

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

BUREAU OF AIR

DIVISION of AIR POLLUTION CONTROL

PERMIT SECTION

PROJECT SUMMARY for the
DRAFT CLEAN AIR ACT PERMIT PROGRAM (CAAPP) PERMIT

Sterigenics EO, Inc.
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Illinois EPA ID Number: 043110AAC

Application Number: 95120085

Application Type: Renewal Permit

Start of Public Comment Period: 09/27/2006

Close of Public Comment Period: 10/27/2006

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(This Project Summary generally describes the source and explains the draft permit. This document has been prepared pursuant to Section 39.5(8)(b) of the Illinois Environmental Protection Act, which requires "a statement that sets forth the legal and factual basis for the draft CAAPP permit conditions.")

I. INTRODUCTION

This source has applied for a renewal of the Clean Air Act Permit Program (CAAPP) operating permit. The CAAPP is the program established in Illinois for operating permits for significant stationary sources as required by Title V of the federal Clean Air Act and Section 39.5 of Illinois' Environmental Protection Act. The conditions in a CAAPP permit are enforceable by the Illinois Environmental Protection Agency (Illinois EPA), the USEPA, and the public. This document is for informational purposes only and does not shield the Permittee from enforcement actions or its responsibility to comply with applicable regulations. This document shall not constitute a defense to a violation of the Act or any rule or regulation.

A CAAPP permit contains conditions identifying the applicable state and federal air pollution control requirements that apply to a source. The permit also establishes emission limits, appropriate compliance procedures, and specific operational flexibility. The appropriate compliance procedures may include monitoring, record keeping, and reporting to show compliance with these requirements. The Permittee must carry out these procedures on an on-going basis to demonstrate that the source is operating in accordance with the requirements of the permit. Further explanations of the specific provisions of the draft CAAPP permit are contained in the attachments to this document, which also identify the various emission units at the source.

Incorporated construction permit 05120010, which allows the back vents to be operated without control devices due to the revised NESHAP.

II. GENERAL SOURCE DESCRIPTION

a. Nature of source

The source is a medical sterilization facility. This sterilization only facility receives and processes primarily medical supplies and pharmaceuticals in addition to treating spices. The sterilization facility utilizes ethylene oxide as the principle sterilant gas, although propylene oxide is sometimes used. All sterilizer vacuum pumps exhaust to a wet (acid) scrubber. After leaving the sterilizing chambers, the product aerates or degasses without any vacuum in one of the aeration rooms or compartments. The product remains in aeration for approximately 18 hours then is moved to a segregated post-processing area.

b. Ambient air quality status for the area

The source is located in an area that is currently designated nonattainment for the National Ambient Air Quality Standards for ozone (moderate nonattainment) and/or PM_{2.5} and attainment or unclassifiable for all other criteria pollutants.

c. Major source status

1. The source requires a CAAPP permit as a major source of VOM emissions.

d. Source Emissions

The following table lists annual emissions of criteria pollutants from this source, as reported in the Annual Emission Reports sent to the Illinois EPA.

| Pollutant | Annual Emissions (tons) | | |
|--------------------------|--------------------------------|-------------|-------------|
| | 2005 | 2004 | 2003 |
| CO | 2.37 | 2.37 | 0.22 |
| NO _x | 3.00 | 3.10 | 0.73 |
| PM | 0.22 | 0.22 | 0.02 |
| SO ₂ | 0.02 | 0.02 | 0.001 |
| VOM | 2.99 | 3.11 | 0.01 |
| Ethylene oxide (top HAP) | 2.90 | 3.00 | 2.60 |

III. NEW SOURCE REVIEW/TITLE I CONDITIONS

This draft permit contains terms and conditions that address the applicability of permit programs for new and modified sources under Title I of the Clean Air Act (CAA) and regulations promulgated thereunder, including 40 CFR 52.21, Prevention of Significant Deterioration (PSD) and 35 IAC Part 203, Major Stationary Sources Construction and Modification. Any such terms and conditions are identified within the draft permit by T1, T1R, or T1N. Any conditions established in a construction permit pursuant to Title I and not revised or deleted in this draft permit, remain in effect pursuant to Title I provisions until such time that the Illinois EPA revises or deletes them. Where the source has requested that the Illinois EPA establish new conditions or revise such conditions in a Title I permit, those conditions are consistent with the information provided in the CAAPP application and will remain in effect pursuant to Title I provisions until such time that the Illinois EPA revises or deletes them.

