GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

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# NARRATIVE

TO: Stephen Damaske

FROM: Heather Brown

DATE: December 28, 2022

| | |
|---|---|
| Facility Name: | **Sterilization Services of Georgia** |
| AIRS No.: | 12100010 |
| Location: | Atlanta, GA (Fulton County) |
| Application #: | 27641 |
| Date of Application: | August 31, 2020 |

## Background Information

Sterilization Services of Georgia is an ethylene oxide sterilization facility located at 6005 Boat Rock Boulevard, Atlanta, Georgia (Fulton County). The facility operates under Air Quality Permit No. 3841-121-0010-S-03-0. The facility is subject to 40 CFR 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities.

## Process Description

Sterilization Services' process introduces ethylene oxide (EtO) gas, under vacuum, into sealed chambers (Source Codes CH1, CH2, and CH3) that contain packaged products to be sterilized. The products are typically pre-humidified, generally at elevated temperatures, prior to the introduction of EtO into the evacuated chamber. EtO is then introduced and continuously recirculated in the chamber open space. Some of the EtO is also absorbed by the product and packaging. The product is exposed to the gas for controlled periods of time that are known to destroy any biological contaminants that may have become part of the product or product packaging. At the end of the sterilization cycle, most of the EtO is evacuated from the chamber and sent to a liquid scrubber (Source Code 1SC). The scrubber mixes EtO with an acid/water solution that converts the gas to ethylene glycol. The scrubber is used to meet control requirements under 40 CFR 63 Subpart O.

When the sterilization chambers are opened, the chamber back vents activate (Source Codes BV1, BV2, and BV3) and additional EtO is extracted. The back vents are currently not regulated by 40 CFR 63 Subpart O however, advances in technology have made controls feasible. In 2020, the facility completed installation and testing of a dry bed reactor system to control emissions from the back vents. The device consists of four beds and has been redesignated as Dry Bed Reactor System 1 (Source Code DB1) for the purposes of this permitting action.

After the sterilization process is complete, product is removed from the chamber and transported to aeration rooms (Source Codes AR1, AR2, and AR3) where air is continuously recirculated around the product. A portion of the recirculating air containing outgassed EtO is continuously removed from the aeration room by exhaust blowers. This residual stream is sent to a catalytic oxidizer (Source Code 1OX), which destroys the EtO via combustion. The catalytic oxidizer is used to comply with the requirements of 40 CFR Part 63 Subpart O.

**Purpose of Application**

Application No. 27641 was received on August 31, 2020. A public advisory was not required because the project results in a reduction in emissions.

The purpose of the application was to further reduce EtO emissions from the sterilization process by adding two control devices, Dry Bed Reactor Systems 2 and 3 (Source Codes DB2 and DB3). The project was undertaken upon EPD's request and was not required by the current version of 40 CFR 63 Subpart O. EPD inspected and verified that the new air pollution control equipment upgrades are installed and operating properly. All air pollution controls were tested in in February 2021, March 2022, and April 2022 and the tests were observed by the EPD.

The project was as follows:

- Capture of fugitive indoor EtO emissions from the following sources, which are now directed to Dry Bed Reactor System 2 (Source Code DB2). The system consists of 4 beds:

    - Chamber Rooms 1, 2, and 3 (Source Codes CH1, CH2, and CH3);
    - Chamber 1 Scale Room [(EtO Scale) Source Code CSR1];
    - Chamber Corridor [(between sterilization chambers in aeration room) Source Code CC1];
    - Scrubber Room [(scrubber tanks, pumps, and controls) Source Code SCR1]; and
    - Scrubber Tank Vent [(for filling and draining of tanks) Source Code STV1].

- Capture of fugitive indoor EtO emissions from the following sources, which are now directed to Dry Bed Reactor System 3 (Source Code DB3). The system consists of 8 beds:

    - Aeration Corridor [(between aeration rooms and shipping area) Source Code AC1]; and
    - Shipping Areas [(for sterilized product prior to shipping) Source Code SH1].

- Verification of the building as a permanent total enclosure under EPA Method 204, meaning all indoor air that comes in contact with sterilized product is collected and routed to the dry bed reactor systems.

