SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

Draft Socioeconomic Impact Assessment For Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

A socioeconomic analysis has been conducted to assess the impacts of Proposed Amended Rule (PAR 1405). The following presents a summary of the analysis and findings.

Key Elements of PAR 1405

PAR 1405 will address ethylene oxide (EtO) emissions from sterilization facilities and related operations and would require controlling stack emissions using updated performance standards, annual source tests and, for large facilities, continuous emission monitoring systems or semi-continuous emission monitoring systems (CEMS or SCEMS). Interim mobile monitoring and fenceline air monitoring of large facilities would be required until CEMS or SCEMS are operating and certified. Facilities would be required to curtail operations if 24-hour data from fenceline air monitoring exceeds a certain trigger threshold. PAR 1405 would also require new fugitive emission control strategies which are reliant on permanent total enclosures (PTE), leak detection and repair (LDAR), and enhanced reporting and notification requirements to South Coast AQMD. PAR 1405 would require warehouses which are registered with the United States Food and Drug Administration (U.S. FDA) and that are 100,000 square feet or larger to track inbound EtO-sterilized palletized units for one year and report to South Coast AQMD and U.S. FDA-registered warehouses that are 250,000 square feet or larger to assess their annual EtO emissions via fenceline air monitoring or conducting a facility study.

Affected Facilities and Industries

As of July 2023, 16 facilities are subject to existing Rule 1405 and are expected to be subject to PAR 1405. Of the 16 facilities, 13 facilities belong to the following sectors: 1) medical product manufacturers; 2) surgical or veterinary facilities; 3) surgical and medical instrument manufacturing; 4) contract sterilizers; 5), electromedical and electrotherapeutic apparatus manufacturing; and 6) all other miscellaneous manufacturing. The remaining three facilities which use less than four pounds per year of EtO belong to the following sectors: 1) college and universities; and 2) zoos and botanical gardens.

PAR 1405 proposes to exempt these three facilities from the interim requirements for venting to control equipment in subdivision (i), the prohibitions in subdivision (n), and the recordkeeping requirements in subparagraph (s)(1)(L) specific to maintaining a log for each sterilization cycle. As such, these three facilities will not be expected to install new control equipment or make other physical modifications such that no additional costs will be incurred.

Of the 16 facilities subject to the PAR 1405, 15 are sterilization facilities which conduct onsite sterilization and one facility conducts post-aeration

storage (e.g., receives materials that have been sterilized with EtO at another facility), and their locations are distributed as follows: seven in Los Angeles County, four in Orange County, four in Riverside County, and one in San Bernardino County. Based on PAR 1405 thresholds, there are 15 sterilization facilities consisting of seven large, two medium, three small sterilization facilities, and three sterilization facilities using less than four pounds per year of EtO.

In addition, PAR 1405 is expected to potentially affect 28 large warehouses which mainly belong to the wholesale trade, and transportation and warehousing sectors. These warehouses are divided into either Tier I or Tier II warehouses. Tier I warehouses have at least one building with at least 250,000 square feet of indoor floor area used for warehousing activities and reports to U.S. FDA as a wholesale distributor or a third-party logistics provider, whereas Tier II warehouses have at least one building with at least 100,000 square feet of indoor floor area used for warehousing activities. Both Tier I and Tier II warehouses are subject to recordkeeping and reporting requirements. Tier I warehouses are also subject to requirements to assess their EtO emissions. The locations of the 28 potentially affected warehouses are distributed as follows: nine are in Los Angeles County, two are in Orange County, nine are in Riverside County, and eight are in San Bernardino County.

Assumptions for the Analysis

The main requirements of PAR 1405 that have cost impacts for the affected facilities are: 1) PTE; 2) point source emissions controls; 3) CEMS or SCEMS; 4) LDAR; 5) recordkeeping and reporting; 6) source testing; and 7) interim mobile monitoring and fenceline air monitoring. In addition, there are additional annual operating and maintenance costs associated with PTE, Dry-Bed Scrubbers, CEMS/SCEMs, and equipment required for ambient monitoring.

The total present value of the compliance cost of the PAR 1405 is estimated at $88.96 million and $65.45 million with a 1% and 4% discount rate, respectively, from 2023 to 2043. Correspondingly, the average annual compliance cost of PAR 1405 are estimated to range from $4.56 million to $4.73 million, depending on the real interest rate assumed (1% to 4%). The following table presents the summary of the average annual cost of PAR 1405 by requirement categories.

Assumptions for the Analysis (concluded)

Cost Categories	Annual Average (2023-2043)	
	1% Real Interest Rate	4% Real Interest Rate
One-Time Cost		
PTE	$217,670	$279,426
Dry-Bed Scrubber	$258,814	$333,557
CEMS/SCEMS	$474,409	$505,937
One-time report for Sterilized Pallet Destinations	$2,220	$2,220
Tier I and Tier II Warehouses One-Time Reports	$8,880	$8,880
Permitting Fees for Controls	$16,343	$16,343
Fenceline Air Monitoring	$2,000	$2,000
FAMP Evaluation Fee	$11,473	$11,473
Weather Station	$4,647	$4,989
Recurring Costs		
PTE (Electricity)	$382,357	$382,357
Dry-Bed Scrubber (Electricity)	$1,085,950	$1,085,950
Dry-Bed Scrubber (Media Changeout)	$1,114,438	$1,114,438
Dry-Bed Scrubber (Source Test)	$48,857	$48,857
CEMS	$385,714	$385,714
Recordkeeping	$11,784	$11,784
LDAR	$229,093	$229,093
Permit Renewal Fees	$67,190	$67,190
Mobile Monitoring	$68,571	$68,571
Fenceline Air Monitoring	$163,095	$163,095
Weather Station	$4,800	$4,800
Total	**$4,558,306**	**$4,726,674**

Compliance Cost

Dry-Bed Scrubbers and CEMS/SCEMS requirements are estimated to account for about 73 percent (%) of the total annual cost of PAR 1405, followed by the PTE requirement and its associated electricity costs which are estimated to account for about 14% of the total annual cost. About 91% of the total average annual compliance cost is expected to be incurred by the seven facilities designated as "large facility" based on PAR 1405 thresholds.

Sectors of Professional, Scientific, and Technical Services, Miscellaneous Manufacturing, and Electromedical and Electrotherapeutic Apparatus Manufacturing where most sterilizing facilities belong, will bear most of the annual compliance cost (92%).

Job Impacts

Direct effects of the proposed project are used as inputs to the Regional Economic Model, Inc (REMI) modeling software to assess secondary/induced impacts for all the industries in the four-county economy on an annual basis and across a user-defined horizon.

When the compliance cost is annualized using a 4% real interest rate, an annual average of 54 net jobs foregone is projected from 2023 to 2043. The 54 annual jobs foregone represents less than 0.0005% of total annual jobs in the four-county area.

In earlier years of PAR 1405 implementation, the compliance expenditures incurred by affected facilities for PTE, Dry-Bed Scrubbers, and CEMS/SCEMS would be expected to create positive job impacts. In 2023, when most of the spending is expected to occur, about three additional jobs are projected to be added to the regional economy. The positive job impact would mainly occur in the sector of construction. However, as affected facilities continue to incur the amortized capital expenditures and annual operation and maintenance (O&M) costs, slight reductions in job growth would set in, resulting in jobs foregone in later years.

