SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

Draft Staff Report
Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

EXECUTIVE SUMMARY

South Coast Air Quality Management District (South Coast AQMD) Rule 1405 - Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes was adopted in 1990 to control ethylene oxide (EtO) and amended in 1991.

In March 2022, following the U.S. EPA's reconsideration of the potential toxicity of EtO, South Coast AQMD began investigating facilities that emit EtO. The 2016 U.S. EPA risk study determined that EtO is 30 to 50 times more carcinogenic than previously reported. The cancer inhalation unit risk factor is also being updated by California's Office of Environmental Health Hazard Assessment (OEHHA) with a draft risk factor about 38 times more carcinogenic than previously reported. During South Coast AQMD's monitoring efforts at several commercial EtO sterilization facilities, the agency became aware of emissions from fugitive sources that were not previously known. South Coast AQMD's investigation identified that existing pollution controls would need to be upgraded and measures would need to be implemented to reduce stack and fugitive emissions.

South Coast AQMD's approach to controlling EtO emission is multifaceted. Rule 1405 is a source specific rule that applies to the general sterilization industry, and includes requirements based on best available technologies. In addition, facilities may also be subject to Rule 1402 – Control of Toxic Air Contaminants from Existing Sources through the AB2588 Hot Spots Program for additional risk reduction measures. South Coast AQMD's other activities such as ambient air monitoring, facility inspections, evaluations of process and control equipment during permitting, along with complaint investigations, can lead to additional measures to further reduce levels of EtO emissions from specific facilities.

Proposed Amended Rule 1405 (PAR 1405) would strengthen requirements to address stack and fugitive emissions based on control measures that have been demonstrated to minimize EtO emissions. In addition, due to concerns about EtO off-gassing from sterilized materials, PAR 1405 would also add certain information-gathering requirements for warehouses to assess the potential of EtO emissions from these operations.

This Draft Staff Report is organized into three chapters. Chapter 1 provides background information regarding PAR 1405 and a general description of sterilization and related operations. Chapter 1 also provides a summary of ambient monitoring activities South Coast AQMD staff conducted at and near sterilization facilities and warehouses receiving sterilized materials. Chapter 2 provides a summary and explanation of provisions in PAR 1405. Chapter 3 provides a summary of the impact assessments and the comparative analysis of PAR 1405.

CHAPTER 1 – BACKGROUND

1.1 INTRODUCTION

Ethylene oxide (EtO) is a flammable, colorless gas used in many industries to make products including antifreeze, textiles, solvents, detergents, and adhesives. EtO also is used to sterilize medical equipment for commercial or on-site use. EtO is a known carcinogen identified by the California Air Resources Board (CARB) as a Toxic Air Contaminant (TAC)[1] and by the United States Environmental Protection Agency (U.S. EPA) as a Hazardous Air Pollutant.[2] California's Office of Environmental Health Hazard Assessment (OEHHA) lists EtO as a chemical that causes developmental and reproductive toxicity in both male and females.[3] U.S. EPA completed a reassessment of the cancer potency of EtO in 2016[4] and OEHHA is currently reassessing the toxicity of EtO, with a draft risk factor released in April 2023.[5]

In January 2022, U.S. EPA proposed to reconsider issues related to risks posed by EtO emissions for certain types of chemical manufacturing after consideration of the risk value proposed by the Texas Commission on Environmental Quality.[6] Following the U.S. EPA reconsideration of the potential toxicity of EtO, South Coast AQMD began investigating facilities that emit EtO in March 2022. During South Coast AQMD's monitoring efforts at several commercial EtO sterilization facilities, the agency became aware of emissions from fugitive sources that were not previously known. South Coast AQMD's investigation has identified that existing pollution controls will need to be upgraded and measures will need to be implemented to reduce stack and fugitive emissions. PAR 1405 will strengthen requirements to address stack and fugitive emissions based on control measures that have been achieved in practice. In addition, due to concerns of EtO off-gassing from sterilized materials, PAR 1405 added certain requirements for warehouses to assess the potential of EtO emissions from these operations.

1.2 HEALTH EFFECTS OF ETHYLENE OXIDE AND RISK

Ethylene oxide is closely associated with a wide range of health effects, including short-term, acute hazards and long-term, chronic health effects including cancer. EtO is a human carcinogen and is also known to interfere with male and female reproductive health.

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[1] CARB Identified Toxic Air Contaminants | California Air Resources Board. (n.d.).
[2] Initial List of Hazardous Air Pollutants with Modifications | U.S. EPA
https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications
[3] Chemicals Considered or Listed Under Proposition 65 – Ethylene oxide | OEHHA
https://oehha.ca.gov/proposition-65/chemicals/ethylene-oxide
[4] IRIS Assessment for Ethylene Oxide | U.S. EPA
https://iris.epa.gov/ChemicalLanding/&substance_nmbr=1025
[5] Draft Cancer Inhalation Unit Risk for Ethylene Oxide | OEHHA
https://oehha.ca.gov/air/crnr/notice-public-comment-period-and-workshops-draft-cancer-inhalation-unit-risk-ethylene-oxide
[6] News Release "EPA to Reconsider Issues Related to Risks Posed by Ethylene Oxide Emissions for Certain Types of Chemical Manufacturing" | U.S. EPA
https://www.epa.gov/newsreleases/epa-reconsider-issues-related-risks-posed-ethylene-oxide-emissions-certain-types

Acute health effects, usually associated with worker exposure to EtO, include headaches, dizziness, trouble breathing, sleepiness, weakness, and fatigue. Exposure to higher concentrations of EtO is also linked to nausea, vomiting, diarrhea, and other gastrointestinal distress.[7]

EtO has been shown to be associated with at least two different classes of cancers: hematopoietic (white blood cell) cancers, such as non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia as well as breast cancer in women.

Non-cancer chronic exposure to EtO, typically caused by low level exposure of EtO over several years, is linked to irritation of the eyes, skin, and respiratory passages effects to the nervous system. In addition, EtO is known to cause reproductive harm to both males and females.

OEHHA is the lead state agency for the assessment of health risks posed by environmental contaminants. OEHHA's current EtO risk values for cancer were last updated in 2009[8] and U.S. EPA updated their EtO cancer risk values in 2016, which is more stringent than current OEHHA risk values. The 2016 U.S. EPA risk study determined that EtO is 30 to 50 times more carcinogenic than previously reported.[9,10] In April 2023, OEHHA released their draft cancer inhalation unit risk factor and the value is about 38 times more carcinogenic than previously identified.[11]

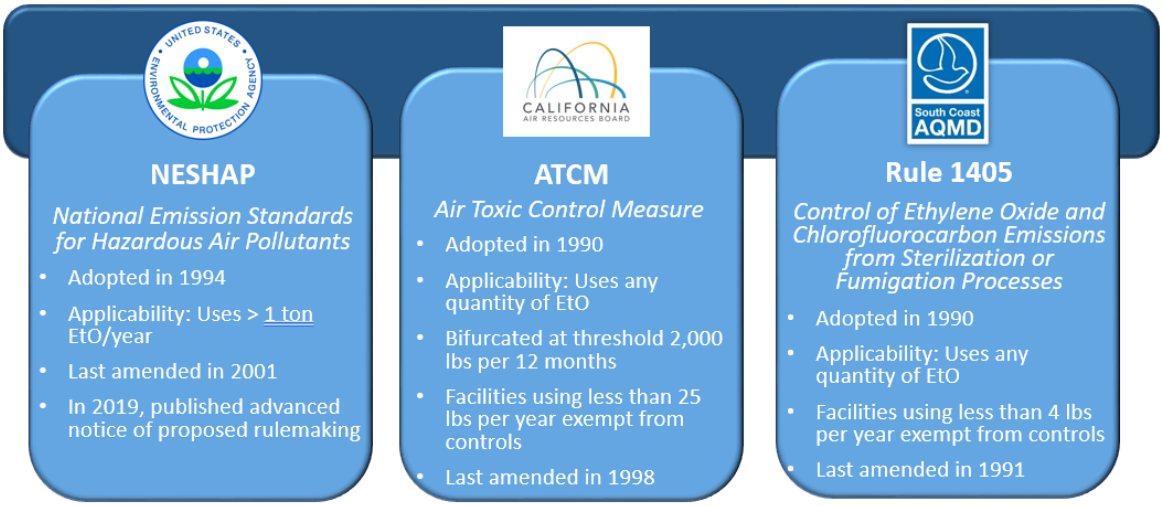
1.3 REGULATORY HISTORY

Federal, State, and Local Ethylene Oxide Sterilization Regulations

In 1990, both the California Air Resources Board and South Coast AQMD adopted regulations to control EtO emissions from sterilization operations in the form of an Air Toxics Control Measure (ATCM) and Rule 1405, respectively. This was due to the harmful health effects listed by U.S. EPA health assessment and OEHHA in the 1980s and the requirement under the Federal Clean Air Act mandating the reduction of hazardous air pollutants, which included EtO. South Coast AQMD Rule 1405 – Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes was adopted in 1990 to control EtO emissions. Rule 1405 was also intended to reduce the emissions from chlorofluorocarbons (CFCs) by eliminating the use of CFC diluents in sterilant gas mixtures by January 1, 1997. In 1994 the National Emission Standard for Hazardous Air Pollutants (NESHAP) Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities was adopted. The figure below shows the Federal, State, and South Coast AQMD regulations for EtO sterilization operations.

[7] https://www.cdc.gov/niosh/topics/ethyleneoxide/default.html
[8] Ethylene Oxide. (2009). California Office of Environmental Health Hazard Assessment. Retrieved February 28, 2023, from https://oehha.ca.gov/chemicals/ethylene-oxide
[9] Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide. (2016, December). U.S. EPA. Retrieved August 30, 2023, from https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf
[10] Health Assessment Document for Ethylene Oxide. (1985, June). U.S. EPA. Retrieved August 30, 2023, from https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=459635
[11] https://oehha.ca.gov/media/downloads/crnr/etocrnriur040723.pdf

Figure 1-1 – Federal, State, and South Coast AQMD Regulations for EtO Sterilization



Rule 1405 Existing Requirements

Rule 1405 currently requires facilities subject to the rule to control EtO emissions using air pollution control devices (APCD) complying with specific control efficiencies. The table below shows the required control efficiencies based on facility size and type of EtO source that is being controlled.

Table 1-1 – Rule 1405 Control Efficiency Requirements for APCDs

Quantity EtO Used	Sterilizer	Aerator	Back-draft	Combined
> 4,000 lbs	99.9%	99%	99%	99.8%
400 – 4,000 lbs	99.9%	95%	95%	99.6%
4 – 400 lbs	99%	95%	Not required	98.8%
Aeration-only	Not applicable	95%	Not applicable	Not applicable

In addition to Rule 1405, facilities are also subject to Rule 1402 which is the implementation of Assembly Bill 2588 (AB2588) Air Toxic "Hot Spots" program by the South Coast AQMD. Unlike source-specific rules like Rule 1405, which address emissions from the industry, Rule 1402 addresses facility-specific risks that a facility may pose to nearby receptors based on the type

(residential, schools, or off-site worker), distances, and unique meteorological conditions. The facility's emissions and unique configuration such as stack height are also taken into consideration.

Recent Ethylene Oxide Sterilization Regulatory Requirements in Other States

EtO is currently used to treat approximately 50% of sterile medical devices used in the United States, totaling 20 billion medical devices annually.[12] In many cases, EtO is the only approved method of sterilization of certain medical devices, despite known health risks associated with the substance. These billions of medical devices are sterilized by approximately 100 domestic commercial sterilization facilities,[13] located in 32 different U.S. states and Puerto Rico.[14] Since 2018, many of these sterilization facilities and related operations have been identified by U.S. EPA or state or local authorities as locations with elevated risk due to EtO emissions, elevated ambient EtO levels in surrounding communities, or both. Several of these States, such as Illinois and Georgia, have already taken steps to reduce their emissions of EtO by implementing new regulatory requirements.

State of Illinois

In 2019, the State of Illinois passed two laws that placed restrictions on the emission of ethylene oxide. Senate Bill 1852, also known as Public Act 101-0022, prohibits EtO sterilization facilities from operating in Illinois unless they continuously monitor ethylene oxide stack emissions, capture 100% of all ethylene oxide emissions within the facility using a permanent total enclosure (PTE), and conduct third-party community monitoring of EtO. Senate Bill 1854, also known as Public Act 101-0023, addresses emissions from "nonnegligible ethylene oxide emission sources," which means a source that currently emits more than 150 pounds of EtO per year and is located in a county with a population of at least 700,000.

Case Study of Sterigenics US, LLC in Willowbrook (Sterigenics Willowbrook)

Sterigenics Willowbrook was a commercial sterilization facility located in the Village of Willowbrook, a suburb of Chicago located in DuPage County. Sterigenics Willowbrook sterilized primarily medical supplies and pharmaceuticals as well as spices, using EtO as its primary sterilant gas; a second sterilant gas, propylene oxide, was also used. Sterigenics Willowbrook originally began operations in 1984, and in 2020, Sterigenics Willowbrook notified authorities of their intent to permanently close the facility.

In 2018, while Sterigenics Willowbrook was still in operation, U.S. EPA released an update to the National Air Toxics Assessment (NATA), referenced as the 2014 NATA. This national screening assessment used emissions and weather data from 2014 to estimate health risks from toxic air pollutants.[15] U.S. EPA used new estimates of the cancer potency of EtO that were issued in 2016 and not available for the previous version of NATA in 2011. The 2014 NATA revealed that the

[12] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[13] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/ethylene-oxide-risk-commercial-sterilizers
[14] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-commercial-sterilization-facilities
[15] https://www.epa.gov/national-air-toxics-assessment

census tract containing Sterigenics Willowbrook and other nearby census tracts had overall cancer risk estimates as high as 500 to 1000 in 1 million.[16]

From November 2018 to March 2019, U.S. EPA monitored ambient EtO levels around Sterigenics Willowbrook.[17] Based on the findings of ambient EtO monitoring, U.S. EPA's Agency for Toxic Substances and Disease Registry (ATSDR) concluded residents and workers are exposed to elevated airborne EtO concentrations from facility emissions, and that if measured and modeled data represent typical EtO ambient concentrations in ambient air, an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.[18]

In February 2019, a Seal Order was issued by the Illinois EPA that effectively stopped sterilization operations at the Willowbrook facility. The seal order was removed after the facility agreed to a Consent Order in July 2019[19] and submitted an application to Illinois EPA to make improvements to control emissions using additional layers of controls that meet a control efficiency of 99.9% or 0.2 ppm, and a permanent total enclosure to capture fugitive emissions to address the sources of EtO that contributed to elevated ambient readings.[20] A test protocol was submitted in October 2019 that included the proposed improvements that would be tested to demonstrate compliance.[21] However, in July 2020, the facility submitted a request to the Illinois EPA to withdraw their operational permits to end operations at the facility.[22]

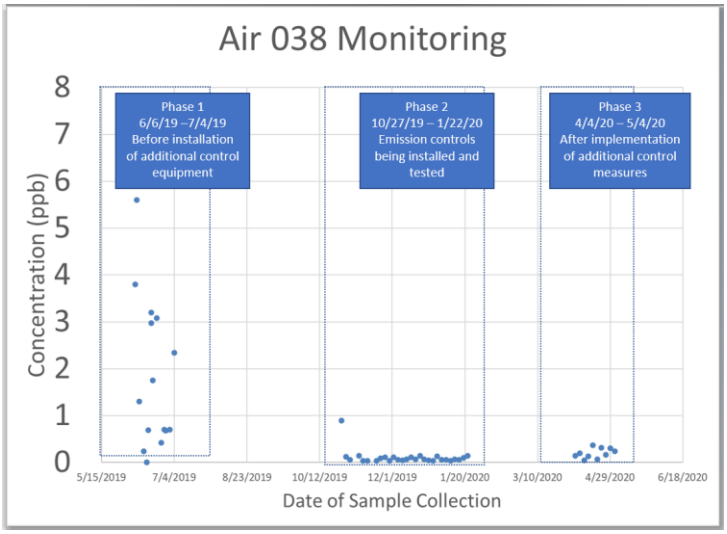
Case Study of Medline Industries, Inc. in Waukegan, IL (Medline Waukegan)

Medline Waukegan is a commercial sterilization facility located in the City of Waukegan, a suburb of Chicago located in Lake County. Medline Waukegan manufactures and sterilizes surgical packs as well as sterilizes pharmaceuticals and laboratory equipment. Beginning in June 2019, air monitoring began at multiple off-site locations in the Waukegan area near the facility. The highest outdoor EtO levels were measured at station Air 038.[23] Also in 2019, Medline Waukegan was issued a Construction Permit to reduce EtO emissions by installing additional control technology, capturing 100% of fugitive emissions with a PTE, and decreasing the number of exhaust points to atmosphere with a single new stack. Medline Waukegan was also required to monitor stack

[16] https://www.epa.gov/sites/default/files/2019-05/documents/risk-assessment-results-sterigenics-willowbrook.pdf
[17] https://www.epa.gov/il/outdoor-air-monitoring-willowbrook-community
[18] https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf
[19] Amended Joint Motion to Enter Proposed Consent Order. (2019, July 19). Illinois EPA. Retrieved August 25, 2023, from https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/sterigenics/documents/sterigenics-18ch1329-amended-joint-motion-to-enter-consent-order-filed-7-19-2019.pdf
[20] Construction Permit Application - Sterigenics Willowbrook. (2019, June 24). Illinois EPA. Retrieved August 25, 2023, from https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/043110aac-sterigenics-19060030-screened.pdf
[21] Protocol for Ethylene Oxide Testing - Willowbrook I Facility. (2019, October 4). Illinois EPA. Retrieved August 25, 2023, from https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/13990-1-sterigenics-eto-final-protocol.pdf
[22] Sterigenics Willowbrook - Request to Withdraw Permits. (2020, July 24). Illinois EPA. Retrieved August 25, 2023, from https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/sterigenics-permit-withdrawal-request.pdf
[23] https://www.lakecountyil.gov/4192/Medline-Independent-EtO-Monitoring-Resul

emissions by using a continuous emission monitoring system.[24] Construction began on these facility improvements in 2019 and were completed in 2020. Ambient EtO monitoring occurred before, during, and after this commissioning period (see figure below). As monitoring data is publicly available, South Coast AQMD staff assessed the monitoring data and compared it to when operations were shut down and control measures were implemented.

Figure 1-2 – Ambient Air Monitor of EtO for Medline Waukegan



The ambient data from station Air 038 revealed that EtO concentrations decreased after implementation of the EtO capture and control measures.

State of Georgia

The State of Georgia, under the Georgia Air Quality Act, designates the Georgia Department of Natural Resources, Environmental Protection Division (EPD) to administer the provisions of the Air Quality Act including the authority to adopt rules or issue permits to sources of emissions. At the present time, Georgia EPD has not promulgated a rule regarding ethylene oxide sterilization but has issued permits to several EtO sterilization facilities stipulating conditions or limitations.

Case Study of Sterigenics US, LLC in Atlanta, GA (Sterigenics Atlanta)

Sterigenics Atlanta is a commercial sterilization facility located in Cobb County within the Atlanta metropolitan area. Sterigenics Atlanta sterilizes medical devices and some spices using the sterilant gas EtO as well as some propylene oxide. The 2014 NATA identified two census tracts in close proximity to Sterigenics Atlanta requiring further study, however the Georgia EPD, after completing modeling analysis of emissions of the facility, determined that the risk associated with Sterigenics Atlanta did not exceed 100 in 1 million lifetime cancer risk.

Despite the modeled risk, in 2019, Georgia EPD and Sterigenics Atlanta voluntarily entered into a Consent Order that required Sterigenics Atlanta to modify their facility and their work practices

[24] Construction Permit, Application No. 19020013 | IEPA https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/medline-industries-19020013-final.pdf

including rerouting emissions from the acid-water scrubber to a dry bed scrubber for additional polishing, installing a taller emission stack, constructing a PTE, installing new air pollution control devices, conducting more frequent leak monitoring, offering initial and annual training of staff, and implementing a continuous emission monitoring system.[25]

Case Study of Becton, Dickinson and Company (BD) Global Distribution Center in Covington

BD Global Distribution Center is a warehouse facility located in the city of Covington, a suburb of Atlanta in Newton County. BD Global Distribution Center receives EtO-sterilized medical devices from two BD sterilization facilities in Georgia and other sterilization facilities outside of the state before shipping these medical devices to customers. In 2019, BD submitted a fugitive emission estimate report for Global Distribution Center to Georgia EPD, estimating that the facility emits approximately 5,600 lbs of EtO per calendar year.[26] Subsequently, Georgia EPD required that BD Global Distribution Center record the amount of sterilized materials received, conduct a variety of ambient EtO air monitoring, submit a permit application, and, within nine months, design and install air pollution control equipment to capture and control EtO emissions.[27]

Non-Air Quality Related Ethylene Oxide Regulations in the United States

In addition to the air quality related regulations for EtO, other agencies have oversight of the potential effects of EtO on patients and consumers. These focus primarily upon residual EtO that remains on medical, dental, veterinary, and food products and are tied to required aeration times for those specific products.

Residual EtO for Sterilization of Medical Products

The U.S. Food and Drug Administration (U.S. FDA) limits the amount of residual EtO[28] that can remain on medical products based on three different classes of products depending on the product's contact time (exposure) with the patient. Two voluntary consensus standards are specified to develop, validate, and control EtO sterilization process for medical devices and ensure acceptable residual levels of EtO remaining on the product: ANSI AAMI ISO 11135:2014 and ANSI AAMI ISO 10993-7:2008(R)2012. The products must follow a validation process specific to the product and the sterilizer to ensure that the products are sterilized to kill pathogens as well as comply with residual EtO levels on the product. A specific aeration time is specified for each product's cycle parameters at a sterilization facility as part of the validation process.

Residual EtO for Fumigation of Food Commodities

Although there are no permitted facilities with the South Coast AQMD that use EtO to fumigate food commodities using EtO, fumigation is considered a form of sterilization. Similar to medical products, there are limits to residual EtO that can remain on food. The U.S. EPA regulates this process as a registered antimicrobial pesticide under 40 CFR §180.151[29] which specifies the

[25] https://epd.georgia.gov/document/document/sterigenics-consent-order/download
[26] https://epd.georgia.gov/press-releases/2019-12-20/statement-georgia-epd-regarding-bd-notice-violation
[27] https://epd.georgia.gov/document/document/december182019nov-bdglobaldistributioncenterpdf/download
[28] https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#how
[29] https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.151

tolerances for residues of EtO for food commodities that may expose consumers to EtO through ingestion.

EtO Worker Protection

The Occupational Safety and Health Administration (OSHA), part of the U.S. Department of Labor, is the lead federal agency for the protection of workers in the workplace. In 2002, OSHA published a Fact Sheet to explain the hazards of EtO and requirements for EtO worker protection at that time (see Appendix A). In 2023, U.S. EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) released a draft risk assessment and a proposed interim decision to update the acceptable use of EtO to reduce risk at workplaces. Updates to EtO worker protection requirements are expected and a new OSHA EtO Fact Sheet may be forthcoming.

1.4 AMBIENT AIR MONITORING NEAR SOUTH COAST AQMD ETHYLENE OXIDE FACILITIES

South Coast AQMD began investigating facilities that emit EtO in March 2022. The South Coast AQMD used a methodical approach to monitor EtO levels near emission sources:

> (1) Conduct initial screening by monitoring VOC signals using a mobile monitoring platform. The platform is equipped with a state-of-the-art Proton Transfer Reaction – Mass Spectrometer (PTR-MS) capable of simultaneous real-time ambient air monitoring of hundreds of VOCs such as ketones, aldehydes, aromatic compounds and many others, in ambient air. This is a fast response instrument (1 second) which has VOC-dependent limits of detection ranging from tens of parts per trillion by volume (pptv) to a few parts per billion by volume (ppbv). This instrument can typically detect enhancements in VOC signals potentially related to EtO that are greater than 1 ppbv over the total background signal. This value is higher than the background levels of EtO in the Los Angeles area that ranged from 0.02 ppb to 0.17 ppb in the 2021 National Air Toxics Trends Stations (NATTS[30]).[31]
>
> (2) If enhanced signals were observed in the step above, ambient air in silica-lined stainless steel Summa grab canister samples would be collected then analyzed using U.S. EPA method TO-15/TO-15A, either as grab samples of air or fenceline air monitoring with 24-hour integrated samples.

Multiple passes around the facility were made during each mobile survey which included accessible drivable routes around the facility.

As of July 2023, South Coast AQMD has conducted mobile ambient air monitoring at seven active sterilization facilities (all permitted to use 2,000 lbs or more of EtO) and ten warehouses that store or may store EtO-sterilized materials. Among these locations, elevated EtO levels were observed at three large sterilization facilities and one warehouse. In addition, South Coast AQMD has

[30] National Air Toxics Trends Stations | Ambient Monitoring Technology Information Center | US EPA Stations. (n.d.). https://www3.epa.gov/ttnamti1/natts.html

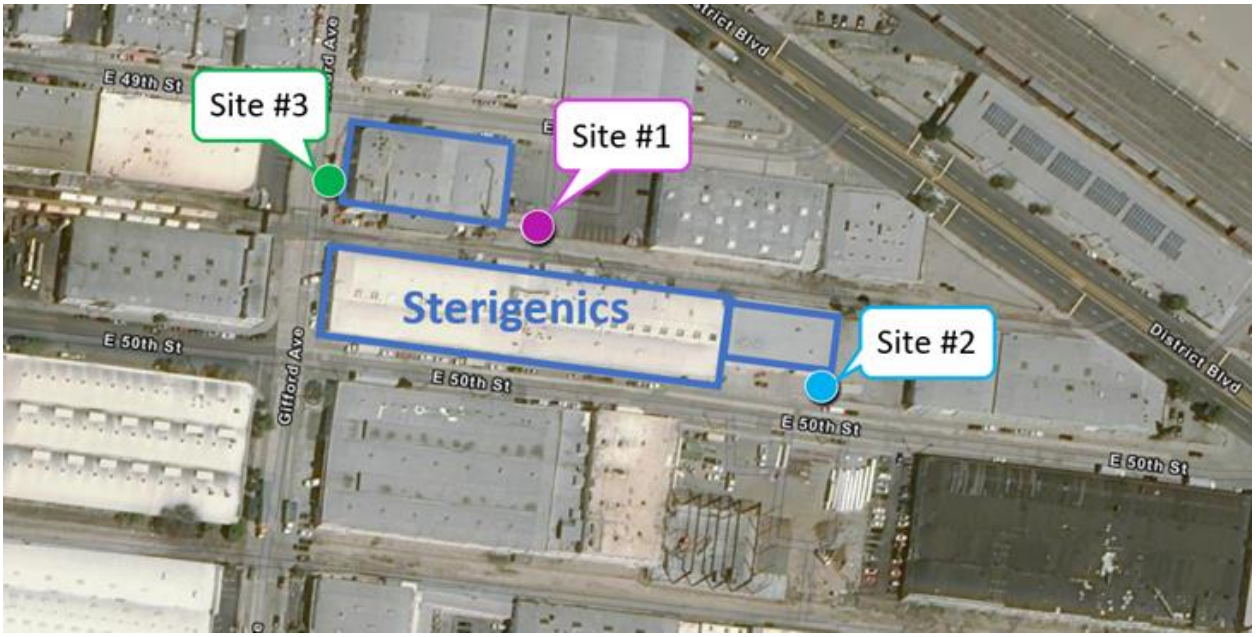
[31] Monitor Values Report - Hazardous air pollutants | US EPA. (2022, October 12). US EPA. https://www.epa.gov/outdoor-air-quality-data/monitor-values-report-hazardous-air-pollutants

conducted fenceline air monitoring using 24-hour canister sampling at the three sterilization facilities with elevated signals of EtO. More details of these three facilities are discussed below.

1.4.1 Sterigenics Vernon Sterilization Facility

The Sterigenics Vernon facility sterilizes medical equipment using EtO and operates within two buildings in an industrial area. The nearest residential area is about 500 feet away, and the nearest school is 1,700 feet away. In March 2022, mobile ambient air monitoring was conducted to monitor VOCs around the facility and the surrounding area. VOC signals associated with EtO were elevated near the facility. Individual grab samples (an air sample collected at one location at one point in time) were taken to confirm elevated EtO levels. Further investigation of EtO emissions at three near-source locations were collected using 24-hour time-integrated samples beginning in April 2022. In March 2022, it was observed that the facility had installed Timilon filter systems without obtaining a permit to reduce fugitive EtO emissions from their sterilized product storage area. Additionally, Sterigenics later reported in April 2022 that they had discovered open hatches for tanks that stored EtO-containing liquids at their facility. A nearby community site at a residential location was included in May 2022. The figure below shows monitoring sites near the Vernon facility.

Figure 1-3 – Location of Monitoring Sites for Sterigenics Vernon

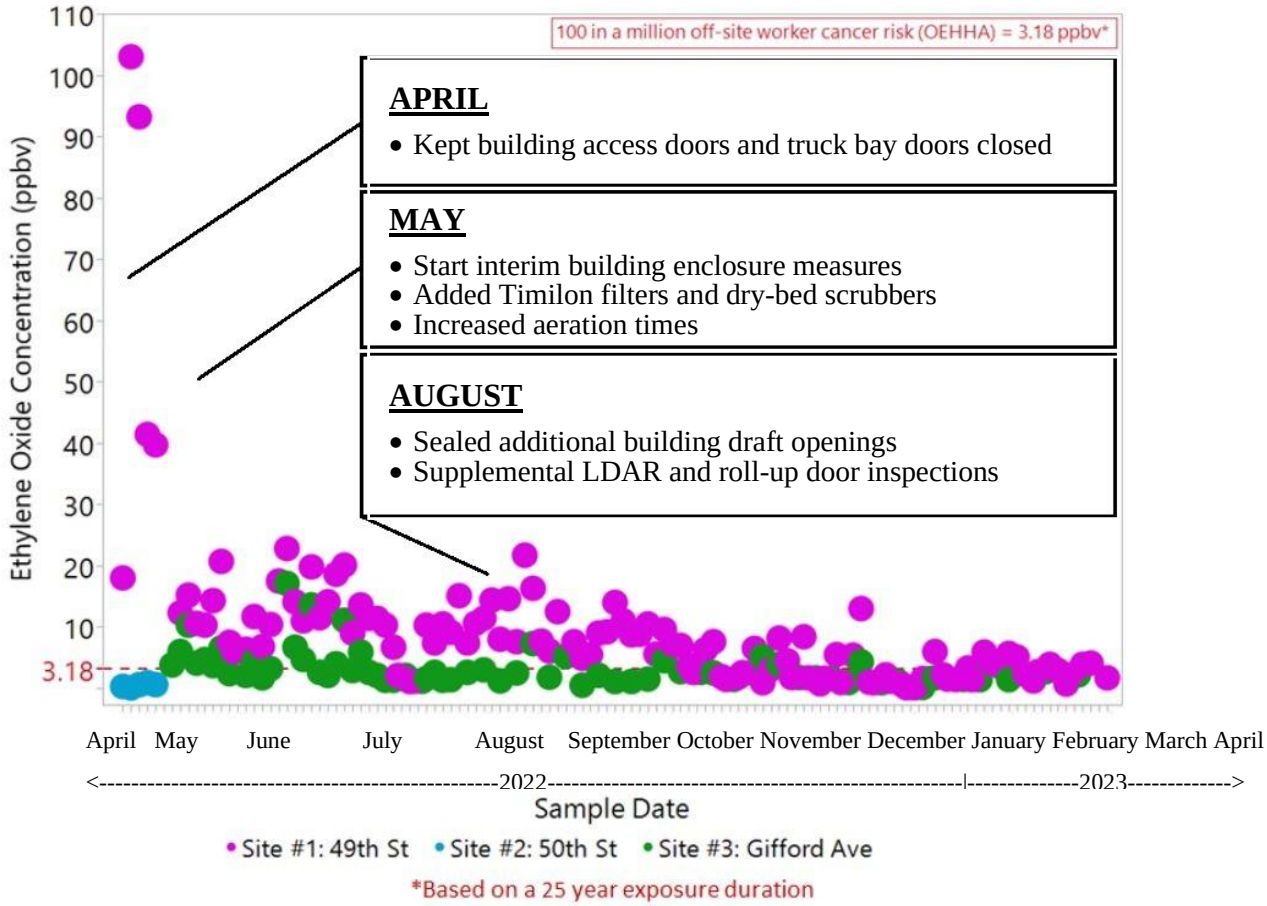


On June 7, 2022 Sterigenics Vernon was designated as a Potentially High-Risk Level Facility under the AB2588 Air Toxic "Hot Spots" program. As part of the Sterigenics Vernon's Early Action Reduction Plan (EARP)[32] under the AB2588 program to control EtO emissions, approved on September 9, 2022,[33] a PTE would be installed to control fugitive emissions. As interim

[32] Early Action Reduction Plan - Sterigenics (Vernon). (2022, September 2). Retrieved February 23, 2023, from https://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp.pdf?sfvrsn=8
[33] https://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp-approval-letter.pdf?sfvrsn=8

measures, the facility kept access doors to process, storage, and shipping areas and truck bay doors closed beginning in April 2022 and implemented other temporary enclosure measures beginning May 2022. The facility also added dry-bed scrubbers and Timilon filter systems to reduce fugitive EtO emissions. In August 2022, the facility completed additional sealing of building draft openings, started daily inspections of roll-up doors, and implemented a supplemental leak detection and repair (LDAR) program. The figure below shows the results of the near-facility EtO levels and the key measures taken at the facility to control EtO emissions in 2022.

Figure 1-4 – 24-Hour Near-Source Samples in Vernon



As shown in the figure above, during the first two weeks of ambient air monitoring, EtO levels (24-hr time integrated samples) at three near-source sites showed were as high as 103 parts per billion by volume (ppbv). Ambient EtO levels decreased below 25 ppbv by mid-May in 2022 and to levels of 10 ppbv or lower during the 4th quarter of 2022. On May 5, 2022, due to the elevated EtO concentrations observed, a Proposition 65 notice was issued notifying Los Angeles County Board of Supervisors, the Los Angeles County Health Officer, and the City of Vernon Director of Health and Environmental Control of the illegal discharge likely to cause substantial injury to public health or safety pursuant to California Public Resources Code 25180.7.

1.4.2 Sterigenics Ontario Sterilization Facility

The Sterigenics Ontario facility sterilizes medical equipment using EtO and operates in an industrial area. The nearest residential area is about 1.4 miles away and the nearest school is about 1.2 miles away. Mobile monitoring was conducted to collect data on VOCs around the facility and the surrounding area and elevated VOC signals associated with EtO were detected near the facility. Individual grab samples (an air sample collected at one location at one point in time) were taken to confirm elevated EtO levels. Beginning in June 2022, South Coast AQMD conducted ambient air sampling to determine levels of EtO near the facility and in the surrounding area, detecting ambient EtO levels several orders of magnitude higher than typical South Coast AQMD ambient EtO levels elsewhere in the Basin.

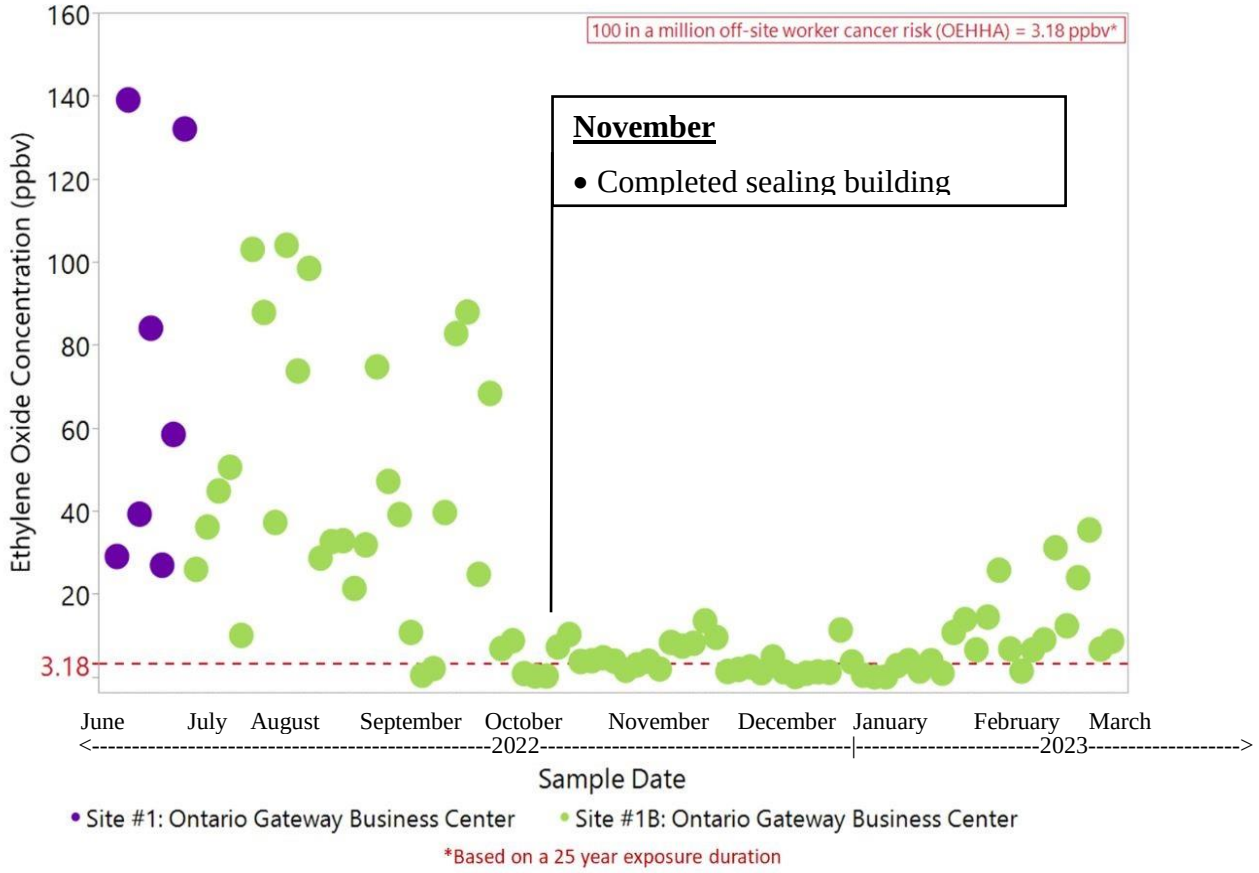
Figure 1-5 – Location of Monitoring Sites for Sterigenics Ontario

One July 1, 2022, due to the elevated EtO concentrations observed, a Proposition 65 notice was issued notifying San Bernadino County Board of Supervisors and the Health Officer for the San Bernadino Department of Public Health of the illegal discharge likely to cause substantial injury to public health or safety pursuant to California Public Resources Code 25180.7. The figure above shows the monitoring sites near the facility.

On September 29, 2022 Sterigenics Ontario was designated as Potentially High-Risk Level Facility under the AB2588 Air Toxic "Hot Spots" program. As part of the Sterigenics Ontario's Early Action Reduction Plan (EARP)[34] under the AB2588 program to control EtO emissions (approved on April 7, 2023),[35] a PTE would be installed to control fugitive emissions no later than July 31,

[34] Early Action Reduction Plan - Sterigenics (Ontario). (2023, April 7). Retrieved April 20, 2023, from http://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp-ontario.pdf?sfvrsn=8
[35] http://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp-approval-letter-ontario.pdf?sfvrsn=9

Figure 1-6 – 24-Hour Near-Source Samples in Ontario



2024. The figure below shows the results of EtO monitoring near Sterigenics Ontario and any key measures taken at the facility to control EtO emissions before the approval of the EARP.

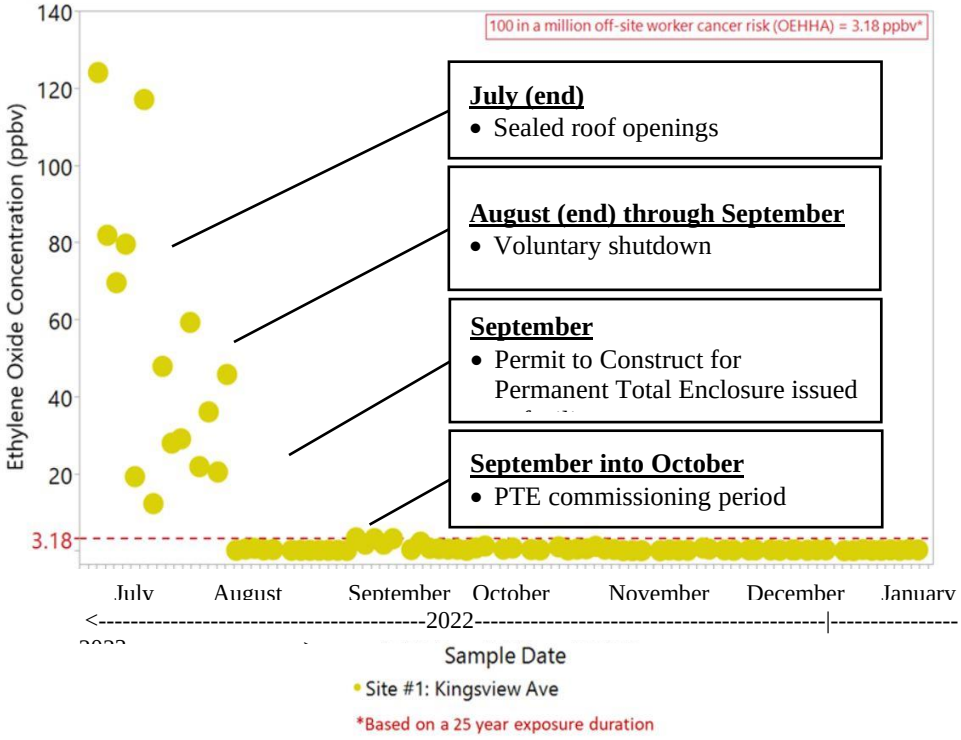
1.4.3 Parter Carson Sterilization Facility

The Parter Carson facility conducts EtO sterilization services for medical device manufacturers with operations that run 24 hours a day, seven days a week. The nearest residential area is about 700 feet and the nearest elementary school is about 2,000 feet from the facility. Mobile ambient air monitoring was conducted to collect data on VOCs around the facility and the surrounding area. VOC signals associated with EtO were elevated near and downwind of the facility. Individual grab samples (an air sample collected at one location at one point in time) were taken to confirm elevated EtO levels. Further investigation of EtO emissions at a near-facility location in addition to three nearby residential communities and school locations were collected using 24-hour time-integrated samples beginning July 2022. On July 28, 2022, due to the elevated EtO concentrations, a Proposition 65 notice was issued notifying Los Angeles County Board of Supervisors, the Los Angeles County Health Officer, and the City of Carson of the illegal discharge likely to cause substantial injury to public health or safety pursuant to California Public Resources Code 25180.7. The figure below shows the monitoring location site near the facility.

Figure 1-7 – Location of Monitoring Site for Parter Carson

On August 19, 2022 Parter Carson was notified that it may be designated as Potentially High-Risk Level Facility under the AB2588 Air Toxic "Hot Spots" program. Beginning late August 2022,

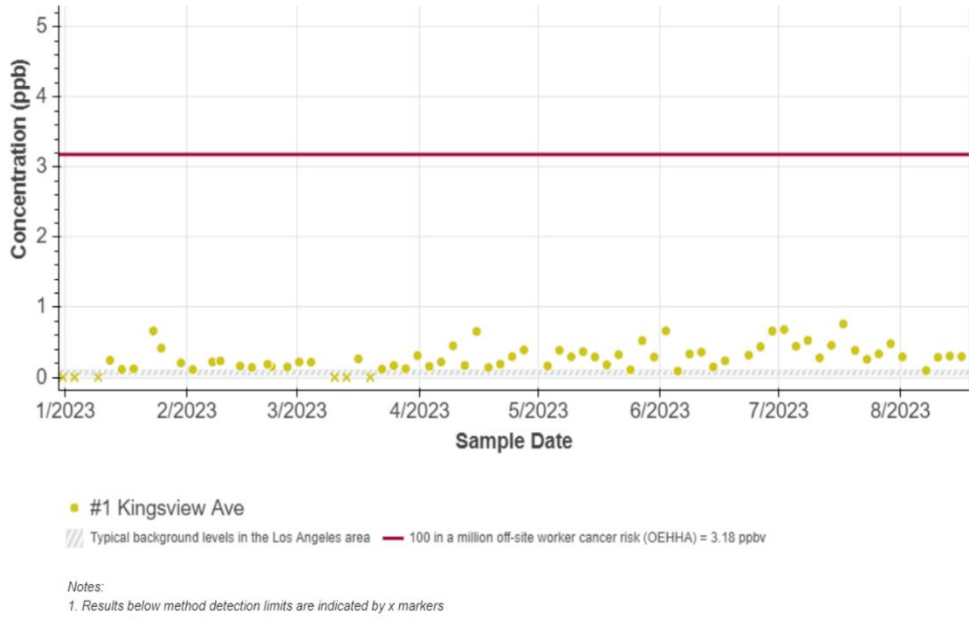
Figure 1-8 – 24-Hour Near-Source Samples in Carson



the facility temporarily ceased operation and voluntarily implemented additional control measures to reduce EtO emissions.

In September 2022, the facility was granted a Permit to Construct to implement a PTE to capture fugitive EtO emissions by installing additional dry bed scrubbers to control fugitive emissions and also polish acid-water scrubber emissions (i.e., second layer of control). Following the implementation of these control measures, fenceline air monitoring showed a decrease in EtO concentrations. The figure above shows the results of EtO monitoring near Parter Carson with the timeline of improvements made by the facility. Fenceline air monitoring results since the improvements have remained, so far in the 2023-year, near background levels as seen in the more detailed view shown in the figure below.

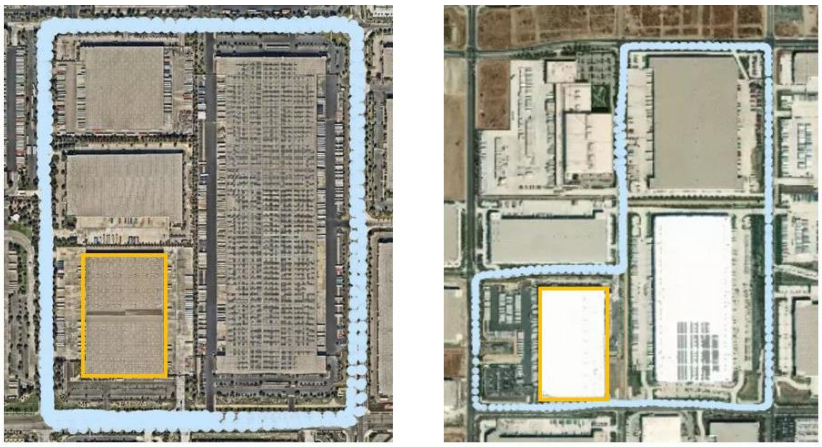
Figure 1-9 – 24 Hour Near-Source Samples in Carson in 2023



1.4.4 Warehouses (Including Aeration-Only Facilities)

As of May 2023, there are 80 facilities reporting to U.S. FDA as wholesale drug distributors or third-party logistics providers that may handle EtO-sterilized products in the South Coast AQMD jurisdiction. Survey requests for information were sent to these facilities but only 14 facilities responded. Of the 14 responses, only three facilities reported receiving EtO-sterilized products while eight reported that they did not; three facilities did not know if they received EtO-sterilized products. As part of the South Coast AQMD monitoring efforts for EtO sources, warehouses were also included and are ongoing. As of July 2023, ten warehouses reporting to U.S. FDA were monitored in the cities of Redlands, Rialto, Riverside, San Bernardino, Sante Fe Springs, and Moreno Valley. These warehouses were prioritized based on their building footprints and a review of online information regarding their association with known EtO sterilization operations nationwide. South Coast AQMD continues to monitor EtO emissions from warehouses. EtO mobile ambient air monitoring measurements have detected significant enhancements in EtO signals at one warehouse near its fenceline. The figure below shows two examples of mobile

Figure 1-10 – Examples of Mobile Monitoring Platform Survey of Warehouses



monitoring platform survey around two warehouses (outlined in orange) and the survey route showing no enhancements in VOC signals (light blue).

1.5 AMBIENT AIR MONITORING TECHNOLOGY

Ambient air monitoring is conducted by measuring the ambient levels of the pollutant(s) of interest, including near the boundaries of a facility or other source of air pollution. Typically, ambient air monitoring methods consist of either sample collection followed by laboratory analysis, or continuous monitoring in real- or near real-time. The following criteria were considered to assess strengths and limitations of available technologies and methods for the purposes of mobile and fenceline EtO measurement applications: 1) documented performance; 2) detection limit; and 3) availability.

- **Documented performance**
  For the purpose of this rule, only well-established technologies will be considered for ambient air monitoring. This will ensure that EtO is properly detected and accurately quantified. The most widely method used by air quality agencies for regulatory purposes include canister sample collection followed by laboratory analysis such as U.S. EPA Compendium Method TO-15 or Method TO-15A. Despite some limitations identified below, these are considered to be the current gold standard for EtO ambient monitoring. Alternatively, emerging technologies such as continuous instruments reporting EtO concentrations in real- or near real-time are being considered and evaluated for certain applications, although their performance has not been fully validated yet. These include Cavity Ring-Down Spectroscopy (CRDS) and Tunable Infrared Laser Direct Absorption Spectroscopy (TILDAS), which have been tested by South Coast AQMD and which performance has been documented in scientific publications or technical reports.

- **Detection Limit**
  The detection limit of an instrument is defined as the lowest concentration or the lowest amount of an air toxic contaminant that can be measured accurately. A low detection limit is important as an established technology should be able to detect pollutants near a source (e.g., emissions emanating from a facility) at levels that can be slightly above those typically

measured in ambient air (background). As discussed in Chapter 1, background levels of EtO in the Los Angeles area range from 0.02 ppb to 0.17 ppb.

- **Availability**
  To ensure that it is feasible for facilities to comply with proposed rule requirements, the monitoring technology considered for implementation should be readily available for purchase. Emerging technologies may have limited availability with long lead times greater than six months compared with established and more mature technologies which have already been adopted. Additionally, there are third-party contractors that already use the technology for ambient air monitoring and offer their services or equipment rental on a contract basis.

The following sections provide an overview of monitoring technologies that can be used for quantifying EtO levels in ambient air. These technologies are classified as either sample collection or continuous real-time/near-real time technologies.

1.5.1 Sample Collection Technologies

These are designed to collect an air sample for subsequent laboratory analysis. Samples are typically collected using either Tedlar bags or Summa canisters. Collection is performed over a preset time period (usually 24-hours) to obtain a time-integrated sample.

Tedlar Bag Collection

➢ Overview of Process

Disposable inert plastic bags are used to collect samples. A separate pump or vacuum source is required to fill the bag. Analysis of the collected sample is later performed in the laboratory using gas chromatograph-mass spectrometry (GC-MS).

- Documented Performance

Although Tedlar bag collection is used for source tests to collect samples of relatively higher concentrations analyzed per CARB Method 431 – Determination of Ethylene Oxide Emissions from Stationary Sources, this technology is not an established technology for outdoor ambient air monitoring of EtO.

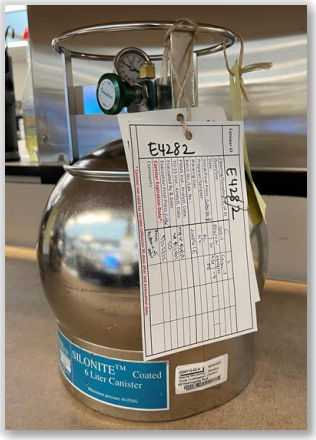
- Detection Limit

The detection limit is in the ppm to sub-ppm range. This technology was used for source testing of EtO with a detection limit of 0.2 ppm (200 ppb).

- Availability

Tedlar bags are readily available in the market for source testing applications.

Summa Canister Collection



➢ Overview of Process

Stainless steel canisters are used to collect samples, which is then analyzed in the laboratory using a GC-MS. Canister and flowmeter are prepared and validated ahead of time by the laboratory for the specific analysis which includes the expected sampled gas composition. Prior to their use, summa canisters are under negative pressure to collect an air sample over a specified interval of time (e.g., 24-hr time-integrated sample) once the valve is open. When the valve is closed at the end of the sampling collection period, the canister should still be under negative pressure to ensure no loss of the collected sample. Key limitations of this technology include creating only a single data point over a time-integrated period and a turn-around time of several days to a week or more to analyze sample and produce a result.

- Documented Performance

For EtO, South Coast AQMD collects samples using silica-lined metal canisters (to prevent contamination and EtO growth) and analyzed per TO-15A for regulatory purposes. Additionally, canister sampling of EtO has been used across the United States by a variety of regulatory agencies. As such, canister sampling is a well-established technology for outdoor ambient air monitoring of EtO.

- Detection Limit

Canister sampling and analyses pursuant to TO-15A allows for low detection limits (approximately 0.02 ppb of EtO) to be achieved, whereas TO-15 typically has detection limits that are an order of magnitude higher (approximately 0.2 ppb of EtO).

- Availability

Based on information collected from analytical laboratories, preparation, and validation of canisters for TO-15A are very labor intensive and required a dedicated supply of canisters. Thus, many laboratories currently do not offer TO-15A analysis. On the other hand, TO-15 is used more widely.

1.5.2 Continuous Real-Time/Near Real-Time Monitoring Technologies

Real-time or Near Real-Time monitoring involves the use of technology that continuously measures the pollutant(s) of interest at short time intervals (e.g., from a few seconds to a few minutes). Typically, modern monitoring technologies can report results in real- or near real-time (shortly after they have been collected). The main advantage of using this type of technology is the quick turnaround time of the monitoring results. Below are well established continuous monitoring technologies being used or considered for monitoring of EtO:

Proton Transfer Reaction Mass Spectrometer (PTR-MS) Sampling

➢ Overview of Process

PTR-MS technology is a non-specific measurement of EtO concentrations, detecting for signals associated with EtO ions. South Coast AQMD uses this technology during mobile surveys for initial screening. When enhanced signals are observed from the PTR-MS instrument, grab canister

samples can be collected and analyzed per TO-15A (see Canister Collection above) to determine actual EtO concentrations.

- Documented Performance

South Coast AQMD uses this technology to collect information on EtO on a mobile platform. As such, this is an established technology for mobile ambient air monitoring of EtO.

- Detection Limit

Although PTR-MS is capable of non-specific measurements of EtO concentrations in the sub-ppb range, the final measurement of EtO is tied to the grab canister sample and associated detection limit (see Canister Collection above).

- Availability

Aside from the South Coast AQMD, at least one third-party contractor is able to monitor EtO-related measurements using this technology.[36,37] However, there might be a long lead time to purchase this technology (PTR-MS component).

Tunable Infrared Laser Direct Absorption Spectroscopy (TILDAS)

➢ Overview of Process

TILDAS measures EtO by passing the beam of a laser tuned to the characteristic absorption wavelength of EtO through a sample cell and measuring reductions of the intensity of the signal using a photodiode. Concentration is determined from this reduction in intensity.

- Documented Performance

In 2022, South Coast AQMD worked with a vendor on an EtO monitor evaluation study using this technology, which included both mobile and fixed-site ambient air monitoring of EtO.[38] This technology was demonstrated in a study in Massachusetts in 2022 and documented in a peer-reviewed journal.[39] During the study, both fixed-site and mobile monitoring were performed. Additional information on this event was presented at the 2022 National Ambient Air Monitoring Conference.[40] Another study was conducted in the Greater Toronto Area near possible EtO sources

[36] PTR-MS for Environmental Analysis | RJ Lee Group, Inc. (RJLG). (n.d.). https://www.rjlg.com/ptr-ms-environmental-analysis/

[37] Montrose Environmental. (2021, April 7). PTR-TOF-MS Mobile Laboratory - Montrose Environmental. https://montrose-env.com/services/testing-lab-services/ptr-tof-ms-mobile-laboratory/

[38] South Coast AQMD Board Meeting Item - Recognize Revenue, Appropriate Funds, Execute Purchase Orders and Contracts to Design and Develop a Mobile Air Toxics Measurement Platform. (2021, February 5). South Coast AQMD. http://www.aqmd.gov/docs/default-source/Agendas/Governing-Board/2021/2021-feb5-005.pdf?sfvrsn=2

[39] Yacovitch, T. I., Dyroff, C., Roscioli, J. R., Daube, C., McManus, J. B., & Herndon, S. C. (2023). Ethylene oxide monitor with part-per-trillion precision for in situ measurements. Atmospheric Measurement Techniques, 16(7), 1915–1921. https://doi.org/10.5194/amt-16-1915-2023

[40] Ethylene Oxide Monitor with Ultra-Low Limit of Detection. (n.d.). [Slide show; Presentation]. 2022 National Ambient Air Monitoring Conference, Pittsburg, United States of America. U.S. EPA. https://www.epa.gov/system/files/documents/2022-10/202208_Pittsburg_NAAQS_Herndon.pdf

in 2021.[41] South Coast AQMD has evaluated published studies and determined this technology meets the criteria for PAR 1405 fenceline air monitoring.

