Prepared for Sterigenics U.S., LLC Ontario, California

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# EARLY ACTION REDUCTION PLAN STERIGENICS U.S., LLC ONTARIO, CALIFORNIA



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# APPENDIX

Appendix A: Fenceline Air Monitoring Plan

# **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 one facility within the city of Ontario (Facility ID 126060). This facility sterilizes medical devices such as surgical kits, medical hardware, gowns and drapes, surgical accessories and medical packaging using ethylene oxide (EtO). The facility is 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 Ontario facility via truck. These products are unloaded, sterilized with EtO, aerated, then shipped out to medical facilities and customers. 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 September 29, 2022, SCAQMD issued a Notice of Designation (Notice) of Sterigenics U.S., LLC. Ontario Facility 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.

	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	

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

# 2. EARLY ACTION REDUCTION PLAN

Sterigenics began to implement reduction measures in June 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 one facility in Ontario CA:

Sterigenics, U.S., LLC (Facility ID 126060) 687 Wanamaker Ave. Ontario, CA 91761

# 2.2 Key Health Risk Driver Identification

Per the September 29, 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 126060
  - Scrubber (Permit No. F98585)
  - Abator (Permit No. G52334)
  - Abator (Permit No. R-G47352)
  - 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 June 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, and physical modifications. 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 enclosure ("PTE," as defined in Section 2.3.3) is installed and operational.

Measures in the early action reduction plan (EARP) were developed in coordination with SCAQMD. Schedules in this EARP refer to the Effective Date of approval of this EARP (April 7, 2023).

In addition to complying with the schedules outlined below, Sterigenics shall document when a measure has been completed or compliance achieved and notify the District within 3 business days via email (Rule1405notifications@aqmd.gov). Whenever an additional plan is to be submitted, Sterigenics will submit all applicable fees along with the plan.

# 2.3.1 Interim Fugitive Emission Control Measures Until the Permanent Total Enclosure (PTE) is Installed and Operational

- 1. For process areas with fugitive Ethylene Oxide (EtO) emission sources, Sterigenics shall:
  - a. Develop and submit for District approval within ten business days of the Effective Date, a plan to conduct parameter monitoring such as via smoke tests, differential pressures,

or inward face velocities, at an appropriate frequency. Sterigenics shall implement the approved monitoring plan within 5 business days of monitoring plan approval; and

b. Maintain records on-Site for two years and provide to the District upon request.

**Schedule:** Sterigenics shall comply with the timelines in this control measure upon approval of this EARP. For areas with fugitive EtO emissions, Sterigenics shall:

- c. 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/or dry bed systems; and
- d. Evaluate other interim measures and technologies and continue to implement any feasible control measures.

**Schedule:** Sterigenics shall comply with 1. c. and d. based on results of 1.a and b., and any applicable permitting requirements. Sterigenics shall provide additional detail regarding the timelines for permit application submission and equipment installation in the Risk Reduction Plan submittal.

2. Sterigenics shall upon approval of this EARP, and no later than 30 calendar 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(a)). Plastic sheeting (10 mil thickness or greater), or other materials approved by the District, over openings shall be considered as acceptable sealing.

**Schedule:** Sterigenics shall complete sealing of all building draft openings within 30 calendar days of the Effective Date.

3. Sterigenics shall keep all access and overhead dock doors in process, storage, and shipping areas closed, except while they are in active use. Sterigenics shall inspect all roll-up door(s) for any damage that may allow for potential fugitive EtO emissions to pass through such door twice daily or at the beginning of each shift, whichever is more frequent. Sterigenics shall maintain a log that documents all inspections. Sterigenics shall also document any incident of damage and repairs. If damage is observed, Sterigenics shall 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 shall submit a notification (<u>Rule1405notifications@aqmd.gov</u>) if a repair takes more than three business days to complete.

Schedule: Sterigenics has already been keeping access doors closed except when in active use.

