exhaust is hydraulically connected with the primary wet acid scrubber, the monitoring parameter that is ultimately selected for the primary wet acid scrubber will also be used for the pre-scrubber.
- (v) the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached.
 - (b) Following the date on which the initial performance test is completed, this sterilization source shall comply with the following provision:
 - (i) for sources continuously measuring the ethylene oxide concentration emitted from the aeration room (after any control device), operation of the source with a 3-hour average 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) for all other sources, operation of the source with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the aeration room vent standard in paragraph (c) of section (1) above, and

 - (iii) operation of the source with the dry bed reactors beyond the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached, shall constitute a violation of the aeration room vent standard in paragraph (c) of section (1), above.
- (5) The following procedures shall be used to determine compliance with the emission limits stated in paragraph (d) of section (1) above:
- (a) During the performance test required in paragraph (e) of section (1) above using the methods approved in 40 CFR 63.365(g), this sterilization source shall determine the following for the dry bed reactor:
 - (i) this sterilization source shall establish as a site-specific operating parameter either:
 - (A) the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached, and
 - (B) dry bed reactor performance.
 - (b) Following the date on which the initial performance test is completed, operation of the source with a dry bed reactor beyond the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached shall constitute a violation of the sterilization chamber exhaust vent standard in paragraph (d) 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).

- (c) 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 2-6 (Emission Reporting)

Since this source is located in Monroe County and the potential to emit any criteria pollutant is less than 100 tons per year, 326 IAC 2-6 does not apply.

326 IAC 2-8-4 (FESOP)

This source is subject to 326 IAC 2-8-4 (FESOP). Pursuant to this rule, either the existing wet acid scrubber system (by CHEMROX) controlling the five (5) ethylene oxide sterilization chambers or, after the source expansion project, the primary wet acid scrubber and the single non-regenerable dry bed reactor controlling the six (6) ethylene oxide sterilization chambers and the wet acid pre-scrubber and three (3) dry bed reactors controlling the thirteen (13) aeration rooms located in the new building addition 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.

326 IAC 5-1 (Visible Emissions Limitations)

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

- (a) Visible emissions shall not exceed an average of forty percent (40%) opacity in twenty-four (24) consecutive readings as determined by 326 IAC 5-1-4,
- (b) Visible emissions shall not exceed sixty percent (60%) opacity for more than a cumulative total of fifteen (15) minutes (sixty (60) readings) in a six (6) hour period.

State Rule Applicability - Individual Facilities

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 expanded 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 will apply to the sterilization process, will control VOC (ethylene oxide) emissions from the sterilization operation to 1.22 tons per year. This control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operation.

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.

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, OAM, 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 permit Section D 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 permit Section D. 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:

- (a) The existing wet acid hydrolysis scrubber and the primary wet acid scrubber controlling sterilization chamber exhaust have applicable compliance monitoring conditions as specified below:
 - (1) Pursuant to 40 CFR 63.364(a), the owner or operator shall monitor the parameters specified in §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;
 - (2) Pursuant to 40 CFR 63.364(b), the owner or operator shall either:
 - i) sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of scrubber liquor using the test methods and procedures in Part 63.365(e)(1). Such sampling is required during a given week only if the scrubber unit has been operated; or

- ii) measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator 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 scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks will be determined during the initial performance test as required by 40 CFR 63.363, Subpart O. The parameter which more accurately reflects site-specific needs in accordance with 40 CFR 63.363 (b) will ultimately be the monitored parameter.

These monitoring conditions are necessary in order to ensure compliance with 326 IAC 14, (40 CFR 63, Subpart O) and 326 IAC 2-8 (FESOP).

- (b) Pursuant to 40 CFR 63.363(f) and information provided by Cook, Inc., the single non-regenerable dry bed reactor controlling chamber exhaust vents will have applicable compliance monitoring conditions as specified below:
 - (1) Monitor and record the number of equivalent sterilization cycles performed while the bed is in service. The source will need to 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 5,350 equivalent sterilization cycles, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed will have to be changed out. The initial performance test as required by 40 CFR 63.363, Subpart O will be used to verify dry bed reactor performance, the accuracy of the model, and the final number of equivalent sterilization cycles that will be used for compliance monitoring. The basis for this approach is the assumption that the mass of ethylene oxide that is vented from a given sterilizer during chamber exhaust venting is consistent and predictable, and that the dry bed reactor continues to remove ethylene oxide from exhaust venting at an efficiency of 99+% until the manufacturer's recommended (and guaranteed) bed capacity is reached.

These monitoring conditions are necessary in order to ensure compliance with 326 IAC 14, (40 CFR 63, Subpart O) and 326 IAC 2-8 (FESOP).

- (c) Pursuant to 40 CFR 63.364(b), 40 CFR 63.363(f), and information provided by Cook, Inc., the combination of the wet acid pre-scrubber and three (3) dry bed reactors controlling the thirteen (13) aeration rooms exhaust have applicable compliance monitoring conditions as specified below:
 - (1) Since the wet acid pre-scrubber that initially treats aeration room exhaust is hydraulically connected with the primary wet acid scrubber, the monitoring parameter that is ultimately selected for the primary wet acid scrubber will also be used for the pre-scrubber.
 - (2) Monitor and record the number of equivalent sterilization cycles performed while the three (3) dry bed reactors are in service. The owner or operator will need to 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 6,330 equivalent sterilization cycles, the

performance of the dry bed reactors is assumed to drop below 99% removal efficiency and the beds will have to be changed out. The initial performance test as required by 40 CFR 63.363, Subpart O will be used to verify dry bed reactor performance, the accuracy of the model, and the final number of equivalent sterilization cycles that will be used for compliance monitoring.

These monitoring conditions are necessary in order to ensure compliance with 326 IAC 14, (40 CFR 63, Subpart O) and 326 IAC 2-8 (FESOP).