- Detection Limit

This technology is capable of measurements of EtO concentrations in the sub-ppb range.

- Availability

At least one third-party contractor is able to monitor EtO using this technology.[42] However, there might be a long lead time to purchase this technology.

Cavity Ring-down Spectroscopy (CRDS)

➢ Overview of Process

CRDS uses a photodetector that senses light inside a cavity and can measure the exponential decay of the light inside the cavity using a laser tuned to the characteristic absorption wavelength of EtO.

- Documented Performance

This technology has been used for fixed-site air monitoring. In June 2021, the State of Washington conducted a study of ambient EtO measurements in western Washington using CRDS at three fixed ambient monitoring sites. Hourly EtO concentrations were measured to be sub-ppb. [43] In October 2021, another study using CRDS was conducted at an EtO chemical facility in the midwestern United States to understand EtO emissions sources and to advance next generation emission measurements.[44] South Coast AQMD has evaluated published studies and determined this technology as appropriate for use with mobile and fixed-site ambient air monitoring of EtO.

- Detection Limit

This technology is able to measure in the sub-ppb range.

- Availability

At least one third-party contractor is able to monitor EtO using this technology.[45] However, there might be a long lead time to purchase this technology.

[41] Galarneau, E., Yacovitch, T. I., Lerner, B., Sheppard, A., Quach, B., Kuang, W., Rai, H., Staebler, R., Mihele, C., & Vogel, F. (2023). From hotspots to background: High-resolution mapping of ethylene oxide in urban air. Atmospheric Environment, 307, 119828. https://doi.org/10.1016/j.atmosenv.2023.119828

[42] Aerodyne Research Inc. (2022, August 19). Aerodyne Mobile Laboratory - Aerodyne. Aerodyne. https://www.aerodyne.com/centers/aerodyne-mobile-laboratory/

[43] Ethylene Oxide Measurements in Western Washington during June 2021. (2022, June). Department of Ecology State of Washington. Retrieved June 20, 2023, from https://apps.ecology.wa.gov/publications/summarypages/2202020.html

[44] Thoma, E. D., Gitipour, A., George, I., Kariher, P., MacDonald, M., Queiroz, G., Deshmukh, P., Childers, J., Rodak, T., & Schmid, V. (2023). Assessment of chemical facility ethylene oxide emissions using mobile and multipoint monitoring. Atmospheric Environment: X, 18, 100214. https://doi.org/10.1016/j.aeaoa.2023.100214

[45] CleanAir Engineering, Inc. (2023, May 31). Ethylene Oxide monitoring Services. CleanAir Engineering. https://www.cleanair.com/ethylene-oxide-monitoring/

Gas Chromatography-Photoionization Detector (GC-PID)

➢ Overview of Process

GC-PID technology measures EtO concentration in near real-time. GC-PID technology is used for monitoring potential worker exposure to EtO indoors but also used for stack emission testing. Ultraviolet light is used to ionize the analyte exiting a heated gas chromatograph column. The concentration is determined from the ions produced and then collected at electrodes.

- Documented Performance

Although this technology is associated with several reference methods including CARB Method 431 – Determination of Ethylene Oxide Emissions from Stationary Sources, U.S. EPA Method 18 – Volatile Organic Compounds by Gas Chromatography, and U.S. EPA Performance Specification 8 and 9, none are referenced for use for ambient air monitoring purposes and no implementation for ambient monitoring is known. As such, this technology is not an established technology for ambient air monitoring of EtO.

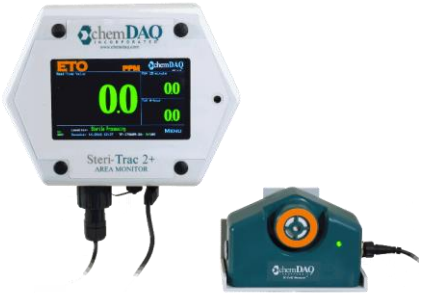
- Detection Limit

This technology is capable of measurements of EtO concentrations in the ppb range, as low as 10 ppb (0.01 ppm).

- Availability

GC-PID technology is readily available from multiple vendors for source testing and indoor environments.

Infrared (IR) Absorption Spectroscopy Sensor



➢ Overview of Process

Infrared light is absorbed by EtO to determine its concentration but subject to interference from other compounds such as water. IR technology is commonly used for indoor worker protection and fire/explosion safety monitors at a facility.

- Documented Performance

No established methods were found for its use for ambient air monitoring by any air quality agency. This technology is not an established technology for ambient air monitoring of EtO.

- Detection Limit

This technology is capable of measurements of EtO concentrations in the ppb range, as low as 100 ppb (0.1 ppm).

- Availability

IR technology is readily available and already widely used in indoor environments.

Fourier Transform Infrared (FTIR)

➢ Overview of Process

Inside a chamber in the detector, infrared light is absorbed by infrared active gases each with unique "fingerprint" wavelengths before being measured.

- Documented Performance

This technology is currently used for EtO stack emission monitoring at a sterilization facility outside of South Coast AQMD using reference method U.S. EPA Performance Specification 15 – Performance Specification For Extractive FTIR Continuous Emissions Monitor Systems In Stationary Sources. Reference methods include U.S. EPA Method 320 – Vapor Phase Organic and Inorganic Emissions by Extractive FTIR, and U.S. EPA Performance Specification 15, though none are referenced for use for ambient air monitoring purposes and no implementation for ambient air monitoring is known. Proposed U.S. EPA Performance Specification 19 – Performance Specifications and Test Procedures for Ethylene Oxide (EtO) Continuous Monitoring Systems is not expected to be referenced for ambient air monitoring.[46] FTIR technology may be useful for other applications including ambient air monitoring, but there is no known application of this technology for ambient air monitoring of EtO. This technology is not an established technology for ambient air monitoring of EtO.

- Detection Limit

Based on available literature this technology has potential for measuring EtO concentrations at sub-ppb levels.

- Availability

There might be a long lead time to purchase this technology of several months up to a year based on conversations with vendors of the technology because of supply chain issues and demand.

Open-Path Fourier Infrared Spectroscopy (OP-FTIR)

➢ Overview of Process

OP-FTIR systems optically transmit IR energy along a fenceline to a reflector and resulting spectra are analyzed for gas concentrations along the open-air light path. The technology is similar to FTIR, but the analyte is in the open-air instead of the chamber of the detector. EtO detection capabilities by OP-FTIR would be affected by environmental conditions as well presence of other pollutants that have strong absorptions in the same spectral region.

- Documented Performance

OP-FTIR is referenced in U.S. EPA Compendium Method TO-16 – Long-Path Open-Path Fourier Transform Infrared Monitoring of Atmospheric Gases for determination of toxic organic compounds in ambient air. However, no published studies or demonstration of its use for ambient air monitoring of EtO were found by the South Coast AQMD

[46] Regulations.gov. (n.d.). https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0491

to properly assess application of this technology for monitoring of this pollutant. OP-FTIR has been used extensively for fenceline air monitoring of ammonia and other air pollutants at refineries and other large industrial facilities. This technology is not an established technology for ambient air monitoring of EtO.

- Detection Limit

The detection limit ranges from a few ppb to a few tens ppb, depending on the compound. As of July 2023, no published documentation was found demonstrating a detection limit in the sub-ppb range for EtO.

- Availability

At least one vendor had indicated they could monitor EtO using this technology at fenceline.[47] However, there might be a long lead time to purchase this technology.

Summary of EtO Monitoring Technologies

The table below summarizes the technologies as of the time of this staff report. As data from emerging technology, such as published studies or demonstrations, become available for South Coast AQMD evaluation, those technologies would be evaluated and may be determined to be acceptable for ambient air monitoring requirements of EtO.

Table 1-2 – Summary of EtO Ambient Monitoring Technologies

Criteria for Outdoor Ambient Air Monitoring of ETO		Sample Collection		Continuous (Real-Time/Near Real-Time)						
		Summa Canister	Tedlar Bag	GC-PID	PTR-MS	IR	FTIR	OP-FTIR	CRDS	TILDAS
Documented Performance	Mobile Platform	No	No	No	√	No	No	No	√	√
	Fixed-Site	√	No	No	No	No	No	No	√	√
Detection Limit	0.2 ppb	√	No	No	No	No	No	No	√	√
	Sub-ppb	√	No	No	√*	No	√	No	√	√
Availability	Contractor Service or Rental	√	√	**	√	**	**	√	√	√
	Purchase Lead Time Less Than 6 Months	**	**	√	No	√	No	No	No	No

* *Detection of signals associated with EtO ions*

** *Not applicable*

[47] http://www.atmosfir.net/d-fenceline

1.6 CURTAILMENT BASED ON FENCELINE AIR MONITORING

Curtailment is the temporary limiting of facility operations. Curtailments have been used to reduce the amount of an air contaminant, typically a toxic air contaminant, in response to observed level of that air contaminant, whether from stack emission or fenceline air monitoring. Curtailments may be a percentage reduction in the feedstock or complete cessation of certain operations believed to be contributing to the elevated levels observed. Below are examples of curtailments in South Coast AQMD.

Stack Emission Based:

- South Coast AQMD Rule – Rule 1420.1 – *Emissions Standards for Lead and Other Toxic Air Contaminants from Large Lead-Acid Battery Recycling Facilities* included curtailment provisions in January 2014. Curtailment rule provisions were implemented on a sliding scale, based on the level of exceedance.

Fenceline Air Monitoring Based:

- Stipulated Orders for Abatement – South Coast AQMD initiated an extensive air monitoring campaign in 2016[48] in the city of Paramount to assess levels of hexavalent chromium and resulted in the identification of multiple sources. Of those, two aerospace facilities were identified to be contributing to elevated concentration levels of hexavalent chromium and subsequently were subject to curtailment provisions under stipulated orders for abatement.[49,50]
- Early Action Reduction Plans (EARP) – Two large sterilization facilities were designated as Potentially High Risk Level Facilities under the AB2588 Hot Spots program in 2022-2023. The two facilities are required to reduce their facility risk through implementation of the EARP, which included curtailment provisions.[51,52]

For EtO, curtailment in EARPs is based on observed levels of EtO at the facility from fenceline air monitoring. Considerations were taken for possible contribution from EtO sources other than the facility subject to curtailment. The examples below describe the curtailment provisions in the approved EARPs at two large sterilization facilities in South Coast AQMD.

1.6.1 Curtailments at Sterigenics Vernon Based on EARP

[48] Paramount Emissions Investigation. (n.d.). http://www.aqmd.gov/home/news-events/community-investigations/air-monitoring-activities

[49] Aerocraft. (n.d.). http://www.aqmd.gov/home/news-events/community-investigations/air-monitoring-activities/facilities---order-for-abatement/aerocraft

[50] Anaplex Corp. (n.d.). http://www.aqmd.gov/home/news-events/community-investigations/air-monitoring-activities/facilities---order-for-abatement/anaplex-corp

[51] Sterigenics - Vernon. (n.d.). http://www.aqmd.gov/home/news-events/community-investigations/sterigenics

[52] Sterigenics - Ontario. (n.d.). http://www.aqmd.gov/home/news-events/community-investigations/sterigenics-ontario

On June 7, 2022, Sterigenics Vernon was designated a Potentially High Risk Level Facility. The facility submitted an EARP which was approved on September 9, 2022. The approved EARP includes requirements for fenceline air monitoring and provisions for curtailment using two thresholds: a lower threshold of 17.5 ppb and an upper threshold of 25.0 ppb. A 20 percent curtailment at the lower threshold and 50 percent curtailment of operation at the upper threshold is required if a 24-hr sample result reaches these thresholds. Repeated exceedances of the threshold within a rolling 30-day period will result in a temporary shutdown of the facility. See table below for a more detailed description of the curtailment schedule and structure. The percentage curtailed is calculated based on the daily average pounds of EtO used by sterilizers or combined sterilizer/aerators in the seven (7) operating days including and prior to the date of the monitoring result or sample that triggered the curtailment.

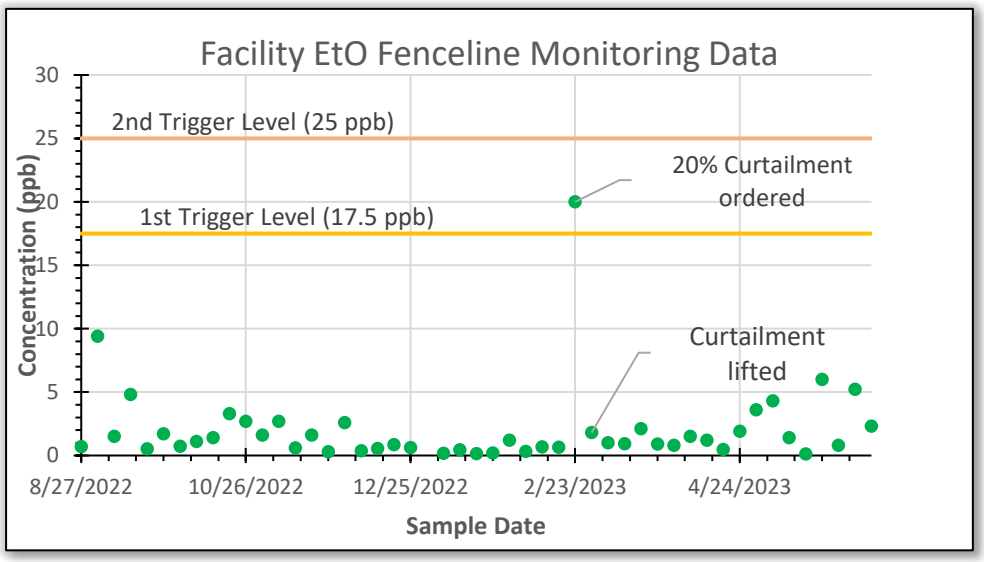
Table 1-3 – Sterigenics Vernon Curtailment Schedule

EtO Level ≥ 17.5 ppb but <25 ppb	Action	EtO Level ≥ 25 ppb	Action
First Sample	20% Curtailment of Operations	First Sample	50% Curtailment of Operations
Second Sample	50% Curtailment of Operations	Second Sample	100% Curtailment of Operation
Third Sample	100% Curtailment of Operations		

Curtailment is only lifted when all monitoring results are below the 17.5 ppb lower threshold. If all monitoring results remain below 17.5 ppb for at least 30 calendar days, the curtailment schedule is reset.

As of July 2023, Sterigenics Vernon had one curtailment event which was triggered by a 20 ppb EtO level observed on February 23, 2023. A 20 percent curtailment began on March 4, 2023 until

Figure 1-11 – Sterigenics Vernon Curtailment of Operations



March 7, 2023 where the monitoring result from March 1, 2023 was below the lower curtailment threshold; see figure below.

1.6.2 Curtailments at Sterigenics Ontario Based on EARP

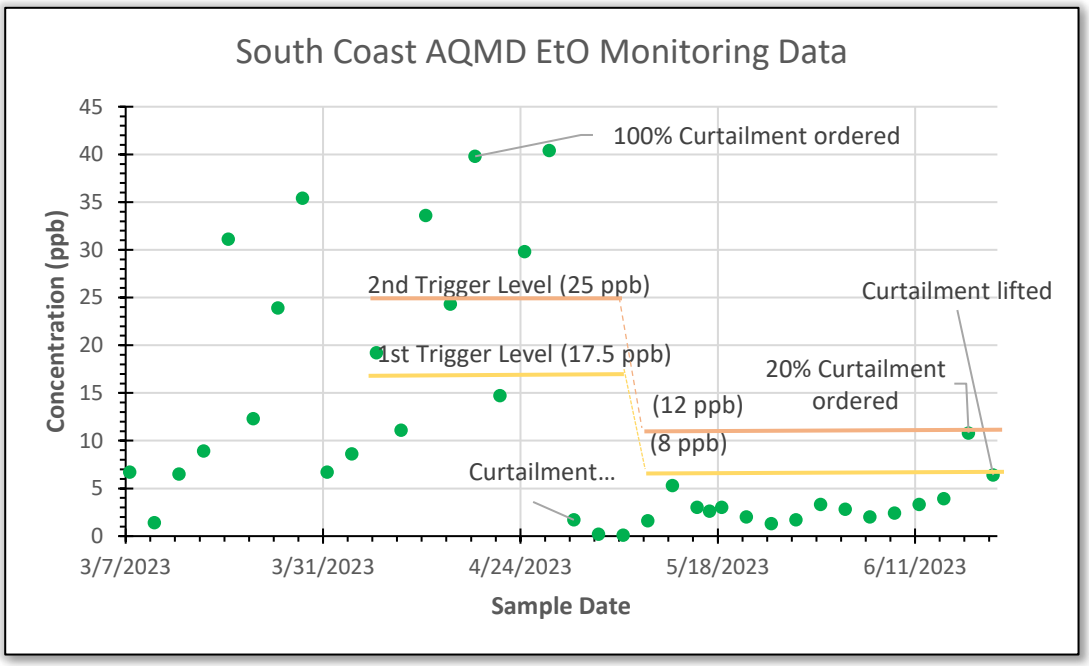
On September 29, 2022, Sterigenics Ontario was designated a Potentially High Risk Level Facility. The facility submitted an EARP which was approved on April 7, 2023. The approved EARP includes requirements for fenceline air monitoring and provisions for curtailment using two thresholds of 17.5 and 25.0 ppb. In May 2023, the two curtailment thresholds were lowered to 8 ppb and 12 ppb. The curtailment schedule is different than that of Sterigenics Vernon due to the lower curtailment thresholds. See table below for a more detailed description of the curtailment schedule and structure. Repeated exceedances of the threshold within a rolling 30-day period will result in a temporary shutdown of the facility. The percentage curtailed is calculated based on the daily average pounds of EtO used by sterilizers or combined sterilizer/aerators in the seven (7) operating days including and prior to the date of the monitoring result or sample that triggered the curtailment.

Table 1-4 – Sterigenics Ontario Curtailment Schedule

EtO Level ≥ 8 ppb but <12 ppb	Action	EtO Level ≥ 12 ppb	Action
Second Sample	20% Curtailment of Operations	First Sample	20% Curtailment of Operations
Third Sample	50% Curtailment of Operations	Second Sample	50% Curtailment of Operation
Fourth Sample	100% Curtailment of Operations	Third Sample	100% Curtailment of Operation

Curtailment is only lifted when all monitoring results are below the 8.0 ppb lower threshold. If all monitoring results remain below 8.0 ppb for at least 30 calendar days, the curtailment schedule is reset. As of July 2023, Sterigenics Ontario has had two curtailment events. The first event occurred due to elevated readings ranging from 24.3 to 39.8 ppb on April 12, 15 and 18, 2023 which resulted in a 100 percent curtailment beginning April 28th until the monitoring result from April 30, 2023 was below the threshold. The second curtailment occurred due to a monitoring level of 13 ppb on June 17, 2023 which resulted in a 20 percent curtailment that began on June 23, 2023. The curtailment was lifted on June 27, 2023; see figure below.

Figure 1-12 – Sterigenics Ontario Curtailment of Operations

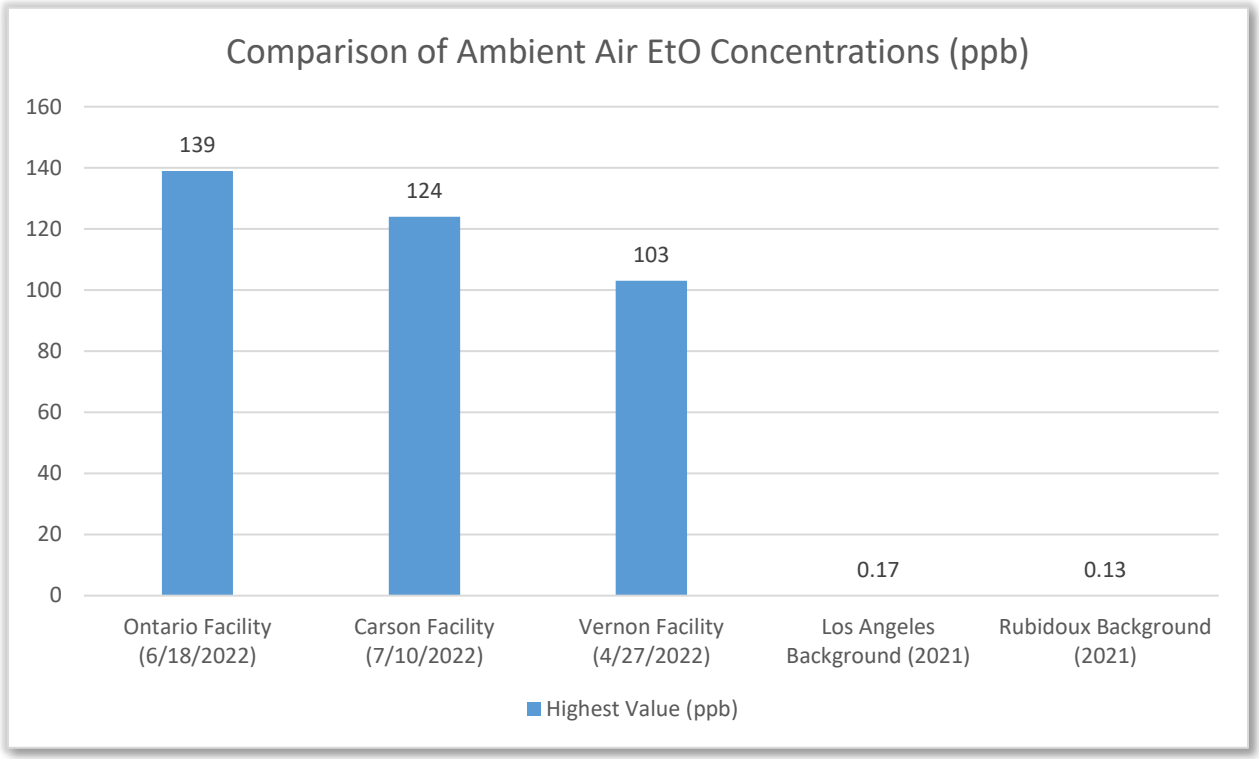


1.6.3 Contributions of Background to Ambient Air EtO Levels

In addition to emissions from sterilization and related operations, there could be other sources of EtO emissions that occur from human activities or occur naturally in the environment. The contributions of these sources on background levels are unclear. As discussed earlier, background levels of EtO were measured to be as high as 0.17 ppb in the South Coast AQMD area in 2021. By comparison, fenceline air monitoring indicated peak EtO concentrations above 100 ppb at three different sterilization facilities in 2022[53] (see figure below). The highest measured EtO concentrations nearby these sterilization facilities were 2-3 order of magnitude greater than the highest background levels. Therefore, there is sufficient information to conclude that background levels did not significantly impact fenceline air monitoring results. The elevated fenceline air monitoring results were from the sterilization facility and no further considerations, such as background subtraction, were required.

[53] https://www.aqmd.gov/docs/default-source/compliance/sterigenics/ontario-sample-data-table.pdf
https://www.aqmd.gov/docs/default-source/compliance/parter/carson-sample-data-table.pdf
https://www.aqmd.gov/docs/default-source/compliance/sterigenics/vernon-sample-data-table.pdf

Figure 1-13 - Comparison of Ambient Air EtO Concentrations



1.6.4 Conclusion

Based on the implementation of EARPs in South Coast AQMD, curtailment based on fenceline air monitoring is an effective means to reduce EtO when elevated EtO levels are observed at fenceline.

1.7 AFFECTED RULE 1405 FACILITIES

Rule 1405 regulates two types of facilities: 1) facilities conducting sterilization onsite (sterilization facilities) and 2) facilities receiving EtO materials which have been sterilized at another facility (aeration-only facilities).

Sterilization facilities use EtO to sterilize products in equipment known as chambers where EtO is introduced and comes in contact with products and any associated packaging to sterilize the contents. Sterilization facilities may sterilize their own products or equipment (manufacturer) or offer their services under contract (contract sterilizer) to manufacturers. The larger sterilizing facilities have sterilization chambers capable of processing multiple pallets of products during each programmed cycle and typically perform aeration activities in a separate area or room. Smaller facilities typically have all-in-one units capable of conducting both sterilization and aeration processes in the same unit where capacity is much less, typically the size of a small cart-load of products. These smaller facilities include research, veterinary, or medical facilities where EtO sterilization is not the primary business of the facility.

Aeration-only facilities receive sterilized products from other facilities in order to aerate the previously EtO-sterilized products through natural or mechanically assisted convection in order to dissipate residual EtO from the sterilized products. Rule 1405's definition of aeration specifies that aeration is complete when the product can be handled, stored, or transported like similar materials that had not been sterilized with EtO. Data on aeration-only facilities is limited as there is only one such facility in the South Coast AQMD area performing aeration-only activities. Data gathering at warehouses by South Coast AQMD staff indicated that some warehouses may not be aware they are receiving EtO-sterilized products.

As of July 2023, there are 16 facilities that are currently subject to Rule 1405, of which 15 facilities using EtO for sterilization include contract sterilizers, medical product manufacturers, surgical or veterinary facilities, or school and zoos. The remaining facility is an aeration-only facility receiving EtO-sterilized materials from sterilizers outside of South Coast AQMD jurisdiction. Based on Rule 1405 thresholds there are six (6) large, three (3) medium, and three (3) small sterilization facilities. There are three (3) PAR 1405 exempt sterilization facilities with permitted EtO sterilization equipment and controls. Finally there is one (1) warehouse that receives EtO-sterilized products that is classified as an aeration-only facility (PAR 1405 redefines this facility now as a post-aeration storage facility).

Since PAR 1405 now defines large facilities as those that are permitted to use 2,000 lbs or more of EtO per year, there are now seven (7) large, three (3) medium, two (2) small sterilization facilities, and three (3) facilities that use four lbs or less of EtO per year. In addition, PAR 1405 will include affect 28 FDA registered warehouses (one is a post-aeration storage facility) with 100,000 square feet or greater warehousing space. The table below shows the affected facilities based on the industry type.

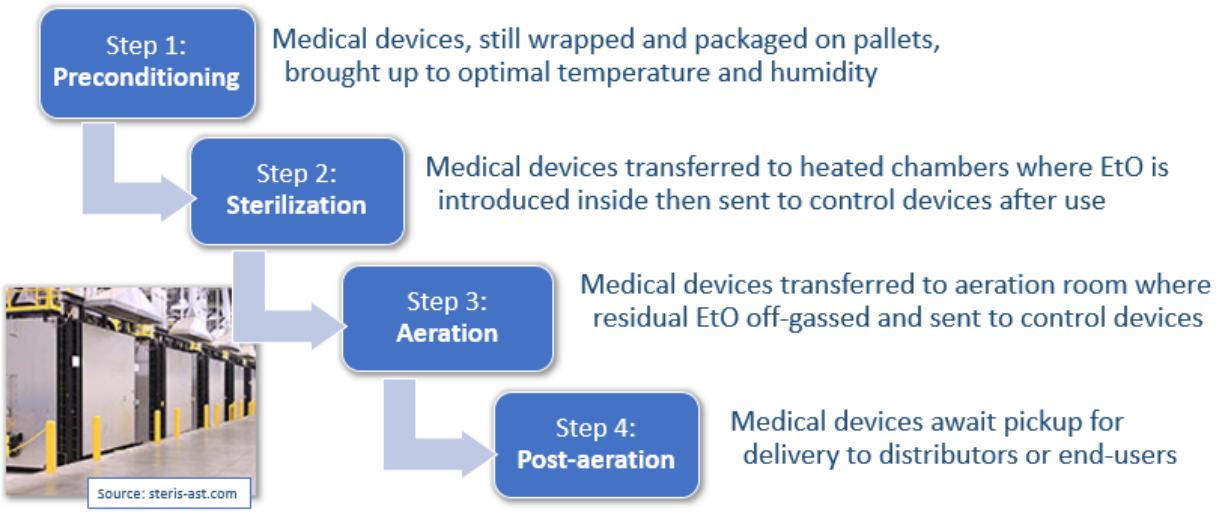
Table 1-5 – Industry Type of PAR 1405 Facilities in the South Coast AQMD

Facility	NAICS Code	Industry Type	PAR 1405 Classification
STERIGENICS US, LLC (Ontario)	339999	All Other Miscellaneous Manufacturing	Large
STERIGENICS US, LLC (Vernon)	339999	All Other Miscellaneous Manufacturing	Large
STERIS, INC.	541380	Testing Laboratories and Services	Large
APPLIED MEDICAL RESOURCES	541611	Administrative Management and General Management Consulting Services	Large
PARTER MEDICAL PRODUCTS INC	561910	Packaging and Labeling Services	Large
AMERICAN CONTRACT SYSTEMS INC	444190	Other Building Material Dealers	Large
ST. JUDE MEDICAL CRMD	334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	Large
MICROVENTION, INC	339112	Surgical and Medical Instrument Manufacturing	Medium
ADVANCED BIONICS, LLC	334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	Medium
LIFE SCIENCE OUTSOURCING, INC	339112	Surgical and Medical Instrument Manufacturing	Medium
ANIMAL EYE VET INC.	541940	Veterinary Services	Small
VCA W COAST SPEC & EMERGENCY ANIMAL HOSP	541940	Veterinary Services	Small
LA CITY, GREATER LA ZOO	712130	Zoos and Botanical Gardens	None
UNIVERSITY OF CALIFORNIA, LOS ANGELES	611310	Colleges and Universities	None
MT. SAN ANTONIO COMMUNITY COLLEGE	611310	Colleges and Universities	None
CARDINAL HEALTH	423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	Post-Aeration Storage Facility
28 LARGE WAREHOUSES	493100	Warehousing	Tier I Warehouses or Tier II Warehouses

1.8 PROCESS DESCRIPTION OF ETHYLENE OXIDE STERILIZATION

In general, the process of EtO sterilization can be divided into four steps: preconditioning, sterilization, aeration, and post-aeration.[54] The figure below provides a simple schematic of commercial EtO sterilization process. And the following sections would describe each of the step in more detail.

Figure 1-14 – Example of Commercial EtO Sterilization Process



Preconditioning

Preconditioning is the process of bringing the products, and usually associated packaging, to optimum temperature and humidity prior to the EtO sterilization step and can take hours to days to complete. Preconditioning is typically performed in a separate area of the facility. Preconditioning allows EtO to efficiently penetrate packaging and sterilize the product during sterilization and thereby minimizing sterilization times and the amount of EtO required to be used.

Sterilization

Sterilization of the products occurs in chambers (sterilizers) that will be filled with a gas mixture containing EtO for a predetermined set time (cycle time). A typical cycle involves: 1) air removal; 2) steam injection; 3) EtO Injection sometimes accompanied by inert gas (N_2) overlay to create top pressure to help push EtO into the load through any packaging; 4) exposure or dwell time for EtO to ensure complete sterilization of the load; 5) several series of vacuum and nitrogen flushing to remove the EtO from the products; and finally 6) ventilation (back-venting) of the chamber during unloading of the sterilized products from the chamber.

[54] U.S. FDA. (2019). Reduction of Ethylene Oxide Sterilization Emissions for Medical Devices and Potential for Utilizing Other Sterilization Modalities. https://www.fda.gov/media/132186/download

Because EtO must penetrate through any accompanying packaging of the product in order to kill any pathogens, EtO will be present inside the packaging or in the packaging material itself. The sterilization time varies from product to product and is prescribed in the validation document for a particular product. After sterilization of product, EtO needs to be removed (flushed) from the sterilization chamber and the product. Because the packaging and product still has residual EtO that will continue to off-gas, before the chamber door is opened, there is additional ventilation (back-vent) where chamber gases are pulled toward the back of the chamber or above the opened chamber door using collection hoods to protect workers from EtO as they unload products out of the sterilizer. Chamber gases collected during back-venting are typically lower in concentration of EtO compared to the removal of EtO during flushing portion because back-vented gases include air when the chamber door is opened, thereby diluting the EtO concentration.

Aeration

Following sterilization using EtO to kill any pathogens, the EtO must be removed to prevent harm to patients through exposure to the product. A separate aeration step is required to allow residual EtO to off-gas to ensure sterilized medical devices meet the U.S. FDA's specified standard for acceptable limits for EtO residuals specified in ANSI/AAMI/ISO Standard 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.[55] Required aeration times for medical devices are developed through the manufacturer's device validation process but would be incorporated into the sterilization cycle parameters that the device manufacturer will specify to the specific sterilization facility as part of the work order for the batch of devices to be sterilized. For some products that are not for commercial use, aeration times are specified in the instructions for use provided by the device manufacturers.

Aeration is typically conducted under heated or ambient conditions in enclosed rooms or areas over a span of several hours to days. Aeration rooms are typically a negative air pressure environment venting to control devices at large facilities.

Post-Aeration

Post-aeration describes the period of time after the required aeration. Although products such as medical devices may have undergone required aeration to meet U.S. FDA requirements, the products and associated packaging still have residual EtO that continues to off-gas.

Off-Site Storage of Sterilized Material

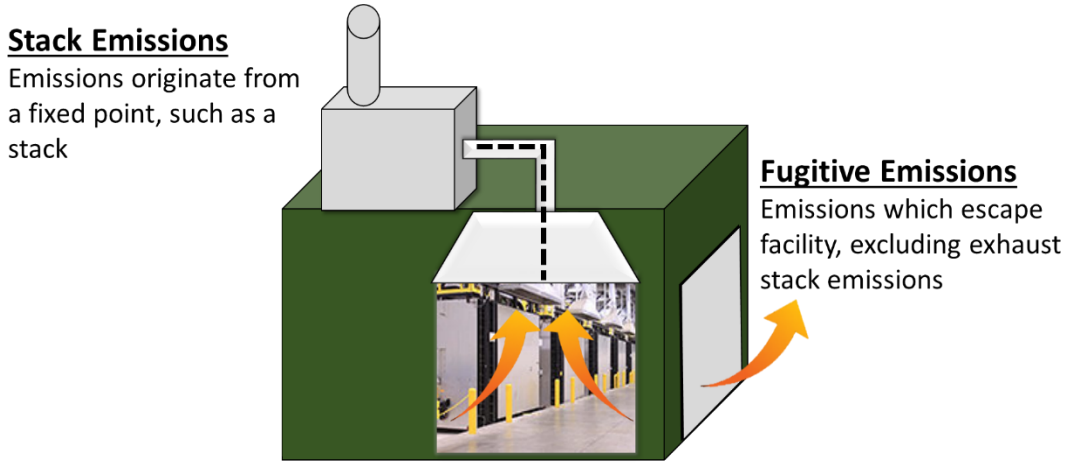
After the sterilization process, sterilized material is transported from the sterilization facility to distribution warehouse or the customer. While U.S. EPA estimates that 99% of EtO emissions exhaust during the sterilization process (e.g., sterilization chamber vent, aeration room vent, chamber exhaust vent, EtO storage/Sterilizer room, post-aeration, control equipment), 1% of EtO used during the sterilization cycle remains on the sterilized materials even after aeration.[56]

[55] ISO 10993-7:2008. (n.d.). ISO. https://www.iso.org/standard/34213.html
[56] https://www.epa.gov/system/files/documents/2022-10/EtO%20sterilizer%202018%20emissions%20calcs.pdf

1.9 FACILITY EMISSION SOURCES AND GENERAL CONTROL APPROACH

Emissions leaving a facility are categorized into two types: stack emissions and fugitive emissions. Stack emissions, also known as point source emissions, are emissions originating from a fixed point such as the opening of an exhaust stack after collection of emissions from a source or group of sources along with any APCDs used to reduce emissions. Fugitive emissions are all other emissions, excluding the stack emissions, that leave the facility. These can include emission sources that are not collected or controlled by APCD at the facility that are allowed to escape the facility building structures through openings often facilitated by air currents passing through the building at openings. Both stack and fugitive emissions can potentially impact nearby receptors. The figure below illustrates the two general types of facility emission sources.

Figure 1-15 – Facility Emission Sources



Stack Emissions

Stack emissions, also known as point source emissions, are emissions that exit the end of an exhaust stack at a facility. These stack emissions can be reduced through the use of an APCD using various technologies appropriate for the pollutant(s). At sterilization facilities, these would be emissions collected from the sterilizer chamber, backvent, aeration rooms or even a PTE that is vented to an APCD. These emissions are required, by many rules, to be quantified through one-time or periodic source tests and sometimes even through stack emission monitoring.

Fugitive Emissions

Fugitive emissions are emissions that escape the facility, excluding exhaust stack emissions. Fugitive emissions, unlike stack emissions, are much harder to characterize and quantify. There may be many contributing sources within the facility's building(s) that may make their way and become fugitive emissions. Examples of these include spills or leaks of materials containing the toxic air contaminant that can be entrained by air currents or tracked out by vehicles or personnel out the building. Inspecting and maintaining ventilation systems to ensure they are collecting emissions and maintaining process equipment in a leak free condition is also important. Proper housekeeping is effective in minimizing these occurrences for toxic air contaminants in liquid and

solid forms. Daily checks for equipment can identify problems early and can mitigate the amount of toxic air contaminants leaked or spilt, minimizing the required cleanup. EtO, at room temperature, is gaseous and cleanup of a spill is not possible so containment in the form of enclosure is the only option. Implementation of regularly conducted monitoring such as leak detection and repair can to minimize EtO emissions that can become fugitive emissions.

An additional measure to prevent toxic air contaminants from leaving the facility is to enclose the building or a portion of the building containing the source(s) of toxic air contaminants in order to minimize outside air currents that can traverse the interior of the enclosure and carry out any toxic air contaminants from leaks and spills or even interfering with the capture efficiency of APCD. Enclosure provisions have been required in recently amended metal toxic rules that limit openings at opposite ends of a building to prevent air currents through the building which can entrain and carry toxic air contaminants, in the form of dry particulates, out the enclosure and become fugitive emissions. Vestibules, small rooms with two sets of doors that are not open at the same time, near entry points into a building function the same way by preventing a clear path for air currents. These measures are effective in controlling fugitive emissions when the enclosure is not required to be under negative pressure (vacuum). More details can be found in the section of "Permanent Total Enclosure" below.

1.10 ETHYLENE OXIDE CONTROL TECHNOLOGIES AND CAPABILITIES

APCDs control the issuance of air contaminants. The level of control can be measured through several metrics including, control efficiency (e.g., 99%), outlet concentration (e.g., 0.1 ppm), or mass emission rate (e.g., 0.3 lb/hr). The APCD technology used is often dictated by the specific air contaminant, the inlet concentration, and other parameters such as temperature and humidity of the gas stream to APCD. The level of control of the air contaminant by a technology can be verified through conducting a source test of the APCD by a third party and is required by many South Coast AQMD rules to demonstrate compliance with an emission limit. Rule 1405 requires EtO APCDs to meet specific control efficiencies.

The following technologies have been implemented at South Coast AQMD sterilization facilities. Staff researched the implementation of these technologies and their levels of control in reducing EtO emissions.

Filtration

Filtration uses proprietary filters in negative air machines or wall-mounted fans to control EtO in enclosed spaces. These were deployed to control EtO concentrations inside one sterilization facility. This technology has control efficiencies between 75% to 90% and observed to be 81% and 85% at one facility when source tested.

Catalytic Oxidation

Catalytic oxidation technology uses a heated catalytic bed to convert EtO to carbon dioxide and water. This technology is suited to control low concentrations of EtO as concentrations near or above EtO's lower explosive limit (LEL) pose a safety concern. EtO gas is combustible and can provide heat during the process but additional heat to maintain the required operational temperature range may require additional heat from either natural gas or electricity. This technology is capable of achieving control efficiency of 95% or greater. Many source tests demonstrated a control efficiency above 99%.

Dry Scrubbing

Dry scrubber (dry-bed) technology uses a bed of dry reactant media to bond EtO to its surface. This technology is suited to control low concentrations of EtO as the media is consumed during the process and must be replaced before there is breakthrough of EtO through the APCD. As with most control technologies that use expendable media, monitoring the outlet of the APCD is important. Less frequent monitoring is required if the APCD is comprised of pair of dry-beds in series. This technology is capable of achieving a control efficiency of 95% or greater.

Historical source tests from permitted dry-bed scrubbers demonstrated a control efficiency above 99% with the exception at an aeration-only facility which ranged between 92% to 99%. The lower control efficiencies were due to low inlet concentrations (as expected for an aeration-only source) and outlet concentration were at or below (≤) the detection limit of the sampling equipment. For calculation purposes for control efficiency, the detection limit is used. A lower detection limit, with an accompanying lower concentration level, could have increased control efficiency numbers. This technology was also used as a secondary control to an acid-water scrubber and a primary dry-bed scrubber to increase the overall control efficiency at a facility with a PTE where overall control efficiency was greater than 99.8%.

Acid-Water Scrubbing

Acid-water scrubber technology uses wet scrubber technology with a scrubber solution with sulfuric acid to convert EtO to ethylene glycol. This technology can control high concentration exhaust streams such as those from the sterilization chamber during the initial purge of EtO during flushing. This technology is capable of achieving a control efficiency of 99.9%. Large facilities employed this technology and demonstrated control efficiencies between 99.97% to 99.99% during recent source tests.

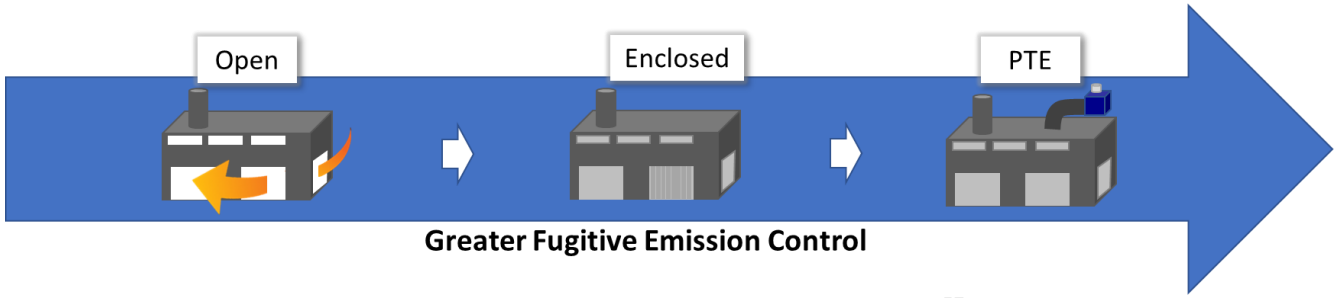
Peak Shaving (with additional control technology)

Peak shaver technology, also known as a balancer system, is a packed tower scrubber that uses a solution to temporarily absorb EtO which can then be stripped off at a steady rate (i.e., concentration) before sending it to a downstream EtO control device, typically a catalytic oxidizer. The peak shaver/balancer itself does not control EtO emissions but is part of a control system that steadies out the concentration levels of EtO to the downstream catalytic oxidizer so that levels never approach the lower explosive limit and also maintains an optimal concentration for the catalytic bed to minimize required natural gas or electricity to maintain the optimal temperatures. The APCD systems were able to demonstrate control efficiencies between 99.95% to 99.99% through source testing.

Permanent Total Enclosure (PTE)

Containing fugitive emissions within the facility prevents them from emitting to the atmosphere. Enclosure, in the form of a physical structure (e.g., waste containers or rooms) or entire building, has been a key requirement in many recent metal toxic air contaminant rules to prevent fugitive emissions. The figure below shows range of enclosure types and their relative effectiveness in controlling fugitive emissions. PTEs are specific enclosed structures under negative pressure (vacuum) where the collected air within the enclosure is vented to APCD and represents the best available control technology to prevent fugitive emissions of toxic air contaminant (T-BACT).

Figure 1-16 – Examples of Building Enclosures to Reduce Fugitive Emissions



The requirements for a PTE are specified by U.S. EPA Method 204.[57] Building openings are designed to be limited in size and required to maintain an inward face velocity of at least 200 feet per minute at each opening, so toxic air contaminants cannot escape the PTE. The negative pressure is created through the use of the APCD's blower that collects the interior air, along with any toxic air contaminants, and sends it to an APCD. PTEs and Method 204 are a common control strategy for limiting sources of process and fugitive VOC emissions to vent them to APCD. Initial and periodic testing is performed to ensure air in flowing into the enclosure (i.e. emissions are not

[57] Method 204 - Permanent (PTE) or Temporary Total Enclosure (TTE) for Determining Capture Efficiency. (2022, September 14). US EPA. https://www.epa.gov/emc/method-204-permanent-pte-or-temporary-total-enclosure-tte-determining-capture-efficiency

flowing out of the enclosure) and also that the air meets the minimum velocity. Continuous monitoring of the PTE is conducted by measuring and recording the difference in pressures between the inside and outside of the enclosure to ensure air continues to flow inward towards the negative pressure created in the PTE.

1.11 SUMMARY OF SOURCE TEST AND CONTINUOUS MONITORING DATA

Source tests are performance tests conducted by an independent third-party to either determine an emission factor or, more commonly, demonstrate compliance with an emission limit by rule or permit condition. A source test collects a sample from an exhaust stack over a certain period of time, and that sample is analyzed to provide the concentration of EtO (in ppm) of the exhaust stream. An exhaust flow measurement is also performed during the test, which can provide the mass emission rate (in lb/hr) when calculated with the exhaust concentration. Source testing results represent a snapshot in time of how effective the control equipment is working to reduce emissions. Rule 1405 requires periodic source testing to ensure that the control equipment is still effective in controlling emissions. To determine the technologically feasible control emission limit for stack emissions, the most recent available source test data were evaluated. The table below shows the source testing results for large sterilization facilities, with Medline Waukegan included as a reference. Among the 15 source test reports analyzed, 12 demonstrated meeting either a control efficiency of 99.99% or a concentration emission limit of 0.01 ppm. The mass emission rates were below 0.015 pounds per hour for four of seven facilities. The table below shows a summary of source test results for other PAR 1405 facilities permitted for less than 2,000 lbs of EtO use. Five out of eight source test reports demonstrated meeting either a control efficiency of 99.9% or a concentration emission limit of 0.01 ppm. One source test report demonstrated an outlet concentration of 0.5 ppm, which is the detection limit of the sampling equipment (collected with a Tedlar Bag) used in the source test.

Table 1-6 – EtO Source Tests Results for Large Sterilization Facilities

Permitted to Use ≥ 2,000 lbs of EtO per Year

Facility	Control Efficiency (%)	Outlet Concentration (ppm)	Mass Emission Rate (lb/hr)
Medline Waukegan [Reference]	99.99	0.032	0.011
Facility A	99.84	<0.0079	<0.00022
Facility A	99.1	<0.010	<0.00006
Facility A	99.7	<0.010	<0.00006
Facility B	99.97	<0.01	<0.0008
Facility C	99.991	31.73	0.031947
Facility C	99.97	<0.010	Not Available
Facility D	99.969	1.178	0.0322
Facility D	99.6683	<0.010	<0.000577

Facility D	99.985	1.113	0.02427
Facility D	99.8769	<0.010	<0.000575
Facility E	99.97	0.219	0.00348
Facility F	99.91	<0.010	<0.000084
Facility F	99.95	<0.010	<0.000081
Facility F	99.94	<0.010	<0.000021
Facility G	99.77	2.495	0.01641

Table 1-7 – EtO Source Tests Results for Non-Large Sterilization Facilities

Permitted to Use < 2,000 lbs of EtO per year

Facility	Control Efficiency (%)	Outlet Concentration (ppm)	Mass Emission Rate (lb/hr)
Facility H	99.998	<0.0070	<0.0000024
Facility I	99.7	0.34	0.00720
Facility I	99.7	0.34	0.00750
Facility I	99.9	<0.10	<0.00216
Facility I	99.9	<0.10	<0.00215
Facility J	99.990	<0.0074	Not Available
Facility K	99.60	<0.500	<0.0000509
Facility L	99.99	<0.10	<0.0000014

CEMS and SCEMS for Stack Emissions

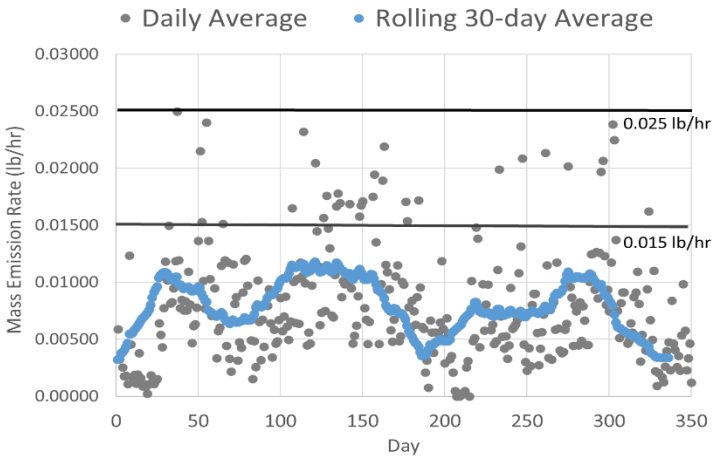
Continuous Emission Monitoring Systems (CEMS) and Semi-Continuous Monitoring Systems (SCEMS) go beyond source testing by using approved and certified systems to monitor stack emissions every minute or every 15 minutes, respectively. CEMS and SCEMS are combined equipment and systems required to sample, analyze, and determine concentrations or mass emission rates of gases in the stack of facilities. Subsystems include those for sampling the stack emissions, an analyzer capable of detecting and measuring the pollutant, and finally a data acquisition system (DAS) to process the information and record the results. Requirements for these systems include daily calibrations using reference gases, quarterly Cylinder Gas Audits (CGA), and annual Relative Accuracy Test Audits (RATA) that test the monitoring system against a reference system of the testing company to ensure accurate monitoring of stack emissions.

These monitoring systems are commonly required and used to measure nitrogen oxides (NOx) and carbon monoxide (CO) for large combustions sources such as natural gas turbines found at power plants. Whereas implementation of CEMS is mature for the monitoring of NOx and CO, currently

there is not a promulgated U.S. EPA performance specification for CEMS for EtO specifically.[58] A draft performance specification for EtO, known as PS-19, has been released but is not yet adopted.

As discussed earlier in the Medline Waukegan study case, the facility was required to install and operate a CEMS to quantify EtO emissions and demonstrate compliance. Medline Waukegan installed a CEMS that used Extractive Fourier Transform Infrared Spectroscopy (FTIR) technology meeting the U.S. EPA Performance Specification 15 (PS-15) from the facility's single combined stack for EtO sources. PS-15 is approved for FTIR CEMS for hazardous air pollutants, the federal equivalent to statewide toxic air contaminants. The CEMS is designed and operated to maintain a limit of quantification that is no greater than 10 ppbv. On 3/5/2020, the EtO CEMS successfully passed a RATA[59] for construction and CEMS certification. Data available on the Illinois EPA website[60] for the Construction Permit showed that the facility's daily EtO emissions were below 0.025 lb/hr for the entire case study period (calendar year 2022). On a rolling 30-day average, the mass emission rate was below 0.015 lb/hr (see figure below).

Figure 1-17 – Medline Waukegan Mass Emission Rates



Other technologies, although not yet achieved in practice like FTIR, have potential to be used to continuously or semi-continuously monitor EtO stack emissions. Cavity ring-down spectroscopy, or CRDS, is another monitoring technology able to produce minute-by-minute data regarding low concentration EtO emissions. CRDS is currently in use in at least one EtO application,

[58] https://www.epa.gov/emc/emc-performance-specifications

[59] Relative Accuracy Test Audit - Medline Industries. (2020, March 26). Illinois Environmental Protection Agency. Retrieved February 27, 2023, from https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Documents/RATA%20Memo%20-%20Medline%20(097190AFG)%20030520.pdf

[60] Illinois EPA information on Ethylene Oxide - Ethylene Oxide. (n.d.). Retrieved February 27, 2023, from https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Pages/default.aspx

continuously monitoring indoor EtO concentrations at a commercial sterilization facility in Puerto Rico.[61]

Gas chromatography-photoionization detection (GC-PID) is another technology which may be used for monitoring EtO stack emissions, albeit on a semi-continuous basis. GC-PID is currently approved for use to perform EtO stack source testing by CARB and U.S. EPA and in that application routinely demonstrates a limit of quantification that is 10 ppbv or less. GC-PID is also in current use in at least one application in the U.S. to semi-continuously monitor stack emissions of a VOC like EtO, specifically benzene, toluene, ethylbenzene, and xylene at concentrations up to 5 ppbv on a 15-minute cycle at a facility in Vermont.[62]

In the proposed NESHAP for sterilization facilities,[63] U.S. EPA proposed to approve other test methods for continuous EtO monitoring, highlighting the technologies available to monitor EtO emissions on a continuous basis.

1.12 NEED FOR PROPOSED AMENDED RULE 1405

As previously discussed in the ambient monitoring results by the South Coast AQMD and elsewhere in the United States, EtO emissions are being released from sterilizers to the ambient environment through stack and fugitive sources. EtO is a potent carcinogen, and South Coast AQMD's investigation revealed that elevated levels of EtO were detected at or near neighboring businesses. The investigation revealed new fugitive emission mechanisms that are not addressed in current regulations. While existing rules and regulations contain requirements addressing stack emissions, they are outdated and insufficient to control fugitive release of EtO, particularly given current knowledge of the increased cancer risks associated with EtO which can be 30 to 50 times more carcinogenic than previously reported. Some facilities have already begun implementing control measures to reduce EtO emissions. PAR 1405 is needed to further reduce EtO emissions and to ensure that the control measures being implemented are being maintained during operations. PAR 1405 accomplishes this by requiring improved performance standards for stack emissions, control or monitoring of fugitive emissions, and continuous monitoring of key parameters. In addition, due to concerns of EtO off-gassing of from sterilized materials, PAR 1405 added certain requirements for warehouses to assess the potential of EtO emissions from these operations.

1.13 PUBLIC PROCESS

Development of PAR 1405 is being conducted through a public process. A PAR 1405 Working Group has been formed to provide the public and stakeholders an opportunity to discuss important details about the proposed rule and provide staff with input during the rule development process.

[61] Steri-Tech Chooses CleanAir Engineering's Picarro-Based Ethylene Oxide Solution for Multi-Point Indoor Air Quality Monitoring at Commercial Sterilization Facility | Picarro https://www.picarro.com/company/press-releases/2021/steritech_chooses_cleanair_engineerings_picarrobased_ethylene_oxide

[62] Instrumentation Information , BTEX (Gas Chromatograph) | State of Vermont, Department of Environmental Conservation. https://dec.vermont.gov/air-quality/monitoring/instrumentation#BTEX

[63] https://www.federalregister.gov/documents/2023/04/13/2023-06676/national-emission-standards-for-hazardous-air-pollutants-ethylene-oxide-emissions-standards-for

The PAR 1405 Working Group is composed of representatives from businesses, environmental groups, public agencies, and consultants. South Coast AQMD has held eight working group meetings conducted virtually using Zoom due to COVID-19 restrictions. The meetings were held on August 17, 2022, September 28, 2022, October 26, 2022, January 17, 2023, February 16, 2023, June 8, 2023, July 6, 2023, and October 4, 2023. In addition, a Public Workshop was held on March 23, 2023 to present PAR 1405 and receive public comment. A Public Consultation Meeting was held on July 26, 2023.

As part of PAR 1405 rule development, staff conducted site visits at eight (8) facilities. Due to COVID-19 concerns, five (5) site visits were conducted remotely and three (3) were conducted in-person. Staff has also held a number of individual meetings with impacted stakeholders. A survey was distributed in early September 2022 to the known universe of EtO sterilization facilities as well as warehouses that may handle EtO-sterilized products to gather information about equipment, operations, throughput, storage, controls, monitoring, and waste and byproduct information. The facility survey was sent to sixteen (16) sterilization facilities and seventy (70) warehouses registered with U.S. FDA as Wholesale Drug Distributors or Third-Party Logistics Providers. Throughput the rule development process, individual meetings have been held with operators of the regulated community, as well as community and environmental groups.

