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DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

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NARRATIVE

TO: Eric Cornwell

FROM: Heather Brown

DATE: January 5, 2021 (revised with Addendum November 24, 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.

Public Comments

Georgia EPD conducted two public hearings via Zoom format on February 9 and February 10. EPD received verbal comments from approximately 13 attendees on the February 9 hearing, and 35 verbal comments on the February 10 hearing.

Georgia EPD received public comment on the draft permit during the public comment period that ran from January 7 to February 25. Approximately 150 comments were received. Some commenters submitted both verbal and written comments.

Georgia EPD received two comments on the permit application itself shortly after receipt of the permit application. No public comment period was advertised at that time. The comments focused on information that the commentors found lacking in the application. Partially due to these comments, Georgia EPD requested additional information from Sterigenics in Fall 2019.

Public Hearing Verbal Comments and EPD Responses.

EPD staff attended the hearings, reviewed the hearing recordings, noted the comments and identified the groups of comments by concept/concern. The overarching concepts are summarized here, focusing on comments relevant to the requirements of the draft permit. To review the actual comments, please go to this link: https://epd.georgia.gov/draft-sterigenics-air-quality-permit to view the recordings of the public hearings. Georgia EPD will focus its response to comments directly related to the draft air quality permit. Many people made very similar verbal comments. For example, the following verbal comments (expressed in different ways) were made repeatedly:

- **Revoke the permit/do not issue the permit**
- **Self-reporting of emissions is not acceptable**
- **EPD should conduct fenceline ambient monitoring**
- **Sterigenics has a history of violations and lack of transparency**
- **A plant of this nature does not belong in a residential area**
- **Safety concerns for children and family members living in the area.**

Verbal Comment 1

Trucks containing EtO-sterilized products can emit EtO via product offgassing. The work practice plan should address truck activity to minimize offgassing near the Sterigenics facility. Illegal sterilized product warehouses and trucks hauling such products may contribute significantly to the background EtO detected by ambient monitoring.

EPD Response – Condition 5.8 has been expanded to include work practices to minimize EtO emissions that may occur from offgassing in loaded trucks remaining onsite.

Verbal Comment 2

EtO is needed to sterilize some medical devices and is the only method approved by FDA in some cases. Sterigenics has greatly reduced emissions.

EPD Response – comment noted

Verbal Comment 3
EPD should not grant any permit to Sterigenics – the risk is too great from a cancer concern as well from an explosive or safety concern.

EPD Response –

Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Georgia issues air quality permits in accordance with Georgia's State Implementation Plan, approved by US EPA, Georgia's Air Quality Act, and Georgia Rules for Air Quality Control- Chapter 391-3-1. Rule 391-3-1-.03 states that an air permit shall be issued upon a determination by the Director that the facility can reasonably be expected to comply with all the provisions of the Act and the rules and regulations promulgated thereunder. In the Air Protection Branch's assessment, there is reasonable evidence that the facility can comply with all applicable provisions of the Act and the rules and regulations and we are recommending issuance of the draft permit.

Air Quality permits issued by EPD do not and are not required by US EPA to address risk issues such as explosions and other non-emissions related issues. Such issues are beyond the scope of the Georgia State Implementation Plan that prescribes Georgia EPD's duties and authorities.

Verbal Comment 4
The permit does not contain sufficient tracking/monitoring for EtO leaks. The use of a CEMS in the stack is not adequate because it does not account for leaks. The equations used to estimate EtO emissions are based on old math and may not be accurate.

EPD Response –
The draft permit contains the requirement, set forth by SB 426, which became law effective January 1, 2021, to track and report all leaks to EPD within 24 hours. Additionally, Condition 7.10 states "The Permittee shall calculate monthly EtO emissions using the CEMS data recorded in accordance with Condition 5.6. Total emissions shall also include losses due to any malfunction, leaks, spills, etc.…"

Any leak that occurs inside the plant negative airflow area will be controlled via the currently operating air pollution control system. Upon installation of the CEMS, leaks that occur inside this workspace will be accounted for in the CEMS data as part of the workspace emissions.

The emissions calculation equation provided in Condition 7.10 of the draft permit applies only until the CEMS is installed and operational. The emissions calculations are based on information provided by the US EPA as part of the background information for their commercial sterilizer rule MACT Subpart O. The

values used to calculate the controlled workspace and warehouse emissions are based on stack testing conducted in 2020. The CEMS will be used to calculate emissions after it is installed and operational.

Verbal Comment 5
EPD should consider using the Texas risk factor for EtO, instead of EPA's IRIS value.

EPD Response- EPD will use the EPA IRIS value as detailed in Georgia Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions. The EPA IRIS value was used by US EPA in their NATA and represents the value EPA is currently using in their risk assessments for EtO.

Verbal Comment 6
The draft permit requires a CEMS, but CEMS for EtO are still a very new development. There is no EPA-approved Relative Accuracy Test Audit (RATA) procedure for an EtO CEMS, and the non-detect values are not verified at this time.

EPD Response –While the technology for EtO CEMS is somewhat new, there are at least two vendors of these CEMS. For example, Illinois EPA has required EtO CEMS at facilities in their state. EPD confirmed from Illinois EPA that the CEMS are operational with acceptable results. Furthermore, the draft permit is allotting time before the CEMS must be installed in order to allow time to select the CEMS and develop and submit a monitoring plan for the CEMS.

Verbal Comment 7
The annual EtO emissions cap in the draft permit of 84 pounds per year is too low because it is based on stack tests without any room for variability and thus achievability is questionable.

EPD Response –
The 84 pound per year EtO cap in the January 2021 draft permit was proposed as an additional performance assurance measure for the air pollution controls installed and operating at the facility. It was based on single stack tests, with no accounting for the variability that may occur due to control equipment performance, stack test/lab analyses, or CEMS accuracy. EPD has reviewed the comments received on the cap, along with other information available to us. The ethylene oxide emissions cap is not in the final permit. EPD determined that additional data is needed in order to establish a cap. EPD may establish an emissions cap in the future; after US EPA finalizes expected revisions to the federal rule for ethylene oxide commercial sterilizers. The facility will still be required to report monthly EtO emissions in each semiannual report.

The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

The permit remains protective of human health. EPD reserves the right to establish a facility-wide emissions cap in the future, based on additional information, including upcoming revisions to 40 CFR 63 Subpart O by US EPA.

See end of this document for updated permit conditions summary.

Verbal Comment 8
The permit for Sterigenics should be revoked because the plant emits EtO, a known carcinogen, has in the past emitted large quantities of EtO, and is located in a residential area.