Air Toxic Emissions

Indiana presently requests applicants to provide information on emissions of the 187 hazardous air pollutants set out in the Clean Air Act Amendments of 1990. These pollutants are either carcinogenic or otherwise considered toxic and are commonly used by industries. They are listed as air toxics on the Office of Air Management (OAM) FESOP Application Form GSD-08.

- (a) This source will emit levels of air toxics less than those which constitute a major source according to Section 112 of the 1990 Amendments to Clean Air Act.
- (b) See attached calculations for detailed air toxic calculations (pages 2 and 4 of 6)

Conclusion

The operation of this medical device manufacturing and sterilization operation will be subject to the conditions of the attached proposed **FESOP No. F105-8436-00030**.

Table A

Stack/Vent ID: PS01 and SV01			
Stack/Vent Dimensions: Ht: 30' Dia: 8" & 14" Temp: 120°F Flow: 360 & 2,000 acfm			
Emission Unit: Six (6) Sterilization Chambers			
Date of Construction: 1985-1998			
Alternative Scenario: Utilize Oxyfume 2002 or pure ethylene oxide instead of Oxyfume 2000			
Pollution Control Equipment: primary wet acid scrubber and dry bed reactor			
General Description of Requirement:	scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks for scrubber	number of equivalent sterilization cycles performed while the bed is in service	
Numerical Emission Limit:	99% ethylene oxide control efficiency	99% ethylene oxide control efficiency / a maximum of 5,350 sterilization cycles	
Regulation/Citation:	40 CFR 63, Subpart O and 326 IAC 2-8	40 CFR 63, Subpart O and 326 IAC 2-8	
Compliance Demonstration:	monitoring and record keeping	monitoring and record keeping	
PERFORMANCE TESTING			
Parameter/Pollutant to be Tested:	control efficiency and maximum scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks to maintain 99% control efficiency	control efficiency and number of equivalent sterilization cycles performed while the bed is in service to maintain 99% control efficiency	
Testing Method/Analysis:	Per 40 CFR 63.365	Per 40 CFR 63.365	
Testing Frequency/Schedule:	within 180 days after initial startup	within 180 days after initial startup	
Submittal of Test Results:	60 days following completion of the performance test	60 days following completion of the performance test	
COMPLIANCE MONITORING			
Monitoring Description:	scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks	number of equivalent sterilization cycles performed while the bed is in service	
Monitoring Method:	Per 40 CFR 63.364(b)(1) or 63.364(b)(2)	Per 40 CFR 63.365(g)	
Monitoring Regulation/Citation:	40 CFR 63.364(b)(1) or 63.364(b)(2)	40 CFR 63.365(g)	
Monitoring Frequency:	once per week	once daily	
RECORD KEEPING			
Parameter/Pollutant to be Recorded:	scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks	number of equivalent sterilization cycles performed while the bed is in service	
Recording Frequency:	once per week	once daily	
Submittal Schedule of Reports:	semiannually	semiannually	
REPORTING REQUIREMENTS			
Information in Report:	N/A	N/A	
Reporting Frequency/Submittal:	N/A	N/A	
Additional Comments:	(1)	(1)	

(1) If the scrubber liquor level or scrubber liquor ethylene glycol concentration falls outside range or maximum number of sterilization cycles is exceeded, maintenance procedures will be initiated.

Table B

Stack/Vent ID: HV01			
Stack/Vent Dimensions: Ht: 30' Dia: 18" Temp: 115°F Flow: 3,900 acfm			
Emission Unit: Thirteen (13) aeration rooms			
Date of Construction: 1989 & 1998			
Alternative Scenario: Utilize Oxyfume 2002 or pure ethylene oxide instead of Oxyfume 2000			
Pollution Control Equipment: wet acid pre-scrubber and three (3) dry bed reactors			
General Description of Requirement:	scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks for pre-scrubber	number of equivalent sterilization cycles performed while the beds are in service	
Numerical Emission Limit:	99% control efficiency	99% ethylene oxide control efficiency / a maximum of 6,330 sterilization cycles	
Regulation/Citation:	40 CFR 63, Subpart O and 326 IAC 2-8	40 CFR 63, Subpart O and 326 IAC 2-8	
Compliance Demonstration:	monitoring and record keeping	monitoring and record keeping	
PERFORMANCE TESTING			
Parameter/Pollutant to be Tested:	control efficiency and maximum scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks to maintain 99% control efficiency	number of equivalent sterilization cycles performed while the beds are in service to maintain 99% control efficiency	
Testing Method/Analysis:	Per 40 CFR 63.365	Per 40 CFR 63.365(g)	
Testing Frequency/Schedule:	within 180 days after initial startup	within 180 days after initial startup	
Submittal of Test Results:	60 days following completion of the performance test	60 days following completion of the performance test	
COMPLIANCE MONITORING			
Monitoring Description:	scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks	number of equivalent sterilization cycles performed while the beds are in service	
Monitoring Method:	Per 40 CFR 63.364(b)(1) or 63.364(b)(2)	Per 40 CFR 63.365(g)	
Monitoring Regulation/Citation:	40 CFR 63.364(b)(1) or 63.364(b)(2)	40 CFR 63.365(g)	
Monitoring Frequency:	once per week	once daily	
RECORD KEEPING			
Parameter/Pollutant to be Recorded:	scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks	number of equivalent sterilization cycles performed while the beds are in service	
Recording Frequency:	once per week	once daily	
Submittal Schedule of Reports:	semiannually	semiannually	
REPORTING REQUIREMENTS			
Information in Report:	N/A	N/A	
Reporting Frequency/Submittal:	N/A	N/A	
Additional Comments:	(1)	(1)	

(1) If the scrubber liquor level or scrubber liquor ethylene glycol concentration falls outside range or maximum number of sterilization cycles is exceeded, maintenance procedures will be initiated.