CHAPTER 2 – SUMMARY OF PROPOSED AMENDED RULE 1405

2.1 OVERALL APPROACH

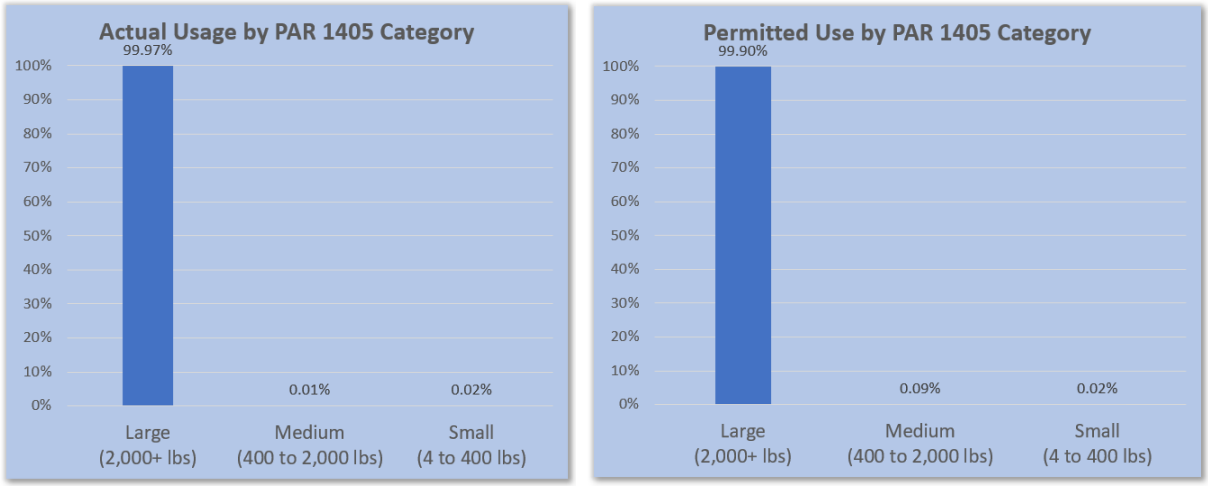
PAR 1405's objective is to further reduce stack emissions of EtO as well as prevent fugitive emissions from facilities that conduct EtO sterilization and related operations. PAR 1405 accomplishes this with revisions to Rule 1405 to establish new emission limits based on achieved in practice levels observed at EtO sterilization facilities and provisions to prevent, detect, repair, and capture any potential EtO emissions from becoming fugitive emissions. Permanent Total Enclosure (PTE) requirements for equipment and areas with known EtO emissions will prevent fugitive emissions from leaving facilities by containing and controlling any EtO gases inside the PTE. PAR 1405 will amend the minimal throughput for classification as a large sterilization facility to align with both state ATCM and federal NESHAP, going from 4,000 to 2,000 pounds per year of EtO, for the most stringent requirements of the proposed rule. PAR 1405 includes interim fenceline air monitoring requirements for large sterilization facilities until CEMS or SCEMS are in place. Certain large warehouses, defined and described later in Chapter 2, that receive EtO sterilized products would be required to provide records and emissions data to help assess EtO emissions from warehouses. Curtailment of sterilization facilities, to reduce fenceline levels of EtO, based on observed 24-hour fenceline monitoring conducted either by the facility or the South Coast AQMD are included in PAR 1405.

Facility Categories and Requirements

Rule 1405 had different requirements for facilities based upon annual EtO usage which could have subjected an individual sterilization facility to different requirements year to year. PAR 1405 categorizes sterilization facilities into different size categories ("Large Facility", "Medium Facility", and "Small Facility") based on their permitted annual EtO limit that now aligns to the same Federal NESHAP and State ATCM thresholds. In addition, Rule 1405 identified Aeration-Only Facility which receive materials that have been sterilized in another facility; this term is updated in PAR 1405 and this facility type is now referred to as a Post-Aeration Storage Facility. Facilities permitted to use 4 pounds or less of EtO were exempt from all emission-related requirements in Rule 1405 and continue to be exempt from the interim requirements in subdivision (i) and specific prohibitions in subdivision (n) in PAR 1405.

Large facilities typically use separate sterilization chambers capable of receiving multiple pallets of products per sterilization cycle and separate equipment/areas for aeration. At medium and small facilities, aeration is almost exclusively performed in smaller all-in-one sterilizers (defined in PAR 1405 as a Combined Sterilizer/Aerator) where there is no transport of off-gassing sterilized products between the sterilization chamber and separate aeration area used at Large Facilities. For the 2021 year, facilities using 2,000 pounds or more of EtO made up about 99.9% of all the EtO, both usage and permitted. The figure shows the actual and permitted EtO limits for PAR 1405 facilities for the 2021 year.

Figure 2-1 – PAR 1405 EtO Usage for Facilities in the South Coast AQMD



In addition to high EtO throughput, South Coast AQMD monitoring efforts showed elevated ambient levels of EtO from three large facilities. As such, requirements for large facilities are the most stringent requirements compared to medium, small, and post-aeration storage facilities. This is consistent with Federal and State regulations, where the most stringent requirements are for facilities that use 2,000 pounds or more of EtO per year. PAR 1405 will include requirements for stack emissions which are feasible based on source test reports and continuous monitoring at facilities. Fugitive control measures represent the most stringent enclosure controls used for VOCs, both in South Coast AQMD and elsewhere in the country (see Chapter 1 above).

Regarding stack emissions, there are several different control performance metrics that a rule may require. These include control efficiency, emission concentration, or mass emission rate. Rule 1405 currently specifies control efficiency requirements only. While an APCD with a 99.9% high control efficiency is considered high, this metric alone will not guarantee that a facility's EtO emissions from the APCD would be low, as air volume is not taken into consideration. This is also true for emission concentration limits expressed as parts per million by volume (ppmv). The flowrate of air moved through an APCD is typically expressed as standard cubic feet per minute. At higher flowrates, the APCD with a high control efficiency of 99.9% or low concentration can still be emitting many pounds of EtO over the course of a year. Additionally, APCD controlling relatively low concentrations of EtO have a harder time demonstrating high control efficiency's such as 99.9% compared with an APCD controlling high concentration sources such as sterilization chambers.

To address the above considerations, PAR 1405 would require that each stack source at the facility meet either a control efficiency, based on the permitted EtO throughput of the facility, or a concentration limit. This approach provides compliance flexibility but also ensures that EtO emissions remain low. The emission limit for control efficiency and outlet concentration limits are based on source tests data that demonstrate performance that could be achieved in practice. Large facilities would also be required to comply with a facility-wide mass emission limit from all stacks combined. The emission limit for the facility-wide mass emission rate is based on the permitted EtO usage limit of the highest throughput facility in South Coast AQMD at 99.99%

control efficiency, which is also in line with the continuous monitoring data of Medline Waukegan's or, alternatively, a calculated emission rate based on the facility's permitted EtO usage limit and a compliant 99.99% control efficiency, as detailed in Appendix 1 of PAR 1405. The table below shows the proposed emission standards for PAR 1405.

Table 2-1 – Proposed Emission Limits for PAR 1405

Annual Permitted Throughput (lbs)	Source Test Performance Standard	
	Facility-wide	Each Stack
> 2,000 (Large)	≤ 0.015 lb/hr OR Calculated Emission Rate	≥ 99.99% control efficiency OR ≤ 0.01 ppm
≤ 2,000 (Medium & Small)	No proposed amendment	≥ 99.9% control efficiency OR ≤ 0.01 ppm

For large facilities where continuous monitoring is required, outlet concentration and facility-wide emission rate will be determined using a rolling 30-day average. The 30-day average allows for fluctuations in the emissions concentrations, but ensures the long term emission rate remains low.

PAR 1405 will control fugitive emission through the use of PTE and LDAR. PTE represents the most stringent approach to contain, capture, and reduce fugitive emissions from identified sources associated with EtO emission. Large facilities will include the most comprehensive list of equipment that will be required to be under PTE compared to smaller facilities. LDAR requirements will help identify, routinely inspect, and repair key areas of potential leaks that may become fugitive emissions. Equipment in PTE will not be required to be under a LDAR program as any leaks would be contained in the PTE.

As an interim measure for a large facility until continuous monitoring (CEMS or SCEMS) is installed and verified to be reporting accurately (i.e., certification by South Coast AQMD), fenceline air monitoring will be required to ensure fenceline levels remain below specified thresholds which can trigger curtailment of EtO sterilization operations to reduce the observed elevated levels of EtO. Curtailment requirements apply to EtO sterilization facilities and will be based on 24-hour monitoring data conducted either by the facility fenceline air monitoring or a regulatory body such as the South Coast AQMD. As fenceline air monitoring will require time to prepare, submit, as well as review and approve a fenceline air monitoring plan (FAMP), mobile

monitoring around large sterilization facilities will be required until fenceline air monitoring is implemented pursuant to the approved FAMP.

Warehouses reporting to U.S. FDA as either a Whole Distributor or Third-Party Logistics Provider with at least 250,000 square feet in size are classified as Tier I warehouses and will be required to: 1) perform one (1) year fenceline air monitoring for EtO; or 2) demonstrate with an emission study they emit less than 4 lbs of EtO per year; or 3) fund a South Coast AQMD-led demonstration program for real-time fenceline air monitoring. Warehouses reporting U.S. FDA with at least 100,000 square feet, classified as Tier II warehouses, as well as Tier 1 warehouses, are required to track and report the number of pallets received sterilized with EtO for one (1) year.

2.2 PROPOSED AMENDED RULE STRUCTURE

PAR 1405 includes the following subdivisions and appendices that will contain all the requirements for the control of EtO emissions at sterilization and post-aeration facilities as well as data collection from large warehouses that receive EtO-sterilized shipments from sterilization facilities.

(a) Purpose
(b) Applicability
(c) Definitions
(d) Large Facility Requirements
(e) Medium Facility Requirements
(f) Small Facility Requirements
(g) Post-Aeration Storage Facility Requirements
(h) Warehouse Requirements
(i) Interim Requirements
(j) SCEMS or CEMS Requirements for Stack Emissions
(k) Permanent Total Enclosure Requirements
(l) Source Test Requirements
(m) Leak Detection and Repair (LDAR) Program Requirements
(n) Prohibitions
(o) Facility Performing Sterilization Exceeding Applicable Ethylene Oxide Usage
(p) Interim Fenceline Air Monitoring Requirements
(q) Curtailment of Sterilization Operations
(r) Plan Administration
(s) Recordkeeping
(t) Reporting
(u) Exemptions

2.3 PROPOSED AMENDED RULE 1405

Rule Title Change

The title of this rule will be amended for clarity. Chlorofluorocarbons are no longer allowed to be used and certain associated warehouses that receive EtO-sterilized shipments will be required to

perform fenceline air monitoring, keep recordkeeping, and submit reports. Thus, the rule title is changed from "Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes" to "Control of Ethylene Oxide Emissions from Sterilization and Related Operations."

Subdivision (a) – Purpose

The purpose of this rule is to protect public health by reducing ethylene oxide emissions from sterilization and related operations and to collect information from warehouses receiving - materials sterilized with ethylene oxide.

Subdivision (b) – Applicability

This rule applies to an owner or operator of any facility performing ethylene oxide sterilization, any post-aeration storage facility, any Tier I Warehouse, and any Tier II Warehouse. Facilities subject to the rule may not be subject to all the provisions of this rule.

Subdivision (c) – Definitions

PAR 1405 includes definitions for specific terms. These terms will be capitalized when they appear in the rule for easy identification of a defined term. Some of the definitions are based on definitions from existing South Coast AQMD rules with slight modifications, while other definitions are unique to PAR 1405. For certain definitions, additional clarification is provided in this chapter where the definition is used with a specific provision. Please see the proposed rule for the full list of definitions.

Deletions:

- AERATION ONLY FACILITIES
  Because of the revised definition of aeration, this group of facilities is now defined as Post-Aeration Storage Facilities (see below).
- PERSONS
  Because PAR 1405 uses the term "owner or operator" to be consistent with recent rules or amended rules, this definition is no longer needed.
- RECOVER and RECLAIM
  These definitions were removed as chlorofluorocarbons are now prohibited and the provisions for its recovery and reclamation were also removed.

Revisions or additions:

- AERATION
  The definition of aeration aligns with how the term is used by industry to reduce confusion and add clarity. Sterilization facilities follow prescribed temperature, humidity, minimum holding time, and, in some cases, maximum holding time in an aerator in order to meet general consensus standards set forth by U.S. FDA, other regulatory agencies, or device manufacturers to limit the amount of residual EtO on medical devices or other products that come in contact with end users. These prescribed conditions for aeration are

to ensure the safety of an individual product for an individual user that comes in direct physical contact with the product. However, sterilized products and accompanying packaging will continue to off-gas EtO even after completing aeration.

The prescribed minimum and maximum aeration times are typically specified in work orders that travel with batches of products, in some cases multiple pallets. Sterilization facilities also typically record time-in and time-out of the aerator to ensure conformance with minimum and maximum aeration times. The source of these aeration times come from a variety of sources including U.S. FDA-approved or U.S. FDA-registered validation documents, draft protocols during the testing and validation phase to correlate aeration times with residual EtO levels, or published instructions for use by device manufacturers.

For large facilities in the South Coast AQMD, the aerator is typically separate from the sterilizer with exceptions: one large facility performs sterilization and aeration in a single unit. For medium and small facilities in South Coast AQMD, aeration is usually completed in a single-unit combined sterilizer/aerator, however one facility completes aeration in a separate aerator. Aeration is complete when the prescribed minimum aeration time has elapsed and the products are removed from the aerator or combined sterilizer/aerator.

- AERATOR
  The definition has been revised for clarity to exclude stand-alone sterilizers, typically found at large facilities, and combined sterilizer/aerators, typically found at medium and small facilities and are separately defined.
- BACK-DRAFT VALVE
  The definition has been revised to include hoods that also collect EtO during the unloading of sterilized materials.
- BASELINE OPERATIONS
  The definition was added to clarify the 7-day average amount of EtO, in pounds, used by the sterilization facility in order to calculate curtailments specified in subdivision (q). The table below illustrates an example of a curtailment event during a 30-day period for a facility using a 1-in-6 day 24-hour canister sampling schedule where the rolling seven day averages, calculating from the last 7 days of operation (usage in yellow boxes), are used to calculate the respective Curtailed Daily Limits for 1/7/2025 and 1/19/2025 curtailment events.

Table 2-2 – Example of Baseline Operation Calculation for Curtailment

Date	Daily EtO Usage (lbs)	Rolling Seven Day Average (lbs)	Sample Results Received	Above Trigger Level	Subject to Curtailment	Curtailed Daily Limit (lbs)
1/1/2025	400		No samples collected	No samples collected	No	No limit
1/2/2025	600					
1/3/2025	800					
1/4/2025	900					
1/5/2025	1000					
1/6/2025	600					
1/7/2025	800	729	Yes	Yes	20%	583
1/8/2025	400	729	No samples collected	No samples collected	20%	583
1/9/2025	200	671				
1/10/2025	500	629				
1/11/2025	580	583				
1/12/2025	580	523				
1/13/2025	300	480	Yes	No	No	No limit
1/14/2025	700	466	No samples collected	No samples collected	No	No limit
1/15/2025	1000	551				
1/16/2025	1000	666				
1/17/2025	1000	737				
1/18/2025	1000	797				
1/19/2025	1000	857	Yes	Yes	50%	429
1/20/2025	390	870	No samples collected	No samples collected	50%	429
1/21/2025	380	824				
1/22/2025	390	737				
1/23/2025	390	650				
1/24/2025	390	563				
1/25/2025	390	476	Yes	No	No	No limit

- 20% curtailment triggered effective 24 hours of results
- Curtailment lifted after results below trigger level
- 50% curtailment triggered effective 24 hours of results

- COMPONENT
  The definition was added to describe portions of sterilization or control equipment that are susceptible to leaks of EtO and thus are subject to the LDAR program unless located inside a PTE.
- CONTINUOUS EMISSION MONITORING SYSTEM (CEMS)
  The definition was needed due to new requirements of stack emission monitoring for large facilities and is based on the existing definition found in Rule 218 regarding Continuous Emission Monitoring. Building off of the definition found in Rule 218, this definition also defines CEMS as able to take and record at least one measurement every one minute.
- COMBINED STERILIZER/AERATOR
  The definition was added to identify the all-in-one units typically found at medium and small facilities that are capable of completing sterilization and aeration in a single unit.
- CONTROL SYSTEM
  The definition was added to more accurately describe one or more air pollution control devices, in series or in parallel, that reduce emissions of Ethylene Oxide and exhaust to one or more stacks to meet the performance standards specified in PAR 1405. An example of a multistage control system is a dry-bed scrubber to polish the exhaust stream from an acid-water scrubber in series. To determine EtO control efficiency, compare the sum of mass of EtO at the outlet(s) to the sum of mass of EtO at the inlet(s). The sampling location and methodology would be specified in the source test protocol which includes a description by the facility of how the control system is configured. A facility would specify the air pollution control devices that would be considered part of a control system in either a permit to operate, Title V permit, Control System Implementation Plan, or a Facility Implementation Plan.
- ELEMENT
  The definition was added to describe any type of container that contains undiluted or diluted EtO sterilant gas or solid or liquid EtO-contaminated wastes. These containers or vessels have the potential to be sources of fugitive emissions of EtO. Examples would

include tanks, cartridges, or ampules of sterilant gas or barrels of liquid used sterilizer vacuum pump working fluid.

- EXHAUST STREAM
  The definition was expanded to include gaseous effluent from any source, such as a combined sterilizer/aerator or a permanent total enclosure.
- FACILITY
  The definition was added for clarity as Rule 1405 defined and used the term "person" extensively. PAR 1405 uses the term "owner or operator" and facility to be consistent with recent rules or amended rules. The definition is synonymous or nearly synonymous with the definitions of facility in Rules 1302 and 1402 and any and all facilities identified under those rules as a single facility will be considered a single facility under PAR 1405 as well.
- FIRST DESTINATION
  The definition was added for clarity for data tracking of EtO-sterilized materials by sterilization facilities as the materials may have travel to many locations before reaching its final destination such as a hospital.
- LARGE FACILITY, MEDIUM FACILITY, and SMALL FACILITY
  The definitions were added to identify subgroups of sterilization facilities based on permitted EtO limits for purposes of determining requirements in PAR 1405.
- LEAK
  The definition was added to clarify meaning and identify the appropriate method of determination: CARB Test Method 21.
- LEEWARD WALL and WINDWARD WALL
  These definitions were added to clarify specific walls to determine placement of differential pressure monitors needed for a PTE.
- PALLETIZED UNIT
  The definition was added to identify large units of EtO-sterilized materials that need to be labeled for recordkeeping and reporting purposes by sterilization facilities and certain warehouses. Palletized units are identified as sterilized palletized units after undergoing sterilization with EtO. For most contract sterilizers, palletized units are received, sterilized, and shipped out with the same collection of products (i.e., palletized unit) as it arrived with.
- PERMANENT TOTAL ENCLOSURE
  Also known as a PTE, the definition was added to accurately describe this fugitive control measure. This definition was based on the definition in Rule 1469 – Hexavalent Chromium Emissions from Chromium Electroplating and Chromic Acid Anodizing Operations but slightly modified to clarify that the Executive Officer of the South Coast AQMD would be considered the "Administrator" for the purposes of evaluation of U.S. EPA Method 204 criteria.
- POST-AERATOR
  The definition was added because aeration was redefined. This new term refers to any equipment, area, or room used to hold Sterilized materials at a facility after Aeration. The definition also contains three exclusions. Aerators are excluded from being considered post-aerators for clarity. In addition, motor vehicles are not to be considered Post-Aerators to allow for the loading, unloading, and transport of the sterilized materials. A

motor vehicle should be considered as any self-propelled vehicle by which a person or property may be propelled, moved, or drawn upon a highway. A trailer, if connected to a self-propelled vehicle, will be a motor vehicle but a trailer unconnected to a vehicle will not be a motor vehicle. A vehicle that is used as storage area of EtO-sterilized materials will be considered as a post-aerator.

- POST-AERATION STORAGE FACILITY
  The definition was added to replace the previously defined term aeration-only facility due to the revised definition of aeration. The new term refers to a facility that does not perform sterilization but receives and stores sterilized materials that continues to off-gas residual EtO from the product or its packaging which are then collected and sent to a control system.
- PRECONDITIONER
  The definition was added to identify products already being prepared for sterilization at a sterilization facility that may be eligible for exemption in subdivision (u) to curtailment requirements in subdivision (q). Preconditioners are typically rooms where the products are exposed to increased humidity and temperature to minimize the amount of EtO required to be used later in the sterilizer or combined sterilizer/aerators. Also see section 1.8 above.
- PRODUCT
  The definition was added to clarify the basic unit of materials that undergo sterilization that include both the device itself and its accompanying primary packing to maintain sterility. An example of a product with primary packaging is a tongue depressor and its protective paper wrapper. Secondary packaging refers to the packaging around one or more products in primary packaging, often containing safety, marketing, or other retail information on the outside. Secondary packaging is sometimes referred to as a "carton". An example is a paper carton of multiple sterilized tongue depressors. Tertiary packaging refers to corrugated cardboard boxes containing one or more products in secondary packaging. Corrugated boxes of products are commonly assembled on pallets into palletized units, as defined in PAR 1405. The term can refer to the product before, during, or after sterilization and does not describe whether or not the product has residual EtO.
- SEMI-CONTINUOUS EMISSION MONITORING SYSTEM (SCEMS)
  The definition was needed due to new requirements of stack emission monitoring for large facilities and is based on the existing definition found in Rule 218 regarding Semi-Continuous Emission Monitoring. Building off of the definition found in Rule 218, this definition also defines CEMS as able to take and record at least one measurement every 15 minutes.
- STERILANT GAS
  The definition was added to clarify its use in existing and amended rule language.
- STERILANT GAS DISPENSING AREA
  The definition was added to identify the area where containers of sterilant gas containers are connected to sterilizer or combined sterilizer/aerator in order to dispense sterilant gas.
- STERILANT GAS STORAGE AREA
  The definition was added to specify the areas that store containers of sterilant gas received by the facility used for sterilization. Examples include a dedicated fire cabinet,

an indoor explosion-proof room, or a building enclosure. This does not include the areas where the sterilant gas container is connected to the sterilizer or combined sterilizer/aerator.

- STERILIZATION
  The definition "STERILIZATION/FUMIGATION" has been revised to sterilization alone and incorporate the term sterilant gas in this definition. Despite the removal of the term fumigation, the definition clarifies that fumigation using sterilant gas is still a form of sterilization. The examples previously illustrated have been removed to be consistent with recent rules or amended rules.
- STERILIZATION CYCLE
  The definition was added to describe the collection of actions that sterilizers or combined sterilizer/aerators perform to achieve sterility of products and any accompanying packaging. Not all sterilization facilities sterilize products the same way. Large facilities typically sterilize the product, primary packaging, secondary packaging carton, tertiary packaging corrugated boxes, and pallets all together. Small and medium facilities typically sterilize the product and the primary packaging, then finalize packaging in the secondary and tertiary packaging after sterilization, if products are repackaged at all and not used onsite.
- STERILIZED
  The definition was added to clarify the status of product or materials before and after exposure to sterilant gas in the use of this definition in the rule. Materials can include wooden pallets and dunnage, dummy samples similar to the products needed for sterilization validation, that are put through a sterilization cycle. Because these materials absorb sterilant gas or are similar to products for distribution, they can still off-gas EtO.
- STERILIZER
  The definition has been revised to differentiate this type of equipment from combined sterilizer/aerator which was added as a new definition for use in PAR 1405. Incorporation of the term sterilant gas in place of "ethylene oxide or ethylene oxide mixture" was made for clarity without change in meaning.
- STERILIZER EXHAUST VACUUM PUMP
  The definition has been revised for consistency for the use of new or revised definitions including sterilization cycle, sterilizer, and combined sterilizer/aerator without changing the original meaning.
- TIER I WAREHOUSE and TIER II WAREHOUSE
  These definitions were added to the expanded applicability of PAR 1405 to include wholesale distributors and third-party logistics providers appropriately licensed and reporting licensure and other information to U.S. FDA annually[64] with at least 100,000 square feet of warehousing space for recordkeeping and reporting requirements. Tier I Warehouses have at least 250,000 square feet of warehousing space, with additional requirements to assess their EtO emissions.
- TRIGGER RESULT

[64] https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/annual-reporting-prescription-drug-wholesale-distributors-and-third-party-logistics-providers

The definition was added to describe a result of a 24-hour averaged EtO concentration from fenceline air monitoring by either a facility or a regulatory body, collected or conducted by the primary party or an independent third-party contractor on behalf of the primary party. In addition, other rules or programs (e.g., AB2588) may require fenceline air monitoring of EtO and may produce a trigger result. A result over a specified threshold could be used in determination of curtailments at EtO sterilization facilities.

- WAREHOUSING ACTIVITIES
  The definition was added to clarify what areas of indoor floor area should not be included for determination if a warehouse is a Tier I Warehouse or Tier II Warehouse based on square footage.
- WASTE STORAGE AREA
  The definition was added to specify the areas that store containers of wastes generated by the facility created as a byproduct sterilization and associated processes, such as the chemical reaction that occurs in acid-water scrubbers to form ethylene glycol. Examples include a dedicated cabinet, a storage room, or a building enclosure.

Subdivision (d) – Large Facility Requirements

This subdivision contains requirements specific for sterilization facilities classified as a large facility. Where applicable, references to additional requirements found in other subdivisions may be made such as requirements pertaining to PTEs in subdivision (k).

Paragraph (1) – Stack Emission Requirements

Beginning September 1, 2025 or 60 days after final SCEMS or CEMS certification is issued by South Coast AQMD for each control system at the facility, whichever is earlier, as specified in Table 1 located immediately after paragraph (3), existing large facilities are required to meet the control efficiency of 99.99% or a concentration limit of 0.01 ppm or better for each control system. As shown in Chapter 1, 99.99% control efficiency has been achieved in practice at Medline Waukegan and some large facilities within South Coast AQMD. To account for control systems with low inlet concentrations, such as control systems dedicated to controlling aerators, an EtO concentration limit is also available to demonstrate compliance. Large facilities would also have a facility-wide mass emission limit of 0.015 pound per hour or a facility-wide mass emission rate limit, based on pounds of EtO permitted to be used annually and the required control efficiency of 99.99%, determined pursuant to Appendix 1. As shown in Chapter 1, a mass emission limit of 0.015 pounds per hour has been achieved in practice at Medline Waukegan. The alternative calculated facility-wide mass emission rate limit as calculated in Appendix 1, may be appropriate for large facilities permitted to use more EtO than the Medline Waukegan facility. Determination of the facility-wide emission rate based on source tests of more than one control system will be the sum of all mass emission rates results from the applicable source test reports. If a control system was source tested at both maximum load for demonstration of control efficiency and at normal operation, the source test results at normal operation should be used to demonstrate compliance with the facility-wide emission rate limit.

Large facilities would be required to source test at least annually for each control system to demonstrate compliance with the applicable performance standard. Once a large facility is monitoring stack emissions using SCEMS or CEMS, annually source testing is not required if the

control system demonstrates compliance with the 0.01 ppm performance standard and passes annual relative accuracy test audits (RATA). A RATA test is an audit comparing the CEMS or SCEMS against a reference method (i.e., the testing company's reference equipment). A facility that is complying with the control efficiency of 99.99% would still need to conduct annual source tests.

Paragraph (2) – Stack Emission Monitoring Requirements

Beginning 18 months after receiving approval from Executive Officer on the application of SCEMS or CEMS, as specified in Table 1, large facilities are required to monitor the EtO emissions from each exhaust stack of each Control System, using the SCEMS or CEMS to demonstrate compliance with the facility-wide mass emission rate limit and concentration limit (if applicable), both averaged over a rolling 30-day period. These operations include sterilization and related operations with the potential to release EtO such as aeration or storage of EtO-sterilized materials, wastes, or sterilant gas. SCEMS and CEMS are the most advanced in-stack monitoring systems used to quantify emission from a facility and to determine compliance with emission limits. Facilities that demonstrated compliance for control system using control efficiency during source testing would not need to monitor for control efficiency on the SCEM or CEMS of that Control System. Guidance on how these calculations are made is located in Appendix 1 – Calculations.

Paragraph (3) – Fugitive Emission Requirements

Beginning September 1, 2025 or 60 days after final SCEMS or CEMS certification is issued by South Coast AQMD for each control system at the facility, whichever is earlier, as specified in Table 1, existing large facilities would be required to maintain within a PTE the following: sterilizers, combined sterilizer/aerators, back-draft valves, sterilizer exhaust vacuum pumps, aerator, post-aerators, elements of a sterilant gas storage area, elements in a sterilant gas dispensing area, and elements of a waste storage area.

In lieu of maintaining the above equipment and areas within a PTE, alternatives are available for post-aerators and sterilant gas storage for existing large facilities (permitted as a large facility as of the date of amendment).

An alternative to maintaining all post-aerators within PTE is to maintain sterilized materials within PTE for at least seven (7) calendar days after completing aeration. This alternative is available for existing large facilities permitted to use 40,000 lbs of EtO or less per calendar year. The seven (7) day hold is required as preliminary but unfinalized data indicates that the highest day of post-aeration EtO off-gassing following aeration is the first day and each day after aeration results in less EtO off-gassed. The bulk of off-gassed EtO occurs in the first seven (7) days after completing aeration and at least one (1) facility already holds post-aerated products from distribution to warehousing areas for seven (7) days while awaiting biological indicator (BI) testing results. Any facility utilizing this alternative would also be required to propose and maintain at least two (2) monitoring locations in the fenceline air monitoring plan for interim Phase II monitoring. While these warehousing areas would not be subject to additional fugitive emission requirements in PAR 1405, these areas could be subject to additional controls or requirements based on monitoring or related findings in future rulemaking.

In lieu of storing sterilant gas within a PTE, the facility may monitor the sterilant gas storage area and address the sterilant gas container that is the source of elevated reading. During the

development of PAR 1405, staff observed a variety of methods to store sterilant gas ranging from storage in the open air to storage in an enclosed building. A limited number of stakeholders expressed safety concerns with storing sterilant gas in a building enclosure. The alternative approach requires the use of a real-time EtO monitoring system sensitive to 1.0 ppb EtO or lower at one (1) minute intervals. Three (3) permanent monitoring locations are required as well as an emergency enclosure that vents to a control system. If an ambient EtO concentration of 3.0 ppb is detected, an immediate leak inspection is required, and the leaking element is to be placed in the emergency enclosure. This detection/response practice is similar to certain manufacturer recommendation for addressing smaller ampules of EtO for combined sterilizers/aerators.

Control systems would need to be included in an LDAR program if not within PTE. This paragraph requires that waste storage areas used to store wastes such as waste barrels of sterilizer exhaust vacuum pump working fluid or other elements like drums, containers, bins, or other vessels used to store other EtO-contaminated liquids or solids, be under PTE control. This differs from the requirements of fixed storage tanks of ethylene glycol, produced as byproducts of the interaction between EtO and acid in an acid-water scrubber. These storage tanks are typically described in an acid-water scrubber Permit to Operate and are considered part of the control system. Control systems, including associated ethylene glycol storage tanks, are required to be under an LDAR program or a PTE.

These fugitive emissions requirements, including maintaining PTE, apply to any large facility performing sterilization. Periods of planned maintenance are when the facility is not performing sterilization, there is no sterilant gas in ethylene oxide service connected to sterilizers or combined sterilizer/aerators, there is no sterilized materials in aerators and post-aerators, and all sterilization and related equipment is either not electrically connected or circuits are de-energized and locked out/tagged out of service. During those periods, these equipment units cease to meet their respective definitions in PAR 1405 and thus are not required to comply with fugitive emission requirements, including maintain PTE.

Following paragraph (3), PAR 1405 includes Table 1, an implementation schedule for existing large facilities, operating as large facilities as of the date of amendment, and new or modified large facilities, either not operating as of the date of amendment or in operation but not permitted as a large facility as of the date of amendment, respectively. New and modified large facilities are expected to meet all PAR 1405 large facility requirements prior to operating as a large facility. Existing large facilities are configured to comply with existing Rule 1405 and are granted additional time to comply. Existing large facilities are expected to continue to comply with existing Rule 1405 in the interim, reorganized into subdivision (i) and identified as Interim Requirements.

Paragraph (4) – Labeling and Facility Diagram Requirements

Beginning 90 days after date of rule amendment, large facilities must label sterilized palletized units before they leave a post-aerator. Large facilities must also clearly label specific equipment and areas at the facility and also maintain a facility diagram so these equipment and areas can be easily located and identified by workers and South Coast AQMD staff. Finally, documents accompanying outbound shipments (e.g., bill of lading) with EtO-sterilized materials must indicate the shipment contains EtO-sterilized materials with the prescribed text. These labels and documents will assist warehouses with their recordkeeping and reporting requirements.

Paragraph (5) – Submittal of Permit and SCEMS or CEMS Applications

No later than May 1, 2024, large facilities must submit complete permit application to South Coast AQMD to modify the facility to comply with those paragraphs. Additionally, applications for the CEMS or SCEMS are due no later than May 1, 2025.

Paragraph (6) – Control System Implementation Requirements

Requirements specific to the technologies used for a control system such as acid-water scrubbers, catalytic oxidation units, and thermal oxidation units are listed in this section, consistent with State ATCM requirements.

Paragraph (7) and (8) – Interim Mobile Monitoring Requirements and Interim Fenceline Air Monitoring

PAR 1405 requires permanent continuous monitoring for stack emissions and PTE monitoring for fugitive emissions. However, time is needed to comply with both requirements due to feasibility and the time it takes to go through the CEMS or SCEMS certification process. As such, PAR 1405 requires interim mobile and fenceline air monitoring around the sterilization facility until permanent monitoring is in place. Based on the prior investigations conducted for EtO, the following actions were taken when elevated EtO were observed: 1) identify the source(s) within the facility; 2) determine if the source(s) might have contributed to emissions; and 3) determine if the emissions could have been released into ambient air. The Executive Officer might also place fixed site monitoring to determine fenceline EtO levels which could help determine if the emissions pose a risk to the nearby communities.

Mobile monitoring, as discussed in Chapter 1, can provide an assessment of levels of pollutants around the facility and nearby areas with a high spatial resolution. This monitoring method can be deployed quickly but provides a limited amount of information due to the temporary nature of this method. Mobile monitoring would serve as a bridge until stationary fenceline air monitoring begins. Stationary fenceline air monitoring would take additional time due to the development of a FAMP, approval of a FAMP, and implementation of a FAMP. It is expected that mobile monitoring would be in place for several months and fenceline air monitoring would be in place until 2026 or 2027.

Interim Mobile Monitoring Requirements

Beginning February 1, 2024 and until the implementation of a South Coast AQMD-approved FAMP, a large facility would be required to conduct mobile monitoring. The facility can either select: 1) a third-party contractor to conduct mobile monitoring, or 2) the Executive Officer or third-party contractor selected by the Executive Officer to conduct mobile monitoring. If the facility hires a third-party contractor, a measurement protocol would be submitted to the Executive Officer for approval prior to the start of mobile monitoring. The mobile monitoring measurement protocol would specify key measurement parameters such as instrumentation to be used, mobile platform configuration (sampling inlet configuration, residence times, demonstration of laminar flow, etc.), mobile monitoring route and strategy, data handling and validation procedures, and other information deemed relevant, by the third-party contractor.

For South Coast AQMD-led mobile monitoring, the fee structure is established in Appendix 2 of PAR 1405. While other South Coast AQMD rules and other requirements in PAR 1405 do not explicitly indicate that it could be a South Coast AQMD or third-party contractor, the requirements

are party specific as the specific fee may vary if interim mobile monitoring is performed by South Coast AQMD or if performed by a third-party contractor on behalf of South Coast AQMD.

If the facility elects to switch from having the Executive Officer conduct mobile monitoring to having a third-party contractor conduct mobile monitoring, a formal notice must be provided to the Executive Officer 30 days before ending service. The facility would be responsible for contracting out mobile monitoring until it is no longer required.

Interim Fenceline Air Monitoring

Large facilities are required to conduct fenceline air monitoring pursuant to an approved FAMP to ensure that ambient EtO concentrations are below specified thresholds. The requirements and process for a FAMP are specified in subdivision (p).

Paragraph (9) – Submittal of Plans

The plans specified in this paragraph are optional and provide a pathway to streamline the permitting process. For example, the owner or operator may submit an application for a Control System Implementation Plan where there is complex configuration of multiple APCD on separate permits to operate. Additionally, an application for a Facility Implementation Plan may be submitted to establish a facility-wide EtO limit in lieu of modifying existing multiple permits to operate. This is a permit streamlining mechanism that would allow a facility to have a single enforceable document to identify facility wide requirements rather than having to modify multiple permits for emission sources and control equipment at a facility. This mechanism is available for large, medium, or small facilities.

Subdivision (e) – Medium Facility Requirements

This subdivision contains requirements specific for sterilization facilities classified as a medium facility. Where applicable, references to additional requirements found in other subdivisions may be made such as requirements pertaining to PTE in subdivision (k).

Paragraph (1) – Stack Emission Requirements

Beginning January 1, 2026, medium facilities are required to meet the control efficiency of 99.9% or a concentration limit of 0.01 ppm or better for each control system demonstrated through annual source testing.

Post-aerators first used to store sterilized materials after aeration are required to be controlled as specified in subparagraph (e)(1)(A).

Paragraph (2) – Fugitive Emission Requirements

Beginning January 1, 2026, medium facilities would be required to operate the first post-aerator that stores sterilized materials after aeration within a PTE. Areas used for transport, loading, or unloading between a combined sterilizer/aerator are not required to be under PTE control.

In addition, if a medium facility does not exclusively aerate materials within a combined sterilizer/aerator and instead completes aeration in a separate aerator, including ambient aeration areas, these sterilizers and aerators would also need to be under PTE control in addition to back-

draft valves, sterilizer exhaust vacuum pumps, and elements in a sterilant gas dispensing and storage areas.

For all other potential sources of fugitive EtO emissions, combined sterilizer/aerators, components up to the exhaust stack of a control system, and elements in a waste storage at medium facilities must maintain these under PTE or include them in a LDAR program to prevent fugitive EtO emissions.

Paragraph (3) – Labeling and Facility Diagram Requirements

Beginning 90 days after date of rule amendment, medium facilities must label sterilized palletized units before they leave the first post-aerator. Medium facilities must also clearly label specific equipment and areas at the facility and maintain a facility diagram so these equipment and areas can be easily located and identified by workers and South Coast AQMD staff. Finally, documents accompanying outbound shipments (e.g., bill of lading) with EtO-sterilized materials must indicate the shipment contains EtO-sterilized materials with the prescribed text. These labels and documents would assist warehouses with their recordkeeping and reporting requirements.

Paragraph (4) – Submittal of Permit Applications

This paragraph specifies the deadline that a medium facility must meet when submitting any required permit applications to the South Coast AQMD to comply with stack and fugitive emissions requirements specified in paragraphs (e)(1) and (e)(2), respectively.

Paragraph (5) – Submittal of Plans

A permit streamlining mechanism for a medium facility, discussed further in subdivision (d), paragraph (9).

Subdivision (f) – Small Facility Requirements

This subdivision contains requirements specific for sterilization facilities classified as a small facility. Where applicable, references to additional requirements found in other subdivisions may be made such as requirements pertaining to PTE in subdivision (k).

Paragraph (1) – Stack Emission Requirements

Beginning January 1, 2026, small facilities are required to meet the control efficiency of 99.9% or a concentration limit of 0.01 ppm or better for each control system demonstrated through annual source testing.

Paragraph (2) – Fugitive Emission Requirements

Beginning January 1, 2026, if a small facility does not exclusively aerate materials within a combined sterilizer/aerator and instead completes aeration in a separate aerator, including ambient aeration areas, these sterilizers and aerators would also need to be under PTE control in addition to backdraft-valves, sterilizer exhaust vacuum pumps, and elements in a sterilant gas dispensing area.

For all other potential sources of fugitive EtO emissions, combined sterilizer/aerators, components up to the exhaust stack of a control system, and elements in a sterilant gas storage area or a waste

storage at small facilities must maintain these under PTE or include them in a LDAR program to prevent fugitive EtO emissions.

Paragraph (3) – Labeling and Facility Diagram Requirements

Beginning 90 days after date of rule amendment, small facilities must clearly label specific equipment and areas at the facility and also maintain a facility diagram so these equipment and areas can be easily located and identified by workers and South Coast AQMD staff. Paragraph (4) – Submittal of Permit Applications

This paragraph specifies the deadline that a small facility must meet when submitting any required permit applications to the South Coast AQMD to comply with stack and fugitive emissions requirements specified in paragraphs (f)(1) and (f)(2), respectively.

Paragraph (5) – Submittal of Plans

A permit streamlining mechanism for facility, discussed further in subdivision (d), paragraph (9).

Subdivision (g) – Post-Aeration Storage Facility Requirements

Post-aeration storage facilities are facilities that receive EtO-sterilized materials that continue to off-gas EtO and collect and control EtO emissions with a control system.

Subdivision (g) specifies the requirements for a post-aeration storage facility equipped with a control system to collect the exhaust stream of a post-aerator. The control system must demonstrate a control efficiency of 95% or greater through annual source testing. Post-aeration storage facilities must also monitor all components of each control system under an LDAR program or place their control systems under PTE. Post-aeration storage facilities must clearly label specific equipment and areas at the facility and also maintain a facility diagram so these equipment and areas can be easily located and identified by workers and South Coast AQMD staff. Post-aeration storage facilities may also be subject to warehouse requirements in subdivision (h) if they meet the definition of a Tier I Warehouse or Tier II Warehouse.

Subdivision (h) – Warehouse Requirements

There is limited data on warehouses and associated emissions from EtO-sterilized materials they may be receiving. Warehouses that receive EtO-sterilized products are potential sources of EtO emissions as sterilized products continued to off-gas after the completion of aeration.

Subdivision (h) specifies the requirements for specific warehouses defined as Tier I Warehouses or Tier II Warehouses. Both Tier I Warehouses and Tier II Warehouses are subject to recordkeeping and a one-time report on the number of sterilized palletized units received directly from EtO sterilization facilities, including the sterilization facilities from outside the South Coast AQMD jurisdiction, for the one (1) time period from April 1, 2024 to March 31, 2025. Additionally, Tier I Warehouses would be required to provide additional information to assess EtO emissions by: 1) conducting fenceline air monitoring for one year pursuant to subdivision (p); 2) performing an EtO emission study demonstrating four pounds or less of EtO emission per year; 3) funding and participating in a real-time fenceline air monitoring demonstration program; or 4) not

receiving sterilized palletized units during the one (1) year period specified above for recordkeeping and reporting. If an EtO emission study is conducted and shows more than four pounds of EtO emissions per year, the warehouse would be required to conduct one (1) year of fenceline air monitoring. The data collected will help South Coast AQMD assess if additional rulemaking is required to address and control EtO emissions from warehouses receiving EtO-sterilized products.

Subdivision (i) – Interim Requirements

Subdivision (i) is needed to keep the existing requirements of Rule 1405 in place to prevent a regulatory gap until the new requirements in PAR 1405 are in effect. The interim requirements will sunset based on the schedule specified in exemptions found in subdivision (u) Table 8 for the respective requirements so that there will not be duplicate requirements for facilities.

Paragraph (i)(7) was revised to allow the source test protocol to specify the required operating conditions and parameters to be measured during the source test that are specific to equipment being tested.

Subdivision (j) – SCEMS or CEMS for Stack Emissions

Subdivision (j) specifies the requirements associated with semi-continuous and continuous emission monitoring systems that are required for large facilities to demonstrate continued compliance beyond the source testing requirements of all control systems. These systems are especially important to monitor the amount of EtO that is emitted and ensure that large facilities comply with the rolling 30-day averages of facility-wide mass emission rate limit, and if applicable, the 0.01 ppm concentration limit. These stack monitoring systems will also be subject to requirements for CEMS or SCEMS in Regulation II, specifically Rule 218–- Continuous Emission Monitoring, Rule 218.1–- Continuous Emission Monitoring Performance Specifications, Rule 218.2–- Continuous Emission Monitoring System: General Provisions, and Rule 218.3–- Continuous Emission Monitoring System: Performance Specifications. Applicable requirements refer to the situation specific to the facility and not a choice made by the facility or the South Coast AQMD. For example, a facility operating a SCEMS will be object to the applicable SCEMS requirements in Rule 218 through Rule 218.3.

Paragraph (j)(1) specifies the requirements of the SCEMS or CEMS, including the parameters, locations, performance specification certification and quality assurance, and DAS. EtO resolution of at least 0.001 ppm is required every one (1) minute for CEMS or every 15 minutes for SCEMS.

Paragraph (j)(2) specifies the manner in which the facility-wide total mass emission rate is calculated from the sum of individual stack mass emissions values of the CEMS/SCEMS. For example, a facility with three (3) stacks with daily average mass emission rates of 0.003, 0.001, and 0.004 pound per hour respectively for each stack would have a facility-wide total mass emission rate of 0.008 pound per hour for that calendar day. Instructions and examples to calculate the facility-wide emission rate are located in Appendix 1 – Calculations.

Paragraph (j)(3) requires that SCEMS or CEMS be equipped with an uninterruptible power supply that can keep equipment operating for at least 60 minutes in case of a power interruption. Power events, even a transient power surge, can cause computerized system without backup power to crash, resulting not only in the loss of monitoring data when the computerized system is offline, but possibly data corruption of recorded data files. A review of breakdown reports submitted by sterilization facilities pursuant to Rule 430 indicated that power blackouts or brownouts lasted only a few seconds or minutes. The required minimum 60 minutes of backup power would ensure the collection of data during these temporary power interruptions.

Paragraph (j)(4) requires that each SCEMS or CEMS meet the applicable requirements of Rule 218 through Rule 218.3, but specifies that the maintenance and calibration of SCEMS or CEMS including the daily calibration error checks, quarterly cylinder gas audits (CGA), and annual relative accuracy test audits (RATA) are required to ensure data integrity. CGAs are conducted quarterly except for the quarter the annual RATA is conducted.

Paragraph (j)(5) specifies that, beginning 30 months after receiving final certification for an application for the SCEMS or CEMS, the number of hours of missing data or invalid data shall not exceed 96 hours on a rolling 30-day period per SCEMS or CEMS for days when sterilization cycle is performed. This is more stringent than Rules 218 and 218.2 which allow for any number of 96 consecutive hours of downtime. The allowance in paragraph (j)(5) is based on the need for periodic calibration and maintenance of a SCEMS/CEMS and the estimated time to resolve a potential minor unexpected failure of a SCEMS/CEMS. For example, daily calibration error testing may take one hour per day, or 30 hours in a 30-day period. Quarterly cylinder gas audit (CGA) or annual relative accuracy test audits (RATA) may take an entire day, or 24 hours in a 30-day period.

Currently FTIR CEMS is being used at Medline Waukegan facility using U.S. EPA's PS-15 but amendments to the NESHAP Subpart O are expected and would allow additional technologies such as Cavity Ring-down Spectroscopy and others to be used through a new draft performance specification accompanying the NESHAP known as PS-19. PAR 1405 incorporates provisions and an extended implementation schedule to allow the South Coast AQMD to review and approve these systems that meet the required performance specifications and quality assurance criteria.

Subdivision (k) – Permanent Total Enclosure Requirements

Subdivision (k) specifies the requirements associated with PTE where required in earlier subdivisions. As PTE requirements will require facilities to retrofit and modify an existing structure or building, the implementation schedule provides adequate time for the facility to obtain required planning, permitting, and construction to complete the PTE. PAR 1405 specifies this type of enclosure to capture, collect, and control EtO emission sources within a PTE. A PTE is required to meet the requirements specified in U.S. EPA Method 204 – Permanent (PTE) or Temporary Total Enclosure (TTE) for Determining Capture Efficiency. Method 204 Criteria 5.1 requires all emitting points (EtO source) be at least four equivalent opening diameters of the natural draft opening (NDO) unless otherwise specified by the Administrator. For the purposes of implementing Method 204 under South Coast AQMD Rule 1405, the Administrator refers to the Executive Officer of South Coast AQMD. EtO-sterilized materials are EtO emitting points as they continue to off-gas after completion of aeration. Consideration is needed in cases where EtO-sterilized

products need to be moved out of the PTE through a rollup door or a loading dock for outbound shipping.

Method 204 requirements allow the assumption that the collection efficiency is 100% for all emissions within the PTE being vented to a control system. As such, equipment inside a PTE is not being required to be under the LDAR program, as any leaks inside the PTE are being captured and controlled in PAR 1405.

Paragraph (k)(1) specifies the requirement to ensure the PTE is kept under a specified negative pressure threshold. A 15-minute averaging time, consistent with PTE averaging times in other South Coast AQMD toxic rules such as Rule 1420.1, is specified as intermittent opening of doors for ingress and egress may cause instantaneous changes in the readings outside the required threshold level specified.

Paragraph (k)(2) specifies the parameter monitoring equipment and locations required within the PTE for monitoring the negative pressure specified in paragraph (k)(1). This equipment is required to be maintained and calibrated to ensure measurements are accurate. The monitoring system is required to be equipped with a data recording system to demonstrate compliance. A backup power supply is also required in case of power outages. The required audible alarm will alert the facility should the negative pressure not meet the requirements specified in paragraph (k)(1).

Paragraph (k)(3) specifies additional testing beyond Method 204, to ensure inward face velocity of at least 200 fpm for each natural draft opening is tested at least once each calendar quarter. Appendix 4 is included in PAR 1405 to provide additional instructions and clarifications on how these measurements are to be performed and recorded.

Subdivision (l) – Source Test Requirements

Subdivision (l) specifies the source test requirements required of all control systems that are subject to emission limits. An annual source test is required to ensure that the control system is continuing to operate as designed and meeting the emission limits unless the control system demonstrates compliance with all applicable performance standards with a South Coast AQMD-certified CEMS or SCEMS. Stack monitoring using CEMS or SCEMS provides real-time monitoring of EtO emissions exiting the stack of the control system controlling EtO sources at the facility. Control systems demonstrating compliance with the 0.01 ppb outlet concentration through a certified CEMS or SCEMS and conducting required annual relative accuracy test audits (RATAs) would not be required to conduct annual source tests. Requirements for CEMS and SCEMS are specified in subdivision (j) and include daily calibration error tests and quarterly cylinder gas audits along with RATAs to ensure the data is accurate and valid, making annual source tests unnecessary.

Control systems complying through the 99.99% control efficiency provision would be required to source test annually as both inlet and outlet measurements are needed to determine the control efficiency, whereas the inlet measurement is not required to be measured continuously. Source tests conducted to demonstrate compliance with the 99.99% control efficiency provision may be conducted under maximum load conditions to show that the control system is able to handle the worst-case scenario of maximum allowable permitted EtO through these control systems. Paragraph (l)(1) specifies requirements for source test protocols (protocols) submitted to be

reviewed and approved by South Coast AQMD to help ensure that the source test will be conducted in a manner suitable to demonstrate compliance with the more stringent control efficiency or concentration as well as the facility-wide emission rate limit in PAR 1405. Since these source tests are meeting more stringent performance standards, a new source test protocol must be submitted and approved by South Coast AQMD prior to conducting the first source test after adoption of this rule. The protocol would be required to include key testing parameters such as the planned operating parameters and performance standards the source test is intended to demonstrate compliance with. While a source test may measure many operating parameters, only the specified parameter could be evaluated to determine compliance. For example, if the facility conducts a source test to determine compliance with the control efficiency performance standard and the results indicates a facility-wide mass emission rate limit greater than the performance standard, the facility would not be in violation of exceeding the facility-wide mass emission rate limit. However, if the facility conducts a source test to determine compliance with both control efficiency and facility-wide mass emission rate, both performance standards would be evaluated to determine compliance.

Paragraph (l)(2) specifies the conditions where a revised protocol is required to be submitted and approved by the South Coast AQMD prior to retesting after the source test conducted pursuant to the approved source test protocol in paragraph (l)(1). A revised source test protocol would be required any time there was a change to the EtO source, process, or control system referenced in the earlier source test protocol, rendering the earlier approved source test protocol no longer suitable for use for the reconfigured system. These changes or reconfigurations typically would have required permit modifications with the South Coast AQMD. A new or revised source test protocol may also be requested by the Executive Officer. This may occur if the Executive Officer determines that the former approved source test protocol no longer is appropriate to accurately quantify EtO emissions or performance during source testing. If there have been no changes and the Executive Officer does not request a new or revised source test protocol, the facility's source testing contractor may use the most recent approved source test protocol by the South Coast AQMD.

Paragraphs (l)(3) and (l)(4) specify notification requirements for source tests that allow for source testing observations by South Coast AQMD.

Paragraph (l)(5) specifies that the source test protocol must be approved by the Executive Officer and requirements for source testing that include operational conditions that would accurately quantify emissions from control systems and also allow for specific testing protocols needed to accommodate certain control technologies where safety concerns exist due to the flammability of EtO at high concentrations.

Paragraph (l)(6) specifies requirements for submittal of the source test report for review by South Coast AQMD. A source test may be considered unacceptable if the protocol was not followed. If a source test fails to demonstrate compliance with a performance standard, the facility would need to determine the cause, take corrective action, then conduct another source test to demonstrate that the control system is meeting applicable performance standard(s) and back into compliance prior to operating equipment that are EtO sources controlled by that control system(s).

Subdivision (m) – Leak Detection and Repair (LDAR) Program Requirements

Subdivision (m) specifies the LDAR program requirements. As discussed earlier in Chapter 2, leak inspection is a method to identify leaks and address them in a timely manner. Rule 1405 required a semi-annual leak check of specific equipment that potentially could be a leak. PAR 1405 expands the requirements by requiring the identification of permanent components to be inspected through a prepared diagram and tags on the individual components, daily audio-visual checks, and leak checks at least once every 60 days, including items that are not permanently installed at the facility (elements), such as sterilant gas containers or EtO-waste containers that are delivered or hauled away. The daily checks and periodic leak inspections apply to elements present at the facility on those days, respectively. This approach is consistent with other VOC regulations addressing fugitive emissions from oil fields, refineries, and chemical plants. PAR 1405 is more stringent than other regulations with a lower leak threshold and no allowance for facilities to have an extended repair window for self-identified leaks.

Paragraphs (m)(1) and (m)(2) require a facility to maintain a plot-plan that identifies components and to maintain a clear label (tag) on the components. Components include items such as seals, gaskets, or connection points where EtO may leak. For example, oil fields and refineries utilize tags (see graphic) to identify components that would be subject to the LDAR program.

Paragraphs (m)(3) and (m)(5) require that all components and elements subject to the LDAR program be free of leaks greater than 2 ppm above background and inspected at least once every 60 days using a portable detector to check for leaks pursuant to CARB Test Method 21. CARB Test Method 21 section 8.3.2 specifies how background is assessed in the process area and recorded.[65] If EtO is not used as the calibration gas, the manufacturer's correction factor must be applied for the calibration gas used and be corrected to EtO. The portable detector should be maintained and operated per the manufacturer to ensure accurate measurements. While components would be identified in the plot-plan, elements may change on regular basis as both waste material and raw EtO may leave the facility. Only elements that are at the facility when components are inspected for the day would be required to be inspected.

Paragraph (m)(4) requires a daily audio-visual inspection of components. The daily inspections allow the early identification of leaks between leak inspections using a portable detector. Audio-visual inspections are expected to occur at ground level and within auditory and visual range of all components.

[65] METHOD 21 - DETERMINATION OF VOLATILE ORGANIC COMPOUND LEAKS. (2017, August 3). U.S. EPA. Retrieved March 15, 2023, from https://www.epa.gov/sites/default/files/2017-08/documents/method_21.pdf

Subdivision (n) – Prohibitions

Subdivision (n) specifies the general prohibitions for a sterilization facility. PAR 1405 retained and updated prohibitions that were previously in Rule 1405. Four (4) new prohibitions were added: three (3) to prohibit the release of uncontrolled fugitive emissions and one (1) to prohibit backsliding by post-aeration storage facilities.