4. Sterigenics shall install signage on both sides of personnel and vehicle access doors for areas with known fugitive EtO emissions. The signs shall have the following wording: "Caution Ethylene Oxide. Door(s) shall be kept closed when not in use," or other wording approved by the District. Letters shall be at least 72-point type and shall be visible to personnel using the doors.

Schedule: Sterigenics will install required signage within 30 calendar days of the Effective Date.

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

- 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 shall 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  $(\pm 10)$  meters of the midpoint of a straight line between the two other monitors specified for the leeward wall and windward wall. The midpoint monitor shall 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 shall 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 Measures 1, 2 or 3.

**Schedule:** The building differential pressure monitoring plan shall be submitted for District approval within 30 calendar days of the Approval of this EARP. After SCAQMD approval, the building differential pressure and monitoring plan shall be implemented after the negative pressure system is installed and operational (per Measure 12).

6. At least daily, Sterigenics shall inspect temporary enclosure measures for integrity against breaches. If breaches in temporary enclosures or seals are observed, Sterigenics shall make immediate repairs or, if such repairs are not able to be immediately made, Sterigenics shall immediately make arrangements for repairs at the earliest feasible time. For temporary enclosures not already covered by Measures 1, 2, or 3, records of inspection and any repairs shall be maintained daily and kept onsite. Sterigenics shall submit a notification to (<u>Rule1405notifications@aqmd.gov</u>) if a repair takes more than two business days to complete. The notification shall include the reason the repair could not be completed during the operating shift, interim corrective actions, and the proposed completion date.

**Schedule:** Sterigenics shall begin daily inspection of temporary enclosure measures within 10 business days of approval of the EARP.

7. Sterigenics shall increase aeration time where practical in the aeration room(s) up to the maximum extent of the allowable ranges, and Sterigenics shall use its best efforts to ensure sufficient physical space in the aeration room(s) to achieve such increases in aeration time. Sterigenics shall 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 shall provide the District, within 30 calendar days of the Effective Date, records that demonstrate the increase over the baselines of aeration after the Effective Date, compared to a baseline of January 2023, 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), shall be maintained for two years and made available to the District upon request. Sterigenics shall, within 45 calendar days of this EARP, 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 shall provide this report to the District (<u>Rule1405notifications@aqmd.gov</u>) on a monthly basis. For avoidance of doubt, this requirement shall terminate upon successful implementation of the Permanent Total Enclosure.

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 EARP 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 shall comply with the timelines in this measure upon approval of this EARP.

8. Sterigenics shall continue to conduct leak detection pursuant to the procedures in the current version of Rule 1405 at least monthly. Sterigenics shall 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 Ontario facility shall be reviewed weekly to see if there are increased EtO levels near this equipment. If increased levels at or above 1 ppm are detected, Sterigenics shall 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 shall 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 has begun preparation of a supplemental LDAR Plan. This LDAR plan shall be finalized and implemented beginning in the month following approvals of this EARP.

9. Sterigenics shall report (<u>Rule1405notifications@aqmd.gov</u>) any EtO leaks greater than or equal to 2 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 2 ppm EtO, Sterigenics shall, within 3 calendar days of discovery of the leak, submit (<u>Rule1405notifications@aqmd.gov</u>) a written report with a root cause analysis and details on corrective actions taken.

**Schedule:** Sterigenics shall comply with this requirement as needed.

10. Sterigenics shall 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 shall 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. This shall be implemented with the LDAR program in Measure 8.

11. Sterigenics shall immediately repair or take out of service any components with any instrument-detected leaks of EtO (as provided for in Measure 9) or ethylene glycol (as provided for in Measure 10). Leaking components must be repaired before they are returned to service. Sterigenics shall maintain a log of which components were taken out of service, including the date and time that they were taken out of service, as well as the date and time that they were reinstalled or brought online.

Schedule: Sterigenics shall comply with this requirement as needed.