**Appendix A: Emission Calculations
Insignificant Activity Natural Gas Combustion
MM Btu/hr 0.3 - < 10**

Company Name: Cook Inc.
Address City IN Zip: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP: F105-8436
Plt ID: 105-00030
Reviewer: Trish Earls
Date: July 22, 1997

Heat Input Capacity
MMBtu/hr

Potential Throughput
MMCF/yr

11.3

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
	12.0	12.0	0.6	100.0	5.3	21.0
Potential Emission in tons/yr	0.60	0.60	0.03	4.97	0.26	1.04

Methodology:

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

Emission Factors for NOx: uncontrolled = 100, Low Nox Burner = 17, Flue gas recirculation = 36

Emission Factors for CO: uncontrolled = 21, Low NOx Burner = 27, Flue gas recirculation = ND

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

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

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

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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: F105-8436
Plt ID: 105-00030
Reviewer: Trish Earls
Date: July 22, 1997

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)

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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: F105-8436
Plt ID: 105-00030
Reviewer: Trish Earls
Date: July 22, 1997

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)

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

Addendum to the
Technical Support Document for Federally Enforceable State Operating
Permit (FESOP)

Source Name:	Cook, Inc.
Source Location:	6330 North Matthews Drive Ellettsville, Indiana 47429
SIC Code:	3841
County:	Monroe
Operation Permit No.:	F105-8436-00030
Permit Reviewer:	Trish Earls/EVP

On December 12, 1997, the Office of Air Management (OAM) had a notice published in The Herald Times, Bloomington, Indiana, stating that Cook, Inc. had applied for a Federally Enforceable State Operating Permit (FESOP) to operate a medical device manufacturing and sterilization operation. The notice also stated that OAM proposed to issue a FESOP for this operation and provided information on how the public could review the proposed FESOP and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this FESOP should be issued as proposed.

Upon further review, the OAM has decided to make the following changes to the FESOP:

1. Condition B.1 of the FESOP has been replaced with a new condition which reads as follows:

B.1 Permit No Defense [326 IAC 2-1-10] [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.

2. Condition B.6 of the FESOP has been revised to read as follows:

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.

3. Subsection (c) of Condition B.8 of the FESOP has been revised to read as follows (changes in bold):

(c) Upon request, the Permittee shall also furnish to IDEM, OAM, copies of records required to be kept by this permit. For information claimed to be confidential, the Permittee shall furnish such records **to IDEM, OAM, along with a claim of confidentiality under 326 IAC 17. If requested by IDEM, OAM, or the U.S. EPA, the Permittee shall furnish such confidential records directly to the U.S. EPA along with a claim of confidentiality under 40 CFR 2, Subpart B.**

4. Condition B.11 of the FESOP was revised such that an additional rule cite was added to the title, subsection (b) was revised, and the rule cite in subsection (c) was changed. The Condition now reads as follows (changes in bold):

B.11 Certification [326 IAC 2-8-3(d)] [326 IAC 2-8-4(3)(C)(i)] [326 IAC 2-8-5(1)]

- (a) Any application form, report, or compliance certification submitted under this permit shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, and any other certification required under this permit, 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, on the attached Certification Form, with each submittal.**
- (c) A responsible official is defined at **326 IAC 2-7-1(34)**.
5. Subsections (a) and (b) of Condition B.12 of the FESOP have been revised and subsection (d) has been deleted. Condition B.12 now reads as follows (changes in bold and deletions in strike out):

B.12 Annual Compliance Certification [326 IAC 2-8-5(a)(1)]

- (a) The Permittee shall annually certify that the source has complied with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. **The certification 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 Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

and

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

- (b) **The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAM, on or before the date it is due.**
- (c) The annual compliance certification report shall include the following:
- (1) The 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 compliance of the source, currently and over the reporting period consistent with 326 IAC 2-8-4(3); and
- (5) Such other facts, as specified in Sections D of this permit, as IDEM, OAM, 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 “responsible official” as defined by 326 IAC 2-7-1(34).

~~(d) The Permittee shall also annually certify that this source is in compliance with additional requirements as may be specified under Sections 114(a)(3) and 504(b) of the Clean Air Act.~~

6. Condition B.13 has been revised to read as follows (changes in bold and deletions in strikethrough):

B.13 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 prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days after issuance of this permit, including the following information on each:**
 - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing **emission units and associated** emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions;
 - ~~(3) Corrective actions that will be implemented in the event an inspection indicates an out of specification situation;~~
 - ~~(4) A time schedule for taking such corrective actions including a schedule for devising additional corrective actions for situations that may not have been predicted; and~~
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.
- (b) **The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that lack of proper maintenance does not cause or contribute to a violation of any limitation on emissions or potential to emit.**
- (c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM.

7. Subsection (b)(4) of Condition B.14 of the FESOP has been revised as follows (strike out indicates portion that has been deleted):

- (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAM, 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 Management, Compliance Section) or,

Telephone No.: 317-233-5674 (ask for Compliance Section)

Facsimile No.: 317-233-5967

~~Failure to notify IDEM, OAM, by telephone or facsimile within four (4) daytime business hours after the beginning of the emergency, or after the emergency is discovered or reasonably should have been discovered, shall constitute a violation of 326 IAC 2-8 and any other applicable rules. [326 IAC 2-8-12(f)]~~

8. Condition B.15 has been revised to read as follows (changes in bold):

B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-8-4(3)(C)(ii)]

- (a) Deviations from any permit requirements (for emergencies see Section B - Emergency 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 Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

within ten (10) calendar days from the date of the discovery of the deviation.

- (b) Written notification shall be submitted on the attached **Emergency/Deviation Occurrence Reporting Form** or its substantial equivalent.

