1 2 3 4 5 6 7 8	OFFICE OF THE GENERAL COUNSEL SOUTH COAST AIR QUALITY MANAGEMEN NICHOLAS A. SANCHEZ, State Bar No. 207998 Assistant Chief Deputy Counsel BRIAN TOMASOVIC, State Bar No. 314279 Principal Deputy District Counsel JOSEPHINE LEE, State Bar No. 308439 Senior Deputy District Counsel 21865 Copley Drive Diamond Bar, California 91765-0940 Telephone: (909) 396-2302 Fax: (909) 396-2961 Attorneys for Petitioner SOUTH COAST AIR QUALITY MANAGEMEN	
9	BEFORE THE HEARIN	G BOARD OF THE
10	SOUTH COAST AIR QUALITY	MANAGEMENT DISTRICT
11	In the Matter of	CASE NO. 6225-1
12	SOUTH COAST AIR QUALITY	PROPOSED FINDINGS AND
13	MANAGEMENT DISTRICT,	DECISION FOR AN ORDER FOR ABATEMENT (STIPULATED)
14	Petitioner,	
15	v.	Health & Safety Code § 41700, District Rule 402
16	STERIGENICS US, LLC [Facility ID Nos. 126197 and 126191]	
17	Respondent.	Date: August 9, 2022
18		Time: 9:00 a.m. Place: 21865 Copley Drive
19		Diamond Bar, CA 91765
20		
21		
22	This petition for a Stipulated Order for Abate	ement was heard on August 9, 2022, pursuant
23	to notice and in accordance with the provisions of th	e California Health & Safety Code Section
24	40823 and District Rule 812. The following member	rs of the Hearing Board were present: Cynthia
25	Verdugo-Peralta, Chair; Robert Pearman, Vice-Chai	r; Micah Ali, Mohan Balagopalan, and Allan
26	Bernstein, DPM. The Executive Officer of the South	n Coast Air Quality Management District
27	(hereinafter referred to as "South Coast AQMD" or	"District" or "Petitioner"), was represented by
28	Brian Tomasovic, Principal Deputy District Counsel	l, and Josephine Lee, Senior Deputy District

Findings and Decision – Sterigenics US, LLC (Fac. ID Nos. 126197 and 126191) Case No. 6225-1

1	Counsel. Respondent Sterigenics US, LLC (hereinafter referred to as "Sterigenics" or	
2	"Respondent"), headquartered in Illinois, was represented by Maya Lopez Grasse, Esq. of Alston	
3	& Bird LLP. The public was given the opportunity to testify. Evidence was received and the	
4	matter was submitted.	
5	The Hearing Board finds and decides as follows:	
6	FINDINGS OF FACT	
7	1. Petitioner is a body corporate and politic established and existing pursuant to	
8	Health and Safety Code §§ 40000, et seq. and §§ 40400, et seq., and is the sole and exclusive local	
9	agency with the responsibility for comprehensive air pollution control in the South Coast Basin.	
10	2. Respondent, Sterigenics US, LLC, operates a medical sterilization business,	
11	including two neighboring buildings in the city of Vernon that are located within South Coast	
12	AQMD's jurisdiction and subject to South Coast AQMD's rules and regulations. The two	
13	facilities have the following addresses and facility ID designations: 4900 South Gifford Avenue,	
14	Los Angeles, CA 90058, with Facility ID No. 126197 ("49 <sup>th</sup> Street facility"), and 4801-63 East	
15	50 <sup>th</sup> Street, Los Angeles, CA 90058, with Facility ID No. 126191 ("50 <sup>th</sup> Street facility")	
16	[collectively the "Vernon Facilities"].	
17	3. Respondent's sterilization operations at portions of the Vernon Facilities involve	
18	the use of Ethylene Oxide ("EtO"), which has been identified by the Office of Environmental	
19	Health Hazard Assessment ("OEHHA") as a known human carcinogen by inhalation.	
20	4. Respondent's sterilization operations at the Vernon Facilities result in the release	
21	of fugitive EtO emissions.	
22	5. California Health & Safety Code § 41700 provides, in pertinent part, that no	
23	person "shall discharge from any source whatsoever such quantities of air contaminants or other	
24	materials that cause injury, detriment, nuisance, or annoyance to any considerable number of	
25	persons or to the public, or that endanger the comfort, repose, health, or safety of any of those	
26	persons or the public, or that cause, or have a natural tendency to cause, injury or damage to	
27	business or property."	
28		