12. Sterigenics shall construct and operate a negative pressure system at the Ontario facility as soon as possible after issuance of all applicable government approvals, but in no case later than December 23, 2023. The negative pressure system shall be constructed and operated per the building differential pressure monitoring plan in Measure 5. Sterigenics shall complete an assessment to determine if existing emission controls can suffice to maintain negative pressure, capture indoor air and control indoor emissions of EO. Upon full operation of the negative pressure system, if the facility exceeds an EtO concentration of 1.0 ppm on an 8-hour rolling average (measured with the internal GC system and reviewed daily) in the shipping area outside of the aeration room(s), Sterigenics shall 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 shall submit (Rule1405notifications@agmd.gov) a written report with a root cause analysis within two business days. The report shall provide details on the airflow and capture of emissions by the emission control devices, as demonstrated by a smoke test, or details on the relevant differential pressure monitor(s) to confirm that sufficient negative pressure exists. Sterigenics shall provide final notification to the District (Rule1405notifications@aqmd.gov) within one 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, shall be used to monitor EtO concentrations in the shipping area outside of the Ontario facility aeration room(s). Sterigenics shall maintain records sufficient to demonstrate compliance with this measure and provide them to the District upon request. Sterigenics shall continue to monitor the operation of the Donaldson Abator (Oxidizer 1) and make improvements wherever practicable. If the unit unexpectedly shuts down, the facility shall report the incident in accordance with Rules 430 and 1405. In addition, Sterigenics shall evaluate the cause of the malfunction and take immediate steps to correct the cause and restart the unit as soon as possible.

**Schedule:** Sterigenics shall comply with the timelines in this measure upon approval of this EARP. Within 7 business days of full operation of the negative pressure system in the facility, Sterigenics shall maintain continuous negative pressure of at least 0.001 inches of water within the facilities' shipping areas until construction of the PTE is completed. To the extent that significant construction activities may impede compliance with this measure, Sterigenics shall notify the District (<u>Rule1405notifications@aqmd.gov</u>) 24 hours in advance, or as soon as

practicable. Sterigenics shall install and maintain building pressure differential monitors, and shall 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 shall notify the District (<u>Rule1405notifications@aqmd.gov</u>) within 24 hours. Sterigenics shall maintain records sufficient to demonstrate compliance with this measure and provide them to the District upon request.

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

#### 2.3.2 Install and Perform Air Monitoring

1. Sterigenics shall, within 14 calendar 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 District Rule.

**Schedule:** Sterigenics shall comply with the timeline in this measure upon approval of this monitoring plan. Sterigenics will install a wind monitoring system and data logging system at a location approved by the District as provided in the next paragraph.

2. Sterigenics shall install a wind monitoring system/sensor and data logging system at a location approved by the District within two weeks of receiving approval from the District. Sterigenics shall submit (<u>Rule1405notifications@aqmd.gov</u>) 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 shall include individual readings and shall be provided in Excel format.

**Schedule:** Sterigenics shall comply with the timeline in this measure upon approval of this monitoring plan.

#### 2.3.3 Construction Schedules

 Sterigenics shall construct and operate a PTE, with an additional GC monitoring system, within twelve months of all applicable permit approvals, unless Sterigenics seeks an extension of time from the Executive Officer. In any case, PTE shall be constructed and operational no later than July 31, 2024 for the Ontario facility. The PTE shall be constructed consistent with U.S. EPA Method 204, except as otherwise specified in the permit for the PTE issued by the District. ("PTE" as used in this EARP means the PTE as described in the immediately preceding sentence).

**Schedule:** Sterigenics shall construct the PTE within 12 months of applicable permit approvals unless an extension is needed.

 Sterigenics shall notify the District within 7 calendar days of completion of construction of the PTE. Until satisfaction of this measure, Sterigenics shall submit (<u>Rule1405notifications@aqmd.gov</u>) a monthly report to the District with status updates for construction of the PTE.

**Schedule:** Sterigenics shall notify the District within 7 calendar days of construction completion for the PTE. Upon EARP approval, Sterigenics shall begin submitting a monthly report to the District with updates on construction progress.

