South Coast
Air Quality Management District
21865 Copley Drive, Diamond Bar, CA 91765-4178
(909) 396-2000 • www.aqmd.gov

Via Email and Certified Mail, return receipt requested

June 12, 2024

Kevin Wagner
VP Environmental Health & Safety
Sterigenics US, Inc.
4801-63 E 50th St.
Los Angeles, CA 90058-2709

Sterigenics US, Inc.
4900 Gifford Ave.
Los Angeles, CA 90058-2785

Subject: Approval of Modified Health Risk Assessment and Request for Revision of the Risk Reduction Plan for **Sterigenics US, Inc.** (South Coast AQMD Facility ID **126191** & **126197**)

Dear Mr. Wagner:

The purpose of this letter is two-fold. First, this letter serves as notice that the Health Risk Assessment (HRA) submitted by the Sterigenics US, Inc. facility located in the city of Vernon (Sterigenics Vernon), as modified pursuant to Rule 1402(e)(2)(D) by the South Coast Air Quality Management District (South Coast AQMD), is approved. As noted in the modified HRA Summary Form (Attachment A), the risks posed by Sterigenics Vernon are above both the Notification Risk Level and the Action Risk Level specified in Rule 1402.

Second, consistent with Rule 1402(f)(1) and following the HRA modification, South Coast AQMD is requiring that the Risk Reduction Plan (RRP) be revised and resubmitted by Sterigenics Vernon. South Coast AQMD Rule 1402 (f)(2)(B) provides that the Risk Reduction Plan (RRP) shall be based on the approved HRA. Staff has reviewed the RRP and identified certain deficiencies, which are listed in an attachment to this letter (Attachment B). South Coast AQMD is requesting that Sterigenics Vernon address the specified deficiencies in a revised RRP to be submitted to South Coast AQMD within 30 days of this letter, or by **July 12, 2024**.

Background

On June 7, 2022, South Coast AQMD sent a letter designating Sterigenics Vernon as a Potentially High Risk Level facility under Rule 1402. As detailed within that letter, Rule 1402

required the submittal of an Air Toxics Inventory Report (ATIR) within 150 days of the date of notification and an HRA within 180 days of the date of notification. South Coast AQMD staff received the ATIR on November 4, 2022, and the HRA and the RRP were received on December 6, 2022.

After staff review, on December 2, 2022, the ATIR was rejected due to multiple deficiencies. Your facility was given 30 days to revise and resubmit the ATIR to address all the deficiencies. However, since a revised ATIR was not submitted by Sterigenics Vernon, in accordance with South Coast AQMD Rule 1402 (d)(4)(D), staff modified the ATIR to address the necessary corrections and approved the modified ATIR on May 26, 2023. In accordance with South Coast AQMD's *AB 2588 and Rule 1402 Supplemental Guidelines,* the HRA must utilize the approved ATIR and associated Emissions Inventory File, which were provided to Sterigenics Vernon in electronic format.

On June 15, 2023, South Coast AQMD subsequently rejected the HRA and identified the deficiencies in the HRA including that the HRA was not based on the emission inventory from the approved ATIR. A revised HRA was required to be submitted within 60 days of the date of the letter addressing all deficiencies. Sterigenics Vernon submitted a revised HRA on August 15, 2023, however it did not address all deficiencies noted by South Coast AQMD staff in the rejection letter. Consequently, the HRA was modified by staff to address the following necessary corrections:

1. The South Coast AQMD modified HRA used the U.S. Environmental Protection Agency's (U.S. EPA) methodology for estimating fugitive emissions of ethylene oxide, which is consistent with the approved ATIR. The original and revised HRA submittals by Sterigenics Vernon used an unapproved methodology to estimate emissions. On July 7, 2022, South Coast AQMD initially rejected the use of the Willowbrook study as a Reference Source, as defined under Rule 1402 (c)(17). The reasons supporting this decision included:
    - The differences between the Willowbrook facility and the Vernon facility;
    - Insufficient data regarding assessed release points;
    - The use of portable ionization detectors to measure concentrations at the release points;
    - Gas chromatograph readings at the Vernon facility did not validate the results of the Willowbrook study; and
    - The emission factor used is substantially different from U.S. EPA's emission factor, which is based on a larger dataset.

    Although Sterigenics maintains that the Willowbrook study is the most accurate way to calculate fugitive emissions from the Sterigenics Vernon facility, Sterigenics has not provided any specific data about the study to substantiate using the study as a Reference Source.

