Prepared for
Sterigenics US, LLC
Facility ID's 126191 and 126197
Vernon, California

Prepared by
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EARLY ACTION REDUCTION PLAN

STERIGENICS U.S., LLC

VERNON, CALIFORNIA

RAMBOLL

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APPENDIX

ACRONYMS AND ABBREVIATIONS

EARP:	Early Action Reduction Plan
EtO:	Ethylene oxide
FDA:	Food and Drug Administration
GC:	Gas chromatograph
LDAR:	Leak Detection and Repair
Measure or measure:	The measures expressed in Section 2.3 of this EARP
ppb:	Parts per billion
ppm:	Parts per million
PTE:	Permanent total enclosure
SCAQMD:	South Coast Air Quality Management District
TTE:	Temporary total enclosure
U.S. EPA	United States Environmental Protection Agency

1. INTRODUCTION

1.1 Facility Information

Sterigenics U.S., LLC (Sterigenics) operates a medical sterilization business, including two facilities within the city of Vernon (Facility ID 126191, also referred to as the 50th Street Facility, and Facility ID 126197, also referred to as the 49th Street Facility). These facilities sterilize medical devices such as surgical kits, delivery systems, and COVID test swabs using ethylene oxide (EtO). The two Sterigenics facilities are joint operationally and subject to South Coast Air Quality Management District (SCAQMD or District) rules and regulations, including Rule 1405, "Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes."

Medical devices are shipped to the Vernon facilities via truck. These products are unloaded, sterilized with EtO, aerated, then shipped out to medical facilities and customers. At each facility, EtO process emissions are treated through scrubbers and abators. The operations also result in the release of fugitive emissions.

1.2 Early Action Reduction Plan Overview

On June 7, 2022, SCAQMD issued a Notice of Designation (Notice) of Sterigenics U.S., Inc. – Los Angeles Facility (SCAQMD ID's 126191 & 126197) as a Potentially High Risk Level Facility. In response to that Notice, Ramboll is submitting this Early Action Reduction Plan (EARP or Plan) on behalf of Sterigenics. This EARP has been prepared in accordance with the requirements of Rule 1402.

Per Rule 1402(g)(2)(A) the required elements of an EARP are:

Rule 1402(g)(2)(A) EARP Requirement	Location in EARP
1. The name, address, and SCAQMD facility identification number;	See Section 2.1 below
2. Identification of device(s) or process(es) that are the key health risk driver(s);	See Section 2.2 below
3. Risk reduction measure(s) that can be implemented by the owner or operator that includes but are not limited to procedural changes, process changes, physical modifications, and curtailments; and	See Section 2.3 below
4. A schedule for implementing the specified risk reduction measures.	See Section 2.3 below

Measures in the EARP were developed in coordination with SCAQMD. On August 10, 2022, Sterigenics' President, Michael Rutz, transmitted a letter to SCAQMD Executive Officer Wayne Nastri stating that voluntary compliance with the measures would commence August 10, 2022 (the "Effective Date"). Accordingly, schedules in this EARP may refer to the Effective Date of August 10, 2022.

2. EARLY ACTION REDUCTION PLAN

Sterigenics began to implement reduction measures in April 2022. Additional early action reduction measures have since been identified, as provided in this Plan.

2.1 Name, Address, and SCAQMD Facility Number

Sterigenics operates two neighboring facilities in Vernon, CA. Their addresses are:

Sterigenics, U.S., LLC (Facility ID 126191)
4801-63 E. 50th Street
Vernon, CA 90058

Sterigenics, U.S., LLC (Facility ID 126197)
4900 S. Gifford Avenue
Vernon, CA 90058

2.2 Key Health Risk Driver Identification

Per the June 7, 2022 Notice from SCAQMD to Sterigenics, Sterigenics is required to expeditiously reduce risks from the facility based on the levels of ethylene oxide from local ambient air quality monitoring data and other findings from site visits at the Sterigenics facilities. Based on this information and various discussions with SCAQMD staff, Sterigenics has identified ethylene oxide emissions from the following sources as key health risk drivers for the purposes of this EARP:

- Facility ID 126191
  - Scrubber (Permit No. G2974)
  - Abator (Permit No. G44886)
  - Various Fugitive Sources
- Facility ID 126197
  - Scrubber (Permit No. R-G43812)
  - Abator (Permit No. G44884)
  - Various Fugitive Sources

In addition, Sterigenics has identified risk-reducing procedural changes beyond specific devices or processes for early implementation.