- (c) **Proper notice submittal under 326 IAC 2-7-16 satisfies the requirement of this subsection.**

9. Subsection (a) and subsection (b)(1) of Condition B.17 of the FESOP have been revised as follows (changes in bold or strikeout):

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

- (a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAM 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**).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6015

Indianapolis, IN 46206-6015

(b) Timely Submittal of Permit Renewal [326 IAC 2-8-3]

(1) ~~The Permittee has a duty to submit a timely and complete permit renewal application.~~ 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, OAM, on or before the date it is due. [326 IAC 2-5-3]**

10. Subsections (b) and (d) of Condition B.19 of the FESOP have been revised as follows (changes in bold):

(b) Minor modification of this permit shall follow the procedures specified under **326 IAC 2-7-12(b), except as provided by 326 IAC 2-8-11(c).**

(d) The Permittee may make the change proposed in its minor permit modification application immediately after it files such application **provided that the change has received any approval required by 326 IAC 2-1.** After the Permittee makes the change allowed under minor permit modification procedures, and until IDEM, OAM takes any of the actions specified in 326 IAC 2-8-11(b)(5), the Permittee must comply with both the applicable requirements governing the change and the proposed permit terms and conditions. During this period, the Permittee need not comply with the existing permit terms and conditions it seeks to modify. If the Permittee fails to comply with its proposed permit terms and conditions during this time period, the existing permit terms and conditions it seeks to modify may be enforced against it. [326 IAC 2-8-11(b)(6)]

11. Subsection (d) of Condition B.20 of the FESOP has been revised as follows (changes in bold):

(d) Significant modifications of this permit shall meet all requirements of 326 IAC 2-8, including those for application, public participation, **review by affected states**, and review by U.S. EPA, as they apply to permit issuance and renewal.

12. Condition B.22 of the FESOP has been revised as follows (changes in bold):

B.22 Changes Under Section 502(b)(10) of the Clean Air Act [326 IAC 2-8-15(b)]

The Permittee may make Section 502(b)(10) of the Clean Air Act changes **(this term is defined at 326 IAC 2-7-1(36))** without a permit revision, subject to the constraint of 326 IAC 2-8-15(a) and the following additional condition:

For each such change, the required written notification shall include a brief description of the change within the source, the date on which the change will occur, any change in emissions, and any permit term or condition that is no longer applicable as a result of the change.

13. Subsection (b) of Condition B.23 of the FESOP has been revised as follows (changes in bold):

(b) For each such **Section 502(b)(10) of the Clean Air Act** change, the required written notification shall include the following:

- (1) A brief description of the change within the source;
- (2) The date on which the change will occur;
- (3) Any change in emissions; and
- (4) Any permit term or condition that is no longer applicable as a result of the change.

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

14. Condition B.24 of the FESOP has been revised as follows (changes in bold):

B.24 Construction Permit Requirement [326 IAC 2]

Except as allowed by Indiana P.L. 130-1996 Section 12, as amended by P.L. 244-1997, modification, construction, or reconstruction shall be **approved** as required by and in accordance with 326 IAC 2.

15. Subsection (b) of Condition B.26 of the FESOP has been revised as follows (changes in bold):

(b) The written notification shall be sufficient to transfer the permit to the new owner **by an administrative amendment pursuant to 326 IAC 2-8-10.**

16. Condition B.27 of the FESOP has been revised to read as follows (changes in bold or strikeout):

B.27 Annual Fee Payment [326 IAC 2-8-4(6)] [326 IAC 2-8-16]

- (a) The Permittee shall pay annual fees to IDEM, OAM, **within thirty (30) calendar days of receipt of a billing, or in a time period** consistent with the fee schedule established in 326 IAC 2-8-16.
- (b) Failure to pay may result in administrative enforcement action **or** revocation of this permit. ~~referral to the Office of Attorney General for collection, or other appropriate measures.~~
- (c) ~~The Permittee shall pay the annual fee within thirty (30) calendar days of receipt of a billing by IDEM, OAM or in a time period that is consistent with the payment schedule issued by IDEM, OAM.~~
- (c) If the Permittee does not receive a bill from IDEM, OAM, thirty (30) calendar days before the due date, the Permittee shall call the following telephone numbers: 1-800-451-6027 or 317-233-0425 (ask for OAM, **Technical Support and Modeling Section**), to determine the appropriate permit fee. The applicable fee

is due April 1 of each year.

17. Conditions C.3, C.5, and C.6 of the FESOP have been revised to read as follows (changes in bold):

C.3 Open Burning [326 IAC 4-1] [IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. **The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1. 326 IAC 4-1-3(a)(2)(A) and (B) are not federally enforceable.**

C.5 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

C.6 Operation of Equipment [326 IAC 2-8-5(a)(4)]

All air pollution control equipment listed in this permit shall be operated at all times that the emission unit vented to the control equipment is in operation, as described in Section D of this permit.

18. Conditions C.8 through C.17 of the FESOP have been revised to read as follows (changes in bold or strikeout):

C.8 Performance Testing [326 IAC 3-2.1]

(a) All testing shall be performed according to the provisions of 326 IAC 3-2.1 (Source Sampling Procedures), **except as provided elsewhere in this permit**, utilizing methods approved by IDEM, OAM.

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 Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days before the intended test date. ~~[326 IAC 3-2.1-2(a)]~~

(b) **All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the Commissioner, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.**

C.9 Compliance Monitoring [326 IAC 2-8-4(3)] [326 IAC 2-8-5(a)(1)]

Compliance with applicable requirements shall be documented **as required by this permit**. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment no more than ninety (90) days after receipt of this permit. If due to circumstances beyond its control, this schedule cannot be met, the Permittee shall notify:

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

in writing no more than ninety (90) days after receipt of this permit, with full justification of the reasons for inability to meet this date and a schedule which it expects to meet. If a denial of the request is not received before the monitoring is fully implemented, the schedule shall be deemed approved.