## Updated Equipment List

### EQUIPMENT LIST

| Source Code | Description | Control Device | Description | Stack ID |
|---|---|---|---|---|
| CH1<br>CH2<br>CH3 | 13 Pallet Sterilization Chamber<br>8 Pallet Sterilization Chamber<br>13 Pallet Sterilization Chamber | 1SC | Scrubber | EP1 |
| AR1<br>AR2<br>AR3 | Aeration Room 1<br>Aeration Room 2<br>Aeration Room 3 | 1OX | Catalytic Oxidizer | EP5 |
| BV1<br>BV2<br>BV3 | CH1 Chamber Back Vent<br>CH2 Chamber Back Vent<br>CH3 Chamber Back Vent | DB1 (4 Bed Unit) | Dry Bed Reactor System 1 | EP2 |
| CHR1<br>CHR2<br>CHR3<br>CSR1<br>CC1<br>SCR1<br>STV1 | Chamber Room 1<br>Chamber Room 2<br>Chamber Room 3<br>Chamber 1 Scale Room (EtO Scale)<br>Chamber Corridor (between sterilization chambers and aeration room)<br>Scrubber Room (scrubber tanks, pumps, and controls)<br>Scrubber Tank Vent (for filling and draining of tanks) | DB2 (4 Bed Unit) | Dry Bed Reactor System 2 | EP4 |
| AC1<br>SH1 | Aeration Corridor (between aeration rooms and shipping area<br>Shipping Area (for sterilized product prior to shipping) | DB3 (8 Bed Unit) | Dry Bed Reactor System 3 | EP3 |

## Emissions Summary

Potential emissions of EtO from the source have been reduced as a result of the project. EtO is classified as a hazardous air pollutant (HAP) and a volatile organic compound (VOC). The calculation methods used to review the project are summarized after the facility-wide emissions table.

### Facility-Wide Emissions
(in pounds per year)

| Pollutant | Emissions | | |
|---|---|---|---|
| | Potential Emissions Before Mod. | Potential Emissions After Mod. | Estimated Actual Emissions After Mod. |
| $PM/PM_{10}/PM_{2.5}$ | 0 | 0 | 0 |
| NOx | 0 | 0 | 0 |
| $SO_2$ | 0 | 0 | 0 |
| CO | 0 | 0 | 0 |
| VOC | 2,250 | 1,538 | 58.8 |
| Max. Individual HAP (EtO) | 2,250 | 1,538 | 58.8 |
| Total HAP | 2,250 | 1,538 | 58.8 |

***Pre-Modification Calculations[1]***

Potential emissions before the modification were estimated based on 150,000 pounds per year of EtO usage and 99.0% control of the sterilization chamber vacuum pumps, the aeration room vents, and the chamber backvents. The 99.0% control efficiency was based on the requirements specified in 40 CFR 63 Subpart O and the backvent control requirements in the existing permit. The indoor air is uncontrolled for the purposes of these calculations.

The pre-modification EtO emissions were estimated as follows:

E = Usage * {[A * (1-.99)] + [B * (1-.99)] + [C * (1-.99)] + [D]}

Where:

E = Yearly emission in pounds of EtO;
Usage = Yearly usage in pounds of EtO;
A = Predicted fraction vented through chamber vacuum pumps: 95%;
B = Predicted fraction vented through aeration: 4%;
C = Predicted fraction vented through backvents: 1%; and
D = Fraction assumed associated with workspace: 0.5%.

E = 150,000 * {[0.95 * (1-.99)] + [0.04 * (1-.99)] + [0.01 * (1-.99)] + [0.005]}
E = 2,250 pounds EtO per year (approximately 1.13 tons per year)

***Post-Modification Calculations***

The post-modification EtO emissions were estimated as follows:

E = Usage * {[A * (1-.99)] + [B * (1-.99)] + [C * (1-.99)] + [D * (1-.95)]}

Where:

E = Yearly emission in pounds of EtO;
Usage = Yearly usage in pounds of EtO;
A = Predicted fraction vented through chamber vacuum pumps: 95%;
B = Predicted fraction vented through aeration: 4%;
C = Predicted fraction vented through backvents: 1%; and
D = Fraction assumed associated with workspace: 0.5%. Estimated average control efficiency is 95%. An efficiency greater than 95%, including 99%, is achievable most of the time. However, if inlet concentrations are very low efficiency may decrease.

