SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

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

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South Coast AQMD Air Quality Management District 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. During South Coast AQMD's monitoring efforts at several commercial EtO sterilization facilities, the agency became aware of fugitive emissions from sources that were not previously known. South Coast AQMD's investigation identified that existing pollution controls would need to be upgraded and measures would be needed to reduce 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[1] 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 contains provisions related to warehouses that receive EtO-sterilized materials from sterilization facilities. Certain large warehouses are required to track and report the amount of EtO sterilized materials received.

This Preliminary 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.

[1] http://www.aqmd.gov/home/rules-compliance/compliance/toxic-hot-spots-ab-2588

1 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)[2] and by the United States Environmental Protection Agency (U.S. EPA) as a Hazardous Air Pollutant.[3] 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.[4] U.S. EPA completed a reassessment of the cancer potency of EtO in 2016[5] and OEHHA is currently reassessing the toxicity of EtO.

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 fugitive emissions from 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 be needed to reduce 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.

[2] CARB Identified Toxic Air Contaminants | California Air Resources Board. (n.d.).
[3] Initial List of Hazardous Air Pollutants with Modifications | U.S. EPA
https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications
[4] Chemicals Considered or Listed Under Proposition 65 – Ethylene oxide | OEHHA
https://oehha.ca.gov/proposition-65/chemicals/ethylene-oxide
[5] IRIS Assessment for Ethylene Oxide | U.S. EPA
https://iris.epa.gov/ChemicalLanding/&substance_nmbr=1025
[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.[8]

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[9] and U.S. EPA updated their EtO cancer risk values in 2016, which is more stringent than current OEHHA risk values. OEHHA is currently in the process of revising the risk values for EtO.

1.3 REGULATORY HISTORY

Federal, State, and Local Ethylene Oxide Sterilization Regulations

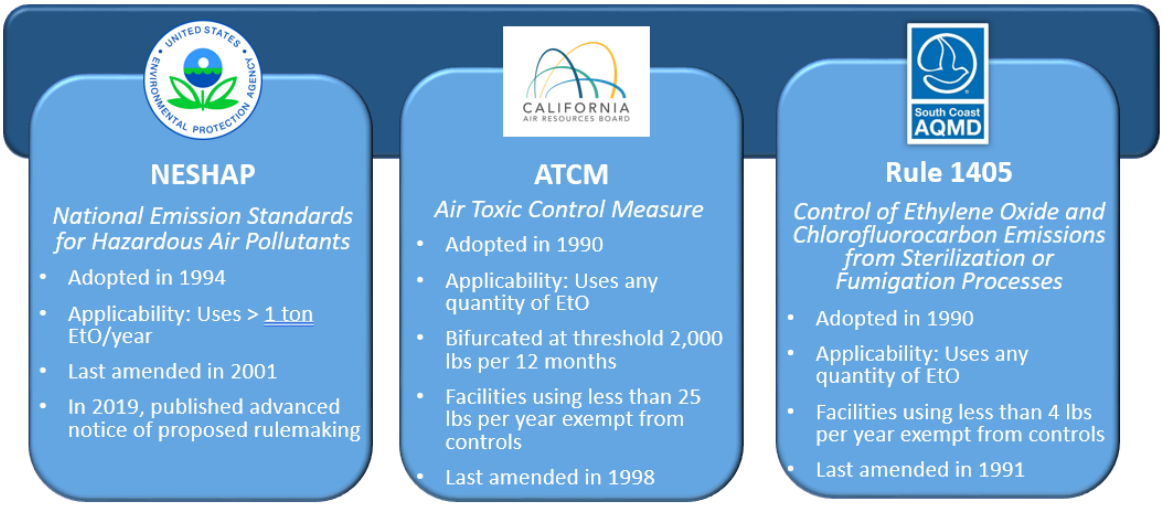
In 1990, both the California Air Resources Board and South Coast AQMD adopted regulations to control EtO emissions from sterilization operations in the form of an Air Toxics Control Measure (ATCM) and Rule 1405, respectively. This was due to the harmful health effects listed by U.S. EPA health assessment 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 ethylene oxide (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. Figure 1-1 shows the Federal, State, and South Coast AQMD regulations for EtO sterilization operations.

[7] https://www.cdc.gov/niosh/topics/ethyleneoxide/default.html

[8] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto

[9] Ethylene Oxide. (2009). California Office of Environmental Health Hazard Assessment. Retrieved February 28, 2023, from https://oehha.ca.gov/chemicals/ethylene-oxide

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. Table 1-1 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 address 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.[10] These billions of medical devices are sterilized by approximately 100 domestic commercial sterilization facilities,[11] located in 32 different U.S. states and Puerto Rico.[12] 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

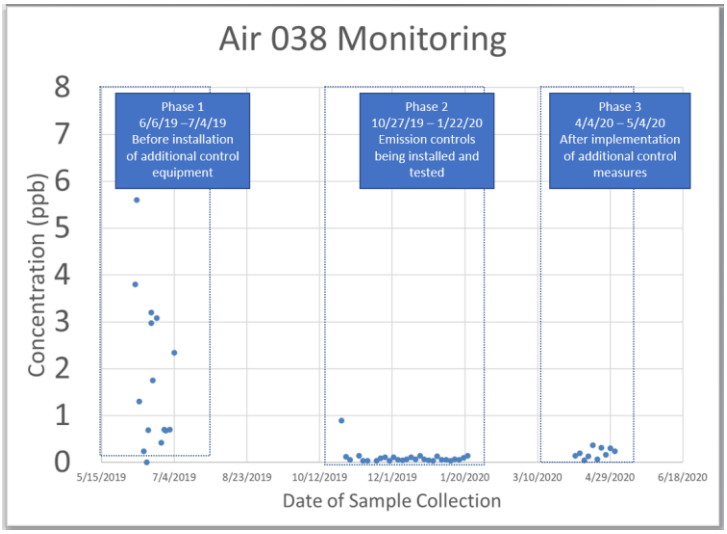
In 2019, the State of Illinois passed two laws that placed restrictions on the emission of ethylene oxide. Senate Bill 1852, also known as Public Act 101-0022, prohibits EtO sterilization facilities from operating in Illinois unless they continuously monitor ethylene oxide stack emissions, capture 100% 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 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.[13] 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 emissions by using a continuous emission monitoring system.[14] 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 1-2 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.

[10] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[11] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/ethylene-oxide-risk-commercial-sterilizers
[12] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-commercial-sterilization-facilities
[13] https://www.lakecountyil.gov/4192/Medline-Independent-EtO-Monitoring-Resul
[14] Construction Permit, Application No. 19020013 | IEPAhttps://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/medline-industries-19020013-final.pdf

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. 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 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.[15]

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

[15] https://epd.georgia.gov/document/document/sterigenics-consent-order/download

emits approximately 5,600 lbs of EtO per calendar year.[16] 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.[17]

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[18] 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[19] which specifies the tolerances for residues of EtO for food commodities that may expose consumers to EtO through ingestion.

