GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

Air Protection Branch
4244 International Parkway
Suite 120
Atlanta, Georgia 30354
404-363-7000

NARRATIVE

TO: Eric Cornwell

FROM: Heather Brown

DATE: January 5, 2021

Facility Name:	**Sterigenics U.S. LLC**
AIRS No.:	06700093
Location:	Atlanta, GA (Cobb County)
Application #:	27153
Date of Application:	July 30, 2019

Background Information

Sterigenics U.S. LLC (Sterigenics) is a commercial contract ethylene oxide and propylene oxide sterilization facility located at 2971 Olympic Industrial Drive SE, Suite 116, Atlanta, Georgia (Cobb County). The facility operates under Air Quality Permit No. 7389-067-0093-S-05-0 issued on May 27, 2014 and three amendments. The facility is subject to 40 CFR 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities[1].

Process Description

Sterigenics' Atlanta facility utilizes ethylene oxide (EtO) to sterilize customers' products including medical devices. It also can use propylene oxide (PO) to treat nutmeats and cosmetic ingredients. EtO and PO are sterilants that regulatory agencies such as the U.S. Food and Drug Administration and U.S. Environmental Protection Agency (administering the Federal Insecticide, Fungicide, and Rodenticide Act) allow to be used on products. In addition, medical devices must meet a certain level of sterility as regulated by the U.S. Food and Drug Administration and other regulatory agencies.

When EtO is used for medical device sterilization, the medical devices must have a specifically defined sterilization process, which is validated for a specific sterilization chamber or chambers. The Atlanta facility uses ten sterilization chambers (Source Codes SEV-1 through SEV-8, SEV-10, and SEV11) ranging in size from 6 pallets up to 30 pallets. While all ten sterilization chambers are similar in design, each chamber may only process products approved for that chamber and cannot process other products that have not been validated and approved by the appropriate regulatory agency for that specific chamber. As a contract sterilization facility, Atlanta sterilizes many different products from many different customers.

[1] Additional details on the national Ethylene Oxide Emissions Standards for Sterilization facilities available at https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

Receiving and Pre-Conditioning
Customers ship packaged products to Sterigenics. The first step after receipt of the product is to place the product into a preconditioning room. Preconditioning rooms are enclosed rooms which are heated and maintained at high humidity to prepare the product for sterilization. The product is in the preconditioning room for the time required for the specific product. No EtO is introduced or present in this step of the process.

Sterilization
Once preconditioning is complete, the product is moved to the appropriate sterilization chamber. A chamber is sized based on the number of pallets that it can hold and range from six pallets to thirty pallets. Once the product is loaded into the chamber, the chamber is closed and sealed. At the beginning of each sterilization cycle, safety checks are performed to ensure EtO does not escape from the chamber during the cycle. In addition, the cycle is monitored to ensure that vacuum is maintained within acceptable parameters.

As mentioned above, there is a validated cycle for each product. This validated cycle must meet specific regulatory requirements outside the scope of this air quality permit and will detail the times, parameters, and testing required for each product and the specific chamber approved. The sterilization process begins with evacuating the air from the chamber and introducing nitrogen. While under negative pressure inside the chamber, EtO is introduced into the sterilization chamber to sterilize the product. Once EtO is introduced, the dwell stage can last from 30 minutes up to several hours according to the validated cycle for the product. Once complete, the sterilization chamber vacuum pumps remove most of the EtO from the chamber by exhausting and purging with nitrogen multiple times. Prior to the 2020 control device upgrade, vacuum pump emissions were routed to the Ceilcote Scrubber (Source Code EC3). Emissions are now vented to the Ceilcote Scrubber followed by the ATT Scrubber System with Dry Bed Adsorbers (Source Code EC2).

