GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

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

Compliance Monitoring Report

1. General Information

Date of Inspection:	August 21, 2020
Date of Report Completed:	September 3, 2020
Compliance Monitoring Category:	Announced Inspection
Inspector Name:	Sherry Waldron
Reviewing Manager:	Stephen Damaske

2. Facility Information

Facility Name:	Sterigenics U.S. LLC
Facility AIRS No.:	067-00093
Facility Location:	2971 Olympic Industrial Drive SE, Suite 116 Atlanta, Georgia 30339, Cobb County
Facility Mailing Address:	2015 Spring Road, Suite 650 Oak Brook, Illinois 60523
Facility Contact:	Daryl Mosby, General Manager 404-355-4485 dmosby@sterigenics.com Elbert Sabb, Operations Manager
CMS Designation:	Synthetic Minor Source

Air Quality Permit No. 7389-067-0093-S-05-0 **Effective Date: May 27, 2014**

Issued for the operation of an ethylene oxide and propylene oxide sterilization facility. The Permit is also for the installation and operation of a 30-pallet sterilization chamber and an aeration room.

Air Quality Permit Amendment No. 7389-067-0093-S-05-1 **Effective Date: November 17, 2014**

Issued for change of address from Smyrna to Atlanta.

Air Quality Permit Amendment No. 7389-067-0093-S-05-2 **Effective Date: April 1, 2015**

Issued for the installation and operation of a new 30-pallet chamber and vacuum pump.

Air Quality Permit Amendment No. 7389-067-0093-S-05-3 **Effective Date: August 27, 2015**

Issued for the installation and operation of a new 30-pallet chamber and vacuum pump (Chamber 11: SEV-11 and CEV-11), an ownership and address change, and the routing of the sterilization chamber back vents to the existing AAT scrubber (EC2).

Permit(s) can be accessed at epd.georgia.gov/air

3. Inspection Summary / Recommended Actions:

The inspection was conducted to verify compliance with the requirements of Georgia Air Quality Permit No. 7389-067-0093-S-05-0, effective May 27, 2014, as amended.

No deviations from the Permit were discovered during the inspection.

Based upon my observations and the records reviewed, it appeared that the facility was in compliance with Georgia Air Quality Permit No. 7389-067-0093-S-05-0 and its amendments at the time of the inspection.

4. Previous Enforcement Actions and Inspections:

Consent Order No. EPD-AQC-6980 was executed on August 7, 2019. The Order required the facility to install additional controls for fugitive emissions from those portions of the facility where the products that had been sterilized were temporarily transported through or stored. In addition, a Work Practice Plan for implementing work practices for minimizing fugitive emissions and to enhance fugitive emission capture was required. The Order was terminated on May 12, 2020.

The most recent previous inspection was conducted on October 25, 2017.

See attached Full Compliance Evaluation (FCE) Report for details.

5. Complaint Investigations since last Full Compliance Evaluation:

Table 5

Complaint Tracking System Number	Date Received	Nature of Complaint	Status
85858	4/4/2018	Facility reported release notification	Closed
86815	7/10/2018	Facility reported an isolated deflagration without a release	Closed
90554	7/25/2019	Caller expressed general concern about health risks from living nearby	Closed
90624	8/2/2019	Caller alleges release of EtO to the atmosphere, occurring for quite some time	Closed
91046	8/27/2019	Facility reported possible leak	Closed
92635	2/19/2020	Activity was observed at the facility despite prohibition by County against operation	Closed

6. Applicable Requirements, Description of Regulated Emission Units, and Inspection Determinations:

Table 6

Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
SEV-1	Six-pallet Sterilization Chamber 1 vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber	Yes. In compliance. Each sterilizing chamber was observed, although identification of individual units was not attempted. All chambers are all located within one area of the facility. No chamber doors were open during the inspection, nor was there any unloading/loading operations in that area occurring during the inspection. The aeration room was observed from outside of access doors through the glass. All areas subject to indoor air control were observed. Particular attention was spent looking at vent and piping integrity. Scrubbers were observed, and the most recent determinations of pH, ethylene glycol concentration, and tank level were obtained. All observations indicated compliance. No issues were noted with the scrubbers. Floors and piping were free of obvious spills or leaks and housekeeping was excellent throughout the facility. Outer walls in the negative pressure area were scanned for openings, with several previous openings now covered permanently (such as a very large back rollup door originally installed to place the large sterilization chambers inside the facility). No truck loading operations were being conducted at the time of the inspection.
SEV-2	Six-pallet Sterilization Chamber 2 vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-3	Nine-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-4	Five-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-5	Thirteen-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-6	Thirteen-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-7	Thirteen-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-8	Thirteen-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
SEV-10	Thirty-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 6.2, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		

Table 6						
Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
SEV-11	Thirty-pallet Sterilization Chamber vacuum pump	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.3, 6.1, 6.2, 6.4, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.1, 8.2, 8.3	EC2 EC3	AAT Scrubber System (with Dry Bed Adsorber) Ceilcote Scrubber		
CEV-1	Back vent for Chamber 1	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-2	Back vent for Chamber 2	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-3	Back vent for Chamber 3	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-4	Back vent for Chamber 4	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-5	Back vent for Chamber 5	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-6	Back vent for Chamber 6	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-7	Back vent for Chamber 7	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-8	Back vent for Chamber 8	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-9	Back vent for Chamber 9	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-10	Back vent for Chamber 10	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
CEV-11	Back vent for Chamber 11	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 3.1, 4.1, 4.2, 4.3, 6.5	EC2	AAT Scrubber System (with Dry Bed Adsorber)		
AR-1	Aeration Room 1	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.4, 6.1, 6.3, 7.1, 7.2, 7.3, 7.4, 7.6, 7.7, 8.1, 8.2, 8.3	EC2	AAT Scrubber System (with Dry Bed Adsorber)		

7. Compliance Monitoring Activities – Details not included in table above:

a. Describe any deviation from compliance noted during the inspection listed on Table 6: None observed.

b. Describe any compliance assistance provided during inspection: None needed.

c. Describe any action taken by the facility to come back into compliance during the inspection: None needed.

d. Deviations noted during the inspection, not previously listed. Include equipment ID or equipment description and condition number: None identified.