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 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

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

(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.

(2) If enhanced signals were observed in the step above, ambient air in silica-lined stainless steel Summa canister samples would be collected then analyzed using U.S. EPA method TO-15/TO-15A, either as grab samples of air or fenceline monitoring with 24-hour integrated samples.

As of February 2023, South Coast AQMD has conducted mobile monitoring at seven active sterilization facilities (all permitted to use 2,000 lbs or more of EtO) and nine warehouses that store or may store EtO-sterilized materials. In addition, South Coast AQMD has conducted ambient fenceline monitoring 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 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 April 2022, open hatches for tanks that stored EtO-containing liquids were observed at the facility. A nearby community site at a residential location was included in May 2022. Figure 1-3 shows monitoring sites near the facility.

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

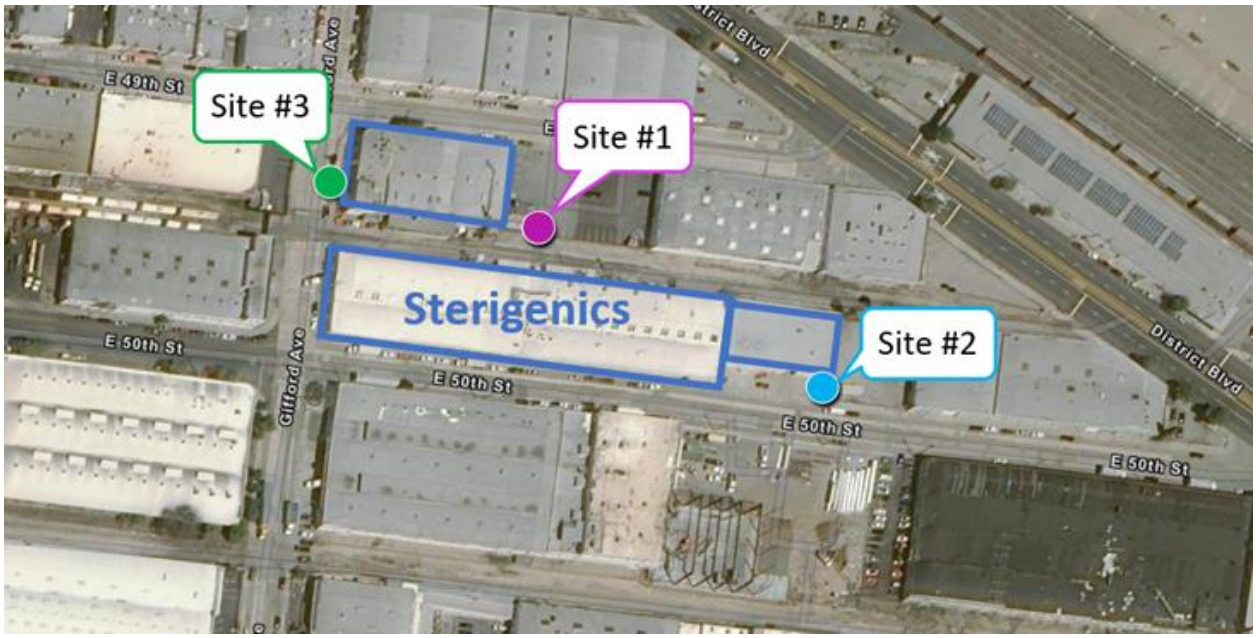
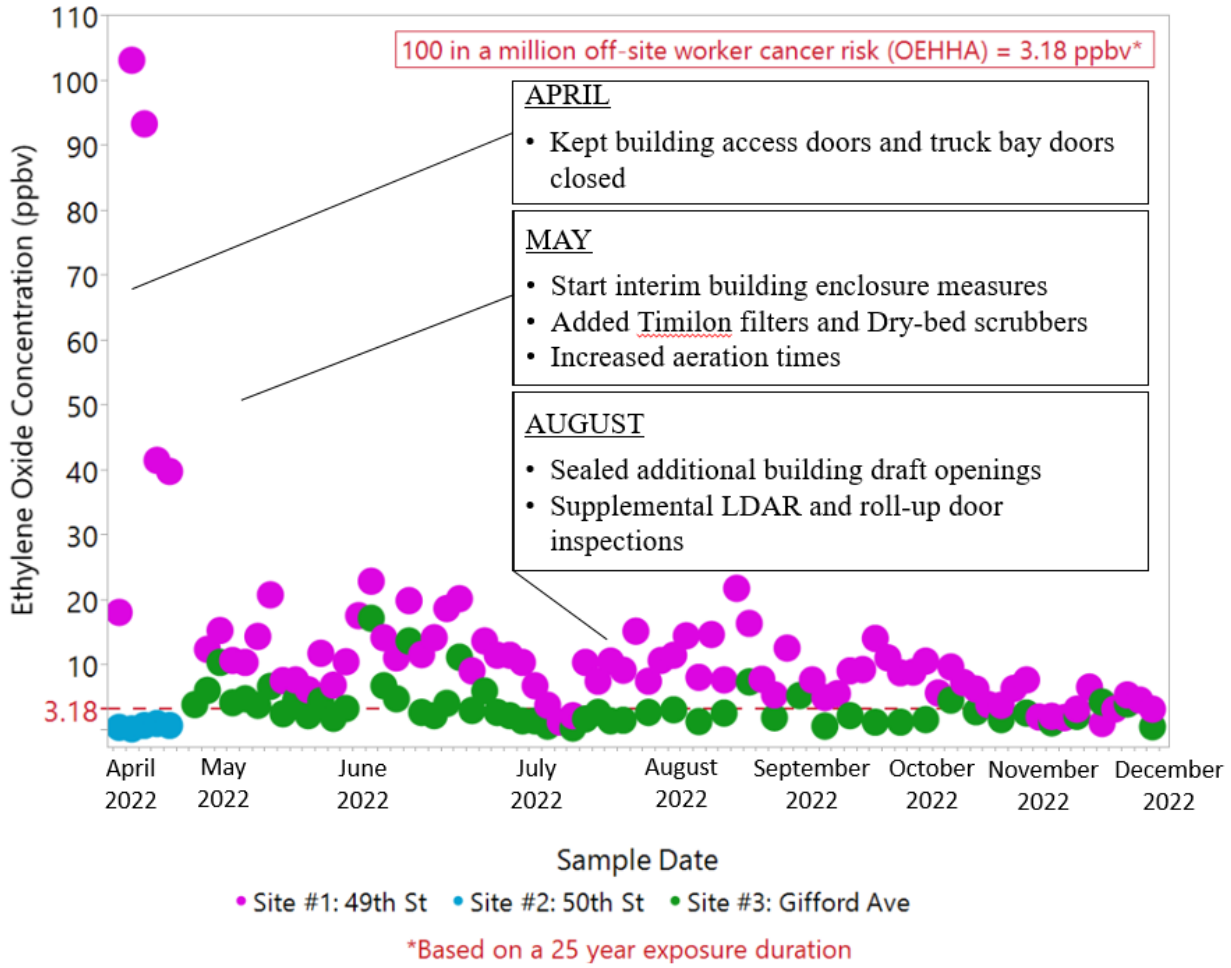


Figure 1-4 – 24-Hour Near-Source Samples in Vernon



On June 7th, 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)[20] under the AB2588 program to control EtO emission, approved on September 9, 2022,[21] a PTE would be installed to control fugitive emissions. As interim 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. Figure 1-4 shows the results of the near-facility EtO levels and the key measures taken at the facility to control EtO emissions.