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

C.10 Maintenance of Monitoring Equipment [326 IAC 2-8-4(3)(A)(iii)]

~~(a) The Permittee shall perform all necessary maintenance and make all necessary and reasonable attempts to keep all required monitoring equipment in proper operating condition at all times.~~

(a) In the event that a breakdown of the monitoring equipment occurs, a record shall be made of the times and reasons of the breakdown and efforts made to correct the problem. To the extent practicable, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less frequent than required in Section D of this permit until such time as the monitoring equipment is back in operation. In the case of continuous monitoring, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less than one (1) hour until such time as the continuous monitor is back in operation.

(b) The Permittee shall install, calibrate, quality assure, maintain, and operate all necessary monitors and related equipment. **In addition, prompt corrective action shall be initiated whenever indicated.**

~~(d) Preventive Maintenance Plans of the monitors shall be implemented. In addition, prompt corrective action shall be initiated whenever indicated.~~

C.11 Monitoring Methods [326 IAC 3]

Any monitoring or testing performed to meet the requirements of this permit shall be performed, ~~whenever applicable~~ according to the provisions of 326 IAC 3, or 40 CFR 60, Appendix A, **or other approved methods as specified in this permit.**

C.12 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61.140]

- (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
 - (3) 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 Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015
- (e) **Procedures for Asbestos Emission Control**
The Permittee shall comply with the emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-4 emission control requirements are mandatory 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) **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 that the inspector be accredited is federally enforceable.**

C.13 Risk Management Plan [326 IAC 2-8-4] [40 CFR 68.215]

If a regulated substance, **subject to 40 CFR 68**, is present in more than the threshold quantity, 40 CFR 68 is an applicable requirement and the Permittee shall:

- (a) Submit:
 - (1) A compliance schedule for meeting the requirements of 40 CFR 68 by the date provided in 40 CFR 68.10(a); or
 - (2) As a part of the compliance certification submitted under 326 IAC 2-8-5(a)(1), a certification statement that the source is in compliance with all the requirements of 40 CFR 68, including the registration and submission of a Risk Management Plan (RMP); and
 - (3) A verification to IDEM, OAM, that a RMP or a revised plan was prepared and submitted as required by 40 CFR 68.
- (b) Provide annual certification to IDEM, OAM, that the Risk Management Plan is being properly implemented.

C.14 Compliance Monitoring Plan - Failure to Take Corrective Action [326 IAC 2-8-4(3)]

- (a) The Permittee is required to implement a compliance monitoring plan to ensure that reasonable information is available to evaluate its continuous compliance with applicable requirements. This compliance monitoring plan is comprised of:
 - (1) This condition;
 - (2) The Compliance Determination Requirements in Section D of this permit;
 - (3) The Compliance Monitoring Requirements in Section D of this permit;
 - (4) The Record Keeping and Reporting Requirements in Section C (Monitoring Data Availability, General Record Keeping Requirements, and General Reporting Requirements) and in Section D of this permit; and
 - (5) **A Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. CRP's shall be submitted to IDEM, OAM upon request and shall be subject to review and approval by IDEM, OAM. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee and maintained on site, and is comprised of:**
 - (A) **Response steps that will be implemented in the event that compliance related information indicates that a response step is needed pursuant to the requirements of Section D of**

this permit; and

(B) A time schedule for taking such response steps including a schedule for devising additional response steps for situations that may not have been predicted.

- (b) For each compliance monitoring condition of this permit, appropriate **response steps** ~~as described in the Preventive Maintenance Plan~~ shall be taken when indicated by the provisions of that compliance monitoring condition. Failure to perform the actions detailed in the compliance monitoring conditions or failure to take the **response steps within the time prescribed in the Compliance Response Plan**, shall constitute a violation of the permit unless taking the **response steps** set forth in the **Compliance Response Plan** would be unreasonable.
- (c) After investigating the reason for the excursion, the Permittee is excused from taking further **response steps** for any of the following reasons:
- (1) The monitoring equipment malfunctioned, giving a false reading. This shall be an excuse from taking further **response steps** providing that 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 or;
 - (3) An automatic measurement was taken when the process was not operating; or
 - (4) **The process has already returned to operating within "normal" parameters and no response steps are required.**
- (d) Records shall be kept of all instances in which the **compliance related information was** not met and of all **response steps** taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

C.15 Actions Related to Noncompliance Demonstrated by a Stack Test

- (a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, **the Permittee shall take appropriate corrective actions. The Permittee shall submit a description of these corrective actions to IDEM, OAM, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. IDEM, OAM shall notify the Permittee within thirty (30) days, if the corrective actions taken are deficient. The Permittee shall submit a description of additional**

corrective actions taken to IDEM, OAM within thirty (30) days of receipt of the notice of deficiency. IDEM, OAM reserves the authority to use enforcement activities to resolve noncompliant stack tests.

- (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, OAM that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAM may extend the retesting deadline.** Failure of the second test to demonstrate compliance with the appropriate permit conditions may be grounds for immediate revocation of the permit to operate the affected facility.

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

C.16 Monitoring Data Availability [326 IAC 2-8-4(3)] [326 IAC 2-8-5(1)]

- (a) **With the exception of performance tests conducted in accordance with Section C- Performance Testing,** all observations, sampling, maintenance procedures, and record keeping, required as a condition of this permit shall be performed at all times the equipment is operating at normal representative conditions.
- (b) **As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above,** when the equipment listed in Section D of this permit is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this permit.
- (c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.
- (d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.
- (e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.
- (f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

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

- (a) Records of all required monitoring data and support information 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 kept at the source

location and available within one (1) hour upon verbal request of an IDEM, OAM representative, for a minimum of three (3) years. They may be stored elsewhere for the remaining two (2) years providing they are made available within thirty (30) days after written request.