8. Additional Permit Requirements:

a. Periodic Reports:
Submitted as required.
See attached Full Compliance Evaluation (FCE) Report for details.

b. Permit Fees:
Paid as required.
See attached Full Compliance Evaluation (FCE) Report for details.

c. For any overall emission/production/usage limit:

Table 8.d.

Permit Condition	Permit Limit	Actual
2.1, 2.2, 2.3, 2.4	Meet requirements of Ethylene Oxide Emission Standards for Sterilization Facilities – Subpart O Reduce emissions from each Sterilization Vent by 99%. Reduce emissions from Aeration Vent AR-1 to 1 ppm or by 99%, whichever is less stringent.	In compliance. Last tested on June 24-25, 2020. See attachment for performance test details. See below for details of specifics of compliance with Subpart O.
2.6	Fire only natural gas in all fuel burning units. Periodic testing of liquid fuel shall not exceed 48 hours during any calendar year	In compliance. I verbally confirmed this with Mr. Mosby during the inspection. No fuel oil has been burned for some time at the facility.

9. Attachments:

a. Inspection Observations:
See attachment

b. Performance Tests:
See attachment

c. Full Compliance Evaluation (FCE) Report:
See attachment

d. Inspection Attachments:
Printout of Chain of emails Requesting Records/Inspection Plan
Example training records
Example daily EH&S Logsheet, July 13, 2020
Example AAT Aeration/Indoor Air Sample log
Replacement date for the AAT Aeration dry scrubber

Attachment: Inspection Observations

Fugitive Emissions

Permit Condition	Permit Limit	Observation
3.1	Minimize fugitive emissions.	In compliance. No fugitive emissions were observed during the inspection. A negative pressure system is now employed by the facility to control fugitive EtO emissions within non-process areas where sterilized product is transported or stored prior to shipment. This dry bed scrubber system was in operation. Individual pressure sensors are located on each bed, and the overall pressure drop is also monitored.

Process & Control Equipment

Permit Condition	Permit Limit	Observation
4.1	Conduct routine maintenance as needed. Maintain maintenance records.	In compliance. An in-house system, EAM (Enterprise Asset Management), is used to track and schedule routine maintenance and generate work orders for repairs. The good housekeeping and appearance of the facility indicated maintenance is conducted. Records such as calibration records were reviewed to confirm compliance as well.
4.2	A spare parts inventory for control equipment shall be maintained.	In compliance. Control equipment parts are primarily within the vacuum pumps and those needed to ensure the vent system is air tight. Redundant parts are maintained for critical systems. The process shuts down automatically if a vacuum is not established, according to Mr. Mosby. The spare parts list includes blower pump parts, booster fan parts, pressure sensors, and extra dry bed material (currently 18 super sacs).
4.3	Implement repairs to control equipment as expeditiously as possible.	In compliance. Repairs appeared to be made as required based on observations of the facility conditions and the presence of maintenance employees actively working on ancillary equipment during the inspection.

Monitoring

Permit Condition	Monitoring Requirement	Observation
5.1	All monitoring systems shall be in continuous operation. Maintenance and repair shall be conducted to minimize periods of non-service.	In compliance. Monitoring systems consist of the tank level indicator (a visual non-mechanical indicator), a separate pH meter, a gas chromatograph and an ethylene oxide concentration meter. Additional pressure drop monitors had been installed since the last inspection in areas where negative pressure is required to be maintained as well as across dry bed scrubbers.
5.2, 5.3	For the AAT Scrubber (Source Code EC2) and the Ceilcote Scrubber (Source Code EC3) install and maintain monitoring devices for the measurement of scrubber liquor level in the recirculation tank (a liquid level indicator) and the pH of the scrubber liquor for each of the scrubbers. Maintain the level of the scrubber liquor at or below the levels established during the initial performance testing. The pH levels of the scrubber liquor shall be maintained in accordance with the pH levels recommended by the manufacturers. Measurements shall be made weekly.	In compliance. pH levels below 2? YES – 0.9 for the Ceilcote, 0.54 for the AAT. Based on records, the max this level has been recently is 1.2. Tank levels on EC-2 126 inches, 89 inches for the AAT; max levels recently were 150/100 inches based on review of records Glycol concentration: 39% for the Ceilcote, 37.2% for the AAT (these are typical concentrations) (not a compliance parameter) Weekly records were also spot-checked and indicated compliance. An example checklist is attached.
5.4	Maintain and operate the AAT Scrubber System (Source Code: EC2) to ensure a maximum emission level of 1 ppmv or a reduction of 99% for aeration room vents (Source Code: AR-1) and a reduction efficiency of 99% for sterilization chamber vents (Source Codes SEV-1 through SEV-8, SEV-10 and SEV-11). a. For Source Code AR-1, collect and record the concentrations of a 15-minute ethylene oxide bag sample from both the inlet and the outlet of the dry bed adsorber monthly. i. When complying with the 1 ppmvd standard, if the concentration of ethylene oxide in the outlet sample of the dry bed adsorbers increases to 0.9 ppmv or greater, replace the dry bed material	