6. District Rule 402 provides as follows: "A person shall not discharge from any
 source whatsoever such quantities of air contaminants or other material which cause injury,
 detriment, nuisance, or annoyance to any considerable number of persons or to the public, or
 which endanger the comfort, repose, health or safety of any such persons or the public, or which
 cause, or have a natural tendency to cause, injury or damage to business or property. The
 provisions of this rule shall not apply to odors emanating from agricultural operations necessary
 for the growing of crops or the raising of fowl or animals."

7. In April 2022, the District initiated ambient air monitoring for EtO by collecting
24-hours samples in and around the Vernon Facilities, specifically at a site located downwind of
the Vernon Facilities on 49<sup>th</sup> Street ("49<sup>th</sup> St. site" or "Site No. 1"). Two more monitors were set
up in May 2022, one on Gifford Avenue ("Gifford site") and one in the nearest residential
community on Fruitland Avenue ("Fruitland site"). Presently, the District has set up two air
monitoring locations around the Vernon Facilities and one community air monitoring location at
the Fruitland site to measure ambient EtO levels.

8. Measurements from the District's monitors may vary according to a facility's
 operations and extant environmental conditions, such as prevailing wind direction or rain on the
 day the measurement is taken. Based upon knowledge and observations of the Vernon Facilities'
 operations, monitored levels of EtO, prevailing wind directions, and other environmental
 conditions, District staff believes that the elevated levels of ambient EtO concentrations at or
 around the Vernon Facilities are due in part to fugitive emissions from Respondent's operations.

9. District staff is required to use health values and methodologies developed by
 OEHHA when estimating health risks in its air toxics program. Using OEHHA health values and
 methodology, District staff has determined that EtO concentrations at 3.18 ppb pose a significant
 cancer risk of 100 in a million as applicable to off-site workers with long-term exposure.

10. Between April 22, 2022 and July 25, 2022, the average EtO concentration
measured from ambient air monitoring at the 49<sup>th</sup> St. Site (Site No. 1) was 18.3 ppb. Using
OEHHA health values and methodology, District staff estimates the off-site worker cancer risk
from the Vernon Facilities to be 575 in a million, assuming these levels have persisted for a 25-

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year worker exposure. The data collected within the residential community, the nearest being
 about 600 feet away, shows levels of EtO in the community to be within background levels at the
 District's regional monitoring sites.

11. Based on the monitoring data collected, District staff contends that the Vernon
Facilities pose a risk multiple times greater than the significant risk level to those exposed for
many years to the EtO concentrations measured recently outside of the Facilities. Therefore, the
District contends that emissions believed to be originating from Respondent's Vernon Facilities
endanger the health of a considerable number of persons.

9 12. On July 15, 2022, Petitioner filed a Petition for Order for Abatement alleging that
10 Respondent's Vernon Facilities were operating in violation of Health & Safety Code § 41700 and
11 District Rule 402 due to fugitive EtO emissions from operations causing a significant cancer risk
12 to members of the public.

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13. On July 26, 2022, upon stipulation of the parties, Petitioner filed an AmendedPetition for Order for Abatement (Stipulated).

15 14. Respondent does not admit that it is in violation of the District's Rules and does 16 not admit that the Vernon Facilities' operations using EtO pose a risk to anyone working or living 17 in the community. Respondent contends that the site of the District's air monitor at Site No. 1 is 18 located in a private, industrial parking lot, where there are no workers present for 8 hours per day, 19 at the fenceline immediately adjacent to the railway tracks, and that selection of that site as an offsite worker receptor reflects a conservative and protective receptor location at the place of highest 20 potential impact.

15. Respondent has taken and continues to implement actions to identify and minimize
potential sources of fugitive EtO emissions. Respondent also contends that such actions have
already contributed to the reduction of fugitive EtO reflected in the EtO concentrations measured
by the District.

16. Respondent has committed to modifying the Vernon Facilities to install permanent
total enclosures. Until permanent total enclosures are installed and operational, Respondent has
committed to interim control measures to minimize fugitive EtO emissions.