Competitiveness

According to the REMI Model, PAR 1405 is projected to have a maximum single-year increase in the cost of production for the miscellaneous manufacturing industry by 0.015% and electromedical and electrotherapeutic apparatus manufacturing by 0.002% in the South Coast region. The maximum increase in delivered prices for these sectors are projected to be 0.012% and 0.002%, respectively. The single-year maximum cost and price increases are expected to take place in 2026.

Overall, PAR 1405 is not expected to have a significant impact on the competitiveness of the affected industries in the region as these industries are regional businesses and could pass on the costs to their end users. For example, due to the inelastic nature of demand for sterilized health products, the compliance cost incurred by sterilization facilities could potentially be

passed on from sterilization facilities to downstream customers of medical and surgical supplies and to hospitals and end-use consumers.

Health Effects From Exposure to Ethylene Oxide

This report does not quantify the health effects of EtO. However, the exposure to EtO is known to increase the risk of lymphoid cancer (including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, for females, breast cancer (U.S. EPA, 2016 and 2023). Noncancer health effects from chronic exposure to EtO could include irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. In addition, there is evidence linking EtO exposure to reproductive effects (U.S. EPA, 2018) as it could act directly on DNA and cause chromosome damage.

Overall, PAR 1405 is expected to reduce EtO concentrations, and therefore reduce the adverse public health impacts due to reduced exposure to EtO emissions.

INTRODUCTION

PAR 1405 will address ethylene oxide (EtO) emissions from sterilization facilities and related operations and would require controlling stack emissions using updated performance standards, periodic source tests and, for large facilities, and continuous or semi-continuous emission monitoring systems (CEMS or SCEMS). PAR 1405 would also require new fugitive emission control strategies using permanent total enclosures (PTE), leak detection and repair (LDAR), and enhanced reporting and notification requirements. Interim mobile monitoring and fenceline air monitoring would be required for large facilities until CEMS or SCEMS are in place and certified. PAR 1405 would require U.S. FDA registered warehouses that are 100,000 square feet or larger to track inbound EtO-sterilized palletized units for one year and report to South Coast AQMD and U.S. FDA registered warehouses that are 250,000 square feet or larger to assess their annual EtO emissions.

PAR 1405 categorizes sterilization facilities into different size categories (Large, Medium, and Small Facilities) based on their permitted annual EtO limit which aligns with the federal National Emission Standards for Hazardous Air Pollutants (NESHAP) and the state Air Toxic Control Measures (ATCM) thresholds. In addition, while existing Rule 1405 identifies Aeration-Only Facilities as facilities which receive materials that have been sterilized in another facility, PAR 1405 refers to this type of facility as a Post-Aeration Storage Facility. Both sterilization and post-aeration storage facilities are subject to PAR 1405 requirements.

Additionally, certain large warehouses are also subject to applicable tracking, reporting, and emission assessment requirements in PAR 1405. A Tier I warehouse is a warehouse that has at least 250,000 square feet of indoor floor area used for warehousing activities and reports to U.S. FDA as a wholesale distributor or a third-party logistics provider, whereas a Tier II warehouse is a warehouse with at least 100,000 but less than 250,000 square feet of indoor floor area used for warehousing activities. Both Tier I and Tier II warehouses would be subject to recordkeeping and reporting requirements. Tier I Warehouses would also be required to assess their EtO emissions.

LEGISLATIVE MANDATES

The legal mandates directly related to the assessment of PAR 1405 include South Coast AQMD Governing Board resolutions and various sections of the Health and Safety Code.

South Coast AQMD Governing Board Resolutions

On March 17, 1989, the South Coast AQMD Governing Board adopted a resolution that calls for an economic analysis of regulatory impacts that includes the following elements:

- Affected industries
- Range of probable costs

- Cost-effectiveness of control alternatives
- Public health benefits

Health and Safety Code Requirements

The state legislature adopted legislation which reinforces and expands the Governing Board resolutions for socioeconomic impact assessments. Health and Safety Code Section 40440.8, which became effective on January 1, 1991, requires a socioeconomic impact assessment to be performed for any proposed rule, rule amendment, or rule repeal which "will significantly affect air quality or emissions limitations."

Specifically, the scope of the socioeconomic impact assessment should include the following:

- Type of affected industries;
- Impact on employment and the regional economy;
- Range of probable costs, including those to industry;
- Availability and cost-effectiveness of alternatives to the rule;
- Emission reduction potential; and
- Necessity of adopting, amending, or repealing the rule in order to attain state and federal ambient air quality standards.

Health and Safety Code Section 40728.5, which became effective on January 1, 1992, requires the South Coast AQMD Governing Board to actively consider the socioeconomic impacts of regulations and make a good faith effort to minimize adverse socioeconomic impacts. It also expands socioeconomic impact assessments to include small business impacts, specifically it includes the following:

- Type of industries or business affected, including small businesses; and
- Range of probable costs, including costs to industry or business, including small business.

Finally, Health and Safety Code Section 40920.6, which became effective on January 1, 1996, requires that incremental cost effectiveness be performed for a proposed rule or amendment that imposes Best Available Retrofit Control Technology (BARCT) or “all feasible measures” requirements relating to ozone, carbon monoxide (CO), oxides of sulfur (SOx), oxides of nitrogen (NOx), and their precursors. Since the focus of PAR 1405 is to reduce EtO risk and does not impose BARCT or all feasible measures for these other pollutants, this statute does not apply to PAR 1405. Moreover, cost effectiveness in terms of dollars per ton is not meaningful for risk-related rules and regulations since many other factors besides the amount of pollution affect the risk such as the toxic potency and the location of receptors.

AFFECTED FACILITIES

PAR 1405 would affect three types of facilities: 1) facilities conducting onsite sterilization (Sterilization Facilities): 2) non-sterilization facilities that have installed EtO control equipment (Post-Aeration Storage Facilities) and that receive EtO materials which have been sterilized at another facility; and 3) certain large warehouses receiving EtO-sterilized palletized units and which are registered with the U.S. Food and Drug Administration as a Prescription Drug Wholesale Distributor or a Third-Party Logistics Provider.

As of July 2023, 16 facilities are subject to existing Rule 1405 and are expected to be subject to PAR 1405. Of the 16 facilities, 13 facilities belong to the following sectors: 1) medical product manufacturers; 2) surgical or veterinary facilities; 3) surgical and medical instrument manufacturing; 4) contract sterilizers; 5), electromedical and electrotherapeutic apparatus manufacturing; and 6) all other miscellaneous manufacturing. The remaining three facilities which use less than four pounds per year of EtO belong to the following sectors: 1) college and universities; and 2) zoos and botanical gardens.

Of the 16 facilities subject to the PAR 1405, 15 are sterilization facilities which conduct onsite sterilization and one facility conducts post-aeration storage (e.g., receives materials that have been sterilized with EtO at another facility), and their locations are distributed as follows: seven in Los Angeles County, four in Orange County, four in Riverside County, and one in San Bernardino County. Based on PAR 1405 thresholds, there are 15 sterilization facilities consisting of seven large, two medium, three small sterilization facilities, and three sterilization facilities using less than four pounds per year of EtO.