	within 30 days. ii. When complying with the 99% reduction efficiency standard, if the AAT Scrubber System reduction efficiency decreases to 99.1% or less, replace the dry bed material within 30 days. The AAT Scrubber System reduction efficiency shall be calculated by comparing the ethylene oxide loading into the AAT Scrubber System to the ethylene oxide mass exiting the dry bed adsorbers. b. For Source Code AR-1and Source Codes SEV-1 through SEV- 8, SEV-10 and SEV-11, when sterilization chamber exhausts and aeration room exhausts are simultaneously vented through the AAT Scrubber System, comply with the 99% reduction efficiency standard. Collect and record the concentration of a 15-minute ethylene oxide bag sample from the outlet of the dry bed adsorbers within 96 hours of the changeover. The AAT Scrubber System reduction efficiency shall be calculated by comparing the ethylene oxide loading into the AAT Scrubber System to the ethylene oxide mass exiting the dry bed adsorbers. If the reduction efficiency for the AAT Scrubber System is less than 99.1%, the Permittee shall not route any sterilization chamber exhausts through the AAT Scrubber System until the dry bed material has been replaced. Bag testing shall continue at a sampling frequency of once per week during the changeover of the sterilization chamber vents from the Ceilcote Scrubber (Source Code: EC3) to the AAT Scrubber System. c. For a and b above, the AAT Scrubber System reduction efficiency shall be recorded for each sampling event. d. The dates of dry bed material replacement shall be recorded and maintained on file.	In compliance. The facility uses a gas chromatograph to determine ethylene oxide concentrations from the inlet and outlet of the dry bed system. Records were spot-checked. A sample analysis for both the Aeration Room AAT and the Indoor System is attached. Records indicate the max inlet of the Indoor Air system was 0.9 with the outlet being nondetect each time. Max AAT Aeration system inlet was 17.3, although this is typically closer to zero as well, with nondetect at the outlet. Previous inspection: Dry beds last replaced on August 15, 2014. Current Inspection: The dry bed had been replaced on December 17, 2019 based on the memo documenting the event, attached. Records indicated that replacement has not been necessary based on dry bed material inlet and outlet concentrations. Recent testing has also confirmed the material is performing well above the required reduction efficiency.

Notification, Reporting and Record Keeping

Permit Condition	Permit Limit	Observation
7.1	Maintain records of any startup, shutdown, or malfunction, any malfunction of the air pollution control equipment or any periods during which a continuous monitoring system or monitoring device is inoperative. Retain records for a period of five years.	In compliance. Files for operating records are maintained as required.
7.2	Maintain a file of all measurements required by this permit, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system	In compliance. The facility maintains all measurements, some of which are not required but are used

Permit Condition	Permit Limit	Observation
	performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this part recorded in a permanent form suitable for inspection for five years.	operationally. All records requested were readily available.
7.3	Maintain general records and CMS records as specified by 40 CFR 63.10(b)(2) and (c), respectively, and Table 1 of 40 CFR 63 Subpart O.	In compliance. All records requested were provided. Startup/shutdown and batches are tracked for operational purposes as well, to meet required sterilization protocols. An example of the routine daily monitoring sheet is attached.
7.4	Include the following information in the semiannual report. a. For the AAT Scrubber System (Source Code EC2), any occurrence when analysis of the dry bed adsorber outlet sample indicates that the concentration exceeds 1 ppmv. b. For the AAT Scrubber System (Source Code EC2), any occurrence when AAT Scrubber System reduction efficiency indicates that the efficiency is less than 99%. c. For the acid-water scrubbers [AAT Scrubber System (Source Code EC2) and Ceilcote Scrubber (Source Code EC3)], any occurrence when the ethylene glycol concentration in the acid-water scrubber liquor is in excess of the maximum ethylene glycol concentration established during initial performance testing. d. For the acid-water scrubbers [AAT Scrubber System (Source Code EC2) and Ceilcote Scrubber (Source Code EC3)], any occurrence when the liquor recirculation tank level of the acid-water scrubber is in excess of the maximum liquor tank level established during initial performance testing. e. For the acid-water scrubbers [AAT Scrubber System (Source Code EC2) and Ceilcote Scrubber (Source Code EC3)], any occurrence when the scrubbing liquor pH rises above the manufacturers' recommended level of 2. f. For the AAT Scrubber System (Source Code EC2), any occurrence when analysis of the dry bed adsorber outlet sample indicates that the concentration exceeds	In compliance. Semiannual reports are submitted as required. No recent deviations have been reported. Records reviewed were consistent with reports.

Permit Condition	Permit Limit	Observation
	0.9 ppmv, but is less than or equal to 1 ppmv. g. For the AAT Scrubber System (Source Code EC2), any occurrence when AAT Scrubber System reduction efficiency indicates that the efficiency is less than 99.1%, but is greater than or equal to 99%. h. For the AAT Scrubber System (Source Code EC2), any instance when the AAT Scrubber System breaches a dry bed adsorber material replacement threshold, but the dry bed material is not replaced within 30 days.	
6.4, 6.5, 7.5, 7.8	Submit notifications when proposed construction is completed. Test the control systems afterwards.	Obsolete Condition. Construction and performance tests were completed as required.
7.6	Submit the following reports as per Subpart O: a. Deviation reports; and b. Continuous Monitoring System performance and summary reports	In compliance. All reports have been submitted as required and are consistent with records reviewed during the inspection.