2.3 Early Risk Reduction Measures and Schedule

Sterigenics has already implemented numerous risk reduction measures and continues to assess others. As early as April 2022, after SCAQMD raised concerns based on the nearby air monitoring results, Sterigenics began identifying actions they could quickly take to reduce emissions, and thus risk, through procedural changes, process changes, physical modifications, and curtailments. The subsequent report sections summarize the risk-reduction measures that Sterigenics has implemented thus far and additional actions that they plan to take in both the short and long term. Except as otherwise provided, these measures will remain in place until the permanent total enclosures ("PTEs," as defined in Measure 23) are installed and operational and associated fugitive emission controls are constructed.

2.3.1 Interim Fugitive Emission Control Measures Until the Permanent Total Enclosures (PTE)s are Installed and Operational

1. For process areas with fugitive Ethylene Oxide (EtO) emission sources, Sterigenics will:

a. Install and maintain temporary enclosures, where feasible, using physical barriers such as plastic sheeting (10 mil thickness or greater), plastic strip curtains, accordion doors, etc. These areas include the transfer corridor from chamber room(s) to the aeration room(s) at 49th Street facility; and the warehouse/shipping area(s) at both 49th and 50th Street facilities. The installation of temporary enclosures will be reevaluated upon commissioning of the dry beds in the 49th Street and 50th Street facilities' shipping areas, and Sterigenics may propose, subject to the District's approval, the removal of some or all of these enclosures if it can be demonstrated that their presence reduces the overall effectiveness of the dry beds;

b. Direct fugitive emissions to control equipment if feasible;

c. Develop and submit for District approval within ten days of the Effective Date, a plan to conduct parameter monitoring for measures 1(a) and 1(b), such as via smoke tests, differential pressures, or inward face velocities, at an appropriate frequency. Sterigenics will implement the approved plan within 5 business days of plan approval; and

d. Maintain records onsite and provide to the District upon request.

Schedule: Temporary enclosures using physical barriers were installed between May 2022 and the present; installation efforts are ongoing. Fugitive emissions were directed to control equipment where feasible between April and May, 2022. A plan to conduct parameter monitoring was required to be submitted for District approval within 10 days of the Effective Date. This Parameter Monitoring Plan was submitted on August 19, 2022.

2. For areas with fugitive EtO emissions, Sterigenics will:

   a. Vent (or otherwise direct air from) areas with fugitive EtO to portable capture and control equipment, including additional fans routed to existing emission controls, portable Timilon filter systems, and dry bed systems; and

   b. Evaluate other interim measures and technologies and continue to implement any feasible control measures.

   Schedule: Sterigenics has been installing portable capture and control equipment throughout both facilities on beginning May 2022 and further installation work is ongoing.

3. Sterigenics will immediately commence – and no later than 30 days after the Effective Date, complete – sealing of all building draft openings (except as otherwise specified in this EARP) that are not under negative pressure as verified by conducting smoke testing or differential pressure measurements (except as otherwise specified in these measures and consistent with Measure 1(c)). Plastic sheeting (10 mil thickness or greater), or other materials approved by the District, over openings will be considered as acceptable sealing.

   Schedule: Sterigenics began sealing of all building draft openings on August 10, 2022. Work is scheduled to be complete on or before September 9, 2022.

4. Sterigenics will keep all access doors in process, storage, and shipping areas closed, except while they are in active use.

Schedule: Sterigenics has been keeping access doors closed except when in active use since April 2022.

5. Sterigenics will install signage on both sides of personnel and vehicle access doors for areas with known fugitive EtO emissions. The signs will have the following wording: "Caution Ethylene Oxide. Door(s) will be kept closed when not in use," or other wording approved by the District. Letters will be at least 85-point type and will be visible to personnel using the doors.

   Schedule: Sterigenics installed required signage on August 11, 2022.

6. Sterigenics will where possible keep truck bay doors closed during loading and unloading, or ensure that truck bay doors remain closed except when personnel are actively involved in truck movement and/or truck loading and unloading.

   Schedule: Sterigenics has been keeping truck bay doors closed except when in active use since April 2022.

7. On a daily basis, Sterigenics will inspect all roll-up door(s) for any damage that may allow for potential fugitive EtO emissions to pass through such door. Sterigenics will maintain a log that documents all daily inspections. If damage is observed, Sterigenics will immediately make repairs or make arrangements for repairs at the earliest feasible time, record the repairs, and provide records sufficient to demonstrate compliance with this measure to the District upon request. Sterigenics will submit a notification (Rule1405notifications@aqmd.gov) if a repair takes more than 3 business days to complete.