Backvents and Aeration Emissions
Once the sterilization chamber process is complete and the chamber door is partially opened, the backvent (Source Codes CEV-1 through CEV-8, CEV-10, and CEV-11) fan activates to extract residual amounts of EtO from the chamber. This fan remains on while the chamber door is open. After fifteen minutes, the pallets of product are removed from the sterilization chamber and placed into an Aeration Room to further off-gas residual EtO. During spice fumigation, the chamber process includes additional gas washes to remove EtO from the product which eliminates the need for time in an aeration room. Both the backvents and aeration room are ducted to an existing AAT Scrubber System with Dry Bed Adsorbers (Source Code EC2).

Drum Storage
EtO is stored in sealed drums in an outside storage area before use. No dispensing takes place in the drum storage area. To dispense EtO, the drums are moved with a drum cart from the storage area to the dispensing stations located inside the chamber room area. Once in place at the dispensing station, the EtO drum is connected to the dispensing system for the specific sterilization chamber.

Purpose of Application

Application No. 27153 was received on July 31, 2019 and was accepted into the expedited permitting program on August 6, 2019. 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 an additional control device, rerouting existing controlled emissions to additional controls, and making control of the backvents mandatory. 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 and upgrades are installed and operating properly. All air pollution controls were tested to verify that they met the performance levels stated in the permit application[2]. EPD observed the tests.

The project was as follows:

1) Originally, the existing Ceilcote Scrubber (Source Code EC3) exhausted to atmosphere via a dedicated stack. Sterigenics has ducted the outlet of the Ceilcote Scrubber to the existing AAT Scrubber System with Dry Bed Adsorbers (Source Code EC2) to further reduce sterilization chamber vacuum pump emissions.

2) Originally, the existing AAT Scrubber System with Dry Bed Adsorbers (Source Code EC2) exhausted to atmosphere via a dedicated stack. Sterigenics ducted the outlet of the system to a different existing stack measuring 80 feet tall and 16 inches in diameter. This higher and larger stack which was in place but was not previously used by the facility will improve the dispersion of air emissions from the facility.

3) A negative pressure system (Source Code IA-1) has been installed to capture air internally from chamber rooms, work aisles, processed product storage, and shipping areas. With this negative pressure system, the facility routes the indoor air to a new dry bed control system, the Indoor Air Dry Bed Adsorber System (Source Code EC4) consisting of 18 dry beds. These dry beds exhaust to atmosphere via an existing stack measuring 80 feet tall and 2 feet in diameter.

   The indoor air area has been created by building a permanent wall between the sterilized product forklift aisle and the area where the facility receives unsterilized material. As a result, all air that comes in contact with sterilized product is collected and routed to the dry bed control system.

4) The permit has been updated to include control of the backvents (Source Code CEV-1 through CEV-8, CEV-10, and CEV-11), which are not required by the current version of 40 CFR Part 63 Subpart O, but will include the same level of control required by Subpart O (minimum control efficiency of 99%, or exit loading of 1 ppmv). The backvents emissions are controlled by the AAT Scrubber System with Dry Bed Adsorbers (Source Code EC2). The facility has been controlling emissions from the backvents since 2016.

The application included the proposed installation and operation of a spice room dedicated to storing treated spices after the fumigation process was complete. The facility withdrew the request to build the spice room; therefore, it was not included in the new permit. The removal of the spice room did not impact the emission calculations or modeling associated with the application.

[2] All test reports and EPD test reviews are available at https://epd.georgia.gov/sterigenics-tests-monitoring-reports-and-engineering-studies .

Updated Equipment List

The equipment list has been updated to reflect the new control scheme.