E = 150,000 * {[0.95 * (1-.99)] + [0.04 * (1-.99)] + [0.01 * (1-.99)] + [0.005 *(1-.95)]}
E = 1,538 pounds EtO per year (approximately 0.77 tons per year)

[1] The fractional breakdown in the potential pre-modification and potential post-modification calculations results in slightly more than 100% of the emissions being accounted for. US EPA used 0.05% in developing the original 40 CFR Part 63 Subpart O to account for the "D" fraction.

***Estimated Post-Modification Actual Emissions***

Please see Appendix D of the application for the complete actual emissions analysis.

Actual emissions were calculated based on EPA and site specific data such as:

- 2021 sterilization chamber usage scaled up to a target usage of 90% (utilization cannot be 100% due to chamber turn-time and necessary movement of sterilized and unsterilized product through the facility);
- Average EtO usage per load, based on chamber size;
- US EPA percentages for mass flow of EtO developed through industry survey; and

**Gas Flow Through Process – As Surveyed By US EPA**

| EtO Used in Gas Sterilization | Percent of Gas Used |
|---|---|
| Evacuated from the Chamber to a Scrubber | 93.36% |
| Exhausted from the Chamber Out the Back Vent at the End of Cycle | 1.00% |
| Carried from the Sterilization Chamber to Aeration Rooms | 4.00% |
| Released as Fugitives While in Transition or Storage at the Facility | 0.64% |
| Encapsulated in Product Shipped from Facility | 1.00% |
| Total Gas | 100.00% |

- Control device efficiencies documented through performance testing conducted in 2022.

**Control Device Efficiencies**

| Control Device | Efficiency | 40 CFR 63 Subpart O Requirement |
|---|---|---|
| Scrubber (chamber evacuation) | 99.993% | 99% |
| Dry Bed Reactor System 1 (backvents) | 99.890% | Not regulated |
| Dry Bed Reactor System 3 (corridors and shipping areas specified in equipment list) | 97.590% | Not regulated |
| Dry Bed Reactor System 2 (corridors and rooms specified in equipment list) | 98.800% | Not regulated |
| Catalytic Oxidizer (aeration room vents) | 99.500% | 99% or 1 ppm |

E = Scrubber + DB1 + DB3 + DB2 + Catalytic Oxidzer
E = 9.80 lbs + 1.65 lbs + 11.6 lbs + 5.76 lbs + 30.0 lbs
E = 58.8 pounds EtO per year (approximately 0.029 tons per year)

**Regulatory Applicability**

Sterilization Services is subject to 40 CFR 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities. The regulation requires the following:

- The facility must reduce emissions from each sterilization chamber vacuum pump by at least 99% in accordance with 40 CFR 63.362(a) and (c). The facility is in compliance with this provision.

- The facility must reduce emissions from each aeration room by at least 99% or to a maximum outlet concentration of 1 part per million by volume, whichever is less stringent in accordance with 40 CFR 63.362(a) and (d). The facility is in compliance with this provision.

40 CFR 63 Subpart O does not require control of the backvents as specified in 40 CFR 63.362(a). The Sterilization Services permit was modified in 2019 to require control of the backvents at a minimum control efficiency of 99%. The language has been updated to include the 1 ppmv outlet concentration compliance option for consistency.

**Monitoring and Testing**

*Scrubber 1SC*
The scrubber controls EtO emissions from the sterilization chamber pumps. The scrubber has been tested and demonstrates compliance with the destruction efficiency required by regulation. The facility monitors the scrubber liquor tank level in order to determine proper operation of the control device. A performance test is required within 6 months of the issuance date of this permit.

*Catalytic Oxidizer 1OX*
The catalytic oxidizer controls EtO emission from the aeration room vents. The catalytic oxidizer has been tested and demonstrates compliance with the destruction efficiency required by regulation. The facility monitors temperature in order the determine proper operation of the control device. A performance test is required within 6 months of the issuance date of this permit.

*Dry Bed Reactor System DB1*
The dry bed reactor system controls emissions from the sterilization chamber backvents. The backvents are currently unregulated in 40 CFR 63 Subpart O, however, GA EPD has required at least 99%. The permit has been updated to also allow compliance with a 1 ppm limit. The dry bed reactor system has been tested and meets the GA EPD requirements. The current monitoring is bag sampling and the facility must replace the bed material as prescribed in the permit. A performance test is required within 6 months of the issuance date of this permit.