   Schedule: Sterigenics began daily inspections on August 10, 2022.

8. Sterigenics will as soon as possible, but no later than 30 days from the Effective Date, develop and submit (Rule1405notifications@aqmd.gov) for District review and approval a building differential pressure monitoring plan. Upon approval, the plan will be implemented and considered enforceable as a measure under this Plan. The plan will:

   a. Entail the installation, operation, maintenance of a differential pressure monitoring system for each total enclosure as follows:

      i. A minimum of one building differential pressure monitoring system will be installed and maintained at each of the following three walls in each total enclosure having a total ground surface area of 10,000 square feet or more:

         1. The leeward wall;
         2. The windward wall; and
         3. An exterior wall that connects the leeward and windward wall at a location defined by the intersection of a perpendicular line between a point on the connecting wall and a point on its furthest opposite exterior wall, and intersecting within plus or minus ten (±10) meters of the midpoint of a straight line between the two other monitors specified for the leeward wall and windward wall. The midpoint monitor will not be

located on the same wall as either of the other two monitors specified for the leeward wall and windward wall.

ii. A minimum of one building differential pressure monitoring system will be installed and maintained at the leeward wall of each total enclosure that has a total ground surface area of less than 10,000 square feet.

b. Include provisions for maintenance, recordkeeping, and reporting unless already required by Paragraphs 1(c), 3 or 7.

Schedule: The building differential pressure monitoring plan will be submitted for District approval by September 9, 2022. After SCAQMD approval, the building differential pressure and monitoring plan will be implemented after the dry bed systems are installed and operational (per Item 16).

9. At least daily, Sterigenics will inspect temporary enclosure measures for integrity against breaches. If breaches in temporary enclosures or seals are observed, Sterigenics will make immediate repairs or, if such repairs are not able to be immediately made, Sterigenics will immediately make arrangements for repairs at the earliest feasible time. For temporary enclosures not already covered by Paragraphs 1(c), 3 or 7, records of inspection and any repairs will be maintained daily and kept onsite. Sterigenics will submit a notification (Rule1405notifications@aqmd.gov) if a repair takes more than 2 business days to complete.

   Schedule: Sterigenics began daily inspection of temporary enclosure measures on August 10, 2022.

10. Sterigenics will increase aeration time 24 hours or more where practical in the aeration room(s) to the maximum extent of the allowable ranges, and Sterigenics will use its best efforts to ensure sufficient physical space in the aeration room(s) to achieve such increases in aeration time. Sterigenics will not be required to aerate materials less than minimum or more than maximum durations established in the approved U.S. FDA sterilization cycles for those materials. Sterigenics will provide the District, within 30 days of the Effective Date, records that demonstrate the increase over the baselines of aeration times in June 2022, compared to a baseline of January 2022, including percentage measurements. Records that identify the materials undergoing aeration and log the aeration times, and corresponding customer and/or U.S. FDA aeration specifications, along with records of warehouse holding times (between the time the product exits aeration and the time the product is shipped from the facilities), will be maintained and made available to the District upon request. Sterigenics will, within 45 days of this Plan, initiate a report that consolidates the relevant aforementioned data, including aeration times, U.S. FDA and/or customer aeration specifications, and warehouse holding times, and will provide this report to the District (Rule1405notifications@aqmd.gov) on a monthly basis.

    a. Sterigenics and the District may meet and confer regarding evaluation of this data. Sterigenics acknowledges the District may evaluate records submitted under this measure and may, with a demonstration of good cause, seek modification of this Plan to seek to increase aeration times (without requiring

Sterigenics to exceed maximum aeration times as specified in U.S. FDA and/or customer aeration specifications) or otherwise seek to enhance this measure.

Schedule: Sterigenics began complying with this requirement in early May 2022.

11. Sterigenics will continue to conduct leak detection pursuant to the procedures in the current version of Rule 1405 at least monthly. Sterigenics will maintain its other existing internal leak detection methods and practices, which include leak tests during every sterilization cycle and continuous measurement of EtO concentrations near EtO-containing equipment. The interior gas chromatograph ("GC") data for the 49th Street and 50th Street facilities will be reviewed to see if there are increased EtO levels near this equipment. If increased levels at or above 1 ppm are detected, Sterigenics will further inspect and document equipment for EtO leaks using handheld instruments with an electrochemical detector or other EtO-specific instrumentation with a low detection limit at or below 0.5 ppm. Leak detection procedures must be directed to any equipment or components handling EtO that are under positive pressure (e.g., vacuum pumps, control equipment piping, or storage). Sterigenics will also develop a supplemental EtO Leak Detection and Repair (LDAR) program for monthly inspection of the scrubber and oxidizer external piping that is under positive pressure (which, together with the vacuum pumps, control equipment piping, or storage described in the preceding sentence, comprises the "Relevant Equipment"). LDAR data must be recorded in a format approved by the District and provided to District personnel upon request.