Liquid Scrubber Systems				
	Liquor flow (gpm)	**Storage tank level (inches)**	**Scrubber liquor pH**	**Glycol concentration %**
Ceilcote	Target: 140 min Reading: 167	Limit: 186 max Reading: 126	Limit: 2 max Reading: 0.9	Target: N/A Reading: 39%
AAT System	Target: 1,300 min Reading: 1562	Limit: 105 max Reading: 89	Limit: 2 max Reading: 0.54	Target: N/A Reading: 37.2%
Dry Bed Systems				
	Most recent outlet EtO concentration determination			
Negative Pressure Dry Beds	Non-detect			
AAT Aeration System Dry Beds	Non-detect			
	Negative pressure system pressure differential readings, Inches of water column			
Zone A (chamber room)	-0.0098			
Zone B (work aisle)	-0.0116			
Zone C (shipping)	-0.0165			

The inspection was announced due to the ongoing COVID-19 pandemic. An example for each type of record was provided prior to the inspection in order to be able to familiarize myself with the logs and minimize my time on site. Expectations for social distancing and face coverings were discussed prior to the inspection. Sanitizing prior to and after review of the paper records was implemented. A visibility vest and safety glasses are the only personal protective equipment required for this facility; the vest was provided by Mr. Mosby, General Manager.

I met Mr. Mosby at the pre-set arrival time, in the facility lobby. Mr. Elbert Sabb, Operations Manager, joined us. I first conducted a thorough review of the records previously requested to be available. These included dry bed EtO concentration records, weekly scrubber pH, tank level records, the spare parts inventory, and the most recent calibration record for the GC (conducted 8/20/2020). All records reflected compliance with the monitoring, maintenance, and operational requirements of the permit.

In addition to the permitted requirements, I evaluated the additional Work Practice Plan requirements. These procedures had been instituted in order to ensure the effective capture of fugitive emissions from indoor air at the facility. These include an initial and annual training for facility personnel on the SOP. Records indicated that 20+ employees were initially trained on December 17, 2019 for the SOP. Pressure within the negative pressure area is determined daily, as noted on the daily EH&S log, for three zones within the facility – Zone A (chamber room area), Zone B (work aisle area), and Zone C (shipping area). The negative pressure system is also monitored by determining the concentration of EtO from the exhaust side of the system. A daily pressure drop across the entire dry bed system is also recorded. All records indicated compliance.

We next donned our PPE and conducted a facility walkthrough. Particular attention was paid to the outside walls of the facility, where previous openings had been eliminated in order to ensure the negative pressure system capture efficiency. All shipping bay doors were closed during the inspection. A former large roll-up door that had been used to install the chamber units had been permanently walled off. The negative pressure in each zone was read. In addition, the sample locations of the exhaust concentration determinations were identified. All observations were consistent with compliance with the permit and the intent of control of any fugitive EtO emissions. While walking through the facility, each emissions vent that was visible was inspected for integrity. In addition, the piping and components in EtO service were visually inspected where possible. No visible signs of poor repair, leaks, or spillage were apparent.

After the facility walkthrough, I thanked Mr. Mosby and Mr. Sabb for their time, concluded the inspection, and left the facility.

Attachment: Performance Tests

Previous test results

Source Tested	Pollutant	Date of Test	Required Testing Frequency	Limit	Actual	Percent of Allowable
Sterilization Chamber SEV-10 Scrubber EC-2	EtO	October 23, 2014	Upon startup	99% DRE	99.95% DRE	N/A
Aeration Chamber AR-1 Scrubber EC-3	EtO	March 17-18, 2016	Upon startup	99% DRE	99.9999% DRE	N/A
Indoor Air Control System	EtO	March 24, 2020	Initial	100% capture efficiency	100% capture efficiency	N/A
Total System (Ceilcote Scrubber, AAT Scrubber, Vacuum Pump)	EtO	June 25, 2020	Upon request	99% DRE	99.9987%	N/A
AAT Scrubber - Aeration	EtO	June 24, 2020	Upon request	99% DRE	99.85%	N/A
AAT Scrubber – Backvents	EtO	June 24, 2020	Upon request	N/A	99.88%	N/A
Indoor Air Control System	EtO	June 2, 2020	Upon request	N/A	0.00280 lb/hr 21.1 ppb	N/A

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DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

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

Full Compliance Evaluation Report

Sterigenics U.S. LLC, Atlanta — 067-00093

Facility description: Ethylene Oxide Sterilization

2971 Olympic Industrial Drive, suite 116
Atlanta, GA 30339

Cobb County
Lat: 33.831, Long: -84.467

Operating status:	Operational
Classification:	Synthetic minor
CMS status:	SM
SIC code:	7389
NAICS code:	561910
Air Programs:	SIP, MACT
Classifications:	None

Full Compliance Evaluation

FCE Year: **2020**

Reviewed by: Waldron, Sherry

On-site inspection conducted

Comments: N/A

FCE tracking number: 10398

Date completed: 4-Sep-2020

Supporting compliance data for September 4, 2019 through September 4, 2020

Inspections

Tracking #	Date	Inspector	Reason for inspection	Operating	Compliance status
85265	21-Aug-2020	Waldron, Sherry	Planned Announced	Yes	Compliant

RMP Inspections

None

Annual Compliance Certifications

None

Reports

Tracking #	Report period	Date received	Reviewer	Deviations reported

85145	First Semiannual 1-Jan-2020 – 30-Jun-2020	3-Aug-2020	Waldron, Sherry	No
82081	Second Semiannual 1-Jul-2019 – 31-Dec-2019	31-Jan-2020	Waldron, Sherry	No
	Comments: Subpart O and semiannual report.			
81305	Other 6-Nov-2019	6-Sep-2019	Waldron, Sherry	No
	Comments: Inital submittal of WorkPractice Plan for Condition #3 of Consent Order EPD-AQC-6980. Second amended submittal received October 21, 2019. Approval letter issu October 31, 2019.			

