Sterigenics
A Sotera Health company

October 31, 2019

Mr. Eric Cornwell
Program Manager
Stationary Source Permitting
Georgia EPD – Air Protection Branch
4244 International Parkway, Suite 12
Atlanta, Georgia 30354-3906

Subject: Testing Protocol and Response to Request for additional information regarding
Application No. 27153
Sterigenics U.S., LLC Atlanta, AIRS No: 06700093

Dear Mr. Cornwell;

This letter is in response to the Georgia Environmental Protection Division's (EPD's) October 9, 2019 letter requesting Sterigenics to submit testing protocols for approval, and reply to additional engineering questions. Accordingly, the requested testing protocols are attached and responses to EPD's technical question are set forth below. The procedures have been developed in a manner to ensure that the tests generate accurate ethylene oxide emissions data at maximum operating rates and ensure employee, tester, and observer safety.

1) ***Ethylene oxide performance testing of the sterilization chamber vents.*** Attached is a proposed test protocol for testing of the sterilization chamber vents. We propose using Method 320 instead of Method 18 or Method 25A. Method 320 is an approved USEPA test method that can detect EO concentrations in the parts per billion range. Methods 18 and 25A are less sensitive and given the very low level of expected emission rates, Method 320 is a better fit. .
    a. EPD asks that the testing of the chamber vents should occur at the maximum loading. Maximum loading will be determined by a review of the current customer products and identifying the largest quantity of EO for each chamber. 40 CFR 63.365 requires one empty chamber to be charged with a typical amount of EO. Instead, one empty chamber will be charged with this maximum amount of EO for the test. Also, in order to provide test data on more than one chamber and maximize the flow rate to the scrubber, Sterigenics proposes one test run of 3 chambers in first evacuation; one test run of 2 chambers in first evacuation; and one test run of 1 chamber in first evacuation. This will meet the maximum flow rate requested by Georgia with test run 1 and also meet 40 CFR 63.365 with test run 3. Please note that the design rating for the Ceilcote scrubber is 2000 ACFM.
    b. Direct testing of the vacuum pump stream prior to the Ceilcote cannot be completed safely. In order to test the inlet to the Ceilcote scrubber, three openings would need to be in the piping to insert the testing probes. Two of the holes would need to be 2 inches in diameter and the third hole would need to be 1.5 inches. To put this in perspective, the inlet piping is approximately 8 inches in diameter. The vacuum pump draws the EO out of the chamber and creates a positive pressure in the piping which flows to the

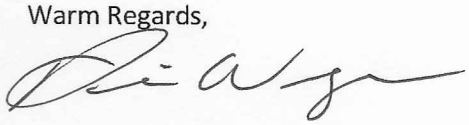
Ceilcote. Due to the positive pressure in the piping, the possibility of leaking is greater on the negative pressure side of the piping, which increases the chance of an EO leak indoors. During the test, this could cause EO to escape as the probe will not seal the entire opening. Even after the test, plugging these holes in some way presents a weak point in the piping presenting a greater risk of leaks over time. For safety purposes, our corporate practices limit the number of connections, equipment or devices and other openings in high concentration piping and ductwork. Any leak, especially a high concentration leak, presents a clear and obvious hazard to our employees, the testers, any observers of the test and ultimately the community. Accordingly, the protocol does not provide for testing the high concentration stream to the Ceilcote scrubber.