EPD Response – Georgia issues air quality permits in accordance with Georgia's State Implementation Plan, approved by US EPA, Georgia's Air Quality Act, and Georgia Rules for Air Quality Control- Chapter 391-3-1. Rule 391-3-1-.03 states that an air permit shall be issued upon a determination by the Director that the facility can reasonably be expected to comply with all the provisions of the Act and the rules and regulations promulgated thereunder. In the Air Protection Branch's assessment, there is reasonable evidence that the facility can comply with all applicable provisions of the Act and the rules and regulations and we are recommending issuance of the draft permit.

The continued operation of the new air pollution controls ensures that EtO emissions, as documented in recent performance testing, are controlled to levels that result in a modeled maximum ambient concentration that is well within the acceptable health risk range used by US EPA.

Zoning is outside of the scope of the air permitting process.

Verbal Comment 9
The permit should not allow Sterigenics to self-report the EtO emissions levels, both as reported using the equation in the permit and the CEMS. Georgia EPD should operate and manage the CEMS to ensure accurate reporting of emissions. The reasons are that Sterigenics has a history of noncompliance and lack of transparency.

EPD Response – Concerns about self-reporting were cited by many commentors. "Self-Reporting" – that is, requiring a regulated source to document compliance with emissions standards and associated monitoring, is the basis and the compliance assurance mechanism in every air quality regulation, both state and federal. 40 CFR contains the requirements governing reporting, as set forth in the Clean Air Act. Every emissions standard for every federal maximum achievable control technology standard (MACT), generally achievable control technology standard (GACT), and new source performance standard (NSPS), and the EPA's toxic release inventory (TRI) requires the facility to accurately report under penalty of law. The monitoring, recordkeeping and reporting by the permittee are thoroughly examined by EPD staff as part of the onsite inspection process.

Based on the information available to EPD at this time, Sterigenics is operating in compliance with its current air quality permit, including all reporting requirements. The are no provisions in the Georgia Rules or Georgia Air Act that authorize a permit to be revoked on the basis of a lack of transparency.

Verbal Comment 10
Sterigenics failed to satisfy EPD's information request letter. They did not prove that 95% of the EtO used goes to the vacuum pump and did not test under worst case scenarios.

EPD Response- Sterigenics was unable to test as initially requested by EPD; the explosivity of EtO at the concentrations in vacuum pump area made direct sampling in that area too dangerous. The testing conducted on March 24, 2020 and June 24-26, 2020 was conducted according to testing protocols agreed upon by EPD. Upon installation of the CEMS, the emissions from the facility will be measured in real time at the two exhaust points, thus making emissions tracking though math equations unnecessary.

Verbal Comment 11
Georgia EPD should require, or conduct themselves, fenceline monitoring of ambient concentrations of EtO. The reason for this is that the emissions calculations methods in the permit may not be accurate and may underreport the actual emissions. Recent ambient monitoring shows that ambient levels of EtO when Sterigenics is operating is much higher than modeling results show.

EPD Response-
EPD began conducting ambient monitoring of EtO in 2019 at various locations around the state, including locations near Sterigenics. The results are posted here.

- *The concentrations EPD is measuring near Sterigenics are very similar to the concentrations that we are measuring at our South DeKalb monitoring site, which is a National Air Toxics Trends Site, and not near any known source of EtO emissions. The concentrations measured at General Coffee State Park, our rural background site, are averaging slightly lower.*
- *The data is variable and the data precision is not good. This indicates that the EPA method for analyzing for EtO needs improvement at the very low concentrations present in ambient air.*
- *The EtO concentrations being measured at our background sites indicate that there are other sources of EtO contributing to the EtO concentration in the air.*
- *Other states are finding similar results at their National Air Toxics Trends Sites.*

The draft permit will not be revised to require ambient monitoring; no air quality permit issued in Georgia currently requires such monitoring.

Verbal Comment 12
The permit should require a special alert to neighbors if a leak is detected.

EPD Response-
Condition 7.15 of the draft permit 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). Georgia Code O.C.G.A. § 12-9-6(b)(8) requires EPD to post the information on the EPD website.

Verbal Comment 13
Sterigenics does not have a valid building permit in Cobb County and has banned the fire marshal from access to the facility.

EPD Response – This comment is beyond the scope of the air quality permit application review. Air permit application reviews are governed by state and federal air quality laws and rules and are independent of local building codes and inspections.

Verbal Comment 14
Permit Condition 4.3 requires that controls be fixed as expeditiously as possible. The permit should require the facility to shut down upon any malfunctions.

EPD Response
Condition 4.3 of the draft permit is a template condition. A template condition is a condition that is included in all permits of the same classification – synthetic minor permit classification in the case of Sterigenics. The draft permit specifies that the emissions control requirements apply at times. The draft permit includes specific time frames for correcting malfunctions in other conditions (e.g., Conditions 5.4 and 5.5).

Verbal Comment 15
The permit is deficient because it is impossible to have zero fugitive emissions.

EPD Response
The draft permit does not require zero fugitive emissions. The draft permit ensures the fugitive emissions are minimized to the maximum extent possible by requiring the operation and monitoring of a negative airflow system inside the plant to ensure EtO in the workspace or sterilized product warehouse and shipping area are captured and routed to air pollution control devices.

Verbal Comment 16
The EPD PTM document must be revised to contain EtO testing and monitoring procedures.

EPD Response
This comment is outside the scope of the draft permit, but EPD will work to update the Georgia Procedures for Testing and Monitoring (PTM) as necessary. Such an update to the PTM is not required to issue an enforceable and valid air permit.

Verbal Comment 17
The annual limit of 84 lb/yr of EtO is too high.

EPD Response
The commenter did not provide any explanation of what an appropriate limit should be and how such a figure was derived based on technical data.

Verbal Comment 18
The permit is deficient because data from the Illinois operations show that fugitive emissions of EtO are 10 times higher than expected/represented.

EPD Response
The draft permit requires the capture and control of EtO emissions within the facility through a negative airflow system inside the plant. This system ensures that workspace air that may contain EtO is routed through air pollution controls, and not released as "fugitive" emissions.

Verbal Comment 19
The permit should require longer aeration times to minimize EtO offgassing in trucks

EPD Response
EPD Response – Condition 5.8 has been expanded to include work practices to minimize EtO emissions that may occur from offgassing in loaded trucks remaining onsite.

Verbal Comment 20
The permit should contain clear consequences for violations, including associated fines, and potential requirements to shut down operations.

EPD Response
The draft permit will not be revised to contain such prescriptive information. Enforcement actions are determined in a manner consistent with the Air Protection Branch's Compliance Assurance Strategy.

Verbal Comment 21
If aeration works so well, why is the EtO value at warehouses so high?

EPD Response
Aeration does not remove all EtO from the sterilized medical products. EPD recognizes this and the draft permit contains air pollution control requirements for the sterilized product warehouse/shipping area after product has been aerated. These controls ensure EtO released after the aeration cycle are captured and controlled. Emissions at off-site warehouses are outside of the scope of the draft permit.