- (b) Records of required monitoring information shall include, where applicable:
- (1) The date, place, and time of sampling or measurements;
 - (2) The dates analyses were performed;
 - (3) The company or entity performing the analyses;
 - (4) The analytic techniques or methods used;
 - (5) The results of such analyses; and
 - (6) The operating conditions existing at the time of sampling or measurement.
- (c) Support information shall include, where applicable:
- (1) Copies of all reports required by this permit;
 2. All original strip chart recordings for continuous monitoring instrumentation;
 - (3) All calibration and maintenance records;
 - (4) **Records of preventive maintenance shall be sufficient to demonstrate that improper maintenance did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this permit, and whether a deviation from a permit condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.**
- (d) 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)]

- (a) **To affirm that the source has met all the requirements stated in this permit, the source shall submit a Quarterly Compliance Report. Any**

deviation from the requirements and the date(s) of each deviation must be reported.

- (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 Management
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, OAM on or before the date it is due.**
- (d) Unless otherwise specified in this permit, any quarterly report shall be submitted within thirty (30) days of the end of the reporting period.**
- (e) All instances of deviations must be clearly identified in such reports. A reportable deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit or a rule. It does not include:**
- (1) An excursion from compliance monitoring parameters as identified in Section D of this permit unless tied to an applicable rule or limit; or**
 - (2) An emergency as defined in 326 IAC 2-7-1(12); or**
 - (3) Failure to implement elements of the Preventive Maintenance Plan unless lack of maintenance has caused or contributed to a deviation.**
 - (4) Failure to make or record information required by the compliance monitoring provisions of Section D unless such failure exceeds 5% of the required data in any calendar quarter.**

A Permittee's failure to take the appropriate response step when an excursion of a compliance monitoring parameter has occurred or failure to monitor or record the required compliance monitoring is a deviation.

- (f) Any corrective actions or response steps taken as a result of each deviation must be clearly identified in such reports.**
- (g) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period.**

19. The rule cite for Preventive Maintenance Plan in Condition D.1.3 of the proposed FESOP has been changed from 326 IAC 2-8-4(9) to 326 IAC 2-8-3(c)(6). The condition, now re-numbered as Condition D.1.4, reads as follows (changes in bold):

D.1.4 Preventive Maintenance Plan **[326 IAC 2-8-3(c)(6)]**

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

20. The Certification Form and the Deviation Occurrence Report Form (now the Emergency/Deviation Occurrence Report Form) included with the FESOP have been modified. An additional report form, the Quarterly Compliance Report Form, has also been added and is standard to all FESOPs.

On January 9, 1998, Bill Klein submitted comments on behalf of Cook, Inc. on the proposed FESOP. The summary of the comments and corresponding responses is as follows:

Comment #1

In Section A, Sub-section A.1, General Information, of the FESOP, please change Cook's mailing address to include their post office box (P.O. Box 277).

Response #1

The mailing address in Section A.1 of the FESOP, page 4 of 36, has been changed accordingly.

Comment #2

As a point of clarification in Section A, Sub-section A.3, Insignificant Activities, of the FESOP, the four (4) 100% ethylene oxide storage cylinders identified in paragraph (b)(2) are portable cylinders that will be connected to the process. In addition, Cook will store up to eight (8) additional filled cylinders on site.

Response #2

Item (b) of Condition A.3 of the FESOP, page 4 of 36, and item (b) of the Insignificant Activities section of the TSD, page 2 of 14, have been revised to read as follows (changes in bold):

- (b) the following storage containers:
- (1) 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
 - (2) 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;**
 - (3) **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;**

Comment #3

In Section D.1, Sub-section D.1.1, Ethylene Oxide, paragraph D.1.1(d)(2) was revised to include three sub-provisions (i), (ii), and (iii). These sub-provisions were formerly numbered (i), (i)(a), and (ii)(b). We believe the original numbering sequence was more appropriate, especially when combined with the original lead-in, "Following the date on which the original performance test is completed, this sterilization source shall comply with *either* of the following provisions:".

The first sub-provision, (i), will not be applicable to Cook since it involves compliance with the 1 ppm aeration standard and its (defacto) corresponding requirement for continuous monitoring. Given the unit operations in its emissions control system, Cook fits into the "all other sources" category which can be better described by the numbering sequence (ii)(a) and (ii)(b) rather than (ii) and (iii).

Since the same language is repeated verbatim in the Technical Support Document, Section (b)(4)(b), under Federal Rule Applicability, the revised numbering system should also be used there.

Response #3

Paragraph (d)(2) of Condition D.1.1 of the FESOP, is revised to read as follows (changes in bold):

- (2) Following the date on which the initial performance test is completed, this sterilization source shall comply with **either of** the following provisions:
 - (i) for sources continuously measuring the ethylene oxide concentration emitted from the aeration room (after any control device), operation of the source with a 3-hour average 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 (3) of section (a) above; or
 - (ii) **the following:**
 - (a) for all other sources, operation of the source with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the aeration room vent standard in paragraph (3) of section (a) above, and
 - (b) operation of the source with the dry bed reactors beyond the maximum number of equivalent sterilization cycles that can be run until the manufacturer's recommended (and guaranteed) bed capacity is reached, shall constitute a violation of the aeration room vent standard in paragraph (3) of section (a), above.

Paragraph (b)(4)(b) under the Federal Rule Applicability section of the TSD, has also been revised accordingly.

Comment #4

Paragraphs (a) and (b), of the compliance schedule for Cook, Inc., on pages 25 and 26 of 33 of the

FESOP, specify that the CHEMROX scrubber will continue to limit emissions from the current sterilizers until they are moved to the new facility, and that the existing (current) sterilizers will be connected to the new emissions control system upon being moved to the new building addition. Since the physical location of the CHEMROX scrubber will interfere with moving some of the sterilizers, the construction sequence will require some or all of the existing sterilizers to be temporarily connected to the new scrubber so the CHEMROX scrubber can be removed. We therefore request that paragraphs (a) and (b) be revised to reflect this.