As shown in Figure 1-4, during the first two weeks of monitoring, monitoring (24-hr time integrated samples) at three near-source sites showed EtO levels as high as 103 parts per billion

[20] 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
[21] https://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp-approval-letter.pdf?sfvrsn=8

by volume (ppbv). Ambient EtO levels decreased below 25 ppbv by mid-May and to levels of 10 ppbv or lower during the 4th quarter of 2022.

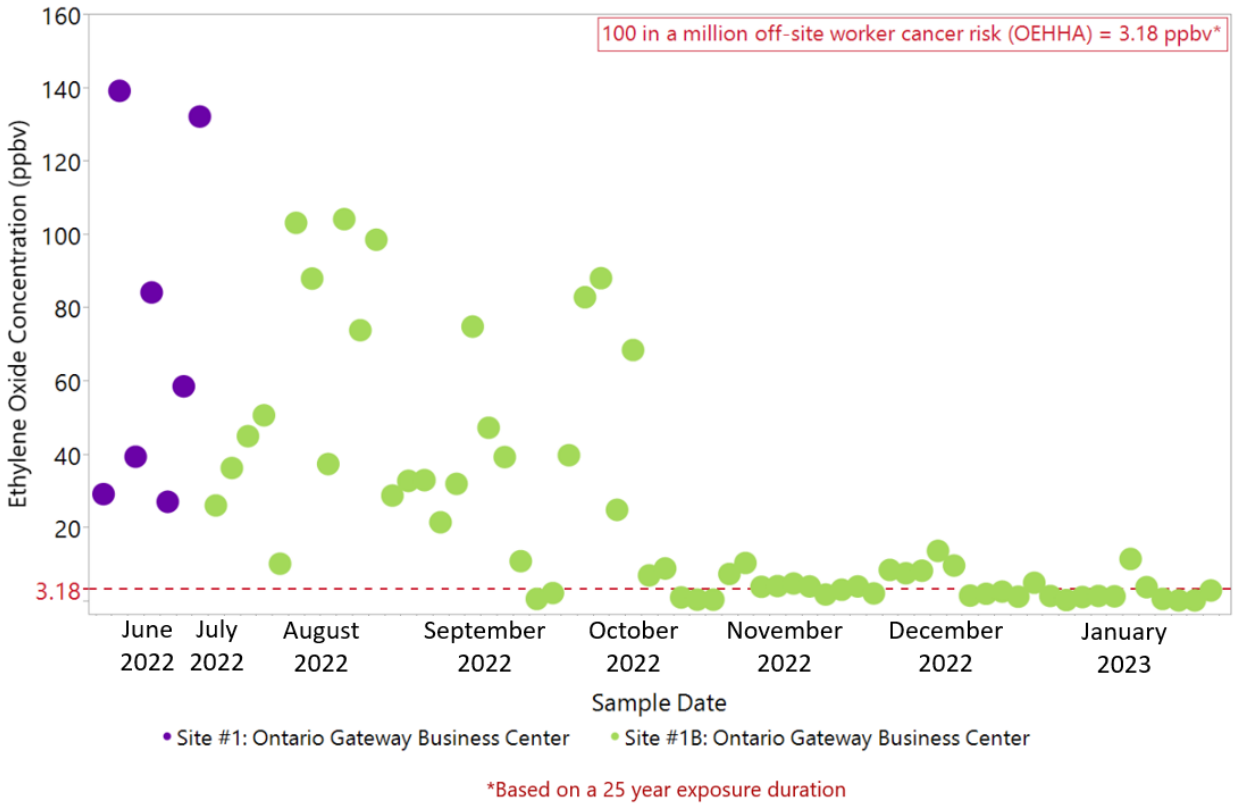
1.4.2 Sterigenics Ontario Sterilization Facility

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. 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 shows the monitoring sites near the facility.

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

On September 29th, 2022 Sterigenics Ontario was designated as Potentially High-Risk Level Facility under the AB2588 Air Toxic "Hot Spots" program. As required by Rule 1402, Sterigenics Ontario submitted a draft EARP for review by the South Coast AQMD, committing to changes to their facility and practices to reduce EtO emissions. Figure 1-6 shows the results of EtO monitoring near Sterigenics Ontario.