Verbal Comment 22
The use of a higher stack for better dispersion is the wrong approach, it will result in more people being affected.

EPD Response
Comment noted. Higher stacks typically result in greater dispersion, which lowers overall concentrations. The stack parameters provided were used to model EtO concentrations outside the facility.

Verbal Comment 23
EPD should conduct a public health assessment.

EPD Response
Conducting a public health assessment is beyond the scope of the draft permit and EPD's authority. EPD is sharing all modeling, monitoring and air pollution control information with the Georgia Department of Public Health and the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR held community availability sessions in September 2021 for community members living near Sterigenics as part of their public health consultation process.

Written public comments and EPD Responses.
EPD staff has reviewed the comments and identified the groups of comments by concept/concern. The overarching concepts are summarized here, focusing on comments relevant to the requirements of the draft permit. Many people made very similar comments. For example, the following comments (expressed in different ways) appeared repeatedly:

- **Revoke the permit/do not issue the permit**
- **Self-reporting of emissions is not acceptable**
- **EPD should conduct fenceline ambient monitoring**
- **Sterigenics has a history of violations and lack of transparency**
- **A plant of this nature does not belong in a residential area**
- **Safety concerns for children and family members living in the area.**

Georgia EPD will focus its response to comments directly related to the draft air quality permit. All comments were read, but repeat comments are not included.

To review the actual comments, email ask.epd@dnr.ga.gov to obtain a file containing all email text and attachments.

Written Comment 1
Sterigenics failed to comply with the EPD information request letter dated Oct 9, 2019, because they only cited the federal rule amendment for 40 CFR 63 Subpart O to document that 95% of EtO used went to the vacuum pumps. Furthermore, they did not conduct estimates at worst case scenarios. The permit should not rely on the unproven values presented by Sterigenics.

EPD Response
Sterigenics was unable to test as initially requested by EPD; the explosivity of EtO at the concentrations in vacuum pump area made direct sampling in that area too dangerous. The testing conducted on March 24, 2020, and June 24-26, 2020 was conducted according to testing protocols agreed upon by EPD. Upon installation of the CEMS, the emissions from the facility will be measured in real time at the two exhaust points, thus making emissions tracking through math equations unnecessary.

Written Comment 2
The permit should contain the enforcement actions/consequences/fines EPD will enforce for violating the annual limit or other aspects of the permit, or if ambient monitoring indicates that elevated ambient EtO is due to issues at Sterigenics.

EPD Response
The draft permit will not be revised to contain such prescriptive information. Enforcement actions are determined in a manner consistent with the Air Protection Branch's Compliance Assurance Strategy.

Written Comment 3
The permit should include a requirement for fenceline ambient monitoring to demonstrate that the EtO offgassing of products in trucks (which is considered fugitive emissions).

EPD Response
EPD began conducting ambient monitoring of EtO in 2019 at various locations around the state, including locations near Sterigenics. The results are posted here.

- *The concentrations EPD is measuring near Sterigenics are very similar to the concentrations that we are measuring at our South DeKalb monitoring site, which is a National Air Toxics Trends Site, and not near any known source of EtO emissions. The concentrations measured at General Coffee State Park, our rural background site, are averaging slightly lower.*
- *The data is variable and the data precision is not good. This indicates that the EPA method for analyzing for EtO needs improvement at the very low concentrations present in ambient air.*
- *The EtO concentrations being measured at our background sites indicate that there are other sources of EtO contributing to the concentration in the air.*
- *Other states are finding similar results at their National Air Toxics Trends Sites.*

Condition 5.8 has been expanded to include work practices to minimize EtO emissions that may occur from offgassing in loaded trucks remaining onsite.

Written Comment 4
Please clarify the term CMS in Condition 7.3

EPD Response
CMS stands for Continuous Monitoring System. The draft permit will be amended to clarify this term.

Written Comment 5
Permit should be modified to reconcile release reporting in Condition 7.15 with semiannual reporting in Condition 7.6. Condition 7.15 should indicate that the release reporting will be available on the EPD website.

EPD Response
Condition 7.15, which specifies the spill reporting requirements of Georgia Code O.C.G.A. § 12-9-7(a), is independent of Condition 7.6 for semi-annual reporting. The requirement in SB 426 that the (EPD) "…director shall make publicly available on the division's website information regarding any spill or release of EtO reported to the division pursuant to paragraph (3) of subsection (a) of Code Section 12-9-7;" is a requirement for EPD, not the permittee. No changes to the permit are needed.

Written Comment 6
The draft permit should require more routine disclosure of monitoring results, especially from the CEMS, in an electronic format that would be convenient for EPD and the public to review.

EPD Response
The draft permit contains semiannual reporting of the 12-month rolling total emissions to EPD in a format specified by EPD. EPD maintains an EtO webpage that includes reports submitted by commercial sterilizers. EPD intends to maintain the webpage for the foreseeable future.

Written Comment 7
The work practice plan should address fugitive emissions from offgassing of sterilized products in trucks and limit the time that loaded trucks can remain on property.

EPD Response
Condition 5.8 has been expanded to include work practices to minimize EtO emissions that may occur from offgassing in loaded trucks remaining onsite.

Written Comment 8
The permit should require the tracking of amounts and destinations of sterilized products.

EPD Response
Tracking of materials beyond the permitted stationary source is beyond the scope of the permit and authority of EPD.

Written Comment 9
The permit and narrative should be modified to better explain why Sterigenics is permitted as a synthetic minor source and not a major source.

EPD Response
The Sterigenics facility is currently permitted as a "synthetic minor" source because potential emissions of Hazardous Air Pollutants (HAP) are less than 10 tons of any single HAP and less than 25 tons of all HAP combined. Sterigenics emits two HAPs – EtO and propylene oxide.

Written Comment 10
The permit should require Sterigenics to report EtO releases to the US EPA Toxic Release Inventory (TRI) (aka Form R, SARA 313).

EPD Response
Such a requirement is beyond the authority of EPD. The TRI reporting requirements are set by US EPA.

Written Comment 11
Sterigenics should follow stricter regulations, and switch from EtO if possible. The plant should not be allowed to operate if they cannot stay safe or comply with regulations.

EPD Response
The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

According to the Food and Drug Administration's website, the medical product manufacturer determines the method of sterilization, which is then submitted to the FDA for review.[4]

[4] Ethylene Oxide Sterilization for Medical Devices | FDA, last visited August 13, 2021.

Written Comment 12
EPD should revoke the Sterigenics permit because EtO is a known carcinogen and the health risks are too great to allow operation. There are lots of residents and schools close by, and the cancer rates around the plant are much higher than other areas. No EtO should be emitted.