Also, the compliance schedule was added to Section D.1.1 in a manner that could create confusion. We suggest that the compliance schedule be given its own section entitled, D.1.2 Compliance Schedule and all subsequent sections (D.1.2 through D.1.6 in the proposed FESOP) be renumbered D.1.3 through D.1.7.

Response #4

A new Condition D.1.2, Compliance Schedule, now on page 27 of 36, has been added to section D.1 of the FESOP, and will include what were formerly paragraphs (a) through (d) at the end of Condition D.1.1. All subsequent conditions have been re-numbered as Conditions D.1.3 through D.1.7. Based on the suggested revisions of Bill Klein, on behalf of Cook, Inc., to the compliance schedule, Condition D.1.2 now reads as follows (changes in bold or strikeout):

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. ~~disconnected from the existing emissions control unit (that controls only sterilization chamber vents), moved to the new building addition, and connected to the new emissions control system where both chamber vents and exhaust vents will be controlled.~~ 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.

Comment #5

In Section D.2, Sub-section D.2.5, First Time Operation Permit, of the FESOP, the last sentence of paragraph (b) should be deleted since it is non-specific and uses a non-applicable example.

Response #5

The last sentence of paragraph (b) of Condition D.2.5 of the FESOP states that any operation conditions associated with operation start up dates shall be applicable to each individual phase of construction if construction is completed in phases. The language regarding stack testing for New Source Performance Standards (NSPS) is just an example of a condition that may require operation start up dates. If there are no conditions requiring operation start up dates, than this does not apply and can be ignored. The paragraph will remain unchanged.

Comment #6

On page 1 of 14 of the TSD, under Unpermitted Emission Units and Pollution Control Equipment, there is a typographical error in paragraph (a), where "five (4)" should be changed to "five (5)". This same error

should be corrected in paragraph (a)(1) under Enforcement Issue, on page 3 of 14.

Response #6

Item (a) under the Unpermitted Emission Units and Pollution Control Equipment section of the TSD, page 1 of 14, and item (a)(1) under the Enforcement Issue section of the TSD, page 3 of 14 are revised to read as follows:

Unpermitted Emission Units and Pollution Control Equipment

The existing source consists of the following unpermitted facilities/units:

- (a) five (5) ethylene oxide sterilization chambers, identified as S1, S2, S3, S4, and S5, each using Oxyfume 2000 for sterilization, with all sterilization chamber vacuum vents exhausting to one (1) existing wet acid scrubber which, in turn, exhausts through one (1) stack, identified as T01. All sterilization chamber exhaust back vents are uncontrolled and exhaust through one (1) stack, identified as S01;

Enforcement Issue

- (a) IDEM is aware that the following equipment has been constructed and operated prior to receipt of the proper permit:
 - (1) five (5) ethylene oxide sterilization chambers, identified as S1, S2, S3, S4, and S5, each using Oxyfume 2000 for sterilization, with all sterilization chamber vacuum vents exhausting to one (1) existing wet acid scrubber which, in turn, exhausts through one (1) stack, identified as T01. All sterilization chamber exhaust back vents are uncontrolled and exhaust through one (1) stack, identified as S01;

Comment #7

Under the State Rule Applicability - Entire Source section of the TSD, page 9 of 14, the second sentence of paragraph 326 IAC 2-8-4 (FESOP) should be revised to read "...and the wet acid pre-scrubber **and/or the** three (3) dry bed reactors.....". The **and/or** is necessary to allow the dry bed reactors to be operated independent of the pre-scrubber. While not the routine operating mode, this mode of operation is necessary to allow aeration to proceed without interruption during scrubber maintenance and while preparing for scrubber solution changeouts. This will have no effect on emissions or emission rates since the emissions calculations took no credit for the removal efficiency of the wet acid pre-scrubber except for its role in extending the useful life of the three (3) dry bed reactors.

As a point of clarification, under normal operating conditions, all three of the aeration dry bed reactors will be in continuous operation. During bed change-out, one reactor at a time will be taken off-line while the other two reactors will remain in service. This will allow aeration to proceed without interruption during bed change-outs. This will have no effect on the removal efficiency of the process, just the flow rate will be diminished until all three reactors are back in service. Bed change-out time for each reactor is on the order of one (1) hour.

Response #7

Since the three (3) dry bed reactors will be in continuous operation, with or without the wet acid pre-scrubber, but the wet acid pre-scrubber is never operated without the three (3) dry bed reactors, the paragraph discussing the applicability of 326 IAC 2-8-4 under the State Rule Applicability - Entire Source section of the TSD, page 9 of 14, is revised to read as follows (changes in bold):

326 IAC 2-8-4 (FESOP)

This source is subject to 326 IAC 2-8-4 (FESOP). Pursuant to this rule, either the existing wet acid scrubber system (by CHEMROX) controlling the five (5) ethylene oxide sterilization chambers or, after the source expansion project, the primary wet acid scrubber and the single non-regenerable dry bed reactor controlling the six (6) ethylene oxide sterilization chambers and the three (3) dry bed reactors **with or without** the wet acid pre-scrubber controlling the thirteen (13) aeration rooms located in the new building addition 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.

Comment #8

In the Compliance Requirements section of the TSD, page 10 of 14, under paragraph (a), the existing (CHEMROX) wet acid hydrolysis scrubber has been included in the compliance monitoring program, whereas the same was not done in the permit body, Section D.1.5. While it is possible to monitor the scrubber on a weekly basis, since the existing scrubber will be removed from service before Subpart O goes into effect, there will be no means by which to validate the monitoring parameter. Therefore, we request that monitoring requirements not apply to the existing CHEMROX scrubber.