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



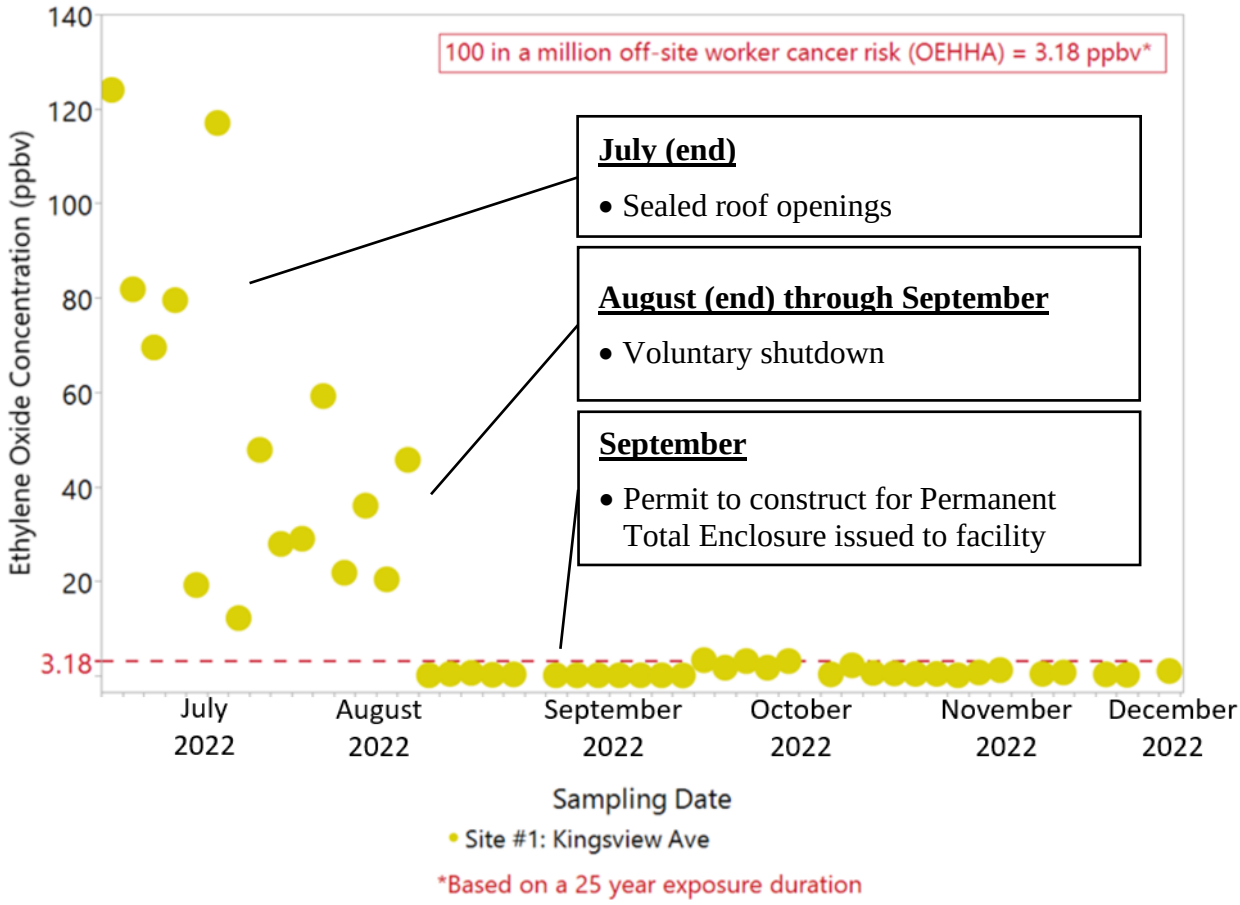
1.4.3 Parter Carson Sterilization Facility

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 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 28th, 2022. Figure 1-7 shows the monitoring location near the facility.

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

On August 19th, 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 at the end August, 2022,he facility temporarily ceased operation voluntarily to implement 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. Following the implementation of these control measures, ambient EtO monitoring showed a decrease in EtO concentrations. Figure 1-8 shows the results of EtO monitoring near Parter Carson.

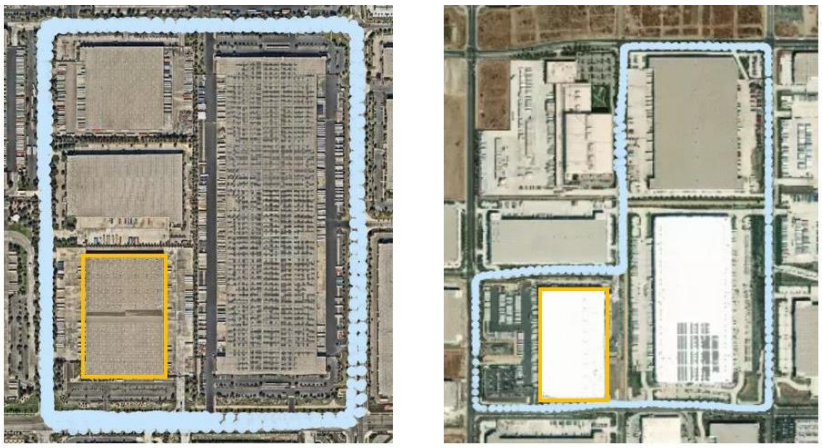
Figure 1-8 - 24-Hour Near-Source Samples in Carson



1.4.4 Warehouses (Including Aeration-Only Facilities)

There are 70 facilities registered with 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 February 2023, nine warehouses registered with U.S. FDA as Wholesale Drug Distributors or Third-Party Logistics Providers were monitored in the cities of Redlands, Rialto, Riverside, San Bernardino, and Sante Fe Springs. EtO mobile monitoring measurements have not detected significant enhancements in EtO signals near warehouses. 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. Future versions of the staff report would update the monitoring efforts as information becomes available. Figure 1-9 shows two examples of mobile monitoring platform survey around two warehouses (outlined in orange) and the survey route showing no enhancements in VOC signals (light blue).

Figure 1-9 - Examples of Mobile Monitoring Platform Survey of Warehouses



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 the 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 February 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. Table 1-3 shows the industry type.

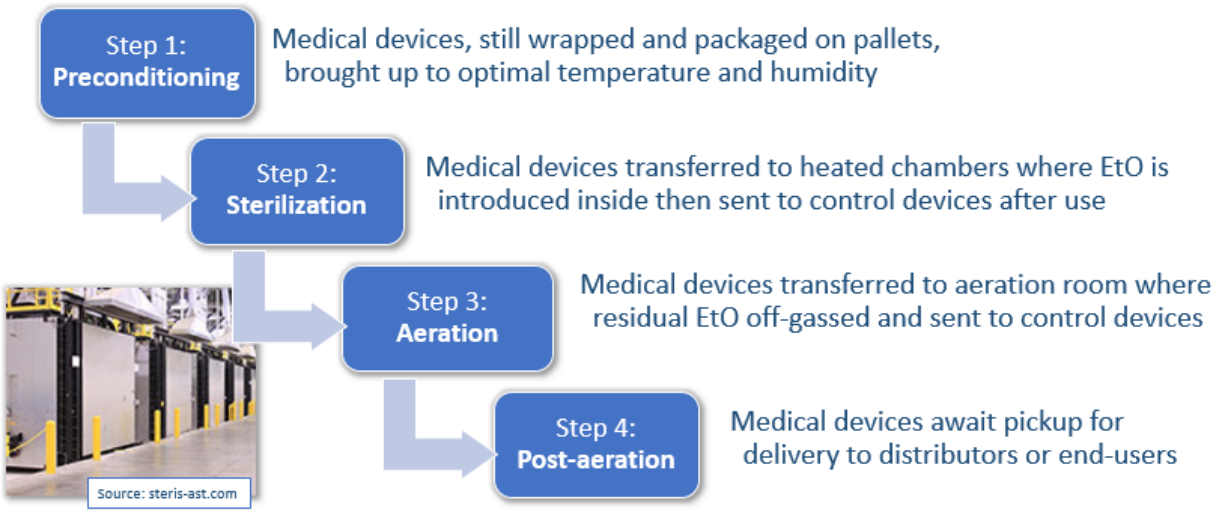
Table 1-2 - Industry Type of Rule 1405 Facilities in the South Coast AQMD