*Dry Bed Reactor System DB2 and DB3*
The dry bed reactor systems control emissions from the indoor air as specified in the equipment list. Indoor air is currently unregulated in 40 CFR 63 Subpart O, however, GA EPD is requiring that all building air that comes into contact with EtO or EtO treated products be directed to a control device. The facility is required to conduct bag sampling and the facility must replace the bed material as prescribed in the permit. A performance test is required within 6 months of the issuance date of this permit.

*Continuous Emissions Monitoring Systems*
The new permit requires the facility to install and operate CEMS for measuring and recording EtO emissions from each stack. The CEMS may subsume the monitoring for the scrubber and catalytic oxidizer depending on future rulemaking. The GA EPD has the authority to allow the CEMS to be used as monitoring for the dry beds and will require the facility to do so once the monitors are in place.

**Permit Conditions**

Conditions 1.1 through 1.5 are general requirements that apply to all facilities.

Condition 2.1 is an existing requirement that limits the usage of EtO at the facility to 150,000 pounds per consecutive 12-month period.

Condition 2.2 states the emission reduction requirements apply at all times of facility operation. This GA EPD provision subsumes 40 CFR 63 Subpart O, which has an exception for malfunctions.

Conditions 2.3 and 2.4 are existing requirements that state the facility must comply with 40 CFR 63 Subpart A – General Provisions and 40 CFR 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization facilities.

Condition 2.5 is an existing requirement that specifies the EtO control requirements for sterilization chamber vents under 40 CFR 63 Subpart O.

Condition 2.6 is an existing requirement that specifies the EtO control requirements for the aeration room vents under 40 CFR 63 Subpart O. The language has been updated to include the 1 ppm option as allowed by the subpart and to be consistent with the Sterigenics U.S. LLC permit.

Condition 2.7 is an existing requirement that states the facility must control EtO emissions from the sterilization chamber backvents. The original language listed a control efficiency of least 99.0%. The condition has been updated to include a 1 ppm option to be consistent with the Sterigenics U.S. LLC permit. The compliance date of December 31, 2019 has passed and has been removed.

Condition 3.1 is a standard fugitive emission requirement that applies to all sources.

Conditions 4.1 through 4.3 are standard air pollution control equipment requirements that apply to all sources.

Condition 4.4 requires the facility to use the CEMS data to determine when the catalyst needs to be replaced for the catalytic oxidizer. The language previously required the facility to conduct a yearly performance test to determine replacement needs. Because the new permit requires the facility to install a CEMS, and will rely on that data instead of the yearly test, the old language has been removed. The use of the CEMS to determine the catalyst replacement schedule is permitted under 40 CFR 63 Subpart O.

Conditions 4.5 through 4.9 are new conditions that specify where each EtO vent must exhaust in order to meet the control requirements in Section 2.

Condition 5.1 is a standard monitoring condition that applies to all sources.

Conditions 5.2 through 5.7 specify the parameters that must be monitored for Scrubber 1SC and Catalytic Oxidizer 1OX. Monitoring frequency for the scrubber has been changed from weekly to daily until the CEMS is installed. The conditions apply unless the CEMS is operating and the US EPA allows the use of the CEMS as an alternative monitoring option.

Condition 5.8 specifies the monitoring requirements for the dry bed reactor system controlling emissions from the chamber backvents. The language has been updated from the previous permit to include monitoring for the 1 ppm compliance option and to allow the use of the CEMS in lieu of weekly bag sampling.

Condition 5.9 requires the facility to conduct weekly sampling for the indoor air dry bed reactor systems in order to ensure proper operation of the units. The sampling will be replaced with the CEMS once it is in place. The dry bed material must be replaced when monitoring results require it to be done as specified in the condition.

Condition 5.10 requires the facility to equip the stacks with EtO continuous emission monitoring systems, flow rate monitoring systems, and any other systems necessary to convert concentrations to mass emission rates. The deadline to install the CEMS is 12 months after the permit is issued, to allow the Permittee time to purchase, install, and set up the device(s).

Condition 5.11 requires the facility to submit a monitoring plan for the CEMS prior to installation. The plan is subject to review and approval by the Division. The plan will include accuracy and sensitivity levels to be approved by the Division based on expected commercially-available CEMS specifications (for example, a non-detect level of 10 ppb and an accuracy of 10 ppb). The plan will also include plans for conducting Relative Accuracy Test Audits (RATA).