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17. Respondent has further committed to fund the installation, sampling, and
 monitoring of four District-approved EtO air monitors located at District-approved sites around
 the fenceline of the Vernon Facilities to allow Respondent to conduct periodic compliance
 monitoring while subject to the Order for Abatement.

5 18. The parties seek this stipulated order to impose conditions and enforceable
6 increments of progress through the issuance of the Order for Abatement.

7

#### **CONCLUSION**

The parties have stipulated to the issuance of this Order for Abatement, pursuant to
 Health & Safety Code Section 42451(b). In accordance with that section and District Rule 806(b),
 the Hearing Board is not required to make a finding that Respondent is in violation of Health &
 Safety Code Section 41700 or District Rule 402. Good cause exists to grant this Stipulated Order
 for Abatement.

2. This Stipulated Order for Abatement is not intended to be, nor will it act as, a
 variance. Respondent is subject to all rules and regulations of the District and to all applicable
 provisions of California law. Nothing herein shall be deemed or construed to limit the authority
 of the District to issue Notices of Violation, to seek civil penalties or injunctive relief, or to seek
 other administrative or legal relief. The Findings of Fact are based on evidence presented by
 Petitioner and Respondent as of the date hereof.

The issuance of the Order for Abatement is not expected to result in the closing or
 elimination of an otherwise lawful endeavor, but if it does result in such closure or elimination,
 the District contends that it would not be without a corresponding benefit in reducing air
 contaminants.

4. Issuance of this Stipulated Order for Abatement, upon a fully noticed hearing, will
not constitute a taking of property without due process of law.

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### <u>ORDER</u>

THEREFORE, in reliance on the stipulation of the parties, the aforesaid statements,
additional evidence and testimony, and good cause appearing, Respondent is hereby ordered to
cease and desist from all violations of Health & Safety Code § 41700 and District Rule 402 or, in

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the alternative, to comply with the following conditions until the permanent total enclosures 1 ("PTEs," as defined in Condition 23) are installed and operational, and associated fugitive 2 emission controls are constructed<sup>1</sup>: 3 Interim Fugitive Emission Control Measures Until the PTEs are Installed and Operational 4 1. For process areas with fugitive Ethylene Oxide (EtO) emission sources, Respondent 5 shall: 6 Install and maintain temporary enclosures, where feasible, using physical 7 a. barriers such as plastic sheeting (10 mil thickness or greater), plastic strip 8 curtains, accordion doors, etc. These areas include the transfer corridor from 9 chamber room(s) to the aeration room(s) at 49<sup>th</sup> Street facility; and the 10 warehouse/shipping area(s) at both 49<sup>th</sup> and 50<sup>th</sup> Street facilities. The installation 11 of temporary enclosures shall be reevaluated upon commissioning of the dry 12 beds in the 49<sup>th</sup> Street and 50<sup>th</sup> Street facilities' shipping areas, and Sterigenics 13 may propose, subject to the District's approval, the removal of some or all of 14 these enclosures if it can be demonstrated that their presence reduces the overall 15 effectiveness of the dry beds; 16 Direct fugitive emissions to control equipment if feasible; b. 17 Develop and submit for District approval within ten days of the issuance of c. 18 this Order, a plan to conduct parameter monitoring for measures 1(a) and 19 1(b), such as via smoke tests, differential pressures, or inward face 20 velocities, at an appropriate frequency. Respondent shall implement the 21 approved plan; and 22 d. Maintain records onsite and provide to the District upon request. 23

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# 28 <sup>1</sup> The conditions for the fenceline air monitoring plan in this Order shall continue in force for no less than two consecutive months following commencement of the operation of all Permanent Total Enclosures.

For areas with fugitive EtO emissions, Respondent shall:

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Vent (or otherwise direct air from) areas with fugitive EtO to portable a. 1 capture and control equipment, including additional fans routed to existing 2 emission controls, portable Timilon filter systems, and dry bed systems; and 3 Evaluate other interim measures and technologies and continue to implement b. 4 any feasible control measures. 5 3. Respondent shall immediately commence – and no later than 30 days after the 6 issuance of this Order, complete - sealing of all building draft openings (except as otherwise 7 specified in these conditions) that are not under negative pressure as verified by conducting smoke 8 testing or differential pressure measurements (except as otherwise specified in these conditions and 9 consistent with Condition 1(c)). Plastic sheeting (10 mil thickness or greater), or other materials 10approved by the District, over openings will be considered as acceptable sealing. 11 4. Respondent shall keep all access doors in process, storage, and shipping areas 12 closed, except while they are in active use. 13 5. Respondent shall install signage on both sides of personnel and vehicle access doors 14 for areas with known fugitive EtO emissions. The signs shall have the following wording: "Caution 15 Ethylene Oxide. Door(s) shall be kept closed when not in use," or other wording approved by the 16 District. Letters shall be at least 85-point type and shall be visible to personnel using the doors. 17 6. Respondent shall where possible keep truck bay doors closed during loading and 18 unloading, or ensure that truck bay doors remain closed except when personnel are actively 19 involved in truck movement and/or truck loading and unloading. 207. On a daily basis, Respondent shall inspect all roll-up door(s) for any damage that 21 may allow for potential fugitive EtO emissions to pass through such door. Respondent shall 22 maintain a log that documents all daily inspections. If damage is observed, Respondent shall 23 immediately make repairs or make arrangements for repairs at the earliest feasible time, record the 24 repairs, and provide records sufficient to demonstrate compliance with this condition to the District 25 upon request. Respondent shall submit a notification (Rule1405notifications@aqmd.gov) if a repair 26 takes more than 3 business days to complete. 27 28

1	8. Respondent shall as soon as possible, but no later than 30 days from the issuance of
2	this Order, develop and submit ( <u>Rule1405notifications@aqmd.gov</u> ) for District review and
3	approval a building differential pressure monitoring plan. Upon approval, the plan shall be
4	implemented and considered enforceable as a condition of this Order. The plan shall:
5	a. Entail the installation, operation, maintenance of a differential pressure
6	monitoring system for each total enclosure as follows:
7	i. A minimum of one building differential pressure monitoring system
8	shall be installed and maintained at each of the following three walls
9	in each total enclosure having a total ground surface area of 10,000
10	square feet or more:
11	1. The leeward wall;
12	2. The windward wall; and
13	3. An exterior wall that connects the leeward and windward wall
14	at a location defined by the intersection of a perpendicular
15	line between a point on the connecting wall and a point on its
16	furthest opposite exterior wall, and intersecting within plus or
17	minus ten $(\pm 10)$ meters of the midpoint of a straight line
18	between the two other monitors specified for the leeward wall
19	and windward wall. The midpoint monitor shall not be
20	located on the same wall as either of the other two monitors
21	specified for the leeward wall and windward wall.
22	ii. A minimum of one building differential pressure monitoring system
23	shall be installed and maintained at the leeward wall of each total
24	enclosure that has a total ground surface area of less than 10,000
25	square feet.
26	b. Include provisions for maintenance, recordkeeping, and reporting unless
27	already required by Paragraphs 1(c), 3 or 7.
28	
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9. At least daily, Respondent shall inspect temporary enclosure measures for integrity
 against breaches. If breaches in temporary enclosures or seals are observed, Respondent shall make
 immediate repairs or, if such repairs are not able to be immediately made, Respondent shall
 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 shall be
 maintained daily and kept onsite. Respondent shall submit a notification

7 (<u>Rule1405notifications@aqmd.gov</u>) if a repair takes more than 2 business days to complete.

10. Respondent shall increase aeration time 24 hours or more where practical in the 8 aeration room(s) to the maximum extent of the allowable ranges, and Respondent shall use its best 9 efforts to ensure sufficient physical space in the aeration room(s) to achieve such increases in 10aeration time. Respondent shall not be required to aerate materials less than minimum or more than 11 maximum durations established in the approved U.S. FDA sterilization cycles for those materials. 12 Respondent shall provide the District, within 30 days of the issuance of this Order, records that 13 demonstrate the increase over the baselines of aeration times in June 2022, compared to a baseline 14 of January 2022, including percentage measurements. Records that identify the materials 15 undergoing aeration and log the aeration times, and corresponding customer and/or U.S. FDA 16 aeration specifications, along with records of warehouse holding times (between the time the 17 product exits aeration and the time the product is shipped from the facilities), shall be maintained 18 and made available to the District upon request. Respondent shall within 45 days of this Order 19 initiate a report that consolidates the relevant aforementioned data, including aeration times, U.S. 20FDA and/or customer aeration specifications, and warehouse holding times, and shall provide this 21 report to the District (<u>Rule1405notifications@aqmd.gov</u>) on a monthly basis. 22

a. The Parties may meet and confer regarding evaluation of this data.
Respondent acknowledges the District may evaluate records submitted under
this condition and may, with a demonstration of good cause, seek
modification of this Order to seek to increase aeration times (without
requiring Respondent to exceed maximum aeration times as specified in U.S.