Facility	NAICS Code	Industry Type	Rule 1405 Classification
STERIGENICS US, LLC (Ontario)	339999	All Other Miscellaneous Manufacturing	> 4,000 lbs per year
STERIGENICS US, LLC (Vernon)	339999	All Other Miscellaneous Manufacturing	> 4,000 lbs per year
STERIS, INC.	541380	Testing Laboratories and Services	> 4,000 lbs per year
APPLIED MEDICAL RESOURCES	541611	Administrative Management and General Management Consulting Services	> 4,000 lbs per year
PARTER MEDICAL PRODUCTS INC	561910	Packaging and Labeling Services	> 4,000 lbs per year
AMERICAN CONTRACT SYSTEMS INC	444190	Other Building Material Dealers	> 4,000 lbs per year
ST. JUDE MEDICAL CRMD	334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	400 – 4,000 lbs per year
MICROVENTION, INC	339112	Surgical and Medical Instrument Manufacturing	400 – 4,000 lbs per year
ADVANCED BIONICS, LLC	334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	400 – 4,000 lbs per year
LIFE SCIENCE OUTSOURCING, INC	339112	Surgical and Medical Instrument Manufacturing	4 – 400 lbs per year
ANIMAL EYE VET INC.	541940	Veterinary Services	4 – 400 lbs per year
VCA W COAST SPEC & EMERGENCY ANIMAL HOSP	541940	Veterinary Services	4 – 400 lbs per year
LA CITY, GREATER LA ZOO	813410	Civic and Social Organizations	< 4 lbs per year
UNIVERSITY OF CALIFORNIA, LOS ANGELES	611310	Colleges, Universities, and Professional Schools	< 4 lbs per year
MT. SAN ANTONIO COMMUNITY COLLEGE	611210	Junior Colleges	< 4 lbs per year
CARDINAL HEALTH	423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	Aeration-Only Facility

1.5 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.[22] Figure 1-10 provides a simple schematic of commercial EtO sterilization process. And the following sections would describe each of the step im more detail.

Figure 1-10 - 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.

[22] 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.[23] 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

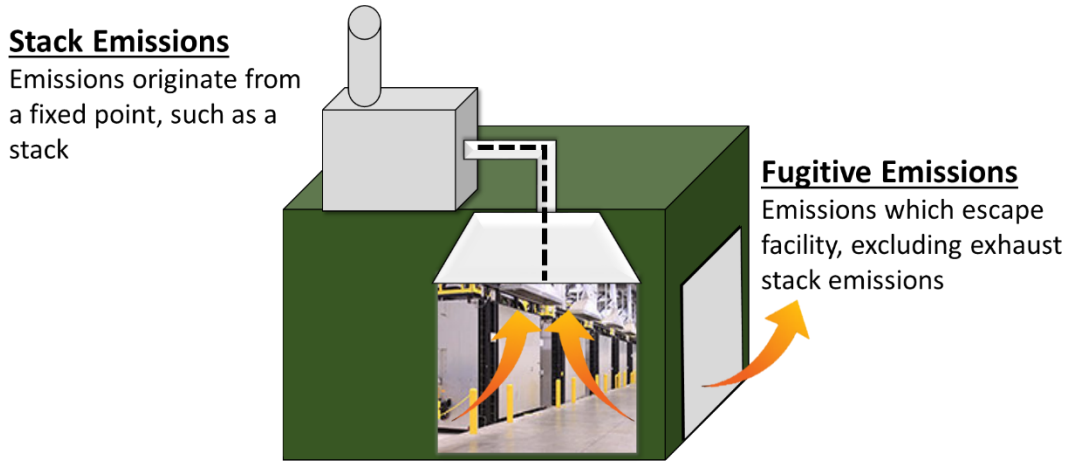
After the sterilization process, sterilized material is transported from the sterilization facility to distribution warehouse or the customer. While U.S. EPA estimates that 99% of EtO emissions exhaust during the sterilization process (e.g., sterilization chamber vent, aeration room vent, chamber exhaust 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.[24]

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

1.6 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 emission 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 through air currents passing through the building at openings. Both stack and fugitive emissions can potentially impact nearby receptors. Figure 1-11 illustrate the two general types of facility emission sources.

Figure 1-11- 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 leaving the facility, except stack emissions. Fugitive emissions, unlike stack emissions, are much harder to characterize. 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. 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). See PTEs below.

1.7 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)

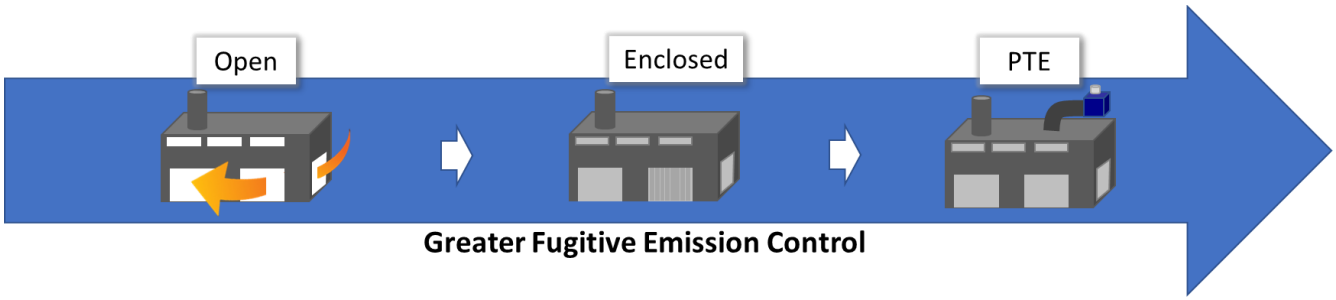
Peak shaver technology, also known as a balancer system, is a packed tower scrubber that uses a solution to temporarily absorb EtO which can then be stripped off at a steady rate (i.e., concentration) before sending it to a downstream EtO control device, typically a catalytic oxidizer. The peak shaver/balancer 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 emissions prevents them from becoming fugitive. 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. Figure 1-12 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 1-12 - Examples of Building Enclosures to Reduce Fugitive Emissions



The requirements for a PTE are specified by U.S. EPA Method 204.[25] Building openings are limited and also required to maintain an inward face velocity of at least 200 feet per minute at each opening so no toxic air contaminants can escape the PTE. The negative pressure is created through the use of the APCD's blower motor that collects the interior air, along with any toxic air contaminants, and sends it to an APCD.

1.8 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. 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. Table 1-3 shows the source testing results for large sterilization

[25] 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

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 0.025 pounds per hour for four of seven facilities. Table 1-3 shows a summary of source test results for other PAR 1405 facilities such as sterilization 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 1-3 - EtO Source Tests Results for Sterilization Facilities Permitted for ≥2,000 lbs 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 1-4 - EtO Source Tests Results for Sterilization Facilities Permitted for <2,000 lbs 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 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.