Emission Units			Associated Control Devices	
Source Code	**Description**	**Install Date**	**Source Code**	**Description**
SEV-1	Six-pallet Sterilization Chamber 1 vacuum pump	1967	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-2	Six-pallet Sterilization Chamber 2 vacuum pump	1967	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-3	Nine-pallet Sterilization Chamber vacuum pump	1967	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-4	Five-pallet Sterilization Chamber vacuum pump	1967	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-5	Thirteen-pallet Sterilization Chamber vacuum pump	1987	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-6	Thirteen-pallet Sterilization Chamber vacuum pump	1992	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-7	Thirteen-pallet Sterilization Chamber vacuum pump	1994	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-8	Thirteen-pallet Sterilization Chamber vacuum pump	1994	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-10	Thirty-pallet Sterilization Chamber vacuum pump	2014	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
SEV-11	Thirty-pallet Sterilization Chamber vacuum pump	2015	EC3 EC2	Ceilcote Scrubber AAT Scrubber System with Dry Bed Adsorbers
CEV-1	Backvent for Chamber 1	1967	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-2	Backvent for Chamber 2	1967	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-3	Backvent for Chamber 3	1967	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-4	Backvent for Chamber 4	1967	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-5	Backvent for Chamber 5	1987	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-6	Backvent for Chamber 6	1992	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-7	Backvent for Chamber 7	1994	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-8	Backvent for Chamber 8	1994	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-10	Backvent for Chamber 10	2014	EC2	AAT Scrubber System with Dry Bed Adsorbers
CEV-11	Backvent for Chamber 11	2015	EC2	AAT Scrubber System with Dry Bed Adsorbers
AR-1	Aeration Room 1	2014	EC2	AAT Scrubber System with Dry Bed Adsorbers
IA-1	Indoor Air (Chamber Rooms, Work Aisles, Processed Product Storage, Shipping Areas)	2019	EC4	Indoor Air Dry Bed Adsorber System

Emissions Summary

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

Facility-Wide Emissions (pounds per year)

Pollutant	Potential Emissions		
	Before Mod.	After Mod.	Emissions Change
$PM/PM_{10}/PM_{2.5}$	0	0	0
NOx	0	0	0
SO_2	0	0	0
CO	0	0	0
VOC	9,750	84.7	-9,665
Max. Individual HAP (EO)	9,375	84	-9,291
Total HAP	9,750	84.7	-9,665

The facility has two natural gas Cleaver Brooks Boilers rated at 4.5 MMBtu/hr and 1.3 MMBtu/hr. The units are exempt from permitting under Georgia Rule 391-3-1-.03(6)(b).

Pre-Modification Calculations[3]

Potential emissions before the modification were estimated based on 625,000 pounds per year of EtO usage, 25,000 pounds per year of PO usage, and 99.0% control of the sterilization chamber vacuum pumps, the aeration room vent, and the chamber backvents. The 99.0% control efficiency was used because of the requirements specified in 40 CFR 63 Subpart O. 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 = 625,000 * {[0.95 * (1-.99)] + [0.04* (1-.99)] + [0.01* (1-.99)] + [0.005]}
E = 9,375 pounds EtO per year (approximately 4.69 tons per year)

[3] The fractional breakdown in the pre-modification and 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.

The same equation was used to calculate pre-modification potential PO emissions:

E = 25,000 * {[0.95 * (1-.99)] + [0.04* (1-.99)] + [0.01* (1-.99)] + [0.005]}
E = 375 pounds PO per year (approximately 0.19 tons per year)

Total Potential Pre-Modification VOC/HAP Emissions = 9,375 + 375 = 9,750 pounds (approximately 4.86 tons)

Post-Modification Calculations

Permitted emissions of EtO after the control improvement project are based on a usage limit of 625,000 pounds per year, PO usage of 5,000 pounds per year, and the results of performance testing conducted in June 2020. The June testing demonstrated a control efficiency of 99.9987% from the sterilization chamber vacuum pumps combined controls (Ceilcote EC3, and AAT EC2), 99.85% for the aeration room vents controls (AAT EC2), and 99.88% for the backvent emissions (AAT EC2). The calculations include the control of all indoor air at 99.0% efficiency. The efficiency of EC2 for backvents vs aeration room are slightly different due to different inlet concentrations from these processes.