    Schedule: Sterigenics began preparation of a supplemental Leak Detection and Repair Plan in May 2022. This plan will be implemented beginning on August 29, 2022.

12. Sterigenics will report (Rule1405notifications@aqmd.gov) any EtO leaks greater than or equal to 10 ppm from the Relevant Equipment within two hours of discovery, and the report will detail the action plan and repair timeline. For any leak greater than or equal to 10 ppm EtO, Sterigenics will, within 3 days of discovery of the leak, submit (Rule1405notifications@aqmd.gov) a written report with a root cause analysis and details on corrective actions taken.

    Schedule: Sterigenics will comply with this requirement as needed.

13. Sterigenics will develop and implement a protocol that includes daily inspection of the acid scrubber systems for potential ethylene glycol leaks, and a protocol for repair or removal of components found to be leaking ethylene glycol. Sterigenics will keep records of all such inspections and repairs and provide to District personnel upon request.

    Schedule: Sterigenics began development of the required protocol in conjunction with development of the LDAR program in May of 2022. The LDAR protocol will be implemented beginning August 29, 2022. Additionally, Sterigenics has continued with its ongoing daily leak inspections, which include inspections for leaks of ethylene glycol.

14. Sterigenics will immediately repair or take out of service any components with any instrument-detected leaks of EtO (as provided for in Measure 12) or ethylene glycol (as provided for in Measure 13). Leaking components must be repaired before they are returned to service.

    Schedule: Sterigenics will comply with this requirement as needed.

15. Sterigenics will within 30 days of the Effective Date, submit to (Rule1405notifications@aqmd.gov) a report that evaluates the use of interior GC systems as a tool for assessing and implementing other measures to ensure on-site worker safety while reducing exterior EtO emissions, including evaluating the development of a daily GC summary report that calculates and reports periodic average EtO concentrations for review and assessment. The evaluation will include a prioritization of areas to locate ports where possible; an evaluation of relocating ports during construction of the PTE; and a review of the system daily calibration along with periodic testing at various ports with samples of known EtO gas concentration.

    Schedule: Sterigenics will submit the required report within 30 days of the Effective Date.

16. Sterigenics will construct and operate the dry beds at the 49th and 50th Street facility as soon as possible after issuance of all applicable government approvals, but in no case later than March 31, 2023 (exclusive of any additional dry bed(s) installed in conjunction with construction of the PTE at the 49th Street facility). These dry beds are intended to control fugitive emissions, as indicated in permit applications submitted to the District on June 6, 2022. Upon full operation of the dry beds, if either facility exceeds an EtO concentration of 1.0 ppm on an 8-hour rolling average in the shipping area outside of the aeration room(s), Sterigenics will notify the District (Rule1405notifications@aqmd.gov) within 24 hours. If 8-hour rolling average EtO concentrations persist above 1.0 ppm in the shipping area outside of the aeration room(s) for more than 48 hours, then Sterigenics will submit (Rule1405notifications@aqmd.gov) a written report with a root cause analysis within 2 business days. The report will provide details on the airflow and capture of emissions by the dry beds, as demonstrated by a smoke test, or details on the relevant differential pressure monitor(s) to confirm that sufficient negative pressure exists. Sterigenics will provide final notification to the District (Rule1405notifications@aqmd.gov) within 1 business day when the facility sustains 8-hour rolling average EtO concentrations less than 1.0 ppm for 24 hours. The internal GC, or in the event of the GC system's inaccuracy, another reasonable method put forth by Sterigenics, will be used to monitor EtO concentrations in the shipping area outside of the 49th and 50th Street facilities' aeration room(s). Sterigenics will maintain records sufficient to demonstrate compliance with this measure and provide them to the District upon request.

    Schedule: Sterigenics submitted applications for permits to operate new dry beds throughout their facilities on June 6, 2022, and has subsequently submitted a request for expedited processing of these applications. The dry beds should be fully operational as soon as possible after issuance of all applicable government approvals, but in no case later than March 31, 2023 (exclusive of any additional

dry bed(s) installed in conjunction with construction of the PTE at the 49th Street facility).