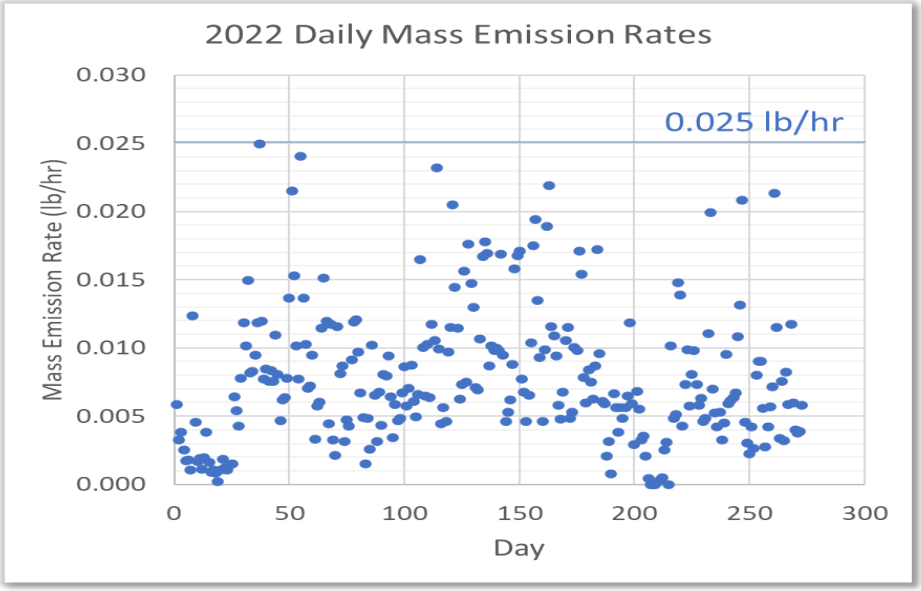
These monitoring systems are commonly required and used to measure nitrogen oxides (NOx) and carbon monoxide (CO) for large combustions sources such as natural gas turbines found at power plants. Whereas implementation of CEMS is mature for the monitoring of NOx and CO, currently there is not a promulgated U.S. EPA performance specification for CEMS for EtO specifically.[26] A draft performance specification for EtO is expected to be released.

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

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

successfully passed a RATA[27] for construction and CEMS certification. Data available on the Illinois EPA website[28] for the Construction Permit showed that the facility's EtO emissions were below 0.025 lb/hr for the entire case study period (1st, 2nd, and 3rd quarters of calendar year 2022). See Figure 1-13 below.

Figure 1-13 - 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, continuously monitoring indoor EtO concentrations at a commercial sterilization facility in Puerto Rico.[29]

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

[27] 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

[28] 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

[29] 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

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.[30]

1.9 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 to the ambient environment through stack and fugitive sources. While existing rules and regulations contain requirements addressing stack emissions, they are insufficient to control fugitive release of EtO. 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.

1.10 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. The PAR 1405 Working Group is composed of representatives from businesses, environmental groups, public agencies, and consultants. South Coast AQMD has held five 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, and February 16, 2023. In addition, a Public Workshop is scheduled on March 23, 2023 to present PAR 1405 and receive public comment.

As part of PAR 1405 rule development, staff conducted site visits at seven (7) facilities. Due to COVID-19 concerns, five (5) site visits were conducted remotely and two (2) were conducted in-person. Staff also distributed a survey 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.

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

2 CHAPTER 2 - SUMMARY OF PROPOSED AMENDED RULE 1405

2.1 OVERALL APPROACH

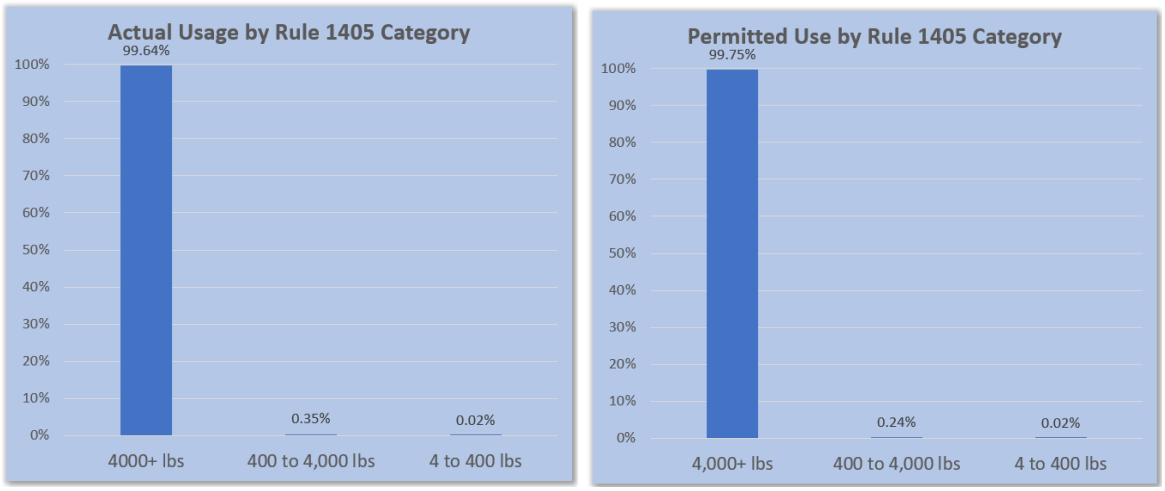
PAR 1405's objective is to further reduce stack emissions of EtO as well as prevent fugitive emissions from facilities that conduct EtO sterilization and related operations. PAR 1405 accomplishes this with revisions to Rule 1405 to establish new emission limits based on achieved in practice levels observed 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. Additionally, 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 2000 pounds per year of EtO, for the most stringent requirements of the proposed rule.

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 the prohibitions in subdivision (o) 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 4,000 pounds or more of EtO made up over 99% of all the EtO, both usage and permitted. Figure 2-1 shows the actual and permitted EtO limits for Rule 1405 facilities for the 2021 year.

Figure 2-1 - Rule 1405 EtO Statistics for Facilities in the South Coast AQMD



In light of the 2021 data above, it is expected that Large Facilities (facilities permitted to use 2,000 pounds or more of EtO) would have a similar if not slightly greater percentage of EtO in the Basin. 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 to meet either a control efficiency or concentration limit based upon the permitted EtO throughput of the facility. The emission limit for control efficiency and outlet concentration limits are based on source tests data which shows real word data 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 Medline Waukegan's source test and CEMS data. Table 2-1 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)	≤ 0.025 lb/hr	≥ 99.99% control efficiency **OR** ≤ 0.01 ppm
≤ 2,000 (Medium & Small)	No proposed amendment	≥ 99.9% control efficiency **OR** ≤ 0.01 ppm

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 PAR 1405 includes updated performance standards to address EtO emissions, permit applications to modify existing equipment and to construct new equipment are anticipated. An evaluation of the applicable fee schedule and permitting structure is being performed. Additional clarification and information will be provided in future public meetings or in a future release of the staff report.