Paragraph (n)(1) prohibits the release of sterilizer exhaust vacuum pump working fluid to the wastewater stream. This was an existing requirement in Rule 1405 located in paragraph (d)(7).

Paragraph (n)(2) prohibits the use of chlorofluorocarbon diluents in sterilization. This was an existing prohibition in Rule 1405 located in paragraph (d)(9) with an effective date of January 1, 1997. As the date has passed, the effective date has been removed.

Paragraph (n)(3) prohibits the uncontrolled release of EtO emissions from any PTE. As previously discussed in Chapter 2, implementing a PTE is a compliance pathway to prevent the release of fugitive emissions by collecting emissions and exhausting to a control system. Sterilization facilities that are required to continuously or semi-continuously monitor at the exhaust would be able to quantify collected emissions that would include fugitive emissions. However, if the control system is inoperable or if the PTE is compromised, an unquantifiable amount of fugitive emissions may be released. PAR 1405 allows the owner or operator different compliance pathways to address situations where the control system may be temporarily inoperable. This can include installing a back-up power system to power the control system or installing a redundant control system. South Coast AQMD has requirements for addressing breakdowns of control equipment under Rule 430 that include notification and shutdown procedures.

Paragraph (n)(4) prohibits the removal of sterilized materials from the facility before aeration can be completed. Although these materials still continue to off-gas after aeration, emissions are greater prior to completing aeration where they are required to be controlled either in aerator or combined sterilizer/aerator equipped with controls. Samples taken for the purposes of required testing such as for validation and biological indicator (BI) purposes may be removed prior to completion of aeration from the facility.

Paragraph (n)(5) prohibits the removal of installed control equipment at a post-aeration storage facility unless the equipment is being replaced with a control system that meets the applicable performance standards.

Paragraph (n)(6) prohibits the storage of any materials that contain EtO, other than sterilant gas, in a sterilant gas storage area if not maintained under PTE. To minimize potential sources of elevated readings.

Subdivision (o) – Facility Exceeding Applicable Ethylene Oxide Usage

Subdivision (o) specifies the requirements for a sterilization facility that uses more than its category amount (i.e., ≥2,000 lbs for sterilization facilities other than a large facility, >400 lbs for sterilization facilities other than a large facility or medium facility). In addition to being in violation with other applicable South Coast AQMD rules and regulation, sterilization facilities would be required to submit permit applications within 12 months and would be subject to the requirements of the permitted usage based on the exceedance usage within 24 months from the day of exceeding

based on thresholds specified on Table 7 – Applicable Ethylene Oxide Usage in paragraph (t)(4). Even if the sterilization facility does not apply for a change in permitted usage, it would still be subject to the more stringent requirements. Any continued exceedance of the facility's current permitted limit would be subject to compliance action.

Subdivision (p) – Interim Fenceline Air Monitoring Requirements

Subdivision (p) specifies that the requirements for fenceline air monitoring for 1) large facilities and 2) Tier I Warehouses that receive sterilized palletized units directly from EtO sterilization facilities that elect this option to assess their EtO emissions or where their emission study shows more than four (4) pounds of EtO emissions per year.

Paragraph (p)(1) specifies FAMP submission due date based on facility type. The information required to be included in the FAMP is specified in Appendix 5. This paragraph specifies the process from submission of the FAMP to its approval by the Executive Officer. As new data from studies on emerging technologies are available for review or the technology made available for demonstration and evaluation, South Coast AQMD may allow these technologies to be used for determination of compliance with rule requirements. Documentation of previous implementation of a monitoring technology proposed for use for fenceline air monitoring of EtO at a facility should be included with the FAMP application so the South Coast AQMD can evaluate and approve its use. Results from fenceline air monitoring must be accurate and defensible as the data can be the basis for curtailment of facility operations.

Paragraph (p)(2) specifies the implementation of a FAMP. Subparagraph (p)(2)(A) requires implementation of the approved FAMP no later than 90 days after approval by Executive Officer unless other specified in the FAMP. Based on assessment of monitoring technology discussed in Chapter 1, real-time/near real-time monitoring provides the most amount of data, but there remain concerns regarding it being an established method, able to discern from background levels, and available for purchase and use. As such, PAR 1405 would allow canister sampling or real-time /near real-time monitoring to be used to meet the requirements of paragraph (p)(2).

Subparagraph (p)(2)(B) specifies the procedures for implementing a FAMP using canister collection technology, requiring a 1-in-6 day sampling schedule unless otherwise approved in the FAMP, U.S. EPA Compendium Method TO-15 or Method TO-15A, and a method detection limit (MDL) of 0.2 ppb or lower. The proposed MDL was based on limits that could be achieved by laboratories. Although Method TO-15 allows for a higher MDL of 0.5 ppb, a 0.2 ppb can and has been achieved by laboratories.

Subparagraph (p)(2)(C) specifies the procedures for implementing a FAMP using real-time/near real-time monitoring technology, requiring an established method with a MDL of 1.0 ppb or lower and capable of generating a measurement every 15 minutes. The 1.0 ppb MDL was based on the current performance that could be achieved by real-time/near real-time monitoring technologies. Some real-time monitoring technologies have demonstrated that they could detect EtO reliably less than 1 ppb. The real-time/near real-time monitoring technology must be approved by the Executive Officer in the FAMP. Information on past and recent implementation of the particular real-time/near real-time monitoring technology at other facilities demonstrating fenceline air monitoring of EtO should be included for evaluation by the Executive Officer.

Subparagraph (p)(2)(D) places additional requirements for real-time/near real-time monitoring, requiring a Method TO-15 or Method TO-15A 24-hour canister sample be collected if the real-time/near real-time concentration, when averaged over 3 hours, exceeds thresholds outlined in Table 4. This is because the real-time/near real-time monitoring technology may not be an approved method. The hold time for unused canisters, prepared by the laboratory, is 30 days so they may be kept readily available for use.

Subparagraph (p)(2)(E) requires collection of wind speed and direction data and subparagraph (p)(2)(F) specifies allowable missing data.

Paragraph (p)(3) specifies when fenceline air monitoring is no longer required for a large facility or Tier I Warehouse.

Subdivision (q) – Curtailment of Sterilization Operations

Subdivision (q) specifies the process of curtailment of sterilization operations at large, medium, and small facilities based on 24-hr EtO fenceline air monitoring results. Curtailment involves a reduction from a calculated baseline operations of daily EtO usage from the six days preceding and the day of the real-time monitoring result or the sampling day completion. Fenceline air monitoring results (i.e., trigger results) determined by either the sterilization facility (e.g., under the FAMP) or by U.S. EPA, CARB, or South Coast AQMD may be used to trigger curtailment provisions.

Prior to implementation of enhanced stack and fugitive emission control measures, trigger levels for curtailment are at 17.5 and 25.0 ppb. These values are consistent with trigger levels specified in an Early Action Reduction Plan and accompanying FAMP for a large facility in South Coast AQMD. After implementation of the enhanced stack and fugitive measures, the trigger level is a single value at 3.0 ppb EtO over a 24-hr period. This value is set at three times the highest method detection limit allowed (1.0 ppb) for FAMP implementation. Setting limits at three times detection values is consistent with U.S. EPA policy and procedure to allow for variability and uncertainty in the lower detection range. The concentration of 3.0 ppb is also at least one order of magnitude greater than the highest background EtO concentration detected (0.29 ppb) by two different South Coast AQMD ambient air monitors over two years of gathering background concentrations of various toxic air contaminants for the U.S. EPA National Air Toxics Trends Stations study. Additionally, ambient air monitoring from Medline Waukegan and from Parter Carson show fenceline air monitoring results consistently below 1 ppb after implementation of PTE and layered control measures to control EtO emissions. Below are two examples how the progressive curtailment would work using level 1 (> 17.5 ppb and ≤ 25.0 ppb) and level 2 (> 25.0 ppb) trigger types based on Table 6 – Curtailment Amounts if there were sample results that varied in trigger levels.

Example 1

	First	Second*	Third*
24-hr Result	18 ppb	30 ppb	18 ppb
Trigger Level	Level 1	Level 2	Level 1

New daily limit	80% of Baseline Operation	50% of Baseline Operation	0% of Baseline Operation

**Within 30 consecutive calendar days of first result*

Example 2

	First	Second*
24-hr Result	30 ppb	18 ppb
Trigger Level	Level 2	Level 1
New daily limit	50% of Baseline Operation	0% of Baseline Operation

**Within 30 consecutive calendar days of first result*

Paragraphs (q)(1) and (q)(3) specify the timeline and process of curtailment. Curtailment progression is specified in Table 6 – Curtailment Amounts and is dependent on the magnitude of exceedance. Curtailments are progressive but can result in complete cessation of all sterilization operations at the facility. Curtailment ends with the monitoring results at all required monitoring locations demonstrating levels below the applicable Level 1 or Level 3 concentrations. Curtailment would also end if the Executive Officer determines, based on credible evidence, that the trigger result was not due to the facility's emissions.

Paragraph (q)(2) allows for the completion of any sterilization cycles already in progress in the event of a 100% curtailment. This provision is necessary as some sterilization cycles can span multiple days. Additionally, the facility is still allowed to operate other equipment such as aerators and post-aerators and continue to process EtO-sterilized products to ship out provided the permitted equipment is complying with permit conditions.

Paragraph (q)(4) specifies when the trigger threshold counter (i.e., first, second, or third result) referenced in Table 6 would reset to zero after 30 consecutive calendar days of being below the applicable trigger thresholds at all fenceline locations.

Subdivision (r) – Plan Administration

Subdivision (r) specifies that facilities are subject to South Coast AQMD fees specified in Rule 306 – Plan Fees for the processing and evaluation of the following: 1) Emission Study Plan; 2) FAMP; 3) Control System Implementation Plan; and 4) Facility Implementation Plan.

Subdivision (s) – Recordkeeping

Subdivision (s) specifies recordkeeping that the facilities are required to keep in order to demonstrate compliance required in other subdivisions. The recordkeeping provisions of the state ATCM regarding annual and semi-annual reports was also incorporated into this subdivision. Standard record retention requirements of five years with the recent two years of records kept onsite for inspection purposes are also included.

Subdivision (t) – Reporting

Subdivision (t) specifies reporting requirements that facilities must perform.

Paragraphs (t)(1) and (t)(2) incorporate the State ATCM reporting requirements into PAR 1405.

Paragraphs (t)(3) and (t)(4) specifies the requirement for a sterilization facility to report if it exceeded a limit of permitted use of EtO that can either be an equipment specific limit or a facility-wide limit. Additional notification is required if a sterilization facility exceeds the equivalent threshold of the next higher size category specified in Table 7 – Applicable Ethylene Oxide Usage. This report would assist in determining if the sterilization facility would be subject to subdivision (o) and the day when compliance with the new requirements would be required.

Paragraph (t)(5) specifies first destination reporting requirements for large sterilizers on outbound shipments of sterilized products for data collection on destination warehouses. If the sterilized palletized units are picked up by the customer and the final destination is not known, then specific customer information would need to be reported.

Paragraphs (t)(6) and (t)(7) specify the reporting requirements for large facilities from mobile monitoring and fenceline air monitoring pursuant to the FAMP, respectively.

Paragraph (t)(8) specifies the reporting requirements if curtailment is triggered when a triggered level is exceeded pursuant to subdivision (q).

Paragraph (t)(9) specifies reporting requirements for stack emission CEMS or SCEMS exceedances.

Paragraph (t)(10) specifies reporting requirements for facilities for PTE related events.

Paragraph (t)(11) specifies reporting requirements for operational noncompliance for two specific situations: noncompliant source tests and EtO leaks detected.

Subdivision (u) – Exemptions

Subdivision (u) specifies the exemption from specific provisions of the rule.

Paragraph (u)(1) exempts facilities that are permitted to use four lbs or less of EtO per calendar year from the requirements of subdivision (i) – Interim Requirements and (n) – Prohibitions. This exemption is modified from the original exemption in Rule 1405 that was based on the feasibility of controlling four lbs or less of EtO. PAR 1405 modifies the exemption to be based on permitted amount instead, which is more stringent.

Paragraph (u)(2) exempts facilities from the interim requirements specified in subdivision (i) as new PAR 1405 requirements would be in effect. In order to avoid duplicate or conflicting requirements the facility would need to comply with either the interim requirement or the new requirements.

Paragraph (u)(3) exempts PTE requirements in the event of a power outage or other unplanned event outside the owner or operator control provided the event was reported pursuant to paragraph (t)(10). In lieu of complying with the PTE requirements, the owner or operator would need to enact practices for all equipment the facility has as specified in subparagraphs (A), (B), and (C), that would prevent the uncontrolled release of EtO emissions as these emissions would not be collected. Additionally, as the fugitive emissions from the PTE would not be quantified, the owner or

operator is required to conduct daily monitoring at each natural draft opening (NDO) using a handheld monitor, such as a photoionization detector, to serve as a temporary surrogate for emission monitoring. While sterilization and other active processes that are sources of EtO may cease, off-gassing of sterilized material would continue making it imperative that these measures are taken to prevent the release.

Paragraph (u)(4) exempts a large facility from the requirements of subdivision (d) provided the owner or operator has taken steps with the Executive Officer to reduce their permitted amount EtO below 2,000 lbs/yr. To keep this exemption, the facility must keep facility-wide monthly EtO usage below 167 lbs until the permit(s) or plan are issued by the South Coast AQMD.

Paragraph (u)(5) exempts a large facility from the requirements of mobile monitoring if: 1) Executive Officer is already conducting fenceline air monitoring at a sampling frequency of at least 1-in-6 days; or 2) facility is conducting fenceline air monitoring for EtO pursuant to a plan approved by the Executive Officer.

Paragraph (u)(6) exempts a large facility from the facility-wide mass emission rate limit performance standard provided the facility has: 1) ceased sterilization operations for at least 48 hours after being unable to comply with the performance standard; 2) provided the Executive Officer with a 24-hour prior notification when sterilization operations would resume; and 3) facility-wide mass emission remains below the applicable facility-wide mass emission rate on a daily average after resuming sterilization. This exemption is included to prevent an extended shutdown of sterilization in order for the rolling 30-day average to drop back down to compliant levels in the event the results of a single day or a few days are very high. Troubleshooting and repairs can be made during the 48-hour downtime to return equipment to good operating conditions. If the above requirements are met, the facility could operate under this exemption until the rolling 30-day average once again complies with (d)(2)(C) at which point this exemption would end for the event.

Paragraph (u)(7) exempts a large facility from the stack outlet concentration performance standard that is similar to that found in (u)(6) except it is for the concentration limit of 0.01 ppm for EtO.

Paragraph (u)(8) exempts a facility required to monitor stack emissions with SCEMS or CEMS from the data collection performance standard of no more than 96 hours of missing data over a rolling 30-day period, provided the facility does not operate for 48 hours, misses no more than one (1) hour of data per day, and reports resuming sterilization to South Coast AQMD.

Paragraph (u)(9) exempts a large facility from collecting a 24-hour canister sample when there is a real-time monitoring technology for EtO that is approved by a regulatory body that it is a legally defensible method.

Paragraph (u)(10) exempts a new large facility, a facility that did not operate prior to rule amendment and is permitted to use more than 2,000 lbs of EtO per year, or modified large facility, a facility that did operate prior to rule amendment but was not permitted to use more than 2,000 lbs of EtO per year at that time, from interim requirements or transitional requirements that an existing large facility would need to comply with the amended requirements. The interim requirements would not be required as a large facility permitted after the date of amendment would be required to comply with the amended stack, fugitive, and stack monitoring requirements specified in paragraphs (d)(1) through (d)(3).

Paragraph (u)(11) exempts products located in the preconditioner that would no longer be suitable for use if the Sterilization Cycle is not completed within a specified period of time. This would include products that would be rejected and be disposed of, but not products that could go through a sterilization cycle later when curtailment is lifted.

Paragraph (u)(12) exempts medical devices, including pallets containing medical devices, that are reasonably likely to experience a reduced supply and critical to public health, as determined by federal, state or local health agencies or hospitals or medical centers in California, from being subject to curtailment provisions. This communication can be to the Executive Officer or from the owner or operator of the sterilization facility. This would require specific reporting, recordkeeping, and labeling during the curtailment exemption period. The curtailment provisions still apply to products not listed as reasonably likely to experience reduced supply.

For example, when determining whether a device is "reasonably likely to experience a reduced supply" the U.S. FDA considers information similar to determine whether a device is in shortage, including but not limited to:

- Indications of supply disruptions (for example, 506J notifications and additional manufacturer information);
- Indications of distribution pressures (for example, from distributors and group purchasing organizations);
- Indications of demand or projected demand, such as availability issues reported from users (for example, patients, healthcare providers, hospitals and healthcare facilities, and associations representing these groups);
- International factors (for example, export restriction); and
- Certain actions taken to help prevent or mitigate shortages including, but not limited to, actions taken by manufacturers, the FDA, or other stakeholders.

For example, when determining whether a medical device is in shortage, the U.S. FDA considers the entirety of relevant and reliable information and data available to the U.S. FDA at the time of a decision.

For example, when determining a device to be "critical to public health", the U.S. FDA considers:

- Devices that are critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or
- For which the Secretary determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency.

There are expected to be limited occurrences where an entity (federal, state or local health agencies or hospitals or medical centers in California) reports directly and confidentially to the Executive Officer of specific products that should not be subject to curtailment.

Paragraph (u)(13) exempts a Tier I Warehouse from the recordkeeping and reporting requirements provided the Tier I Warehouse submits a notification and does not receive products in the warehouse recordkeeping and reporting period.

Appendices

Appendix 1 – Calculation – provides guidance and examples of how to calculate 30-day rolling average for concentration and facility-wide emission rate as an alternative to the 0.015 lb/hr limit.

Appendix 2 – Mobile Monitoring Fee and Program – provides the fee structure if a large facility elects to have the South Coast AQMD conduct mobile monitoring or if a Tier I Warehouse elects to fund a real-time Fenceline Air Monitoring demonstration program lead by the South Coast AQMD.

Mobile Monitoring Fee

Under PAR 1405, facilities can use a third-party contractor with an approved sampling protocol to conduct mobile monitoring, or they can elect to have the Executive Officer conduct mobile monitoring. The Executive Officer would typically conduct mobile monitoring once per month, but resources, technical issues, or other unforeseen circumstances may prevent the Executive Officer from conducting mobile monitoring. The facility would be billed an hourly rate of $209.31 for hours needed to conduct mobile monitoring that include field monitoring, data processing, data validation, data approval, unknowns analysis, and calibration. The $209.31 is consistent for laboratory or source testing hourly rate specified in Rule 301 – Permitting and Associated Table IIB CEMS, FSMS, ACEMS Fee Schedule. In addition to labor, materials and consumables would be charged for each monitoring day, which include gasoline and other laboratory consumables such as grab canister sampling and analysis. A maximum daily fee of $33,000 could be assessed per mobile monitoring day.

Real-time Fenceline Air Monitoring Demonstration Program Fund

A Tier I Warehouse that receives sterilized palletized units can elect to fund a real-time fenceline air monitoring demonstration program as an alternative to either conducting fenceline air monitoring or an emission study required in subdivision (h). This option would consist of an initial payment not to exceed $150,000 due within six (6) months of rule amendment and a second payment not to exceed $100,000 due within 18 months of rule amendment. The collected funds would be used to recover costs associated with monitoring EtO sources using real-time technologies to demonstrate that the technology is appropriate for use in fenceline air monitoring.

Appendix 3 – Emission Study Plan specifies the content of what is to be included in an Emission Study Plan conducted by a Tier I Warehouse to assess ethylene oxide emissions. The Executive Officer may disapprove the plan based on failing to meet the criteria specified in the appendix.

Appendix 4 – PTE Inward Face Air Velocity Measurement Procedures specifies the procedures to measure inward face velocity at NDO for PTE. The procedures are consistent with other South Coast AQMD toxic rules when measuring airflow at a plane. The measurement across five-point would be required for most NDO, except for small openings that measure one square foot or less. The measurement with the anemometer should be performed where a steady reading is obtained and recorded at each measurement point. Steady reading means where the narrowest range of fluctuations are observed with no movement of the anemometer. It is normal to observe small changes in values due to the quick response of the instrument.

Appendix 5 – Fenceline Air Monitoring Plan specifies the required contents of a FAMP, minimum number of fenceline air monitors, and the procedures to modify the monitoring location. The

Executive Officer may disapprove the plan based on failing to meet the criteria specified in this appendix.

Appendix 6 – Contents of Semi-Annual Summary Reports specifies the content of the semi-annual report required to be submitted by large facilities.

Appendix 7 – Contents of Semi-Annual Excess Emission Reports specifies the content of the semi-annual excess emission report required to be submitted by large facilities.

CHAPTER 3 – IMPACT ASSESSMENT

3.1 AFFECTED SOURCES

Based on the South Coast AQMD permit database and site visits conducted, a total of 16 facilities would be subject to requirements in PAR 1405, including 15 facilities that conduct EtO sterilization and one post-aeration storage facility that maintains EtO-sterilized materials with control equipment (see Appendix B for a list of existing sterilization and post-aeration storage facilities within South Coast AQMD impacted by PAR 1405).

Warehouse recordkeeping and reporting requirements impact Tier I Warehouses and Tier II Warehouses that report to the U.S. FDA as wholesale drug distributors or third-party logistics providers with an indoor space of 250,000 square feet or more and those between 100,000 and 250,000 square feet, respectively. As of May 2023, 80 facilities that report to the U.S. FDA are located with South Coast AQMD. To determine the indoor area of these facilities, warehouse surveys and a database obtained from a data vendor (CoStar) were used,[66] which identified 28 of the 80 facilities in these two tiers. As such, it is estimated that 28 large warehouses will be subject to the tracking and reporting requirements in PAR 1405; the name and addresses of these 28 warehouses are listed in Appendix C. PAR 1405 requires Tier I Warehouses and Tier II Warehouses, for the one-year reporting period, to track the number of pallets that are sterilized by EtO received directly from entities performing sterilization. Furthermore, PAR 1405 will require Tier I Warehouses to provide additional assessment of EtO emissions. To assist with identifying sterilization facilities in the U.S., Appendix D of this staff report lists the commercial sterilization facilities subject to NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations. If the applicable warehouses received shipments directly from these commercial sterilization facilities or directly from sterilization facilities outside of the U.S., owners or operators need to identify whether the shipments have been sterilized by EtO and record them accordingly.

3.2 EMISSIONS IMPACT

PAR 1405 affects 16 facilities conducting sterilization or related operations using ethylene oxide. PAR 1405 affects 28 warehouses that receive ethylene oxide sterilized materials.

Fugitive emissions will be reduced through implementation of leak detection and repair programs while permanent total enclosure requirements will ensure that ethylene oxide emissions from sources inside the PTE do not leave the facility as fugitive emissions. Monitoring data has demonstrated that ambient air concentrations of EtO were reduced after the implementation of measures such as those proposed in PAR 1405. Fugitive emissions cannot be quantified because there is no methodology/technology previously or currently available. Thus, while fugitive emissions are expected to be minimized as a direct consequence of implementing PAR 1405, the quantity of fugitive emission reductions cannot be estimated.

[66] https://www.costar.com/

PAR 1405 will reduce stack emissions by amending the 1991 emission limits to more stringent emission limits based on achieved-in-practice, feasible performance standards for control efficiency, concentration limits and, for large facilities, include a facility-wide mass emission rate limit. Stack emissions at large facilities will be monitored continuously or semi-continuously through the implementation of CEMS or SCEMS, respectively, to ensure continued compliance with the emission limits. Existing Rule 1405 requires the facility owner or operator to demonstrate compliance via control efficiency, which by itself cannot determine EtO emissions without additional information such as flow rate and outlet concentration. While PAR 1405 allows a compliance demonstration via control efficiency or a concentration performance standard, both compliance demonstration methods do not provide a direct way to quantify the actual amount of potential emission reductions from the stack outlet. For this reason, the amount of anticipated EtO emission reductions could not been quantified.

3.3 CALIFORNIA ENVIRONMENTAL QUALITY ACT

Pursuant to the California Environmental Quality Act (CEQA) Guidelines Sections 15002(k) and 15061, the proposed project (PAR 1405) is exempt from CEQA pursuant to CEQA Guidelines Section 15061(b)(3). A Notice of Exemption will be prepared pursuant to CEQA Guidelines Section 15062, and if the proposed project is approved, the Notice of Exemption will be filed with the county clerks of Los Angeles, Orange, Riverside, and San Bernardino counties, and with the State Clearinghouse of the Governor's Office of Planning and Research.

3.4 SOCIOECONOMIC IMPACT ASSESSMENT

A separate socioeconomic impact assessment has been prepared and will be released for public review and comment together with this staff report at least 30 days prior to the South Coast AQMD Governing Board Public Hearing, which is anticipated to be held on December 1, 2023.

3.5 DRAFT FINDINGS UNDER HEALTH AND SAFETY CODE SECTION 40727

Requirements to Make Findings

Health and Safety Code Section 40727 requires that prior to adopting, amending or repealing a rule or regulation, the South Coast AQMD Governing Board shall make findings of necessity, authority, clarity, consistency, non-duplication, and reference based on relevant information presented at the public hearing and in the staff report.

Necessity

PAR 1405 is needed to reduce emissions of ethylene oxide from sterilization and related operations, as well as related community health impacts caused by those emissions.

Authority

The South Coast AQMD Governing Board has authority to adopt PAR 1405 pursuant to Health and Safety Code Sections 39002, 39650 et. seq., 39666, 40000, 40001 40440, 40441, 40702, 40725 through 40728, 41508, and 41700.

Clarity

PAR 1405 is written or displayed so that its meaning can be easily understood by the persons directly affected by it.

Consistency

PAR 1405 is in harmony with and not in conflict with or contradictory to, existing statutes, court decisions or state or federal regulations.

Non-Duplication

PAR 1405 will not impose the same requirements as or in conflict with any existing state or federal regulations. The proposed amended rule is necessary and proper to execute the powers and duties granted to, and imposed upon, the South Coast AQMD.

Reference

By adopting PAR 1405, the South Coast AQMD Governing Board will be implementing, interpreting or making specific the provisions of the Health and Safety Code Sections 40001 (rules to achieve and maintain ambient air quality standards) and 41700 (nuisance), and Federal Clean Air Act Section 112 (Hazardous Air Pollutants) and Section 116 (Retention of State authority).

3.6 COMPARATIVE ANALYSIS

Health and Safety Code Section 40727.2 requires a comparative analysis of the proposed amended rule requirements with those of any State, Federal or South Coast AQMD rules and regulations applicable to the same equipment or source category.

The proposed requirements in PAR 1405 will affect facilities conducting sterilization using EtO as well as some large warehouses that receive materials sterilized by EtO. PAR 1405 has been compared to the State ATCM – *Ethylene Oxide Airborne Toxic Control Measure for Sterilizers and Aerators* and Federal NESHAP Subpart O – *Ethylene Oxide Emissions Standards for Sterilization Facilities* (commonly referred to as Subpart O). Below is a table summarizing the key requirements of PAR 1405, State ATCM and Federal NESHAP.

Rule Element	PAR 1405	State ATCM	NESHAP Subpart O
Applicability	Facilities that conduct ethylene oxide (EtO) sterilization, post-aeration storage facilities, and warehouses that store materials sterilized with EtO, except, for emission standards, sterilization facilities using less than 4 lbs per calendar year	Sterilizers and aeration-only facilities except, for emission standards, sterilizers using less than 25 lbs per consecutive 12 months	All sterilization sources except beehive fumigators, research or laboratory facilities, human or animal healthcare facilities, or, for emission standards, sources using less than 1 ton
Processes	Sterilization, aeration, post-aeration, and storage operations	Sterilization and aeration operations	Sterilization and aeration operations
Performance Standards	Performance standards based on permitted throughput below: 2,000 lb/year or more permitted EtO facility ("large"): • 99.99% control efficiency (CE) OR 0.01 ppm by volume; AND • Facility-wide 0.015 lb/hr or calculated emission limit based on permitted usage 400 lb/year or more permitted EtO facility ("medium"): • 99.9% CE OR 0.01 ppmv 4 lb/year or more permitted EtO facility ("small"): • 99.9% CE OR 0.01 ppmv Post-aeration storage facility: • 95% CE	Performance standards based on actual usage: 20,000 lbs or more per 12 months: • 99.9% CE for sterilizers • 99% CE for aerators and others 5,000 – 20,000 lbs per 12 months: • 99.9% CE for sterilizers • 99.0% CE for aerators and others 2,000 – 5,000 lbs per 12 months: • 99.9% CE for sterilizers • 95% CE for aerators and others 600 – 2,000 lbs per 12 months: • 99.9% CE for sterilizers • 95% CE for aerators • 99.7% CE for sterilizer/aerators 25 – 600 lbs per 12 months: • 99.0% CE for sterilizers 95% CE for aeration-only facilities	Performance standards based on actual usage below: 20,000 lb/year or more EtO usage facility: • 99% CE for sterilizers • 99% CE OR 1 ppmv for aerators 2,000 lb/year or more EtO usage facility: • 99% CE
Continuous Stack Monitoring Requirements	Large sterilization facility: • Continuous Emission Monitoring System (CEMS) or Semi-Continuous Monitoring System (SCEMS)	Not required	Not required

Rule Element	PAR 1405	State ATCM	NESHAP Subpart O
Fugitive Emission Control Requirements	• Permanent total enclosure (PTE) – U.S. EPA Method 204 o Post-aerator alternative o Sterilant gas storage area alternative • Continuous differential pressure monitoring • Periodic Natural draft opening (NDO) testing • Leak detection and repair (LDAR) for specific equipment and areas not under PTE o Periodic inspections using detectors o Daily audio/visual inspections	Exhaust systems and EtO supply systems must be leak free	None
Interim Monitoring Requirements	Large sterilization facility: • Phase I mobile monitoring • Phase II fenceline air monitoring	Not required	Not required
Curtailment of Sterilization Operations	Progressive reduction in allowable facility EtO usage based on elevated fenceline air monitoring results	Not applicable	Not applicable
Recordkeeping	• EtO usage records • Air pollution control malfunctions • Records demonstrating compliance with performance standards • Large facilities: First destination for customer recordkeeping • 5 years of records required. Most recent 2 years required onsite	• EtO usage records • Air pollution control malfunctions • Records demonstrating compliance with performance standards • 5 years of records required. Most recent 2 years required onsite	• EtO usage records • General recordkeeping requirements per 40 CFR 63.10(b) • Additional records for continuous monitoring systems per 40 CFR 63.10(c) • 5 years of records required. Most recent 2 years required onsite

Rule Element	PAR 1405	State ATCM	NESHAP Subpart O

Reporting	• Semi-annual and annual reporting (incorporation of ATCM requirements)
	• Reporting of:
	  ○ Non-compliant/missing data for differential pressures of PTEs
	  ○ Exceeding threshold to next higher permitted EtO tier, triggering requirements for that tier
	  ○ Failed source test
	  ○ LDAR leak
	• Large facilities: shipments of EtO-sterilized materials for one year
	• Tier I Warehouses and Tier II Warehouses: receiving of EtO-sterilized materials for one year
		• Semi-annual and annual reporting	• Reporting requirements per 40 CFR 63.10(d) and (e) excluding those relating to opacity monitors, SSM plan, and excess emissions and monitoring system performance reports
			• If using more than 10 tons, construction or reconstruction reporting per 40 CFR 63.5
			• Notifications requirements per 40 CFR 63.9

APPENDIX A – ETHYLENE OXIDE FACT SHEET (OSHA 2002)

OSHA FACT Sheet

Ethylene Oxide

What is ethylene oxide?

Ethylene oxide (EtO) is a flammable, colorless gas at temperatures above 51.3 °F (10.7 °C) that smells like ether at toxic levels. EtO is found in the production of solvents, antifreeze, textiles, detergents, adhesives, polyurethane foam, and pharmaceuticals. Smaller amounts are present in fumigants, sterilants for spices and cosmetics, as well as during hospital sterilization of surgical equipment.

How can ethylene oxide harm workers?

In addition to eye pain and sore throat, exposure to EtO can cause difficult breathing and blurred vision. Exposure can also cause dizziness, nausea, headache, convulsions, blisters and can result in vomiting and coughing. Both human and animal studies show that EtO is a carcinogen that may cause leukemia and other cancers. EtO is also linked to spontaneous abortion, genetic damage, nerve damage, peripheral paralysis, muscle weakness, as well as impaired thinking and memory. In liquid form, EtO can cause severe skin irritation upon prolonged or confined contact.

What should employers know about ethylene oxide?

Employee exposure is limited to one part EtO per million parts of air (1 ppm) measured as an 8-hour time-weighted average (TWA). Employee exposure may not exceed the short-term excursion limit of 5 ppm EtO averaged over any 15-minute sampling period. These limits are called permissible exposure limits (PELs).

Most occupational exposures to EtO are covered by the OSHA standard. The standard does not apply, however, when employers can demonstrate that the processing, use, or handling of products containing EtO will not release airborne concentrations of EtO at or above the standard's action level of 0.5 ppm. The action level is calculated as an 8-hour TWA and is the threshold for increased compliance activities (e.g., air monitoring, medical examinations, labeling, employee information, and training).

For details of the requirements in OSHA's EtO standard for occupational exposures, see *Title 29 of the Code of Federal Regulations* (*CFR*) Part 1910.1047. *Note*: Workplaces are exempt from this standard when objective data shows that the processing, use, or handling of products containing EtO cannot release airborne concentrations of EtO at or above the action level or in excess of the excursion limit during normal conditions.

What must employers do when exposures exceed the standard's permissible exposure limits?

If employee exposures exceed either the PEL or the excursion limit, employers must take the following actions:

- Use engineering controls and work practices to control employee exposure.
- Establish and implement a written compliance program to reduce exposures to or below the TWA and exposure limit.
- Establish personal air monitoring as well as information and training programs for employees exposed to EtO at or above the action level or above the excursion limit. Conduct training upon initial job assignment and annually.
- Establish a regulated area wherever airborne concentrations of EtO are expected to exceed the 8-hour TWA or the excursion limit.
- Establish a medical surveillance program for employees exposed to EtO at concentrations above the action level of 0.5 ppm, measured as an 8-hour TWA, for more than 30 days per year.
- Place warning labels on all containers that might cause employee exposures at or above the action level or excursion limit.
- Remember that employee rotation is prohibited as a means of compliance with the 8-hour TWA or exposure limit.
- Select, provide, and maintain appropriate personal protective equipment and ensure that employees use it to prevent skin and eye contact.

When must employers require workers to use respirators?

Employers must ensure that workers use respirators to control EtO exposure in the following circumstances:

- During installation or implementation of feasible engineering controls and work practices;
- During maintenance, repair, and certain operations when engineering and work practice controls are not feasible;
- When engineering and work practice controls are not currently available to reduce exposures to or below the PEL; and
- During emergencies.

What are employers required to do concerning exposure monitoring?

To help protect workers, employers must conduct the following exposure monitoring:

- Initial monitoring to determine the airborne concentrations of EtO that workers are exposed to (representative sampling of employees' exposures is permitted).
- Periodic exposure monitoring if the airborne concentration of EtO is at or above the action level or above the 15-minute excursion limit.
- Additional monitoring if there has been a change in workplace conditions, such as a change in the

Ethylene Oxide

process or materials used, and if the change could increase employee exposures.

Note: If the exposure level is maintained below the action level, you may discontinue TWA monitoring until there is a change in production, equipment, processes, personnel, or control measures that may result in new or additional exposure to EtO.

Employers must also do the following:

- Allow affected employees or their designated representatives to observe the monitoring.
- Notify affected employees of the results of the monitoring within 15 working days of receiving the results.

Do all businesses where EtO is present need medical surveillance programs?

Employers must implement a medical surveillance program, conducted or supervised by a licensed physician, for an employee under the following circumstances:

- If the employee is assigned to an area where exposure to EtO may be at or above the action level for 30 days or more during the year.
- If the employee has been exposed to EtO in an emergency situation.

What steps must employers take to communicate with workers about EtO exposure?

Employers must do the following to communicate information to affected workers:

- Establish regulated areas where occupational exposure to EtO exceeds the 8-hr TWA or excursion limit, and clearly mark them to limit the number of workers in the regulated area and to allow only authorized persons to enter.
- Provide the signs and labels specified by the standard clearly indicating EtO's carcinogenic and reproductive hazards in regulated areas.
- Train workers upon initial assignment and then annually if they are at risk of exposure at or above the action level or above the excursion limit.
- Maintain a material safety data sheet for EtO that conforms to the provisions of OSHA's hazard communication standard, 29 *CFR* 1910.1200(g).

Are there any recordkeeping requirements concerning employee exposures to EtO?

Employers are required to maintain the following records relating to employee exposure to EtO:

- Retain employee exposure records for 30 years.
- Keep employee medical records for the duration of employment plus 30 years.
- Keep records of objective data supporting any claimed exemption from the requirements of the OSHA standard.

What should employees do to protect themselves from EtO exposure?

To protect against EtO exposure, follow these safety precautions:

- Wear goggles and skin protection at all times in areas where there is a risk of splashes from liquid EtO.
- Wear proper protective clothing and other approved personal protective equipment when working with EtO.
- Discard clothing that has been degraded by EtO.
- See a doctor if you are exposed to EtO.
- Do not eat, drink, or smoke while working with EtO.

How can you get more information on safety and health?

OSHA has various publications, standards, technical assistance, and compliance tools to help you, and offers extensive assistance through workplace consultation, voluntary protection programs, grants, strategic partnerships, state plans, training, and education. OSHA's *Safety and Health Program Management Guidelines* (*Federal Register* 54:3904-3916, January 26, 1989) detail elements critical to the development of a successful safety and health management system. This and other information are available on OSHA's website.

- For one free copy of OSHA publications, send a self-addressed mailing label to OSHA Publications Office, 200 Constitution Avenue N.W., N-3101, Washington, DC 20210; or send a request to our fax at (202) 693-2498, or call us at (202) 693-1888.
- To order OSHA publications online at **www.osha.gov**, go to **Publications** and follow the instructions for ordering.
- To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, contact your nearest OSHA office under the "U.S. Department of Labor" listing in your phone book, or call toll-free at **800) 321-OSHA (6742)**. The teletypewriter (TTY) number is (877) 889-5627.
- To file a complaint online or obtain more information on OSHA federal and state programs, visit OSHA's website.

This is one in a series of informational fact sheets highlighting OSHA programs, policies, or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to *Title 29 of the Code of Federal Regulations*. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999. See also OSHA's website at **www.osha.gov**.

OSHA
Occupational Safety and Health Administration
U.S. Department of Labor
2002

APPENDIX B – IMPACTED FACILITIES (STERILIZATION AND POST-AERATION STORAGE FACILITIES)

List of Sterilization and Post-Aeration Storage Facilities

Facility	Address
STERIGENICS US, LLC (ONTARIO)	687 WANAMAKER AVE, ONTARIO, CA 91761
STERIGENICS US, LLC (VERNON)	4801-63 E 50TH ST & 4900 S GIFFORD AVE, VERNON, CA 90058
STERIS, INC.	43425 BUSINESS PARK DR, TEMECULA, CA 92590
APPLIED MEDICAL RESOURCES	9401 TOLEDO WAY, IRVINE, CA 92618
PARTER MEDICAL PRODUCTS INC	17115 KINGSVIEW AVE, CARSON, CA 90746
AMERICAN CONTRACT SYSTEMS INC	14528 MERIDIAN PKY STE B, RIVERSIDE, CA 92518
ST. JUDE MEDICAL CRMD	15900 VALLEY VIEW CT, SYLMAR, CA 91342
MICROVENTION, INC	35 ENTERPRISE, ALISO VIEJO, CA 92656
ADVANCED BIONICS, LLC	28515 WESTINGHOUSE PL, VALENCIA, CA 91355
LIFE SCIENCE OUTSOURCING, INC	830 CHALLENGER ST, BREA, CA 92821
ANIMAL EYE VET INC.	26023 JEFFERSON AVE, MURRIETA, CA 92562
VCA W COAST SPEC & EMERGENCY ANIMAL HOSP	18300 EUCLID, FOUNTAIN VALLEY, CA 92708
LA CITY, GREATER LA ZOO	5333 ZOO DR, LOS ANGELES, CA 90027
UNIVERSITY OF CALIFORNIA, LOS ANGELES	405 HILGARD AVE, LOS ANGELES, CA 90095
MT. SAN ANTONIO COMMUNITY COLLEGE	1100 N GRAND AVE, WALNUT, CA 91789
CARDINAL HEALTH	6275 LANCE DR, RIVERSIDE, CA 92507

APPENDIX C – IMPACTED FACILITIES (WAREHOUSES)

List of Tier I Warehouses

Facilities Registered with U.S. FDA as Wholesale Drug Distributors or Third-Party Logistics Providers as of March 1, 2023 with Estimated Indoor Floor Area of At Least 250,000 Square Feet

Facility Name	Address	City
B. Braun Medical Inc.	1151 Mildred Avenue	Ontario
BECTON, DICKINSON AND COMPANY	2200 W San Bernardino Ave	Redlands
Bluecana LLC	2323 Main Street	Irvine
Cardinal Health 200 LLC - Ontario	4551 E Philadelphia Street	Ontario
Cardinal Health 200, LLC - Riverside	6275 Lance Drive	Riverside
Exel Inc.	9211 Kaiser Way	Fontana
McKesson Corporation	9501 S Norwalk Blvd	Chino
McKesson Medical-Surgical Inc.	18543 E Gale Ave.	City Of Industry
Medline Industries, LP	16415 Cosmos St	Moreno Valley
Medline Industries, LP	1960 W Miro Way	Rialto
Medline Industries, LP	42500 Winchester Rd	Temecula
Owens & Minor Distribution - Southern California DC 65	5125 Ontario Mills Parkway	Ontario
PHOENIX ASSURANCE, LLC	22150 Goldencrest Drive	Moreno Valley
UPS SUPPLY CHAIN SOLUTIONS, INC.	11991 Landon Dr	Mira Loma
UPS Supply Chain Solutions, Inc.	11811 Landon Drive Suite 100	Mira Loma
Walgreen Co.	17500 Perris Blvd	Moreno Valley

List of Tier II Warehouses

Facilities Registered with U.S. FDA as Wholesale Drug Distributors or Third-party Logistics Providers as of March 1, 2023 with Estimated Indoor Floor Area Between 100,000 and 250,000 Square Feet

Facility Name	Address	City
AIT Worldwide Logistics, Inc.	1820 195th Street	Torrance
AmerisourceBergen Drug Corporation	1851 California Ave	Corona
Baxalta - Van Nuys	15903 Strathern Street	Van Nuys
Boxout, LLC	1560 S Baker Ave Ste A	Ontario
Cardinal Health-Valencia	27680 Avenue Mentry	Valencia
Concordance Healthcare Solutions LLC	5010 Azusa Canyon Road	Irwindale
Concordance Healthcare Solutions LLC	14540 Innovation Drive	Riverside
Cypress Medical Products LLC	1938 W Malvern Ave	Fullerton
Grifols USA, LLC	13111 Temple Ave	City of Industry
ICU Medical Sales, Inc.	13939 Borate St.	Santa Fe Springs
Puretek Corporation	7900 Nelson Rd	Panorama City
TWIN MED, LLC	11333 Greenstone Avenue	Santa Fe Springs

APPENDIX D – U.S. FACILITIES SUBJECT TO ETO NESHAP

List of U.S. Facilities Subject to EtO NESHAP

Commercial Sterilization Facilities subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations (Subpart O), as of June 6, 2023[67]

Facility Name	Address	City, State
ARIZONA		
American Contract Systems, Inc.	7300 W. Detroit Street	Chandler, AZ
Stryker Sustainability Solutions	10232 S. 51st Street	Phoenix, AZ
ARKANSAS		
Baxter Healthcare Corporation	1900 North Highway 201	Mountain Home, AR
CALIFORNIA		
Microvention, Inc.	35 Enterprise	Aliso Viejo, CA
Life Science Outsourcing, Inc.	830 Challenger Street	Brea, CA
Parter Medical Products Inc.	17115 Kingsview Avenue	Carson, CA
Applied Medical Products Inc.	9401 Toledo Way	Irvine, CA
Sterigenics US, Inc.	4801-63 50th Street	Los Angeles, CA
Blue Line Sterilization Services	401 Bel Marin Keys Blvd, Unit C	Novato, CA
Sterigenics US, LLC	687 Wanamaker Avenue	Ontario, CA
American Contract Systems Inc.	14528 Meridian Parkway, Ste B	Riverside, CA
The Jackson Laboratory	1650 Santa Ana Avenue	Sacramento, CA
Steris Isomedix Services Inc.	7685 Saint Andrews	San Diego, CA
St. Jude Medical CRMD	15900 Valley View Court	Sylmar, CA
Steris, Inc.	43425 Business Park Dr.	Temecula, CA
COLORADO		
LivaNova	14401 W. 65th Way	Arvada, CO
Western	5421 Western Ave	Boulder, CO
Terumo BCT Sterilization Service, Inc.	11308 W. Collins Avenue	Lakewood, CO
Jorgensen Labs, Inc.	2211 West 8th Street	Loveland, CO

[67] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-commercial-sterilization-facilities

CONNECTICUT		
Covidien LP	195 McDermott Road	North Haven, CT
FLORIDA		
Arthrex Manufacturing Inc Finishing	6861 Arthrex Commerce Drive	Ave Maria, FL
Fort Myers Facility	11600 Adelmo Lane	Fort Myers, FL
International Sterilization Laboratory	217 Sampey Road	Groveland, FL
Medtronic ENT	6743 Southpoint Dr N	Jacksonville, FL
American Contract Systems, Inc.	7802 E Telecom Pkwy	Temple Terrace, FL
GEORGIA		
Sterigenics U.S. LLC	2971 Olympic Industrial Court SE, Suite 116	Atlanta, GA
Sterilization Services of Georgia	6005 Boat Rock Boulevard	Atlanta, GA
KPR U.S. LLC d/b/a Kendall Patient Recovery U.S., LLC	1430 Marvin Griffin Road	Augusta, GA
BD (Becton, Dickinson and Company)	8195 Industrial Boulevard	Covington, GA
BD (Becton, Dickinson and Company)	1211 Mary Magnan Boulevard	Madison, GA
IOWA		
American Contract Systems, Inc.	1601 SE Gateway Drive, Suite 120	Grimes, IA
ILLINOIS		
Medline Industries	1160 S Northpoint Boulevard	Waukegan, IL
INDIANA		
Cook Incorporated	6330 North Matthews Drive	Ellettsville, IN
MASSACHUSETTS		
Isomedix Operation, Inc.	435 Whitney Street	Northborough, MA
Professional Contract Sterilization, Inc.	40 Myles Standish Boulevard	Taunton, MA
MARYLAND		
Fuchs North America	3800 Hampstead Mexico Road	Hampstead, MD
Elite Spice, Inc.	1415 Magellan Drive	Hanover, MD
Elite Spice, Inc.	7151 Montevideo Road	Jessup, MD
Trinity Sterile, Inc.	201 Kiley Drive	Salisbury, MD

MINNESOTA		
Cardiac Pacemakers Inc/Boston Scientific	4100 Hamline Ave N	Arden Hills, MN
STERIS Inc.	380 90th Avenue Northwest	Coon Rapids, MN
Medtronic Inc - Rice Creek	7000 Central Ave NE	Fridley, MN
MISSOURI		
Midwest STERILIZATION Corporation	1204 Lenco Avenue	Jackson, MO
American Contract Systems	2610 NE Industrial Dr Ste 220	North Kansas City, MO
NORTH CAROLINA		
Sterigenics US, LLC	10821 Withers Cove Park Drive	Charlotte, NC
Andersen Scientific	1001 Aviation Pkwy Suite	Morrisville, NC
NEBRASKA		
Becton Dickinson Pharmaceutical Systems	920 E 19th Street	Columbus, NE
NEVADA		
Elite Spice, Inc.	1225 E. Greg Street #102	Sparks, NV
NEW HAMPSHIRE		
J-Pac, LLC	25 Centre Road	Somersworth, NH
NEW JERSEY		
Cosmed Group Inc dba Cosmed of NJ	19 Park Drive	Franklin, NJ
ETO Sterilization-Plant #2	2500 Brunswick Ave	Linden, NJ
Steris Isomedix Services Inc	3459 S Clinton Ave	South Plainfield, NJ
NEW MEXICO		
Sterigenics-Santa Teresa, NM	2400 Airport Road	Santa Teresa, NM
NEW YORK		
Long Island Sterilization	175 Wireless Blvd	Hauppauge, NY
Sterigenics US LLC – Kingsbury	84 Park Road	Queensbury, NY
OHIO		
American Contract Systems, Inc.	85 Shaffer Park Drive	Tiffin, OH
OKLAHOMA		
LEMCO Ardmore	3204 Hale Road	Ardmore, OK

PENNSYLVANIA		
B Braun Med Inc/Allentown	901 Marcon Blvd	Allentown, PA
Cosmed Group LLC/Erie	2205 E 33rd Street	Erie, PA
American Contract Systems	4040 Jackson Pointe Court, Building 4000	Zelienople, PA
PUERTO RICO		
Edwards Lifesciences Technology Sàrl	Parque Industrial Carr. PR-402, Km. 1.4 N	Añasco, PR
St. Jude Medical Puerto Rico, LLC.	Carr 682 Int Santana Industrial Park Bo. Santana	Arecibo, PR
Guidant Puerto Rico, B.V. (dba Boston Scientific Puerto Rico)	Road 698 lot No. 12	Dorado, PR
Customed, Inc.	Carretera Igualdad #7	Fajardo, PR
Medtronic Puerto Rico Operations Company (MPROC Juncos)	Carr. PR-31, Km 24.4	Juncos, PR
Steri-Tech, Inc.	Carretera 701 Km 0.7 Salinas Industrial Park	Salinas, PR
Medtronic PR Operation Co.	Carr. 151, Bo. Villalba Arriba	Villalba, PR
RHODE ISLAND		
Boston Scientific Corporation	8 Industrial Drive	Coventry, RI
SOUTH CAROLINA		
STERIS-Isomedix Services	2072 Southport Road	Spartanburg, SC
SOUTH DAKOTA		
3M Company	601 22nd Avenue South	Brookings, SD
TENNESSEE		
Sterilization Services of Tennessee	2396 Florida Street	Memphis, TN
DeRoyal Industries, Inc.	1135 Highway 33 South	New Tazewell, TN
TEXAS		
Steritec, Inc.	1705 Enterprise Street	Athens, TX
Dynatec Scientific Laboratories	11940 Golden Gate Rd	El Paso, TX
Isomedix Operations, Inc.	1435 Isomedix Place	El Paso, TX
Isomedix Operations, Inc.	1175 Isuzu Pkwy	Grand Prairie, TX

Sterigenics U.S. LLC	1302 Avenue T	Grand Prairie, TX
American Contract Systems, Inc.	7702 Parnell St	Houston, TX
Midwest Sterilization Corporation	12010 General Milton	Laredo, TX
Ethicon, Inc.	3348 Pulliam Street	San Angelo, TX
UTAH		
Ethylene Oxide Commercial Sterilization Plant	5725 West Harold Gatty Drive	Salt Lake City, UT
BD Medical	9450 South State Street	Sandy, UT
VIRGINIA		
Central Virginia Health Network	2521 Brittons Hill Road	Richmond, VA
Sterilization Services of Virginia	5674 Eastport Boulevard	Henrico, VA
Lifenet Health	5733 Bayside Rd - Suite 104	Virginia Beach, VA
WEST VIRGINIA		
ALCON - Advance Optic Device Center North	2 Vision Lane	Lesage, WV

APPENDIX E – RESPONSES TO COMMENTS

TABLE OF CONTENTS

EOSA The Ethylene Oxide Sterilization Association, Inc.
Managed by B&C® Consortia Management, L.L.C.

April 6, 2023

Via E-mail

Mr. Michael Krause
Assistant Deputy Executive Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: SCAQMD Proposed Amended Rule 1405, Control of Ethylene Oxide Emissions from Sterilization and Related Operations

Dear Mr. Krause:

On behalf of its members, the Ethylene Oxide Sterilization Association, Inc. (EOSA) appreciates the opportunity to comment on the South Coast Air Quality Management District's (SC AQMD) Proposed Amended Rule (PAR) 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations.

EOSA members represent a broad spectrum of the U.S. ethylene oxide (EtO) sterilization industry. EOSA is a nonprofit organization that represents EtO suppliers, spice processors, contract sterilizers, sterilization equipment manufacturers, medical device manufacturers, analytical equipment and systems suppliers, and laboratories. EOSA members work diligently to assist in providing life-saving sterile healthcare products around the world, over 50% of which are sterilized using EtO, and assist in providing safe and wholesome spices for consumers. EOSA works to educate industry, regulators, and the public on the essential uses and benefits of EtO sterilization, for which no direct replacement is currently, and not for the foreseeable future, available. EOSA also works to improve safety standards, foster industry communication, and provide a forum for many subjects related to EtO sterilization.

EOSA and its members believe that the safety of surrounding communities and workers in the EtO sterilization industry is critically important. The EtO sterilization industry has historically undertaken, and will continue to undertake, significant efforts to reduce the emissions and potential worker exposure of EtO utilizing the best available technologies and practices. EOSA is providing these comments to ensure that regulatory decisions reflect accurate facts, the best available science, and proven technologies and practices.

{00606.003 / 111 / 00391718.DOC 10}

EOSA

Mr. Michael Krause
April 6, 2023
Page 2

EOSA appreciates SC AQMD's openness and transparency during the process and supports the development of a rule that is clear and workable, enabling the continued and safe use of EtO. EOSA urges SC AQMD to consider the points outlined below, many of which are addressed in more detail in comments that others have provided to SC AQMD:

General comments regarding PAR 1405:

- There is limited time to comment on the PAR 1405 given its potentially significant impact on the global supply chain and healthcare industry. EOSA members are concerned that the scope and requirements of the proposed rule will drive sterilization facilities out of the state and will impact the medical device sterilization industry, which is at or near its capacity. If it is no longer able to operate these facilities, deep and lasting adverse impacts on hospitals and health care systems in southern California, and in the entire country, could occur. EOSA requests SQ AQMD to ensure that the rule does not prevent sterilization facilities from staying open and serving patients, and that the new rule requirements are workable and can be implemented without even temporarily closing facilities; — Comment 1-1

- Implementation timelines are too short given limitations in technology, the limited supply base, complexity of upgrades, limited resources and available equipment, and significant impact of these proposed timelines on current capacity. EOSA members are concerned that some facilities will not be able to modify and meet the new requirements in these short timelines, and/or that local building authorities may impose additional requirements for facility upgrades, which will further increase the complexity and timelines of compliance; — Comment 1-2

- Given the significant differences in products and processes, EOSA strongly encourages SC AQMD to adopt performance-based standards for emission control. This is critical to balance the continuity of sterilized medical device supplies with environmental improvements; and — Comment 1-3

- EOSA notes that the U.S. Environmental Protection Agency (EPA) is in the process of releasing regulations that will have significant impact on the EtO sterilization facilities in the United States, including those within the SC AQMD area. Such regulatory documents include a proposed rule to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization facilities and a Proposed Interim Registration Review Decision (PID) for the re-registration of EtO under its pesticide regulations. EOSA believes that SC AQMD should — Comment 1-4

{00606.003 / 111 / 00391718.DOC 10}

EOSA

Mr. Michael Krause
April 6, 2023
Page 3

consider these regulatory documents, which are planned for publication soon, and their impacts before completing PAR 1405. These rules could have conflicting requirements to those been proposed by PAR 1405, which could be very problematic.

Comment 1-4 cont.