17. Within 7 days of full operation of the dry beds in a facility, Sterigenics will maintain continuous negative pressure of at least 0.001 inches of water within the facilities' shipping areas until construction of the PTEs is completed. To the extent that significant construction activities may impede compliance with this measure, Sterigenics will notify the District (Rule1405notifications@aqmd.gov) 24 hours in advance, or as soon as practicable. Sterigenics will install and maintain building pressure differential monitors, and will log differential pressure readings at least once per shift (shifts are 8 hours), sufficient to demonstrate compliance with this measure. If Sterigenics does not maintain continuous negative pressure in accordance with this measure, and no prior notice due to significant construction activities has been provided, Sterigenics will notify the District (Rule1405notifications@aqmd.gov) within 24 hours. Sterigenics will maintain records sufficient to demonstrate compliance with this measure and provide them to the District upon request.

    Schedule: Sterigenics will comply with the timeline in this Plan measure.

18. Sterigenics will, within 30 days of the Effective Date, submit (Rule1405notifications@aqmd.gov) a report that evaluates whether connection of the scrubber exhaust to the Donaldson abator stacks, or other permitted air pollution control equipment, would be a feasible, acceptable, and suitable means to further reduce process EtO emissions. If a connection is not already implemented, this may be addressed in the risk reduction plan.

    Schedule: Sterigenics will provide the requested report by September 9, 2022.

2.3.2 Post-Aeration Testing

19. Sterigenics will submit a test protocol to the District for review and approval to conduct an enclosure testing program of representative pallets and products[1] coming out of the aeration room(s) to characterize and quantify residual off-gassing of EtO. The test protocol will follow guidelines described below in subdivision (a). The source test program will be initiated within 2 weeks of District approval of the protocol, subject to the District's availability to observe the test. Sterigenics will notify the District of initiation of the enclosure testing program no less than 7 days prior to data and sample collection, and the District will be allowed to observe the test and collect duplicate samples. A final source test report will be submitted to the District (Rule1405notifications@aqmd.gov) within 30 days of completion of the test program. Sterigenics will append the District's written comments or evaluation of the final report, if any, to the final report if Sterigenics distributes the final report to any working groups of the EtO sterilization industry or the U.S. FDA for participation in the development of post-sterilization process evaluations.

    a. The Test Protocol will include an initial method validation evaluation to determine the appropriate size of a pallet enclosure and inlet and exhaust ducts and air flow rate to allow effective capture and laminar flow required

[1] "Products" in this measure will refer to representative products that are not customer products.

for quantitative emissions evaluation. Validation steps in the pilot evaluation will include, at a minimum, release of a known mass and concentration of EtO relevant to residual expected from processing through normal operations, to allow recovery, repeatability and time to equilibrium to be established and calculation of the rate of depletion of the EtO over time. The validation step will not include the use of sterilized material, since the amount of EO in this test must be known and the goal is to validate the chamber parameters and monitoring equipment. Sterigenics will notify the District of the initial method validation no less than 7 days prior to the evaluation, and the District will be allowed to observe. The results of the validation evaluation will be submitted to the District. After demonstration of appropriate test conditions and ability to track degradation rates and approval of the developed methodology by the District, quantitative Pallet Enclosure Testing will be conducted over a 4-week period to test pallets of material processed via different cycles reflective of the range of normal operations. A Temporary Total Enclosure (TTE) will be built for this purpose. The enclosure will be designed to accommodate one (1) or more pallet(s) of materials representative of those processed via the range of sterilization cycles in normal operations and held after leaving the aeration room(s). The enclosure will be equipped with inlet and exhaust ducting and will not require contact with the sterilized products. Sterigenics will use representative part(s) and pallet(s) for testing. Inlet air will be supplied from a clean ambient source. The exhaust duct will be connected to a blower and directed to an area under air pollution control. The exhaust duct will be equipped with sample ports to enable measurement of air flow and EtO concentrations. Air flow and concentration will be measured for the selected pallet(s) or part(s) on a continuous or semi-continuous basis as well as quantified at approved timepoints with integrated canister sample results throughout a period representative of the duration that different product batches would be held before shipping. Pallet Enclosure Testing results will be made available to the District (Rule1405notifications@aqmd.gov) on a rolling 2-week basis following collection.