2.2 PROPOSED AMENDED RULE STRUCTURE

PAR 1405 includes the following subdivisions 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 Reporting Requirements
(i) Interim Requirements
(j) CEMS, SCEMS, and other Monitoring Requirements for Stack Emissions
(k) Permanent Total Enclosure Requirements
(l) Recordkeeping
(m) Source Test Requirements

(n) Leak Detection and Repair (LDAR) Program Requirements
(o) Prohibitions
(p) Reporting
(q) Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage
(r) 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 associated warehouses that receive EtO-sterilized shipments will be required to 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 assess potential ethylene oxide emissions from warehouses.

Subdivision (b) – Applicability

This rule applies to an owner or operator of any facility performing ethylene oxide sterilization, any post-aeration storage facility, or warehouse storing materials sterilized with ethylene oxide. 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 has been revised to align 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.
- 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 adjoining air pollution control devices that reduces emissions of Ethylene Oxide and exhausts to a single stack 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. PAR 1405 requirements specify both source testing and SCEMS/CEMS requirements based on each exhaust stack of a control system at a facility.
- DESIGNATED WAREHOUSE
  The definition was added to describe warehouses that are notified by the Executive Officer of the South Coast AQMD that they are subject to the recordkeeping and reporting requirements required of large warehouses.
- ELEMENT
  The definition was added to describe equipment that contain 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 ampoules of sterilant gas or barrels of liquid used sterilizer vacuum pump working fluid.
- EXHAUST STREAM
  The definition was expanded to include 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.
- 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.
- LARGE WAREHOUSE and NEW LARGE WAREHOUSE
  These definitions were added to identify a subgroup of warehouses. This subgroup was determined based on the warehouse size and also if reporting to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as required by the Drug Supply Chain Security Act, which may be a warehouse receiving EtO-sterilized materials. New large warehouse is needed to establish an implementation schedule for future large warehouses.
- 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.
- 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 two 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.
- 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.
- 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 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 before and after exposure to sterilant gas in the use of this definition in the rule.
- STERILIZER
  The definition has revised to differentiate this type of equipment from combine 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.
- WAREHOUSE
  The definition was added to due to the expanded applicability of PAR 1405 to include a subset of these facilities for recordkeeping and reporting requirements as part of data gathering.
- 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. 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) – Control of Stack Emissions

Beginning December 31, 2024, facilities are required to meet the most stringent 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 0.025 pound per hour. As shown in Chapter 1, a mass emission limit of 0.025 pounds per hour has been achieved in practice at Medline Waukegan. Source testing would also be required annually. Large facilities would be required to source test at least annually to demonstrate compliance with the applicable performance standard.

Paragraph (2) – Stack Emission Monitoring Requirements

Beginning December 31, 2025 or within 12 months of approval of a South Coast AQMD-certified SCEMS or CEMS, whichever is sooner, facilities are required to monitor the EtO emissions from the exhaust stack of each Control System, one or more adjoined APCD venting to atmosphere with one single stack, using the SCEMS or CEMS to demonstrate compliance with the facility-wide mass emission rate limit and concentration limit, both averaged over the calendar day, from midnight to midnight, that it was operated. These operations include sterilization and related operations with the potential to release EtO such as aeration or storage 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.

Paragraph (3) – Control of Fugitive Emissions

Beginning December 31, 2024, large facilities would be required to maintain within a PTE the following: sterilizers, combined sterilizer/aerators, back-draft valves, aerator, post-aerators, elements of a sterilant gas storage area, and elements of a waste storage area. Control systems not within the PTE would need to be included in a LDAR program as there is no PTE to capture any leaks.

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 ethyl glycol storage tanks, are required to be under an LDAR program or a PTE.

Paragraph (4) – Other Requirements

Beginning three months after date of rule amendment, large facilities must record the destinations of sterilized palletized units, would be subject to labeling requirements for sterilized materials, equipment, and bills of lading, and must maintain a facility diagram. Incorporation of ATCM reporting requirements is also included.

Paragraph (5) – Permit Application Submission Schedule

No later than December 31, 2023, or approximately six months after rule amendment and 12 months before stack emission control requirements in paragraph (d)(1) and fugitive emission control requirements in paragraph (d)(3) take effect, large facilities must submit complete permit application to South Coast AQMD to modify any existing equipment to comply with those paragraphs.

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) – Control of Stack Emissions

Beginning July 1, 2025, 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. Source testing would be required annually to demonstrate compliance with the performance standard.

Paragraph (2) – Control of Fugitive Emissions

Beginning July 1, 2025, medium facilities, regardless of configuration, would be required to operate a PTE for the post-aerator used to store sterilized materials directly from an aerator or a combined sterilizer/aerator. Areas used for transport, loading, or unloading between a combined sterilizer/aerator and the post-aerator used for storage are not required to be under PTE control. When these sterilized materials are needed, they may be removed from the post-aerator/PTE environment and would not be required to held under PTE at the facility any further.

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.

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

Paragraph (3) – Other Requirements

Beginning three months after date of rule amendment, a medium facility would be subject to the labeling requirements for equipment and must maintain a facility diagram.

Paragraph (4)

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.

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) – Control of Stack Emissions

Beginning December 31, 2025, 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. Source testing would be required annually to demonstrate compliance with the performance standard

Paragraph (2) – Control of Fugitive Emissions

Beginning December 31, 2025, 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.

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

Paragraph (3) – Other Requirements

Beginning three months after amendment, a small facility would be subject to the labeling requirements for equipment and must maintain a facility diagram.

Paragraph (4)

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.

Subdivision (g) – Post-Aeration Storage Facility Requirements

Post-aeration storage facilities are storage facilities like warehouses that receive EtO-sterilized materials from sterilization facilities that continue to off-gas EtO.

Subdivision (g) specifies the requirements for a post-aeration storage facility which is 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 place their control systems under PTE or monitoring their components under an LDAR program. Post-aeration storage facilities also would be subject to the labeling requirements for equipment and must maintain a facility diagram.

Subdivision (h) – Warehouse Reporting 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 large warehouses including new large warehouses for data gathering purposes through recordkeeping and reporting requirements. Other warehouses may become designated warehouses and be subject to recordkeeping and reporting requirements of this subdivision if the Executive Officer of the South Coast AQMD receives information that the warehouse may be source of EtO emissions. The basis of a designation is expected to primarily come from the reporting requirements of large EtO sterilization facilities based on where their EtO-sterilized materials are being shipped but may be the result of South Coast AQMD activities such as complaint investigations, inspections, or ambient air monitoring. The warehouse reporting data collected will help South Coast AQMD determine 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 of PAR 1405's implementation schedules are in effect. The interim requirements will sunset based on the schedule specified in exemptions found in subdivision (r) Table 3 for the respective requirements so that there will not be duplicate requirements for facilities.