Notifications

Tracking #	Date received	Reviewer	Notification type
83947	25-Apr-2020	Waldron, Sherry	N/A
	Comments: Email notification to Karen Hays: We had elevated internal EO readings within our chamber room at the Atlanta facility yesterday at about 1pm ET. All of the EO was captured within the negative pressure system and controlled with the new emission controls. There were no uncontrolled EO emissions to the environment. The increased internal EO readings resulted from our Chamber #2 vacuum pump system wh we were starting up Chamber #2 for the first routine production cycle since we temporarily suspended operations in August. Upon further investigation, we identified a minor maintenance issue with the oil/water separator tank that is connected to Chamber #2 vacuur pump. We have not had this issue with any other chamber during our startup period and inspected all other chambers to ensure that there are no similar issues. We estimate the increased EO contributions within the internal negative pressure system to be about 0.8 to 1.(pounds of EO. Again, we confirmed that the new negative pressure capture and control system was working properly at the time and that there were no uncontrolled EO emissions tc the environment. Kathleen Hoffman, Senior Vice President - Global Environmental, Health & Safety, Sotera Health Follow-up 4/27: Given the negative pressure capture and emissions control system operation we estimate the amount of EO discharge post-control to the environment to be about one quarter of one ounce or less.		
81655	3-Jan-2020	Waldron, Sherry	N/A
	Comments: Report of EO leak incidents for December 2019. No leaks reported.		
81529	3-Dec-2019	Waldron, Sherry	N/A
	Comments: Report of EO leak incidents for November 2019. No leaks reported.		
81308	4-Nov-2019	Waldron, Sherry	N/A
	Comments: Report of EO leak incidents for October 2019. No leaks reported.		
81307	31-Oct-2019	Waldron, Sherry	N/A
	Comments: Report of EO leak incidents for September 2019. No leaks reported.		

81306	31-Oct-2019	Waldron, Sherry	N/A

Comments: Report of EO leak incidents for August 2019. No leaks reported.

Source Tests

Tracking #	Test Ref #	Date received	Reviewer	Compliance status
85003	202000818	18-Aug-2020	Waldron, Sherry	In Compliance
	Source tested: Ethylene Oxide - Indoor Air Control System			
85002	202000817	18-Aug-2020	Waldron, Sherry	In Compliance
	Source tested: Ethylene Oxide - AAT Scrubber - Backvents			
85001	202000816	18-Aug-2020	Waldron, Sherry	In Compliance
	Source tested: Ethylene Oxide - AAT Scrubber - Aeration			
85000	202000815	18-Aug-2020	Waldron, Sherry	In Compliance
	Source tested: Ethylene Oxide - Total System (Ceilcote Scrubber, AAT Scrubber, Vacuum Pump)			
84216	202000598	12-Jun-2020	Waldron, Sherry	In Compliance
	Source tested: Ethylene Oxide - Indoor Air Control System			

Fees Data

Fee year	Invoiced amount	Amount paid	Balance	Status
2019				Facility Enrolled in the Fee System
2018	$1,700.00	$1,700.00	$0	Paid in Full
2017	$1,700.00	$1,700.00	$0	Paid in Full
2016	$1,700.00	$1,700.00	$0	Paid in Full
2015	$1,700.00	$1,700.00	$0	Paid in Full

Five-Year History of Enforcement Actions

Tracking #	Staff responsible	Date	Type
2303	Waldron, Sherry	7-Aug-2019	Consent Order #EPD-AQC-6980

Waldron, Sherry

From: Mosby, Daryl <DMosby@sterigenics.com>
Sent: Thursday, August 20, 2020 8:36 AM
To: Waldron, Sherry
Subject: Inspection plan
Attachments: Replacment of Dry Beds Marterial for AAT.pdf; Week of July 12 - Negative Pressure Dry Bed Testing.pdf; Week of July 12 - AAT Dry Bed Testing.pdf; Week of July 12 - Negative Pressure Readings and Checking of Dock Door Seals.pdf; Training Records for Negative Air Best Practices.pdf

Hi Sherry,

Please see attached records. I redacted the names on the training records, hopefully this is not a problem.

I will call you this morning to discuss them with you.

Let me know what time works best for you.

Thanks,
Daryl-

From: Waldron, Sherry <Sherry.Waldron@dnr.ga.gov>
Sent: Wednesday, August 19, 2020 8:46 AM
To: Mosby, Daryl <DMosby@sterigenics.com>
Subject: [EXTERNAL] Re: Inspection plan

That is fine for the records of longer duration, but please submit the information requested that is just one record. In addition, please submit an example of each record requested, from the week of July 12, 2020, for each of the records of longer duration so I can familiarize myself with them prior to my review.

Thank you,

Sherry Waldron
Environmental Engineer
Georgia Environmental Protection Division
Air Protection Branch
404-362-4569

From: Mosby, Daryl <DMosby@sterigenics.com>
Sent: Tuesday, August 18, 2020 5:10 PM
To: Waldron, Sherry <Sherry.Waldron@dnr.ga.gov>
Subject: RE: Inspection plan

Hi Sherry,

Due to the amount of records requested, it would be best to review them onsite. We will have them ready in an organized manner to ensure we are able to limit the amount of time you are onsite.

I will provide enough social distancing for your review.

Regards,
Daryl-

From: Waldron, Sherry <Sherry.Waldron@dnr.ga.gov>
Sent: Thursday, August 13, 2020 3:23 PM
To: Mosby, Daryl <DMosby@sterigenics.com>
Subject: [EXTERNAL] Inspection plan

Attached. Please let me know what records are not as easily sent electronically and will be best reviewed on site, so I can estimate the time I need.
Thank you!