In addition, PAR 1405 is expected to potentially affect 28 large warehouses which mainly belong to the wholesale trade, and transportation and warehousing sectors. These warehouses are divided into either Tier I or Tier II warehouses. Tier I warehouses have at least one building with at least 250,000 square feet of indoor floor area used for warehousing activities and reports to U.S. FDA as a wholesale distributor or a third-party logistics provider, whereas Tier II warehouses have at least one building with at least 100,000 square feet of indoor floor area used for warehousing activities. Both Tier I and Tier II warehouses are subject to recordkeeping and reporting requirements. Tier I warehouses are also subject to requirements to assess their EtO emissions. The locations of the 28 potentially affected warehouses are distributed as follows: nine are in Los Angeles County, two are in Orange County, nine are in Riverside County, and eight are in San Bernardino County.

Table 1 presents the affected facilities and warehouses with their industry type and North American Industrial Classification System (NAICS) Code.

Table 1

Affected Facilities by Industry Types

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

Small Business

The South Coast AQMD defines a "small business" in Rule 102 – Definition of Terms for purposes of fees as one which employs 10 or fewer persons and which earns less than $500,000 in gross annual receipts. The South Coast AQMD also defines "small business" for the purpose of qualifying for access to services from the South Coast AQMD's Small Business Assistance Office (SBAO) as a business with an annual receipt of $5 million or less, or with 100 or fewer employees. In addition to the South Coast AQMD's definitions of a small business, the federal Small Business Administration (SBA) and the federal 1990 Clean Air Act Amendments (1990 CAAA) also provide definitions of a small business.

The 1990 CAAA classifies a business as a "small business stationary source" if it: 1) employs 100 or fewer employees; 2) does not emit more than 10 tons per year of either VOC or NOx; and 3) is a small business as defined by SBA. The SBA definitions of small businesses have employee count thresholds that may vary according to designated six-digit NAICS codes. Generally, a small business must have no more than 500 employees for most manufacturing and mining industries. More specifically, the surgical and medical instrument manufacturing (NAICS 339112) has a 1,000-employee threshold and electromedical and electrotherapeutic apparatus manufacturing (NAICS 334510) has a 1,250-employee threshold below which a business is considered as small.

Dun and Bradstreet data on the number of employees and revenues are available for 13 out of the 16 affected facilities. Based on this data, there is only one facility that meets the South Coast AQMD's definitions of a small business in both Rule 102 and SBAO. Based on SBA's definition of a small business, nine out of 13 facilities would be classified as small businesses. Under the 1990 CAAA definition, there are no facilities meeting the criteria to be considered as small businesses.[1]

The Final Socioeconomic Impact Assessment for Rule 2305 - Warehouse Indirect Source Rule (ISR) assessed the distributional impacts by industry and small businesses.[2] The economic impacts on the affected warehouses resulting from PAR 1405 are expected to be similarly distributed and would mainly affect the facilities in transportation and warehousing. About 25% of the affected facilities can be considered as small businesses for potential access to services from the South Coast AQMD's Small Business Assistance Office. However, none of these facilities qualify as a small business based on the definition in the South Coast AQMD Rule 102 (e.g., employing 10 or fewer employees and earning less than $500,000 in annual sales).

As presented in Table 2, ratios of the annual compliance cost to gross annual revenues of the affected facilities are expected to be less than one percent, with the exception of one facility.

[1] Based on facility-level data on NOx and VOC emissions for calendar years 2018, 2019, and 2022.

[2] See:http://www.aqmd.gov/docs/default-source/Agendas/Governing-Board/2021/2021-May7-027.pdf, page 1704.

Table 2
Projected Ratio of Annual Compliance Cost to the Gross Annual Sales of Affected Facilities (Ranked High-to-Low by Estimated Compliance Cost)

Affected Facility	% of Annual Cost to Revenue Ratio
Facility A	0.18%
Facility B	0.11%
Facility C	0.02%
Facility D	0.08%
Facility E	0.00%
Facility F	N/A*
Facility G	0.31%
Facility H	0.12%
Facility I	0.01%
Facility J	0.52%
Facility K	0.00%
Facility L	5.78%
Facility M	0.00%
28 Tier I and Tier II Warehouses	N/A*
Total Facilities	**$4,726,674**

* Data is not available.

COMPLIANCE COST

PAR 1405 will address EtO emissions from sterilization facilities and related operations. The main requirements of PAR 1405 that have cost impacts for affected facilities are: interim mobile monitoring, interim fenceline air monitoring, PTE, point source emissions controls, CEMS or SCEMS, LDAR, recordkeeping, reporting, and source testing. In addition, there are additional annual operating and maintenance costs associated with PTE, dry-bed scrubbers, CEMS/SCEMS and weather stations.

All the costs discussed in this section are expressed in 2023 dollars. For the purpose of projecting the future compliance cost, it is assumed that these costs would remain the same in the foreseeable future, with any increase being a result of inflation. Additionally, while it is considered in this analysis that all estimated costs would be borne by the affected facilities, due to the inelastic nature of the demand for sterilized health products, the compliance cost incurred to sterilization facilities and warehouses could potentially be passed on to downstream customers of medical and surgical supplies and to hospitals and end-use consumers.

Many of the costs estimated in this analysis are highly dependent on site-specific factors and on business decisions made by facilities subject to PAR 1405. It is also important to note that when conducting the cost analysis, every effort was made to represent costs as realistically as possible, given that many factors would ultimately dictate what price a business will pay to implement a control. The estimated cost for each line item was either represented by an industry average or a reasonable range, based on the information and data available. The procedure and assumptions for each cost estimate are discussed below.

The total cost is calculated over 21 years, from 2023 to 2043. As presented in Table 3, the total present value of compliance cost of PAR 1405 is estimated at $88.86 million and $65.45 million, respectively, depending on the discount rate assumed (1% to 4%).[3] Correspondingly, the average annual compliance cost of PAR 1405 are estimated to range from $4.56 million to $4.73 million, depending on the real interest rate assumed (1% to 4%). Table 3 presents total and average annual compliance cost of PAR 1405 by requirement categories.

[3] In 1987, South Coast AQMD staff began to calculate cost-effectiveness of control measures and rules using the Discounted Cash Flow method with a discount rate of 4 percent. Although not formally documented, the discount rate is based on the 1987 real interest rate on 10-year Treasury Notes and Bonds, which was 3.8 percent. The maturity of 10 years was chosen because a typical control equipment life is 10 years; however, a longer equipment life would not have corresponded to a much higher rate-- the 1987 real interest rate on 30-year Treasury Notes and Bonds was 4.4 percent. Since 1987, the 4 percent discount rate has been used by South Coast AQMD staff for all cost-effectiveness calculations, including a best available control technology (BACT) analysis, for the purpose of consistency. The incremental cost reported in this assessment was thus annualized using a real interest rate of four percent as the discount rate. As a sensitivity test, a real interest rate of one percent is also used.