This draft permit would not establish any new Title I requirements or revised Title I requirements.

I added T1 conditions from Permit 05120010 which took off the control for the back vents. NESHAP Subpart O no longer requires them due to risk of an explosion.

IV. COMPLIANCE INFORMATION

The source has certified compliance with all applicable rules and regulations; therefore, a compliance schedule is not required for this source. In addition, the draft permit requires the source to certify its compliance status on an annual basis.

V. PROPOSED ILLINOIS EPA ACTION/REQUEST FOR COMMENTS

It is the Illinois EPA's preliminary determination that this source's permit application meets the standards for issuance of a CAAPP permit. The Illinois EPA is therefore proposing to issue a CAAPP permit, subject to the conditions proposed in the draft permit.

Comments are requested by the Illinois EPA for the draft or proposed permit, pursuant to 35 IAC Part 252 and Sections 39.5(8) and (9) of the Illinois Environmental Protection Act. A final decision on the draft or proposed permit will not be made until the public, affected states, and USEPA have had an opportunity to comment. The Illinois EPA is not required to accept recommendations that are not based on applicable requirements. If substantial public interest is shown in this matter, the Illinois EPA will consider holding a public hearing in accordance with 35 IAC Part 166.

ATTACHMENT 1: Summary of Source-Wide Requirements

The following table indicates the source-wide emissions control programs and planning requirements that are applicable to this source. These programs are addressed in Sections 5 and 6 of the draft permit.

| Program/Plan | Applicable |
|---|-------------------|
| Emissions Reduction Market System (ERMS) ^x | x |

- x The ERMS is a market-based program designed to reduce VOM emissions from stationary sources located in the Chicago ozone non-attainment area in order to contribute to reasonable further progress toward attainment (35 IAC Part 205). If applicable, this program is further described in Section 6.0 of the draft permit, including the Illinois EPA’s determination of the source’s baseline emissions and allotment of trading units under the ERMS.

ATTACHMENT 2: Summary of Requirements for Specific Emission Units

The following tables include information on the requirements that apply to significant emission units at this source. The requirements are found in Section 7 of the draft permit, which is further divided into subsection, i.e., Section 7.1, 7.2, etc., for the different categories of units at the source. A separate table is provided for each subsection in Section 7 of the draft permit. An explanation of acronyms and abbreviations is contained in Section 2 of the draft permit.

Table 1 (Section 7.1 of the draft permit)

| Emission Unit | |
|----------------------------|---|
| Name | Sterilization Chambers and Back Vents |
| Description | <p>At a scheduled time, the “lot” is placed into the sterilizer. Here the products are sterilized using the chamber vacuum process. All vacuum pump exhausts from the sterilizers flow to the acid/wet scrubber. The typical in-chamber sterilization cycle consists of four phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, and (4) air wash.</p> <p>There are six chambers with a capacity of six pallets, six with a capacity of thirteen pallets and one chamber with a capacity of three pallets at Willowbrook I. The source operates two air pollution control systems. Acid Water Scrubber System #1 or the Deox system is typically used to control emissions from the sterilization chamber vacuum pumps. This system consists of a wet scrubber used to control high concentrations of ethylene oxide in the exhaust stream. The second system, which is used as an alternate operating scenario for the sterilizer vacuum pumps, consists of a wet acid scrubber followed by a dry bed reactant system. This system is typically used to control emissions from the aeration rooms/chambers and was installed to meet the ethylene oxide MACT requirements.</p> <p>At the conclusion of the sterilizing cycle, the sterilizing chamber is returned to ambient temperature and back up to atmospheric pressure. The chamber door is then opened, enabling the chamber exhausts to automatically activate. This chamber air exhaust or “back vent” is an exhaust system that forcefully ventilates the chamber with fresh air. Indoor air is ventilated into the front open door through the chamber and to the back exhaust, and some chambers may have a smaller front “hood” vent as well. This chamber exhaust is responsible for removing sterilant gas from the void space in the sterilizer chamber.</p> |
| Date Constructed | 1984 |
| Emission Control Equipment | Acid Water Scrubbers, dry bed reactor |