Technical comments regarding PAR 1405 and the draft staff report:

- EOSA encourages SC AQMD to use a technology neutral approach, and take into consideration technology limitations, to enable facilities to select an effective control method to meet new emissions targets while remaining open and operating safely. For example, PAR 1405 (d)(1)(C) requires that a facility demonstrate EtO emission control efficiency of 99.99% or greater or demonstrate emissions of EtO at a concentration of ≤0.01 ppm for each control system. In fact, the proposed rule of 99.99% destruction efficiency or < 0.01 ppm is not achievable for the dry bed adsorber systems typically used to control EtO emissions from high volume, low flow sources such as aeration rooms and chamber back vents. Additionally, the detection limit for the test method used has been as high as 0.01 ppm, so proving a concentration below that is not possible. It will be extremely difficult, if not impossible, to consistently meet the control efficiency and/or concentration limits proposed in the draft rule language;

Comment 1-5

- PAR 1405 (d)(1)(D) sets a mass emission rate of ≤0.025 lb/hr, which EOSA believes based on a single mid-size EtO contract sterilization facility permit. The percentage control efficiency performance requirement set in PAR 1405 (d)(1)(C) should have properly controlled the emissions from the facility, and a mass emission rate limit should not be set, or if necessary, should correspond to existing EtO permitted use amount within the state of California;

Comment 1-6

- Methods of EtO monitoring can be unreliable. On page 1-23 of the preliminary draft staff report, SC AQMD notes that gas chromatography-photoionization detection (GC-PID) "is another technology which may be used for monitoring EtO stack emissions, albeit on a semi-continuous basis." Significant challenges measuring EtO ambient concentrations have been noted by many regulatory agencies, including EPA, Georgia Environmental Protection Division, and West Virginia Department of

Comment 1-7

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EOSA

Mr. Michael Krause
April 6, 2023
Page 4

Environmental Protection.[1,2] These agencies have challenged the existing test method to measure low EtO concentrations and have pointed to other existing sources of EtO, both natural and human-made. Such challenges need to be properly considered and noted in the development of this rule. Furthermore, there have been no feasible fenceline ambient monitoring methods that would address such concerns and provide timely measurements of EtO near sterilization sources;

Comment 1-7 cont.

- Continuous Emission Monitoring Systems (CEMS) and Semi-Continuous Emission Monitoring Systems (SCEMS) equipment are relatively new technologies and their application in commercial sterilization is still an emerging technology. In fact, EPA has recognized the limitations of technology in correspondence related to passive methods such as Method TO-15. Additionally, existing real-time methods based on Fourier Transform Infrared Spectroscopy (FTIR/OE-FTIR) and Gas Chromatography (GC) may not consistently meet the detection limit requirements being proposed by SCAQMD. With only one method currently developed specifically for EtO through the recent publication of EPA Other Test Method 47 (OTM-47),[3] facilities have few options for meeting these stringent requirements. The current demand for such equipment is already driving up lead times and the installation and integration of such systems is lengthy as well; and

Comment 1-8

- PAR 1405(o)(3) states that the owner or operator of a facility performing sterilization shall not allow the release of uncontrolled emissions of EtO to the atmosphere from any Permanent Total Enclosure (PTE) at any time. It

Comment 1-9

1 Ethylene Oxide Monitoring Report, Georgia Department of Natural Resources, Environmental Protection Division. May 12, 2022, available at https://epd.georgia.gov/ethylene-oxide-information.

2 Ethylene Oxide Monitoring – Characterization of South Charleston and Institute, West Virginia and Surrounding Areas, West Virginia Department of Environmental Protection, Division of Air Quality. February 21, 2023. Available at https://dep.wv.gov/key-issues/Documents/EtO/Final%20Report/Final%20Report%20Body%202-21-2023.pdf.

3 Other Test Method 47 (OTM-47) Measurement of Ethylene Oxide Emissions from Stationary Sources by Cavity Ring-Down Spectroscopy. March 23, 2023. Available at https://www.epa.gov/system/files/documents/2023-03/Other%20Test%20Method%2047_R0.pdf.

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EOSA

is not possible for facilities to comply with this condition during unforeseen power outages. Facilities have systems in place to shut down the processes during events such as power outages. Fans, however, can continue to run for some period of time on their own inertia even when scrubber pumps are immediately shut down. Backup generation can take 30 seconds or more to detect the outage, start up, and generate enough power to run processes.

Comment 1-9 cont.

- Other technical comments:
  - EOSA has concerns on the application of Method 204. In mixed use facilities, Method 204 may not be achievable due to Good Manufacturing Practice (GMP) requirements for other U.S. Food and Drug Administration-regulated occupancies; and

Comment 1-10

  - Reporting of the number of pallets does not directly translate to calculation of emissions due to differences in product, cycles, product release, processing location, and logistics.

Comment 1-11

- It is also critically important to take into consideration the background levels of EtO in the ambient air and the numerous other sources of EtO emissions such as decaying plant material, and those from ubiquitous consumer items like cars and trucks, lawn mowers, gas generators, etc.

Comment 1-12

Thank you for your consideration of these comments. It is critical that SQ AQMD consider the information outlined in these comments. It is of paramount importance not to overestimate the potential risk of EtO from its critical sterilization use, and to be able to continue using this life sustaining, life-saving, and irreplaceable substance, to sterilize healthcare devices and pasteurize certain food products.

Sincerely,

Meibao Zhuang
Senior Manager
The Ethylene Oxide Sterilization Association, Inc.

{00606.003 / 111 / 00391718.DOC 10}

Responses to Ethylene Oxide Sterilization Association, Inc Comment Letter, submitted 4/6/2023

1-1 Response: PAR 1405 has been in development for over a year with multiple opportunities for stakeholder involvement. The public rulemaking process began in August 2022 with eight working group meetings held through October 2023 to solicit public comments. These working group meetings addressed background on EtO, the sterilization process, monitoring data, case studies, proposed rule concepts, the initial rule language, fenceline air monitoring, and ultimately curtailment provisions. The initial PAR 1405 was first released on February 10, 2023. In response to feedback from stakeholders, a second version of PAR 1405, known as preliminary draft rule language, together with the preliminary draft staff report was released on March 17, 2023. A third version of PAR 1405 referred to as revised preliminary draft rule language was released on July 21, 2023. A second revised preliminary draft rule language, the fourth version of PAR 1405, was released on September 28, 2023.

A public workshop for PAR 1405 was held on March 23, 2023 to obtain feedback from the affected business and the public. The deadline to submit written comment was set on April 6 to allow for time for updates to the rule language and staff report as necessary. Stakeholders who reached out to staff for additional time were granted an extension of one additional week. A public consultation meeting for PAR 1405 was held on July 26, 2023 to obtain additional feedback with a deadline to submit written comment on August 9. Public comments on PAR 1405 are accepted throughout the public process including the Public Hearing (scheduled for December 1, 2023).

Staff understands that EtO sterilization plays a critical role in the supply chain of medical devices and patient health, and has given careful consideration to the implementation requirements in PAR 1405.

1-2 Response: Staff has received public comments regarding the implementation timeframe, and the concerns of supply chain, time needed for engineering evaluation, time to obtain building permit for PTE construction, increasing lead time of control and monitoring equipment driven by the release of the proposed NESHAP. As a result, PAR 1405 has been revised to increase implementation timelines by six (6) to eight (8) months for sterilization facilities.

1-3 Response: PAR 1405 sets performance standards based on best available technology achieved-in-practice. PAR 1405 is technology-neutral and requires that control systems demonstrate compliance with performance standards based on control efficiency, outlet concentration, and/or mass emission rates that are

achieved-in-practice. Each performance standard, monitoring strategy, or control requirement in PAR 1405 has been evaluated by reviewing source testing reports, permits, facility surveys, site visits, vendor meetings, or other methods to determine if proposed performance standards or control requirements are technologically-feasible. See Chapter 1 of this staff report on the source test / monitoring data and technologies evaluated.

1-4 Response: Staff has carefully considered the proposed NESHAP for ethylene oxide from commercial sterilization known as Subpart O, released on April 11, 2023, to ensure that there are no conflicting requirements. The proposed NESHAP will go through its public process and U.S. EPA has signed a consent decree to finalize the regulation by March 1, 2024. Staff is committed to evaluate again for any conflict between PAR 1405 and NESHAP once it is approved, and amend PAR 1405 as necessary. Please note that it is possible that the requirements of PAR 1405, while not in conflict with the NESHAP, may include provisions that are more stringent than the NESHAP. PAR 1405 includes control and monitoring requirements to address stack and fugitive EtO emissions with timely implementation schedules. Approval of PAR 1405 will provide regulatory certainty and obligate facility operators to control emissions by the implementation deadlines.

1-5 Response: Based on the public comments and the proposed NESHAP, PAR 1405 has been revised to change the averaging time of the outlet concentration from daily averaging to a rolling 30-day average.

See Response 1-3 on technological feasibility of performance standards in PAR 1405.

1-6 Response: PAR 1405 has been revised to allow for a facility-wide mass emission rate limit to be set to correspond to the existing EtO permitted use amount and the 99.99% control efficiency standard. PAR 1405 also takes into consideration rounding and Appendix 1 includes procedures to determine this facility-specific value and an example of the calculation.

1-7 Response: Staff disagrees with this characterization of EtO monitoring technologies. CEMS using FTIR technology was implemented to monitor EtO stack emissions at a sterilization facility in 2019 and successfully passed a Relative Accuracy Test Audit in 2020. SCEMS using GC-PID technology was implemented to continuously monitor stack emissions of certain volatile organic compounds (VOCs) at a facility in Vermont since 1993 and GC-PID technology has been used to measure stack emissions during source testing for many years. A third technology, cavity ring-down spectroscopy (CRDS), was implemented to continuously monitor low concentration indoor EtO levels at a sterilization facility in 2021. In addition, the U.S. EPA has also

proposed continuous monitoring requirements in its proposed NESHAP and proposed to add additional test methods for continuous monitoring of EtO.

For fenceline air monitoring, PAR 1405 relies on a variety of proven, established technologies. One compliance path is U.S. EPA Compendium Method TO-15, now in its second edition and promulgated in 1999. Another path is U.S. EPA Method TO-15A, an update to TO-15 and another canister sampling method. In addition, PAR 1405 allows the use of real-time monitoring, providing more timely data acquisition. As this field is relatively new, PAR 1405 allows for these emerging technologies if established to meet certain performance standards.

See Response 1-3 on technological feasibility of performance standards in PAR 1405.

1-8 Response: See Response 1-7 regarding EtO CEMS monitoring technologies.

1-9 Response: PAR 1405 has been revised to list the requirements formerly located in the Prohibitions subdivision within the Exemptions subdivision regarding PTEs during the loss of power or other unplanned event outside of the control of the owner or operator.

1-10 Response: PTEs complying with U.S. EPA Method 204 have been implemented at multiple sterilization facilities, both within the South Coast AQMD and elsewhere. Staff is aware of challenges regarding the quality of supplied air coming into PTEs but intake filters may be used to remove particulates or dust from makeup air.

1-11 Response: Staff agrees that the potential of EtO emissions from warehouses depends on many factors. PAR 1405 has been revised to include fenceline air monitoring for certain large warehouses, referred to as Tier I Warehouses, to determine their impacts on ambient air EtO concentrations. PAR 1405 also allows for Tier I Warehouses to perform an emission study to quantify their emissions or fund a demonstration program to determine ambient air EtO concentrations in real-time.

1-12 Response: As noted in PAR 1405 rulemaking materials, background EtO concentrations have been detected at levels at or below 0.17 ppb at ambient air monitoring locations within South Coast AQMD in 2021 and preliminary data indicates background EtO levels at or below 0.29 ppb in 2022. This value was considered in crafting trigger levels for curtailment with the lowest curtailment trigger level more than one order of magnitude greater than the highest background EtO concentration detected. Background EtO is an area of concern but is otherwise outside of the scope of PAR 1405 rulemaking.

Areio Soltani

From: Jeffrey Chuang <jchuang@lso-inc.com>
Sent: Thursday, April 6, 2023 5:20 PM
To: Areio Soltani; Neil Fujiwara; Kalam Cheung; Michael Krause
Cc: Souk Phimphasone
Subject: Public Comments for SCAQMD Rule 1405 Proposed Rule Language

Dear SCAQMD team,

Thank you for working so diligently to draft the proposed amendment to SCAQMD Rule 1405. Please accept this email as my official communication for public comment, superseding my previous email on April 4th, 2023.

Please see below questions and comments regarding the March 2023 draft language:

1. (c) Definitions
   a. "Dunnage" is not defined, nor mentioned, in the draft rule.
      i. Many ethylene oxide (EO) sterilization cycles are only qualified for a single load configuration.
      ii. To ensure load uniformity for sterilization, dunnage is often required to backfill the empty space in loads.
      iii. Dunnage usually consists of packaging material and device surrogates.
      iv. Dunnage is often stored on-site at the sterilizer.
      v. Dunnage is often re-used for multiple sterilization cycles.
   b. (35) Waste Storage Area: Other than OSHA and Cal/OSHA requirements, is there a specific rule for waste handling?
2. (e)(2)(A)(iii) Post-Aerator
   a. To release sterilized product and dunnage (from aeration and post-aerators) to the warehouse, is there any guidance (e.g., an air emissions target)?
      i. Products may not have defined aeration parameters and/or EO residue limits, especially those for engineering studies research & development, and validation.
      ii. Dunnage is often stored on-site. It is often re-used for multiple sterilization cycles.
   b. If a product's emissions are below a certain limit, are there cases where the use of a post-aerator can be bypassed?
      i. For some materials (e.g., metals), the use of a post-aerator would not significantly change the amount of EO being emitted.
   c. For products that are not medical devices, where EO residues are not regulated, what would be the requirements?
      i. Rule 1405 still applies to labware, foodstuffs, cosmetics, prototype devices, and other products sterilized by EO.
      ii. ISO 10993-7 only sets limits for medical devices with patient contact.
      iii. ISO 10993-7 does not apply to other products, product packaging, or air quality emissions.
3. (h)(1) Warehouse Reporting Requirements
   a. For a facility that both sterilizes in-house AND warehouses EO-sterilized products from contract sterilizers, does the Sterilized Palletized Units include or exclude the number of units sterilized in the same building?
      i. The current verbiage states, "excluding Sterilized Palletized Units received from other Warehouses".

Comment 2-1

Comment 2-2

Comment 2-3

Comment 2-4

Comment 2-5

Best Regards,

Jeffrey Chuang, CISS-EO, CISS-RAD
Principal Microbiologist
AAMI-Certified Industrial Sterilization Specialist

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Life Science Outsourcing
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Bringing Medical Innovations to Life.

Responses to Life Science Outsourcing Comment Email, submitted 4/6/2023

2-1 Response: Staff agrees that "dunnage" is not specifically defined in PAR 1405. As dunnage is sterilized by EtO in the same manner as the products intended to be sterilized for later distribution, dunnage is considered as "sterilized materials" once it has gone through a sterilization cycle.

2-2 Response: PAR 1405 has several requirements regarding waste handling. PAR 1405 requires that elements, such as drums, containers, bins, or other vessels, in a waste storage area be maintained within a PTE at large or medium facilities or monitored under a Leak Detection and Repair (LDAR) program at small facilities. PAR 1405 also requires waste storage areas be identified on the facility diagram, and prohibits the discharge of sterilizer exhaust vacuum pump working fluid to the wastewater stream.

Owners or operators shall comply with all other regulatory requirements regarding EtO waste handling.

2-3 Response: PAR 1405 does not include an air emission target or quantifiable emission rate for Post-Aerator. For medium facilities, PAR 1405 requires that the first storage area following the Aerator or Combined Sterilizer/Aeration be kept in a PTE.

2-4 Response: In the situation identified where "residuals are not regulated", PAR 1405 would defer to protocols, work orders or manufacturer's instructions for the required aeration time, as included in the definition of aeration in PAR 1405.

2-5 Response: For the purpose of subdivision (h) Warehouse Requirements, Tier I Warehouses and Tier II Warehouses would track and report the number of sterilized palletized units shipped from entities performing sterilization.

Large facilities are subject to the requirements in subdivision (d), which requires the recording of destinations of the sterilized palletized units shipped or customer ordering the sterilization service.

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April 6, 2023

Michael Krause
Assistant Deputy Executive Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Via e-mail at: mkrause@aqmd.gov

Re: SCAQMD Proposed Amended Rule 1405, Control of Ethylene Oxide Emissions from Sterilization and Related Operations, Preliminary Draft Rule Language

Dear Mr. Krause,

Sterigenics US, LLC (Sterigenics) appreciates the opportunity to participate in the Working Group Meetings (WGMs) for South Coast Air Quality Management District (SCAQMD or District) Proposed Amended Rule 1405, Control of Ethylene Oxide Emissions from Sterilization and Related Operations (PAR 1405).

Sterigenics operates three facilities within SCAQMD to sterilize medical devices such as surgical kits, delivery systems, medical hardware, gowns and drapes, surgical accessories, and medical packaging. Sterigenics' facilities play an important role in safeguarding public health by using a Food and Drug Administration (FDA)-validated, non-invasive method to sterilize medical equipment prior to use. This FDA-validated method requires use of EtO and is the only method available for sterilizing large quantities of packaged medical equipment. Sterilization prevents biological contamination in health care settings that can lead to patient infections, and in severe cases, deaths. The FDA notes that about 50 percent of all sterilized medical devices are sterilized using EtO.[1] The Sterigenics facilities within the SCAQMD sterilize over 90 million essential medical devices and supplies each year, including surgical kits, catheters, cardiac implants, stents, IV sets and more. These products are supplied to nearly 100 healthcare product manufacturers, including dozens in the greater Los Angeles-area, as well as local hospitals.

As the District considers PAR 1405, we urge that you also take into account the greater context within which Sterigenics' facilities operate. The national capacity for EtO sterilization is limited, and shortages of sterilized products and equipment can have – and have had – direct, significant health consequences. Sterigenics supports efforts to reduce EtO emissions to the extent feasible, and to identify alternative methods of sterilization. However, as the FDA acknowledged recently, "[w]hile signs of innovation are promising, other methods of sterilization cannot currently replace the use of EtO for many devices. To that end, we are equally concerned about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations."[2] Without EtO sterilization, infection

[1] See: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#what; please also see Attachment A.
[2] See Attachment A, also available at: https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

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risk associated with surgical procedures and other forms of healthcare would be meaningfully increased.[3]

Sterigenics has been an active participant in the PAR 1405 rulemaking process. On March 17, 2023, SCAQMD released preliminary draft rule language and a preliminary draft staff report for PAR 1405.[4,5] Sterigenics appreciates the diligence with which staff has been working with stakeholders but continues to have concerns about the proposed rule language as well as information presented in the staff report, and accordingly offers the following comments.

I. COMMENTS ON THE DRAFT RULE LANGUAGE

1. Rule Impacts to Sterilization Operations in the District.

Sterigenics is extremely concerned that the scope and requirements of the proposed rule will drive sterilization facilities out of the state, which would have deep and lasting impacts on hospitals and health care systems in Southern California. A decrease in regional sterilization capacity also would increase criteria air pollutant and greenhouse gas emissions if healthcare facilities and local medical device manufacturers are required to ship products out of state for sterilization. Sterigenics intends to continue working with the District to improve the rule language such that facilities can continue to operate within the District.

Comment 3-1

2. PAR 1405(d), Large Facility Requirements:

(d)(1)(C): Control Efficiency

PAR 1405 (d)(1)(C) requires that a facility demonstrate EtO emission control efficiency of 99.99% or greater or demonstrate emissions of EtO at a concentration of ≤0.01 ppm for each "Control System." The detection limit for the subject test method has been as high as 0.01 ppm, so proving a concentration below that limit is not possible. Accordingly, it will be extremely difficult, if not impossible, to consistently meet the control efficiency and/or concentration limits proposed in the draft rule language. Additionally, specifying such a control efficiency requirement could have the unintended consequence of discouraging facilities from installing equipment that may be beneficial and the only control technology available to achieve emissions reductions from certain emissions streams, but that could not meet the control efficiency because of the nature of the equipment or the emissions stream.

For example, Sterigenics is in the process of installing dry beds in the Vernon facilities pursuant to its District-approved Early Action Reduction Plan (EARP) under Rule 1402 to treat small amounts of low-concentration fugitive emissions. The dry beds cannot meet the proposed control efficiency or the proposed concentration limit in the rule, nor will the manufacturer provide a guarantee of such a control efficiency. These dry beds will be part of

Comment 3-2

[3] Included here as Attachment B is a presentation published by the FDA illustrating the issues surrounding shortages with EtO-sterilized equipment in particular. The presentation includes information on the clinical impact of such shortages with an example illustration of a child suffering an infection at a tracheostomy insertion point.
[4] PAR1405: Preliminary Draft Rule Language. Available at http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdrl_031723_draftfinal.pdf?sfvrsn=8.
[5] PAR 1405: Preliminary Draft Staff Report. Available at: http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8.

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the permanent total enclosure required by the proposed rule. Additionally, the facilities' oxidizers would also not meet these control efficiency requirements, in part due to low inlet loadings.

We do not believe that the District intends to eliminate or discourage measures such as the dry beds by imposing a control efficiency requirement. Accordingly, Sterigenics urges that the proposed rule language of (d)(1)(C) be revised to provide that a facility must demonstrate a total control efficiency of 99.99% for *all* EtO emissions, not for each individual "Control System." This will encourage achieving the highest control efficiencies in equipment where this is possible, while allowing flexibility to incorporate other emissions reductions measures, such as dry beds, that necessarily have a lower control efficiency simply because of the nature of the emissions they are controlling. Alternatively, we suggest that the control efficiency requirement be revised to 99.9% or a 0.1 ppm concentration limit, which would be more stringent than the Illinois requirement of 99.9% efficiency or 0.2 ppm concentration limit cited by the District in the staff report. Ultimately, however the District addresses this important issue, it should take into account that EtO emissions reductions may be achieved by a suite of measures, including some that may not be contemplated at this time, not all of which may be capable of achieving a specified control efficiency but nonetheless contribute to overall reductions.

We also suggest that a corresponding revision to the definition of "Control System" in (c)(1)(8) may be necessary. The currently-proposed definition would have the unintended consequence of subjecting emissions reducing equipment like the dry beds and oxidizers to control efficiencies that are not achievable for that equipment. (Separately, we believe that the word "adjoining" could be misleading, when what we understand the definition to intend is "in series" or similar language.) Other corresponding changes to other rule provisions may be warranted for consistency.

Comment 3-2 cont.

(d)(1)(D): Mass Emission Rate

PAR 1405 (d)(1)(D) requires that large facilities demonstrate the sum of mass emission rates measured at each exhaust stack is ≤0.025 lb/hr of EtO from all control systems. Sterigenics believes this value to be derived from a recently issued permit for the Medline Industries (Medline) facility located in Northfield Illinois. The Medline facility permit limits EtO usage to 375 tons/year. In contrast, the Sterigenics Ontario facility is permitted to use 657 tons/year of EtO. It is therefore not reasonable to require a similar mass emission rate for a facility that processes significantly more EtO. Additionally, the mass emission rate for the Medline facility is provided on a monthly and annual basis. Because the health risk of EtO is based on long term exposure, an hourly mass emission limit is not appropriate. Sterigenics recommends eliminating the mass emission limit or using a limit that corresponds to existing EtO usage amounts. Such rule language should be updated as follows (with our proposed changes shown in bold underlined font for **additions** and bold strikethrough font for ~~**deletions**~~):

> *(d)(1)(D) Demonstrate the sum of mass emission rates measured at each exhaust stack is* ~~***0.025 pounds per hour (lbs/hr)***~~ ***380 pounds per year (lb/yr)*** *or less of Ethylene Oxide from all Control Systems by a source test that meets the requirements in subdivision (m); and*

Comment 3-3

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To the extent other provisions warrant corresponding revisions for consistency (for example, to the monitoring requirements set forth in (d)(2)(B)), we recommend those changes be made accordingly.

Comment 3-3 cont.

(d)(2): Stack Emission Monitoring Requirements

PAR 1405(d)(2) requires that large facilities monitor EtO emissions from each exhaust stack with a SCEMS or CEMS by December 31, 2025 or within 12 months of approval of such system, whichever is sooner. Such SCEMS or CEMS equipment is relatively new technology with very few current equipment suppliers and installation and integration companies. The current lead times for such equipment is very lengthy and the installation and integration of such systems can be lengthy. In addition, as we saw in the initial stages of the RECLAIM CEM program, there will be a substantial increase in demand for EtO CEMs given the adoption of PAR 1405 and the NESHAP. Sterigenics suggests extending the SCEMS or CEMS installation date to December 31, 2026 or within 18 months of approval, whichever is later, in order to avoid the inevitable administrative burdens associated with numerous requests for variances from a deadline that we can predict now will be difficult to meet.

Comment 3-4

(d)(3)A: Permanent Total Enclosure (PTE) area

PAR 1405(d)(3)(A) requires that all elements in a Sterilant Gas Storage Area be included within the PTE area. Because of explosion safety concerns and National Fire Protection Association (NFPA) code requirements, Sterigenics has traditionally used exterior EtO storage areas and implemented alternative leak monitoring procedures to ensure there are no fugitive emissions. Because of the explosive nature of EtO, Sterigenics believes that it is much safer to utilize the external storage area with leak detection monitoring rather than enclosing this area and routing this air to a control device. The PAR 1405 leak detection protocols, as well as Sterigenics' facility protocols, are robust and adequately protective. Therefore, Sterigenics suggests eliminating the elements of the sterilant gas storage area from the PTE requirements.

Comment 3-5

(d)(4)(F): Annual Report

PAR 1405(d)(4)(F) requires that an annual report be submitted by January 30 each year. Sterigenics recommends that this date be updated to align with the Annual Emission Report due date.

Comment 3-6

3. **PAR 1405(i), Interim Requirements:**

While our understanding is that Sterigenics' facilities would not be subject to these Interim Requirements because we are instead subject to requirements under subsection (d), we nonetheless note that some provisions of the Interim Requirements warrant further clarification.

Comment 3-7

(i)(5): Test Requirements

PAR1405(i)(5) provides concentration limits and test requirements. However, it is unclear what type of testing would be subject to these requirements. Sterigenics requests

Comment 3-8

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clarification as to whether these requirements pertain to leak detection and repair (LDAR) programs, or other test requirements.

Comment 3-8 cont.

(i)(5)(A): Sterilant Gas Concentration

PAR 1405(i)(5)(A) requires that the maximum sterilant gas mass flow be less than 10 ppm EtO. Values measured in ppm represent concentration. Sterigenics recommends the rule language be updated as follows:

(i)(5)(A) The maximum Sterilant Gas ~~***mass flow***~~ ***concentration*** *shall be less than 10 parts per million Ethylene Oxide, as measured one (1) centimeter away from any portion of a Sterilizer, Combined Sterilizer/Aerator, Aerator, or Control System that could have an Ethylene Oxide leak*

Comment 3-9

(i)(5)(B): Test conditions

PAR 1405(i)(5)(B) requires owners or operators to test during conditions of maximum sterilant gas flow, but does not specify which tests are required. If the requirement is specific to LDAR programs, we note that the flow rate does not affect the leak rate. Sterigenics requests further clarification on this requirement in the rule language.

Comment 3-10

(i)(7)(C): Source Test Operating Conditions

PAR 1405(i)(7)(C) requires that source tests be conducted under normal operating conditions. 40 CFR Part 63 Subpart O provides Ethylene Oxide Emissions Standards for Sterilization Facilities and includes monitoring requirements.[6] The operational conditions for source tests in the proposed rule should mirror the requirements of the NESHAP.

Comment 3-11

(i)(8): Test Methods

PAR 1405(i)(8) requires that tests be conducted using CARB Test Method 21. Although this requirement appears to be related to an LDAR program, the language in the rule should be clarified.

Comment 3-12

4. **PAR 1405(k), Permanent Total Enclosure Requirements:**

(k)(1): Averaging Time for Negative Pressure Demonstration of Compliance

PAR 1405 (k)(1) requires that a facility demonstrate that the permanent total enclosure (PTE) is maintained at a negative pressure of at least 0.007 inches of water column averaged over one minute. Sterigenics agrees that it is necessary to demonstrate compliance with the negative pressure requirements of the rule, but a 15-minute average is a more reasonable time period for compliance demonstration. SCAQMD has set precedent in Rule 1420.2 for allowing the demonstration to be made on a 15-minute average.[7] Sterigenics recommends the rule language be updated as follows:

Comment 3-13

[6] 40 CFR Part 63, Subpart O. Available at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O.
[7] SCAQMD Rule 1420.2, Emission Standards for Lead from Metal Melting Facilities. Available at: http://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/Rule-1420-2rev.pdf.

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(k)(1) Demonstrate the Permanent Total Enclosure is maintained at a negative pressure of at least 0.007 inches of water column averaged over ~~*one (1) minute*~~ ***fifteen (15) minutes****;*

Comment 3-13 cont.

5. **PAR 1405(o), Prohibitions:**

(o)(3): Emission Releases

PAR 1405(o)(3) states that the owner or operator of a facility performing sterilization shall not allow the release of uncontrolled emission of EtO to atmosphere from any PTE at any time. It is not possible for facilities to comply with this condition during unforeseen power outages. Facilities have systems in place to shut down the processes. However, fans can continue to run on their own inertia even when scrubber pumps are immediately shut down. Backup generation can take 30 seconds or more to detect the outage, start up, and generate enough power to run process equipment. Sterigenics recommends the rule language be updated as follows:

The owner or operator of a Facility performing Sterilization shall not allow the release of uncontrolled emission of Ethylene Oxide to atmosphere from any Permanent Total Enclosure at any time ***during normal operations****.*

Comment 3-14

6. **PAR 1405(r), Exemptions**

(r)(3): Exemptions During Loss of Power or Other Unplanned Event

PAR 1405(r)(3) includes exemptions from certain requirements during the loss of power or other unplanned event outside the control of the owner or operator. Sterigenics agrees with this exemption but believes it should be expanded to include Section (o)(3) for the reasons stated above. Sterigenics recommends the rule language be updated as follows:

(r)(3) The requirements of paragraph (k)(1) ***and (o)(3)*** *do not apply to any owner or operator during the loss of power or other unplanned event outside of the control of the owner or operator provided, as applicable:*

Comment 3-15

New Section (r)(4)

Source tests on units equipped with CEMS is not necessary, as it would provide no additional information on equipment emissions. Sterigenics recommends that a new section be added to the rule as follows:

(r)(4) Units equipped with a CEMS or SCEMS pursuant to paragraph (d)(2) are not subject to source testing requirements in this rule.

Comment 3-16

New Section (r)(5)

PAR 1405(k)(2) requires differential pressure monitoring placed at certain walls within the Permanent Total Enclosure. Sterigenics recommends that only walls with natural draft openings be subject to this requirement. Sterigenics recommends that a new section be added to the rule as follows:

Comment 3-17

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Sterigenics
A Sotera Health company

(r)(5) In a Permanent Total Enclosure, walls that do not contain natural draft openings are not subject to the differential pressure monitoring requirements of paragraph (k)(2).

Comment 3-17 cont.

II. COMMENTS ON THE DRAFT STAFF REPORT

1. Methods of EtO Monitoring Can Be Unreliable

We note that the draft staff report discusses the ambient EtO monitoring conducted around several facilities, including Sterigenics', in the last two years. Although the District has taken action based on ambient EtO monitoring, we believe the District is aware that significant challenges measuring EtO ambient concentrations have been noted by many regulatory agencies, including the U.S. Environmental Protection Agency (EPA), Georgia Environmental Protection Division, and West Virginia Department of Environmental Protection. These agencies have challenged the existing test method to measure low EtO concentrations and have pointed to other existing sources of EtO. Such challenges should be duly considered in both the development and enforcement of this rule.[8]

Furthermore, there have been no fenceline ambient monitoring methods that would address such concerns and provide timely measurements of EtO near sterilization sources. Sterigenics notes that any need for such potentially unreliable, inaccurate monitoring would be further obviated by the implementation of the robust PTE and CEMS / SCEMS requirements under this rule. We believe that such prioritization of emissions reductions measures under the rule are appropriate.

Comment 3-18

2. Fugitive Emissions

The fugitive emissions from EtO sterilization facilities are very difficult to quantify. In the draft staff report, SCAQMD assumed that the measured EtO concentrations near some facilities were from fugitive emissions. However, such measurements could be from the dispersion of process emissions downstream of compliant emission control systems.

Comment 3-19

3. CEQA Impact

When evaluating the potential environmental impacts of PAR 1405, the District should consider whether the rule could result in the closing or curtailing of any affected businesses, and must disclose whether that could result in the need to ship EtO-sterilized medical products and equipment from out of state or out of area in order to assess potential impacts to air quality and greenhouse gas emissions.

Comment 3-20

4. Socioeconomic Impact

[8] Attached as Exhibit C are relevant documents illustrating some of the challenges recognized by other agencies, including Ethylene Oxide Monitoring Report, Georgia Department of Natural Resources, Environmental Protection Division. May 12, 2022 (available at: https://epd.georgia.gov/ethylene-oxide-information) and Ethylene Oxide Monitoring – Characterization of South Charleston and Institute, West Virginia and Surrounding Areas, West Virginia Department of Environmental Protection, Division of Air Quality. February 21, 2023.

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Sterigenics
A Sotera Health company

We understand that the socioeconomic impact report is currently in development. We request that this report take into consideration the impact of potential closures or curtailment of facilities subject to PAR 1405, along with economic impacts on the medical industry and resulting challenges – including health risks and treatment of infections or even deaths resulting from inadequately sterilized medical products and equipment.

In addition, many medical device manufacturers and hospitals are dependent on EtO sterilization facilities within the SCAQMD area to supply necessary sterilized product to their customers. Without these facilities, the socioeconomic impact to these end customers and the general public would be substantial.

Comment 3-21

III. CONCLUSION

It should also be noted that the US EPA is in the process of releasing regulations that will have significant impact on the EtO sterilization facilities within SCAQMD's jurisdiction. Such rules include proposed updates to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization facilities and a Preliminary Interim Decision (PID) for the re-registration of EtO under US EPA's pesticide regulations. Sterigenics believes that SCAQMD should wait for these rules to be published and their impacts better understood before completing the PAR 1405. These rules could impose requirements that conflict with those proposed in PAR 1405.

Comment 3-22

Sterigenics appreciates the opportunity to provide these comments related to PAR 1405. As outlined above, there are multiple items requiring further analysis and thorough discussion prior to rule adoption. We look forward to continued discussion of this important rulemaking. If you have any questions, please contact me at (630) 928-1771 or via e-mail at kwagner@sterigenics.com.

Sincerely,

Kevin Wagner
Vice President – Global EH&S

Attachments

Cc: Wayne Nastri, SCAQMD
Sarah Rees, SCAQMD
Areio Soltani, SCAQMD
Neil Fujiwara, SCAQMD
Kalam Chung, SCAQMD

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Responses to Sterigenics US, LLC Comment Letter, submitted 4/6/2023

3-1 Response: Staff understands that EtO sterilization plays a critical role in the supply chain of medical devices and patient health. Staff has given careful consideration to the implementation requirements in PAR 1405.

In the rulemaking process, individual meetings were held with facility operators, and no operators expressed that they plan to move out of state because they could not comply with PAR 1405.

3-2 Response: The performance standards established in PAR 1405 are based on best available technology that has been achieved in practice. Large facilities are required to comply with either the 99.99% control efficiency performance standard or the 0.01 ppm outlet concentration performance standard for each control system, encouraging the highest control efficiencies in equipment where possible while understanding the physical limits of detection for lower inlet concentration exhaust streams. Based on source test results analyzed, at least two technologies were able to demonstrate compliance with the proposed performances standards.

The concentration limit of 0.01 ppm is based on evaluation of recent source test reports. See Chapter 1 of this staff report for more details on the data evaluation. The averaging time for the concentration limit has been updated from daily to a rolling 30-day average. See Response 1-5 for more details.

Lastly, Staff has revised PAR 1405 to include "in series or parallel" and "one or more stacks" to the definition of Control System. This would allow a Control System with multiple stacks to be considered one Control System.

3-3 Response: See Response 1-6.

3-4 Response: Staff has reached out to vendors and suppliers, and agreed that the lead time to obtain CEMS or SCEMS are longer, and is expected to increase with the release of proposed NESHAP. As such, the implementation timeframe of continuous monitoring for stack emissions has been revised to begin 18 months after receiving approval from the Executive Officer for an application SCEMS or CEMS, whereas the deadline to apply for a SCEMS or CEMS is May 1, 2025.

3-5 Response: While indoor sterilant gas storage is feasible and achieved in practice, PAR 1405 has been revised to allow for an alternative to PTE for elements in the sterilant gas storage area, expected to be equally as effective at preventing fugitive EtO emissions.

3-6 Response: PAR 1405 has been revised to increase time to submit required reports and to align annual and semi-annual reporting requirement deadlines to South Coast AQMD Title V annual and semi-annual reporting requirement deadlines specified in paragraphs (p)(1) and (p)(2) accordingly.

3-7 Response: Sterigenics's two sterilization facilities using EtO would be subject to the Interim Requirements in paragraph (i)(1) until the sunset date of as listed in PAR 1405. Sterilization facilities would be subject to the new requirements specified in the applicable subdivisions.

3-8 Response: The concentration limits and test requirements in paragraph (i)(5) pertain to interim requirements in PAR 1405 to ensure the listed equipment is "leak free", as described in the existing Rule 1405 language. As the term "leak" is redefined in PAR 1405 and used with a "leak detection and repair" (LDAR) program, the term "leak" was not used in paragraph (i)(5).

3-9 Response: PAR 1405 has been revised to use the term "concentration" in paragraph (i)(5).

3-10 Response: PAR 1405 has been revised to increase clarity in interim requirements while ensuring continuity with existing Rule 1405 language.

3-11 Response: See Responses 3-7 and 3-10.

3-12 Response: See Responses 3-7 and 3-10.

3-13 Response: PAR 1405 has been revised to a 15-minute averaging period.

3-14 Response: PAR 1405 has been revised to exempt owners and operators from the prohibition of emission releases during the loss of power or other unplanned events outside of the control of the owner or operator under certain conditions provided that certain conditions are met. The conditions are set to ensure fugitive emissions are minimized to the maximum feasible extent.

3-15 Response: See Response 3-14.

3-16 Response: Staff disagrees that source tests on units equipped with CEMS (or SCEMS) is not necessary and would provide no additional information on equipment emissions. CEMS and SCEMS continuously or semi-continuously monitor stack emissions and do not monitor inlet EtO concentrations to control systems. As a result, CEMS or SCEMS are unable to determine control efficiency of control systems. If not required to demonstrate the control efficiency of control systems, CEMS or SCEMS coupled with annual RATA is sufficient and additional source testing is not required.

3-17 Response: The requirements for differential pressure monitoring included in PAR1405 are very similar to those included in Rule 1420.1. Even for walls with no natural draft openings, a differential pressure monitoring device could

quantify the level of differential pressure in the area and thereby serve as a tool to verify compliance with requirements in PAR 1405.

3-18 Response: PAR 1405 is a technology-based rule reducing stack and fugitive emissions of EtO. PAR 1405 includes various continuous monitoring requirements for stack emissions and differential pressure to verify continuous compliance with proposed performance standards.

Until continuous monitoring of stack emissions and differential pressure are in place, PAR 1405 requires initially interim mobile monitoring and then interim fenceline air monitoring of fenceline EtO concentrations. See Response 1-7 regarding fenceline air monitoring and Response 1-12 regarding background EtO concentrations in South Coast AQMD.

3-19 Response: The Executive Summary and Section 1.1 of the PAR 1405 Staff Report have been revised to reflect contributions from both stack and fugitive emissions.

3-20 Response: The commenter provides no evidence that a business would close and other businesses would ship EtO-sterilized products into the area. Pursuant to CEQA Guidelines Section 15131(a), "[e]conomic or social effects of a project shall not be treated as significant effects on the environment." CEQA Guidelines Section 15131(b) states further, "[e]conomic or social effects of a project may be used to determine the significance of physical changes caused by the project."

However, of the various provisions included in PAR 1405 aimed at further reducing stack and fugitive EtO emissions from sterilization operations, the potential installation of monitoring equipment, control equipment, and PTEs at a select few facilities are the only activities which would involve physical modifications, if any, which may be achieved via minimal construction equipment. Further, no direct or indirect physical changes resulting from economic or social effects have been identified. Thus, it can be seen with certainty that implementing PAR 1405 would not cause a significant adverse effect on the environment, and is therefore, exempt from CEQA pursuant to CEQA Guidelines Section 15061(b)(3) – Common Sense Exemption.

3-21 Response: The Socioeconomic Impact Assessment considers potential compliance cost to be incurred by the affected facilities. It also evaluates the cost-to-revenue ratio for those affected facilities with available revenue data. It is highly speculative that PAR 1405 would result in facility curtailment or even closure, along with the associated impacts mentioned in the comment.

3-22 Response: See Response 1-4.

April 11, 2023

Sarah Rees
Deputy Executive Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization

Dear Deputy Executive Director Rees,

I write to you on behalf of California Life Sciences regarding South Coast Air Quality Management District's (SCAQMD) proposed amended Rule 1405 – Control of Ethylene Oxide (EtO) and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes. California Life Sciences represents over 1,200 entities representing pharmaceutical, biotechnology, medical technology, and academic research institutions throughout California.

First, California Life Sciences thanks the SCAQMD and its staff for your openness and transparency during this process. Your willingness to meet with and accept feedback from stakeholders in your district throughout this process is greatly appreciated. California Life Sciences wishes to express the following 3 concerns:

First, we are asking for a technology-neutral approach to meet new emissions targets that enable facilities to select an effective control method while remaining open and operating safely. Second, we also request consideration of background levels of EtO in the ambient air, both natural and human causes, and recognition of the numerous other sources of EtO emissions – including those from ubiquitous consumer items like lawn mowers and gas generators. Finally, we seek consideration of the update to the EtO NESHAP expected this year from U.S. Environmental Protection Agency (EPA). This multi-year process has involved significant stakeholder and community engagement; conflicting or overlaying requirements could cause significant confusion and result in disruption to the timely and safe sterilization of essential medical devices. Notably, each year well over 100 million medical devices are sterilized in the SCAQMD region and any impact to the system is likely to result in severe disruptions to the medical device supply chain.

Additionally, we would like to encourage SCAQMD to also take into consideration that EtO sterilization is a critical process used to make these medical devices safe for our patients. Any requirement that could cause the customers of these EtO sterilization facilities to make any changes in the sterilization process, location, or handling may take several years to implement due to external regulatory timelines. Many of the products sterilized in these facilities are distributed globally and are not only governed by the FDA but other agencies' rules and regulations. Approvals for changes to the sterilization process are

Comment 4-1

considered so critical to all governing bodies that they will require extensive regulatory review for each impacted product.

Any disruption in the operations of the facilities governed by this rule will destabilize the supply of the lifesaving medical devices sterilized at these facilities and could constitute an immediate public health risk. The IRIS study assessed long-term health risk in the communities based on an assumed 70-year exposure period. CLS and the members that it represents strongly encourages rules that 1) Protect the long- term health of communities surrounding these facilities and 2) provides thoughtful and achievable rulemaking in order to ensure a stable and sustainable solution to keep these-life saving medical devices in our hospitals and available to our patients. We encourage SCAQMD to take a risked based approach when making these rules to ensure that the risk of life is protected in both instances.

Unfortunately, the proposed rule in its current form is neither clear nor workable. It is not technology neutral, does not sufficiently recognize the existence of EtO in the ambient air, and from other sources unrelated to sterilization, and is being done on a timeline that could cause significant confusion with the expected release of the EPA EtO NESHAP.

Comment 4-1 cont.

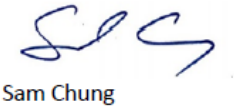
Below are some concerns specific to the draft rule:

Our more specific concerns include:

- Some of the levels and requirements may not be technologically-feasible — Comment 4-2
- The prohibition of releasing product prior to completion of aeration negates the need for a post-aeration facilities — Comment 4-3
- These rules and regulations for PTE are inconsistent with other rules and regulations governed by AQMD for other industries — Comment 4-4
- Relying on, or requiring use of, non-existent or unproven technology — Comment 4-5
- Lack of clarity in multiple definitions and standards — Comment 4-6
- Lack of understanding for implications of requirements for total facility containment — Comment 4-7
- Introducing complexity to otherwise well-defined and understood standards, for example LDAR requirements — Comment 4-8
- Unachievable timeline for compliance based on technology and equipment availability, validation, and regulatory approval — Comment 4-9
- Vague definitions and structure relating to unique warehouse tracking and reporting requirements — Comment 4-10
- Lack of understanding of FDA sterilization requirements; conflicting elements of draft amendment with FDA mandated procedures — Comment 4-11
- Potential conflicts with federal regulations given that the NESHAP and FIFRA rules have yet to be published — Comment 4-12

SCAQMD staff has indicated their intention to present a final draft rule to the Governing Board at the June 3, 2023, meeting. We will work with your staff to address our concerns within this time frame. It is our further hope that SCAQMD staff and the Board recognize the need to avoid unnecessary disruptions to the medical device supply chain rather than adhering to a subjective deadline and that the Board will look to avoid potential conflict and confusion with pending federal regulations. We look forward to the continued open dialogue in the coming months. If you have any additional questions, please feel free to contact me at schung@califesciences.org.

Sincerely,



Sam Chung
Vice President, State Government Relations
California Life Sciences

Responses to California Life Sciences Comment Letter, submitted 4/11/2023

4-1 Response: PAR 1405 is a technology-neutral rule that relies on innovative measures to control both stack and fugitive emission sources of EtO based on strategies achieved-in-practice and demonstrated by independent third-party testing. See Response 1-12 regarding background EtO concentrations in South Coast AQMD.

Consideration has been given on the concerns regarding the surge in demand, supply chain constraints, and long lead time of equipment, and the implementation schedule for large and medium facilities have been extended by six to eight months.

See Response 1-4 for responses related to comments on proposed NESHAP.

4-2 Response: Each performance standard, monitoring strategy, or control requirement in PAR 1405 has been evaluated by reviewing source testing reports, permits, facility surveys, site visits, vendor meetings, or other methods to determine if proposed performance standards or control requirements are technologically-feasible and achieved-in-practice. See Chapter 1 of this staff report on the data and technology evaluated.

4-3 Response: Even after completing aeration, products and their associated packaging continue to off-gas EtO and at least one post aeration storage facility within South Coast AQMD maintains Permits to Operate for control systems to capture and control EtO emissions from products and their associated packaging after completing aeration off-site. As such, PAR 1405 includes capture and control requirements for certain post-aeration areas.

4-4 Response: Staff agrees that the requirements for PTE under PAR 1405 go above and beyond the requirements of U.S. EPA Method 204 or other South Coast AQMD rules. Because of the nature of EtO as a VOC and a toxic air contaminant, and the high toxicity of EtO, additional requirements are necessary to ensure capture of fugitive EtO emissions.

4-5 Response: See Responses 1-3 and 1-8.

4-6 Response: The commenter did not provide specific areas where clarity should be improved. However, updates have been made throughout PAR 1405 to improve clarity since the release of the Preliminary Draft Rule.

4-7 Response: PAR 1405 does not require “total facility containment”. Various parts of the EtO sterilization process, depending on the throughput and nature of the facility, are required to be maintained under a Permanent Total Enclosure while other parts are required to be monitored for leaks under an LDAR

program. If a facility performs manufacturing or other processes unrelated to EtO, those processes are unaffected by the requirements of PAR 1405 and containment is not required.

4-8 Response: One of the potential sources of EtO emissions identified during the PAR 1405 rulemaking process is fugitive emissions. PAR 1405 enhances semi-annual leak check required by existing Rule 1405 into a robust LDAR program, currently required for at least one sterilization facility in the state of Georgia and used extensively by the oil and gas industry. PAR 1405's LDAR program would require daily audio-visual checks and leak inspections every 60 days of specific potential leak-points at a lower threshold than existing Rule 1405 to reduce potential fugitive emissions.

4-9 Response: See Response 1-2.

4-10 Response: The commenter did not provide specific areas where clarity should be improved. However, updates have been made throughout PAR 1405 to improve clarity.

The warehouse reporting and fenceline air monitoring requirements are required for one year in order for South Coast AQMD to better understand these sources of potential emissions and the number of sterilized palletized units received at warehouses.

4-11 Response: Staff has engaged with U.S. FDA staff to understand U.S. FDA sterilization requirements as they relate to air emissions of EtO. South Coast AQMD is unaware of any conflicts between PAR 1405 and U.S. FDA mandated procedures and is unable to respond or resolve conflicts without additional detail.

4-12 Response: See Response 1-4 regarding proposed NESHAP.

Regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), staff is aware that sterilant gas that contains EtO is considered a pesticide under federal law. In April 2023, U.S. EPA released a proposed interim decision for EtO to protect workers and community members. Staff has carefully studied the proposed interim decision and did not identify any conflict with PAR 1405. The proposed FIFRA requirements will go through its public process. Staff is committed to evaluate again for any conflict between PAR 1405 and the requirements once they are approved, and amend PAR 1405 as necessary.

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614-757-5350 tel

cardinalhealth.com

April 13, 2023

Via E-mail

Kalam Cheung
Planning & Rules Manager
Planning, Rule Development, and Implementation
South Coast Air Quality Management District
21865 Copley Drive, Diamond Bar, CA 91765

Re: SCAQMD Proposed Amended Rule 1405, Control of Ethylene Oxide Emissions from Sterilization and Related Operations

Dear Ms. Cheung:

Cardinal Health (Cardinal) appreciates the opportunity to offer the following comments on the South Coast Air Quality Management District's (SCAQMD) proposed amended Rule (PAR) 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations:

1. Confirmation of the relationship of the proposed "Post Aeration Storage Facility" and "Large Warehouse" categories.

It is Cardinal's understanding, based on the PAR 1405 Preliminary Draft Staff Report dated March 17, 2023, that the only facility within SCAQMD's jurisdiction that currently falls within the category of "Post Aeration Storage Facility" is Cardinal's facility in Riverside, which previously applied for and received a permit from SCAQMD as an "aeration-only" facility under the current version of Rule 1405. It is our understanding based on the proposed text of PAR 1405 and discussions with SCAQMD representatives on April 5, 2023, that Riverside would qualify as both a "Post Aeration Storage Facility" and a "Large Warehouse" under PAR 1405. Cardinal requests formal confirmation that any "Post Aeration Storage Facility" which also satisfies the definition of a "Large Warehouse" is intended to qualify as both a "Warehouse" and a "Post Aeration Storage Facility" for purposes of PAR 1405.

Comment 5-1

2. Confirmation of relationship between PAR 1405 and Title 17, Sections 93108 & 93108.5 of the California Code of Regulations.

Cardinal requests confirmation from SCAQMD how the classifications under PAR 1405 relate to the categories of EtO sources subject to regulation under California state law, specifically, 17 CCR Sections 93108 & 93108.5. Title 17 of the California Code of Regulations, at Section

Comment 5-2

93108 specifies requirements applicable to "Aeration-Only" facilities (defined as "a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility"), namely, 95% control efficiency for EtO emissions. The current version of SCAQMD Rule 1405 includes a category for "Aeration-Only" facilities, but PAR 1405 deletes that "Aeration-Only" category and adds a "Post Aeration Storage Facility" category. PAR 1405's distinction between aeration units at sterilization facilities and the "post-aeration" that Cardinal instituted at its Riverside facility reasonably reflects actual industry activity, but Cardinal requests clarification regarding whether this proposed change in PAR 1405 is intended to affect categorization of such facilities for purposes of 17 CCR Sections 93108 & 93108.5. Cardinal further comments that PAR 1405 should be interpreted consistently with 17 CCR Sections 93108 & 93108.5 so as to avoid conflicts between state and local regulation and avoid any confusion regarding regulatory applicability. Cardinal believes that PAR 1405 can be interpreted consistently if "Post Aeration" facilities are interpreted to be "Aeration Only" facilities for purposes of 17 CCR Section 93108 given the definition of "Aeration" in 17 CCR Section 93108 and the fact that the control efficiency requirements imposed on "Aeration-Only" facilities under 17 CCR Section 93108 is consistent with that imposed on "Post Aeration" facilities under PAR 1405. Likewise, facilities or portions of facilities that do not include control devices for EtO but merely store sterilized product on the same terms as other stored product are not Post-Aeration facilities under PAR 1405 or Aeration-Only facilities under 17 CCR Sections 93108, consistent with 17 CCR Section 93108's exclusion from the definition of "aeration" of "any equipment or space in which materials that have previously undergone ethylene oxide sterilization and aeration can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide." Accordingly, Cardinal understands that the post-aeration trailer venting units permitted at its Riverside facility would be a "Post-Aeration" facility under PAR 1405 and an "Aeration-Only" facility for purposes of 17 CCR § 93108, and the storage area where such product is stored after post-aeration is considered a "Warehouse" under PAR 1405 and likewise not an aeration area under 17 CCR § 93108.

Comment 5-2 cont.

3. Permanent Total Enclosure requirements should be based solely on EPA Method 204.

The definition of Permanent Total Enclosure (PTE) included in PAR 1405 expressly relies on the parameters of EPA Method 204. However, subsection (k) of the PAR 1405 includes additional parameters that go far beyond those required by EPA Method 204, such as continuous pressure monitoring using specific technological sensitivities, averaged over one minute periods. Cardinal is not aware of any facility meeting the definition of a "Post Aeration" facility that has demonstrated that these requirements in excess of EPA Method 204 are technically and economically feasible, especially to the extent they required any retrofit of existing facilities. It is Cardinal's understanding that the PAR 1405 subsection (k) requirements are based on aeration rooms at various sterilization facilities that had recently undergone costly retrofits. But as PAR 1405 itself recognizes, there are material differences between aeration facilities at sterilization plants and the post-aeration units like those installed at Riverside, which are designed to vent loaded trailers. Because no post-aeration facility SCAQMD or Cardinal is aware of has installed the continuous monitors that would be required for any facility complying with PAR 1405 subsection (k), it is not possible to estimate at this time what capital costs would be required to

Comment 5-3

meet those continuous pressure monitoring requirements, and whether or not substantial retrofit coasts would be incurred, because that would require an engineering analysis and validation testing under operating conditions that has not yet been demonstrated or performed at a similar facility. By contrast, EPA Method 204 is an industry standard test that has been demonstrated in practice across a variety of industries and control devices. Accordingly, Cardinal proposes that PTE requirements be based solely on EPA Method 204.

Comment 5-3 cont.

4. The change in Method 21 Leak Detection and Repair (LDAR) frequency is unnecessary and unjustified.

Cardinal's Riverside facility, the only facility in the jurisdiction of SCAQMD that has proactively installed and permitted post-aeration controls, is already required by its current permits issued by SCAQMD to perform Method 21 LDAR testing on a semiannual basis. As SCAQMD is aware, the results of those LDAR tests have been consistently "clean" (i.e., demonstrated a consistent absence of leaks) and have not provided any reason to believe that more frequent testing is necessary or justified. Likewise, PAR 1405 only requires semiannual reports concerning any exceedances found during LDAR. The proposed increase in frequency to monthly Method 21 tests will increase costs related to such testing by at least 600%. Cardinal preliminarily estimates that the increased frequency Method 21 testing is likely to add approximately $50,000 in additional expenses per facility on an annual basis. Bringing any such testing in-house as opposed to third party testing services is not likely to alleviate cost increases, and may not even be feasible, because existing facilities may not have the excess staffing flexibility absent additional hires. Accordingly, given the additional costs associated with more frequent testing, and the lack of any demonstrated need for additional testing, Method 21 LDAR testing should only be required on a semiannual basis. Alternatively, SCAQMD should consider a graduated requirement that further incentivizes good design and maintenance, such as continuing current requirements of semiannual Method 21 testing for facilities with consistently clean LDAR results, with more frequent testing required for facilities that demonstrate leaks above regulatory thresholds during a given reporting period.

Comment 5-4

5. Regarding Warehouse reporting requirements

To the extent that any Warehouse is subject to reporting under PAR 1405, reporting should not be based on palettized units because that information is not necessarily readily available or standardized. Instead Cardinal suggests that any such reporting be based on the number of trailer truck loads received directly from a sterilizer. Relatedly, the rule should expressly state that reporting is only required for any trailers trucks or palletized units received directly from a sterilization facility. The current PAR 1405 attempts to reach a similar result by exempting reporting of units received from other Warehouses, and this is a justified exclusion since EtO offgassing rapidly dissipates the longer it is from the time of sterilization. But the current exclusion is not as well tailored as a definition specifically stating that only units received directly from EtO sterilization facilities are subject to reporting. For example, although Cardinal's Riverside warehouse stores product as a Warehouse after post-aeration, it is conceivable that another facility or entity could choose to create or use a Post Aeration unit that

Comment 5-5

is not at the same contiguous facility as a Warehouse area, and it would not be rational to treat such product that has gone through any such additional post aeration more stringently than product that has been received from a Warehouse that has not chosen to install additional aeration controls.