2. A facility, as defined in South Coast AQMD Rule 1402, means "any source, equipment, or grouping of equipment or sources, or other air contaminant-emitting activities which are located on one or more contiguous properties within the District, in actual physical contact or separated solely by a public roadway or other public right-of way, and are

owned or operated by the same person (or persons under common control) or an outer continental shelf (OCS) source as defined in 40 CFR § 55.2."

Sterigenics US, Inc. currently holds two distinct Facility IDs for its two buildings in Vernon. However, these buildings are separated solely by an abutting public-right of-way; the single set of rail tracks between the buildings crosses the public right-of-way, as well, but it does not give a sufficient basis to treat these sterilization operations under common control as being from definitionally separate facilities.
Consistent with South Coast AQMD Rule 1402, and notwithstanding the two distinct Facility IDs, the South Coast AQMD interprets the two buildings of Sterigenics Vernon as a single facility.

3. Additional minor technical adjustments were made to align the document with both the Office of Environmental Health Hazard Assessment (OEHHA) Guidelines and the approved ATIR. These changes are outlined within the modified HRA

Next Step: Public Notification

As summarized in Attachment A, the cancer risk at the Maximally Exposed Individual Resident (MEIR) receptor is estimated to be **40.8** chances in-one-million. The cancer risk is due to ethylene oxide emissions from fugitive sources. Additionally, the cancer risk at the Maximally Exposed Individual Worker (MEIW) receptor is estimated to be **77.1** chances in-one-million. Note that both the residential and worker cancer risks exceed the Notification Risk Level specified in Rule 1402. Therefore, public notification is required.

As stated in South Coast AQMD's Public Notification Procedures[1], public notification typically consists of three components: distribution of the approved HRA, distribution of public notification materials, and a public meeting. Sterigenics Vernon must distribute the facility's approved modified HRA and public notification materials pursuant to South Coast AQMD Public Notification Procedures within **30** days of the approval date on this letter, or **July 12, 2024.** A map showing the areas with health risk levels exceeding the Notification Risk Level is also attached to this letter (Attachment C). The public notification materials must be approved by South Coast AQMD and sent to all addresses within the notification area contour (cancer risk of 10-in-a million or greater and non-cancer chronic hazard of 1.0 or greater) found in Attachment C. The public meeting must take place within **30** days of the distribution of public notification materials.

The modified HRA and associated modelling files are provided to you in electronic format. South Coast AQMD will post the approved modified HRA on our website. If there is any business confidential information contained within the modified HRA, please let us know and provide us with a redacted version of the modified HRA, in electronic format, within two weeks, or no later than **June 26, 2024.** Any redactions made shall be limited to trade secrets and confidential information only.

[1] http://www.aqmd.gov/docs/default-source/planning/risk-assessment/pn_procedures.pdf

In addition, given the short timeframe for conducting public notification, please schedule a meeting with us within one week to discuss the next steps for public notification. If you have questions regarding this letter, please contact me at (909) 396-3754 or Victoria Moaveni, AB 2588 Program Supervisor at (909) 396-2455.

Sincerely,

Scott A. Epstein

Scott Epstein, Ph.D.
Planning & Rules Manager
Planning, Rule Development & Implementation

Attachments
- A. Modified HRA Summary Form
- B. List of Identified Deficiencies in the RRP
- C. Public Notification Area Map
- D. Modified HRA Report (sent by email only)
- E. Modelling Files (sent by email only)

cc:
Kathy Hoffman, Sotera Health
Joseph Hower, Ramboll US Consulting, Inc
Brian Tomasovic, South Coast AQMD
Karin Manwaring, South Coast AQMD
Sarah Rees, South Coast AQMD
Ian MacMillan, South Coast AQMD

SE:VM:FC:AJ:VT

Attachment A – Modified HRA Summary Form

South Coast Air Quality Management District
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HEALTH RISK ASSESSMENT SUMMARY FORM

(Required in Executive Summary of HRA)

Facility Name : Sterigenics US, LLC
Facility Address: 4801-63 E 50th St, Vernon, CA 90058 and
4900 Gifford Ave, Vernon, CA 90058
Type of Business: Medical Sterilization
SCAQMD ID No.: 126191 and 126197

A. Cancer Risk

(One in a million means one chance in a million of getting cancer from being constantly exposed to a certain level of a chemical over a period of time)

1. Inventory Reporting Year : 2021
2. Maximum Cancer Risk to Receptors : *(Offsite and residence = 30-year exposure, worker = 25-year exposure)*
   a. Offsite 4,760.2 in a million Location: 390064 m E, 3762419 m N
   b. Residence 40.8 in a million Location: 390046 m E, 3762227 m N
   c. Worker 77.1 in a million Location: 390088 m E, 3762439 m N
3. Substances Accounting for 90% of Cancer Risk: Ethylene Oxide
   Processes Accounting for 90% of Cancer Risk: Fugitive Emissions
4. Cancer Burden for a 70-yr exposure: *(Cancer Burden = [cancer risk] x [# of people exposed to specific cancer risk])*
   a. Cancer Burden 0.11
   b. Number of people exposed to >1 per million cancer risk for a 70-yr exposure 28,150
   c. Maximum distance to edge of 70-year, 1 x 10^{-6} cancer risk isopleth (meters) 1,720