The post-modification EtO emissions are calculated as follows:

E = Usage * [[A * (1-.999987)] + [B * (1-.9985)] + [C * (1-.9988)] + [D * (1-.99)]}

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%;
D = Fraction assumed associated with workspace: 0.5%.

E = 625,000 * {[0.95 * (1-.999987)] + [0.04 * (1-.9985)] + [0.01 * (1-.9988)] + [0.005 * (1-.99)]}
E = 84 pounds EtO per year (approximately 0.042 tons per year)

Based on these calculations, the EPD has established an emission cap of 84 pounds of EtO per year (approximately 0.042 tons per year).

The same equation was used to calculate post-modification potential PO emissions:

E = 5,000 * {[0.95 * (1-.999987)] + [0.04 * (1-.9985)] + [0.01 * (1-.9988)] + [0.005 * (1-.99)]}
E = 0.7 pounds PO per year (approximately 0.00034 tons per year)

Total Potential Post-Modification VOC/HAP Emissions = 84 + 0.7 = 84.7 pounds (approximately 0.042 tons)

Regulatory Applicability

Sterigenics 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). Sterigenics is in compliance with this provision. The control equipment demonstrated an efficiency of 99.9987% during the June 2020 testing.

- 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). Sterigenics is in compliance with this provision. The control equipment demonstrated an efficiency of 99.85% during the June 2020 testing.

40 CFR 63 Subpart O does not require control of the backvents as specified in 40 CFR 63.362(a). Sterigenics has controlled the backvents since 2016 and the new permit specifies a minimum control efficiency of 99% or 1 ppmv outlet concentration for consistency.

Testing and Monitoring

Compliance with the emission cap will be determined through the use of ethylene oxide continuous emission monitoring systems (CEMS), and prior to CEMS installation, usage rates and control efficiency test results. Stack testing will be conducted on a biennial basis.

Ceilcote Scrubber EC3
The performance test for the Ceilcote Scrubber involves sending exhaust from one or more chamber vacuum pumps to the control device. The inlet emissions to the scrubber are determined using the Ideal Gas Law and the known chamber conditions at the beginning and end of the first chamber evacuation. At the same time, EtO emissions from the outlet of the scrubber are determined using direct source sample and EPA approved test methods. The known amount of EtO exhausted to the scrubber and the EtO outlet results collected using a gas chromatograph (GC) are used to calculate the control efficiency. Control equipment parameter monitoring during the test is used to establish the maximum ethylene glycol concentration, the maximum liquor tank level, and maximum pH for the scrubber. It is not possible to take direct samples at the inlet of the Ceilcote Scrubber due to the high inlet concentration of the gas, which would pose an explosion danger.

For monitoring, the parameters of scrubber ethylene glycol concentration, or liquor tank level are checked and recorded daily, in accordance with 40 CFR 63 Subpart O. Although Subpart O requires weekly monitoring, the permit will require daily monitoring until the CEMS is installed and operating, after which, sampling may return to weekly. pH is also checked and recorded daily. Currently, Subpart O does not address the use of CEMS as a monitoring requirement; the permit is written such to allow the CEMS in lieu of scrubber parameter monitoring if US EPA allows such as alternative monitoring.

AAT Scrubber with Dry Bed Adsorbers EC2
The performance test for the AAT System involves sampling at the inlet and outlet of the system. The control efficiency is calculated from those samples, via direct source sample and EPA approved test methods. Control device (scrubber) parameter monitoring during the test is used to establish the maximum ethylene glycol concentration, the maximum liquor tank level, and maximum pH for the scrubber portion of the system.

For monitoring, the parameters of scrubber ethylene glycol concentration, or liquor tank level are checked and recorded daily, in accordance with 40 CFR 63 Subpart O. Although Subpart O requires weekly monitoring, the permit will require daily monitoring until the CEMS is installed and operating, after which, sampling may return to weekly. pH is also checked and recorded daily. Currently, Subpart O does not address the use of CEMS as a monitoring requirement; the permit is written such to allow the CEMS in lieu of scrubber parameter monitoring if US EPA allows such as alternative monitoring.