Table 3
Total Present Worth and Average Annual Estimated Costs of PAR 1405

	Present Worth Value (2023)		Annual Average (2023-2043)	
Cost Categories	**1% Discount Rate**	**4% Discount Rate**	**1% Real Interest Rate**	**4% Real Interest Rate**
One-Time Cost				
PTE	$5,246,106	$3,847,117	$217,670	$279,426
Dry-Bed Scrubber	$6,272,661	$4,624,736	$258,814	$333,557
CEMS/SCEMS	$9,486,164	$6,924,567	$474,409	$505,937
One-time report for Sterilized Pallet Destinations	$45,854	$43,678	$2,220	$2,220
Tier I and II Warehouses One-Time Reports	$183,415	$174,710	$8,880	$8,880
Permitting Fees for Controls	$337,103	$319,852	$16,343	$16,343
Fenceline Air Monitoring	$41,310	$39,349	$2,000	$2,000
FAMP Evaluation Fee	$237,360	$227,205	$11,473	$11,473
Weather Station	$100,199	$88,018	$4,647	$4,989
Recurring Costs				
PTE (Electricity)	$7,134,193	$5,125,101	$382,357	$382,357
Dry-Bed Scrubber (Electricity)	$20,268,296	$14,574,836	$1,085,950	$1,085,950
Dry-Bed Scrubber (Media Changeout)	$20,798,374	$14,952,191	$1,114,438	$1,114,438
Dry-Bed Scrubber (Source Test)	$911,876	$655,726	$48,857	$48,857
CEMS	$7,162,199	$5,064,331	$385,714	$385,714
Recordkeeping	$219,954	$158,235	$11,784	$11,784
LDAR	$4,306,892	$3,172,725	$229,093	$229,093
Permit Renewal Fees	$1,253,217	$899,234	$67,190	$67,190
Mobile Monitoring	$1,425,743	$1,384,615	$68,571	$68,571
Fenceline Air Monitoring	$3,333,861	$3,080,776	$163,095	$163,095
Weather Station	$98,082	$90,541	$4,800	$4,800
Total	**$88,862,860**	**$65,447,543**	**$4,558,306**	**$4,726,674**

Figure 1 presents the estimated annual compliance cost of PAR 1405 by the requirement categories. Dry-bed scrubbers and CEMS/SCEMS requirements are estimated to account for about 73% of the total annual cost of PAR 1405, followed by the PTE requirement and its associated electricity costs that are estimated to account for about 14% of the total annual compliance cost.

Figure 1
Annual Estimated Costs of the PAR 1405 by the Requirement Categories

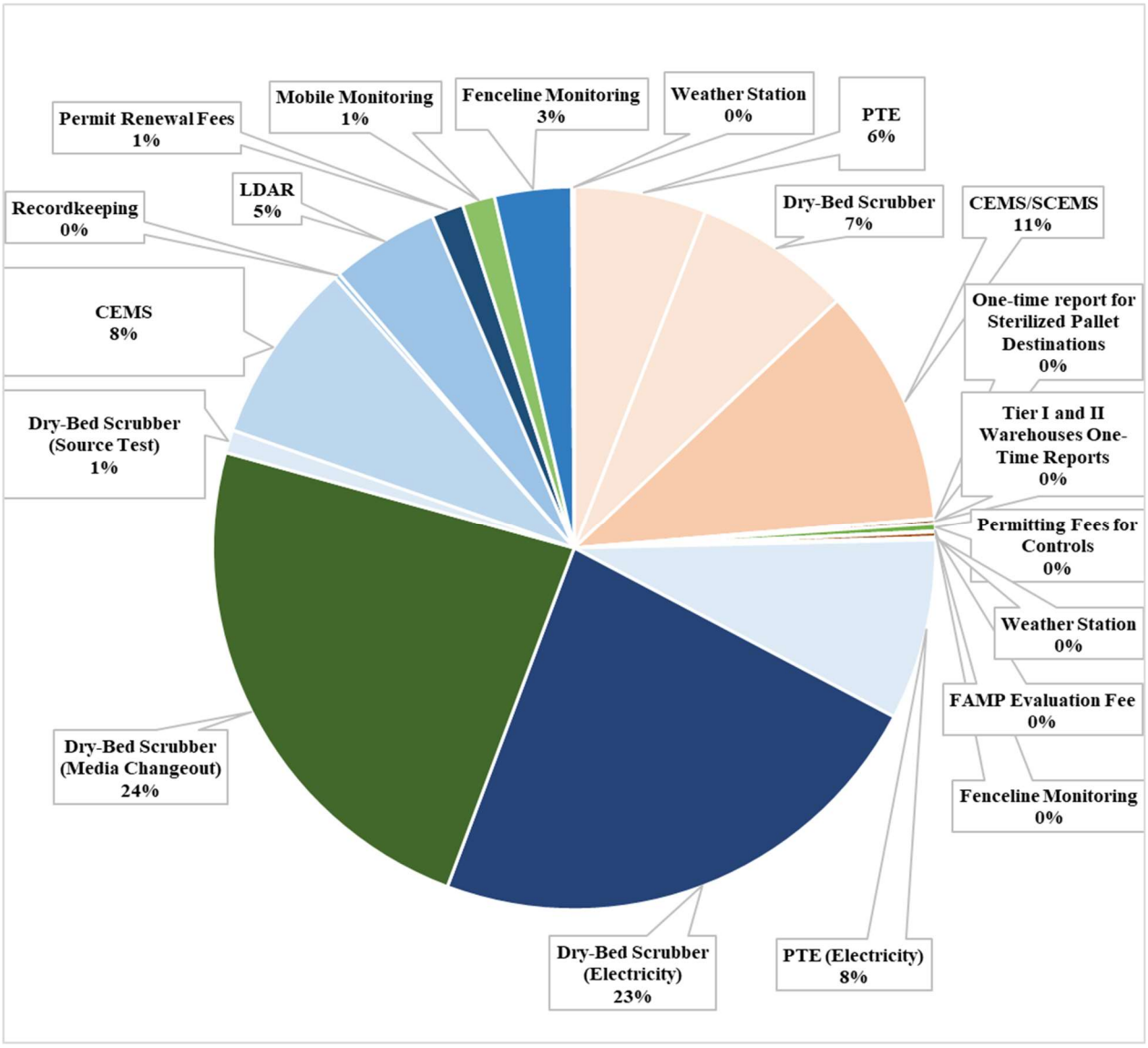

Table 4 presents annual and average annual costs of PAR 1405 by the affected industry. Professional, Scientific and Technical services (NAICS 541), Miscellaneous Manufacturing (NAICS 339) and Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) where most of sterilizing facilities belong, will bear the majority of the annual compliance cost (92%).

Table 4
Annual and Average Annual Estimated Costs of the PAR 1405 by Industry

Industry Name (NAICS)	2023	2030	2035	2043	Average over All Years (2023-2043)
Electromedical and Electrotherapeutic Manufacturing (334)	$470,678	$441,146	$441,146	$441,146	$443,848
Miscellaneous manufacturing (339)	$250,028	$2,491,478	$2,491,478	$2,491,478	$2,326,206
Wholesale trade (42)	$85,527	$10,551	$10,551	$10,551	$77,359
Retail trade (44-45)	$412,442	$151,328	$151,328	$151,328	$172,299
Professional, scientific, and technical services (541)	$913,161	$1,628,038	$1,628,038	$1,628,038	$1,572,891
Administrative and support services (561)	$38,398	$130,240	$130,240	$130,240	$134,071
Total	**$2,170,233**	**$4,852,781**	**$4,852,781**	**$4,852,781**	**$4,726,674**

The compliance cost will mainly fall on large facilities due to stricter requirements for PTEs, additional controls to meet more stringent performance standards, and CEMS/SCEMS requirements as well as interim mobile and fenceline air monitoring requirements. Large and medium facilities have fewer options to use LDAR in lieu of placing specific operations, equipment, or areas under PTE. Table 5 presents average annual cost of PAR 1405 by the affected facilities. About 91% of the total average annual compliance cost is expected to be incurred by the seven facilities designated as “large facility” based on PAR 1405 thresholds. Three affected facilities which use less than four pounds per year of EtO will be exempted from the control requirements of the PAR 1405 and as such they will incur no additional costs.