EPD Response
Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Georgia issues air quality permits in accordance with Georgia's State Implementation Plan, approved by US EPA, Georgia's Air Quality Act, and Georgia Rules for Air Quality Control- Chapter 391-3-1. Rule 391-3-1-.03 states that an air permit shall be issued upon a determination by the Director that the facility can reasonably be expected to comply with all the provisions of the Act and the rules and regulations promulgated thereunder. In the Air Protection Branch's assessment, there is reasonable evidence that the facility can comply with all applicable provisions of the Act and the rules and regulations and we are recommending issuance of the draft permit.

Written Comment 13
The Sterigenics plant should not be allowed to operate because the air dispersion model shows concentrations due to the plant are above the EPD annual AAC.

EPD Response
Georgia Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions, which provide general procedures for new and expanding permitted facilities, allow that a permit may be granted, even if the modeled concentration is above the AAC screening value, if the facility has installed the maximum level of control. The EPD Air Protection Branch has determined that the controls installed at Sterigenics are the maximum level of control achievable.

Written Comment 14
The permit should be revoked because Sterigenics has a history of compliance violations and lack of transparency.

EPD Response
Based on the information available to EPD at this time, Sterigenics is operating in compliance with its current air quality permit, including all reporting requirements. The are no provisions in the Georgia Rules or Georgia Air Act that authorize a permit to be revoked on the basis of a lack of transparency.

Written Comment 15
Sterigenics should not be allowed to self-report their emissions and compliance status because Sterigenics has a history of compliance violations and lack of transparency.

EPD Response
EPD Response – Concerns about self-reporting were cited by many commentors. "Self-Reporting" – that is, requiring a regulated source to document compliance with emissions standards and associated monitoring, is the basis and the compliance assurance mechanism in every air quality regulation, both state and federal. 40 CFR contains the requirements governing reporting, as set forth in the Clean Air Act. Every emissions standard for every federal maximum achievable control technology standard (MACT), generally achievable control technology standard (GACT), and new source performance standard (NSPS), and the EPA's toxic release inventory (TRI) requires the facility to accurately report under penalty of law. The monitoring, recordkeeping and reporting by the permittee are thoroughly examined by EPD staff as part of the onsite inspection process.

Written Comment 16
The permit should address explosions and fires due to EtO.

EPD Response

Sterigenics is subject to the Chemical Accident Prevention Requirements of 40 CFR Part 68, also called EPA's Risk Management Plan (RMP) rule. The RMP rule requires facilities holding more than a threshold quantity of a regulated substance to develop a Risk Management Plan. These plans are available to local fire, police, and emergency response personnel. RMP requirements are not included in air quality permits.

Written Comment 17
EPD should conduct more ambient monitoring and provide data to the public sooner.

EPD Response
EPD is required by US EPA to conduct monitoring in accordance with an approved Quality Assurance Project Plan (QAPP). Due to significant challenges with the current EPA test method, the EtO samples were analyzed by a third-party lab until October 2021. It takes time for the monitoring samples to be analyzed and for the results to be quality assured. EPD's approved QAPP committed to monitoring in the area near Sterigenics for a six-month period, which started in September 2019. The monitoring continued well beyond the six-month period.

Written Comment 18
The permit should require that the plant immediately shut down if ambient concentrations are deemed unsafe.

EPD Response
Ambient concentration data gathered are 24-hour averages and should not be directly compared with the EPA IRIS-derived value, which assumes a lifetime of continuous exposure. Furthermore, the ambient monitoring data collected in Georgia and in other states indicates that there are other sources of EtO in the ambient air.

EPD began conducting ambient monitoring of EtO in 2019 at various locations around the state, including locations near Sterigenics. The results are posted here. The concentrations EPD is measuring near

Sterigenics are very similar to the concentrations that we are measuring at our South DeKalb monitoring site, which is a National Air Toxics Trends Site, and not near any known source of EtO emissions. The concentrations measured at General Coffee State Park, our rural background site, are averaging slightly lower. The EtO concentrations being measured at our background sites indicate that there are other sources of EtO contributing to the concentration in the air. Other states are finding similar results at their National Air Toxics Trends Sites.

Written Comment 19
The permit should only be allowed if the resulting concentration is zero risk of cancer.

EPD Response

This is what US EPA says about acceptable level of risk:[5] *"Unlike other pollutants that EPA regulates, air toxics have no universal, predefined risk levels that clearly represent acceptable or unacceptable thresholds. However, EPA has made case-specific determinations and made general presumptions that apply to certain regulatory programs. As explained below, we use levels that come from these rulings to guide how we interpret risk in NATA.*

The 1989 Benzene[6] *National Emission Standard for Hazardous Air Pollutants (NESHAP) rule set up a two-step, risk-based decision framework for the NESHAP program. This rule and framework are described in more detail in EPA's 1999 Residual Risk Report to Congress.*

First, the rule sets an upper limit of acceptable risk at about a 1-in-10,000 (or 100-in-1 million) lifetime cancer risk for the most exposed person. As the rule explains, "The EPA will generally presume that if the risk to that individual [the Maximum Individual Risk] is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability."

Second, the benzene rule set a target of protecting the most people possible to an individual lifetime risk level no higher than about 1-in-1 million. These determinations called for considering other health and risk factors, including risk assessment uncertainty, in making an overall judgment on risk acceptability."

EtO emissions, as documented in recent performance testing, are controlled to levels that result in a modeled maximum ambient concentration that is well within the acceptable health risk range used by US EPA.

Written Comment 20
The permit should be revoked and the plant closed due to reduction in nearby property values.

EPD Response
Property values are beyond the scope of the EPD permit application review.

Written Comment 21
The permit should contain procedures for enforcement, punishment, and fines for violations.

[5] NATA Frequent Questions | National Air Toxics Assessment | US EPA, accessed July 11, 2021
[6] *Benzene, like ethylene oxide, is classified by EPA as a hazardous air pollutant and a carcinogenic.*

EPD Response
The draft permit will not be revised to contain such prescriptive information. Enforcement actions are determined in a manner consistent with the Air Protection Branch's Compliance Assurance Strategy.

Written Comment 22
The facility should not be allowed to self-report – EPD or a 3rd party should be in charge of the CEMS.

EPD Response
EPD Response – Concerns about self-reporting were cited by many commentors. "Self-Reporting" – that is, requiring a regulated source to document compliance with emissions standards and associated monitoring, is the basis and the compliance assurance mechanism in every air quality regulation, both state and federal. 40 CFR contains the requirements governing reporting, as set forth in the Clean Air Act. Every emissions standard for every federal maximum achievable control technology standard (MACT), generally achievable control technology standard (GACT), and new source performance standard (NSPS), and the EPA's toxic release inventory (TRI) requires the facility to accurately report under penalty of law. The monitoring, recordkeeping and reporting by the permittee are thoroughly examined by EPD staff as part of the onsite inspection process.