2) ***Ethylene oxide performance testing on the sterilization chamber backvents and the aeration room vent***. The performance testing protocol also includes testing of the aeration room vents and backvents. Per 40 CFR 63 Subpart O, after a sterilization chamber cycle is complete, the backvent will be opened for 15 minutes prior to product being unloaded from the chamber. During these 15 minutes, the backvent emissions will be tested. Following the 15 minutes, operations will move product from the chamber into aeration to allow the aeration room to be tested with fresh product.
    a. EPD has specified that testing of the back vents and aeration room should occur at maximum airflow and loading, if possible. In order to get this maximum loading from aeration, the aeration room will need to be filled with sterilized product. Sterigenics will need to run sterilization processes prior to the test and place the product in the aeration room. The AAT scrubber and dry beds are designed using a fan at the outlet. This fan pulls the exhaust through the system and creates the air flow. Since this fan is not variable in speed, the air flow through the system is constant.
3) ***Ethylene oxide performance testing of the Indoor Air System.*** The performance testing protocol also includes testing of the Indoor Air system.
4) ***Provide support for the assumption that at least 95% of the ethylene oxide used is exhausted through the vacuum pump.*** This mass balance is based on USEPA's information and estimates across all commercial sterilization facilities in the US. This information was included in documentation from the original rulemakings. For example, the preamble for the 2001 amendment to the rule references that the backvent and aeration vents represent 1 and 3%, respectively of the uncontrolled ethylene oxide emissions. We are not able to demonstrate this 95% estimate during this upcoming test because we cannot safely measure the inlet to the scrubber and 40 CFR 63.365 requires testing with empty chambers during this test.
5) ***Demonstrate that the Indoor Air System enclosure meets 100% capture.*** Attached is a test protocol to demonstrate that the Indoor Air enclosure meets 100% capture.
6) ***Determine the highest level of sensitivity of the Gas Chromatograph mass spectrometer used for the periodic bag sample monitoring plan, in terms of ppm ethylene oxide.*** Typical gas chromatograph systems can measure 0.1 ppm for ethylene oxide.
7) ***Determine the highest level of sensitivity achievable by the stack testing laboratory.*** The attached performance testing protocol provides that the minimum detection limit that the stack testing laboratory can achieve will be determined and provided in the test report.

8) ***Verify the stack height, airflow, and diameter of each stack.*** This information will be verified. Airflow will be measured in accordance with the test protocol. Stack height and diameter of each stack will be verified and provided at the time of the test report.
9) ***The Division expects that testing of the operations should be completed within 20 days after testing has begun.*** As discussed above, in order to test at maximum loading conditions for aeration, the aeration room will need to be filled with processed product. This requires several sterilization cycles in advance of the test. Since Sterigenics is a commercial sterilizer, Sterigenics does not manufacture products. All medical devices or products sterilized onsite are provided by Sterigenics customers. This means arrangements will need to be made with our customers to determine products that can be shipped to the facility and sterilized. In order to finalize the timing, we will need to work with our sales team and customers to determine the exact products that will be sterilized during this period. In general, we anticipate that approximately 30 days will elapse from the time EO is first used in the sterilization process until all products are removed from aeration. The following is a general sense of timing on process steps
    a. Construction completion: In order to finalize construction, equipment will need to be tested and run prior to releasing the equipment to service. This may require minimal quantities of EO to be used. Depending on the test protocol review and approval timing, there may be a delay in the use of EO for returning equipment to service and the use of EO in sterilization for maximum conditions.
    b. Maximum loading in aeration: In order to prepare for maximum loading conditions, aeration will need to be close to full with space left for freshly sterilized product to be added during testing.
    c. Maximum scrubber conditions: Because EPD intends to use the test results to set the maximum ethylene glycol concentration, maximum liquor tank level, and maximum pH for the scrubbers, the sterilization process may need to run for additional time to establish maximum concentrations and levels.
    d. Conducting EO performance testing: Three days of testing will be scheduled. One day for aeration and backvent testing; one day for vacuum pump emissions; and one day for the negative pressure system.
    e. Completing sterilization cycles: Product will need to be processed on each day of testing. Once the product is sterilized, product is moved from the chamber into aeration. Aeration time can vary depending on the product. We will need to keep operating emission control systems during this aeration period.

If you have any questions, please feel free to contact me.

Warm Regards,



Kevin Wagner
Director, Environmental Health & Safety