#### 2.3.4 Curtailment Provisions

1. Curtailment Provisions shall commence upon EARP approval. Appendix A to the EARP, the Fenceline Monitoring Plan, specifies how this monitoring shall be conducted and provides that results from the monitoring specified in Appendix A shall be reported to the District. 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 at or above the Trigger Level (as defined below) at any ambient air monitoring location specified in Appendix A for a single 24-hour sample, Sterigenics shall notify the District via email to Rule1405notifications@agmd.gov of the result. The email shall include the laboratory results package and any other information to be reviewed by the District. As soon as reasonably possible, but not later than the time curtailment is required to commence, Sterigenics supplementally shall notify the District via email to Rule1405notifications@aqmd.gov of the facility total and average daily EtO usage for the seven calendar days preceding the date for which the ambient air monitoring result at or above the Trigger Level is reported. As used in this Section 2.3.4, "Trigger Level" means 17.5 ppb, if Section 2.3.4(1)(a) is then in effect, and 8 ppb if Section 2.3.4(1)(b) is then in effect. Upon a determination pursuant to Section 2.3.4(5) by the District that curtailment is required, or if no such determination is made then within 24 hours of notification to the District of the monitoring result at or above the Trigger Level, Sterigenics shall commence curtailment activities, subject to other sections of this provision, as follows:

- For monitoring conducted during the 30 calendar days (subject to extension beyond 30 days in accordance with Section 2.3.4(1)(c)) following EARP approval:
  - i. Upon first reading at or above 17.5 ppb, but less than 25.0 ppb, Sterigenics shall curtail operations by 20 percent. Upon a first reading at or above 25.0 ppb, Sterigenics shall curtail operations by 50 percent.
  - Upon a second reading at or above 17.5 ppb, Sterigenics shall curtail operations by 50 percent or, if the first reading was at or above 25.0 ppb, Sterigenics shall curtail operations by 100 percent.
  - iii. Upon a third or any subsequent reading at or above 17.5 ppb, Sterigenics shall curtail operations by 100 percent.
  - Multiple monitors exceeding a threshold on the same day shall not constitute multiple readings for this provision and the highest value shall be used to determine curtailment.
- For monitoring conducted after 30 calendar days (unless such period was extended in accordance with Section 2.3.4(1)(c), in which case this provision is effective at the termination of the extension period) following EARP approval:
  - i. For monitored levels at or above 8 ppb but less than 12 ppb, operations shall be curtailed by 20 percent upon the second reading, 50 percent upon the third reading, and 100 percent upon the fourth or subsequent reading.
  - For monitored levels at or above 12 ppb, operations shall be curtailed by 20 percent upon the first reading, 50 percent upon the second reading, and 100 percent upon the third or subsequent reading.
  - Multiple monitors exceeding a threshold on the same day shall not constitute multiple readings for this provision and the highest value shall be used to determine curtailment.
- Sterigenics may conduct a review of the ambient measurement data and its operations and request an extension of the initial 30-day period in Sections 2.3.4(1)(a) and (b) to a longer period if the review finds extraordinary or

unforeseen conditions that warrant such an extension. Based on this review and Sterigenic's request that includes appropriate supporting information, the District may extend the 30-day period in Sections 2.3.4(1)(a) and (b) to a longer period as the District may determine to be reasonably necessary.

**Schedule:** Sterigenics shall comply with the timelines in this measure upon approval of this EARP.

- 2. If curtailment is triggered:
  - a. Sterigenics may resume normal operations upon the first subsequent monitoring result below the Trigger Level from the monitor yielding the elevated result that triggered curtailment, so long as subsequent, available monitoring results at all monitors are also below the Trigger Level.
  - b. If a period of at least 30 calendar days demonstrates consecutive results below the Trigger Level from all monitors, a subsequent result at or above the Trigger Level shall recommence the curtailment provisions of Section 2.3.4(1)(a) or (b) as a first reading under Section 2.3.4(1)(a) or (b).

If three invalid samples are reported for any single monitor location during a consecutive 30-Day period, then the District 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 the District.