Written Comment 23
EPD should conduct fenceline and regional ambient monitoring and post the results much sooner.

EPD Response
EPD is required by US EPA to conduct monitoring in accordance with an approved Quality Assurance Project Plan (QAPP). Due to the significant challenge with the current EPA test method, the EtO samples are being analyzed by a third-party lab. It takes time for the monitoring samples to be analyzed and for the results to be quality assured. EPD's approved QAPP committed to monitoring in the area near Sterigenics for a six-month period, beginning in September 2019. The monitoring continued beyond the six-month period.

Written Comment 24
Sterigenics does not have the proper county building permits for a high-danger operations.

EPD Response
County building permits are beyond the scope of this permit review.

Written Comment 25
EPD should not use the Texas EtO risk value – it should use the EPA IRIS value.

EPD Response
EPD is using the EPA IRIS value as detailed in Georgia Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions.

Written Comment 25
Conditions 5.6 and 5.7 of the draft permit require a CEMS monitoring plan. The permit should better define the required contents of the plan in order to be enforceable.

EPD Response
The CEMS monitoring plan submitted as required by the draft permit will contain elements specific to the CEMS selected by Sterigenics. The CEMS monitoring plan is subject to approval by EPD. EPD retains the right to require revisions to the CEMS monitoring plan if warranted.

Written Comment 26
Has an ATSDR health study been done in the area?

EPD Response
This question is beyond the scope of the permit review. EPD is sharing all modeling, monitoring and air pollution control information with the Georgia Department of Public Health and the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR held community availability sessions in September 2021 for community members living near Sterigenics as part of their public health consultation process.

Written Comment 27
Condition 7.6 defines excess emissions and requires semi-annual reporting. The permit should require immediate reporting of excess emissions at the time that they happen.

EPD Response
Condition 7.6 is a template permit condition, and the reporting frequency is consistent with the reporting frequency for other sources with synthetic minor permits. In addition to Condition 7.6, the draft permit requires prompt reporting of usage in excess of the usage limits (Condition 7.8 and Condition 7.9). Condition 7.15 requires the reporting of any spill or unpermitted release of EtO within 24 hours.

Written Comment 28
Condition 7.1 of the permit should be modified to extend the recordkeeping requirement from 5 years to 10 years in light of the time it may take the adverse effects of EtO emissions to manifest.

EPD Response
The requirement to maintain records onsite for five years is consistent with all other synthetic minor permits issued by EPD.

Written Comment 29
The draft permit assumes that there are no fugitive emissions of EtO; this is improbable and EPD must add EPD-conducted ambient monitoring to ensure there are no fugitives.

EPD Response
The draft permit does not require zero fugitive emissions. The draft permit ensures the fugitive emissions are minimized to the maximum extent possible by requiring the operation and monitoring of a negative airflow system inside the plant to ensure EtO in the workspace or sterilized product warehouse and shipping area are captured and routed to air pollution control devices.

Written Comment 30
The permit should better establish the EtO CEMS sensitivity and accuracy levels.

EPD Response
The CEMS monitoring plan required by Condition 5.7 is subject to approval by EPD. This plan is expected to cover in detail the sensitivity and accuracy levels to EPD's satisfaction.

Written Comment 31
The draft permit regulates EtO emissions in unprecedented ways. Georgia EPD did not conduct a public comment period on the use of the EtO AAC, which is actually much lower than background concentrations in the air.

EPD Response
The Georgia Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions is not subject to public comment. The guidelines are used in the review of air quality permit applications for sources that emit a Toxic Air Pollutant. The AAC is a screening values and not regulatory limit. EPD agrees that the AAC for EtO is below the background concentrations generally being found in the air. That is why EPD relies on modeling to determine the potential impact of a facility, and not on ambient or fenceline monitoring.

Written Comment 32
CEMS should not be required by the permit because the current CEMS technology is too new and not reliable.

EPD Response
While the technology for EtO CEMS is somewhat new, there are at least two vendors of these CEMS. For example, Illinois EPA has required EtO CEMS at facilities in their state. EPD confirmed from Illinois EPA that the CEMS are operational with acceptable results. Furthermore, the draft permit is allotting time before the CEMS must be installed in order to allow time to select the CEMS and develop and submit a monitoring plan for the CEMS.

Written Comment 33a
The 84 lb/yr cap is too low.

EPD Response
The 84 pound per year EtO cap in the January 2021 draft permit was proposed as an additional performance assurance measure for the air pollution controls installed and operating at the facility. It was based on single stack tests, with no accounting for the variability that may occur due to control equipment performance, stack test/lab analyses, or CEMS accuracy. EPD has reviewed the comments received on the cap, along with other information available to us. The ethylene oxide emissions cap is not in the final permit. EPD determined that additional data is needed in order to establish a cap. EPD may establish an emissions cap in the future; after US EPA finalizes expected revisions to the federal rule for ethylene oxide commercial sterilizers. The facility will still be required to report monthly EtO emissions in each semiannual report.

Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent

performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Other requirements, such as CEMs, emissions tracking, and control equipment parameter monitoring, will remain. The permit remains protective of human health. EPD reserves the right to establish a facility-wide emissions cap based on additional information, including upcoming revisions to 40 CFR 63 Subpart O.

See end of narrative for a list of changed permit conditions.

Written Comment 33b
Because other sources of background EtO exist, EPD should regulate those sources (vehicles, grills, etc.) using the same metrics used for Sterigenics.

Vehicles and grills are exempt from stationary source permitting.

Written Comment 34
EtO is critical for sterilizing medical equipment.

EPD Response
Comment noted.

Written Comment 35
EPD should not issue permits to a facility that is not in good standing with other permits/requirements.

EPD Response
Based on the information available to EPD at this time, Sterigenics is operating in compliance with its current air quality permit. Georgia Air Quality regulations do not address permitting/requirements beyond the authority of EPD.

Written Comment 36
The CEMS should be structured to analyze both the inlet and outlet concentrations of each process (vacuum pumps, backvents, aeration room, and fugitive) to ensure the control devices are achieving the claimed control efficiency and ensure that the fraction attributed to each source (95% for vacuum pumps, etc.) is valid.

EPD Response
The CEMS requirement is there to monitor emissions from the facility as a whole. CEMS may only be used for compliance with Subpart O (which contains a removal efficiency requirement) if EPA approves such a method.

Written Comment 37
EPD should consider EtO risk data from Texas TCEQ and EPA's OPP instead of relying on the EPA IRIS value. The IRIS value was established using incorrect and atypical procedures that overestimate the risk by a factor of roughly one thousandfold.

EPD Response
Georgia EPD will continue to use the IRIS risk value for EtO because the Texas risk value has not been recognized as the national risk metric by EPA. If EPA revises their IRIS risk value for EtO, EPD will use the revised IRIS risk value.