FDA and/or customer aeration specifications) or otherwise seek to enhance this condition.

11. Respondent shall continue to conduct leak detection pursuant to the procedures in 3 the current version of Rule 1405 at least monthly. Respondent shall maintain its other existing 4 internal leak detection methods and practices, which include leak tests during every sterilization 5 cycle and continuous measurement of EtO concentrations near EtO-containing equipment. The 6 interior gas chromatograph ("GC") data for the 49th Street and 50th Street facilities will be reviewed 7 to see if there are increased EtO levels near this equipment. If increased levels at or above 1 ppm 8 are detected, Respondent shall further inspect and document equipment for EtO leaks using 9 handheld instruments with an electrochemical detector or other EtO-specific instrumentation with a 10low detection limit at or below 0.5 ppm. Leak detection procedures must be directed to any 11 equipment or components handling EtO that are under positive pressure (e.g., vacuum pumps, 12 13 control equipment piping, or storage). Respondent shall also develop a supplemental EtO Leak Detection and Repair (LDAR) program for monthly inspection of the scrubber and oxidizer 14 external piping that is under positive pressure (which, together with the vacuum pumps, control 15 equipment piping, or storage described in the preceding sentence, comprises the "Relevant 16 Equipment"). LDAR data must be recorded in a format approved by the District and provided to 17 District personnel upon request. 18

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Respondent shall report (<u>Rule1405notifications@aqmd.gov</u>) any EtO leaks greater
 than or equal to 10 ppm from the Relevant Equipment within two hours of discovery, and the report
 shall detail the action plan and repair timeline. For any leak greater than or equal to 10 ppm EtO,
 Respondent shall, within 3 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.

13. Respondent 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. Respondent shall keep records of all such
inspections and repairs and provide to District personnel upon request.

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

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15. Respondent shall within 30 days submit (Rule1405notifications@aqmd.gov) a 4 report that evaluates the use of interior GC systems as a tool for assessing and implementing other 5 measures to ensure on-site worker safety while reducing exterior EtO emissions, including 6 evaluating the development of a daily GC summary report that calculates and reports periodic 7 average EtO concentrations for review and assessment. The evaluation will include a prioritization 8 of areas to locate ports where possible; an evaluation of relocating ports during construction of the 9 PTE; and a review of the system daily calibration along with periodic testing at various ports with 10samples of known EtO gas concentration. 11

16. Respondent shall construct and operate the dry beds at the 49<sup>th</sup> and 50<sup>th</sup> 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 49<sup>th</sup> Street facility). 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), Respondent shall notify the District

(Rule1405notifications@aqmd.gov) within 24 hours. If 8-hour rolling average EtO concentrations 18 persist above 1.0 ppm in the shipping area outside of the aeration room(s) for more than 48 hours, 19 then Respondent shall submit (Rule1405notifications@aqmd.gov) a written report with a root 20cause analysis within 2 business days. The report shall provide details on the airflow and capture of 21 emissions by the dry beds, as demonstrated by a smoke test, or details on the relevant differential 22 pressure monitor(s) to confirm that sufficient negative pressure exists. Respondent shall provide 23 final notification to the District (Rule1405notifications@aqmd.gov) within 1 business day when the 24 facility sustains 8-hour rolling average EtO concentrations less than 1.0 ppm for 24 hours. The 25 internal GC, or in the event of the GC system's inaccuracy, another reasonable method put forth by 26 Sterigenics, shall be used to monitor EtO concentrations in the shipping area outside of the 49<sup>th</sup> and 27

50<sup>th</sup> Street facilities' aeration room(s). Respondent shall maintain records sufficient to demonstrate
 compliance with this condition and provide them to the District upon request.