Table 5
Projected Annual Compliance Cost by Affected Facilities that Potentially Could Need Additional Pollution Controls (2023 Dollars)
Average Annual (2023-2043)

Facility A	$1,612,392
Facility B	$768,757
Facility C	$708,005
Facility D	$569,874
Facility E	$337,484
Facility F	$172,299
Facility G	$134,071
Facility H	$106,364
Facility I	$106,364
Facility J	$103,933
Facility K	$14,886
Facility L	$14,886
Facility M	$10,382
28 Tier I and Tier II Warehouses	$66,978
Total Facilities	**$4,726,674**

For facilities subject to PAR 1405, incremental costs were estimated for the capital outlays and related expenditures for PTE, dry-bed scrubbers, CEMS/SCEMS, LDAR, source testing, monitoring and recordkeeping and reporting.

Permanent Total Enclosures (PTE)

A PTE is defined in PAR 1405 as any permanent building or containment structure, enclosed with a floor, walls, and a roof to prevent exposure to the elements, (e.g., precipitation, wind, run-off) that has limited openings to allow access for people and vehicles, that is free of breaks or deterioration that could cause or result in fugitive emissions. In addition, a PTE is required to undergo an evaluation to confirm that it is capable of meeting the design requirements set forth in U.S. Environmental Protection Agency (U.S. EPA) Method 204, except the term "Administrator" in provision 5.1 is revised to mean Executive Officer, as defined in South Coast AQMD Rule 102. PAR 1405 requires large facilities that are conducting sterilization using EtO to conduct sterilization operations inside a PTE to minimize the release of EtO emissions from specific EtO sources within the enclosure by a specified compliance date. As specified by Implementation Schedules in Table 1 of PAR 1405, existing large facilities would need to comply with this requirement by September 1, 2025, while any large facility permitted after rule adoption would need to meet these requirements before operating as a large facility. Medium and small facilities would need to comply by January 1, 2026. The primary intent of this requirement is to provide maximum containment and minimize fugitive EtO emissions from any sources within the PTE.

To provide further protection to nearby receptors, PAR 1405 would require all emissions collected by a facility's PTE to be routed to air pollution control equipment that meet the proposed performance standards. In addition, continuous monitoring of each PTE's pressure differential and quarterly face velocity inspections at natural draft openings will need to be conducted.

South Coast AQMD provided notification to three large facilities with elevated EtO readings, that they may be designated as a Potentially High-Risk Level Facility (PHRLF) pursuant to South Coast AQMD Rule 1402 - Control of Toxic Air Contaminants from Existing Sources. Two of the affected three facilities which were designated PHRLF have approved Early Action Reduction Plans which required PTE installations, among other measures, to reduce EtO emissions. The third facility voluntarily installed PTE which reduced EtO emissions from the facility. The PTEs required pursuant to Rule 1402 requirements or those that have already been installed are not considered as incurred costs under PAR 1405; however, cost information was requested from these three facilities that have already installed or are in the process of installing PTEs. The three affected facilities provided information and data on costs incurred for the PTEs.

Cost data provided by one affected sterilization facility, designated as a "large facility" under PAR 1405, indicated the cost for the PTE with air pollution control equipment would be less than $450,000, excluding consulting and engineering, of which approximately $310,000 was attributed to the construction of a 190,000 cubic feet PTE and $140,000 for the air pollution control equipment comprised of two individual dry-bed scrubbers. The facility's building footprint is approximately 27,000 square feet which is larger than the other facilities, except for three large facilities that already have PTE or are required to have PTE under Rule 1402.

Of the remaining facilities, only two facilities have a similar footprint size at approximately 21,000 square feet each; one facility indicated that they already have an enclosure operating under negative pressure and the other facility indicated that they intend to section off a smaller area to be enclosed in a PTE. One facility had sectioned off an area that was over 10,000 square feet. For the other facilities, staff assumed a conservative cost of $500,000 for each PTE area required, which is based on the actual capital cost to implement a PTE.

The unit cost for installing air pollution control equipment was assumed to be $75,000 based on the estimates from one large facility. The cost for controls for other facilities were scaled proportionally based on permitted throughputs. For example, the permitted throughput of the facility that had a known cost was 100,000 pounds of EtO. A facility with a permitted throughput of 500,000 pounds of EtO would have an associated cost of installing air pollution control equipment to be $75,000 X 5 = $375,000.

Two large facilities each have existing enclosures which operate under negative pressure which have not yet been validated to meet PAR 1405 PTE requirements. For these facilities, the analysis conservatively assumed that it would cost $250,000 for additional construction to convert these enclosures to meet the PTE requirements in PAR 1405.

For the purpose of estimating the cost estimates, this analysis assumes that the sterilized materials will continue to off-gas EtO continuously during aeration or post-aeration phases after sterilization. PAR 1405 addresses these fugitive emissions by requiring the installation and operation of a PTE and associated control system. Facilities would be required to maintain negative pressure of the PTE at all times, even when batch sterilization is not taking place to capture and control fugitive EtO emissions.

The annual electricity costs associated with operating PTEs are estimated at $382,357. The total annual cost of the PTE requirements is estimated to be about $661,783.

Point Source Emission Controls - Dry-Bed Scrubbers

PAR 1405 includes enhanced performance standards based on the best technology achieved-in-practice. This analysis assumes that the majority of existing air pollution control systems will be able to comply with the proposed performance standards in PAR 1405. For those that do not, this analysis assumes that additional air pollution control equipment, such as dry-bed scrubber technology, will be installed. The assumed cost to operate a single dry-bed scrubber was $46,500 per year, including $20,000 for media replacement and $26,500 for electricity costs. Staff assumed an electricity cost of $26,500 per year to run each individual dry-bed scrubber based on a 20 hp (15 kW) blower at 100% load, 24 hours per day, 365 days a year at a rate of $0.20 per kW-hr[4]. Annual operating costs for large facilities were scaled proportionally by conducting a comparison of throughput to the cost data provided by a large facility. It is important to note that while sterilization is a batch process, not a continuous process, and air pollution control equipment is effective at controlling point sources of emissions, sterilized materials will continue to off-gas EtO continuously during aeration or post-aeration phases after sterilization. As such, to control fugitive emissions of EtO, PAR 1405 requires facilities to continuously maintain negative pressure of PTEs and operation of the air pollution control equipment at all times even when batch sterilization is not taking place. For these reasons, the projected electricity cost in this analysis represents an upper-bound estimate of recurring costs while the actual electricity cost may be less.