Comment 5-5 cont.

6. Extension of compliance deadlines

It is our understanding that Cardinal's Riverside facility is the only facility subject to the proposed requirements for "Post Aeration" facilities. But as noted above with respect to the PTE requirements of PAR 1405 subsection (k), demonstrating whether any retrofits would be necessary at any existing "Post Aeration" facility under PAR 1405 subsection (k)'s continuous pressure monitoring requirements will require an engineering analysis, and validation testing under operating conditions for a reasonable period of time, altogether a months long process, and if retrofits were required, would take significantly longer to enact, and may require permitting amendments which would also extend the timeline for being able to demonstrate compliance. The current PAR 1405 deadline of three months for Post Aeration facilities is not sufficient for the engineering assessments that would be required to analyze the feasibility of all the requirements of the proposed rule. Accordingly, if SCAQMD continues to require PTE requirements beyond the requirements of EPA Method 204, Cardinal requests a minimum of one year be permitted for compliance with PTE requirements for Post-Aeration facilities.

Comment 5-6

7. Regulations should distinguish between existing permitted facilities and future new facilities.

SCAQMD should grandfather existing sources, requiring compliance with existing permit terms for already permitted sources. There are multiple justifications for this course of action. First, facilities that have proactively installed additional Post-Aeration controls should not be penalized with additional compliance costs simply because they proactively sought to set a corporate standard higher than existing industry standards. Second, any cost justifications underlying PAR 1405 must account for whether a source is an existing or new source, because any retrofit costs are typically much higher than the costs that would be associated with changing designs for a new facility that has not already constructed control systems.

Comment 5-7

Sincerely,

Lindsay Stadge

Lindsay Degnan Stadge
Sr. Counsel, Regulatory
Cardinal Health

Responses to Cardinal Health Comment Letter, submitted 4/13/2023

5-1 Response: The Cardinal Health facility in Riverside (Cardinal Riverside) under PAR 1405 would be considered both a post aeration storage facility (formerly known as an aeration-only facility) as well as a Tier I Warehouse, and should comply with the requirements of a Post Aeration Storage Facility (formerly known as an aeration-only facility) and the requirements of a Tier I Warehouse. A list of applicable warehouses is included in Appendix B of this staff report.

5-2 Response: The term "aeration-only facility" was revised to "post aeration storage facility" in PAR 1405 to more accurately describe this category of EtO emission sources. PAR 1405 would not change how Cardinal Riverside is regulated under any other local, state, or federal regulation.

5-3 Response: See Response 4-4.

5-4 Response: See Response 4-8.

5-5 Response: Staff engaged with multiple warehouse stakeholders regarding tracking and reporting of sterilized palletized units or some other measure such as trailer truck loads. Based on the feedback received, tracking and reporting of sterilized palletized units was selected.

The rule language has been updated to clarify that only units received directly from entities performing sterilization (both within and outside South Coast AQMD jurisdiction) need to be tracked and reported.

5-6 Response: PAR 1405 has been revised to allow post aeration storage facilities until September 1, 2025 to comply with new requirements. Note that PTE is not a mandatory requirement for post aeration storage facilities but is a compliance path should the owner of operator choose to pursue it. PAR 1405 requires post aeration storage facilities to either operate control systems within a PTE or alternatively monitor components of the control system under an LDAR program.

5-7 Response: PAR 1405 addresses stack and fugitive emissions of EtO based on the best available technology achieved-in-practice. The performance standards and other requirements are developed for existing facilities. New facilities will be subject to both Rule 1405 and Rule 1401 – New Source Review of Toxic Air Contaminants including the requirements for Best Available Control Technology for Toxics (T-BACT).

COMMUNITIES FOR A BETTER ENVIRONMENT
40 years | established 1978

April 13, 2023

Areio Soltani
Planning, Rule Development, and Implementation
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

RE: Comments on Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations

Dear Areio Soltani:

Communities for a Better Environment ("CBE") submit these comments on Proposed Rule 1405 ("Proposed Rule"). We appreciate the South Coast Air Quality Management District ("AQMD") revisiting Rule 1405 to strengthen controls of ethylene oxide ("EtO") emissions following the United States Environmental Protection Agency ("USEPA") reconsideration of the potential toxicity of EtO. While we applaud AQMD for new control measures and monitoring requirements, we are concerned that the current language will not meaningfully regulate sterilization and related operations that harbors a known carcinogen identified by the California Air Resources Board ("CARB") as a Toxic Air Contaminant (TAC) and by the USEPA as a Hazardous Air Pollutant.[1]

CBE participates in the Southeast Los Angeles AB 617 Steering Committee. We also participated in the workshops and have met with staff working on this Rule over the past several months. The mission of CBE is to build people's power in California's frontline communities to achieve environmental health and justice by preventing and reducing pollution and building green, healthy, and sustainable communities and environments. It was concerning that AQMD only began investigating facilities that emit EtO *after* the USEPA announced the reconsideration of the potential toxicity of EtO given that Southeast Los Angeles communities are heavily impacted by transportation, industry, warehouses, and many other pollution sources. Stronger requirements under Rule 1405 can help reduce EtO emissions and protect public health.

We hope AQMD will adopt higher standards for Rule 1405 to reduce the health impacts of EtO emissions on the surrounding communities by, but not limited to:

[1] AQMD (2023, March). *Preliminary Draft Staff Report Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations*. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8, pg 1-1.

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1. Revisiting and amending Rule 1405 immediately if the USEPA's assessment of EtO requires higher control performance metrics and equipment.
2. Rescheduling implementation dates of emission control requirements sooner rather than later to avoid any potential fugitive emissions.
3. Requiring fenceline monitoring of facilities that emit EtO and warehouses that receive/store products sterilized by EtO, to ensure control systems are performing to the highest standard.

Comment 6-1

I. Purpose

CBE appreciates AQMD in updating the purpose of this Rule by including warehouses that store materials sterilized with EtO.[2] By including warehouses in this Rule AQMD can monitor if aeration processes and control systems are efficient in reducing fugitive emissions of EtO.

Comment 6-2

II. Large Facility Requirements

CBE would like to address that the timeframes for Large Facilities' Stack Emission, Stack Emission Monitoring, and Fugitive Emission Requirements (d)(1)(2)(3) are too long and can be detrimental for communities who live close to facilities that emit EtO. Instead of implementation starting in 2024 or 2025, AQMD should change the dates closer to the end of 2023 or summer of 2024 given the toxicity of the EtO and how it can stay in the air for several months.[3]

Comment 6-3

III. Medium Facility Requirements

CBE encourages AQMD to add the requirements from Large Facility (d)(4)(A)(B)(D) to Medium Facility Requirements. This is to ensure the safety and protection of workers and residents who live near or work in warehouses that store or receive materials that were sterilized with EtO. While AQMD's Warehouse Facility Questionnaire responses were limited, three facilities reported that they do not know if they receive EtO-sterilized products.[4] USEPA estimates that as much as 1% of EtO used remains on sterilized products even after aeration.[5]

Comment 6-4

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[2] AQMD. (2023 March 23). *Proposed Amended Rule 1405 - Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slide 4]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par-1405---public-workshop_031723_draftfinal.pdf?sfvrsn=8.

[3] AQMD. (2023 March 23). *Proposed Amended Rule 1405 - Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slide 3]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par-1405---public-workshop_031723_draftfinal.pdf?sfvrsn=8.

[4] AQMD. (26 October 2022). *Proposed Amended Rule 1405 - Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes* [slide 16]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_wgm3_102122.pdf?sfvrsn=14.

[5] AQMD. (28 September 2022). *Proposed Amended Rule 1405 - Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes* [slide 32]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405-wgm2-092822.pdf?sfvrsn=14.

Labeling all materials that have been sterilized with EtO can be critical in protecting consumers and workers who are not aware of the toxic gas and its effect on human health.

Additionally, the timeframes for Medium Facilities' Stack and Fugitive Emission Requirements (e)(1)(2) should be shortened and like our recommendation for Large Facility Requirements, implementation should begin sooner either end of 2023 or summer of 2024, given the harmful effects of EtO exposure.

Comment 6-4 cont.

IV. Small Facility Requirements

Similar to the Large and Medium Facility Requirements, CBE also recommends changing the implementation dates for Small Facilites' Stack and Fugitive Emission Requirements (f)(1)(2). Instead of new requirements beginning in 2025 or 2026, requirements should start at the end of 2023 or summer of 2024, given the harmful effects of EtO exposure.

Comment 6-5

V. Warehouse Reporting Requirements

We appreciate AQMD requiring Large, New and/or Designated Warehouses to record the number of Sterilized Palletized Units received each month as well as other warehouse information in section (h)(2). CBE recommends the initial summary report include information such as the location of sensitive receptors within 500ft of warehouses, the wind direction at warehouses, and a diagram showing where pallets are received and stored at a warehouse. Per EPA, it's difficult to know how far EtO can travel due to factors such as concentration, weather conditions, wind speed, and the amount of dispersion.[6] As noted earlier, AQMD has even stated at the March 2023 Public Workshop that EtO can stay in the air for several months.[7]

Comment 6-6

VI. Permanent Total Enclosure Requirements

CBE recommends AQMD to adopt a stronger requirement for Permanent Total Enclosures (PTE) by requiring monthly monitoring of PTE for negative pressure efficiency. All PTE equipment should be regularly inspected every month for maintenance, quality assurance, predictive maintenance (if equipment is shown to be slowly deteriorating or failing) in order to protect workers and nearby communities.

Comment 6-7

VII. Lead Detection and Repair (LDAR) Program Requirements

While CBE appreciates AQMD requiring daily audio/visual checks for the LDAR program, we are concerned with the disadvantages of the LDAR control system. Per AQMD, Working Group #4 presentation stated that the disadvantages of LDAR can result with fugitive emissions being

Comment 6-8

[6] EPA. (2023, January). *Hazardous Air Pollutants: Ethylene Oxide.* USEPA. HYPERLINK "https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto."https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto.

[7] AQMD. (2023 March 23). *Proposed Amended Rule 1405 - Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slide 3]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par-1405---public-workshop_031723_draftfinal.pdf?sfvrsn=8.

emitted when repairs or replacements are conducted.[8] As it stands, the Proposed Rule states Large and Medium Facilities require either Permanent Total Enclosure (PTE) or the LDAR program to control fugitive emissions.[9] Does this mean that a Large and/or Medium Facility will continue operating if the LDAR control system breaks down? No facility that emits EtO should continue to operate without any fugitive emission controls given the dangers of EtO exposures. We urge AQMD to stop facilities who use LDAR from operating until repairs or replacements are resolved. EtO is a known carcinogen that can stay in the air for several months, which harms communities already heavily impacted by many pollution sources.

Comment 6-8 cont.

VIII. Reporting

As it stands, facilities are required to report within 30 days of exceeding the limit of permitted EtO use. CBE believes this is too large of a timeframe given the toxicity of EtO, its proximity to sensitive receptors, and the life span of EtO in the air. Therefore, AQMD should shorten the reporting from 30 days to 1 week to address exceedances in EtO permitted uses in order protect frontline communities.

Comment 6-9

IX. Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage

Similar to Reporting requirements, CBE feels that that the timeframe of 24 months for facilities to adhere to the applicable EtO usage is too long given the dangers of EtO emissions. Any facility that emits more EtO than its category amount should adhere to the requirements of the permitted usage as feasible as possible, preferably less than 6 months. This 24-month timeframe is concerning given the current history of large facilities in the South Coast Air Basin and its high EtO emissions. Facilities using EtO outside their category amount that do not have the proper control equipment and/or systems in place are a danger to nearby communities and the 24-month timeframe is too much of a public health risk.

Comment 6-10

X. Additional Recommendations for Proposed Rule 1405

We urge AQMD to endorse a stronger Rule 1405 by adding additional requirements that provide the following:

Encourage the Adoption of Technologies Above and Beyond Rule Requirements

USEPA is continuing to reassess the toxicity of EtO and current air regulations to determine whether legal standards for EtO emissions can be strengthened.[10] While CBE appreciates the AQMD taking initiative in investigating facilities that emit EtO in early 2022, we recommend

Comment 6-11

[8] AQMD. (17 January 2023). *Proposed Amended Rule 1405 – Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization of Fumigation Processes* [slide 31]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_wgm_presentation_011323.pdf?sfvrsn=8.

[9] AQMD. (17 March 2023). *Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slides 6-9]. , pgs 6-9http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdr1_031723_draftfinal.pdf?sfvrsn=8.

[10] EPA. (2022, December). *What EPA Is Doing to Address Ethylene Oxide and to Learn More About the Chemical.* USEPA. https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/what-epa-doing-address-ethylene-oxide-and-learn-more-about.

that AQMD adopt technologies that go above and beyond Rule 1405 requirements. AQMD noted in the third Working Group meeting that Rule 1405 requirements are currently more stringent than CARB's EtO Airborne Toxic Control Measures.[11] In addition, the California Office of Environmental Health Hazard Assessment is also currently reviewing the carcinogenicity of EtO.[12] This is to say that AQMD already takes the lead in requiring higher standards for controlling EtO emissions and should adopt stringent standards if AQMD has new research, data, and/or technologies that are available and efficient in reducing EtO emissions. This includes additional safety requirements and technologies for workers who are exposed to EtO daily. AQMD should revisit and amend the Rule any time there is new information or technology available for the control of EtO emissions.

Comment 6-11 cont.

Fenceline Monitoring

CBE urges AQMD to do fenceline monitoring at Large and Medium Facilities in order to protect communities who live and/or work near facilities that emit EtO. Fenceline monitoring can serve to better understand if the emissions controls put in place are working. For example, fenceline monitoring can determine how much fugitive emissions are emitted when a facility's LDAR control system is going through repairs. If AQMD does not plan to cease operations when there are LDAR repairs, then implementing a fenceline monitoring system can help make adjustments well before emissions levels become hazardous to the community or workers.

According to the USEPA, there are many benefits of fenceline monitoring. Fenceline monitoring can encourage early detection and correction of problems before they reach high emission levels.[13] Fenceline monitoring can help identify equipment and control system leaks and contribute to ongoing research of EtO emissions on the federal, state, and local level, including the community.[14] AQMD already has a history of using fenceline monitoring of EtO emissions as their Preliminary Draft Staff Report for Rule 1405 states how fenceline monitoring was conducted at three sterilization facilities with elevated signals of EtO.[15] Fenceline monitoring proved to be effective in detecting high EtO emissions and whether Sterigenics Vernon's Early Action Reduction Plan (EARP) and interim measures were successful in reducing and controlling EtO Emissions.[16]

Comment 6-12

[11] AQMD. (26 October 2022) *Working Group #3: Proposed Amended Rule 1405 - Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization of Fumigation Processes* [slide 30]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_wgm3_102122.pdf?sfvrsn=14.

[12] Ibid, slide 30.

[13] EPA. (2016, June). *Petroleum Refinery Fenceline Monitoring Stakeholder Engagement*. USEPA. [slide 9]., pg 9.

[14] Ibid.

[15] AQMD. (2023 March). *Preliminary Draft Staff Report Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations*. SCAQMD. pgs 1-7. http://www.aqmd.gov/docs/default-source/rule-book/Proposed Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8.

[16] Ibid.

Overall, fenceline monitoring provides additional protection for frontline communities who already face cumulative impacts from many pollution sources and serves to measure the efficiency of control systems and technologies of EtO emissions.

Comment 6-12 cont.

Effective and Productive Interagency Coordination

CBE has voiced on separate occasions that AQMD needs to cooperate with other state and local regulatory agencies to enforce facilities to comply with best practices for frontline communities.[17] Given the toxicity of EtO, AQMD should coordinate with CalOSHA to better protect workers - being that they are the most impacted group in polluting facilities, are frequently people of color or low-income and may also live in the local community. AQMD should also coordinate with the State Water Board to ensure that facilities are not discharging any Sterilizer Exhaust Vacuum Pump working fluid or any EtO contaminated liquids to the wastewater stream.[18] Interagency coordination is instrumental in protecting public health and the environment, and AQMD should consider hosting interagency community workshops that foster an inclusive and accessible environment for the community.

Comment 6-13

Alternatives to EtO Sterilization

Currently, ethylene oxide accounts for approximately 50% of devices that require sterilization given its advantage of low temperature, penetration of products, and large capacity usage.[19] But ethylene oxide is a known carcinogen by AQMD, OEHHA, and the USEPA, and yet it continues to be used for sterilization and other industrial usage.[20] CBE encourages AQMD to look at alternatives to EtO sterilization such as ionizing radiation (gamma),[21] steam methods, hydrogen peroxide vapor, [22] and other safe alternatives human health. The lack of material compatibility of EtO and industrial feasibility should not sacrifice the health of communities, workers, and the

Comment 6-14

[17] AQMD. (2022, November) *BOARD MEETING DATE: November 4, 2022: AGENDA NO. 28.* SCAQMD. pg A-31. http://www.aqmd.gov/docs/default-source/Agendas/Governing-Board/2022/2022-Nov4-028.pdf?sfvrsn=6.

[18] AQMD. (2023 March). *Preliminary Draft Rule Language*. SCAQMD. pg 24. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdrl_031723_draftfinal.pdf?sfvrsn=8.

[19] AQMD. (17 August 2022). *Proposed Amended Rule 1405 – Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes*. [slide 14-15]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_wgm1_081122.pdf?sfvrsn=6.

[20] AQMD. (28 September 2022) *Working Group #2: Proposed Amended Rule 1405 - Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes* [slide 10]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405-wgm2-092822.pdf?sfvrsn=14.

[21] Gamma Industry Processing Alliance. (2017 August). *A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products*. Stanford University. pgs 10-11. http://large.stanford.edu/courses/2018/ph241/goronzy2/docs/gipa-aug17.pdf.

[22] Shahbandar, Lena. (2018 November). *Alternatives to Ethylene Oxide*. StopSterigenics. https://www.stopsterigenics.com/post/alternatives-to-ethylene-oxide.

environment. AQMD should reconsider adopting sterilizing alternatives based on material combability as a solution to reduce and control EtO emissions.

Comment 6-14 cont.

XI. Conclusion

We appreciate the work of AQMD on Proposed Rule 1405 and the opportunity to comment. We highly encourage AQMD to endorse a stronger Rule. We welcome the opportunity to discuss these matters.

Sincerely,

Ambar Rivera
Staff Researcher

Responses to Communities for a Better Environment Comment Letter, submitted 4/16/2023

6-1 Response: Staff has considered tighter performance standards than currently proposed and shorter implementation timelines and determined that those are not currently feasible. PAR 1405 now requires that large facilities performing sterilization conduct interim mobile monitoring and fenceline air monitoring until continuous or semi-continuous stack emission monitoring are fully operational. As demonstrated via monitoring data at the two sterilization facilities subject to the EARP, after implementing measures to address stack and fugitive emissions, EtO levels were reduced to near background levels. PAR 1405 requires large facilities to monitor stack emissions and monitor parameters to ensure proper operation of fugitive emission controls. This ensures that sterilization facilities are implementing demonstrated measures to control EtO emissions. Additionally, Tier I Warehouses are required to conduct one year of fenceline air monitoring or other emission evaluations.

See Response 1-4 regarding proposed NESHAP.

6-2 Response: Thank you for the comment.

6-3 Response: Staff has received several public comments regarding the implementation timeframe, and most expressed concerns of supply chain, time needed for engineering evaluation, time needed to obtain building permit for PTE construction, and increasing lead time of control and monitoring equipment driven by the release of proposed NESHAP. PAR 1405 includes extensive requirements including PTE and very stringent stack emission limits. It is anticipated that most large and medium facilities will have to install new control equipment and make modifications to existing building structure to comply with the rule. To better reflect a feasible timeframe, PAR 1405 has been revised to increase implementation timelines by six to eight months for large and medium facilities.

6-4 Response: Staff agrees that extending the labeling requirements to medium facilities could provide benefits as medium facilities are often commercial sterilization facilities. PAR 1405 has been revised to include the labeling requirements for medium facilities.

See Response 6-3 regarding implementation timeframes.

6-5 Response: Staff has received public comments regarding the implementation timeframe, the concerns of supply chain, time needed for engineering evaluation, time needed to obtain building permit for PTE construction, and

increasing lead time of control and monitoring equipment driven by the release of proposed NESHAP. Despite these concerns, the implementation timeframe for small facilities is expected to be feasible (i.e., by January 1, 2026).

6-6 Response: PAR 1405 has been revised to require a diagram showing where pallets are received and stored at a warehouse.

6-7 Response: The PTE requirements for large facilities in PAR 1405 go above and beyond U.S. EPA Method 204 by requiring continuous monitoring of differential pressure and periodic checks of facial velocity at all natural draft openings. These proposed requirements are also more stringent than other South Coast AQMD rules that include PTEs. Staff believes the proposed requirements would ensure capture of all fugitive emissions at subject sterilization facilities.

6-8 Response: PAR 1405 requires facilities to report operational noncompliance, including leaks detected under an LDAR program, to South Coast AQMD for compliance and enforcement action.

6-9 Response: Staff believes 30 days is appropriate to report when facilities exceed a limit of permitted EtO use as PAR 1405 requires owners and operators to maintain records regarding EtO sterilant gas used per calendar month.

6-10 Response: The intent of the subdivision is to provide a mandatory compliance pathway for facilities exceeding EtO thresholds and require these facilities to make changes to their facilities. The implementation timeframe of 24 months is consistent with the implementation schedule for large facilities in PAR 1405.

6-11 Response: PAR 1405 is based on the best available technology achieved-in-practice. Staff is committed to evaluate new technologies reducing EtO as they become available.

6-12 Response: See Response 6-1 regarding fenceline air monitoring.

6-13 Response: Staff has engaged with other regulatory agencies in this rulemaking process and is committed to working cooperatively with regulatory partners to protect public health from EtO.

6-14 Response: As noted in Working Group Meeting #1, there are alternatives to EtO sterilization in commercial use as well as new and emerging technologies in development. As noted in the comment, the lack of material compatibility for some materials remains an issue. According to U.S. FDA, EtO may be the only effective and approved sterilization method for many medical devices. PAR 1405 includes stringent performance standards to ensure EtO

emissions are reduced to the maximum extent possible based on technology achieved-in-practice.

ADVAMED SPECIFIC COMMENTS RE. SCAQMD PRELIMINARY DRAFT AMENDED RULE 1405 -- CONTROL OF ETHYLENE OXIDE EMISSIONS FROM STERILIZATION AND RELATED OPERATIONS (RELEASED IN CONJUNCTION WITH MARCH 23, 2023 PUBLIC WORKSHOP)

Section – Section of the preliminary draft rule.
Comment – Comment.
Rationale – Rationale for the comment.

#	Section	Comment	Rationale for Comment
1	General	As we have outlined in previous feedback and in our overall comments, we continue to have concerns regarding the very short timeframe for consideration and implementation of this proposal given the wide scope and complexity of substantial updates, confusing terminology, reliance on highly specific and unproven technologies, limited supply base and timeline for compliance, and critical capacity considerations for patient access to medical technologies. With the draft EPA proposed rulemaking now released and undergoing a significant review process, this strongly underscores our request for a pause in moving forward with the rule until after EPA completes its update of its EtO rulemaking. This will help inform a meaningful rule that can be implemented in the context of rigorous federal standards and that avoids direct conflict, including provisions that cannot be implemented with different competing processes in direct conflict with each other and rendering recommendations infeasible. Proposing a rule prior to the EPA rulemaking finalization will lead to serious and deleterious conflicts. Understanding the SCAQMD rule is still in draft form, we urge this reasonable pause to assist with relevant and workable consideration of the rulemakings. In short, the dates both for rulemaking and implementation timelines are far too short to execute effective actionable regulation. As FDA and EPA note, EtO is the only viable effective sterilization option for many devices. Any disruption in critical sterilization infrastructure could lead to delays in patient care and jeopardize vital	

#	Section	Comment	Rationale for Comment
		access to sterile medical devices. The expeditious fashion of this rulemaking has stymied public comments and will result in unenforceable rulings, unintended public health risk, and inconsistencies with federal rules. The time period for this rulemaking is much too short.  Please note these comments are not intended to be comprehensive in nature, but they represent feedback we are able to provide in the time period provided for review.	
2	General	On multiple occasions, the proposal references a 'sterilizer' as distinct from a 'sterilizer/aerator'. Most if not all industrial sterilizers are inherently also sterilizers/aerators because aeration inside them can continue via extending the quantity and/or time of the post-EtO dwell gas washes. The amended rule defines 'Sterilizer' as being any chamber or related piece of equipment excluding a combined sterilizer/aerator.	A separate definition for sterilizer/aerator is not needed when an industrial sterilizer fulfills this same functionality.
3	General	There does not appear to be control efficiencies listed for facilities with high volume, low concentration EtO emissions such as from aeration or chamber back vent emission control systems. Their data is only for combined (high volume / low concentration & low volume / high concentration) or high concentration only.	This is a critical gap in the proposed rule. The

Comment 7-1

Comment 7-2

Comment 7-3

#	Section	Comment	Rationale for Comment
			proposed rule of 99.99% destruction efficiency or < 0.01 ppm is not achievable for the dry bed adsorber systems typically used to control EtO emissions from high volume, low flow sources such as aeration rooms and chamber back vents. Based on source test publicly available and typical for AAT dry bed systems, it appears SCAQMD seems to have used specific results as the basis for other parts of their rule such as the 0.025 lbs/hour max emissions limit yet has not accounted

#	Section	Comment	Rationale for Comment
			for EtO concentration coming out of the dry bed system above 0.01 ppm while the destruction efficiency ranges from 99.2% to 99.6% (which is below the proposed 99.99% destruction efficiency).
4		It is unclear why 0.1 ppm is used as a regulatory threshold.	Does this assume uniform concentration throughout the indoor area? There will be variability depending on area. Concentration is also highly dependent on mixing of the air in the space. EtO is heavier than air. Also note that the measurement of control device destruction

Comment 7-3 cont.

Comment 7-4

#	Section	Comment	Rationale for Comment
			efficiency will be problematic at inlet concentrations of 0.1 ppm and below.
5	General	We note that SCAQMD has listed EtO monitoring technologies that may not be able to detect to 0.01 ppm or are new and not tried and proven for industrial EtO sterilization facility use. For instance, some monitoring technologies may not be usable for monitoring stacks of wet acid scrubbers due to moisture content.	Consider the technical limitations of detection and available technology.
6	General	The use of the LOD versus a Lower Limit of Quantification (LLOQ) should be considered. Since 10 ppb (0.01 ppm) is being proposed as the limit, it should be based on what can be determined with certainty better than +/- 50% otherwise undue process interruptions will occur.	The LOD has significant uncertainty (usually +/- 50%). The LLOQ, while 3x the LOD, has greater certainty (+/- 10%-15%). The LOQ should be used instead of the LOD. Specifying a standard of 10 ppb may also eliminate some technologies that are currently available. Raising the standard from
#	Section	Comment	Rationale for Comment
			10ppb to 30 ppb does not obviate the 0.025 lbs per hour limit.
7	General	Requiring 99.99% DRE or 0.01 ppm eliminates the use of many pollution control devices that are currently installed and result in low actual emissions. If the goal is below 0.025 lbs/hour as an average, technology should be allowed that meets that requirement.	Utilize a flexible performance-based standard allowing for technologies deployed that reduce emissions.
8	(c) (6) Definition of Continuous Emission Monitoring System (CEMS)	The requirement for one (1) minute readings is not feasible. Further with respect to the proposed recommendation for a minimum of one measurement (e.g., concentration, mass emission, flow rate) taken and recorded every one minute, this technology is not proven to work with all abatement equipment.	The one-minute reading is limited to a single technology that is not proven to work with all abatement equipment. This is in direct conflict with statement of being technology neutral. Revise to a reasonable interval (i.e., at least 15 minutes) that is recognized and workable with abatement equipment for

Comment 7-4 cont.

Comment 7-5

Comment 7-6

Comment 7-7

Comment 7-8

#	Section	Comment	Rationale for Comment
			purposes of this type of monitoring and CEMS should include examples of the technologies in the SCEMS definition.
9	(c)(9) Definition of Designated Warehouse	There is little information on the basis for the Executive Officer to make the determination that a designated warehouse is a "potential source of Ethylene Oxide emissions." We do not understand what that means.	Definition requires clarification.
10	(c) (10) Definition of Element	It should be clear that sterilized product and shipping containers are not elements.	Definition requires clarification.
11	(c) (16) Definition of Leak	Leak is defined as 2 ppm. The definition simply states 'above background'. There is not a background definition, and CARB Test Method 21 does not need it to be applied as a standard.	Further consideration requested.
12	General-Warehouses, (c)(19), and (h)	This approach may lead to poor rule development. Each pallet will be different in content. Definition of sterilized palletized unit needs to be provided. Unclear if that would include products sterilized as a palletized unit or sterilized individually and then assembled into a palletized unit, or both. Further, the definitions as drafted for warehouse types do not include anything about EtO. This definition is too broad and could capture warehouse spaces that do not have any EtO sterilized product.	Additional definition required. We propose maintaining the sterilized palletized unit reporting
#	Section	Comment	Rationale for Comment
	Warehouse Tracking and Reporting Requirements	Importantly, concept of term "sterilized palletized unit" is not trackable and industry standardized data point for warehouses. Pallets may contain an inconsistent number of products from shipment to shipment. Most systems instead track individual SKUs and their respective quantities. Additionally, while medical device manufacturers and distributors track which product is sterile or not sterile, the specific sterilization modality may not be tracked with inventory management systems given the large universe of sterile items and various methods of sterilization, such as steam, gamma, e-beam, etc. Further, supply chains are global in scale. Product may be sterilized and imported from outside of the United States by third parties – perhaps weeks if not months before transiting through a warehouse located in South Coast's jurisdiction. The original sterilizer may be several companies removed from the final medical device distributor, which further complicates data reporting requirements.	requirements for large sterilization facilities but not imposing reporting requirements for warehouses. With the existing large facility requirements, South Coast will have visibility into product sterilized within and delivered to entities within their jurisdiction. This will allow South Coast to focus data collection for products that were more recently sterilized.
13	(c) (21) Definition of PTE	Defining a PTE as an enclosure that has been evaluated to meeting design requirements set forth in US EPA Method 204 and then promulgating verification requirements in Appendix 3 in excess of Method 204 requirements is not consistent. PTE requirements should match Method 204 requirements. The US EPA FAQ for Method 204 at (Frequently Asked Questions (FAQs) for Method 204 (epa.gov) question 2 states that either a calculation of average face velocity or a measurement of static pressure is sufficient. Both are not required.	Further consideration requested.

Comment 7-8 cont.

Comment 7-9

Comment 7-10

Comment 7-11

Comment 7-12

Comment 7-13

#	Section	Comment	Rationale for Comment
14	(c) (25) Definition of Semi-Continuous Emission Monitoring System (SCEMS)	The definition for SCEMS should be anything greater than 15 minutes. This allows for the use of multiple technologies as outlined in the definition. The Continuous Emissions Monitoring System (CEMS) definition does not include this because there is only a single technology available, and it is proven to not work on all abatement equipment. SCEMS monitoring equipment definition should be included in CEMS.	Fifteen (15) minutes should be the CEMS interval definition and CEMS include the list of technologies included in the SCEMS definition. Further, the relative standard deviation across readings is highly consistent and strongly indicates confidence in readings up to 6 hour intervals in low and / or relatively stable concentration areas, like warehouses. SCEMS should be used for these extended intervals (greater than 15 minutes).
15	(d) Large	Please confirm that all APCD, including those used for PTE in a warehouse, require CEMS or Annual Source Testing.	Clarification.

#	Section	Comment	Rationale for Comment
	Facility Requirements		
16	(d) (1) and (d) 2) Large Facility Stack Emission Requirements and Emission Monitoring Requirements	What is the purpose of requiring annual source testing and CEMS/SCEMS? Additionally, the source testing requirement and the CEMS/SCEMS requirements do not align.	Annual source testing is redundant where approved CEMS /SCEMS is in place. Requiring annual source testing necessitates the use of additional EtO to achieve required input testing concentrations sufficient to demonstrate compliance as the available technology capabilities are not able to meet the source testing requirements outlined.
17	(d) (2) Large Facility Stack Emission	Multiple CEMs for a facility may be cost prohibitive. Consideration of CEMs used for sources that do not have rapid changes in concentration, such as warehouses, should be given.	A CEMs system costs approximately $200-300K per stack. Warehouses

Comment 7-14

Comment 7-15

Comment 7-16

Comment 7-17

#	Section	Comment	Rationale for Comment
	Monitoring Requirements		or other storage areas do not experience rapid changes in concentration. A single CEMs system could be used to sample multiple low concentration stacks and not compromise data quality.
18	(d) (3) Large Facility Fugitives Emissions Requirements	Waste storage areas are not usually part of the enclosed facility since it is a byproduct of the abatement systems. We recommend allowing for LDAR for external sterilant gas storage and waste storage areas and PTE for the remaining internal areas outlined. All components of fugitive emission control systems cannot be physically housed within a PTE, and components under negative pressure will not leak to atmosphere, therefore only LDAR requirements should apply to external control system components under positive pressure.	Neither control technologies nor waste storage systems are able to be located inside buildings / PTEs due to operational and access requirements. Implementing an LDAR system will ensure those areas not within PTE are fully contained and monitored per the intent of the proposed rule.

Comment 7-17

Comment 7-18

#	Section	Comment	Rationale for Comment
19	(g) Post-Aeration Storage Facility Requirements and General	It is critical that reasonable implementation timeframes be set forth in this proposed updated rulemaking.	As with the other proposed rulemaking provisions and regardless of type of sterilizer, the timelines are much too short for implementation in this proposed rulemaking.
20	(h) Warehouse Tracking and Reporting Requirements	Please provide clarification on tracking of shipments to large warehouses (e.g., sterilizer direct to warehouse). Please provide exclusion for limited quantity shipments (e.g., parcel and LTL shipments).	Clarification.
21	(i) Interim Requirements	The implementation date is unclear for these interim requirements.	Clarification.
22	(j)(3) SCEMS, CEMS, or Other Monitoring Requirements	Back power for CEMs is not required during a power outage as there is no flow through the APCD. Backup power systems sufficient to operate the required equipment do not produce electricity instantaneously	Generators typically require 5 to 10 seconds of startup time before providing power. Most equipment fed by the generator would

Comment 7-19

Comment 7-20

Comment 7-21

Comment 7-22

#	Section	Comment	Rationale for Comment
			also then require a re-start.
23	(k) General-PTE	Method 204 PTE is problematic for typical warehouse design and would require significant modification to existing facilities, including additional space, to implement. Method 204 provides for a choice between verification methods and does not require both implemented simultaneously.	Atmospheric conditions may preclude achieving adequate negative pressure and inward air flow velocity (specifically, wind) at all times. This is redundant and does not provide value. Verification of flow method can be done parametrically and fan operation continuously measured and monitored to ensure conformance with the standard.
24	(k) General-PTE	Enclosure is not feasible for all piping and pollution control systems.	We strongly encourage further consideration. Not all facilities are designed and

#	Section	Comment	Rationale for Comment
			engineered in the same manner. Not all components can be physically housed within. Consequently, how one site can achieve acceptable air emission control may not work for another site. It will be dependent on facility design.
25	(k) General-PTE	For internal spaces, can indoor monitoring be done rather than PTE? Overall, clarification needed on whether PTE is required for sterilization, aeration, and storage/transport, etc. or if LDAR and Monitoring are an option since PTE is not feasible between areas of the building.	Clarification.
26	General-PTE and (k)(1)	Doors "closed during routine operations" is problematic for warehouse operation where trucks are routinely loaded and unloaded. This may also be problematic to achieve in facilities subject to FDA GMP requirements. Maintaining at least 0.007 inches of water column for a building with loading/unloading at dock doors may not be achievable at all times	Product movement into and out of the building is part of routine operations at the types of facilities under discussion. Atmospheric conditions may preclude achieving

Comment 7-22

Comment 7-23

Comment 7-24

Comment 7-25

Comment 7-26

#	Section	Comment	Rationale for Comment	
			adequate negative pressure and inward air flow velocity (specifically, wind) at all times.	Comment 7-26 cont.
27	(k)(1) PTE	Indoor monitoring produces varying results depending on the exact location of the sensor relative to product, docks, internal air flow patterns, etc. PTE assumes that the enclosures are separated from each other. As previously mentioned in most facilities, the areas described in the proposed rule are connected to each other and maintaining – 0.007" w.g. from each other is not feasible. For instance, the chamber room air may flow to aeration and therefore is not negative to that space but may be negative to the exterior of the building.	Further consideration requested.	Comment 7-27
28	(k)(1) PTE	Continuous parameter monitoring will already be in place with a reading at least every 15 minutes - requiring an average over just 1 minute does not allow for NDOs (such as an entry or rollup door) that are operated during the period to average the pressure. The language should be adjusted for consistency.	Requirement as written cannot be met during normal operations. Further consideration requested.	Comment 7-28
29	(k)(2) PTE	Why are three monitoring locations required in cases when a single monitoring location is representative of the pressure drop across the openings? Pressure drop measurements performed at a single representative location are enough to verify a functioning PTE. The added expense and effort associated with three measurement locations rather than one is not justified and does not provide sufficient (if any) added value. In addition, not all PTEs will have an exterior wall that is Leeward or Windward – some PTEs may be fully internal to a building.	Further consideration requested.	Comment 7-29

#	Section	Comment	Rationale for Comment	
30	(k) (1), k (2), and k (3) PTE	Continuous Differential Pressure Monitoring and Monthly Inward Air Velocity Measurements. Differential pressure across a PTE and inward air velocity at NDOs are redundant parameters for assessing whether fugitive emissions are being captured by a PTE. For example, EPA Method 204 only requires either differential pressure monitoring or inward air velocity determinations, not both equivalent assessments. Therefore, it is unnecessary to require both continuous differential pressure monitoring and monthly inward velocity determinations. Suggest aligning with Method 204 or other method that meets the intent.	Further consideration requested	Comment 7-30
31	(m)(5)(B) and (m)(5)(C) Source Test Requirements	Testing required at permitted maximum, typical and normal operating conditions. Is the requirement for three (3) runs of testing at both maximum and typical operating conditions for a total of six (6) testing runs? If so, why is more stringent testing than existing standards required?	Clarity needed on requirements	Comment 7-31
32	(m)(5)(C) Source Test Requirements	Not all sterilization/aeration cycles last 60 minutes, especially for small and medium facilities. Rule should allow for test runs for sterilization/aeration cycles of less than 60 minutes to document compliance when appropriate.	Further consideration requested	Comment 7-32
33	(n) General-LDAR	Current EPA Leak Detection and Repair (LDAR) leak definitions generally are 500 ppm and not applicable to EtO.	At 2 ppm TOC, it may be difficult to distinguish between EtO and other VOCs (such as propellants for lubricants), creating a "false positive."	Comment 7-33

#	Section	Comment	Rationale for Comment
34	(n) General-LDAR	As written, including the Control System in the LDAR would unnecessarily include sections of control system that are under negative pressure and would not be considered a source of equipment leaks (Leak Detection and Repair Compliance Assistance Guidance Best Practices Guide). The proposed rule should not include negative pressure components of the control system before or after the treatment system if there are other means of ensuring the ductwork or system is maintained at that negative pressure. Consider exception to LDAR for equipment and piping that are under negative pressure at all times.	Under negative pressure, all flow will be into the equipment/pipe, resulting in no detection of leaks. Leaks on a negative pressure system do not result in releases out of the system and these systems can be monitored continually to ensure proper function.
35	(n) (3) LDAR	In the absence of any specific details regarding "maintaining" Components and Elements subject to the LDAR program free of Leaks greater than 2 ppm above background, would an acceptable approach be for subject sites to document an internal process and/or procedure for maintaining Components and Elements Leak free? For example, sites would document reasonable time periods, based on site resources, for repairing Leaks after found that demonstrate that, if followed, the site is "maintaining" Components and Elements free of Leaks and addressing Leaks in a "timely manner" as specified on page 2-14 of the "Preliminary Draft Staff Report" dated March 2023. Sites would also document plans for addressing a Component or Element Leak that can't physically be repaired to stop the Leak without replacing it with a new Component or Element, including documenting the procedure to be followed when a new Component or Element is not readily available.	Leak free reference is confusing. Clarity needed on requirements.

Comment 7-34

Comment 7-35

#	Section	Comment	Rationale for Comment
36	(n) (3) LDAR	A leak definition of 2 ppm above background is not reasonable per the following considerations. (1) CARB Method 21 equipment (i.e., monitoring instrument, calibration gases) that satisfies the scale (i.e., 2.5% of 2 ppm = 0.05 ppm), calibration precision (<10% of 2 ppm = <0.2 ppm), and calibration gas accuracy (±2% of 2 ppm = ±0.04 ppm) requirements may not be readily available. The added difficulty and effort associated with such a low leak definition is not justified and does not provide sufficient (if any) added value relative to a higher leak definition, such as the existing leak definition that could be more confidently detected (10 ppm).	Further consideration requested.
37	(n)(4) LDAR	Daily audio-visual (AV) checks required. The most frequent periodic AV checks in typical LDAR regulations is weekly. Weekly inspections at most, with an added requirement to respond in the event of any evidence of a potential leak to the atmosphere is found by visual, audible, olfactory, or any other detection method, would be more in line with existing, effective LDAR regulations. The statement included on page 2-14 of the "Preliminary Draft Staff Report" dated March 2023 indicating "[t]his approach is consistent with other VOC regulations addressing fugitive emissions from oil fields, refineries, and chemical plants" is an inaccurate statement.	Further consideration requested.
38	(n) (5) LDAR	Please consider adding reasonable exceptions that are common in LDAR regulations to the monthly inspection requirement. What if a component or element is not readily accessible (e.g., requires a manlift to access)? What if a Component or Element isn't accessible safely on a monthly basis? Can the regulations be modified	Further consideration requested.

Comment 7-36

Comment 7-37

Comment 7-38

#	Section	Comment	Rationale for Comment
		to include for the development of a plan for monitoring such Components and Elements on a greater than monthly frequency if adequate justification is provided in the plan? Might consider frequency of LDAR inspections be aligned with current LDAR programs. They require inspections quarterly (except liquid pumps, which are monthly, and visual checks on liquid service equipment which is daily). Should also allow all methods in CARB 21, not just 2 of the 4 stated.	With the presence of PPM monitoring systems (used to ensure associate exposure remains low), possible leaks in process areas will be identified in a short amount of time. Inappropriately excludes PID and Catalytic Oxidizer types without another approval step.
39	(n) (5) LDAR	There is no detail given for specific requirements of meter characteristics (response time, accuracy, detection threshold, pump vs passive sensing, frequency of meter testing and calibration). The leak threshold must be specific to EtO and not subject to interference from other maintenance chemicals used in the area.	There are a wide variety of meters on the market, with a very wide range of characteristics. Many available meters would not be capable of producing a consistently accurate result.

Comment 7-38 cont.

Comment 7-39

#	Section	Comment	Rationale for Comment
40	(n)(6) LDAR	The requirement to record results of daily audio-visual checks or monthly leak inspections at all components and elements implies either may be performed, but the previous sections indicated both must be performed. Please clarify.	Further consideration requested.
41	Appendix 3 and Related	If negative pressure is continually monitored, monthly face velocity tests are redundant and unnecessarily burdensome.	Requiring both is redundant and not necessary.
42	Appendix 3 and (k)(3)	PTE Inward Face Air Velocity Measurement – EPA Method 204 does not require direct measurements of inward face air velocity at each NDO. Rather, only the calculated facial velocity of air through all NDOs is calculated and compared to the 200 fpm criteria. The proposed PTE Inward Face Air Velocity Measurement procedure will not consistently allow for the determination of representative NDO face velocities. There are established existing EPA Methods for identifying sample points (EPA Method 1 and 1A) and for measuring air velocity (EPA Methods 2-2H) that account for various configurations (e.g., disturbances) and conditions (e.g., ambient) that are completely ignored by the procedure proposed in Appendix 3. The existing facial velocity requirement in EPA Method 204 involves the determination of representative flows which in turn allows for the calculation of a representative facial velocity (FV) for reasonable comparison to the 200 fpm criteria.	Further consideration requested.
43	(o)(4) Prohibitions	Please provide exemption for limited quantity of product where product testing is required (e.g., cycle development, QA/QC, R&D, validation).	Clarification.

Comment 7-40

Comment 7-41

Comment 7-42

Comment 7-43

Responses to AdvaMed Comment Letter, submitted 4/16/2023

7-1 Response: See Response 1-1 about the public process of PAR 1405.

See Response 1-2 regarding implementation timeframe.

See Response 1-4 regarding proposed NESHAP.

7-2 Response: Staff disagrees that a separate definition for combined sterilizer/aerator is not needed. While some off-gassing of EtO occurs in standalone sterilizers, additional time under specific conditions, known as aeration, is required to achieve residual levels of EtO to ensure patient safety. Only specific tested and validated cycles designed for combined sterilizer/aerators complete aeration in-chamber, do not require pre-aeration handling, and do not have EtO emissions associated with pre-aeration handling. As such, PAR 1405 does not require combined sterilizer/aerators be maintained under PTE at medium or small facilities.

7-3 Response: Large facilities with control systems with high volume, low concentration EtO emissions may choose to comply with the 0.01 ppm outlet concentration performance standard as opposed to the 99.99% control efficiency performance standard.

See Response 1-3 regarding technological feasibility of performance standards in PAR 1405.

7-4 Response: PAR 1405 does not include indoor concentration monitoring or a 0.1 ppm regulatory threshold.

7-5 Response: Each EtO monitoring technology has its own specific technical limitations. PAR 1405 is technology-neutral and allows for multiple compliance pathways while still maintaining its goal of reducing and verifying reductions in EtO emissions.

7-6 Response: After careful consideration, PAR 1405 has been revised to require a resolution of at least 0.001 ppm and the averaging time has been revised from daily averaging to rolling 30-day averaging.

7-7 Response: PAR 1405 uses a combination of performance standards at large facilities to address control systems with high inlet concentrations, control systems with low inlet concentrations, and facilities with high throughput. Control efficiency, outlet concentration, and mass emission rate limits, respectively, address each specific facet of EtO air quality concern.

Also see Response 1-3.

7-8 Response: PAR 1405 does not require the use of CEMS and allows for the use of SCEMS with a 15-minute time interval.

7-9 Response: PAR 1405 has been revised to remove this provision.

7-10 Response: PAR 1405 has been revised to add clarity to the definition of element as suggested.

7-11 Response: PAR 1405's definition of leak and the phrase "above background" is consistent with other South Coast AQMD rules that define "leak", such as Rule 1173. Staff disagrees that a definition for "background" is needed in PAR 1405.

7-12 Response: Staff reached out to multiple warehouses stakeholders to determine if sterilized palletized units, trailer truck loads, or some other measure of deliveries of sterilized materials was selected. Based on stakeholder feedback, tracking and reporting of sterilized palletized units is used. PAR 1405 includes tracking and reporting of sterilized palletized units for one 12-month period for large facilities and warehouses.

Staff agrees that the potential of EtO emissions from warehouses depends on many factors and now requires fenceline air monitoring, an emission study, or contribution to a real-time fenceline air monitoring demonstration program for Tier I Warehouses.

7-13 Response: Staff believes continuous PTE monitoring of negative pressure with redundant periodic inward face velocity measurements ensures capture of fugitive EtO emissions.

Also see Response 4-4.

7-14 Response: Defining SCEMS as greater than a 15-minute time interval is not consistent with South Coast AQMD emission monitoring Rules 218, 218.1, 218.2 and 218.3. In addition, the proposed NESHAP includes a 15-minute time interval for continuous monitoring.

7-15 Response: PAR 1405 requires all control systems, regardless of APCD technology, be source tested annually if demonstrating control efficiency or annual RATA if demonstrating 0.01 ppm outlet concentration and the facility-wide mass emission rate with CEMS (or SCEMS) at large facilities.

7-16 Response: See Response 3-16.

7-17 Response: Under PAR 1405, large sterilization facilities may combine multiple exhaust stacks into a single monitored emission stack, monitor multiple exhaust stacks with a single SCEMS or CEMS on a timesharing basis, or employ a dedicated emission monitoring system for each exhaust stack.

7-18 Response: This Draft Staff Report clarifies that fixed tanks associated with acid-water scrubbers, such as ethylene glycol tanks, are not considered elements of a waste storage area and are instead part of a control system and are required to be monitoring under an LDAR program.

7-19 Response: PAR 1405 has been revised to allow post aeration storage facilities until September 1, 2025 to comply with new requirements.

7-20 Response: PAR 1405 defines "palletized unit" and believes the rule language is clear that a parcel or a less than truckload (LTL) shipment, if not in a palletized unit directly from a sterilization facility, is not required to be tracked and reported by a warehouse.

7-21 Response: PAR 1405 interim requirements would take effect immediately upon rule adoption and were written to mirror existing Rule 1405 language and/or meaning with a table of sunset dates listed in PAR 1405.

7-22 Response: After speaking with vendors and other stakeholders regarding emission monitoring systems, staff anticipates CEMS or SCEMS to be equipped with backup battery power, not generators, to deliver primary uninterruptable power and PAR 1405 requires 60 consecutive minutes of backup battery power.

7-23 Response: See Responses 3-13 and 4-4.

7-24 Response: PAR 1405 allows control systems and associated piping either to be held under PTE or alternatively monitored under an LDAR program.

7-25 Response: PAR 1405 does not allow for indoor monitoring as an alternative compliance path to PTE requirements.

7-26 Response: Staff expects some retrofitting to occur at facilities required to maintain some or all their operations under PTE. For natural draft openings, owners or operators may choose to employ measures such as fast-opening rollup doors, double-doors/vestibules, or other measures to comply with PAR 1405.

7-27 Response: Indoor EtO monitoring is not a compliance path within PAR 1405. Regarding PTE, see Response 7-26.

7-28 Response: See Responses 3-13 and 4-4.

7-29 Response: PAR 1405 continuous PTE monitoring requirements are based on monitor strategies achieved-in-practice, specifically continuous PTE monitoring requirements in Rule 1420.1 regarding large lead-acid battery recycling requirements as well as continuous PTE monitoring requirements in a Permit to Operate for an existing EtO sterilization facility in South Coast AQMD.

7-30 Response: See Response 4-4.

7-31 Response: PAR 1405 has been revised to clarify that triplicate runs at either typical or maximum operating parameters are required.

7-32 Response: The minimum testing time is consistent with existing Rule 1405 requirements, and have been performed in many source tests for sterilization facilities including small and medium facilities.

7-33 Response: Staff anticipates changes to implement LDAR programs and the 2 ppm threshold including unit replacement, bulb changeout, new calibration gases, or upgrades with additional software for photoionization detectors to comply with lower leak threshold standards.

7-34 Response: Staff has carefully considered possible exceptions to components under negative pressure but because of the nature of EtO as a VOC and a toxic air contaminant, no exceptions are appropriate under an LDAR program.

7-35 Response: See Response 7-34.

7-36 Response: Because of the nature of EtO as a VOC and a toxic air contaminant and OSHA workplace standards regarding excursion limits, a definition for leak at 10 ppm is not appropriate and a definition for leak below the current EtO excursion limit of 5 ppm, at 2 ppm, is more appropriate.

7-37 Response: Because of the nature of EtO as a VOC and a toxic air contaminant, staff believes more frequent audio-visual checks are warranted but the approach of audio-visual checks is consistent with LDAR programs for oil fields, refineries, and chemical plants.

7-38 Response: See Response 7-34 in response to exceptions. PAR 1405 has been revised to reduce the frequency of leak inspections to every 60 days.

PAR 1405 allows for any method or instrument if approved by the Executive Officer but identified "portable photoionization detector" specifically.

7-39 Response: PAR 1405 refers to CARB Test Method 21 for these specific requirements.

7-40 Response: PAR 1405 has been revised to reflect both checks and inspections must be recorded.

7-41 Response: See Response 4-4.

7-42 Response: See Response 4-4.

7-43 Response: PAR 1405 has been revised to allow for product testing with no further distribution as suggested.

May 11, 2023

COMMUNITIES FOR A BETTER ENVIRONMENT established 1978

Mr. Wayne Nastri
Executive Officer
South Coast Air Quality Management District
21865 Copley Dr
Diamond Bar, CA 91765

VIA ELECTRONIC MAIL

RE: URGING Immediate action on Sterigenics and Stronger and Faster Implementation of Ethylene Oxide Emission Control & Monitoring Measures

Dear Director Nastri,

Communities for a Better Environment ("CBE") appreciates the opportunity to engage in the Ethylene Oxide (EtO) rulemaking process—Rule 1405. CBE is a community-based environmental health and justice organization, organizing with Southeast Los Angeles communities living near the Sterigenics facility in Vernon. We are writing to express our disappointment with the rulemaking process and request a meeting with you to address this urgent air pollution and public health emergency.

EtO has been a known carcinogen since the 1950s. EtO is a flammable, colorless gas that can cause cancer in humans and even damage children's DNA. Exposure to EtO has detrimental health impacts to communities and workers such as debilitating the respiratory system to cancers such as lymphoma. CBE submitted a comment letter on the Proposed Amended Rule 1405 on April 13, 2023. (See Attachment 1) We believe the current draft language will not meaningfully regulate sterilization and related operations that harbors a known carcinogen identified by the California Air Resources Board ("CARB") as a Toxic Air Contaminant (TAC) and by the United State Environmental Protection Agency ("USEPA") as a Hazardous Air Pollutant. It is also disheartening to see that AQMD only began investigating facilities that emit EtO *after* the USEPA announced the reevaluation of the potential toxicity of EtO.

AQMD stated in the April 11, 2023 PAR 1405 study session that fence-line monitoring would not be the most effective tool for PAR 1405 due to other emission capturing and monitoring,[10] but now the USEPA has announced an action proposal that would require continuous air pollution monitoring at the facility to ensure that pollution control equipment is operating

Comment 8-1

[10] AQMD. *Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations Study Session*. April 11, 2023. https://drive.google.com/file/d/1TvxOd5uUIs3MzoVfyLLLszOt2GbR_gnR/view?usp=sharing.

effectively.[11] The continuous emissions monitors required by this proposal are the most accurate type of monitoring for EtO emissions from commercial sterilizers.[12]

Comment 8-1 cont.

CBE requests AQMD impose stronger requirements for facilities that emit EtO such as:

- Requiring Small, Medium, and Large Facilities to adhere to Rule 1405 regulations by end of 2023 instead of 2025-2026. — Comment 8-2
- Requiring facilities to suspend operations when any control equipment or technology breaks down or is going through repairs or replacements. — Comment 8-3
- Requiring facilities to suspend operations when a facility emits more EtO than its category amount. — Comment 8-4
- Requiring Rule updates when stronger control systems and technology becomes available. — Comment 8-5
- Requiring interagency coordination with CalOSHA to educate and better protect workers from EtO exposure by always requiring personal protection equipment and high-quality respirators. — Comment 8-6
- Requiring fence-line monitoring at facilities that emit EtO given that EtO can stay in the air for several months. Recently, the USEPA released a proposal that would require continuous air pollution monitoring at the facility to ensure that pollution control equipment is operating effectively and require data to be submitted to EPA electronically twice a year.[13] Fenceline monitoring can monitor early detection leaks and help evaluate the effectiveness of control systems and equipment to better protect workers and communities from EtO exposure. — Comment 8-7

Frontline communities, such as Southeast Los Angeles, already face a disproportionate amount of pollution from transportation, industry, warehouses, and many other pollution sources. It is critical that AQMD implement a stronger ruling that takes effect immediately rather than a year or two from its adoption date. This is a significant environmental justice issue that impacts all generations of communities, leaving some residents unaware that a facility is harboring a known carcinogen. While environmental justice has been identified as a priority of Governor Newsom, CalEPA, and AQMD Board, we continue to see the same patterns of neglect and injustice in low-income communities of color. We request a meeting with you and your staff to discuss this urgent matter. Please keep in mind that some of the households impacted here are the same that have been severely impacted by the regulatory failures related to Exide. The time to act is now. We appreciate your prompt attention to this issue.

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[11] USEPA. *EPA Proposes to Strengthen Clean Air Act Standards for Ethylene Oxide from Commercial Sterilization Facilities: Fact Sheet*. https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet%20Proposal%20to%20Address%20EtO%20Risks%20from%20Commercial%20Sterilizers.pdf. Pg 1-2.

