

ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

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

October 9, 2019

Kathleen Hoffman Sr. Vice President of EH&S Sterigenics U.S., LLC 2015 Spring Road, Suite 650 Oak Brook, IL 60523

Re: Request for additional information regarding Application No. 27153 received July 31, 2019 Sterigenics U.S., LLC, Atlanta, AIRS No: 06700093

Dear Kathy Hoffman:

I write to notify you that the Division requires additional information to evaluate the modifications Sterigenics proposed in Application No. 27153. Specifically, emissions testing under the new controls configuration is required as detailed in this letter and as authorized by Georgia Rules for Air Quality Control Chapter 391-3-1-.03(2)(c)¹ prior to issuance of a permit authorizing the proposed modifications. The Division also requires certain engineering analyses and documentation as detailed below. Please submit test plans to the Division for our review and approval. Upon receipt of the Division's approval of the test plans, and any necessary approvals from Cobb County, please conduct and complete the following testing/engineering analyses and provide written results/reports to the Division within 30 days after completion.

1. Ethylene oxide performance testing of the sterilization chamber vents. Conduct ethylene oxide (EtO) performance testing of the sterilization chamber vents (Source Codes SEV-1, SEV-2, SEV-3, SEV-4, SEV-5, SEV-6, SEV-7, SEV-8, SEV-10, SEV-11). Conduct the performance testing according to: the procedures listed in 40 CFR 63.7, the applicability of 40 CFR Part 63, Subpart O as identified in Table 1 of 40 CFR 63.360, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. The test results will be used to establish the maximum ethylene glycol concentration, the maximum liquor tank levels, and maximum pH for the scrubbers. The test report shall list the control efficiency of the Ceilcote Scrubber, the AAT Scrubber System with Dry Bed Adsorber, and the total system. The test report shall

¹ See Ga. Comp. R. & Regs. 391-3-1-.02 (c) which provides in relevant that, "as a condition for the issuance of an operating permit, the Director may require the applicant to conduct performance tests and monitoring and provide reports concerning operations, to demonstrate compliance with the Act and the rules and regulations. Such tests and monitoring shall be conducted, and such required reports submitted, in accordance with methods and procedures approved by the Director."

list the final exhaust mass emission rate of ethylene oxide. The tests for each system (Ceilcote and AAT) shall be conducted simultaneously.

- a. Testing of the chamber vents should occur at the maximum loading. When you submit the test plan prior to testing, explain what conditions constitute "maximum loading." Sterigenics should expect that the chamber operating scenario during testing may be used to establish an operational limit in the permit (i.e. limit the number of chambers operating at any given time). Record or otherwise document the maximum airflow of each chamber vacuum pump to ensure that combined airflow shall not exceed 1200 ACFM.
- b. Explain why direct testing of the vacuum pump stream prior to the Ceilcote scrubber is not feasible.
- 2. Ethylene oxide performance testing on the sterilization chamber back vents and the aeration room vent. Conduct ethylene oxide performance testing on the sterilization chamber back vents (Source Codes CEV-1, CEV-2, CEV-3, CEV-4, CEV-5, CEV-6, CEV-7, CEV-8, CEV-10, CEV-11) and the aeration room vent (Source Code AR-1). The testing shall be conducted according to: the procedures listed in 40 CFR 63.7, the applicability of 40 CFR Part 63, Subpart O as identified in Table 1 of 40 CFR 63.360, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. The test shall be used to establish the maximum ethylene glycol concentration, the maximum liquor tank level, and maximum pH for the AAT scrubber (Source Code EC2). The test report shall list the final exhaust mass emission rate of ethylene oxide.
 - a. Testing of the back vents and aeration room should occur at the maximum airflow, and loading, if possible.
- 3. Ethylene oxide performance testing of the Indoor Air System. Conduct ethylene oxide performance testing of the Indoor Air System (IA-1) according to: the procedures listed in 40 CFR 63.7, the applicability of 40 CFR Part 63, Subpart O as identified in Table 1 of 40 CFR 63.360, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. The test report shall list the final exhaust mass emission rate of ethylene oxide.
- 4. Provide support for the assumption that at least 95% of the ethylene oxide used is exhausted through the vacuum pumps. Conduct testing and/or provide engineering analysis to support the assumption that at least 95% of the ethylene oxide used is exhausted through the vacuum pumps (aka chamber vents routed to the Ceilcote Scrubber and AAT Scrubber). These tests shall be conducted using the "worst case" batch cycle recipe. The worst case will result in the lowest percentage of EtO usage being routed to the vacuum pumps and generally means shorter wash times leaving more EtO in product and chamber air. The company shall provide a reasoned explanation for their choice as worst case.

- 5. <u>Demonstrate that the Indoor Air System enclosure meets 100% capture</u>. Conduct testing to demonstrate that the indoor air system enclosure meets 100% capture and provide operating parameters that reflect such conditions (e.g. fan amps, pressure across enclosure, air flow direction at openings).
- 6. Determine the highest level of sensitivity of the Gas Chromatograph mass spectrometer used for the periodic bag sample monitoring, in terms of ppm ethylene oxide. Conduct testing and/or provide engineering analysis that determines the highest level of sensitivity of the Gas Chromatograph mass spectrometer used for the periodic bag sample monitoring, in terms of ppm of ethylene oxide Explain if the unit can achieve a 0.01 ppm detection limit or lower and determine the accuracy at levels below 0.1 ppm. If the unit cannot achieve a detection level of 0.01 ppm, explain why not. For reference, stack exhaust concentrations of 0.01 ppm equate to roughly 10 pounds per year for each stack.
- 7. Determine the highest level of sensitivity achievable by the stack testing laboratory. Provide documentation of the sensitivity achievable by the laboratory selected to analyze the performance testing data.
- 8. <u>Verify the stack height, airflow, and diameter of each stack</u>. Provide documentation verifying the stack height, airflow, and diameter of each stack, and explain how each value was determined.

The Division expects that testing of the operations should be completed within 20 days after testing has begun. If Sterigenics believes a longer test period will be required, submit a detailed justification for a longer test period as part of the test plans submitted to the Division for review. The length of the test period may not extend beyond what is specifically approved by the Division. The test plan submitted for review must also include details regarding Sterigenics' possible sterilization of products during testing. Tests and monitoring shall be conducted only upon the Division's approval of the testing methods and procedures.

An Operating (SIP) Permit Amendment shall be obtained prior to operation of this facility for production purposes. If you have any questions or concerns, please contact me at (404) 363-7020 or via e-mail at eric.cornwell@dnr.ga.gov.

Sincerely,

Eric Cornwell

Manager

Stationary Source Permitting Program

Cermell