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| Applicable Rules and Requirements | |
|---|--|
| Emission Standards | <ul style="list-style-type: none"> • NESHAP Subpart O: The source uses 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996. • 35 IAC 218 Subpart G • 35 IAC 218 Subpart TT |
| Title I Conditions | <ul style="list-style-type: none"> • The draft permit contains limits on operation and emissions in Conditions 7.1.5 and 7.1.6. These limits were incorporated from Permits 84060002, 85110056, 90080038. • Also includes changes granted in Permit 05120010 |
| Non-applicability | The back vents are no longer subject to NESHAP Subpart O because of explosion risk. |
| Periodic Monitoring (other than basic regulatory requirements) | |
| Testing | NESHAP Subpart O [40 CFR 63.363(b)] and 35 IAC 218 Subpart TT |
| Emissions Monitoring | NESHAP Subpart O |
| Operational Monitoring | NESHAP Subpart O, leak detection, no monitoring on back vents |
| Inspections | Monthly inspections of equipment |
| Recordkeeping | Requirements of Subpart O, if there any leaks, malfunction/breakdown records as well |
| Other | |
| Reporting | |
| Prompt Reporting | See Attachment 3 |
| Other Reporting | N/A |
| Other Information | |
| Footnotes | |

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Table 2 (Section 7.2 of the draft permit)

| Emission Unit | |
|---|---|
| Name | Aeration Chambers |
| Description | After the medical products are loaded onto forklifts, they are transferred to aeration rooms or cells. The sterile products are placed in these heated rooms to allow diffusion of any residual sterilant gas from the products prior to quarantine or shipping. This source's aeration rooms are designed to exhaust 10% of the air volume that is recirculated within the room. The sterile products are maintained in the aeration rooms for at least 18 to 24 hours. Following aeration, the product is moved to a post-production or post-aeration storage area awaiting shipment out by the customer. |
| Date Constructed | 1984 |
| Emission Control Equipment | Scrubbers and Dry Bed Reactors |
| Applicable Rules and Requirements | |
| Emission Standards | <ul style="list-style-type: none"> • NESHAP Subpart O: The source uses 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996. • 35 IAC 218 Subpart G • 35 IAC 218 Subpart TT |
| Title I Conditions | The draft permit contains limits on operation and emissions These limits were incorporated from Permit 96120054. |
| Non-applicability | None |
| Periodic Monitoring (other than basic regulatory requirements) | |
| Testing | NESHAP Subpart O, 218 Subpart TT |
| Emissions Monitoring | NESHAP Subpart O |
| Operational Monitoring | NESHAP Subpart O |
| Inspections | NESHAP Subpart O, monthly inspections |
| Recordkeeping | Of aeration rooms and control equipment |
| Other | |
| Reporting | |
| Prompt Reporting | See Attachment 3 |

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| | |
|--------------------------|-----|
| Other Reporting | N/A |
| Other Information | |
| Footnotes | |