**Schedule:** Sterigenics shall comply with the timelines in this measure upon approval of this EARP.

- 3. For curtailment of 20 and 50 percent, the reduction shall be based on a calculation of pounds of EtO usage as follows:
  - a. Sterigenics shall calculate the total pounds of EtO used at the Ontario facility in the seven calendar days preceding the date of the monitoring result at or above the Trigger Level; and
  - b. shall calculate the daily average for the seven-day period; and
  - c. shall reduce by 20 or 50 percent (whichever is applicable) the average daily EtO usage at the Ontario facility in the aggregate for the curtailment period. This reduction shall 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 curtail operations, if products are already in the preconditioning room, Sterigenics may finish the sterilization cycle for those products.

**Schedule:** Sterigenics shall comply with the timelines in this measure upon approval of this EARP.

4. Sterigenics shall maintain daily EtO usage records for at least two years, and shall maintain any records required. The records shall be provided to District personnel upon request.

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

5. Any result at or above the Trigger Level shall be subject to review by the District for determination of curtailment action as follows: Upon informing the District of a reading

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above the Trigger Level, 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 shall consider such evidence in determining whether the result shall trigger a curtailment action and shall 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 shall comply with the timelines in this measure upon approval of this EARP.

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

**Schedule:** Sterigenics shall comply with the timelines in this measure upon approval of this EARP.

7. A result from a District monitor in the vicinity of the Ontario Facility as described in Appendix A, shall constitute a result in these curtailment provisions. Upon notification by the District of an elevated result, all measures shall apply to Sterigenics, except Sterigenics shall not be required to provide the laboratory results package.

**Schedule:** Sterigenics shall comply with the timelines in this measure upon approval of this plan. This measure shall continue until 30 calendar days after the PTE is installed and operational.

#### 2.3.5 Administrative

 Upon presentation of appropriate credentials, Sterigenics shall 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 shall be handled as confidential records pursuant to the California Public Records Act. During inspection or sampling, Sterigenics shall 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 shall continue.

2. Sterigenics may request a postponement of a scheduled sampling day (for any air monitoring under Section 2.3.2 above) due to anticipated meteorological or other exceptional conditions. However, Sterigenics shall not postpone any scheduled sampling without prior written approval from District staff.

**Schedule:** Sterigenics may request use of this measure if necessary due to meteorological or other exceptional conditions.

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# 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 Sterigenics Ontario facility, 687 S Wanamaker Ave, Ontario, CA ("Fenceline Locations"). Analysis shall 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 shall 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 facility are shown on Figure 1. Sterigenics shall aim to locate a monitor at, or as close as possible to, the existing District sampling location (Site 1B) in the parking lot adjacent to 720 S Rochester Ave, Ontario, CA (A1 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. All proposed locations require off-site access and Sterigenics shall make best efforts to secure the sampling site locations within 14 calendar days of Approval of Early Action Reduction Plan, or shall notify the District (<u>Rule1405notifications@aqmd.gov</u>) within two calendar 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 calendar days of the Effective Date, or within 7 calendar days of securing access to the locations if this is later, samples shall be collected at monitor A1 on a minimum 1-in-3 day cycle and at monitors A2 and A3 on a minimum of 1-in-6 day cycle, both cycles following the calendar established by the USEPA Ambient Monitoring Technology Information Center (https://www.epa.gov/amtic/sampling- schedule-calendar). Results from monitor A1 shall be reported to the District within 10 calendar days of sample collection unless Sterigenics provides a reason that results for A1 cannot be reported within 10 calendar days, in which case results for A1 shall be reported as soon as possible thereafter but no later than 14 calendar days after sample collection, except as provided below. Results from monitors A2 and A3 shall be reported to the District within 14 calendar days of sample collection, except as provided below.