b. After Sterigenics has submitted the testing protocol to the District, if Sterigenics does not perform the testing as required, District personnel or District-authorized contractors may elect to perform the testing. Sterigenics will facilitate such program of testing that will be conducted by District personnel or District-authorized contractors. Specifically, Sterigenics will make all reasonable accommodations for the District's program of work to initiate, conduct (for not more than 4 weeks), and conclude an enclosure testing program of representative pallets and products coming out of the aeration room(s) to characterize and quantify any residual off-gassing of EtO pursuant to the test protocol developed by Sterigenics and approved by the District, or pursuant to a test protocol developed by the District that takes into the account relevant variables (e.g., airflow and time). Sterigenics will provide training to District personnel or District-authorized contractors regarding all health and safety requirement applicable in areas in which the study is to be conducted. The testing will commence upon soonest

availability of District personnel. After completion of testing, Sterigenics will within 60 days of billing notification pay the District the costs of materials and testing per applicable fee rates in District Rules 304 and 304.1.

Schedule: Sterigenics will provide the requested test protocol within 90 days of approval of this Early Action Reduction Plan by the District, and meet all subsequent timelines listed in this Plan measure. Testing pursuant to the test protocol will occur at either of the Sterigenics Vernon facilities (Facility ID 126191 and Facility ID 126197) or at the Sterigenics facility in the City of Ontario (Facility ID No. 126060), to be selected by Sterigenics.

2.3.3 Install and Perform Air Monitoring

20. Sterigenics will, within 14 days of the Effective Date, commence the fenceline air monitoring plan included here as Appendix A. Monitoring pursuant to Appendix A shall continue for 60 days after the completion of the final PTE or as required or modified by any applicable South Coast AQMD Rule.

    Schedule: Sterigenics commenced the fenceline monitoring plan on August 24, 2022 at the two locations for which access is available. Sterigenics is working to secure site access to the other two locations.

21. Sterigenics will install a wind monitoring system and data logging system at a location approved by the District.

    Schedule: Sterigenics will install a wind monitoring system and data logging system at a location approved by the District within two weeks of receiving approval from the District. The proposed location of the wind monitoring system was submitted to the District for approval on August 18, 2022.

22. Sterigenics will submit (Rule1405notifications@aqmd.gov) all internal EtO monitoring data (e.g., GC data) on a weekly basis, except as otherwise provided in the measures herein, to the District. All data will include individual readings and will be provided in Excel format.

    Schedule: Sterigenics began submitting required monitoring data on a weekly basis on August 18, 2022.

2.3.4 Construction Schedules

23. Sterigenics will construct and operate PTEs, each with an additional GC system, within twelve months of all applicable permit approvals, unless Sterigenics seeks an extension of time from the Executive Officer. In any case, PTEs will be constructed and operational no later than January 15, 2024 for the 50th Street facility, and May 1, 2024 for the 49th Street facility. The PTEs will be constructed consistent with U.S. EPA Method 204, except as otherwise specified in the permits for PTEs issued by the District. ("PTEs" as used in this Plan means the PTEs as described in the immediately preceding sentence).

    Schedule: Sterigenics will construct the PTEs within 12 months of applicable permit approvals unless an extension is needed.

24. Sterigenics will notify the District within 7 days of completion of construction of each of the PTEs. Until satisfaction of this measure, Sterigenics will submit

(Rule1405notifications@aqmd.gov) a monthly report to the District with status updates in relation to increments of progress for construction of the PTEs.

Schedule: Sterigenics will notify the District within 7 days of construction completion for each of the PTEs. Upon Plan approval, Sterigenics will begin submitting a monthly report to the District with updates on construction increments of progress.

2.3.5 Curtailment Provisions

25. Appendix A to the EARP, the Fenceline Monitoring Plan, specifies how this monitoring will be conducted and provides that results from the monitoring specified in Appendix A will be reported to the District. Appendix A will specify that Monitor M2 will be sampled at a frequency of 1 sample every 3 calendar days, and Monitors M1, M3 and M4 will be sampled as provided in Appendix A. As soon as reasonably possible, but no later than three (3) hours of discovering or receiving notification that laboratory-validated ambient air monitoring results are 17.5ppb or above of EtO at any ambient air monitoring location specified in Appendix A for a single 24-hour sample, Sterigenics will notify the District via e-mail to Rule1405notifications@aqmd.gov of the result. The email will include the laboratory results package and any other information to be reviewed by South Coast AQMD. As soon as reasonably possible, but not later than the time curtailment is required to commence, Sterigenics supplementally will notify the District via email to Rule1405notifications@aqmd.gov of the previous seven calendar days facility total and average daily EtO usage. Upon a determination, pursuant to measure 29, by the District that curtailment is required, Sterigenics shall commence curtailment activities, subject to other provisions of this Section 2.3.5, as follows:

    a. Upon an initial result at or above 17.5 ppb, but less than 25.0ppb, Sterigenics shall curtail operations by 20 percent. Upon an initial result at or above 25.0ppb, Sterigenics will curtail operations by 50 percent.