Sherry Waldron
Environmental Engineer
Georgia Environmental Protection Division
Air Protection Branch
404-362-4569

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Sterigenics

GENERAL TRAINING RECORD

POSITION HELD: SHIFT 01

EMPLOYEE NAME: [redacted]

DATE OF TRAINING: 17 Dec 19

TRAINING PERFORMED BY: Steve Farnsworth & Graham Rose

LENGTH OF TRAINING: 1/2 Day

TRAINING TOPIC(s): Facility General Enhancements

Overview of changes

Operating within Shipping & Receiving

Operating within Production

Operation of new equipment

Facility walk through and identificaction of changes

Door Interlock & PanelView changes

Startup, Shutdown, operation and setpoint changes.

Maintenance and Calibration N/A [redacted] 17-Dec-19

EMPLOYEE SIGNATURE [redacted] DATE 17 Dec 19

TRAINING RECORD APPROVED BY [redacted] DATE

Sterigenics

GENERAL TRAINING RECORD

POSITION HELD: Logistics

EMPLOYEE NAME: [redacted]

DATE OF TRAINING: 17 December 2019

TRAINING PERFORMED BY: Steve Farnsworth & Graham Rose

LENGTH OF TRAINING: 1/2 Day

TRAINING TOPIC(s): Facility General Enhancements

Overview of changes

Operating within Shipping & Receiving

Operating within Production NA [redacted] 17-Dec-19

Operation of new equipment NA [redacted] 17-Dec-19

Facility walk through and identification of changes NA [redacted] 17-Dec-19

Door Interlock & PanelView changes NA [redacted] 17-Dec-19

Startup, Shutdown, operation and setpoint changes. NA [redacted] 17-Dec-19

Maintenance and Calibration NA [redacted] 17-Dec-19

EMPLOYEE SIGNATURE [redacted] DATE 17 December 2019

TRAINING RECORD APPROVED BY [redacted] DATE

Sterigenics
A Sotera Health company

Date: 13 Jul 2020

Daily EH&S System Checks

Acid-Water Scrubbers	Limits or ranges	Cellcote	AAT System	Corrective Action Needed?	Inspector Initials
Record liquor flow rate (gpm):	Targets: Cellcote: 140 MIN AAT: 1300 MIN	149	1554	N/A	CB
Storage tank level (inches): (If liquor is shipped for recycling, record gallons in EAM.)	Cellcote: ≤186 in AAT Tank 2: ≤105 in.	64	Tank 2 BB	N/A	CB
Check scrubber liquor pH:	Limit pH <2	0.8	0.45	N/A	CB
Record glycol concentration (%):	N/A	35.4	37.4	N/A	CB
Check all pumps, pipes, seals, and rings for leaks:	N/A	GOOD	GOOD	N/A	CB

Dry Beds	Negative Pressure Dry Beds	AAT System	Corrective Action Needed?	Inspector Initials
Record outlet EO levels (ppm)	0.00	0.00	N/A	
Record total differential pressure across dry beds (iN W.G.)	8.37	7.76	N/A	CB

Negative Pressure System	Zone A	Zone B	Zone C	Corrective Action Needed?	Inspector Initials
Record negative pressure (in H_2O)	-0.0225	-0.0267	-0.0320	NA	SS

Shipping Dock Seals	Yes	No	Comments
Have shipping dock door seals been inspected this week?	✓		N/A

EO Leaks/Releases	Yes	No	Comments
Was there any occasion of EO levels > 50ppm/10% LEL in past 24 hrs?		✓	N/A
Any EO leaks or releases greater than RQ of 10lbs?		✓	N/A

Number of EO Drums at Facility	Chamber Room	EO Storage
How many EO drums are there in this specific area or location?	10	9
Current Cobb County Limits – Maximum # of drums	10	20

For Corrective Actions: Describe Problem/List Work Order Number:

Reviewed by: [signature] Date: 14-Jul-2020

Sterigenics

AAT Sampling Log

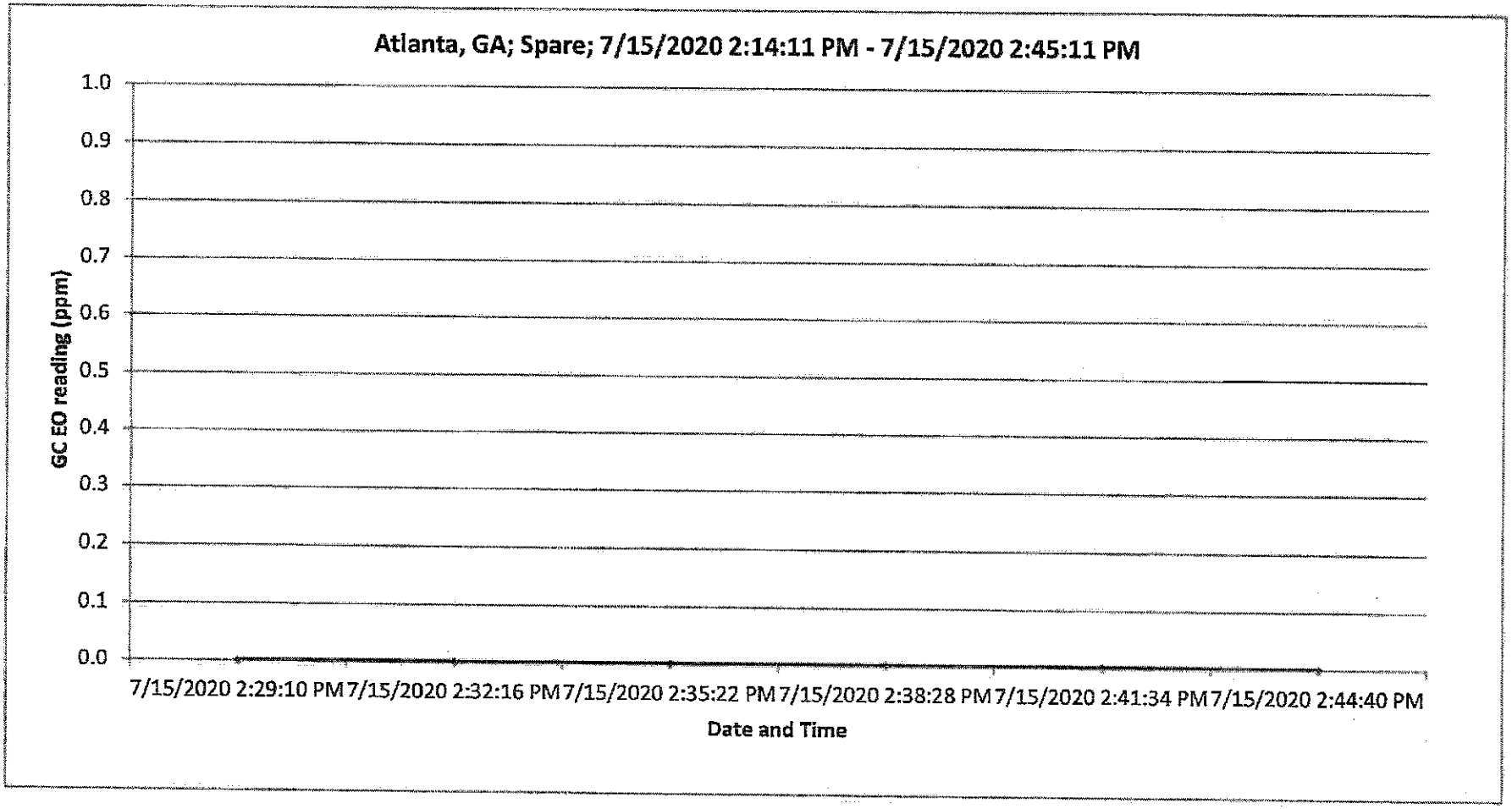
Emission samples of the AAT will be recorded below. The sample will be taken once each month or when needed as per permit.

Date of sample collection/testing: 15-July-2020	
Location / Emission type tested: (Aeration) Chamber	Position tested: (Inlet) (Outlet)
☑ Aeration ☐ 1 Chamber Vacuum	
Person collecting the sample: Ken Martin	
Collection time (15 minute minimum): 14:08 GMT – 14:23 GMT	
Type of bag used and amount of gas collected: SKC TEDLAR	
Analysis system used: ☑ In-house SRI ☐ Other:	
Last system calibration Date & Time: 14/July/2020 @ 19:59:54 GMT	
Sample results: ☐ Inlet	
Run 1: 0.00	Run 2: 0.00 / Run 3: 0.00 / Average: 0.00
Sample results: ☐ Outlet	
Run 1: 0.00	Run 2: 0.00 / Run 3: 0.00 / Average: 0.00
Comments: Test performed in accordance with AT-WI-025.	

Reviewed By: Daryl Mody Date: 15 Jul 2020

Date and Time	EO (ppm)	
7/15/2020 2:29:10 PM	0.0	Outlet
7/15/2020 2:32:16 PM	0.0	Outlet
7/15/2020 2:35:22 PM	0.0	Outlet
7/15/2020 2:38:28 PM	0.0	Inlet
7/15/2020 2:41:34 PM	0.0	Inlet
7/15/2020 2:44:40 PM	0.0	Inlet

AAT*


Atlanta, GA; Spare; 7/15/2020 2:14:11 PM - 7/15/2020 2:45:11 PM
GC EO reading (ppm)
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
7/15/2020 2:29:10 PM
7/15/2020 2:32:16 PM
7/15/2020 2:35:22 PM
7/15/2020 2:38:28 PM
7/15/2020 2:41:34 PM
7/15/2020 2:44:40 PM
Date and Time