Beginning September 1, 2025 for large facilities, and January 1, 2026 for both medium and small facilities, PAR 1405 would require facilities to meet the proposed performance standards. A large facility will have the most stringent performance standards (e.g., 99.99% control efficiency or 0.01 parts per million (ppm) concentration) because they collectively account for more than 99% of EtO usage at sterilization facilities in the South Coast AQMD. Three facilities are assumed to require additional air pollution control equipment and another facility is assumed to replace a near end-of-life air pollution control equipment which is expected to require additional controls at a cost over $800,000.

The analysis also assumed that existing air pollution control equipment operating at most medium and small facilities would meet PAR 1405 performance standards (e.g., 99.9% control efficiency

[4] For more details, please see the U.S. Energy Information Administration's Electric Power Monthly report at: www.eia.gov/electricity/monthly/epm_table_grapher.php?t=epmt_5_6_a.

or 0.01 ppm concentration). However, due to PAR 1405 requirements, medium facilities are assumed to require additional air pollution control equipment for their post-aerators and one small facility would require air pollution control equipment for their aerator. The total annual cost of the dry-bed scrubbers is estimated at about $2.53 million.

Leak Detection and Repair (LDAR)

PAR 1405 requires LDAR as an alternative to PTE depending on the type of facility. Large facilities require most fugitive emission sources to be located inside a PTE while medium and small facilities have greater flexibility to use LDAR. For small facilities, the analysis assumed that all facility operators would elect to use LDAR in lieu of PTE with the exception of one facility which conducts separate aeration outside of their combined sterilizer/aerator units.

Daily audio/visual checks are required and testing using an analyzer to check for leaks every 60 days is required. Consultants and facilities provided cost information with the costs ranging from $500 to $1,500 to have a third-party conduct monitoring using a handheld analyzer. To be on the conservative side, the analysis assumed the cost to be $2,000 for each bi-monthly inspection. The analysis also assumed that all facilities would hire a third-party to conduct the bi-monthly leak tests while having their own workers perform the daily audio/visual checks. Based on wage data for NAICS 54190 (professional, scientific, and technical services), the analysis relied on a prevailing wage of $37 per hour.[5] Further, since large facilities were likely to have more components and areas to monitor, the analysis assumed that performing the audio/visual checks for 365 days a year would take 0.5 hour each day for large facilities and 0.25 hours each day for the other facilities. The total annual cost of the LDAR requirements is estimated to be about $229,093.

Source Tests

PAR 1405 would require demonstration of meeting the performance standards by annual source testing for all control systems for EtO. Large facilities are subject to this requirement by September 1, 2025 whereas both medium and small facilities have until January 1, 2026 to comply. Based on feedback from source testing companies and facilities, a typical cost for each source test at a facility was approximately $5,000 and an additional $4,000 for each additional day of testing, if needed. The analysis assumed that the source tests could all be completed in a single day and would cost $6,000 per control system at a facility even though periodic source tests were already required, with the exception for acid-water scrubbers. Based on these estimates, the annual cost of source tests is estimated at approximately $48,857. Note that this is a conservative estimate as some facilities may not be subject to the annual source test requirements if the air pollution control system is capable of demonstrating compliance with the proposed stack emission requirements via CEMS or SCEMS and passing the related quality control quality assurance test.

[5]https://data.bls.gov/cew/apps/table_maker/v4/table_maker.htm#type=1&year=2022&qtr=3&own=5&ind=5419&supp=0

Continuous Stack Monitoring at Large Sterilization Facilities

Within 18 months of approval of the CEMS/SCEMS application, large facilities are required to perform continuous stack monitoring of EtO emissions using either CEMS or SCEMS, which measure emissions at least once every minute or 15 minutes, respectively. Based on data from vendors, consultants, and facilities, equipment and installation costs ranged from $250,000 to $370,000 each. Staff estimated the cost for the battery backup power to be $80,000. The analysis used the upper bound cost estimate for the CEMS or SCEMS to derive an assumed a cost of $450,000 to install a CEMS or SCEMS including battery backup power. Vendors and installers indicated that specific systems (with quick response times as brief as five seconds) could potentially time-share to monitor multiple stacks, provided the stacks are physically located close to each other. For this reason, the analysis assumed that each monitoring system will be used to monitor emissions from two stacks. Additionally, some facilities indicated that they intended to install dedicated monitoring systems for each stack and/or would not be combining existing stacks so the analysis relied on this information to calculate costs. In addition, some facilities are assumed to install more than one CEMS/SCEMS. A cost of $15,000 was included for the required CEMS/SCEMS evaluation based on Rule 301 Table IIB – CEMS, FSMS, & ACEMS Fee Schedule that specified a base fee of $4,488 up to a maximum fee of $14,787.

Recurring operating costs for CEMS/SCEMS ranged from $30,000 to $55,000 per year, including costs for preventative maintenance plans, calibration gases, and utilities. As such, the analysis assumed a $50,000 per year O&M cost for each CEMS/SCEMS systems as presented in Table 6. The total annual cost of the CEMS/SCEMS requirements is estimated to be about $892,000.

Table 6
Number of CEMS/SCEMS at Large Facilities

Large Facility Continuous Stack Monitoring	Number of Units	Assumed Unit Cost
CEMS/SCEMS with battery backup	10	$450,000
Annual Operation and Maintenance	10	$50,000

Interim Monitoring for Large Sterilization Facilities and Tier I Warehouses

Until a large facility has installed and certified the required stack CEMS or SCEMS, PAR 1405 requires interim ambient air monitoring for EtO. Initial mobile monitoring once a month is required within 30 days of rule adoption while a Fenceline Air Monitoring Plan (FAMP) is prepared and submitted by the facility for review and approval by the South Coast AQMD. Interim fenceline air monitoring, conducted pursuant to the approved FAMP, would replace mobile monitoring.

For mobile monitoring, the analysis assumed that each facility would hire a third-party to conduct mobile monitoring as it would be cheaper than electing to have the South Coast AQMD conduct monitoring for the facility. Based on contacts with vendors of mobile monitoring, quotes range from $5,000 to $30,000 for each facility for each sampling day. The duration of the mobile monitoring is expected to only last between two to 12 months, resulting in an annual cost of $60,000. Three of the seven large facilities with current fenceline air monitoring are not required to conduct mobile monitoring. Thus, the analysis assumed that the remaining four large facilities subject to this requirement would be required to conduct mobile monitoring for one year while their FAMP was prepared, submitted, reviewed, and approved. If any of these four large facilities were to modify their annual EtO permitted usage to less than 2,000 pounds per year of EtO, they would no longer be subject to mobile or fenceline air monitoring requirements.

The same four large facilities and seven Tier I warehouses are required to prepare and submit a FAMP. Based on discussion with consultants, it would take no more than 20 hours to prepare a FAMP. The analysis relied on an hourly rate of $200 per hour and thus the cost for preparing a FAMP for each facility required to conduct fenceline air monitoring would be $4,000. Review and approval by South Coast AQMD would require approximately 88 hours of staff time at an hourly rate of $193.36 per hour based on Rule 306 – Plan Fees, for a total of $17,210 for each FAMP.

PAR 1405 requires Tier I Warehouses to either conduct fenceline air monitoring for one year, conduct an emission study, or fund and participate in a real-time fenceline air monitoring system demonstration program by the South Coast AQMD. Staff conservatively assumed that seven Tier I Warehouses would elect to conduct fenceline air monitoring. Table 7 presents the interim and fenceline air monitoring requirements for large facilities and Tier I and Tier II warehouses.