As required in Section 2.3.4 Curtailment Provisions, ambient air monitoring results that are at or above the Trigger Level at any monitoring location will be provided to the District as soon as reasonably possible, but no later than three (3) hours of Sterigenics discovering or receiving notification of such results. Sterigenics will use timing for the testing and reporting of measurements that end curtailment that is consistent with the timing used for the test results reported that trigger such curtailment. Such consistent timing will result in a minimum curtailment period of 72 hours.

In the event that three consecutive results from either monitor A2 or A3 are higher than the result on the corresponding dates from monitor A1, the single location subject to the 1-in-3 day monitoring frequency and faster reporting provisions above shall be switched to the location with the higher results. If at least 2 consecutive, subsequent results at A1 are again the highest among the monitors, the higher frequency/faster reporting provisions shall switch back to monitor A1.

Samples reflective of conditions over an entire day and night ("24-hr Samples") shall 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 shall be 24 hours +/- 1 hour. Samples shall 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 shall be individually tested and certified for EtO analysis by the laboratory before deployment in the field. If a sampling site cannot be secured with 45 calendar days of the Effective Date, Sterigenics shall compensate the District for the costs of monitoring according to the fee schedule in Rule 304.1. Sterigenics shall pay assessed fees within 60 calendar days after the date shown on a notice of fees from the District's accounting office.

#### Analyses

Sensors used shall be approved by the District. These sensors must have a resolution of  $\pm$  1% of the wind speed reading and  $\pm$  3 degrees of the wind direction.

Laboratory analyses shall 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 calendar 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 Sterigenics, in which case Sterigenics shall notify the District within 2 calendar days of becoming aware that the deadline will be not be met; in such cases, Sterigenics shall request simultaneous release of the sampling results to the District.

If the wind monitoring and data logging system installed pursuant to the EARP records time in a format other than current local time in Ontario, e.g., Universal Standard Time, the logged information shall be supplemented with the addition of a field showing time converted to current local time (Pacific Standard Time or Pacific Daylight Time, as relevant). If speed is recorded in units other than miles per hour, the logged information shall also be supplemented with the addition of a field showing the speed converted to miles per hour.

# Post-Facility Upgrade Modifications

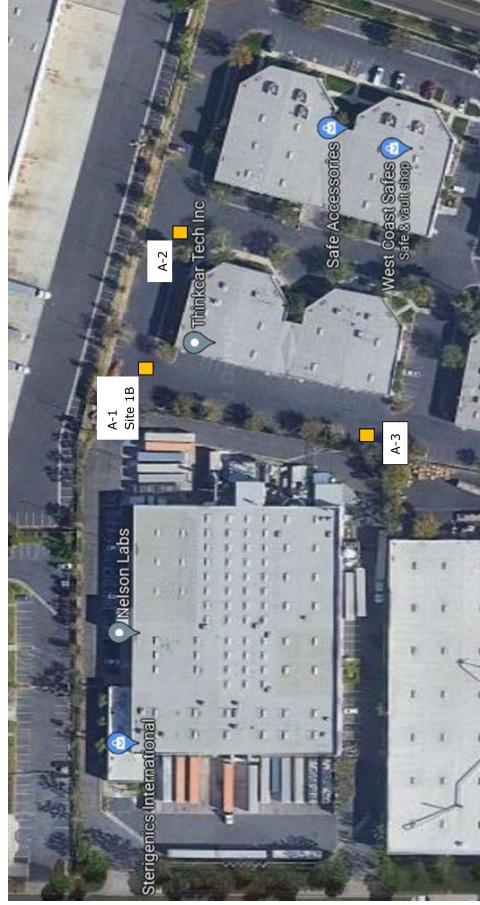
After the stack tie-in project has been completed and demonstrated to function, Sterigenics may demonstrate the stability of the resulting conditions and reduce the monitoring frequency while the facility is operating under normal conditions as follows:

- If 7 consecutive rounds of sampling results following completion of the stack tie-in 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 1.6 ppbv is reported for any of the 1-in-12 samples, the sampling frequency shall 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.

The monitoring frequency may be reevaluated after completion of the negative pressure system.

# 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 (A1, A2, A3)