For dry bed adsorber monitoring, samples from the inlet and outlet of the AAT system will be collected and analyzed via a gas chromatograph (GC) to determine the control efficiency to demonstrate proper operation. If the efficiency is shown to be equal or less than 99.1% or if the outlet concentration is equal or greater than 0.9 ppm, the facility must take measures to replace the dry beds in a timely manner. This is an approved alternative monitoring method for 40 CFR 63 Subpart O. The permit increases the sampling frequency from monthly to weekly until the CEMS is installed and operating, after which sampling may return to monthly.

Further monitoring, beyond what is required by Subpart O has been added for the dry beds, to ensure proper operation.

Indoor Air System
The performance test for the Indoor Air involves sampling at the inlet and outlet of the system. The control efficiency is calculated from those samples, via direct source sample injection into a gas chromatograph (GC).

For dry bed adsorber monitoring, weekly samples from the outlet of the indoor air AAT system will be collected and analyzed via a GC to demonstrate proper operation. In this case, due to the low concentration of ethylene oxide in indoor air (anticipated less than 1 ppm), and the operational limitations of the GC (accuracy and non-detect level), an efficiency target will not be used; instead, the target value is set to 0.5 ppm (similar to that approved by US EPA for Sterigenics Charlotte, NC facility). The facility must take measures to replace the dry beds in a timely manner if samples show outlet concentration at or above 0.5 ppm. Once the required CEMS is operating (which will provide continuous emissions data), the weekly sampling will no longer be necessary.

In addition to the above monitoring, the permit will require a CEMS at the outlet of each system to be installed with 12 months.

Permit Conditions

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

Condition 2.1 is a new requirement that limits usage of EtO at the facility to 625,000 pounds per consecutive 12-month period.

Condition 2.2 is a new requirement that limits emissions of EtO from the facility to 84 pounds or less per consecutive 12-month period.

Condition 2.3 is a new requirement that limits usage of PO at the facility to 5,000 pounds per consecutive 12-month period. The condition also requires the facility to subject the PO to the same control requirements as the EO.

Condition 2.4 states the emission reduction requirements apply at all times of facility operation.

Condition 2.5 and 2.6 require the facility to comply with 40 CFR 63 Subpart A – General Provisions and 40 CFR 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities.

Condition 2.7 specifies the EtO control requirements for sterilization chamber vents under 40 CFR 63 Subpart O.

Condition 2.8 specifies the EtO control requirements for the aeration room vent under 40 CFR 63 Subpart O.

Condition 2.9 requires the facility to control EtO emissions from the sterilization chamber backvents by at least 99.1% or to 1 ppm. These vents are not required to be controlled under 40 CFR 63 Subpart O. The backvents are already controlled by the AAT Scrubber System with Dry Bed Adsorbers. This enforceable requirement has been added as part of the emissions reduction project.

Condition 2.10 limits the use of fuel in the facility boilers to natural gas. Natural gas boilers are not subject to the provisions of 40 CFR 63 Subpart JJJJJJ.

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.

Conditions 4.4 through 4.7 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 and 5.3 specify the parameters that must be monitored for the Ceilcote and AAT acid scrubbers as specified in 40 CFR 63 Subpart O. Monitoring frequency has been changed from weekly to daily until the CEMS is installed. These conditions apply unless the CEMS is operating and US EPA allows the use of the CEMS as an alternative monitoring option.

Condition 5.4 requires sampling of the AAT dry bed adsorber system (EC2) to demonstrate proper operation of this device and is approved as alternative monitoring for Subpart O by US EPA. The frequency has been changed from monthly to weekly until the CEMS is installed. If reduction efficiency falls to or below 99.1% , or, if complying with the 1 ppm standard, if outlet concentration equals or exceeds 0.9 ppmv, the dry beds must be replaced.