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Table 3 (Section 7.3 of the draft permit)

| Emission Unit | |
|---|--|
| Name | Boilers |
| Description | Natural gas-fired boilers are used at the source to generate steam for use in sterilization of medical supplies and spices. |
| Date Constructed | 1984 |
| Emission Control Equipment | None |
| Applicable Rules and Requirements | |
| Emission Standards | <ul style="list-style-type: none"> • None |
| Title I Conditions | <ul style="list-style-type: none"> • None |
| Non-applicability | <p>NSPS Subpart Dc does not apply because boilers has a maximum design heat input capacity of less than 2.9 MW (10 mmBtu/hr)</p> <p>The affected boiler is not subject to 35 IAC 216.121, emissions of carbon monoxide from fuel combustion emission units, because the actual heat input of the affected boiler is less than 2.9 MW (10 mmBtu/hr).</p> <p>35 IAC 217.121, because the actual heat input of the affected boiler is less than 73.2 MW (250 mmBtu/hr).</p> <p>Pursuant to 35 IAC 218.303, fuel combustion emission units are not subject to 35 IAC 218.301, use of organic material.</p> |
| Periodic Monitoring (other than basic regulatory requirements) | |
| Testing | Method 9 upon request |
| Emissions Monitoring | None |
| Operational Monitoring | None |
| Inspections | None |
| Recordkeeping | Fuel usage, emission records |
| Other | |
| Reporting | |

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| | |
|--------------------------|------------------|
| Prompt Reporting | See Attachment 3 |
| Other Reporting | N/A |
| Other Information | |
| Footnotes | |

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ATTACHMENT 3: Prompt Reporting of Deviations

Prompt reporting of deviations is critical in order to have timely notice of deviations and the opportunity to respond, if necessary. The effectiveness of the permit depends upon, among other important elements, timely and accurate reporting. The Illinois EPA, USEPA and the public rely on timely and accurate reports submitted by the permittee to measure compliance and to direct investigation and follow-up activities. Prompt reporting is evidence of a permittee's good faith in disclosing deviations and describing the steps taken to return to compliance and prevent similar incidents.

Any occurrence that results in an excursion from any emission limitation, operating condition, or work practice standard as specified in this CAAPP permit is a deviation subject to prompt reporting. Additionally, any failure to comply with any permit term or condition is a deviation of that permit term or condition and must be reported to the Illinois EPA as a permit deviation. The deviation may or may not be a violation of an emission limitation or standard. A permit deviation can exist even though other indicators of compliance suggest that no emissions violation or exceedance has occurred. Reporting permit deviations does not necessarily result in enforcement action. The Illinois EPA has the discretion to take enforcement action for permit deviations that may or may not constitute an emission limitation or standard or the like, as necessary and appropriate.

Section 39.5(7)(f)(ii) of the Illinois Environmental Protection Act, which mirrors 40 CFR 70.6(a)(3)(iii)(B), requires prompt reporting of deviations from the permit requirements. The permitting authority (in this case, Illinois EPA) has the discretion to define "prompt" in relation to the degree and type of deviation likely to occur. Furthermore, Section 39.5(7)(f)(i) of the Illinois Environmental Protection Act, which mirrors 40 CFR 70.6(a)(3)(iii)(A) requires that monitoring reports must be submitted at least every 6 months. Therefore, USEPA generally considers anything less than 6 months to be "prompt" as long as the selected time frame is justified appropriately (60 Fed. Reg. 36083, 36086 (July 13, 1995)).

The USEPA has stated that, for purposes of administrative efficiency and clarity, it is acceptable to define prompt in each individual permit. *Id.* The Illinois EPA has elected to follow this approach and defines prompt reporting on a permit by permit basis. In instances where the underlying applicable requirement contains "prompt" reporting, this frequency or a shorter frequency of reporting is the required timeframe used in this permit. Where the underlying applicable requirement fails to explicitly set forth the timeframe for reporting deviations, the Illinois EPA has developed a structured manner to determine the reporting approach used in this permit.