Table 7
Interim and Fenceline Monitoring for Large Facilities and Tier I and Tier II Warehouses

Types of Facilities	Interim Mobile Monitoring	FAMP Preparation	Fenceline Air Monitoring
Four Large Facilities	Yes	Yes	Yes
Three Large Facilities*	No	No	No
Seven Tier I Warehouses	N/A**	Yes	Yes
Remaining Tier I warehouses	N/A	No	No
Tier II Warehouses	N/A	N/A	N/A

*Fenceline air monitoring already implemented at three large facilities
**Not applicable

Implementation of fenceline air monitoring is assumed to use the commonly used and available canister sampling technology that has already been implemented at three large facilities. The cost for each canister sample is estimated to be $900 which includes the rental of validated silica coated canister and calibrated flowmeter, analysis, and reporting. In addition, the labor cost for each sampling day is estimated to be $510 based on an hourly rate of $85 with four hours of travel time and two hours of setup. Therefore, the annual cost to conduct fenceline air monitoring was

calculated to be $85,000 for a facility that monitors at a single fenceline location on a 1-in-6 day schedule and $140,000 for a facility that monitors two fenceline locations on a 1-in-6 day schedule.

Each large facility subject to this requirement would be required to conduct fenceline air monitoring pursuant to their approved FAMP for three years while their CEMS or SCEMS are sourced, purchased, installed, and certified to accurately monitor EtO stack emissions at the facility. The total annual cost of fenceline air monitoring, including the semiannual calibration, is estimated at $165,095 ($163,095, and $2,000).

Lastly, each facility is assumed to purchase its own weather station to comply with requirements to keep records pertaining to wind speed and direction at a cost of $6,000 and eight hours for a technician to install at a rate of $100 per hour. Semiannual calibrations and annual data review are assumed to take eight hours and 20 hours, respectively for each service resulting in a $3,600 annual cost per weather station. The total annual cost of installing weather stations, including the semiannual calibration, is estimated at $9,789 ($4,989 and $4,800).

Curtailment of Sterilization Operations due to 24-Hour Fenceline Air Monitoring

PAR 1405 subdivision (q) includes requirements to curtail sterilization operations based on 24-hour monitoring results (i.e., Trigger Result) from either the facility's fenceline air monitoring requirements or South Coast AQMD monitoring efforts. In addition, PAR 1405 subdivision (u) includes an exemption from curtailment requirements to protect public health when specific products such as medical devices may be in shortage. The curtailment schedule and trigger threshold are largely based on the approved Early Action Reduction Plans (EARP) for two of the largest sterilization facilities in South Coast AQMD. With the two facilities installing additional controls to reduce emissions, the impact of curtailment provisions in PAR 1405 is not expected to go beyond the implementation of EARP. For other facilities, monitoring data to date shows that their fenceline levels are below the curtailment trigger thresholds outlined in PAR 1405. Therefore, the impact of the curtailment provision is expected to be minimal.

Permitting Fees

PAR 1405 requires submissions of permit applications by a certain date as specified in the respective subdivisions for the different size sterilization facilities to ensure adequate time for the South Coast AQMD to evaluate and process the required applications. For the cost of initial permitting fees, a $5,200 fee for each application is assumed based on the fee specified in Rule 301 TABLE FEE RATE-A under Schedule C for permit processing. To account for any equipment that may need to be put under two separate Permits to Operate, this analysis doubled the cost.

For annual operating permit renewal fees, a $1,700 fee for each permit is assumed based on the fee specified in Rule 301 paragraph (d)(2) Annual Operating Fees under the Schedule for C and D. To account for any equipment that may need to be put under two separate Permits to Operate, this analysis doubled the cost. The total annual cost of the permit fees for air pollution control

equipment and permit renewal fees is estimated to be about $83,533 (permit fee for air pollution control equipment $16,343 and permit renewal fee $67,190).

Fees for the review and approval of the fenceline air monitoring plan (FAMP) were discussed earlier in the section on monitoring of large facilities and Tier I warehouses.

Recordkeeping and Reporting

PAR 1405 includes recordkeeping and reporting requirements. Recordkeeping for CEMS performance standard measurements and PTE pressure differential readings are expected to be automated and recorded on computerized systems (e.g., the data acquisition systems for CEMS/SCEMS).

The additional recordkeeping required for LDAR for daily audio/visual checks by facility personnel and the bimonthly LDAR inspections by third-party contractors were already discussed in the above LDAR section.

According to PAR 1405, paragraph (t)(5) a large facility would need to track and record the first destination where the sterilized products are shipped for 12 months in preparation for the one-time report submittal to the South Coast AQMD. For this report, the analysis assumed that 10 hours per month for consecutive 12 months would be required to implement shipment tracking of EtO sterilized products to their first warehouse destination. For each large facility, a total of 120 hours at a rate of $37 per hour is assumed to be the incurred cost for this one-time reporting cost, the total of which is annualized at $2,220.

By the schedule specified in PAR 1405 subdivision (h), Table 2, Tier I and Tier II warehouses are required to conduct recordkeeping of received EtO-sterilized palletized units from sterilization facilities during the 2024 and 2025 calendar years in order to generate a one-time summary report to be sent to the South Coast AQMD by the deadline specified in the rule. The analysis also assumed a total of 120 hours at a rate of $37 per hour as the one-time reporting cost for each large warehouse. When annualized, the cost of reporting by the warehouses is estimated at $8,880 per year.

In addition, most of the facilities need to keep records of natural draft opening (NDO) testing, which was assumed to require 32 hours per year at a rate of $37 per hour. The total annual cost of this recordkeeping averaged across all the years (2023-2043) is estimated to be about $11,784.

MACROECONOMIC IMPACTS ON THE REGIONAL ECONOMY

The Regional Economic Model (REMI, PI+ v3) was used to assess the total socioeconomic impacts of PAR 1405.[6,7] The model links the economic activities in the counties of Los Angeles, Orange, Riverside, and San Bernardino, and for each county, it is comprised of five interrelated blocks: 1) output and demand; 2) labor and capital; 3) population and labor force; 4) wages, prices and costs; and 5) market shares.[8]

It should be noted that the REMI model is not designed to assess impacts on individual operations. The model was used to assess the impacts of the proposed project on various industries that make up the local economy. Cost impacts on individual operations were assessed outside of the REMI model and used as inputs into the REMI model.

Impact of Proposed Amendments

The assessment herein is performed relative to a baseline ("business as usual") PAR 1405 would not be implemented. It is assumed that the affected facilities and warehouses would finance the capital and installation costs of the air pollution control equipment, or more specifically, these one-time costs were assumed to be amortized and incurred over the equipment life. The proposed project assumed the implementation of PAR 1405 by the affected facilities, which would create a policy scenario under which the affected facilities would incur an average annual compliance cost of approximately $4.73 million when costs are annualized using a 4% real interest rate, or $4.56 million when evaluated using a 1% real interest rate from year 2023 onwards when all controls are assumed to have been installed.