[12] Ibid.

[13] USEPA. *EPA Proposes to Strengthen Clean Air Act Standards for Ethylene Oxide from Commercial Sterilization Facilities: Fact Sheet*. https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet%20Proposal%20to%20Address%20EtO%20Risks%20from%20Commercial%20Sterilizers.pdf. Pg 1.

Sincerely,

Ambar Rivera, Staff Researcher
Bahram Fazeli, Director of Research and Policy
Communities for a Better Environment

CC:

Wayne Nastri
Executive Officer

Michael Krause
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Kalam Cheung, Ph.D.
Planning and Rules Manager

Areio Soltani
Air Quality Specialist

Responses to Communities for a Better Environment Comment Letter, submitted 5/11/2023

8-1 Response: Thank you for the participation in the public process. Regarding proposed NESHAP for EtO sterilization (Subpart O), continuous stack emission monitoring is optional and there is no requirement for fenceline monitoring under the proposed NESHAP.

8-2 Response: See Response 6-3 regarding implementation timeframes.

8-3 Response: Sterilization facilities are required to comply with all applicable South Coast AQMD rules including Rule 430 *Breakdown Provisions*.

8-4 Response: Facilities using more than their category amount would be in violation of their permits to operate and/or approved plans and would be subject to compliance action. In addition, PAR 1405 requires additional actions such as installation of additional controls, PTE, or CEMS as applicable to comply with the new category.

8-5 Response: PAR 1405 may be amended again in the future for a variety of reasons, including development and availability of more effective control systems or new technologies.

8-6 Response: Staff has engaged with other regulatory agencies in this rulemaking process and is committed to working cooperatively with regulatory partners to protect public health from EtO. Requiring facilities to comply with Cal/OSHA requirements would be outside of the scope of PAR 1405.

8-7 Response: PAR 1405 requires interim fenceline air monitoring until CEMS or SCEMS is installed and certified at large sterilization facilities.

Areio Soltani

From: Chris Collier <chris.collier@rinconstrategies.com>
Sent: Wednesday, July 26, 2023 11:12 AM
To: Areio Soltani
Subject: [EXTERNAL]Written Comment for 7/26 Public Workshop - PAR 1405

July 25, 2023

Dear Supervisor V. Manuel Perez, Mayor Patricia Lock Dawson and Chair Vanessa Delgado,

We appreciate your measured voice on the AQMD, and your commitment to protecting the lives of Californians here in Riverside County and the greater Coachella Valley Region.

As the Board continues to consider Proposed Amended Rule 1405, we are writing to ask that you take all possible consequences into account – from impacts on patients first and foremost, to the implications for medical technology innovators and care providers that have established a robust presence here in the community.

We were glad to join a coalition letter earlier this year to reiterate our concerns, perhaps best summarized by the staggering presence of innovators here in the AQMD's jurisdiction: "Sterilizers have an established role within the Southern California healthcare and business ecosystems, sterilizing over 100 million products annually. Disruptions to the process as a result of cumbersome regulations could significantly diminish our position as a leader in medical device sterilization and impact patient access in the process."

In order to keep Southern California a great place to live, do business, and receive care, we urge you to ensure that any rule – particularly one that has such potential to negatively impact the healthcare supply chain – is fully thought through.

Comment 9-1

Thank you,

Chris Collier

Chief Policy Advisor
Greater Coachella Valley Chamber of Commerce

Greater Coachella Valley Chamber of Commerce Comment Email, submitted 7/26/2023

9-1 Response: The purpose of PAR 1405 purpose is to reduce ethylene oxide emissions from sterilization facilities and related operations. Throughout the rule development process, consideration has been made to minimize disruptions to the medical supply chain for critical products. PAR 1405 includes curtailment exemptions for products that are identified by the U.S. FDA or other local, state, and federal health agency or local hospitals and medical centers as reasonably likely to be in shortage.

July 28, 2023

Wayne Nastri
Executive Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: Continued Concerns Regarding Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization

Dear Executive Officer Nastri:

We are writing today regarding our continued concerns on proposed amended rule (PAR) 1405 – Control of Ethylene Oxide Emissions from Sterilization.

Throughout the rule process have regularly raised consistent concerns with South Coast Air Quality Management District (SCAQMD) regulatory staff. This includes several private meetings, attending nearly all public meetings – including Governing Board Committees, and submitting detailed written comments to the initial proposed amended rule language.

Despite this robust engagement and shared concern from Board members as to the rule's impact on all stakeholders, regulatory staff has not meaningfully addressed concerns on PAR 1405's potential impact on patient access to sterile lifesaving medical devices. What's more, the newest version of PAR 1405 (released July 21, 2023) makes significant modifications – many that heighten these concerns – including relying on unreliable and untimely monitoring technology for rule enforcement, arbitrary curtailment length and thresholds, and continuing to base key parts of the rule on the results from a single sterilization facility in Illinois. Further, regulatory staff continues to propose an unnecessarily abbreviated timeline for approval that restricts the opportunity for thoughtful and informative feedback from both stakeholders and Governing Board members.

Comment 10-1

Notably, this insistent approach is happening in parallel with a draft updated inhalation risk unit factor (IUR) from the Office of Environmental Health Hazard Assessment (OEHHA) that proposing a level below known background levels of EtO. We appreciate SCAQMD's public acknowledgement of this reality and also that medical sterilizers are not the source of the background levels via its public comments to OEHHA and the EPA.

Comment 10-2

Due to uncertainty amongst regulators as to sources of EtO, the multiple moving pieces (i.e., EPA, OEHHA, SCAQMD), and the threat each of these poses to public health and safety, and continued concerns as to the achievability of PAR 1405, we do not believe this rule should move forward as is, especially on its current

Comment 10-3

timeline. Existing enforcement and monitoring authority are sufficient to ensure compliance and continued protection of all elements of public health until these issues are resolved. At a minimum we request additional time for review and consideration of the significant modifications to PAR 1405 to allow for development and submission of meaningful comments, continued discussion with regulatory staff, and additional opportunities for the Governing Board to hear stakeholder concerns.

Comment 10-3 cont.

Our objective remains to collaborate with SCAQMD staff to refine PAR 1405 so that there is no immediate or recurring threat to patient access to critical, sterile medical technology, as well as ensure mitigation of hazardous air pollutants found to pose a threat to the community. Thank you for considering our request.

Sincerely,

/s/
Greg Crist
Head of External Affairs
AdvaMed

/s/
Sam Chung
Vice President, State Government Relations
California Life Sciences

/s/
Jimmy Jackson
Senior Vice President &
Chief Policy Officer
Biocom California

Cc: Vanessa Delgado, Chair, Governing Board, South Coast AQMD
Sarah Rees, Deputy Executive Officer, South Coast AQMD
Michael Krause, Assistant Deputy Executive Officer, South Coast AQMD

Life Sciences Coalition Comment Letter, submitted 7/28/2023

10-1 Response: Thank you for participating in the public process. Regarding the reliance on "unreliable and untimely monitoring technology" in PAR 1405, see Response 1-7 regarding fenceline air monitoring technology.

Regarding "arbitrary curtailment length and thresholds", PAR 1405 requires curtailment when fenceline levels exceed certain trigger thresholds, and curtailment ends when the fenceline levels are below the thresholds. PAR 1405 initial trigger thresholds are based off curtailment thresholds already in practice in approved Early Action Reduction Plan (EARP), which were mutually agreed upon between South Coast AQMD and a local sterilization facility. The final curtailment threshold is based on the detection limits of real-time monitoring technology and consistent with being approximately 10 times greater than background levels.

Regarding basing key parts on "results from a single sterilization facility in Illinois", PAR 1405 requirements are based on data from facilities located within and outside the South Coast Air Basin, including an Illinois sterilization facility. Performance standards are based on technologies achieved-in-practice and are technology-neutral with multiple paths to achieve compliance and reductions in EtO emissions.

Regarding "unnecessarily abbreviated timeline for approval", PAR 1405 rulemaking activity began one year ago with the first working group meeting held in August 2022. In that time, staff has held eight (8) working group meetings, a public workshop, and a public consultation meeting. PAR 1405's schedule for receiving and responding to written comment is consistent with South Coast AQMD policies and procedures.

10-2 Response: PAR 1405's development is occurring in parallel with revisions to IUR from OEHHA, however, PAR 1405 is a technology-based rule, not a risk-based rule, and the emissions reductions proposed are achieved-in-practice by sterilization facilities both within South Coast AQMD and elsewhere. While OEHHA's draft update to the IUR factor for EtO may have impacts for risk-based rules, such as Rule 1402 *Control Of Toxic Air Contaminants From Existing Sources*, the performance standards and rule requirements of PAR 1405 were not developed based on risk numbers.

10-3 Response: The performance standards in PAR 1405 are based on technologies achieved in practice in multiple sterilization facilities, and adequate compliance timeline is given to implement the proposed requirements. Thus, PAR 1405 is not expected to pose a threat to public health and safety. See Response 10-1 regarding PAR 1405 timelines and Response 1-4 regarding NESHAP timelines.

AdvaMed
Advanced Medical Technology Association

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August 9, 2023

Sarah Rees
Deputy Executive Director
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization

Deputy Director Rees:

I'm writing today on behalf of AdvaMed, the Medtech Association, regarding South Coast Air Quality Management District's (South Coast AQMD) proposed amended Rule 1405 – Control of Ethylene Oxide (EtO) and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes. AdvaMed is the world's largest association of medical technology innovators and manufacturers. Our members are transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments, leading to improved outcomes for patients.

Thank you for the opportunity to comment on the updated draft of PAR 1405. AdvaMed has consistently supported the development of a clear and achievable rule that continues to protect public health and mitigates hazardous air pollutants found to pose a threat to the community. Patients around the country rely on properly sterilized medical devices for everything from routine exams to emergency surgeries, and any disruption could lead to negative health outcomes.

As covered in our July 28, 2023, letter to Executive Officer Nastri, the updated draft of PAR 1405 remains neither clear nor workable. Further, though some concerns from our April 2023 comments have been addressed, many remain. These include:

- Definitions and technological feasibility of required technologies;
- Achievability of required emissions standards[1];
- Clarity and necessity of warehouse and pallet tracking and monitoring; and
- Definition of background levels of ethylene oxide.

Comment 11-1

[1] Notably, the updated proposed mass emission rate is lower than the previous version, despite industry concern on the achievability of the previous proposed rate, and the lack of technologies capable of achieving the proposed destruction efficiencies.

As we noted in the June 2023 Stationary Source Committee meeting, key emissions standards rely upon results from a single sterilization facility located in Waukegan, Illinois. Deriving a baseline technological requirement on a single, uniquely designed facility is inappropriate and unachievable. AdvaMed and others have consistently requested a technologically neutral rule allowing each facility to achieve desired emission standards in the manner suited to its layout. Technology based does not equal technology neutral.

Comment 11-2

As to background levels, AQMD itself notes the source[s] of background EtO is unclear but that medical sterilizers are not it. The updated version of PAR 1405 makes several references to background levels without definition yet builds requirements around them. Additional consideration is needed before finalizing a rule with an ambiguous standard.

Comment 11-3

Additional requirements for warehouses also appear unnecessary. The AQMD staff report from March 2023 indicates no elevated levels detected around warehouses. Though staff have indicated this may have changed for one warehouse, this data has not been made public nor has staff indicated why additional monitoring is necessary. Further, tools are already available for AQMD – i.e., Rule 1402 – to mitigate increased levels of EtO that should be applied instead to this situation.

Comment 11-4

The updated version of PAR 1405 introduces fenceline monitoring as an additional enforcement tool. Fenceline monitoring would be unreliable, technically challenging, and unnecessary to monitor EtO emissions for commercial sterilization facilities, and this reasonable conclusion is supported by credible studies and industry experience. Further, proposed allowances for continued operation in curtailment scenarios are unlikely to prevent negative impacts to patients and public health from the widespread sources of EtO unrelated to sterilization facilities.

Fenceline monitoring is problematic due to the presence of many sources of EtO in the environment from sources other than sterilization. For example, fossil fuel combustion, organic matter decomposition, and other commercial products emit EtO. Even an employee or third party smoking a cigarette or cars and trucks near an ambient monitor would materially alter results. Further, results will naturally vary significantly due to wind patterns, weather events, and other geographic conditions. For this reason, results often may not reflect plant operations, nor would an industry-wide standard be fair.

Recent studies also demonstrate that fenceline monitoring is inaccurate and unhelpful for monitoring EtO emissions. The considerable fluctuation in background readings and the still emerging research into other sources of EtO, coupled with variability even among co-located canisters, has resulted in inconsistent and problematic interpretation at the state and local levels. Technology innovations can overcome

Comment 11-5

some of these shortcomings, but existing capabilities are insufficient and incapable of overcoming the current technological hurdles.

For example, a three-year study conducted in Georgia found little to no difference before or after fugitive emission upgrades. This finding was primarily due to EtO occurring naturally across the United States, even in rural areas near no known sources of EtO. Further, in EPA and other state regulatory ambient air studies, researchers found EtO in levels exceeding the IRIS-designated threshold in the middle of national and state parks where there was no known EtO source. These rigorously conducted studies demonstrate numerous known and unknown sources of EtO in the environment well beyond commercial sterilization facilities.

The relative distance between the emission points and boundary lines for commercial sterilization facilities is unsuitable for EPA's typical requirements for fenceline monitoring. The EPA typically requires a fenceline monitor to be at least 50 meters from the source of emissions to the property boundary to allow for dispersion.[2] Meanwhile, the boundaries for commercial sterilization facilities are often the building itself or small easements. Due to the physical configurations of these facilities, the monitoring points are unlikely to be representative of emissions from the release points. As EPA acknowledges, fenceline monitoring would be problematic and "technically challenging to implement for this source category."

Additionally, current technology does not adequately differentiate sterilizer impacts from other near-site impacts. This deficiency could result in false conclusions by the public, agency, or the company regarding fugitive emissions that are not present nor resulting from the facility's operation.

Comment 11-5 cont.

As noted at the beginning of this letter, AdvaMed continues to support the development of a clear and achievable rule that continues to protect public health and mitigates hazardous air pollutants found to pose a threat to the community. PAR 1405 falls short of meeting this standard.

Further, due to uncertainty amongst regulators as to sources of EtO, the multiple moving pieces (i.e., EPA, OEHHA, SCAQMD), and the threat each of these poses to public health and safety, and continued concerns as to the achievability of PAR 1405, we do not believe this rule should move forward as is, especially on its current timeline. Existing enforcement and monitoring authority are sufficient to ensure compliance and the continued protection of all elements of public health until these issues are resolved.

Comment 11-6

Thank you again for the opportunity to submit comments. We look forward to continued discussion on this critical issue for patients.

[2] EPA Method 325A § 8.2.1.

Sincerely,

Bobby Patrick

Bobby Patrick
Vice President, State Government and Regional Affairs
AdvaMed

AdvaMed Comment Letter, submitted 8/9/2023

11-1 Response: Thank you for your participation in this public process.

11-2 Response: See Response 10-1 regarding the basis of PAR 1405 performance standards.

11-3 Response: See Response 1-12.

11-4 Response: As indicated in the comment, South Coast AQMD has detected that at least one Tier I Warehouse has elevated signals associated with EtO near fenceline. This information has been presented in the Stationary Source Committee meeting and included in Chapter 1 of this staff report.

In addition, another Tier I Warehouse in South Coast AQMD has installed a control system to capture and control EtO emissions, further demonstrating potential EtO emissions from this sector.

As emissions from warehouses depend on a wide range of factors, PAR 1405 includes information gathering requirements to assess EtO emissions from facilities downstream of sterilization facilities in the medical device supply chain.

11-5 Response: The primary purpose of fenceline air monitoring is an interim measure until permanent stack emission monitoring is installed and certified at large sterilization facilities. At that point, fenceline air monitoring requirements sunset. Although CEMS is the most accurate method to ensure proper facility operations by quantifying a sterilization facility's EtO emissions, the implementation timeline is long (i.e., several years). For the interim period, fenceline air monitoring is the next best method despite certain challenges.

Fenceline air monitoring has been used to assess emissions from sterilization facilities and designate sterilization facilities as Potentially High Risk Level Facility under Rule 1402. While background levels of EtO exists and there may be contribution from other sources, fenceline concentration of EtO at sterilization facilities were measured to be much higher than background (1 to 3 order of magnitudes higher) making it easier to discern contributions from other sources. Fenceline air monitoring conducted in Illinois and by South Coast AQMD in Carson, California have demonstrated that ambient EtO levels dropped after

implementation of additional capture and control technologies such as PTE and multilayered control systems, both illustrating the value of these technologies and the value of fenceline air monitoring.

The purpose of fenceline monitoring in PAR 1405 is to verify that fenceline levels are below a specified level and not to serve as a diagnostic tool for the sterilization facility.

Proper placement of fenceline air monitors is crucial in maximizing the value of the methodology but logistical concerns such as access, siting, and utilities may also play a role. For those reasons, PAR 1405 requires mobile EtO monitoring quickly after rule adoption while the fenceline air monitoring plan is prepared, submitted, reviewed, and approved. Additionally, PAR 1405 allows the facility to submit information to refute that the EtO emissions that triggered curtailment were from the facility.

The Fenceline Monitoring and CEMS (or SCEMS) Implementation dates in PAR 1405 are deadlines. A facility may choose to expedite their installation of a CEMS (or SCEMS) to reduce the time of the required Fenceline Monitoring. Expedited processing of CEMS (or SCEMS) certification applications is available upon facility request if a facility is interested in lessening the time prior to CEMS (or SCEMS) certification.

11-6 Response: The performance standards in PAR 1405 are based on technologies achieved in practice in multiple sterilization facilities, and adequate compliance timeline is given to implement the proposed requirements. Thus, PAR 1405 is not expected to pose a threat to public health and safety.

August 2023

Attn: SC AQMD PAR 1405 Staff
asoltani@aqmd.gov
mgamoning@aqmd.gov
kcheung@aqmd.gov
mkrause@aqmd.gov

Re: Atmosfir's comments on PROPOSED AMENDED RULE 1405, CLEAN Version 07-21-2023
CONTROL OF ETHYLENE OXIDE EMISSIONS FROM STERILIZATION AND RELATED OPERATIONS

Dear Staff,

Atmosfir Optics extends a warm welcome to the proposed rule aimed at reducing the emissions of ethylene oxide from sterilization facilities. Our team at Atmosfir has extensive expertise in air monitoring technologies and methods. Atmosfir is an R&D, Data & Software integration company that offers advanced air monitoring services globally, operating on a SaaS business model. Our group of companies holds ISO 17025 accreditation for various methods including TO-15 (canisters) and for the TO-16 (OP FTIR) method. Our team carefully read the PAR and would like to share the following notes:

General comments

The most efficient approach to reducing fugitive emissions involves prompt identification of significant leaks and expediting their treatment. This can be achieved to the greatest extent through continuous real time fenceline monitoring, especially in cases of batch processes such as Ethylene Oxide (EtO) sterilization. EtO fugitive emissions can be continuously measured in real-time by Open Path-FTIR according to an official method of US EPA TO-16. Nonetheless, this method is neither preferred nor considered an option in the draft rule, while a non-real-time monitoring method of canister sampling, is considered an option. The latter option may be favored by the owners of facilities in order to minimize monitoring and to exempt from real-time alerting the public and the regulator dangerous EtO concentrations are detected, leading to delays in repairment operations.

Using Real-Time 24/7 fenceline monitoring with a public website as in rule 1180 is the Best Available Technology (BAT) for accomplishing this rule's objectives.

Comment 12-1

Specific comments

1. **Interim Mobile Monitoring Large Facility Requirements – section (d)(7) comments:**
   - Please specify if there are official methods or validated procedures for the mobile monitoring survey. A clear SOP is required to set the required spatial resolution of the sampling along the fence, the appropriate revisit time, and the detection level of the measurement.

Comment 12-2

Atmosfir Optics LTD
Mailing address: 5803 Cypress St, Bldg C, Houston Tx 77074; Phone: 1-713-6688818; www.atmosfir.net

- Mobile Monitoring – schedule - P.11 (d)(7)(D) - Monitoring once a month for two hours covers less than 1% of the entire month. This monitoring rate appears to be very low and is prone to missing most of the emissions, especially when batch operations are applied. It is recommended to schedule the monitoring hours throughout the day to cover all working hours and to conduct at least one mobile monitoring every 5 days.

Comment 12-3

- It is recommended to use an OP-FTIR mobile trailer for conducting EtO measurements in accordance with USEPA TO-16 method. This approach enables continuous measurements over the course of days, utilizing an official method, while incurring lower costs. The operation cost of OP-FTIR for a full week 24/7 with (160 hours) equals one day (2 hours) of mobile monitoring! (13,000$ as of appendix 1.2.iii in p. 44). A mobile OP FTIR trailer can be used for short-term campaigns starting from one week to three years. Mobile OP FTIR trailer can also be rented as a fast solution if required.

Comment 12-4

- Mobile Monitoring – Method detection limit – 1 ppb once every 10 sec – P.10 (d)(7)(A)(i)(I) – Please specify the basis and calculations of this DL. The detection limit should be set in accordance with an official method, and/or a recognized protocol by a standard institute (such as TUV/MCERT/ETV)

Comment 12-5

- Measuring signals associated with Ethylene Oxide - P.10 (d)(7)(A)(i)(II) – the option of indirect EtO measurements seems redundant in light of available precise and selective methods for EtO. In any case, the canister sampling in section (d)(7)(E)(i) will not be relevant to the high signals measurements since sterilizing is a batch process and one-hour late canister monitoring will not reflect the emissions during the exceeding.

Comment 12-6

2. Warehouse Requirements – section (h) comments:

- **Tier I Warehouse** – p. 18 (h)(3) – In our point of view, providing three options is not only unnecessary and confusing, but might lead to the selection of the cheapest option with minimum monitoring coverage and data reporting, specifically, fenceline monitoring by canisters (Option A) and factors calculation (Option B). Following is a short explanation of their limitations.

Comment 12-7

- Option A Fenceline monitoring by canisters - section (p) in the current draft requires canister sampling at a single point once every 6 days that lack the real-time capability for measurements and reporting, lacks spatial coverage, and has poor temporal coverage with monitoring of only 15% of the time. It is either necessary to change the fenceline requirements under section (p) to provide more extensive fenceline measurements (see comment on section (P) below), or to oblige the execution of option C to increase understanding and monitoring capabilities of these facilities.

Comment 12-8

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- Option B, emission study – Determine the annual EtO emissions p.19 (h)(5)(A)) & appendix 3 - annual emissions estimation is based on general emission coefficients or based on momentary measurements that are not sufficient to extrapolate the annual EtO emissions.

  In order to sufficiently estimate annual emissions, measurements should be conducted in a period of at least a year and cover all seasons and a variety of activities. In any case, the annual emission estimate does not reflect short-term daily exceedances nor provides any time-resolved information. We, therefore, recommend at least removing option B, since warehouse owners will choose this minimal monitoring as the cheapest option to stand in the rule requirements while the real emission will remain unknown.

Comment 12-9

- P.5 (36)-(37) Warehouse dividing to Tier I and Tier II by size does not necessarily reflect the Eto expected emissions. Classification according to quantity, mass, and volume of the sterilized products is more appropriate in our point of view.

Comment 12-10

- p.17-18 (h)(1)&(2)(E) Warehouse Requirements - In addition to the number, it is advisable to also record and report the weight and volume of the units, including the time elapsed from sterilization.

Comment 12-11

3. Interim Fenceline Air Monitoring Requirements- section (p) comments:

- The draft rule 1405 requires fenceline monitoring, by canisters or real time measurements, with a trigger threshold of 24 hours (P.5 (38)). It is recommended to add 1-hour acute trigger threshold to protect the public from high concentrations of ethylene oxide and at the same time to help the facility detect and seize the cause for exceedances as quickly as possible.

Comment 12-12

Fenceline by canisters p.29 (p)(2)(B)

The draft rule gives the option for fenceline monitoring using a canister with 24 hours sampling in 1-2 locations (Appendix 4), for 1 out 6 days (p)(2)(B)(i)), and based on method TO-15 or TO-15A ((p)(2)(B)(ii)).

Fenceline EtO monitoring by canisters has specific downsides and issues that should be considered, including the followings:

- The method:
  According to research carried out by the EPA[1], methods TO-15 and even TO-15A are not good enough for measuring EtO concentrations. It is recommended to change to US EPA 327

Comment 12-13

[1] UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Office of Air Quality Planning and Standards, Air Quality Assessment Division, Ambient Air Monitoring Group, Technical Note: The Ethylene Oxide (EtO) Canister Effect, 5/25/2021

[1] UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICE OF RESEARCH AND DEVELOPMENT RESEARCH, MEMORANDUM, SUBJECT: Effect of Canister Type on Background Ethylene Oxide Concentrations, May 7, 2021

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method[2], which is designed for this. Method 327 includes a wide range of quality controls (duplicate and spiked canisters) and cleaning procedures to ensure the results. Using the TO-15 method will inevitably lead to doubtful problematic results.
Even when using the high-quality procedures of method 327, Canister sampling is an extractive sampling that analysis is carried out in a lab, results are due 7-14 days after sampling, which gives a long time after an event to discover an exceeding event as opposed to real time approach.

Comment 12-13 cont.

- The frequency:
  Sampling 1 out of 6 days (p.29 (p)(2)(B)(i)) is only 15% if the time. This requirement is probably due to the high cost of sampling 100% of the time – a canister each day. Real-Time monitoring can give a monitoring coverage of 100%. The owner default choice would be to conduct the less frequent sampling.
  Therefore, it is recommended to require at least 1 sampling every 5 days (20% of the time) – as required by in the latest draft of EPA changes to EtO monitoring from the industry[3].

Comment 12-14

- The time average:
  The EPA acknowledges that there are some drawbacks of time-integrated sampling, including the lack of immediate feedback on the acquired data and the loss of short-term temporal information[4]. The time average of 24 hours (p.29 (p)(2)(B)(i)) allows significant maximum concentrations higher than acute 1-hour threshold values.

Comment 12-15

- Number of sampling locations - Spatial coverage
  Under table 9 in Appendix 4 (p.50) only 1-2 locations are required. 1-2 points do not provide sufficient spatial coverage for fenceline monitoring, namely, do not represent the entire fenceline extent. The number of locations should follow EPA 325 guidelines[5], at least 12 points around the fences.

Comment 12-16

To conclude, canister sampling should not be considered as a fenceline monitoring technology, for its lack of spatial and temporal coverage, especially for the EtO batch process. The canisters sampling does not allow for acute threshold monitoring and quick detection and repair.

Comment 12-17

[2] https://www.epa.gov/system/files/documents/2023-04/Draft%20Method%20327%20%28clean%20proposal%20version%29.pdf
[3] https://www.epa.gov/stationary-sources-air-pollution/synthetic-organic-chemical-manufacturing-industry-organic-national
[4] https://www.epa.gov/stationary-sources-air-pollution/synthetic-organic-chemical-manufacturing-industry-organic-national.P. 25144
[5] https://www.epa.gov/emc/method-325a-volatile-organic-compounds-fugitive-and-area-sources-sampler-deployment-and-voc

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If the option of canister sampling will remain in rule 1405 it is recommended to apply sampling in proper numbers of sampling points, higher frequencies, and lower sampling duration, according to the highest-quality procedures of EPA 327 method.

Comment 12-17 cont.

Fenceline with real time monitoring p.29 (p)(2)(C)

The draft rule gives the option for fenceline monitoring using real time monitoring. Real time open path monitoring is a prior technology (as stated by the EPA[6]), especially with today's capabilities, then the canister sampling for fenceline monitoring, for the following reasons:

- High spatial coverage of the facility - Open path measurements provide much better coverage of the facility, unlike point measurements that have great potential to miss the pollutants plume.
- Real time temporal coverage - 24/7/365 measurements in short timeframes - OP-FTIR measurements are continuous and provide real-time data, with short measurement intervals ranging from 1 minute to 1 hour, which can be averaged over longer durations.
- Ethylene oxide has strong absorption in the IR range and is very suitable for FTIR analysis.
- Combining the short-time measurements with wind monitoring on the same scale, can assist in locating the source (based on EPA OTM-10) and estimating and characterizing emissions from the facility.
- Root cause analysis - The real time 24/7 monitoring together with high spatial coverage of the TO-16 method enables to do root cause analysis in a near real-time manner, allowing a quick repair and reduction in emissions.
- Public trust and transparency can be achieved to a higher extent by real-time measurements and reporting (see rule 1180).
- In-situ method – eliminate the time for analysis and the effect of sampling interferences, traveling and storage.
- Experience – Over 20 years of established EPA method. with three years of good experience implemented in SC AQMD rule 1180.

Comment 12-18

- Considering the above, the rule should prioritize real time measurements, especially based on official methods such as TO-16[7].

Comment 12-19

- Special requirement for real time monitoring p.30 (p)(2)(D)(ii) – we recommend removing this section with respect to real time monitoring, especially if it is conducted according to a valid method such as US EPA TO-16. As explained above, canister sampling is not a good choice for fenceline sampling, especially for batch processes. Sampling even one hour after an exceeding event can do the opposite, a facility will be free from regulation demands, only because the canister sampling missed the exceedance period.

Comment 12-20

[6] https://www.epa.gov/stationary-sources-air-pollution/synthetic-organic-chemical-manufacturing-industry-organic-national.P. 25144

[7] https://www.epa.gov/sites/default/files/2019-11/documents/to-16r.pdf

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Disqualification under the fence line monitoring p.31 (p)(2)(F)(i)

- Please explain the discrimination in allowed disqualification for canister sampling vs. real-time measurements. For canisters, the rule allows disqualification of one sample out of 5 per month, namely 20% of the samples. In comparison, the rule allows , 48 hours disqualification for the real time method that samples 24/7, which is about 7% of the month. Please note that the standard QA for real time measurement is 90% completeness is the standard. That standard should apply to all fenceline methods in the rule.

Comment 12-21

Fenceline Air Monitoring End Date - p.31 (p)(3)

- **Fenceline Air Monitoring End Date - Large Facility** - p.31 (p)(3)(A)- The assumption that the installation of CEMS in the chimney provides a monitoring solution for all fugitive emissions options in the facility is fundamentally lacking, and must be validated per facility. We suggest validation by extending the end date of the fenceline monitoring for additional 1 year from starting the CEMS operation. The simultaneous fence measurements and CEMs measurements at the stacks will provide the necessary validation. If all abnormal concentrations that are measured on the fence can be apportioned and explained by abnormal concentrations in the chimneys CEMs, then the fenceline monitoring can end. In cases of indication of additional sources, the facilities owner will get the incentive for corrective actions.

Comment 12-22

- Fenceline Air Monitoring End Date – warehouse – p.31 (p)(3)(B)- the end date of the fenceline monitoring of warehouses in the current draft is not related to above or below the threshold. That means that no corrective action to reduce emission will be initiated and high emissions will not be reduced. The end date of the fence line monitoring of the warehouses should be when the valid results are also under the threshold.

Comment 12-23

4. **Curtailment - section (q) - comment**

   The rule does not require root cause analysis for exceeding events. The procedure of root cause analysis can reduce emissions in the long run together with curtailments. A root cause analysis is most effective based on real-time measurements and short duration time scales, allowing the facility to investigate the source and cause in a quick and effective way. By implementing this good practice, an overall reduction over time will be larger. This will also allow the facility to return more quickly to normal operation if showing that the corrective action resolved the failure that caused the exceeding. The draft rule should give incentives for facilities to use the real-time monitoring for a good practice of root cause analysis.

Comment 12-24

5. **Other facilities – sections (e)&(g) comment:**

   The assumptions that Permanent Total Enclosure will work smoothly and continuously in all parts of the plant is not realistic, and malfunctions can happen in a small facility as in a large one. Source tests and CEM's are not covering all non-source emissions. It is recommended that at least for a year and until proven otherwise fence monitoring should be carried out together with the CEMs for all kinds of facilities. If the monitoring of the fence does not indicate

Comment 12-25

Atmosfir Optics LTD
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abnormal concentrations, it will be possible to gradually reduce this requirement. If abnormal concentrations are discovered that do not originate in the chimney CEMs, the plant must continue the measurements until a full year is obtained free of abnormalities.

Comment 12-25 cont.

6. **Reporting Requirements - section (t) comment:**

The rule should strive for the most transparent reporting. Implementing the reporting requirement from rule 1180 is recommended, real time measurement with real time reporting. Transparent reporting enhances the obligations of the facilities, and the trust of the public in the regulator and industry.

Comment 12-26

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Summary

A. Considering the health and safety of the communities living in close proximity to the facilities; the dangers posed by EtO chronic and acute exposure; and its explosive nature we recommend using continuous real-time 24/7 fenceline monitoring. — Comment 12-27

B. We also suggest extending the end date of the fenceline monitoring to at least one year of parallel measurements with CEM's measurement. That can give time to evaluate and repair non-source emissions and the total encloser effectiveness.
Using OP-FTIR, fenceline monitoring requires minimal annual cost after initial capital investment, allowing for real time protection, real time alerts, and a reduction in EtO emissions in a cost-effective way that justifies the continuous of the system also after the CEMs are operational. — Comment 12-28

C. Requiring a very minimal and insufficient protocol of sampling, the current draft rule is giving the benefit to canister options and sets the real-time fenceline monitoring in unfavored position. As is it now, owners of the sterilizing facility will choose to do the bare minimum sampling of one 24 hour canister every 6 days. — Comment 12-29

D. Canister sampling option should ~~be removed as a fenceline monitoring option or~~ at least, ~~should be required to~~ obligate proper numbers of locations (4-12), higher sampling frequencies (1 of 5 days at least), and the highest-quality procedures of EPA 327 method. — Comment 12-30

E. A hybrid holistic approach that combines the 2 methods (TO-16 & EPA 327) should be implemented. Using on the fenceline a 24/7 real time OP FTIR , and to evaluate public exposure we recommend placing canister in nearby public receptors downwind. — Comment 12-31

F. For interim mobile monitoring requirement, we suggest using a mobile trailer with OP-FTIR that can be used for short or long campaigns (weeks to months) with cost-effective advantage — Comment 12-32

G. The rule should require root cause analysis when exceeding occures. — Comment 12-33

H. Acute 1 hour threshold should be established. — Comment 12-34

Best regards,

Gilad Shpitzer,
CEO
Atmosfir Optics

For more information you can contact me by e-mail: gilad@atmosfir.net

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Atmosfir Optics Comment Letter, submitted 8/9/2023

12-1 Response: PAR 1405 does not preclude technologies but includes criteria to be met to be used as part of mobile or fenceline monitoring. In the course of PAR 1405 rulemaking, staff expressed concerns regarding the detection limit of OP-FTIR for EtO. Per published peer-reviewed materials, the OP-FTIR EtO detection limit is above 1.0 ppb and would not meet PAR 1405 fenceline air monitoring performance standards. OP-FTIR could be a compliance option for PAR 1405 if demonstrated to meet or exceed 1.0 ppb EtO in ambient air. Both canister sampling and real time monitoring are allowed as part of fenceline monitoring in PAR 1405.

12-2 Response: PAR 1405 specifies the requirements for mobile monitoring. PAR 1405 requires independent third-party operators conducting mobile monitoring to meet a 1.0 ppb performance standard and maintain a sampling protocol approved by the Executive Officer.

12-3 Response: Due to the limited number of vendors available to perform mobile monitoring, once per calendar month is the most frequent sampling schedule deemed feasible. Phase I mobile monitoring is an interim measure until the more frequent Phase II fenceline air monitoring plan (FAMP) is approved and implemented.

12-4 Response: OP-FTIR in accordance with U.S. EPA Compendium Method TO-16 may be used for Phase I Mobile Monitoring if demonstrating a method detection limit of 1.0 ppb once every five (5) seconds and a corresponding sampling protocol is approved by the Executive Officer.

12-5 Response: The performance standard of 1.0 ppb was selected to be inclusive, allowing multiple real-time EtO monitoring technologies, while achieving the goal of measuring ambient air EtO levels close to background EtO levels, detected in the range of 0.02 to 0.17 ppb in South Coast AQMD in 2021.

12-6 Response: Indirect EtO measurement methodologies, such as proton-transfer-reaction mass spectrometry (PTR-MS), are accurate, precise but non-selective, measuring EtO ion signal instead of EtO directly.

12-7 Response: PAR 1405 aims to be technology-neutral, allowing for multiple paths towards compliance and allowing facilities to select the most appropriate path to meet PAR 1405 objectives.

12-8 Response: Real-time monitoring methods have certain advantages over canister sampling methods, such as temporal coverage and lower operating costs over time. Canister sampling methods have other advantages, such as lower detection limits, lower upfront capital costs, and is an established method used for regulatory purposes. PAR 1405 allows for either provided the methods meet the criteria specified in the requirements.

12-9 Response: Shorter term emission studies and source tests to develop emission factors have been used to estimate a facility's annual emissions. As discussed in the rule development process, different types of emission assessment were performed in the State of Georgia to assess warehouse's EtO emissions. The Emission Study Plan would be reviewed by the Executive Officer to ensure that sources are accounted for.

12-10 Response: Binning warehouses by warehousing floor area is consistent with the approach in other South Coast AQMD regarding warehouses such as Rule 2305 *Warehouse Indirect Source Rule – Warehouse Actions And Investments To Reduce Emissions (Waire) Program*. As discussed throughout the rule development process, there is not enough information on warehouses to make determination on the amount of EtO sterilized material received or annual EtO emissions. The purpose of the proposed requirements for warehouses is for data collection and to serve as first evaluation with additional requirements to follow if necessary.

12-11 Response: Requiring sterilized palletized units to be individually weighed and volumes calculated would be unduly burdensome on warehouses. At the present time, the number of sterilized palletized units received directly from facilities performing sterilization should be sufficient to achieve informational goals.

12-12 Response: While there are acute hazards associated with EtO, South Coast AQMD ambient air monitoring has not detected EtO concentrations at acute hazard levels offsite of sterilization facilities. Commercial sterilization facilities maintain a variety of real-time monitoring in the acute EtO range using GC-PID, handheld PID, or IR technologies to identify these hazards.

12-13 Response: Proposed U.S. EPA Method 327 is currently under development for use for rules pertaining to the hazardous organic chemical manufacturing industry. If and when Method 327 is approved by U.S. EPA in the future, there are feasibility concerns regarding laboratory capacity to analyze

canister samples in the near term. U.S. EPA Compendium Method TO-15 or Method TO-15A are more appropriate at the present time.

12-14 Response: PAR 1405 requires continuous stack emission monitoring for large sterilization facilities, expected to be in place in 2026-2027. In the interim, a 1-in-6 day sampling schedule is consistent with other currently approved sampling schedules in South Coast AQMD for EtO or other air contaminants.

12-15 Response: See Responses 12-8 and 12-12.

12-16 Response: U.S. EPA Methods 325A and 325B were crafted for petroleum refineries. The nature of petroleum refineries, expansive open facilities with a large number of dispersed emission points, is fundamentally different from sterilization facilities and warehouses, enclosed facilities with ground-level release points and smaller footprints. While 12 monitoring locations may be appropriate for petroleum refineries, it would be inappropriate for sterilization facilities or warehouses where mobile monitoring has indicated EtO signals at only at a portion of the fenceline.

12-17 Response: See Responses 12-8, 12-13, 12-14, and 12-16.

12-18 Response: OP-FTIR in accordance with U.S. EPA Compendium Method TO-16 may be used for Phase II Fenceline Air Monitoring if demonstrating a method detection limit of 1.0 ppb once every 15 minutes to the satisfaction of the Executive Officer.

12-19 Response: See Response 12-8.

12-20 Response: By exemption, a facility is relieved from canister sampling if implementing an approved FAMP with a real-time monitoring method approved by U.S. EPA such as Compendium Method TO-16.

12-21 Response: PAR 1405 has been revised to allow up to 96 hours of missing real-time fenceline air monitoring data over a rolling 30-day period due to calibration, maintenance, malfunction, or other occurrence beyond the control of the facility, consistent with missing data allowances for stack SCEMS or CEMS.

12-22 Response: PAR 1405 required implementation of the FAMP for 60 days after final certification of SCEMS or CEMS. Staff believes this is sufficient overlap time to ensure ambient air EtO concentrations correlate with SCEMS or CEMS EtO concentrations. In addition, the SCEMS or CEMS will go

through a vigorous certification process and annual RATA, ensuring data quality and accuracy.

12-23 Response: The purpose of fenceline air monitoring at warehouses is information gathering, to better understand how post-aeration EtO emissions from sterilized palletized units contribute to ambient air EtO concentrations. Staff believes one (1) year of study is sufficient to understand these sources and their seasonality.

12-24 Response: While PAR 1405 does not explicitly require root cause analysis, sterilization facilities may conduct their own root cause analysis to avoid future curtailment.

12-25 Response: PAR 1405 already has redundant layers of monitoring to ensure proper operations of PTE, requiring both continuous negative pressure monitoring and periodic inward air flow velocity measurement at natural draft openings, above and beyond U.S. EPA Method 204 requirements. These requirements are sufficient and additional layers of monitoring, such as extended interim fenceline air monitoring timelines are not needed.

12-26 Response: The purpose of Rule 1180 was to require real-time fenceline monitoring systems that would provide air quality information to the public and local response agencies regarding emissions near the property boundary of the refinery. In PAR 1405, the purpose is to reduce ethylene oxide emissions from sterilization facilities, and elevated fenceline levels would result in curtailment or other enforcement action. PAR 1405 and all records associated with it will fully comply with the California Public Records Acts (CPRA) and the guidelines for implementing the CPRA as adopted by the Governing Board on July 5, 2013.

12-27 Response: See Responses 12-8 and 12-12.

12-28 Response: See Responses 12-8, 12-18, and 12-22.

12-29 Response: See Response 12-8.

12-30 Response: See Responses 12-13, 12-14, and 12-16.

12-31 Response: See Responses 12-13 and 12-18.

12-32 Response: See Response 12-4.

12-33 Response: See Response 12-24.

12-34 Response: See Response 12-12.

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August 9, 2023

PAR 1405:
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Re: Proposed Amended Rule 1405-Preliminary Draft of PAR 1405
Control of Ethylene Oxide Emissions from Sterilization and Related Operations
Su: Public Comments Submission

Dear SCAQMD:

The Coalition For A Safe Environment (CFASE) submits our public comments on the Proposed Amended Rule 1405 - Preliminary Draft of PAR 1405. In our research we also discovered that in addition to typical facility fugitive emissions that industrial accidents are a major source of ethylene oxide (EtO) emissions and public exposure. We submit the following concerns and requests.

1. We are concerned that AQMD Staff did not provide a more comprehensive description of public health impacts from Ethylene Oxide (EtO). We request that the following OSHA Fact Sheet Ethylene Oxide (EtO) information be included in the Rule 1405 for workers and the public.

   How can ethylene oxide harm workers?

   In addition to eye pain and sore throat, exposure to EtO can cause difficult breathing and blurred vision. Exposure can also cause dizziness, nausea, headache, convulsions, blisters and can result in vomiting and coughing. Both human and animal studies show that EtO is a carcinogen that may cause leukemia and other cancers. EtO is also linked to spontaneous abortion, genetic damage, nerve damage, peripheral paralysis, muscle weakness, as well as impaired thinking and memory. In liquid form, EtO can cause severe skin irritation upon prolonged or confined contact.

Comment 13-1

1. We are concerned that AQMD Staff did not conduct thorough research on the number and types of ethylene oxide (EtO) accidents which have occurred in the past, in order to further enhance new rule making, safety features and public reporting.

   CFASE conducted a review of U.S. Dept. of Labor OSHA Ethylene Oxide Accidents, which disclosed that there had been 38 Ethylene Oxide reported accidents which should have been included in a review that addressed lessons learned and accident prevention measures which would prevent worker and public exposure to Ethylene Oxide from industrial accidents and fugitive emissions.

   https://www.osha.gov/ords/imis/AccidentSearch.search?acc_keyword=%22Ethylene%20Oxide%22&keyword_list=on

   OSHA has a website link for Hazard recognition of specific chemicals and has a listing for Ethylene Oxide.

   https://www.osha.gov/ethylene-oxide/hazards

   An excellent example is the Sterigenics, Inc. in Ontario, CA explosion on September 3, 2004.

   - U.S. Dept. of Labor - OSHA Accident Report Detail

     https://www.osha.gov/ords/imis/accidentsearch.accident_detail?id=201146065

   - U.S. CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD – Investigation Report

     https://www.csb.gov/assets/1/20/sterigenics_report.pdf?13828

Comment 13-2

2. We support and request amendments to Rule 1405 that include a revision to the purpose to state the following, "The purpose of this rule is to protect worker and public health by preventing the release of ethylene oxide (EtO) and reducing ethylene oxide (EtO) emissions from sterilization."

Comment 13-3

3. We support and request amendments to Rule 1405 that includes one definition of a warehouse. We disagree with AQMD to create two tier types of warehouses because there is no difference in the purpose and operation of a warehouse. Real-Time 24/7/365 Fenceline Air Quality Monitoring and Reporting would be the same for all warehouses.

   AQMD has provided no research, studies or data that supports that there is a direct correlation between the size of the warehouse building and the ethylene oxide (EtO) emission potential. A small warehouse with a higher volume of sterilization traffic of ethylene oxide (EtO) sterilized product can emit more than larger warehouses with low volume traffic of ethylene oxide (EtO) sterilized product.

Comment 13-4

4. We support and request amendments to Rule 1405 that includes a proper industry quantitative standard definition of the amount of ethylene oxide (EtO) used to sterilize products on a pallet. We disagree with AQMD's reference to use the, "Total number of

Comment 13-5

Sterilized Palletized Units." The number of items does not provide any quantitative data of the amount of ethylene oxide needed, used or residue chemical that can adhere to an item for a period of time. We request that the standard definition and formula include an estimate using the weight, surface area, volume or mass or combination thereof in addition to quantity. Recording and Reporting should also include the time elapsed from sterilization, the length of time stored and the range of the warehouse temperature during storage.

Comment 13-5 cont.

5. We support and request amendments to Rule 1405 that include new and enhanced requirements to control, prevent and reduce fugitive emissions at commercial facilities using sterilization and fumigation processes using ethylene oxide (EtO).

Comment 13-6

6. We support and request amendments to Rule 1405 that include new and enhanced requirements to control, prevent and reduce fugitive emissions at commercial facilities while ethylene oxide (EtO) is being delivered, staged in que by tanker truck or train, being unloaded to storage tanks or temporarily parked overnight awaiting unloading and transfer to storage tanks.

Comment 13-7

7. We support and request amendments to Rule 1405 that include new and enhanced requirements to control, prevent and reduce fugitive emissions at commercial facilities that have ethylene oxide (EtO) storage tanks, attached pumping and transfer equipment components.

Comment 13-8

8. We support and request amendments to Rule 1405 that include new and enhanced requirements to control, prevent and reduce fugitive emissions of ethylene oxide (EtO) from products treated, packaged and stored on-site and at off-site warehouse locations.

Comment 13-9

9. We support and request amendments to Rule 1405 that include U.S. EPA approved Method TO-16 Long-Path Open-Path Fourier Transform Infrared Monitoring Of Atmospheric Gases for our requested primary Real-Time 24/7/365 Fenceline Air Quality Monitoring and Reporting Equipment and Software. Long-Path Open-Path Fourier Transform Infrared Monitoring equipment can achieve a Method Detection Limit (MDL) of 1.0 ppb and lower for many chemicals. Ethylene oxide has strong absorption in the IR range and is very suitable for FTIR analysis.

Comment 13-10

10. AQMD Staff answer is, Staff is not aware of an open path monitoring technology with this capability." AQMD Staff has refused our request to research and validate OPEN-PATH FTIR Method Detection Limits (MDL). OPEN-PATH FTIR Method Detection Limit for Ethylene Oxide (EtO) 24hrs. is .02 ppb while the Canister is .07 ppb for 24hrs. OPEN-PATH FTIR MDL is 1 ppb for 30 minutes and a Canister is not capable of real-time or near real-time.

    Fenceline Air Quality Monitoring and Reporting provides extensive nearly 100% spatial coverage of the facility, while canisters may represent only 1%-5% of facility spatial coverage.

    Long-Path Open-Path Fourier Transform Infrared Monitoring Of Atmospheric Gases also allows for the monitoring of numerus other chemicals such as Benzene, 1,3-Butadiene, Ethylene Dichloride and Chloroprene being considered in new rule making by EPA.

Comment 13-11

Real-Time 24/7/365 Fenceline Air Quality Monitoring and Reporting provides the public of the right-to-know of large short-term Ethylene Oxide (EtO) chemical release spikes, time-of-day releases (companies often release at night so the public is not aware), episodes of elevated Ethylene Oxide (EtO) chemical concentrations, location source of release and continuous assessment for increasing elevated levels which allows for quicker public alert notification for sheltering-in-place and emergency evacuations which cannot be done with canisters.

We have brought this request up during the previous Rule 1405 meetings and do not understand why AQMD staff refuses to include this as an option and continues to support a non-real time canister sampling and public reporting method.

Comment 13-11 cont.

11. We support and request amendments to Rule 1405 that include new Real-Time 24/7/365 Fenceline Air Quality Monitoring and Reporting as the primary monitoring and reporting method at commercial facilities using sterilization and fumigation processes using ethylene oxide (EtO). AQMD may use any other sampling method canister or mobile as a secondary validation or during fenceline monitoring equipment downtime such as due to maintenance, a power failure or inclement weather.

Comment 13-12

12. We support and request amendments to Rule 1405 that include new Real-Time 24/7/365 Fenceline Air Quality Monitoring and Reporting as the primary monitoring and reporting method at warehouses packaging and storing products treated with ethylene oxide (EtO). AQMD may use any other sampling method as a secondary validation or during fenceline monitoring equipment downtime such as due to maintenance, a power failure or inclement weather.

Comment 13-13

13. a. We support and request amendments to Rule 1405 that include using the best available Real-Time 24/7/365 Fenceline Air Quality Monitoring and Reporting Equipment with the lowest ethylene oxide (EtO) PPB detection levels. We do not support AQMD giving facilities the option to select equipment that that cannot meet the best and most accurate worker and public safety exposure levels. CFASE has reviewed samples of all Oil Refinery Fenceline Air Quality Monitoring and Reporting Data and we have discovered that there are major differences in what is being reported and the accuracy of what is being reported. In our review it appears that Valero Oil Refinery has the most accurate reporting Fenceline Air Quality Monitoring Equipment.

b. We further request that AQMD compile a comparison chart of the Fenceline Air Quality Monitoring and Reporting Equipment used by each oil refinery so that Environmental Justice Organizations and the public can learn the differences, make educated decisions and recommendations.

Comment 13-14

14. a. We support and request amendments to Rule 1405 that include using the best available Real-Time 24/7/365 Fenceline Air Quality Monitoring, Assessment and Reporting Equipment Software with the lowest ethylene oxide (EtO) PPB detection levels. We do not support AQMD giving facilities the option to select equipment software that that cannot detect, assess or report the most accurate ethylene oxide (EtO) chemical release in order to protect workers and the public. CFASE has reviewed samples of all Oil Refinery Fenceline Air Quality Monitoring and Reporting Data and we have discovered that there are major differences in what is being reported and the accuracy of what is being reported. In our review it appears that Valero Oil Refinery has the most accurate reporting Fenceline Air Quality Monitoring Data and PPB Level Detection Software.

Comment 13-15

b. We further request that AQMD compile a comparison chart of the Fenceline Air Quality Monitoring and Reporting Equipment Software used by each oil refinery so that Environmental Justice Organizations and the public can learn the differences, make educated decisions and recommendations.

Comment 13-15 cont.

15. We support and request amendments to Rule 1405 that include ethylene oxide (EtO) Facility Fenceline Thresholds and Community Public Receptor Thresholds. We support that when determining the Thresholds concentration and exposure level, that acute and chronic risks must also be taken into consideration. We request the following:

    For the Facility Fenceline we request using the threshold from the Agency for Toxic Substances and Disease Registry (ATSDR):

    * Minimal Risk Level Intermediate (daily) health threshold of 70ppb
    * Minimal Risk Level Acute (hourly) health threshold of 400ppb

    For the Public Receptor we request the chronic (70 years) health threshold:

    * CalEPA chronic reference exposure 2.7ppb (0.005 mg/m3)
    * OEHHA Chronic Inhalation REL 16.4 ppb (30µg/m3)
    * TECQ chronic health threshold of 2.4 ppb

Comment 13-16

16. We support and request amendments to Rule 1405 to include an engineering Root Cause Analysis of when a Facility Fenceline Threshold or Community Public Receptor Threshold has been exceeded and what corrective action must be taken.

Comment 13-17

17. We support and request amendments to Rule 1405 to include a public transparent reporting plan and program. We recommend that Rule 1180 be a model.

Comment 13-18

18. We Do Not Support AQMD proposal to use 30-day rolling average or any type of rolling average based on any sampling method because it does not advise workers or the public in real-time that there has been a major release of ethylene oxide (EtO). This deprives the public of the right-to-know, time and opportunity to put on a mask, protective clothing, shelter-in-place or leave to a safe location at a distance from the facility.

Comment 13-19

Respectfully Submitted,

Jesse N. Marquez
Executive Director

Coalition For A Safe Environment Comment Letter, submitted 8/9/2023

13-1 Response: The Occupational Health and Safety Administration (OSHA) Fact Sheet regarding EtO, including the specified information, has been included with the PAR 1405 Staff Report as Appendix A.

13-2 Response: PAR 1405 addresses stack and fugitive emissions from sterilization facilities, while other state and federal requirements addresses accidental releases from EtO uses. While control technology can have co-benefits to on-site workers, it is not the intent nor goal. Worker protection generally falls under the purview of OSHA.

13-3 Response: See Response 13-2.

13-4 Response: See Response 12-10.

13-5 Response: The purpose of PAR 1405 as it pertains to warehouses is to gather information and determine if future rulemaking regarding warehouses is warranted. Additional quantitative data would be appropriate at that time.

13-6 Response: PAR 1405 includes new and enhanced requirements to capture and control fugitive EtO emissions at facilities that perform sterilization including commercial facilities.

13-7 Response: EtO sterilant gas is not typically delivered or stored at sterilization facilities by tanker truck, train, or storage tank. EtO sterilant gas is typically delivered and stored in drums, cylinders, cartridges, or ampules and PAR 1405 has new and enhanced requirements for their storage.

13-8 Response: PAR 1405 applies to EtO sterilization and related operations, including new and enhanced requirements for their EtO storage and dispensing. For example, large facilities must store elements in an EtO dispensing area under PTE.

13-9 Response: The purpose of PAR 1405 as it pertains to warehouses is to gather information and determine if future rulemaking regarding warehouses is warranted. Additional data is needed to determine whether new or enhanced requirements to capture and control EtO emissions at warehouses are necessary.

13-10 Response: See Response 12-18.

13-11 Response: Staff has met with a vendor of OP-FTIR to discuss the capabilities and limitations of the technology. See Response 12-18 regarding a compliance path for OP-FTIR technology. See Response 12-26 regarding public reporting.

13-12 Response: PAR 1405 is technology neutral and allows for any technology that meets the performance standards for fenceline air monitoring. See Response 12-8.

13-13 Response: See Response 13-12.

13-14 Response: See Response 12-8. Discussion and requests regarding oil refinery fenceline air monitoring are outside of the scope of PAR 1405 regarding EtO sterilization and related operations.

13-15 Response: See Response 13-14.

13-16 Response: PAR 1405 is a technology-based rule, not a risk-based rule like Rule 1402. PAR 1405 trigger levels for curtailment from ambient air monitoring were derived from detection limits of monitoring technologies and trigger levels achieved-in-practice for existing EtO fenceline air monitoring plans. PAR 1405 trigger levels are not risk-based. The proposed trigger levels are 24-hour average fenceline levels of 17.5 ppb, 25.0 ppb and 3.0 ppb for Level 1, Level 2 and Level 3 respectively, which are lower than the daily threshold of 70 ppb as proposed by commenter.

13-17 Response: See Response 12-24.

13-18 Response: See Response 12-26.

13-19 Response: PAR 1405 trigger levels for curtailment are based on results of 24-hour time-integrated sampling results. PAR 1405 performance standards; however, facility-wide mass emission rates are based on a 30-day rolling average. The purpose of continuous stack monitoring is to ensure control equipment is performing properly continuously. A 30-day rolling average approach is consistent with South Coast AQMD past practice regarding continuous stack monitoring of performance standards and is also included by U.S. EPA in their proposed NESHAP.