The Illinois EPA generally uses a time frame of 30 days to define prompt reporting of most deviations. Also, for certain permit conditions in individual permits, the Illinois EPA may require an alternate timeframe that is less than 30 days if the permit requirement justifies a shorter reporting time period. Under certain circumstances, EPA may establish a deviation reporting period longer than 30 days, but, in no event exceeding 6 months. Where it has established a deviation reporting period other than 30 days in an individual permit (specifically Section 7.x.10), the Illinois EPA has explained the reason for the alternative timeframe. (See Attachment 2 of this Project Summary.)

The timing for certain deviation reporting may be different when a source or emission unit at a source warrants reporting to address operation, independent of the occurrence of any deviations. This is the case for a source that is required to perform continuous monitoring for the emission unit, for which quarterly or semi-annual "monitoring" reports are appropriate. Where appropriate, reporting of deviations has generally been combined

in, or coordinated with these quarterly or semi-annual reports, so that the overall performance of the plant can be reviewed in a comprehensive fashion. This will allow a more effective and efficient review of the overall performance of the source by the Illinois EPA and other interested parties, as well as by the source itself.

At the same time, there are certain deviations for which quicker reporting is appropriate. These are deviations for which individual attention or concern may be warranted by the Illinois EPA, USEPA, and other interested parties. Under this scenario, emphasis has been placed primarily on deviations that could represent substantial violations of applicable emission standards or lapses in control measures at the source. For these purposes, depending on the deviation, immediate notification may be required and preceded by a follow-up report submitted within 15 days, during which time the source may further assess the deviation and prepare its detailed plan of corrective action.

In determining the timeframe for prompt reporting, the Illinois EPA assesses a variety of criteria such as:

- historical ability to remain in continued compliance,
- level of public interest in a specific pollutant and/or source,
- seriousness of the deviation and potential to cause harm,
- importance of applicable requirement to achieving environmental goals,
- designation of the area (i.e., non-attainment or attainment),
- consistency among industry type and category,
- frequency of required continuous monitoring reports (i.e., quarterly),
- type of monitoring (inspection, emissions, operational, etc.), and
- air pollution control device type and operation

These prompt reporting decisions reflect the Illinois EPA's consideration of the possible nature of deviations by different emission units and the responses that might be required or taken for those different types of deviations. As a consequence, the conditions for different emission units may identify types of deviations which include but are not limited to: 1) Immediate (or very quick) notification; 2) Notification within 30 days as the standard; or 3) Notification with regular quarterly or semi-annual monitoring reports.

The Illinois EPA's decision to use the above stated prompt reporting approach for deviations as it pertains to establishing a shorter timeframe in certain circumstances reflects the criteria discussed as well as USEPA guidance on the topic.

- 40 CFR 71.6(a)(3)(iii)(B) specifies that certain potentially serious deviations must be reported within 24 or 48 hours, but provides for semi-annual reporting of other deviations. (Serious or severe consequences)
- FR Vol. 60, No. 134, July 13, 1995, pg. 36086 states that prompt should generally be defined as requiring reporting within two to ten days of the deviation, but longer time periods may be acceptable for a source with a low level of excess emissions. (intermediate consequences)
- Policy Statement typically referred to as the "Audit Policy" published by the USEPA defines prompt disclosure to be within 21 days of discovery. (Standard for most "pollutant limiting" related conditions)
- Responses to various States by USEPA regarding other States' definition of prompt.

As a result, the Illinois EPA's approach to prompt reporting for deviations as discussed herein is consistent with the requirements of 39.5(7)(f)(ii) of the Act as well as 40 CFR part 70 and the CAA. This reporting arrangement is designed so that the source will appropriately notify the Illinois EPA of those events that might

warrant individual attention. The timing for these event-specific notifications is necessary and appropriate as it gives the source enough time to conduct a thorough investigation into the causes of an event, collecting any necessary data, and to develop preventative measures, to reduce the likelihood of similar events, all of which must be addressed in the notification for the deviation.

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