Subdivision (j) – SCEMS or CEMS, or other Monitoring Requirements 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 annual 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 daily averaged 0.025 pound per hour emission limit and if applicable, the 0.01 ppm concentration limit. These stack monitoring systems will also be subject to requirements 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.

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, potentially through a new performance specification that would accompany the NESHAP. 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 sent 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 one minute averaging time 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.

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 monthly. Appendix 3 is included in PAR 1405 to provide additional instructions and clarifications on how these measurements are to be performed and recorded.

Paragraph (k)(4) specifies notification requirements to South Coast AQMD in the event the negative pressure levels fall below the threshold set in paragraph (k)(1) or if the monitoring is offline, resulting in more than 24 consecutive hours of missing data.

Subdivision (l) – Recordkeeping

Subdivision (l) 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 (m) – Source Test Requirements

Subdivision (m) 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.

Paragraph (m)(1) specifies requirements for source test protocols (protocols) submitted to be reviewed 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 limits 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.

Paragraph (m)(2) specifies the conditions where a revised protocol is required to be submitted and approved by the South Coast AQMD prior to annual retesting after the source test conducted pursuant to the approved source test protocol in paragraph (m)(1). A revised source test protocol would be required any time there was a change to the EtO source 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. If there have been no changes, the facility's source testing contractor may use the most recent approved source test protocol by the South Coast AQMD.

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

Paragraph (m)(5) specifies 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 (m)(6) specifies requirements for submittal of the source test report for review by South Coast AQMD.

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

Subdivision (n) 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 biannual 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 monthly leak checks, 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 scheduled monthly 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 the other regulations with a lower leak threshold and does not allow for facilities to have an extended repair window for self-identified leaks.

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

Paragraphs (n)(3) and (n)(5) requires that all Components and Elements subject to the LDAR program be free of leaks greater than 2 ppm above background and inspected at least every calendar month. CARB Test Method 21 section 8.3.2 specifies how background is assessed in the process area and recorded.[31] 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 (n)(4) requires a daily audio-visual inspection of Components. The daily inspections allow the early identification of leaks outside of monthly leak inspections.

Paragraph (n)(5) requires monthly inspections using a portable analyzer to check for leaks pursuant to CARB Test Method 21. If EtO is not used as the calibration gas, the manufacturer's correction factor must be applied based on the calibration gas used to be corrected to EtO. The portable analyzer should be maintained and operated per the manufacturer to ensure accurate measurements.

Paragraph (n)(6) requires that records of the daily and monthly inspections be documented to demonstrate compliance.

Subdivision (o) – Prohibitions

Subdivision (o) specifies the general prohibitions for a sterilization facility. PAR 1405 retained and updated prohibitions that were previously in Rule 1405. Two new prohibitions were added to prohibit the release of uncontrolled fugitive emissions.

Paragraph (o)(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 (o)(2) prohibits the use of chlorofluorocarbon diluents in sterilization. This was an existing requirement 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 (o)(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 monitor or semi-continuous monitor at the exhaust

[31] 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

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 the installation of a redundant control system.

Paragraph (o)(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 during aeration where they are required to be controlled either in aerator or combined sterilizer/aerator equipped with controls.

Subdivision (p) – Reporting

Subdivision (p) 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 3. This report would assist in determining if the sterilization facility would be subject to subdivision (q) and the day when compliance with the new requirements would be required.

Subdivision (q) – Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage

Subdivision (q) 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 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 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 3 in paragraph (p)(2). 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 (r) – Exemptions

Subdivision (r) specifies the exemption from either specific provisions of the rule or the entire rule.

Paragraph (r)(1) exempts facilities that are permitted to use four lbs or less of EtO per calendar year. 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 (r)(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 (r)(3) exempts PTE requirements in the event of a power outage or other unplanned event outside the owner or operator control. In lieu of complying with the PTE requirements, the owner or operator would need to enact practices 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.

Appendices

Appendix 1 specifies the content of the semi-annual report required to be submitted by large facilities.

Appendix 2 specifies the content of the semi-annual excess emission report required to be submitted by large facilities.

Appendix 3 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.

3 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 control and monitoring requirements in PAR 1405, including 15 facilities that conduct ethylene oxide sterilization and one warehouse that receives ethylene oxide sterilized materials with control equipment. Recordkeeping and reporting requirements may impact up to an additional 70 large warehouses that are registered with the U.S. FDA as wholesale drug distributors or third-party logistics providers with an indoor space of 100,000 square feet or more. Additional warehouses may be impacted as the Executive Officer determines the warehouse to be a potential source of EtO emissions.

3.2 EMISSIONS IMPACT

PAR 1405 affects 16 facilities conducting sterilization or related operations using ethylene oxide. PAR 1405 affects 70 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 ethylene oxide were reduced after the implementation of measures such as those proposed in PAR 1405. Quantifying the fugitive emission reductions is difficult as they previously were unquantified and the amount controlled is unknown.

PAR 1405 will reduce stack emissions by amending the 1991 emission limits to more stringent emissions 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 emission limits. Quantifying the stack emission reductions is difficult as Rule 1405 required demonstration of control efficiency, which by itself cannot determine the EtO emissions without additional information like outlet concentration. In addition, PAR 1405 allows compliance through a demonstration of either a control efficiency or concentration performance standard. Quantification of potential emission stack emission reductions would be speculative and difficult.

PAR 1405 will reduce ethylene oxide emissions, however, it is difficult to quantify the reductions.

3.3 CALIFORNIA ENVIRONMENTAL QUALITY ACT

Pursuant to the California Environmental Quality Act (CEQA) and South Coast AQMD's certified regulatory program (Public Resources Code Section 21080.5, CEQA Guidelines Section 15251(l) and South Coast AQMD Rule 110), the South Coast AQMD, as lead agency, is currently reviewing the proposed project (PAR 1405) to determine if it will result in any potential adverse environmental impacts. Appropriate CEQA documentation will be prepared based on the analysis.

3.4 SOCIOECONOMIC IMPACT ASSESSMENT

A socioeconomic impact assessment will be conducted and released for public review and comment at least 30 days prior to the South Coast AQMD Governing Board Hearing, which is anticipated to be held on June 2, 2023.

3.5 DRAFT FINDINGS UNDER CALIFORNIA HEALTH AND SAFETY CODE SECTION 40727

Requirements to Make Findings

California 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.

Authority

The South Coast AQMD Governing Board has authority to adopt PAR 1405 pursuant to the California 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 California Health and Safety Code Section 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

California Health and Safety Code Section 40727.2 requires a comparative analysis of the proposed rule requirements with those of any Federal or District rules and regulations applicable to the same equipment or source category. The comparative analysis will be conducted and released in the draft staff report at least 30 days prior to the South Coast AQMD Governing Board Hearing on PAR 1405, which is anticipated to be held on June 2, 2023.