    b. Upon a second result at or above 17.5 ppb, Sterigenics will curtail operations by 50 percent or, if the initial result was at or above 25.0ppb, Sterigenics will curtail operations by 100 percent. Multiple monitors exceeding thresholds on the same day shall not constitute multiple results for this provision and the highest value will be used to determine curtailment.

    c. Upon a third or any subsequent result at or above 17.5 ppb, Sterigenics will curtail operations by 100 percent.

    Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

26. If curtailment is triggered:

    a. Sterigenics may resume normal operations upon the first subsequent monitoring result below 17.5 ppb from the monitor yielding the elevated result that triggered curtailment, so long as subsequent, available monitoring results at all monitors are also below 17.5 ppb.

    b. If a period of at least 30 calendar days demonstrates consecutive results below 17.5 ppb from all monitors, a subsequent result at or above 17.5 ppb

shall recommence the curtailment provisions of measure 25(a) through (c) as an initial result under 25(a).

c. If three invalid samples are reported for any single monitor location during a consecutive 30-Day period, then South Coast AQMD may elect to conduct monitoring at that location. The District shall be reimbursed by Sterigenics for monitoring efforts conducted pursuant to this section. Sterigenics may resume their own sampling at the site once a Quality Assurance plan has been submitted and approved by South Coast AQMD.

Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

27. For curtailment of 20 and 50 percent, the reduction will be based on a calculation of pounds of EtO as follows:

    a. Sterigenics will calculate the total pounds of EtO used at the 49th Street and 50th Street facilities in the aggregate in the 7 calendar days preceding the date of the monitoring result at or above 17.5 ppb; and

    b. will calculate the daily average for the seven-day period; and

    c. will reduce by 20 or 50 percent (whichever is applicable) the average daily EtO usage in 27(b) at the 49th Street and 50th Street facilities in the aggregate for the curtailment period. This reduction will be achieved by initiating fewer loads into preconditioning, such that less EtO is required for sterilization cycles. At any such time Sterigenics is required to fully curtail operations, if products are already in the preconditioning chamber, Sterigenics may finish the sterilization cycle for those products.

    Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

28. Sterigenics shall maintain daily EtO usage records for the 49th St and 50th St. facilities for at least two years, and shall maintain any records required pursuant to measure 27. The records shall be provided to District personnel upon request.

    Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

29. Any result of 17.5 ppb or above shall be subject to review by the District for determination of curtailment action as follows: Upon informing the District of a reading above 17.5ppb, Sterigenics may present, within 24-hours, evidence to the District, including data from Sterigenics' meteorological stations, security camera footage, or other credible sources that would demonstrate that the sample result does not accurately capture Sterigenics' contribution to the ambient concentration recorded by the monitor or is invalid due to equipment or sampling failures. The District will consider such evidence in determining whether the result will trigger a curtailment action, and will meet and confer with Sterigenics regarding its determination. Curtailment shall begin after the 24-hour period unless the District provides written notification to end the curtailment based on the data presented.

Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

30. Sterigenics shall notify the District no later than three hours after any changes in curtailment status in measure 26.

    Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

31. A result from a District monitor in the vicinity of the Vernon Facilities, generally consistent with the proximity of the District's monitors at Site 1, 2 and 3 during the period of June-August 2022, shall constitute a result in measures 25 and 26. Upon notification by the District of an elevated result, all conditions shall apply to Sterigenics, except Sterigenics will not be required to provide the laboratory results package in measure 25.

    Schedule: Sterigenics will comply with the timelines in this measure upon approval of this plan.

2.3.6 Administrative

32. Upon presentation of appropriate credentials, Sterigenics will allow District personnel or authorized representatives to enter and inspect the premises, have access to records, and take samples, with the understanding that all records identified or marked "confidential" and/or "trade secret" (or any similar term or phrase) by the Sterigenics will be handled as confidential records pursuant to the California Public Records Act. During inspection or sampling, Sterigenics will not alter normal business operations or equipment to suppress emissions for the purpose of evading detection or concealing emissions during monitoring or testing.

    Schedule: The District has been allowed to enter and inspect the premises, have access to records, and take samples on an ongoing basis. This will continue.