B. Hazard Indices

[Long Term Effects (chronic) and Short Term Effects (acute)]
(non-carcinogenic impacts are estimated by comparing calculated concentration to identified Reference Exposure Levels, and expressing this comparison in terms of a "Hazard Index")

1. Maximum Chronic Hazard Indices:
   a. Residence HI: 0.01 Location: 390046 m E, 3762227 m N toxicological endpoint: Central Nervous System
   b. Worker HI : 0.15 Location: 390088 m E, 3762439 m N toxicological endpoint: Central Nervous System
2. Substances Accounting for 90% of Chronic Hazard Index: Ethylene Oxide
3. Maximum 8-hour Chronic Hazard Index:
   8-Hour Chronic HI: 0.00 Location: 390105 m E, 3762427 m N toxicological endpoint: Respiratory System
4. Substances Accounting for 90% of 8-hour Chronic Hazard Index: Acrolein and Formaldehyde
5. Maximum Acute Hazard Index:
   PMI: 0.00 Location: 390106 m E, 3762427 m N toxicological endpoint: Eyes
6. Substances Accounting for 90% of Acute Hazard Index: Acrolein, Ammonia and Formaldehyde

C. Public Notification and Risk Reduction

1. Public Notification Required? X Yes ___ No
   a. If 'Yes', estimated population exposed to risks > 10 in a million for a 30-year exposure, or an HI >1
   1,642
2. Risk Reduction Required? X Yes ___ No

Attachment B – List of Identified Deficiencies in RRP

1) Measure 8, schedule: Include the approval and implementation dates for the differential pressure monitoring plan.
2) Measure 10: Update the required increase in aeration time to be consistent with the approved amended EARP.
3) Measure 11:
   a. Add a frequency to the GC data review of at least weekly.
   b. Update the schedule to include the implementation date.
4) Measure 12: Notify the District (Rule1405notifications@aqmd.gov) and submit report of any leaks greater than or equal to 2 ppmv from the relevant equipment.
5) Measure 14: Sterigenics shall maintain a log of all components that were taken out of service, including the date and time that they were taken out, as well as the date and time that they were reinstalled or brought back online.
6) Measure 16:
   a. In the opening, clarify that the GC data will be used to determine the 8-hour rolling average and how often the data will be gathered.
   b. Update the schedule to include the installation date of the dry beds.
7) Measure 17: Update the schedule to include the implementation date.
8) Measure 18: Update the schedule to include the completion date.
9) Measure 19: Include the date and location of testing in the schedule.
10) Measure 20: Specify a deadline and remove the following language, "assuming that the permits to construct are granted in time."
11) Measure 21: Update the PTE construction deadlines to be consistent with the approved amended EARP.
12) Reintroduce the following measures:
   a. Perform Air Monitoring
      i. Include a requirement that Sterigenics shall conduct annual cleaning and calibration of the wind monitoring sensor per manufacturer's specification.
   b. Curtailment Provisions
      i. This section shall be consistent with the approved amended EARP.
13) Add a measure, including timelines, for the following requirements:
   a. PTE shall be source tested (consistent with the Permit to Construct requirements);
   b. The source test report shall be submitted to South Coast AQMD for review and approval; and
   c. The approved source test results shall be used to reevaluate the health risks posed by the facility.
14) Throughout the document:
   a. Document when a measure has been completed or compliance achieved and notify the District within 3 business days via email (Rule1405notifications@aqmd.gov).
   b. Define timelines in terms of calendar days. (e.g. …within 30 *calendar* days of approval…). This does not apply to deadlines that give a specific date.
   c. Replace "will" with "shall" as appropriate.
   d. Add clarification when referencing a plan: "upon approval of the plan" or "approval of this plan" are currently used and can cause confusion.
15) Section 4: Update to be consistent with the approved modified ATIR and HRA, except where adjustments are needed to reflect changes to be made during the RRP process. If a change is needed due to an RRP measure, modeled stack parameters and proposed control efficiencies shall be consistent with permit applications that were submitted to South Coast AQMD.
16) Attachment A, Post RRP Tac Emissions: Update using the emissions estimate methodologies in the approved modified ATIR.

Attachment C – Public Notification Area Map