UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

August 26, 2021

Ms. Laura Hartman, EH&S Manager
Sterigenics US, LLC
2015 Spring Road Suite 650
Oak Brook, Illinois 60523

Dear Ms. Hartman:

This is in response to your letter, dated July 13, 2021, which proposed modifications to an alternative monitoring procedure (AMP) that the US Environmental Protection Agency (EPA) Region 4 approved on June 23, 2020. This AMP was for the dry bed adsorber (DBA) that is part of the ethylene oxide (EtO) control system for Aeration Room 2 (AR-2) at the Sterigenics US LLC (Sterigenics) sterilization facility in Charlotte, North Carolina. The Charlotte facility is subject to Title 40, Code of Federal Regulations Part 63, Subpart O (Ethylene Oxide Emissions Standards for Sterilization Facilities). A site-specific AMP is necessary for AR-2 because Subpart O does not specify monitoring procedures for DBA systems. The EPA's previous AMP approval was issued on an interim basis to allow for the completion of performance testing that could be used to evaluate the appropriateness of operational limits included in the EPA's June 23, 2020, letter. The remainder of this letter describes the modifications requested in your July 13, 2021, letter and the EPA position regarding each proposal.

Modification 1 – Type of Flexible Bags Used for EtO Sample Collection

The AMP that the EPA approved in June 2020 relies on periodic sampling to determine the EtO concentration at the outlet of the DBA that controls emissions from a regenerative catalytic oxidizer that is the primary control device for AR-2. Indoor air collected from chamber rooms, work aisles, processed product storage, and shipping areas at Sterigenics' Charlotte facility is also routed to the DBA to control EtO emissions that are not regulated under Subpart O. Our June 2020 approval letter specified the use of Tedlar bags for collecting EtO samples at the outlet of the DBA.

Tedlar is a trade name for polyvinyl flouride film produced by DuPont, and Tedlar-coated bags are widely used for organic compound sampling because the film coating is chemically inert. Your letter asked for the flexibility to use sampling bags made of materials other than Tedlar, and a specific alternative mentioned in your letter was Calibond bags. The chemically inert layer used in Calibond bags is a proprietary form of high-density polyethylene instead of the polyvinyl flouride used for Tedlar bags.

Based upon our review, the use of alternative bags for collecting samples at the DBA outlet is acceptable provided that a recovery study is conducted on the bags in accordance with procedures in Section 8.4.2 of EPA Method 18. Also, the recovery fraction measured during the study must be used for adjusting sampling results in accordance with Equation 12-8 from the EPA Method 18. The requirement to

conduct a recovery study and use the results of the study to adjust analytical results was one of the approval conditions for Tedlar bags in the EPA's interim AMP approval for the Charlotte facility.

Modification 2 - Length for EtO Sampling Line

The interim AMP approval for the Charlotte facility included a requirement that the length of the sampling line between the DBA outlet duct and the Tedlar bag be limited to no more than two feet to avoid sample loss. Your July 13 letter indicated that using a two-foot sample line poses a safety issue because such a short line makes it necessary to elevate sampling personnel in a busy forklift traffic area. To mitigate this safety concern, your letter proposed using a 40-foot Teflon sample line that can be accessed at ground level. This proposal indicates that the sample line will be purged for 15 minutes prior to use to prevent dilution.

Based upon our review, the proposed 40-foot Teflon sample line will be acceptable provided that the line is purged with exhaust from the DBA for 15 minutes prior to sample collection. The basis for this determination is that, considering the EtO concentration level that initially triggers follow-up action under the AMP for the Charlotte facility (0.50 parts per million by volume), a 15-minute purge will ensure the collection of representative samples by drawing dead air out of the line, minimizing potential reactive substances, and helping to passivate any chemically active sites in the line.

Modification 3 - EtO Sample Collection Frequency

Under the interim approval granted by the EPA, samples are collected at the outlet of the DBA on a weekly basis when the EtO concentration is less than 0.50 parts per million by volume (ppmv). Daily sampling is required when the EtO concentration at the outlet of DBA is greater than or equal to 0.50 ppmv, but less than 0.75 ppmv. Under the AMP interim approval, the adsorbent medium in the DBA must be replaced within 30 calendar days when the EtO concentration at the outlet of the control device is greater than or equal to 0.75 ppmv.

Your July 13, 2021, letter proposed an alternative sample collection frequency of three times per week, rather than daily, when the EtO concentration at the outlet of the DBA is greater than or equal to 0.50 ppmv. According to your letter, sampling conducted at the Charlotte facility to date indicates that the EtO concentration at the outlet of the DBA changes gradually over time. Due to the slow change in outlet EtO concentrations, Sterigenics believes that sampling three times per week after the EtO concentration reaches 0.50 ppmv will be sufficient determining when the adsorbent medium in the DBA needs to be replaced (i.e., exceeds 0.75 ppmv).

Based upon the adsorptive capacity of the DBA and the measured EtO loading at the control device inlet during performance testing conducted at the Charlotte facility in January 2021, Sterigenics' proposal to sample three times per week when the EtO concentration reaches 0.50 ppm is acceptable to the EPA. The DBA at the Charlotte facility contains 12 units and is designed to achieve a collection efficiency of greater than 99 percent at an EtO loading of 3,360 pounds (280 pounds per unit). During the January 2021 performance test, the EtO loading at the DBA inlet was 0.45 pounds per hour. Based upon the DBA's adsorptive capacity and the control device's inlet loading, the EtO concentration at the outlet of the control device is expected to change slowly over time. This expectation is supported by the monitoring that Sterigenics has conducted so far under the terms of the interim AMP approval. Therefore, your proposal to collect samples at DBA outlet three times per week, rather than on a daily basis, when the EtO concentration reaches 0.50 ppmv, is acceptable to the EPA.

The Region 4 review of your request for modifications to the AMP for AR-2 has been coordinated with the EPA Office of Enforcement and Compliance Assurance (OECA), the EPA Office of Air Quality Planning and Standards (OAQPS), and the Mecklenburg County Air Quality Division (MCAQD). If you have any questions about our response to the monitoring plan, please contact Mr. David McNeal of the Region 4 staff at (404) 562-9102 or mcneal.dave@epa.gov.

Sincerely,

CAROLINE FREEMAN

Digitally signed by CAROLINE FREEMAN
Date: 2021.08.26 14:35:23 -04'00'

Caroline Y. Freeman
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