Sterigenics

AAT Sampling Log

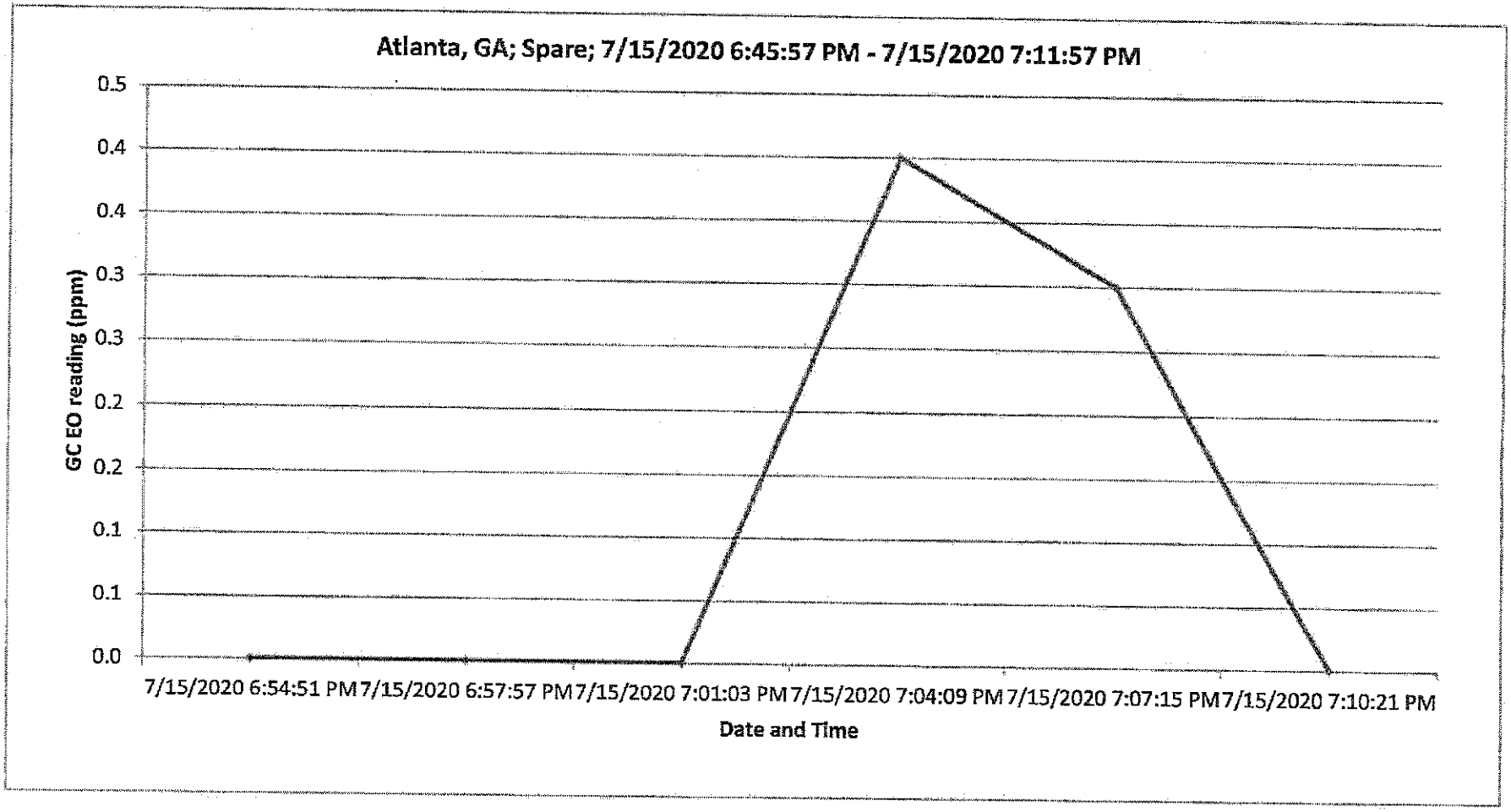
Emission samples of the AAT will be recorded below. The sample will be taken once each month or when needed as per permit.

Date of sample collection/testing: 15-July-2020	
Location / Emission type tested: (Aeration) Chamber	Position tested: (Inlet) (Outlet)
☑ Aeration ☐ 1 Chamber Vacuum	
Person collecting the sample: Ken Martin	
Collection time (15 minute minimum): 18:30 GMT – 18:45 GMT	
Type of bag used and amount of gas collected: SKC TEDLAR	
Analysis system used: ☑ In-house SRI ☐ Other:	
Last system calibration Date & Time: 14/July/2020 @ 19:59:54 GMT	
Sample results: ☐ Inlet	
Run 1: 0.40	Run 2: 0.30 / Run 3: 0.00 / Average: 0.23
Sample results: ☐ Outlet	
Run 1: 0.00	Run 2: 0.00 / Run 3: 0.00 / Average: 0.00
Comments: Test performed in accordance with AT-WI-025.	

Reviewed By: Daryl Mah Date: 15 Jul 2020

Date and Time	EO (ppm)	
7/15/2020 6:54:51 PM	0.0	Outlet
7/15/2020 6:57:57 PM	0.0	Outlet
7/15/2020 7:01:03 PM	0.0	Outlet
7/15/2020 7:04:09 PM	0.4	Inlet
7/15/2020 7:07:15 PM	0.3	Inlet
7/15/2020 7:10:21 PM	0.0	Inlet

Fugitive *


Atlanta, GA; Spare; 7/15/2020 6:45:57 PM - 7/15/2020 7:11:57 PM
GC EO reading (ppm)
0.5
0.4
0.4
0.3
0.3
0.2
0.2
0.1
0.1
0.0
7/15/2020 6:54:51 PM
7/15/2020 6:57:57 PM
7/15/2020 7:01:03 PM
7/15/2020 7:04:09 PM
7/15/2020 7:07:15 PM
7/15/2020 7:10:21 PM
Date and Time

Sterigenics.
A Sotera Health company

To: File of Air Quality Permit (7389-067-0093-S-05-0)

From: Daryl Mosby, General Manager

Date: 17 Dec 2019

Subject: Replacement of AAT Dry Beds

On 17 Dec 2019, the dry beds for AAT were replaced.

Regards,

Daryl Mosby
General Manager

Sterigenics International, Inc.
2971 Olympic Ind. Drive, Ste. 116 Atlanta, GA 30339
Tel 404-355-4485 • Fax 404-355-4852

Waldron, Sherry

From: Mosby, Daryl <DMosby@sterigenics.com>
Sent: Thursday, August 20, 2020 11:05 AM
To: Waldron, Sherry
Subject: RE: Inspection plan

Hi Sherry,

We are able to print out the last calibration of the SRI. I will have that for you in the morning.

Regards,
Daryl-

From: Mosby, Daryl
Sent: Thursday, August 20, 2020 9:32 AM
To: 'Waldron, Sherry' <Sherry.Waldron@dnr.ga.gov>
Subject: RE: Inspection plan

Great, 10 works for me. I will call you.

From: Waldron, Sherry <Sherry.Waldron@dnr.ga.gov>
Sent: Thursday, August 20, 2020 9:23 AM
To: Mosby, Daryl <DMosby@sterigenics.com>
Subject: [EXTERNAL] Re: Inspection plan

Exactly what I needed. Thank you. I am available all morning. How about 10?

Sherry Waldron
Environmental Engineer
Georgia Environmental Protection Division
Air Protection Branch
404-362-4569

From: Mosby, Daryl <DMosby@sterigenics.com>
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Sherry Waldron
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