Response #8

Paragraphs (a) and (c) of the Compliance Requirements section of the TSD, page 10 of 14, have been revised to read as follows (changes in bold):

- (a) **The primary wet acid scrubber controlling sterilization chamber exhaust and the wet acid pre-scrubber controlling aeration room exhaust** have applicable compliance monitoring conditions as specified below:
- (1) Pursuant to 40 CFR 63.364(a), the **source** 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;
 - (2) Pursuant to 40 CFR 63.364(b), the **source** shall either:
 - i) sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of scrubber liquor using the test methods and procedures in Part 63.365(e)(1). Such sampling is required during

a given week only if the scrubber unit has been operated; or

- ii) measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator 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 scrubber liquor level or scrubber liquor ethylene glycol concentration in the recirculation tanks will be determined during the initial performance test as required by 40 CFR 63.363, Subpart O. The parameter which more accurately reflects site-specific needs in accordance with 40 CFR 63.363 (b) will ultimately be the monitored parameter.

These monitoring conditions are necessary in order to ensure compliance with 326 IAC 14, (40 CFR 63, Subpart O) and 326 IAC 2-8 (FESOP).

- (c) Pursuant to ~~40 CFR 63.364(b)~~, 40 CFR 63.363(f) and information provided by Cook, Inc., the ~~combination of the wet acid pre-scrubber and~~ three (3) dry bed reactors controlling aeration room exhaust have applicable compliance monitoring conditions as specified below:

~~(1) Since the wet acid pre-scrubber that initially treats aeration room exhaust is hydraulically connected with the primary wet acid scrubber, the monitoring parameter that is ultimately selected for the primary wet acid scrubber will also be used for the pre-scrubber.~~

- (1) Monitor and record the number of equivalent sterilization cycles performed while the three (3) dry bed reactors are in service. The owner or operator will need to 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 6,330 equivalent sterilization cycles, the performance of the dry bed reactors is assumed to drop below 99% removal efficiency and the beds will have to be changed out. The initial performance test as required by 40 CFR 63.363, Subpart O will be used to verify dry bed reactor performance, the accuracy of the model, and the final number of equivalent sterilization cycles that will be used for compliance monitoring.

These monitoring conditions are necessary in order to ensure compliance with 326 IAC 14, (40 CFR 63, Subpart O) and 326 IAC 2-8 (FESOP).

On January 12, 1998, Lawrence A. Vanore submitted comments on behalf of Cook, Inc. on the proposed FESOP. The summary of the comments and corresponding responses is as follows:

Comment #1

Section B.15(a) of the FESOP is vague because the term "deviation" is undefined. It is Cook's understanding that OAM has adopted a policy and permit language clarifying the meaning of "deviation" for the purposes of reporting. That language should be included here or in the reporting section, Section C.18(d).

Response #1

Condition C.18 of the FESOP has been revised to include a definition of the term "deviation". See the revised Condition C.18 under item 18 of the changes initiated by the OAM to the FESOP on page 13 above.

Comment #2

Section C.9 of the FESOP cannot be complied with as written. The permit calls for a phased construction and includes a compliance schedule. Further, monitoring required by the applicable NESHAP is not required until the NESHAP compliance date in December, 1998. The first two sentences of Section C.9 should be changed to read as follows:

"Compliance with applicable requirements shall be documented in accordance with the requirements of this Permit and with the provisions of 326 IAC 2-8-4(3). The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring relating to that equipment no more than ninety (90) days after receipt of the Operation Permit Validation Letter from the Chief of the Permit Administration and Development Section."

Response #2

Condition C.9 of the FESOP was revised by the OAM so that the first sentence now reads "Compliance with applicable requirements shall be documented as required by this permit". Condition C.9 is for existing emission units with required monitoring. The Section D.1 monitoring requirements for the new emission units and control devices supersedes the Section C monitoring requirements. Therefore, the second sentence will remain unchanged. See the revised Condition C.9 under item 18 of the changes made by the OAM to the FESOP on page 8 above.

Comment #3

Section C.10(a) is overly broad and vague. The section should reference the Preventive Maintenance Plan, which will spell out the necessary maintenance requirements. In section C.10(b), the requirement of supplemental or intermittent monitoring at intervals of one hour is not a regulatory requirement and should not be included. For some parameters, intermittent monitoring at one hour intervals would be impossible. At a minimum, the requirement should be imposed only if practicable.

Response #3

Condition C.10 of the FESOP was revised by the OAM so that what was paragraph (a) has been removed from the condition. The condition will be further revised to indicate that for continuous monitoring, the requirement for supplemental or intermittent monitoring of the parameter at intervals no less than one (1) hour be imposed at intervals no less than one (1) hour or at practicable intervals. Condition C.10 is further revised to read as follows:

-
- C.10 Maintenance of Monitoring Equipment [326 IAC 2-8-4(3)(A)(iii)]
- (a) In the event that a breakdown of the monitoring equipment occurs, a record shall be made of the times and reasons of the breakdown and efforts made to correct

the problem. To the extent practicable, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less frequent than required in Section D of this permit until such time as the monitoring equipment is back in operation. In the case of continuous monitoring, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less than one (1) hour, **or at intervals determined to be practicable**, until such time as the continuous monitor is back in operation.

- (b) The Permittee shall install, calibrate, quality assure, maintain, and operate all necessary monitors and related equipment. In addition, prompt corrective action shall be initiated whenever indicated.

Comment #4

The provisions of Section C.11 are too narrow. Some monitoring methods, for example, will ultimately be spelled out in the applicable NESHAP. Add "or by applicable requirements" at the end of the section.

Response #4

Condition C.11 of the FESOP has been revised to include the phrase "or other approved methods as specified in this permit". See the revised Condition C.11 under item 18 of the changes made by the OAM to the FESOP on page 8 above.