17. Within 7 days of full operation of the dry beds in a facility, Respondent shall 3 maintain continuous negative pressure of at least 0.001 inches of water within the facilities' 4 shipping areas until construction of the PTEs is completed. To the extent that significant 5 construction activities may impede compliance with this condition, Respondent shall notify the 6 District (Rule1405notifications@aqmd.gov) 24 hours in advance, or as soon as practicable. 7 Respondent shall install and maintain building pressure differential monitors, and shall log 8 differential pressure readings at least once per shift (shifts are 8 hours), sufficient to demonstrate 9 compliance with this condition. If Respondent does not maintain continuous negative pressure in 10accordance with this condition, and no prior notice due to significant construction activities has 11 been provided, Respondent shall notify the District (Rule1405notifications@aqmd.gov) within 24 12 13 hours. Respondent shall maintain records sufficient to demonstrate compliance with this condition and provide them to the District upon request. 14

18. Respondent shall, within 30 days, submit (<u>Rule1405notifications@aqmd.gov</u>) 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.

19 **Post-Aeration Testing** 

19. Respondent shall, within 45 days, submit a test protocol to the District for review 20and approval to conduct an enclosure testing program of representative pallets and products<sup>2</sup> 21 coming out of the aeration room(s) to characterize and quantify residual off-gassing of EtO. The 22 test protocol shall follow guidelines described below in subdivision (a). The source test program 23 shall be initiated within 2 weeks of District approval of the protocol. Respondent shall notify the 24 District of initiation of the enclosure testing program no less than 7 days prior to data and sample 25 collection, and the District shall be allowed to observe the test and collect duplicate samples. A 26 final source test report shall be submitted to the District (Rule1405notifications@aqmd.gov) within 27

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<sup>&</sup>lt;sup>2</sup> "Products" in this condition shall refer to representative products that are not customer products. -12-

30 days of completion of the test program. Respondent shall append the District's written
 comments or evaluation of the final report, if any, to the final report if Respondent 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.

The Test Protocol will include an initial method validation evaluation to 5 а determine the appropriate size of a pallet enclosure and inlet and exhaust 6 ducts and air flow rate to allow effective capture and laminar flow required 7 for quantitative emissions evaluation. Validation steps in the pilot evaluation 8 will include, at a minimum, release of a known mass and concentration of 9 EtO relevant to residual expected from processing through normal 10 operations, to allow recovery, repeatability and time to equilibrium to be 11 established and calculation of the rate of depletion of the EtO over time. The 12 validation step will not include the use of sterilized material, since the 13 amount of EO in this test must be known and the goal is to validate the 14 chamber parameters and monitoring equipment. Respondent shall notify the 15 District of the initial method validation no less than 7 days prior to the 16 evaluation, and the District shall be allowed to observe. The results of the 17 validation evaluation will be submitted to the District. After demonstration 18 of appropriate test conditions and ability to track degradation rates and 19 approval of the developed methodology by the District, quantitative Pallet 20 Enclosure Testing will be conducted over a 4-week period to test pallets of 21 material processed via different cycles reflective of the range of normal 22 operations. A Temporary Total Enclosure (TTE) will be built for this 23 purpose. The enclosure will be designed to accommodate one (1) or more 24 pallet(s) of materials representative of those processed via the range of 25 sterilization cycles in normal operations and held after leaving the aeration 26 room(s). The enclosure will be equipped with inlet and exhaust ducting and 27 will not require contact with the sterilized products. Respondent shall use 28

1	representative part(s) and pallet(s) for testing. Inlet air will be supplied from
2	a clean ambient source. The exhaust duct will be connected to a blower and
3	directed to an area under air pollution control. The exhaust duct will be
4	equipped with sample ports to enable measurement of air flow and EtO
5	concentrations. Air flow and concentration will be measured for the selected
6	pallet(s) or part(s) on a continuous or semi-continuous basis as well as
7	quantified at approved timepoints with integrated canister sample results
8	throughout a period representative of the duration that different product
9	batches would be held before shipping. Pallet Enclosure Testing results shall
10	be made available to the District ( <u>Rule1405notifications@aqmd.gov</u> ) on a
11	rolling 2-week basis following collection.
12	b. After Respondent has submitted the testing protocol to the District, District
13	personnel or District-authorized contractors may elect to perform the testing.
14	Respondent shall facilitate such program of testing that will be conducted by
15	District personnel or District-authorized contractors. Specifically,
16	Respondent shall make all reasonable accommodations for the District's
17	program of work to initiate, conduct (for not more than 4 weeks), and
18	conclude an enclosure testing program of representative pallets and products
19	coming out of the aeration room(s) to characterize and quantify any residual
20	off-gassing of EtO pursuant to the test protocol developed by Respondent
21	and approved by the District, or pursuant to a test protocol developed by the
22	District that takes into the account relevant variables (e.g., airflow and time).
23	Respondent shall provide training to District personnel or District-authorized
24	contractors regarding all health and safety requirement applicable in areas in
25	which the study is to be conducted. The testing shall commence upon
26	soonest availability of District personnel. After completion of testing,
27	Respondent shall within 60 days of billing notification pay the District the
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costs of materials and testing per applicable fee rates in District Rules 304 and 304.1.