APPENDIX A
FENCELINE AIR MONITORING PLAN

Appendix A

Fenceline Air Monitoring Plan

Sterigenics shall perform periodic ambient air monitoring to measure concentrations of EtO at locations near the perimeter of the adjoining 49th Street and 50th Street facilities ("Fenceline Locations"). Analysis will be by a standard and generally accepted methodology capable of routinely reporting EtO concentrations of less than 1 part-per-billion by volume (ppbv). The District will be allowed access and be able to conduct technical review of the sampling sites, equipment and methods and also be able to conduct side by side testing upon request.

Sampling Locations

Proposed locations near the perimeter are shown on Figure 1. Respondent shall aim to locate a monitor at, or as close as possible to, the existing District sampling location on 49th Street (M2 in Fig. 1) with the understanding that this location has detected the highest levels of ambient EtO concentrations and continued monitoring at this location would promote continuity of monitoring data. Final siting of station locations shall be informed, to the extent practical, by guidelines in Appendix E of 40 CFR Part 58 regarding obstructions, and subject to final District approval. For sampling locations that require off-site access, Respondent shall make best efforts to secure the sampling site location within 14 days of issuance of Order, or shall notify the District (Rule1405notifications@aqmd.gov) within 2 days of becoming aware that an approved site location cannot be secured. Once sampling locations have been finalized, locations may be moved upon the approval of the District to accommodate traffic, access and safety considerations, or any modifications to equipment at the facilities.

Sampling Methods

Beginning within 14 days of the Effective Date, or, if a sampling location requires securing off-site access, then within 14 days of securing such access, samples will be collected at monitors M1, M3, and M4 on a minimum of 1-in-6 day cycle, while samples will be collected at M2 on a minimum 1-in-3 cycle, both cycles following the calendar established by the USEPA Ambient Monitoring Technology Information Center (https://www.epa.gov/amtic/sampling-schedule-calendar). Results for monitors M1, M3 and M4 will be reported to the District within 14 calendar days of sample collection, except as provided below. For monitor M2, Results will be reported to the District within 10 calendar days of sample collection unless Sterigenics provides a reason that results for M2 cannot be reported within 10 days, in which case results for M2 shall be reported as soon as possible thereafter but no later than 14 calendar days after sample collection, except as provided below.

Samples reflective of conditions over an entire day and night ("24-hr Samples") will be collected using standard equipment suitable for collecting ambient air consistently over this duration (e.g., Summa canisters and mass flow controller valves). Sampling duration for individual samples

may vary in the field based on canister flow rates and the target time range will be 24 hours +/- 1 hour. Samples will be collected from approximate breathing zone height, approximately 4-6 feet from the ground surface.

Each sampling canister to be used in a sampling round will be individually tested and certified for EtO analysis by the laboratory before deployment in the field.

Analyses

Laboratory analyses will be conducted by an independent third-party laboratory that has demonstrated capabilities to measure sub-ppbv EtO concentrations using a method such as USEPA TO-15 and is agreed upon with the District.

Validated results, records of wind direction and speed obtained at an on-site location during the sampling period, and any annotations regarding sample handling or exceptions to collection methods occurring in the field shall be reported to the District for each round of sampling within 14 days after sample collection, unless the laboratory cannot process such samples within a 14-day timeframe (even if expedited processing is requested) due to circumstances beyond the reasonable control of Respondent, in which case Respondent shall notify the District within 2 days of becoming aware that the deadline will be not be met; in such cases, Respondent shall request simultaneous release of the sampling results to the District.

Post-Facility Upgrade Modifications

After the dry bed system has been installed and demonstrated to function, Sterigenics may demonstrate the stability of the resulting conditions and reduce the monitoring frequency while the facility is operating under normal conditions as follows:

- If 7 consecutive rounds of sampling results following installation of the dry bed system demonstrate that all results from each location are less than 1.6 ppbv (one-half of the District guideline for workers in the areas), the sampling frequency can be reduced to 1-in-12 days.
- If a result greater than 2 ppbv is reported for any of the 1-in-12 samples, the sampling frequency will revert to 1-in-6 days for at least 7 rounds of sampling and then a return to 1-in-12 day testing may be requested.

Discontinuation of Monitoring

If the District, in its sole judgment, determines that fenceline monitoring at any or all sites does not yield results that are relevant or useful (either due to the evolution or changes in reliability of the technology, consistency or inconsistency in the data, or any other relevant reasons), the District shall notify Sterigenics that it may cease such monitoring pursuant to this Plan.

Appendix A – Figure 1. Fenceline Air Monitoring Locations (M1, M2, M3, M4).