Written Comment 38
All collected data should be made available to the public in a form comprehensible to the general public.

EPD Response
EPD's EtO webpage is here: https://epd.georgia.gov/ethylene-oxide-information. Additional data will be made available to the public in accordance with the Georgia Open Records Act.

Written Comment 39
Setting the annual EtO emissions cap on single stack test results is arbitrary; the limit should be based on a level aimed at protecting health.

EPD Response
The 84 pound per year EtO cap in the January 2021 draft permit was proposed as an additional performance assurance measure for the air pollution controls installed and operating at the facility. It was based on single stack tests, with no accounting for the variability that may occur due to control equipment performance, stack test/lab analyses, or CEMS accuracy. EPD has reviewed the comments received on the cap, along with other information available to us. The ethylene oxide emissions cap is not in the final permit. EPD determined that additional data is needed in order to establish a cap. EPD may establish an emissions cap in the future; after US EPA finalizes expected revisions to the federal rule for ethylene oxide commercial sterilizers. The facility will still be required to report monthly EtO emissions in each semiannual report.

Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Other requirements, such as CEMs, emissions tracking, and control equipment parameter monitoring, will remain. The permit remains protective of human health. EPD reserves the right to establish a facility-wide emissions cap based on additional information, including upcoming revisions to 40 CFR 63 Subpart O.

See end of narrative for a list of changed permit conditions.

Written Comment 40
Sterigenics actual emissions are currently (emissions chart showing allowable vs actual emissions for year 2016-2019) approximately 5.2% of the allowable as established in the current permit, and with the additional controls, future actual emissions should be less than 100 pounds per year.

EPD Response
Comment noted.

Written Comment 41
Sterigenics contracted with independent 3rd party testing companies to conduct emissions testing and those tests were overseen and reviewed by EPD.

EPD Response
Comment noted.

Written Comment 42
The 84 lb/yr annual emissions cap is not the potential emissions from the facility, PTE is defined as the emissions physically capable taking into account legally and practically enforceable limitations. The variability associated with stack testing makes a limit based on a single test technically unsound. US EPA has ruled that a permitting agency has the discretion to set an emissions limit based on a control efficiency that is lower than the tested, or optimal value. An annual emission limit is not necessary, and if a limit is required by EPD, it should be no less than 153 lb/yr to take into account even the slightest variability in test results or EtO fractions going to the vacuum pumps. The difference between 84 lb/yr and 153 lb/yr is only 7 ten thousandths of a percent difference in tested control efficiency on the vacuum pump controls. And 2 tenths of one percent on the tested control efficiency for the aeration room and backvent controls.

EPD has reduced required control efficiencies in other permits (including Transcontinental Albany in 2020)

EPD Response
The 84 pound per year EtO cap in the January 2021 draft permit was proposed as an additional performance assurance measure for the air pollution controls installed and operating at the facility. It was based on single stack tests, with no accounting for the variability that may occur due to control equipment performance, stack test/lab analyses, or CEMS accuracy. EPD has reviewed the comments received on the cap, along with other information available to us. The ethylene oxide emissions cap is not in the final permit. EPD determined that additional data is needed in order to establish a cap. EPD may establish an emissions cap in the future; after US EPA finalizes expected revisions to the federal rule for ethylene oxide commercial sterilizers. The facility will still be required to report monthly EtO emissions in each semiannual report.

Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent

performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Other requirements, such as CEMs, emissions tracking, and control equipment parameter monitoring, will remain. The permit remains protective of human health. EPD reserves the right to establish a facility-wide emissions cap based on additional information, including upcoming revisions to 40 CFR 63 Subpart O.

See end of narrative for a list of changed permit conditions.

In regard to Transcontinental Albany, the efficiency was reduced because it was not a statutory requirement, the facility demonstrated compliance with Georgia Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions at the reduced efficiency level, and the reduction did not affect the facility's overall emission limit.

Written Comment 43
Condition 7.4 of the permit, requiring a reporting of CEMS readings of 0.1 ppm, should be removed from the permit and put in the CEMS plan in Condition 5.5 because this value has not been evaluated to determine if it is appropriate.

EPD Response
EPD agrees. EPD will delete subparagraph 7.4h. CEMS will continue to be required to track emissions from the control devices.

Written Comment 44
The permit should be modified to allow for a review period while using the CEMS and opportunity to raise any annual emissions limit based on the performance of the CEMS because any difference between stack test accuracy and CEMS accuracy can result in a determination of violation of the cap, even if the control equipment is still operated as always. For example, the stack method used in 2020 required special EPA approval and has a lower detection limit than the existing method used for NESHAP Subpart O compliance. If the existing test method would have been used, the tested efficiency would be less due to non-detect readings.

EPD Response
The permit allows one year after the permit is issued to install and begin operating the CEMS. This is ample time to prepare and evaluate the performance of a CEMS.

Comment 45
The requirement in Conditions 6.2, 6.3, and 6.4 of the proposed permit to conduct stack tests every 24 months in unnecessary once the CEMS is installed and operational. A periodic Relative Accuracy Test Audit (RATA) should be done instead of performance tests. The CEMS can be used to estimate the overall efficiency of the plantwide controls by comparing the EtO usage and the CEMS emissions data.

EPD Response
The draft permit has been amended to require an initial performance test after permit issuance, subsequent 24-month performance tests and re-establishing scrubber parameters has been removed. A condition has been added requiring a RATA every 12 months. EPD understands that RATA will be an essential part of CEMS operations and those RATA must be performed at a frequency that is stricter than the proposed testing.

Written Comment 46
Conditions 6.2 and 6.3 require that scrubber pH ranges be reset during a compliance test. This is unnecessary and should be removed.

EPD Response
To ensure that control equipment maintain efficiency throughout the equipment lifetime, periodic re-evaluations of such parameters are standard protocol for EPD air quality permits.

Written Comment 47
Proposed permit Condition 5.4c should be revised to allow the facility 30 days to replace the dry beds upon two consecutive sample bag reading greater than 0.5 ppm. The bed depletion is a gradual process and the beds will still absorb EtO emissions for a period. This is consistent with requirements in other areas of the nation.

EPD Response
This requirement is only temporary until the CEMS is installed and ensures that periods of less than optimal operation of the dry bed are minimized.

Written Comment 48
Condition 5.4 requires monitoring of the AAT to meet the required reduction efficiency of 99% for the chamber vents and the requirement, for the aeration and backvent emissions, of a reduction efficiency of 99% or 1 ppm concentration. Since the chamber vent reduction efficiency is met with the Ceilcote scrubber alone, the facility is not relying on the AAT to meet 99% for the chamber vent. Therefore, we interpret 5.4 to mean that the monitoring can be based on the 99% reduction outlined in 5.4a or 1 ppm outlet concentration outlined in 5.4b. Please confirm that this assumption is correct.