August 9, 2023

COMMUNITIES FOR A BETTER ENVIRONMENT
40 years | established 1978

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RE: Comments on Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations

Dear Areio Soltani:

Communities for a Better Environment ("CBE") submit these comments on Proposed Rule 1405 ("Proposed Rule"). We appreciate the South Coast Air Quality Management District ("AQMD") revisiting Rule 1405 to strengthen controls of ethylene oxide ("EtO") emissions following community concerns on the Preliminary Draft Rule Language released in March 2023.[1] While we appreciate AQMD updating the Proposed Rule with additional measures and requirements, we are disappointed that AQMD continues to fall short in requiring mitigation measures that meaningfully protect environmental justice communities that already face a disproportionate amount of air pollution from transportation, industry, warehouses, and many other sources.

CBE has been involved in the Proposed Rule 1405 process since August 2022 and has continuously advocated for stronger requirements to reduce and control EtO emissions from sterilization facilities. While we acknowledge AQMD for including additional measures such as fenceline monitoring and curtailment of sterilization operations in the Revised Preliminary Draft Rule Language, we are alarmed that these rule additions and updates also fall short in protecting nearby communities that are at risk of high EtO exposure.

As previously mentioned in our April and May 2023 comment letters CBE requests AQMD effectuate strong requirements for facilities that emit EtO such as:

- Requiring Small, Medium, and Large Facilities to adhere to Rule 1405 regulations end of 2023 instead of 2025-2026. — Comment 14-1
- Requiring facilities to suspend operations when any control equipment or technology breaks down or is going through repairs or replacements. — Comment 14-2
- Requiring Rule updates when stronger control systems and technology becomes available. — Comment 14-3
- Requiring interagency coordination with local, state, and federal agencies to educate and better protect workers from EtO exposure by always requiring personal protection equipment and high-quality respirators. — Comment 14-4

[1] AQMD. (2023, March). *Preliminary Draft Staff Report Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations*. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8.

- Requiring the initial summary report to include information such as the location of sensitive receptors within 500ft of warehouses, the wind direction at warehouses, and a diagram showing where pallets are received and stored at a warehouse. Per EPA, it's difficult to know how far EtO can travel due to factors such as concentration, weather conditions, wind speed, and the amount of dispersion.[2] As noted earlier, AQMD has even stated at the March 2023 Public Workshop that EtO can stay in the air for several months.[3]
- Requiring a Rule update when new technologies and data are available. This includes additional safety requirements and technologies for workers who are exposed to EtO on a daily basis. AQMD should revisit and amend the Rule any time there is new information or technology available for the mitigation of EtO emissions.
- Requiring interagency coordination with state and federal agencies to enforce facilities to comply with best practices for frontline communities. Given the toxicity of EtO, AQMD should coordinate with CalOSHA to better protect workers - being that they are the most impacted group in polluting facilities, are frequently people of color or low-income and may also live in the local community. AQMD should also coordinate with the State Water Board to ensure that facilities are not discharging any Sterilizer Exhaust Vacuum Pump working fluid or any EtO contaminated liquids to the wastewater stream.[4] Interagency coordination is instrumental in protecting public health and the environment, and AQMD should consider hosting interagency community workshops that foster an inclusive and accessible environment for the community.
- Requiring AQMD to reconsider alternatives to EtO sterilization such as ionizing radiation (gamma),[5] steam methods, hydrogen peroxide vapor,[6] and other safe alternatives to human health. The lack of material compatibility of EtO and industrial feasibility should not sacrifice the health of communities, workers, and the environment. AQMD should reconsider adopting sterilizing alternatives based on material compatibility as a solution to reduce and control EtO emissions.

Comment 14-5

Comment 14-6

Comment 14-7

Comment 14-8

[2] EPA. (2023, January). *Hazardous Air Pollutants: Ethylene Oxide.* USEPA. HYPERLINK "https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto."https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto.

[3] AQMD. (2023 March 23). *Proposed Amended Rule 1405 - Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slide 3]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par-1405---public-workshop_031723_draftfinal.pdf?sfvrsn=8.

[4] AQMD. (2023 March). *Preliminary Draft Rule Language*. SCAQMD. pg 24. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdrl_031723_draftfinal.pdf?sfvrsn=8.

[5] Gamma Industry Processing Alliance. (2017 August). *A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products*. Stanford University. pgs 10-11. http://large.stanford.edu/courses/2018/ph241/goronzy2/docs/gipa-aug17.pdf.

[6] Shahbandar, Lena. (2018 November). *Alternatives to Ethylene Oxide.* StopSterigenics. https://www.stopsterigenics.com/post/alternatives-to-ethylene-oxide.

While the Revised Preliminary Draft Rule Language has included and revised some of our concerns listed above, the Proposed Rule continues to be ineffective in controlling and preventing EtO emissions particularly with the technology used for fenceline monitoring.

- According to AQMD's Working Group #6 presentation,[7] out of the six EtO monitoring technologies proposed by AQMD, only one meets the criteria – the canister collection – which still faces availability challenges due to potential surge in demand. As for the other EtO monitoring technology, there are issues either with detection limits, established methods, and/or availability. What happens if the Continuous Emission Monitoring System (CEMS) doesn't work and there isn't fenceline monitoring to alert high EtO emissions (since fenceline monitoring will discontinue once CEMS kicks in)?[8] What type of monitoring will take place? We urge AQMD to continue investigating better EtO monitoring technology that detects EtO emissions at the lowest limit to protect nearby communities.

Comment 14-9

It is critical that AQMD revisit the Preliminary Draft Rule Language and implement a stronger ruling with high quality technology, real-time measurements and analysis, and continuous fenceline monitoring paired with CEMS. AQMD should not take lightly the dangers of EtO exposure and carcinogen toxicity given the reassessments by state and federal agencies.[9] Environmental justice communities have suffered enough and should not face neglect and injustice by weak and neutral technology and policies that sacrifice their health. We urge AQMD to continue strengthening the Proposed Rule and we welcome the opportunity to discuss these matters.

Comment 14-10

Sincerely,

Ambar Rivera
Staff Researcher

[7] AQMD. (2023 June 8). *Proposed Amended Rule 1405 - Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slide 37]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par-1405_wgm6_final.pdf?sfvrsn=6.

[8] AQMD. (2023 July 6). *Proposed Amended Rule 1405 - Control of Ethylene Oxide Emissions from Sterilization and Related Operations* [slide 11]. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/pr-1405-wgm7-presentation-063023.pdf?sfvrsn=12.

[9] AQMD (2023, March). *Preliminary Draft Staff Report Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations*. http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8, pg 1-1.

Communities for a Better Environment Comment Letter, submitted 8/9/2023

14-1 Response: See Response 6-3.

14-2 Response: See Response 8-3.

14-3 Response: See Response 8-5.

14-4 Response: See Response 8-6.

14-5 Response: See Response 6-6.

14-6 Response: See Responses 8-5.

14-7 Response: See Response 6-13.

14-8 Response: See Response 6-14.

14-9 Response: Before SCEMS or CEMS are fully certified, fenceline monitoring is required for the interim time period. In addition, annual performance testing of SCEMS or CEMS, such as a Relative Accuracy Test Audit (RATA) will ensure that data is accurate.

14-10 Response: PAR 1405 already has redundant layers of monitoring for stack and fugitive emissions for large facilities. Stack emissions would be required to be monitored with SCEMS or CEMS, which are verified to operate correctly with annual relative accuracy test audits and, as applicable, periodic source testing. A PTE, the method to prevent fugitive emissions, is required to be continuously monitored for negative differential pressure as well as periodic inward face velocity measurements to demonstrate that no emissions are leaving the structure. Before these permanent monitoring requirements are in place, interim fenceline monitoring is required. PAR 1405 contains performance standards based on the best available control technology achieved in practice to ensure EtO is reduced to the maximum extent feasible.

Areio Soltani

From: Jeffrey Chuang <jchuang@lso-inc.com>
Sent: Wednesday, August 9, 2023 2:00 PM
To: Areio Soltani
Cc: Neil Fujiwara; Kalam Cheung; Michael Krause
Subject: [EXTERNAL]Public Comments for PAR 1405

Dear Mr. Soltani,

As I had mentioned at the end of the presentation on July 26th, please see my comments below regarding the draft rule language:

1. (c)(19) PACKAGING AREA: Please update the first sentence to read: "PACKAGING AREA is any area used to perform packaging or re-packaging of Sterilized materials that have completed Aeration."
    a. This change removes "and biological indicator sterility testing" at the end of the sentence.
    b. Biological indicators (BIs) may not be required for products undergoing sterilization.
        i. Example 1: Unlike conventional release, parametric release does not use BIs.
        ii. Example 2: Engineering or validation runs might not use BIs.
    c. If passing BI test results are required to move forward with packaging, this only penalizes smaller companies that do not have resources to validate parametric release or rapid-release BIs.
        i. Parametric release (ISO 11135:2014, §3.25) does not rely on BIs, as confirmation of physical parameters is sufficient to release a load.
        ii. Though rapid BI results may be available before aeration is complete, conventional BI results may take up to 11 days post-aeration.
        iii. For many companies, packaging activities occur while BI testing is in progress.
        iv. For companies using conventional release, large storage areas would be needed to store quarantined work-in-progress.
2. (e)(3)(C) and (e)(3)(D): Please update the verbiage from "STERILIZED WITH ETHYLENE OXIDE (EtO/EO)" to "TREATED WITH ETHYLENE OXIDE (EtO/EO)".
    a. As the word "Sterilized" is synonymous with "Sterile", it would be misleading to apply a "Sterilized" label, when products have not met the regulatory requirements to be labelled "Sterile".
        i. Certain products subjected to certain sterilization cycles might not be considered "sterile", or "free from viable microorganisms" (ISO 11139:2018).
        ii. For medical devices to be labeled "sterile", devices must meet the proper sterility assurance level (ANSI/AAMI ST67:2019).
    b. "TREATED WITH ETHYLENE OXIDE (EtO/EO)" would better encompass all exposed products and cycle validation states.

Comment 15-1

Comment 15-2

Thank you,

Jeff Chuang, CISS-EO, CISS-RAD
Principal Microbiologist

Life Science Outsourcing
830 Challenger Street, Brea, CA 92821
lso-inc.com
Bringing Medical Innovations to Life.

Life Science Outsourcing Comment Email, submitted 8/9/2023

15-1 Response: The definitions and provisions regarding a packaging area have been removed from PAR 1405.

15-2 Response: Thank you for the comment. Suggested updates were incorporated within PAR 1405.

Sterigenics
A Sotera Health company

August 9, 2023

Michael Krause
Assistant Deputy Executive Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Via e-mail at: mkrause@aqmd.gov

Re: SCAQMD Proposed Amended Rule 1405, Control of Ethylene Oxide Emissions from Sterilization and Related Operations, Draft Rule Language Version 07-21-2023

Dear Mr. Krause,

Sterigenics US, LLC (Sterigenics) appreciates the opportunity to participate in the Working Group Meetings (WGMs) for South Coast Air Quality Management District (SCAQMD or District) Proposed Amended Rule 1405, Control of Ethylene Oxide (EtO) Emissions from Sterilization and Related Operations (PAR 1405).

Sterigenics operates three facilities within SCAQMD to sterilize medical devices such as surgical kits, delivery systems, medical hardware, gowns and drapes, surgical accessories, and medical packaging. Sterigenics' facilities play an important role in safeguarding public health by using a Food and Drug Administration (FDA)-mandated non-invasive method to sterilize medical equipment prior to use. This method requires use of EtO and is the only method available for sterilizing large quantities of packaged medical equipment. Sterilization prevents biological contamination in health care settings that can lead to patient infections, and in severe cases, deaths. Sterigenics' facilities within the SCAQMD sterilize over 90 million essential medical devices and supplies each year, including surgical kits, catheters, cardiac implants, stents, IV sets and more. These products are supplied to nearly 100 healthcare product manufacturers, including dozens in the greater Los Angeles-area, as well as local hospitals.

As the District considers PAR 1405, we urge you to continue to consider the greater context within which Sterigenics' facilities operate. The national capacity for EtO sterilization is limited, and shortages of sterilized products and equipment can have – and have had – direct, significant health consequences. Sterigenics supports efforts to reduce EtO emissions to the extent feasible, and to identify alternative methods of sterilization. However, as the FDA has acknowledged, "While signs of innovation are promising, other methods of sterilization cannot currently replace the use of EtO for many devices. To that end, we are equally concerned about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations."[1] Without EtO sterilization, infection risk associated with surgical procedures and other forms of care could be meaningfully increased.[2]

Comment 16-1

[1] FDA, Press Announcement, Jeffrey E. Shuren, MD, JD, Director – CDRH Offices, FDA Continues Efforts to Support Innovation in Medical Device Sterilization (Aug. 3, 2022), https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization.

[2] Based on a presentation published by the FDA illustrating the issues surrounding shortages with EtO-sterilized equipment in particular. https://wayback.archive-it.org/7993/20201225232724/https://www.fda.gov/media/132345/download

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Sterigenics has been an active participant in the PAR 1405 rulemaking process over the past year. On July 21, 2023, SCAQMD released revised draft rule language and a public presentation for PAR 1405,[3,4] although it did not update its staff report, released with an earlier version of the draft proposed rule in March 2023.[5] Sterigenics appreciates the diligence with which staff has been working with stakeholders, but continues to have concerns about the proposed rule language and the apparent bases for some of these provisions, to the extent they are articulated in the March staff report or July presentation. We offer the following comments on PAR 1405; however, we feel strongly that all stakeholders would benefit from additional time to further develop rule language that addresses the issues below and adequately harmonizes the potentially competing requirements from other oversight agencies, and accordingly request that consideration of the rule be delayed by at least 90 days.

Comment 16-1 cont.

I. COMMENTS ON REVISED DRAFT RULE LANGUAGE

1. Rule Impacts to Sterilization Operations in the District

Sterigenics is extremely concerned that the scope and requirements of the proposed rule will drive sterilization capacity out of the state by forcing facilities to close and/or reduce their throughput. This outcome could have deep and lasting impacts on hospitals and health care systems in southern California. It also has the potential to cause an increase in transportation-related criteria air pollutant, toxic air contaminant and greenhouse gas emissions if health care facilities are required to ship products out of state for sterilization. Sterigenics is also concerned that PAR 1405 could require facilities already subject to early action reduction plans (EARPs) to replace equipment that was installed under the EARP. Sterigenics intends to continue working with the District to improve the rule language such that facilities can continue to operate within the District.

Comment 16-2

2. Interim Fenceline Air Monitoring and Curtailment Provisions

The draft rule currently has three different curtailment provisions, something that has never been done before by the SCAQMD. Sterigenics is strongly opposed to the recently added fenceline air monitoring and curtailment provisions (PAR 1405(p) and (q) sections) because such monitoring is not reliable for EtO emissions, yet the curtailment that could be triggered would have a deleterious effect on sterilization operations which, in turn, will harm healthcare services locally and across the country.

We know this from experience: As part of Early Action Reduction Plans (EARP) under Rule 1402 implemented at our Vernon and Ontario facilities, we have been employing such

Comment 16-3

One example used in this presentation is a shortage in recent years of sterilized pediatric tracheostomy tubes, resulting in infections at the insertion point. FDA, GHPUDP Nov. 6-7, 2019, FDA Presentation - Ethylene Oxide.

[3] PAR1405: Preliminary Draft Rule Language. Available at http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_revised_pdrl_072123.pdf?sfvrsn=15

[4] PAR 1405: Public Presentation available at http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par-1405_publicconsultationmeeting_072123.pdf?sfvrsn=8

[5] March 2023 Preliminary Draft Staff Report. Available at: http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8.

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monitoring, along with monitoring-based curtailment triggers, and it has had considerable adverse impacts on our operations and processing capacity, which undoubtedly has had a ripple effect on healthcare. However, we agreed to these monitoring and curtailment provisions in the EARP with the understanding that they would be in place only until construction of the Permanent Total Enclosures at each of our three facilities, after which time such unreliable monitoring, and the related curtailment triggers, would no longer be necessary. It was an interim effort to monitor fugitive EtO – which occurs throughout the basin and rapidly dissipates – with tools that are not ready for prime time, for the reasons discussed below.

In the year that we have been subject to fenceline EtO monitoring, we have extensively evaluated our monitoring results, including those that triggered curtailment, and have concluded that the monitoring results are not consistent with facility operations or potential emissions. In other words, monitoring results are a poor proxy for facility operations. This is consistent with what other agencies have noted in their efforts to evaluate EtO fenceline monitoring.

Other regulatory agencies, including the US EPA and the Georgia Environmental Protection Division have determined that fenceline monitoring for contract sterilization facilities is not sufficiently reliable to identify emission control problems and support interventions. In addition, there are also other known and unknown sources of EtO that could bias fenceline monitoring results. Further, the Utah Department of Environmental Quality recently published a study that indicates a strong seasonal impact on background EtO concentrations and concentrations measured near sterilization facilities.

Based on the available evidence and data from our facilities, fenceline monitoring and associated curtailment provisions are likely to lead to lengthy facility shutdowns that will impact the availability of sterilized medical devices, even where facility emissions are within permitted levels. Moreover, given the demonstrated inability to reasonably relate monitoring results to operations, the curtailment provision is purely punitive and, troublingly, it would force the closure of a lawfully operating facility without a rational nexus to facility operations or emissions. There are many other problems with these curtailment provisions. To cite one example, the proposed monitoring trigger of 3 ppb could be triggered by vehicles or railroad engines idling near to a monitor. **For all of these reasons, Sterigenics strongly urges SCAQMD to eliminate the Interim Fenceline Air Monitoring Requirements in section (p) and all of the Curtailment of Sterilization Operations requirements in section (q) that were recently added to PAR 1405.**

If curtailment provisions are retained, they must be revised such that facilities will not be fully curtailed for extended periods of times. We recognize that SCAQMD is proposing an exemption from curtailment where the availability of sterilized medical devices is limited. However, the rule should set forth the process for securing such an exemption, and allow for sufficient operations to justify sterilizing those devices. FDA does not have adequate tracking nor regular reports of the availability or shortages of medical products in place to properly report such shortages. It is unclear what data, action by FDA or another third-party or other intervention would be necessary to trigger this exemption process.

Comment 16-3 cont.

3. **PAR 1405(d), Large Facility Requirements:**

(c) Definitions:

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(c)(4) for curtailment defines baseline operation as follows:

> *"BASELINE OPERATION is the daily average pounds (lbs) of Ethylene Oxide used in the seven (7) Sterilizer or Combined Sterilizer/Aerator operating days including and prior to the date of the monitoring result or sampling day completion."*

This definition is vague and could be interpreted multiple ways. We recommend that the definition be revised as follows:

> *"BASELINE OPERATION is the daily average pounds (lbs) of Ethylene Oxide used in the seven (7) Sterilizer or Combined Sterilizer/Aerator operating days including and prior to the date of the continuous monitoring result or sampling day completion."*

Comment 16-4

(c)(9): The definition of Control System is not clear, and possibly problematic. (c)(9) states:

> *"CONTROL SYSTEM is equipment and ducting installed for the purposes of collecting Exhaust Streams and reducing Ethylene Oxide emissions consisting of one (1) or more adjoining air pollution control devices in series or parallel and exhausts to one (1) or more stacks."*

It appears that all of the control equipment at a facility may be in one "Control System", despite having separate systems with separate stacks. That could cause problems in using the alternatives in section (d)(1)(C). We believe that all control systems combined, including separate systems, should each be able to use the alternatives in (d)(1)(C).

Comment 16-5

(d)(1)(C): Control Efficiency

PAR 1405 (d)(1)(C) requires that a facility demonstrate EtO emission control efficiency of 99.99% or greater or demonstrate emissions of EtO at a concentration of ≤0.01 ppm for each control system. The detection limit for the test method used has been as high as 0.01 ppm, so documenting a concentration below that is not possible. It will be extremely difficult, if not impossible, to consistently meet the control efficiency and/or concentration limits proposed in the draft rule language. Additionally, Sterigenics recently installed dry beds in the Vernon facilities pursuant to its District-approved EARP under Rule 1402. Operating pursuant to design specifications, the dry beds do not meet the proposed control efficiency in the rule, nor will the manufacturer provide a guarantee of such an efficiency or an outlet concentration that meets 0.01 ppm. These dry beds will be part of the permanent total enclosure required by the proposed rule, and as such they fall under (d)(1)(C) as a result of the problematically broad definition of "Control System" in PAR 1405 (c)(9).

Comment 16-6

(d)(1): Mass Emission Rate using Source Tests

Section (d)(1) would stop sterilization cycles starting on July 1, 2025 based on a single set of source tests if a source test shows an exceedance of 0.015 lbs/hr and less than 99.99% reduction or 0.01 ppm. This provision overrides the 0.015 lbs/hr 30-day average limit in section (d)(2)(B), to an average over the few hours of the source test period. This is a separate curtailment provision on top of the curtailment provisions based on ambient monitoring, and would not have a sunset date. The minimum curtailment period for exceeding the 0.015 lb/hr or 0.01 ppm limits would be 48 hours, but lifting the curtailment

Comment 16-7

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would require a new source test. This requirement could result in a facility being shut down for several months. There is no provision in PAR 1405 that would even allow a restart to conduct a second test if this curtailment occurs before the continuous emissions monitoring systems (CEMS) are in place. Given the schedule that the SCAQMD has proposed for its review of CEMS, it seems almost certain that the CEMS will not be in place before the July 1, 2025 date.

PAR 1405(u)(6) provides a path to restart only after the CEMS is in place, and it is structured as an exemption:

"The requirements of subparagraph (d)(2)(B) do not apply to an owner or operator of a Large Facility that demonstrates the total mass emission rate of Ethylene Oxide from all exhaust stack(s) at the Facility exceeds 0.015 lbs/hr during the present rolling 30-day period, provided the owner or operator:
(A) Did not perform Sterilization in the last 48 hours;
(B) Demonstrates by using the SCEMS or CEMS that the sum of mass emission rates, averaged over a calendar day and measured at each exhaust stack, is 0.015 lbs/hr or less of Ethylene Oxide after resuming Sterilization. . ."

It is certainly possible that the CEMS would have shown compliance with these requirements even though a source test showed non-compliance with (d)(2)(B), which could cause a series of start-ups and curtailments. We request that this curtailment provision be removed.

Comment 16-7 cont.

(d)(2)(A): and Table 1 – Implementation Schedule for CEMS

(d)(2)(A) and Table 1 require installation of a CEMS within 18 months of approval of the CEMS application. The deadline for the application in subsection (d)(5) is March 1, 2025, which we understand is because the District will need 18 months to two years to evaluate CEMS technology. This means that the CEMS may not be installed until late 2026, and possibly much later as there is no deadline for the SCAQMD's review of the application. Sterigenics is willing to install CEMS much sooner than this but cannot do so without the SCAQMD's approval of the plan.

Comment 16-8

(d)(2)(B): Mass Emission Rate Using CEMs

PAR 1405 (d)(2)(B) requires that large facilities demonstrate the sum of mass emission rates measured at each exhaust stack is ≤0.015 lb/hr of EtO from all control systems on a rolling 30-day basis. Sterigenics understands that SCAQMD derived this value from a recently issued permit for the Medline Industries (Medline) facility located in Waukegan, Illinois. The Medline facility permit limits EtO usage to 375 tons/year, and we understand that SCAQMD does not have throughput data to match the emissions data from the Medline CEMS, but it is likely considerably lower than the permit limit. In contrast, the Sterigenics Ontario facility is permitted to use 657 tons/year of EtO. It is therefore not reasonable to require a similar mass emission rate for a facility that processes significantly more EtO. Additionally, the mass emission rate for the Medline facility is provided on a monthly and annual basis. Because the health risk of EtO is dependent upon long term exposure, an hourly mass emission limit is not appropriate. Sterigenics recommends that the mass emission limit be increased and provided in the rule on a daily basis. Sterigenics recommends the rule language be updated as follows:

Comment 16-9

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(d)(2)(B) Demonstrate the sum of mass emission rates measured at each exhaust stack is 0.025 pounds per hour (lbs/hr) or less of Ethylene Oxide from all Control Systems on a 90-day rolling average basis

Comment 16-9 cont.

(d)(3)A: Permanent Total Enclosure (PTE) area

PAR 1405(d)(3)(A) requires that all elements in a Sterilant Gas Storage Area be included within the PTE area. However, Sterigenics has traditionally used exterior EtO storage areas (and implemented alternative leak monitoring procedures to ensure there are no fugitive emissions) both as a best management practice for potential explosive hazards and in compliance with National Fire Protection Association (NFPA) code requirements. Given the potentially explosive nature of EtO, Sterigenics believes that it is much safer to utilize the external storage area with the leak detection monitoring rather than capturing the fugitive emissions from this area and routing them to a control device. Additionally, the provision risks conflicting with other applicable requirements by other oversight agencies, such as NFPA 55 and OSHA PSM requirements. The PAR 1405 leak detection protocols, as well as Sterigenics' facility protocols, are robust and adequately protective. Therefore, Sterigenics requests elimination of the elements of the sterilant gas storage area from the PTE requirements.

Comment 16-10

(d)(4)(F): Annual Report

PAR 1405(d)(4)(F) requires that an annual report be submitted by January 30 each year. Sterigenics recommends that this date be updated to align with the Annual Emission Report due date.

Comment 16-11

4. **PAR 1405(i), Interim Requirements:**

(i)(5): Test Requirements

PAR1405(i)(5) provides concentration limits and test requirements, and we appreciate the clarifications from the prior version. However, the type of testing to which this requirement applies is unclear. Sterigenics requests clarification as to whether these requirements pertain to leak detection and repair (LDAR) programs, or other test requirements. This section also refers to "meeting the requirement as specified in paragraph (i)(8)", but that section has been removed in the current draft rule.

Comment 16-12

(i)(7)(C): Source Test Operating Conditions

PAR 1405(i)(7)(C) requires that source tests be conducted under normal operating conditions. Virtually all of the source test data available for sterilizers uses the methods in 40 CFR Part 63 Subpart O, which provides Ethylene Oxide Emissions Standards for Sterilization Facilities and includes monitoring requirements.[6] It is quite likely that using the methods required in (i)(7)(C) will result in lower efficiencies than the current NESHAP method, making compliance far more difficult. The operational conditions for source tests in the proposed rule should mirror the requirements of the current NESHAP.

Comment 16-13

[6] 40 CFR Part 63, Subpart O. Available at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O.

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5. **PAR 1405(k), Permanent Total Enclosure Requirements:**

(k)(1): Averaging Time for Negative Pressure Demonstration of Compliance

PAR 1405 (k)(1) requires that a facility demonstrate that the permanent total enclosure (PTE) is maintained at a negative pressure of at least 0.007 inches of water column averaged over one minute. Sterigenics agrees that it is necessary to demonstrate compliance with the negative pressure requirements of the rule, but a 15-minute average is a more reasonable time period for compliance demonstration, to accommodate pressure swings caused by wind gusts and other disturbances. SCAQMD has set precedent in Rule 1420.2 for specifying the demonstration - be made on a 15-minute average.[7] Sterigenics recommends the rule language be updated as follows:

> *(k)(1) Demonstrate the Permanent Total Enclosure is maintained at a negative pressure of at least 0.007 inches of water column averaged over ~~one (1) minute~~ fifteen (15) minutes;*

Comment 16-14

6. **PAR 1405(n), Prohibitions:**

(n)(3): Emission Releases

PAR 1405(n)(3) states that the owner or operator of a facility performing sterilization shall not allow the release of uncontrolled emission of EtO to atmosphere from any PTE at any time. It is not possible for facilities to comply with this condition during unforeseen power outages. Facilities have systems in place to shut down the processes. However, fans can continue to run on their own inertia even when scrubber pumps are immediately shut down. Backup generation can take 30 seconds or more to detect the outage, start up, and generate enough power to run processes. Sterigenics recommends the rule language be updated as follows:

> *The owner or operator of a Facility performing Sterilization shall not allow the release of uncontrolled emission of Ethylene Oxide to atmosphere from any Permanent Total Enclosure at any time during normal operations.*

Comment 16-15

7. **PAR 1405(r), Exemptions**

New Section (u)(10)

PAR 1405(k)(2) requires differential pressure monitoring placed at certain walls within the Permanent Total Enclosure. Sterigenics recommends that only walls with natural draft openings be subject to this requirement, since no emissions would be possible from walls without any natural draft openings. Sterigenics recommends that a new section be added to the rule as follows:

> (r)(5) In a Permanent Total Enclosure, walls that do not contain natural draft openings are not subject to the differential pressure monitoring requirements of paragraph (k)(2).

Comment 16-16

[7] SCAQMD Rule 1420.2, Emission Standards for Lead from Metal Melting Facilities. Available at: http://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/Rule-1420-2rev.pdf.

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8. PAR 1405 (t)(5) First Destination Reporting

Sterigenics customers handle the logistics of picking up the products, and accordingly, Sterigenics may not have First Destination information. This requirement needs to be removed, as Sterigenics cannot comply.

Comment 16-17

Sterigenics appreciates the opportunity to provide these comments related to PAR 1405. As outlined above, there are multiple items requiring further analysis and thorough discussion prior to rule adoption. We look forward to continued discussion of this important rulemaking. If you have any questions, please contact me at (630) 928-1771 or via e-mail at kwagner@sterigenics.com.

Sincerely,

Kevin Wagner
Vice President, Global Environmental Health & Safety

Cc: Wayne Nastri, SCAQMD
Sarah Rees, SCAQMD
Areio Soltani, SCAQMD
Neil Fujiwara, SCAQMD
Kalam Chung, SCAQMD
Governing Board Members, SCAQMD

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Responses to Sterigenics US, LLC Comment Letter, submitted 8/9/2023

16-1 Response: Thank you for your participation in this public process.

16-2 Response: See Response 3-1. Regarding replacement of equipment installed under EARPs, staff is sensitive to the issue of stranded assets. However, without additional detail regarding these early actions, staff cannot address specific concerns. Generally speaking, as implied by the title Early Action Reduction Plan, some early actions could be temporary by their nature. PAR 1405 requires permanent measures based on the best available control technology achieved-in-practice.

16-3 Response: Interim fenceline air monitoring and curtailment provisions within PAR 1405 are based largely on fenceline air monitoring and curtailment provisions within two EARPs mutually agreed upon by South Coast AQMD and the two Sterigenics facilities locations in Vernon and Ontario, respectively.

Analysis of curtailment reveals that aside from one initial 100% curtailment at one facility, Sterigenics Vernon and Sterigenics Ontario have operated largely in compliance with EARP provisions and avoided "lengthy facility shutdowns" that would disrupt medical device supply chains. PAR 1405 interim fenceline air monitoring and curtailment provisions, largely based on EARP provisions, are expected to function similarly. PAR 1405 allows for a more frequent sampling schedule, such as 1-in-3 days, or conducting real-time monitoring. Both options would potentially allow an end to curtailment sooner than a sampling schedule of 1 in 6 as data to verify fenceline levels would be available sooner. On top of this, after implementation of measures in EARP, fenceline levels are expected to be reduced.

The primary purpose of interim fenceline monitoring is to ensure fenceline EtO are below certain levels while facilities make improvements to meet proposed stack and fugitive emission requirements. Fenceline data collected based on 24-hour time integrated samples on a 1-in-3 or 1-in-6 days frequency might not provide the temporal resolution to represent facility operations. However, fenceline monitoring coupled with curtailment provisions allow an immediate response to elevated fenceline EtO concentrations. Based on the fenceline monitoring data at Sterigenics Vernon and Ontario, curtailment is an effective means to reduce fenceline EtO levels at sterilization facilities.

In addition, as noted in the Comment Letter, PAR 1405 has an additional exemption allowing medical devices to continue to be sterilized if declared reasonably likely to be in shortage by U.S. FDA or other federal, state, or local health authorities or California hospitals or medical centers. Curtailment as a consequence of interim fenceline air monitoring is expected to be minimally impactful, serving as a deterrent for elevated ambient air EtO concentrations until the certified stack CEMS or SCEMS is in place. While curtailment provisions do not sunset, the trigger level does change, however, evidence from a sterilization facility with multilayer stack control and PTE fugitive control indicate fenceline air monitoring levels are well below that trigger level.

16-4 Response: PAR 1405 has been revised to incorporate the suggested change.

16-5 Response: Each Control System, however defined by Permit to Operate, Control System Implementation Plan, or Facility Implementation Plan, must demonstrate compliance with either the 99.99% control efficiency or the 0.01 ppm outlet concentration performance standard. All of the air pollution control devices controlling EtO emissions from a facility could be considered a single Control System, or separate grouping of smaller Control Systems. For example, three dry bed scrubbers with three separate stacks could be considered one, two or three Control Systems as long as it is clearly specified in permits/plans. The definition allows flexibility due to variety of sterilization control implementations in South Coast AQMD.

16-6 Response: Due to technical feasibility, the control efficiency requirement will be demonstrated only through source tests. For low inlet scenarios, it is expected that the alternative performance standard of 0.01 ppm is achievable based on source test data evaluated.

16-7 Response: The phrasing “the owner or operator of a Large Facility shall not perform Sterilization unless the following requirements are met” has been revised to “the owner or operator of a Large Facility shall” followed by the respective requirements.

16-8 Response: As stated at the August 2023 Stationary Source Committee Meeting by Jason Aspell, Deputy Executive Officer of South Coast AQMD’s Engineering and Permitting Division, the processing of permit applications for PAR 1405 equipment is one of the Division’s highest priorities and have been acted on expeditiously.

The South Coast AQMD Governing Board at their September meeting authorized the purchase of real-time monitoring technology, which would assist in the certification of SCEMS/CEMS. The compliance deadlines represent the deadline when facilities are required to comply with certain

requirements, facilities are encouraged to work with South Coast AQMD closely to accelerate the certification process and to submit the applications earlier than the proposed deadlines.

16-9 Response: PAR 1405 has been revised to allow a facility-wide mass emission rate determined by calculation of a specific facility's permitted EtO throughput and a compliant control efficiency of 99.99%, expressed to the thousandths of a percent.

16-10 Response: See Response 3-5.

16-11 Response: See Response 3-6.

16-12 Response: Interim test requirements do not pertain to LDAR programs as LDAR programs are only required after interim test requirements sunset. This interim test requirement was formerly known as a "leak test" but the term "leak" has been modified under PAR 1405. Paragraph (i)(8) of PAR 1405 was formerly known as paragraph (f)(2) under *Test Methods*.

16-13 Response: Paragraph (i)(7) are interim requirements for source testing that were previously included in Rule 1405. PAR 1405 would not change the existing source testing requirements. However, PAR 1405 source testing requirements specified in subdivision (l) would source testing to be conducting during maximum or typical operating conditions, to be specified in the source test protocol.

16-14 Response: See Response 3-13.

16-15 Response: See Response 3-14.

16-16 Response: See Response 3-17.

16-17 Response: PAR 1405 has been revised to require either the First Destination or the customer information to be recorded.

From: Evan Sanford <Evan@redlandschamber.org>
Sent: Wednesday, August 30, 2023 11:14 AM
To: Clerk of Board <clerkofboard@aqmd.gov>
Subject: [EXTERNAL]Written Comment (PAR 1405)

Dear SCAQMD Governing Board,

I hope this message finds you well. I am writing to submit a written comment for the upcoming South Coast Air Quality Management District (SCAQMD) Governing Board meeting on September 1st, specifically concerning Proposed Amended Rule (PAR) 1405.

Thank you for your dedication to maintaining the well-being of our community. The significance of sterilization facilities in California extends beyond the prevention of infections; they are integral to securing continued access to vital medical devices that countless patients rely upon. As you deliberate the potential implementation of this regulation, I kindly urge you to conduct a comprehensive assessment of the potential consequences associated with PAR 1405.

Comment 17-1

Best Regards,
Evan Sanford
Executive Director, Redlands Chamber of Commerce
47 N. First St | Redlands, CA | 92373
Phone: (909) 793-2546
Cell: (818) 425-5667
Email: evan@redlandschamber.org

Redlands Chamber of Commerce Comment Email, submitted 8/30/2023

17-1 Response: Thank you for your participation in this public process. Please refer to the PAR 1405 Socioeconomic Impact Assessment for a comprehensive assessment of the potential economic consequences associated with PAR 1405.

Regarding non-economic impacts, staff understands that EtO sterilization plays a critical role in the supply chain of medical devices and patient health, and has considered the implementation requirements in PAR 1405. Working with sterilization facilities, community and environmental stakeholders, and regulatory agencies like U.S. FDA, PAR 1405 reduces stack and fugitive emissions of the known human carcinogen EtO in a feasible 21-month timeframe with achieved-in-practice technology while ensuring hospital and medical centers continue to receive sterilized medical devices without reduced supply. PAR 1405 also includes a curtailment exemption to allow sterilization to continue if product is reasonably likely to experience reduced supply and is critical to public health. The exemption from curtailment for certain products ensures hospitals and medical centers continue to receive sterilized medical devices without reduced supply of products that would are critical to public health.

Areio Soltani

From: Jeffrey Chuang <jchuang@lso-inc.com>
Sent: Wednesday, October 4, 2023 4:04 PM
To: Areio Soltani
Cc: Kalam Cheung; Neil Fujiwara; Michael Krause
Subject: [EXTERNAL]Comment for PAR 1405

Dear Mr. Soltani,

Could you please update the definition of (c)(36) Tier II Warehouse for clarity? Per the September 28, 2023, Version, the definition may be read ambiguously as either:

A) TIER II WAREHOUSE is a Facility
1. with at least 100,000 square feet and
2. less than 250,000 square feet of indoor floor area used for Warehousing Activities, and
3. reports to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment].

or

B) TIER II WAREHOUSE is a Facility
1. with at least 100,000 square feet and less than 250,000 square feet of indoor floor area used for Warehousing Activities, and
2. reports to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment].

I recommend changing the wording to:
TIER II WAREHOUSE is a Facility, which reports to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment], with an indoor floor area used for Warehousing Activities of at least 100,000 square feet and less than 250,000 square feet.

Comment 18-1

Thanks,
Jeff Chuang, CISS-EO, CISS-RAD
Principal Microbiologist

Life Science Outsourcing
jchuang@lso-inc.com
830 Challenger Street, Brea, CA 92821
lso-inc.com
Bringing Medical Innovations to Life.

Life Science Outsourcing Comment Email, submitted 10/4/2023

18-1 Response: The definitions for both Tier I Warehouse and Tier II Warehouse have been updated to remove ambiguity in their readings.

AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
W:: AdvaMed.org

October 13, 2023

Sarah Rees
Deputy Executive Officer
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: Revised Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization

Deputy Officer Rees:

I'm writing today on behalf of AdvaMed, the Advanced Medical Technology Association, regarding South Coast Air Quality Management District's (South Coast AQMD) proposed amended Rule 1405 – Control of Ethylene Oxide (EtO) and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes. AdvaMed is the world's largest association of medical technology innovators and manufacturers. Our members are transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments leading to improved patient outcomes.

We appreciate the opportunity to submit comments and the willingness of South Coast AQMD staff to meet with stakeholders on outstanding concerns. Our goal has been consistent since the beginning: a rule that is workable, achievable, and continues to protect public health. The supply of sterile medical technology is an essential part of the latter portion of this goal and the continued, safe use of EtO is important to achieving it.

EtO is used to sterilize approximately 20 billion medical devices annually. The volume of EtO used to sterilize these devices – about 50% of all medical devices – amounts to ½ of 1 percent of all EtO used each year. EtO exists ambiently even in areas far from any known human sources and, as SCAQMD itself has noted, commercial sterilizers are not the source of the ambient EtO.

We appreciate the continued engagement of SCAQMD staff with us, our members, and others impacted by PAR 1405 and are grateful that the current draft contains several meaningful changes to help prevent disruptions to patient care. A few issues still need resolution, however, to continue protecting both patient access and public health.

Comment 19-1

Unreliable Compliance Methods Risks Disruption to Patient Care

Fenceline monitoring, as proposed in PAR 1405, uses unreliable technology that is easily manipulated and influenced by sources of EtO other than commercial sterilizers. For example, results can vary significantly due to wind patterns, weather events, and other geographic conditions. This reliance risks significant disruptions to patient care by triggering sterilizer curtailment without any link to actual facility compliance or increased protection of public health. Further, the analysis of the results from this monitoring is – at best – available days after the reading was taken, resulting in curtailment being applied well after any alleged violation. Notably, other jurisdictions have contemplated using fenceline monitoring for compliance; none have adopted it due to the inconsistent and problematic readings.

To account for patient care disruptions, the updated draft proposes several mechanisms for obtaining an exemption for medical technology that may be in short supply. These exemptions are merely a band-aid on the larger issue: that the rule itself is likely to trigger multiple – if not continuous – curtailment of facilities due to factors outside their control, namely the myriad of other sources of EtO which include decaying plants, human respiration, and diesel engines. These unnecessary curtailments could then trigger the very shortages the rule is trying to avoid through proposed exemptions.

In practice, the proposed implementation process also lacks clarity and practicality. For example, it requires a regulatory body or hospital to certify that a product is in short supply but is unclear on how hospitals can or will implement this documentation. Further, sterilizers run multiple cycles of different products and would be required to obtain additional certification from multiple companies across various divisions. Additionally, staff has suggested the FDA medical device shortage list as documentation, however, this list does not encompass the full scope of products or devices that would be impacted by the curtailment.

Attempting to mitigate the negative supply chain impacts through an unworkable exemption fails to acknowledge the underlying issue that fenceline monitoring is unreliable and should not be used for compliance.

Comment 19-2

Additional Remaining Concerns

In addition to the above concerns, the following issues remain:

- **The current timeline is still not feasible.** Once the rulemaking is complete, and regulatory operational requirements are finalized, facilities will need to upgrade control systems. This includes designing and planning, budgeting, ordering equipment, and

Comment 19-3

installing and testing the new control systems before January 2026. Existing supply chain issues and competition for consultants and parts will all impact this timeline.

- **Two-hour notification for trigger-level reporting.** The two-hour notification requirement for trigger-level reporting is unreasonable. It is unclear how this will be implemented. Some labs run 24/7 and may deliver results at any time but it is unclear how facilities would handle these varying circumstances.
- **One-minute sample interval for CEMS (c(7)).** The one-minute reading is limited to a single technology not proven to work with all abatement equipment. We recommend revising this to a reasonable interval that is recognized and workable with abatement equipment.
- **Permanent total enclosure requirements – inward face air velocity measurement procedures.** We are concerned with the practical application of K(3) as this requirement may be problematic for some NDOs. Facial velocity measurements, performed by the methodology specified in the proposed Appendix 4, may not be possible in some instances and may lead to results that are not representative. This is likely due to flow disturbances near the NDOs or configurations of the NDOs. NDOs are often odd shapes, such as slits under doors or the circular area surrounding a pipe entering a PTE, and rarely resemble the rectangle example provided in Appendix 4.
- **Leak detection and repair (LDAR) program required daily audio-visual (AV) checks (m(3))**. Required daily audio-visual checks are impractical and excessive. The employee risk of accessing some components subject to LDAR outweighs the value of daily AV inspections. These inspections sometimes require ladders and lifts and/or access to roofs or mezzanines. Weekly inspections would be more appropriate and consistent with the most conservative EPA-required AV inspection frequency for other industries (e.g., 40 CFR Part 63, Subpart H). Rather than require daily checks, employees working in areas subject to LDAR could also be trained to report potential leaks identified during their normal activities to supplement the weekly inspections.
- **Reporting timelines.** In section (t)(7)(A)(i) for fenceline air monitoring, we recommend changing the language "(i) No later than 10 days after the date of sampling," to "After receipt of results." Facilities cannot control contract laboratory delays in processing samples. We also consider the (t)(10)(A) & (B) and (t)(11)(B) 24-hour reporting for PTE delta P and LDAR Exceedance, respectively, as constituting excessive/burdensome reporting. These types of exceedances would be addressed by facilities in a reasonable timeframe and would not be representative of a potential release to the environment.

Comment 19-3 cont.

Comment 19-4

Comment 19-5

Comment 19-6

Comment 19-7

Comment 19-8

Thank you for the opportunity to submit written comments. We look forward to continuing to work with staff to ensure the rule is achievable and protects patient access.

Sincerely,

Bobby Patrick, VI
Vice President, State Government, Regional Affairs, and Alliance Development
AdvaMed

AdvaMed Comment Letter, submitted 10/13/2023

19-1 Response: Thank you for your participation in this public process. We appreciate the perspective of AdvaMed on these issues including background EtO.

However, the characterization of the position of the South Coast AQMD regarding background EtO is inaccurate and is outside the scope of this rulemaking activity.

19-2 Response: Regarding "unreliable technology", see Response 1-7 regarding fenceline air monitoring technology.

Staff disagrees that the curtailment exemption process "lack clarity and practicality". Rule staff, working closely with stakeholders including U.S. FDA, have carefully crafted the curtailment exemption to streamline the exemption process and remove unnecessary hurdles that were present in previous iterations of the exemption.

PAR 1405 does not require "a product is in short supply" but instead, after feedback from U.S. FDA, applies the standard of "reasonably likely to experience a reduced supply". Certification of "reasonable likely" is a communication, such as a website or letter, and is more thoroughly explained in the Staff Report. The U.S. FDA medical device shortage list website was offered as an example only, and was not the only communication acceptable by PAR 1405.

19-3 Response: Staff believes that 21 months after rule amendment until the September 1, 2025 compliance deadline for a Large Facility or a Post-Aeration Storage Facility and 25 months until the January 1, 2026 compliance deadline for a Medium Facility or a Small Facility are sufficient for stack and fugitive emission control requirements in PAR 1405.

19-4 Response: Rule language has been updated to report "as soon as reasonably possible, but no later than 9:00 a.m. of the next operating day after receiving the results" to account for overnight laboratories and results delivered at any time of day.

19-5 Response: PAR 1405, consistent with the South Coast AQMD Rule 218 series, defines a CEMS as able to take record a measurement every one (1) minute and an SCEMS, or a semi-continuous emission monitoring system, as able to take and record a measurement every 15 minutes. Both CEMS and SCEMS are acceptable for stack monitoring for PAR 1405 and allow a wide range of technologies, such as GC-PID, FTIR, CRDS, and tunable infrared laser direct absorption spectroscopy (TILDAS).

19-6 Response: Staff is aware of the performance standard in U.S. EPA Method 204 and expects some facilities to modify their building envelopes to permanently close some natural draft openings (NDOs) and create new ones to meet the PTE performance standard at all NDOs. Measurements taken using this method would be representative of the actual operating conditions at the facility. Obstructions or configurations that lead to a deficient inward face velocity would need to removed or corrected.

19-7 Response: Staff believes that Components, Elements, and other equipment capable of leaking EtO should be, at minimum, inspected daily by sight and sound, to see or hear for leaks. As the audio-visual inspection can occur at ground level, it would not be necessary to perform these inspections with a ladder or lift. While the 40 CFR Part 63, Subpart H requires a weekly audio-visual inspection, it is not the most stringent requirement. South Coast AQMD Rule 1173 requires an audio-visual inspection every 8-hour shift.

19-8 Response: Staff has reviewed existing fenceline air monitoring plans (FAMPs) for two sterilization facilities in the region and reached out to several laboratories performing U.S. EPA Compendium Method TO-15 analysis. Existing FAMPs contain deadlines ranging from 10 days to 14 days after sampling. After careful review, PAR 1405 has been revised to require results 14 days after the date of sampling.

Regarding operational noncompliance reporting, staff does not consider either a telephone call or an email, at the facility's choosing, within 24 hours of an EtO leak or failing to maintain sufficient negative pressure within a PTE as excessively burdensome upon a facility.

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

October 18, 2023

Sarah Rees
Deputy Executive Director
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization: Medical Product Distribution Concerns

Dear Deputy Executive Director Rees:

On behalf of the Health Industry Distributors Association (HIDA), I write to provide additional information on the potential impact that Proposed Amended Rule (PAR) 1405 – Control of Ethylene Oxide Emissions from Sterilization – could have on the medical products supply chain. I appreciate the opportunity to share how the PAR could negatively affect the entire care continuum, from timely access to sterile medical products to the quality of patient care.

HIDA is the industry trade association representing 118 medical product distribution companies operating 500+ medical distribution centers across the care continuum nationwide. HIDA members deliver medical products and supplies, manage logistics, and offer customer services to virtually every healthcare provider. In 2020 and 2021, they reliably delivered over 90 billion units of PPE "the last mile" to providers.

HIDA appreciates South Coast Air Quality Management District's (AQMD's) commitment to addressing Ethylene Oxide (EtO) risk using the best science and regulatory tools available under the law to protect community members and employees at sterilization facilities. Healthcare distributors also want to protect public health, and to do so they must be able to deliver sterile critical medical products to providers without interruption in the supply chain. Regulatory policies that limit or abolish the use of EtO as a sterilization agent would have a profound negative effect on healthcare providers and patients.

Sterilized medical products are critical to healthcare. Medical devices are composed of many different types of materials that can be damaged if exposed to the wrong type of sterilization. For many medical devices, EtO is the only sterilization method that does not damage a device during the sterilization process. For example, radiation can make plastics brittle, steam can damage electronics, and heat can melt acrylics. Poor or incomplete sterilization can lead to transmission of infectious diseases or compromised patient health. EPA stated in the Federal Register, "Commercial sterilization facilities play

Comment 20-1

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a vital role in maintaining an adequate supply of medical devices," and about 50% of all medical devices are sterilized with EtO. This amounts to more than 20 billion devices annually.

Comment 20-1 cont.

As you deliberate on PAR 1405, we ask that you consider the following:

Availability Of Sterile Product
Due to our healthcare system's need for sterile medical products and devices for safe patient care, EtO sterilization is currently at capacity. This means that regulations that would have the effect of limiting or restricting commercial sterilization would be catastrophic to the healthcare supply chain, resulting in a public health crisis. EtO sterilizes 95% of all surgical kits. As previously mentioned, it is also the only safe, effective method of sterilization for about 20 billion medical products a year.

Comment 20-2

Fenceline Monitoring
The updated version of PAR 1405 introduces fenceline monitoring as an additional enforcement tool. Fenceline monitoring is not reliable due to the presence of EtO in the environment from sources other than sterilization. EtO is a naturally occurring gas, and comes from other sources such as buses, charcoal grills, lawn mowers, and other commercial products. As a result, EtO has been measured in places that are nowhere near a commercial sterilization facility. It is for this reason that establishing a baseline threshold is problematic as testing results often may not reflect plant operations.

Comment 20-3

Additional Warehouse Requirements
The additional requirements for warehouses appear unnecessary. A March 2023 AQMD staff report indicates no elevated levels detected around warehouses. In addition, tools are already available for AQMD (i.e., Rule 1402) to mitigate increased levels of EtO that should be applied instead to this situation. AQMD should utilize current rules to address these situations rather than creating a new and redundant policy.

Comment 20-4

Thank you for taking our comments on PAR 1405 into consideration. If you have any questions, I can be reached at rouse@hida.org.

Sincerely,

Linda Rouse O'Neill
Senior Vice President, Supply Chain Policy
Health Industry Distributors Association

510 King Street, Suite 200 • Alexandria, VA 22314
Phone: 703-549-4432 • **HIDA.org**

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HIDA Comment Letter, submitted 10/18/2023

20-1 Response: Thank you for your participation in this public process. We appreciate the perspective of the Health Industry Distributors Association (HIDA) on these issues.

20-2 Response: Staff disagrees that PAR 1405 would limit or restrict commercial sterilization. Working with sterilization facilities, community and environmental stakeholders, and regulatory agencies like U.S. FDA, PAR 1405 reduces stack and fugitive emissions of the known human carcinogen EtO in a feasible 21-month timeframe with achieved-in-practice technology while ensuring hospital and medical centers continue to receive sterilized medical devices without reduced supply. PAR 1405 includes a calculation method to derive the facility-wide mass emission rate, based on a compliant 99.99% control efficiency control system, from the sterilization facility's specific EtO usage limit, to ensure sterilization is not limited. PAR 1405 also includes a curtailment exemption to allow sterilization to continue if product is reasonably likely to experience reduced supply and is critical to public health. The exemption from curtailment for certain products ensures hospital and medical centers continue to receive sterilized medical devices without reduced supply of products that would are critical to public health.

20-3 Response: See Response 1-7 regarding fenceline air monitoring.

20-4 Response: See Response 11-4 regarding elevated EtO signal detected near at least one Tier I Warehouse.

The additional requirements are to assess EtO emissions from warehouses, which are necessary given the lack of emission data from these type of facilities. A survey of warehouse facilities revealed that three (3) of 14 responding warehouses, or more than 20%, were not even aware whether or not they were receiving sterilized pallets. Recordkeeping and emission data would assist in determining the need for additional control requirements. While Rule 1402 is used to address risk from a particular facility, EtO emissions could potentially be emitted from all or a subset of warehouse facilities. Addressing risk facility by facility would be lengthy, resource intensive for both the facility and agency, and could cause a delay in addressing the public's exposure to EtO emissions.

HOSPITAL ASSOCIATION of Southern California

October 25, 2023

The Governing Board
South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, CA 91765

Re: Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization

Dear Members of the South Coast Air Quality Management District Governing Board:

On behalf of the Hospital Association of Southern California (HASC). I am writing to express our concern in relation to the Proposed Amended Rule 1405 in relation to the control of Ethylene Oxide (EtO) emissions from sterilization. HASC represents over 180 member hospitals and 35 health systems across 6 counties, with the goal of improving the operating environment for hospitals in order to provide quality healthcare to the communities they serve.

We understand the critical role that the South Coast Air Quality Management District (SCAQMD) plays in protecting public health and the environment and appreciate your efforts to maintain a safe and healthy environment for all Californians.

Hospitals in Southern California provide care to patients around the clock, 365 days a year. Access to reliable medical equipment is essential to our ability to deliver life-saving care to those in need. While we recognize and support the need to remove toxic air pollutants from our environment, including the reduction of EtO emissions, we are sensitive to the potential impact a new policy on EtO may have on the supply chain to our hospitals.

Our members have expressed concern over potential supply chain disruptions related to the proposed changes to EtO emissions restrictions from sterilization. Some critical medical items, such as surgical kits, heart valves, pacemakers, and catheters, currently rely on EtO sterilization as the only large scale, viable and safe option. Approximately 20 billion medical devices are sterilized using EtO annually nationwide, highlighting the magnitude of its importance in the healthcare sector.

Comment 21-1

1

HOSPITAL ASSOCIATION of Southern California

Historically, when sterilization facilities in other states have experienced shutdowns or disruptions, California hospitals have felt the immediate impact. Accessing essential medical devices is becoming increasingly challenging, which directly affects patient care and safety. These disruptions can have life-threatening consequences for our patients.

HASC kindly requests that SCAQMD collaborate closely with sterilization organizations and the healthcare industry to ensure that the good intentions of Proposed Amended Rule 1405 are realized while minimizing the impact on the availability of EtO sterilized medical devices.

We value the opportunity to work collaboratively with SCAQMD to find a balanced solution that prioritizes both environmental protection and the uninterrupted availability of critical medical supplies for healthcare providers. Together, we can strive to achieve cleaner air and a healthier environment without jeopardizing patient care for the communities across Southern California.

Thank you for your attention to this matter, and we look forward to continuing our dialogue and collaboration with SCAQMD to find a solution that safeguards public health while ensuring the continuity of healthcare services.

Comment 21-1 cont.

Sincerely,

George W. Greene, Esq.
President and CEO
Hospital Association of Southern California

HASC Comment Letter, submitted 10/26/2023

21-1 Response: Thank you for your participation in this public process. We appreciate the perspective of the Hospital Association of Southern California (HASC) on these issues. See Response 16-3 regarding curtailment exemptions declared by California hospitals or medical centers.

Based on feedback from sterilization facilities, community and environmental stakeholders, and regulatory agencies, like U.S. FDA, PAR 1405 reduces stack and fugitive emissions of the known human carcinogen EtO in a feasible 21-month timeframe with achieved-in-practice technology. PAR 1405 also includes a curtailment exemption to allow sterilization to continue if product is reasonably likely to experience reduced supply and is critical to public health. The exemption from curtailment for certain products ensures hospital and medical centers continue to receive sterilized medical devices without reduced supply of products that would are critical to public health.