## 3 Install and Perform Air Monitoring

4 20. Respondent shall, within 14 days of the issuance of this Order, commence the
5 fenceline air monitoring plan included here as Appendix A.

6 21. Respondent shall install a wind monitoring system and data logging system at a
7 location approved by the District.

8 22. Respondent shall submit (<u>Rule1405notifications@aqmd.gov</u>) all internal EtO
9 monitoring data (e.g., GC data) on a weekly basis, except as otherwise provided in the conditions
10 herein, to the District. All data shall include individual readings and shall be provided in excel
11 format.

## 12 Construction Schedules

23. Respondent shall construct and operate PTEs, each with an additional GC system,
within twelve months of all applicable permit approvals, unless Respondent seeks an extension of
time before the Hearing Board. In any case, PTEs shall be constructed and operational no later than
January 15, 2024 for the 50<sup>th</sup> Street facility, and May 1, 2024 for the 49<sup>th</sup> Street facility. The PTEs
shall 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 Order means the PTEs as described
in the immediately preceding sentence.)

20 24. Respondent shall notify the District within 7 days of completion of construction of
21 each of the PTEs. Until satisfaction of this condition, Respondent shall submit

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

24 Curtailment Provisions

25 25. Within one (1) hour of Respondent discovering or receiving notification that
ambient air monitoring results are 31.8 ppb or greater at any Respondent-operated, Districtapproved ambient air monitoring location as specified in Appendix A, or any District-operated
ambient air monitoring location, for two consecutive 24-hour samples, Respondent shall not initiate

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any new sterilization cycles in the chambers. Operations may resume upon confirmation by the
 District that subsequent samples at all Respondent-operated, District-approved monitoring
 locations as specified in Appendix A, or any District-operated ambient air monitoring location, on a
 single sampling day are less than 31.8 ppb.

26. Within one (1) hour of Respondent discovering or receiving notification that 5 ambient air monitoring results are 63.6 ppb or greater at any Respondent-operated, District-6 approved ambient air monitoring location as specified in Appendix A, or any District-operated 7 ambient air monitoring location, for any single 24-hour sample, Respondent shall not initiate any 8 new sterilization cycles in the chambers. Operations may resume upon confirmation by the District 9 that subsequent samples at all Respondent-operated, District-approved monitoring locations 10 specified in Appendix A, or any District-operated ambient air monitoring location, on a single 11 sampling day are less than 63.6 ppb, unless otherwise required by Condition 25. 12

#### 13 Administrative

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

21 28. The Hearing Board may modify the Order for Abatement without the stipulation of
22 the parties upon a showing of good cause, therefore, and upon making the findings required by
23 Health and Safety Code Section 42451(a) and District Rule 806(a). Any modification of the Order
24 shall be made only at a public hearing held upon 10 days published notice and appropriate written
25 notice to Respondent.

26 29. Petitioner shall notify the Clerk of the Board in writing when final compliance has27 been achieved.