Condition 5.12 requires the facility to operate in accordance with a Division-approved Work Practice Plan. The plan must include a monitoring protocol for the negative pressure system associated with the indoor air sources.

Condition 5.13 requires the facility to develop and implement a leak detection and repair program.

Condition 6.1 lists standard test requirements that apply to all sources.

Condition 6.2 through 6.6 require the facility to conduct performance testing, using the procedures specified in 40 CFR 63 Subpart O or other procedures approved by EPA and/or the Division on all emission exhausts. The facility is required to use the testing to establish the operating parameters for the catalytic oxidizer and scrubber. The conditions also require reporting of emissions in terms of a mass emission rate. These tests will be used to demonstrate compliance with the percent reduction requirements in Subpart O and will be used for emissions calculation purposes until the CEMS is installed.

Condition 6.7 requires the facility to conduct RATAs on the CEMS.

Conditions 7.1 and 7.2 are standard record keeping requirements that apply to all sources.

Condition 7.3 is a requirement of 40 CFR 63 Subpart O and requires the Permittee to keep records as specified in the rule and in 40 CFR 63 Subpart A. The language has been added to the permit for completeness.

Condition 7.4 is an existing requirement for recordkeeping for the catalytic oxidizer.

Condition 7.5 specifies the deviations the facility must report. Reporting includes occurrences of scrubber parameter deviations, catalytic oxidizer temperature deviations, occurrences of high dry bed outlet concentrations, and instances where dry bed material is not replaced as specified in the Permit. The language has been updated to include reporting for the two new dry bed reactor systems and the 1 ppm compliance option for the chamber backvents. Deviations also include failure of either indoor air control system.

Condition 7.6 is an existing requirement for the submittal of reports under 40 CFR 63 Subpart O. The language has been updated for completeness purposes.

Condition 7.7 requires the facility to submit a semiannual report relating to any excess emissions, exceedances, and/or excursions, in addition to monitor malfunctions. The language has been updated for completeness purposes.

Condition 7.8 is existing language that requires the facility to maintain records of the amount of EtO used daily.

Conditions 7.9 and 7.10 are existing language that require the facility to maintain records of EtO usage on a monthly and 12-month rolling basis. The records will be used to demonstrate compliance with the 150,000 pounds per 12-consecutive month period limit. The conditions also require the Permittee to report when monthly usage exceeds 1/12th of the limit and if the 12-month rolling limit is exceeded.

Conditions 7.11 and 7.12 require the facility to calculate emissions of EtO from the source on a monthly and 12-month rolling basis. Until the CEMS is installed, emissions will be calculated using actual ethylene oxide usage, tested control efficiencies and emission rates, and the mass fraction based on Subpart O background documents, including a recent draft document from EPA regarding fugitive emissions from sterilizers. The language has been updated to include a calculation for the indoor air emissions and the LDAR components, which were not included in the previous permit.

Condition 7.13 is existing language that requires the facility to include EtO usage and EtO emissions with the semiannual report.

Condition 7.14 requires the facility to notify the Division of all unpermitted releases, in accordance with recent revisions to Georgia Code O.C.G.A. § 12-9-7(a).

Condition 7.15 is new to the permit and prohibits the start-up of new sterilization cycles if performance testing at the control devices indicates non-compliance with the applicable control efficiency requirement.

Condition 8.1 is a standard requirement that applies to all sources.

Condition 8.2 requires the facility to pay annual fees.

Condition 8.3 revokes the permit previously issued to the source.

Previous Condition 7.12 required the facility to provide notification of the startup of the backvent control device. This has been completed and is no longer necessary.

**Toxic Impact Assessment**

Application No. 27641 was an emission reduction project. A Toxic Impact Assessment was not required. The Permittee conducted modeling and the results were reviewed by EPD. See the EPD Modeling Memorandum for more information.

**Summary & Recommendations**

A public advisory was not required for Application No. 27641 because the application resulted in a reduction in emissions from the source. The facility continues to be classified as a synthetic minor source and continues to comply with the provisions of 40 CFR 63 Subpart O. Compliance responsibility is maintained by the Stationary Source Compliance Program of the Air Protection Branch. I recommend the issuance of Air Quality Permit No. 3841-121-0010-S-04-0 to Sterilization Services of Georgia for the emission reduction project as described in Application No. 27641.