EPD Response
Condition 5.4 has been revised to remove the reference to the chamber vents, which can comply with the MACT using the Ceilcote scrubber alone. The 99% reduction efficiency refers to the optional 99% or 1 ppm limit as they apply to the backvents and aeration room.

Written Comment 49
The proposed monthly reporting of EO usage and emissions is overly complicated. Permit Conditions 7.8 and 7.10 require monthly reporting when monthly EO usage exceeds 52,083 pounds or monthly EO emissions exceed 7 pounds. These values were calculated using the annual limit and dividing by 12 months in a year. Because of daily and monthly variations, the monthly EO usage and emissions may commonly exceed 1/12 of a rolling 12-month amount even though the annual usage and emissions will not exceed their limits. In addition, planned maintenance shutdowns occur at least annually. These shutdowns will result in less EO usage and emissions during that month; this, in turn, will cause unrepresentative variability in the EO monthly usage and emission estimates.

The draft permit also imposes several other reporting requirements for usage and emissions as follows:
1. Monthly reporting when 12-month rolling usage and emission limits are exceeded (Condition 7.9 and 7.11)
2. Semi-annual reporting of monthly EO usage and emissions and 12 month rolling usage and emissions (Condition 7.14)
3. Immediate reporting of any spill or release within 24 hours of incident. (Condition 7.15)

The immediate, monthly, and semiannual reporting requirement required in Conditions 7.9, 7.11, 7.14 and 7.15 should be sufficient information to determine status of compliance. Requiring another report when permit limits are not exceeded does not provide any additional insight into the compliance status of the facility. In addition, Conditions 7.8 and 7.10 require an explanation of how the facility intends to maintain compliance with the limits. However, as stated previously the monthly usage and emissions are expected to vary due to the nature of a batch process and the explanation is inherent in the definition of a batch process. We ask that EPD not include Conditions 7.8 or 7.10 in the final permit and incorporate more flexibility for the varying monthly amounts.

Condition 7.6 requires that a semiannual report be postmarked by August 29 and February 28 to meet 40 C.F.R. § 63.10(e) and Georgia Rule 391-3-1-.02(6)(b)1. However, 40 C.F.R. § 63.10(e) requires this report to be postmarked 30 days following the reporting period, which would be July 30 or January 30. Please clarify the expected report due date.

Similar to the monthly EO usage reporting requirement, Condition 7.12 requires reporting of propylene oxide if usage exceeds 416 pounds in a month. This value was calculated using the annual limit and dividing by 12 months in a year. Propylene oxide is used for a limited number of products that are received very few times during the year. Therefore, monthly propylene oxide usage reporting is not necessary nor would it indicate a potential compliance.

EPD Response
EPD will amend the permit to require all reports due within 30 days after the semiannual period.

Written Comment 50
Raising the annual cap from 84 lb/yr to 153 lb/yr would have no significant impact on EtO air dispersion modeling results, and the impacts from the facility are well below the background EtO level measured via ambient monitoring in the local area and in other parts of Georgia.

EPD Response
Comment noted

Written Comment 51
The measured air quality of EtO when the Sterigenics facility was closed down was much lower (non-detects to threshold for cancer risk concerns), but when the plant reopened, the ambient monitoring showed values well above the threshold and even tripled during a reported spill.

EPD Response
Ambient air monitoring results are beyond the scope of this permit action.

EPD began conducting ambient monitoring of EtO in 2019 at various locations around the state, including locations near Sterigenics. The results are posted here.

- *The concentrations EPD is measuring near Sterigenics are very similar to the concentrations that we are measuring at our South DeKalb monitoring site, which is a National Air Toxics Trends Site, and not near any known source of EtO emissions. The concentrations measured at General Coffee State Park, our rural background site, are averaging slightly lower.*

- *The data is variable and the data precision is not good. This indicates that the EPA method for analyzing for EtO needs improvement at the very low concentrations present in ambient air.*
- *The EtO concentrations being measured at our background sites indicate that there are other sources of EtO contributing to the EtO concentration in the air.*
- *Other states are finding similar results at their National Air Toxics Trends Sites.*

Written Comment 52
The permit, if granted, should contain stipulations for damages to neighbors if the company violates the permit.

EPD Response
Enforcement actions are determined in a manner consistent with the Air Protection Branch's Compliance Assurance Strategy. Georgia Law requires any monetary penalty assessed for air quality violations to be deposited in the State Treasury to the credit of the general fund. In accordance with Code Section 12-2-2(e), the funds are to be available for appropriation by the General Assembly to the Division for inclusion in the Hazardous Waste Trust Fund.

Written Comment 53
The permit, if granted, should contain a provision to revoke the permit if new data showing even higher risk becomes available.

EPD Response
Condition 8.1 of the draft permit states "At any time that the Division determines that additional control of emissions from the facility may reasonably be needed to provide for the continued protection of public health, safety and welfare, the Division reserves the right to amend the provisions of this Permit pursuant to the Division's authority as established in the Georgia Air Quality Act and the rules adopted pursuant to that Act."

Written Comment 54
The permit should require strict notification requirements to neighbors.

EPD Response
Requiring a permittee to notify the neighbors is beyond the scope of the air quality permitting process. The requirement in SB 426 that the (EPD) "…director shall make publicly available on the division's website information regarding any spill or release of EtO reported to the division pursuant to paragraph (3) of subsection (a) of Code Section 12-9-7;" is a requirement for EPD, not the permittee.

Written Comment 55
EPD or other agencies should commission research on the environmental impact of this facility's emissions of EtO and offer training and technology resources to assist with dealing with EtO in the air.

EPD Response
Comment noted.

Written Comment 56
Sterigenics and the EtO industry have known for years of the hazards and toxicity of EtO, but failed to act to minimize emissions, and acted to strike down a more stringent version of the MACT Subpart O which would have required backvent controls years ago.

EPD Response
Comment noted.

Written Comment 57
The penalty/enforcement action for violating the permit should be immediate shut down, not just a monetary fine.

EPD Response
Enforcement actions are determined in a manner consistent with the Air Protection Branch's Compliance Assurance Strategy.

Written Comment 58
The strict emission limit set at stack tested efficiencies appears to punish Sterigenics for having good pollution controls and does not allow for any variation on performance efficiency of the control equipment, or even variations in monitoring conditions. Permit limits should be based on day-to-day operations and should realistically be set to achieve compliance. This limit sets the stage for non-compliance situations and potential curtailment of production to comply. This does not set a good precedent for air quality permits in Georgia.