To ensure proper operation of the acid scrubbers and dry beds in EC2, additional provisions have been added. The facility must take measures to replace the dry beds in a timely manner if two consecutive weekly required samples show outlet concentration at or above 0.5 ppm. This requirement will no longer be required upon installation of the CEMS because the CEMS will be used to identify proper operation, as explained later.

The Subpart O monitoring in this condition applies unless the CEMS is operating and US EPA allows the use of the CEMS as an alternative monitoring option.

Condition 5.5 requires weekly inlet and outlet sampling of the indoor air dry bed adsorber system (EC4) to demonstrate proper operation of this device. This is a new requirement. If outlet concentrations raise above 0.5 ppm for two consecutive readings, the beds must be replaced. This condition applies unless the CEMS is operating (Subpart O does not apply to indoor air controls), which will provide continuous emissions rate data.

Condition 5.6 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 5.7 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 5.8 requires the facility to operate in accordance with the Division-approved Work Practice Plan. The plan was required to be submitted by Consent Order EPD-AQC-6980 executed on August 7, 2019. The plan includes a monitoring protocol for the negative pressure system associated with the Indoor Air (Source Code IA-1) System. A revised plan will be required to address the updated requirements in this permit. A link to the current Work Practice Plan is found here:
https://epd.georgia.gov/document/document/sterigenics-workpracticeplanpdf/download

Condition 5.9 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 6.4 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 operating parameters for the acid scrubbers. The conditions also require reporting of emissions in terms of a mass emission rate. The testing is to be repeated once every 24 months. 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.

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.

Condition 7.4 specifies the deviations the facility must report. Reporting includes occurrences of acid scrubber parameter deviations, occurrences of high dry bed outlet concentrations, and instances where dry bed material is not replaced as specified in the Permit.

Condition 7.5 is a requirement of 40 CFR 63 Subpart O and requires the Permittee to submit deviation reports and continuous monitoring system performance reports.

Condition 7.6 requires the facility to submit a semiannual report (including the items in Condition 7.4) relating to any excess emissions, exceedances, and/or excursions, in addition to monitor malfunctions.

Conditions 7.7 requires the facility to maintain records of the amount of EtO and PO used daily.

Conditions 7.8 and 7.9 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 625,000 pound per 12-consecutive month period limit. The conditions also require the Permittee to report when monthly usage exceeds $1/12^{th}$ of the limit and if the 12-month rolling limit is exceeded.

Conditions 7.10 and 7.11 require the facility to calculate emissions of EtO from the source on a monthly and 12-month rolling basis. The records will be used to demonstrate compliance with the 84 pounds per 12-consecutive month period limit. The conditions also require the Permittee to report when monthly emissions exceed $1/12^{th}$ of the limit and if the 12-month rolling limit is exceeded. 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.

Conditions 7.12 and 7.13 require the facility to maintain records of PO usage on a monthly and 12-month rolling basis. The records will be used to demonstrate compliance with the 5,000 pound per 12-consecutive month period limit. The conditions also require the Permittee to report when monthly usage exceeds $1/12^{th}$ of the limit and if the 12-month rolling limit is exceeded.

Condition 7.14 requires the Permittee to include the EtO usage and emissions in the semiannual report. The facility is also required to report PO usage.

Condition 7.15 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 7.16 prohibits the start-up of new sterilization cycles if performance testing at the control devices indicate 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.

Toxic Impact Assessment

Application No. 27153 was an emission reduction project, including routing of emissions to two 80 foot stacks. A Toxic Impact Assessment is not required. The Permittee conducted modeling for the emission reduction project. Results of that modeling were reviewed by EPD. See the EPD Modeling Memorandum for more information.

Summary & Recommendations

A public advisory was not required for Application No. 27153 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. 7389-067-0093-S-06-0 to Sterigenics U.S. LLC for the emission reduction project as described in Application No. 27153.