1	The Hearing Board shall retain jurisdiction over this matter until May 1, 2024 or until
2	Respondent has fully complied with the terms of this Order, whichever occurs later unless this Order
3	is amended and modified.
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5	Good cause appearing, it is so ordered.
6	For the Board:
7	Date Signed:
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	-17- Findings and Decision – Sterigenics US, LLC (Fac. ID Nos. 126197 and 126191) Case No. 6225-1

**SO STIPULATED:** Maya Lopez Grasse Josephine Lee Counsel for Respondent Senior Deputy District Counsel Sterigenics US, LLC South Coast Air Quality Management District -18-Findings and Decision - Sterigenics US, LLC (Fac. ID Nos. 126197 and 126191) Case No. 6225-1

Appendix A 1 **Fenceline Air Monitoring Plan** 2 Sterigenics shall perform periodic ambient air monitoring to measure concentrations of EtO 3 at locations near the perimeter of the adjoining 49<sup>th</sup> Street and 50<sup>th</sup> Street facilities ("Fenceline 4 Locations"). Analysis will be by a standard and generally accepted methodology capable of routinely 5 reporting EtO concentrations of less than 1 part-per-billion by volume (ppby). The District will be 6 allowed access and be able to conduct technical review of the sampling sites, equipment and methods 7 and also be able to conduct side by side testing upon request 8 Sampling Locations 9

Proposed locations near the perimeter are shown on Figure 1. Respondent shall aim to locate 10 a monitor at, or as close as possible to, the existing District sampling location on 49<sup>th</sup> Street (M2 in 11 Fig. 1) with the understanding that this location has detected the highest levels of ambient EtO 12 concentrations and continued monitoring at this location would promote continuity of monitoring 13 data. Final siting of station locations shall be informed, to the extent practical, by guidelines in 14 Appendix E of 40 CFR Part 58 regarding obstructions, and subject to final District approval. For 15 sampling locations that require off-site access, Respondent shall make best efforts to secure the 16 sampling site location within 14 days of issuance of Order, or shall notify the District 17 (Rule1405notifications@aqmd.gov) within 2 days of becoming aware that an approved site location 18 cannot be secured. Once sampling locations have been finalized, locations may be moved upon the 19 approval of the District to accommodate traffic, access and safety considerations, or any 20modifications to equipment at the facilities. 21

#### 22 Sampling Methods

Beginning within 14 days of issuance of the Order, or, if a sampling location requires securing off-site access, then within 14 days of securing such access, samples will be collected at all locations on a minimum of 1-in-6 day cycle following the calendar established by the USEPA Ambient Monitoring Technology Information Center (https://www.epa.gov/amtic/sampling-schedulecalendar) and results reported to the District within 14 calendar days of 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.

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

9 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 13 the sampling period, and any annotations regarding sample handling or exceptions to collection 14 methods occurring in the field shall be reported to the District for each round of sampling within 14 15 days after sample collection, unless the laboratory cannot process such samples within a 14-day 16 timeframe (even if expedited processing is requested) due to circumstances beyond the reasonable 17 control of Respondent, in which case Respondent shall notify the District within 2 days of becoming 18 aware that the deadline will be not be met; in such cases, Respondent shall request simultaneous 19 release of the sampling results to the District. 20

### 21 **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:

25

- 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-
- 28 12 days.

1	• If a result greater than 2 ppbv is reported for any of the 1-in-12 samples, the sampling
2	frequency will revert to 1-in-6 days for at least 7 rounds of sampling and then a return to 1-
3	in-12 day testing may be requested.
4	Discontinuation of Monitoring
5	If the District, in its sole judgment, determines that fenceline monitoring at any or all sites
6	does not yield results that are relevant or useful (either due to the evolution or changes in reliability
7	of the technology, consistency or inconsistency in the data, or any other relevant reasons), the District
8	shall notify Sterigenics that it may cease such monitoring pursuant to this Plan.
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	Findings and Decision – Sterigenics US, LLC (Fac. ID Nos. 126197 and 126191) Case No. 6225-1
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Appendix A – Figure 1. Fenceline Air Monitoring Locations (M1, M2, M3, M4).

1	CERTIFICATE OF SERVICE
2	I hereby certify that on August 4, 2022, I emailed the <i>Proposed Findings and Decision for</i>
3	<i>an Order for Abatement (Stipulated)</i> in Case No. 6225-1 to the Clerk of the South Coast AQMD Hearing Board with accompanying emailed service on the counsel for Respondent, Ms. Maya
4	Grasse, at <u>Maya.Grasse@alston.com</u> . The Respondent in this case had agreed to accept emailed service of the petition and documents filed to the docket, as acknowledged by email sent on July
5	15, 2022 to the Clerk.
6	DATED: August 4, 2022 SOUTH COAST AIR QUALITY
7	MANAGEMENT DISTRICT
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9	By: Josephine Lee
10	Attorney for Plaintiff
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