EPD Response
The 84 pound per year EtO cap in the January 2021 draft permit was proposed as an additional performance assurance measure for the air pollution controls installed and operating at the facility. It was based on single stack tests, with no accounting for the variability that may occur due to control equipment performance, stack test/lab analyses, or CEMS accuracy. EPD has reviewed the comments received on the cap, along with other information available to us. The ethylene oxide emissions cap is not in the final permit. EPD determined that additional data is needed in order to establish a cap. EPD may establish an emissions cap in the future; after US EPA finalizes expected revisions to the federal rule for ethylene oxide commercial sterilizers. The facility will still be required to report monthly EtO emissions in each semiannual report.

Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Other requirements, such as CEMs, emissions tracking, and control equipment parameter monitoring, will remain. The permit remains protective of human health. EPD reserves the right to establish a facility-wide emissions cap based on additional information, including upcoming revisions to 40 CFR 63 Subpart O.

See end of narrative for a list of changed permit conditions.

Written Comment 59
EPD should consider using a different risk factor than the IRIS, and EPD should consider using a different risk rate; for example, the MON uses 200 in a million as acceptable risk. Setting such tight limits in order to meet a risk factor is unprecedented and a bad precedent for Georgia air permits.

EPD Response
Such limits are not unprecedented. Georgia has issued many permits spanning decades that contain emission limits developed with the use of the Georgia Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions.

Written Comment 60
Kevin Wagner – Sterigenics – source test statistical analysis showing variability.

EPD Response
The 84 pound per year EtO cap in the January 2021 draft permit was proposed as an additional performance assurance measure for the air pollution controls installed and operating at the facility. It was based on single stack tests, with no accounting for the variability that may occur due to control equipment performance, stack test/lab analyses, or CEMS accuracy. EPD has reviewed the comments received on the cap, along with other information available to us. The ethylene oxide emissions cap is not in the final permit. EPD determined that additional data is needed in order to establish a cap. EPD may establish an emissions cap in the future; after US EPA finalizes expected revisions to the federal rule for ethylene oxide commercial sterilizers. The facility will still be required to report monthly EtO emissions in each semiannual report.

Sterigenics has an existing air quality permit, which remains in effect. The draft permit ensures the continued operation of the new air pollution controls, which were installed for the purpose of reducing EtO emissions. The draft permit goes beyond the current air quality permit and the current federal rule regulating EtO emissions from commercial sterilizers. The draft permit also includes enhanced emissions monitoring and emissions reporting. The control equipment required to be operated by this permit is considered "New Source MACT" as per Georgia's Guideline for Ambient Impact Assessment Of Toxic Air Pollutant Emissions. "New Source MACT" is defined as the control technology which reflects the maximum degree of reduction in emissions of hazardous air pollutants that the Director determines is achievable by the source, provided that such control technology is no less effective than the level of emission control which is achieved in practice by the best controlled similar source. EtO emissions, as documented in recent performance testing, are controlled in the draft permit to levels that result in a modeled maximum ambient concentration that is well within the acceptable risk range used by US EPA.

Other requirements, such as CEMs, emissions tracking, and control equipment parameter monitoring, will remain. The permit remains protective of human health. EPD reserves the right to establish a facility-wide emissions cap based on additional information, including upcoming revisions to 40 CFR 63 Subpart O.

See end of narrative for a list of changed permit conditions.

Narrative changes:

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	9,750	532	84.7
Max. Individual HAP (EO)	9,375	528	84
Total HAP	9,750	532	84.7

POTENTIAL EtO emissions (after mod) are calculated as follows:

E = Usage * [[A * (1-.9999)] + [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%; Effective required minimum control efficiency based on design and Subpart O is 99.99% - 99% for ceilcote, 99% for AAT scrubber
B = Predicted fraction vented through aeration: 4%; Effective required minimum control efficiency based on Subpart O is 99% for AAT
C = Predicted fraction vented through backvents: 1%; Required control efficiency in permit is 99%
D = Fraction assumed associated with workspace: 0.5%. Estimated average control efficiency is 95%. 99% is achievable most of the time, but if inlet concentrations get low, efficiency may decrease (overall outlet concentrations are expected to remain fairly constant)

E = 625,000 * {[0.95 * (1-.9999)] + [0.04 * (1-.99)] + [0.01 * (1-.99)] + [0.005 * (1-.95)]}
E = 528 pounds EtO per year

The same equation was used to calculate post-modification potential PO emissions:
E = 5,000 * {[0.95 * (1-.9999)] + [0.04 * (1-.99)] + [0.01 * (1-.99)] + [0.005 * (1-.95)]}
E = 0.4 pounds PO per year

Estimated actual emissions will remain as stated in the original narrative for allowable emissions – 84 lb/yr of EtO.

Permit Conditions changed due to public comment (not including minor formatting or punctuation changes made to some Conditions):

Existing Condition 2.2 (emissions cap). Condition deleted and all subsequent conditions in Section 2 renumbered accordingly.

Conditions 4.4, 4.5, 4.6, 4.7 were revised to remove the reference to prior Condition 2.2 (emissions cap).

Condition 5.4 was revised to remove reference to chamber vents because the Ceilcote Scrubber (not the AAT Scrubber System with Dry Bed Adsorbers) is used to comply with Subpart O.

Condition 5.4 a. and b. - The last sentence allowing less frequent monitoring upon CEMS installation has been deleted. Monitoring per this requirement will remain weekly.

Condition 5.4c. - Added a requirement to use the CEMS to ensure performance of the AAT dry beds. If the 30-day rolling average (each day starts a new period) is greater than 0.2 ppm, the bed material must be changed within 30 days unless EPD approves a different schedule. This trigger value is lower than the "bag sample" trigger value of 0.5 ppm because the CEMS will allow for a lower detection limit and will provide for a longer averaging time to "smooth out" any short-term measurements that are outside the normal range.

Condition 5.5c. - Added a requirement to use the CEMS to ensure performance of the AAT dry beds. If the 30-day rolling average (each day starts a new period) is greater than 0.2 ppm, the bed material must be changed within 30 days unless EPD approves a different schedule. This trigger value is lower than the "bag sample" trigger value of 0.5 ppm because the CEMS will allow for a lower detection limit and will provide for a longer averaging time to "smooth out" any short-term measurements that are outside the normal range.

Condition 5.8 - additional requirement were added to address on-site truck operations.

Conditions 6.2, 6.3, 6.4 – revised to remove the subsequent stack testing every 2 years. This is not needed due to required use of a CEMS.

Condition 6.5 was added to require an annual Relative Accuracy Test Audit (RATA) on the CEMS. A RATA is essentially a stack test.

Condition 7.4 h. has been removed. The newly added requirements in Conditions 5.4c. and 5.5c. make this provision unnecessary.

Condition 7.6 – reporting requirement revised from 60 days to 30 days.

Condition 7.10 – removed the prompt reporting requirement because the emissions cap has been removed.

Condition 7.11 - removed the prompt reporting requirement because the emissions cap has been removed.