Direct effects of the proposed project are used as inputs to the REMI model in order for the model to assess secondary and induced impacts for all the industries in the four-county economy on an annual basis and across a user-defined horizon: 2023 (first year when the affected facilities are assumed to incur the compliance cost due to PAR 1405 implementation) to 2043 (last year that costs associated with operation and maintenance are incurred). Direct effects of PAR 1405 include: 1) additional costs that the facilities would incur by installing control equipment; 2) additional sales by local vendors of equipment, devices, or services which are needed to meet the proposed requirements; and 3) increased regulatory activities by South Coast AQMD, including inspection

[6] Regional Economic Modeling Inc. (REMI). Policy Insight® for the South Coast Area (70-sector model). Version 3. 2023.

[7] REMI v3 has been updated based on The U.S. Economic Outlook for 2021-2023 from the University of Michigan's Research Seminar in Quantitative Economics (RSQE) release on May 21, 2021, The Long-Term Economic Projections from CBO (supplementing CBO's March 2021 report, The 2021 Long-Term Budget Outlook), and updated BEA data for 2020 (revised on May 27, 2021).

[8] Within each county, producers are made up of 156 private non-farm industries and sectors, three government sectors, and a farm sector. Trade flows are captured between sectors as well as across the four counties and the rest of U.S. Market shares of industries are dependent upon their product prices, access to production inputs, and local infrastructure. The demographic/migration component has 160 ages/gender/race/ethnicity cohorts and captures population changes in births, deaths, and migration. (For details, please refer to REMI online documentation at http://www.remi.com/products/pi.)

and grant/renewal of permits.

Whereas all the compliance expenditures that are incurred by the affected facilities would increase their cost of doing business, the additional spending on PTE, LDAR, dry-bed scrubbers, and CEMS/SCEMS and their associated expenditures would increase the spending and sales of businesses in various sectors, some of which may be located in the South Coast AQMD region. Table 8 lists the industry sectors modeled in REMI that would either incur cost or benefit from the compliance expenditures.

Table 8
Industries Incurring *vs.* Benefitting from Compliance Cost/Spending

Sources of Compliance Cost	REMI Industries Incurring Compliance Cost	REMI Industries Benefitting from Compliance Spending
Permanent Total Enclosure (PTE)	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) Wholesale Trade (42)	*One-time-Capital:* Construction (NAICS 23) *Recurring:* Utilities (NAICS 22) Machinery Manufacturing (NAICS 333)
Continuous Emission Monitoring System (CEMS)	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334)	*One-time-Capital:* Machinery Manufacturing (NAICS 333) Electrical Equipment and Appliance Manufacturing (NAICS 335) *Recurring:* Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561)
Photoionization Detector	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) Wholesale Trade (42)	*One-time-Capital:* Machinery Manufacturing (NAICS 333) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) *Recurring:* Machinery Manufacturing (NAICS 333)
Dry-Bed Scrubber	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) Wholesale Trade (42)	*One-time-Capital:* Machinery Manufacturing (NAICS 333) *Recurring:* Machinery Manufacturing (NAICS 333) Utilities (NAICS 22)

Sources of Compliance Cost	REMI Industries Incurring Compliance Cost	REMI Industries Benefitting from Compliance Spending
Permitting for Controls and CEMS; Permit Renewal	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334)	*One-time:* State and Local Government (NAICS 92) *Recurring:* State and Local Government (NAICS 92)
One-time Report	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) Wholesale Trade (42)	*One-time:* Professional, Scientific and Technical Services (NAICS 54)
Recordkeeping for NDO Testing, Including Inspection	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) Wholesale Trade (42)	*Recurring:* None
Source Test (for Dry-Bed)	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334)	*Recurring* Miscellaneous Manufacturing (NAICS 339)
Mobile and Fenceline Air Monitoring	Miscellaneous Manufacturing (NAICS 339) Professional, Scientific and Technical Services (NAICS 54) Administrative and Support Services (NAICS 561) Retail Trade (NAICS 44-45) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) Wholesale Trade (42)	*One-time:* Professional, Scientific and Technical Services (NAICS 54) State and Local Government (NAICS 92) Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334) *Recurring:* State and Local Government (NAICS 92) Professional, Scientific and Technical Services (NAICS 54)

Regional Job Impacts

When the compliance cost is annualized using a 4% real interest rate, it is projected that an annual average of 54 net jobs foregone will occur from 2023 to 2043. The 54 annual jobs foregone represents less than 0.0005% of total annual jobs in the four-county area.

In earlier years of PAR 1405 implementation, the compliance expenditures made by affected facilities for PTE, LDAR, dry-bed scrubbers, and CEMS/SCEMS, and fenceline air monitoring are expected to create a few additional jobs. In the first year of implementation, when most of the spending is expected to occur, about three additional jobs are projected to add in the regional economy. The positive job impact would mainly occur in the sector of construction. Operating and maintenance expenditures would benefit the industries involved in electricity generation, transmission, and distribution. However, as affected facilities continue to incur the amortized capital expenditures and annual O&M costs, slight reductions in job growth would set in, resulting in jobs foregone in later years.

The projected reduction in disposable income from the overall jobs foregone in the later years would dampen the demand for goods and services in the local economy, thus contributing to jobs foregone in sectors such as the rest of manufacturing, retail trade, wholesale, and accommodation and food services. As presented in Table 9, many major sectors of the regional economy would experience negative, albeit minor, job impacts in later years from the secondary and induced effects of PAR 1405 implementation.

Table 9
Projected Job Impacts of PAR 1405 for Select Industries by Year

Industry	2023	2027	2031	2035	2039	2043	Average Annual (2023-2043)	Baseline Average Annual (2023-2043)	% Change from Baseline
Miscellaneous manufacturing (339)	0	-7	-10	-11	-10	-9	-9	65,984	-0.0130%
Electromedical and Electrotherapeutic Apparatus Manufacturing (334)	-2	-6	-7	-7	-6	-5	-6	117,556	-0.0049%
Retail trade (44-55)	-3	-7	-7	-6	-5	-4	-6	805,858	-0.0007%
State and Local Government (92)	6	-5	-6	-6	-6	-5	-5	942,598	-0.0005%
Professional, scientific, and technical services (54)	0	-5	-6	-5	-5	-4	-4	953,864	-0.0004%
Ambulatory health care services (621)	0	-4	-4	-3	-3	-3	-3	613,270	-0.0005%
Construction (23)	4	-9	-5	-2	-1	-1	-3	506,420	-0.0005%
Food services and drinking places (722)	0	-3	-3	-3	-3	-3	-3	687,711	-0.0004%
Administrative and support services (561)	0	-3	-3	-3	-3	-2	-3	805,398	-0.0003%
Real estate (531)	0	-3	-3	-2	-2	-2	-2	559,990	-0.0004%
Wholesale trade (42)	0	-2	-2	-1	-1	-1	-1	415,711	-0.0003%
Machinery manufacturing (333)	1	1	1	0	0	0	1	24,110	0.0024%
Utilities (22)	0	1	1	1	1	1	1	20,012	0.0042%
All Industries	**3**	**-70**	**-70**	**-63**	**-56**	**-50**	**-54**	**11,349,378**	**-0.0005%**

Figure 2 presents a projected time series of job impacts over the period from 2023 to 2043. Based on Abt Associate's 2014 recommendation to enhance socioeconomic analysis by conducting scenario analysis on major assumptions, this analysis contains an alternative scenario (worst-case scenario) where the affected facilities would not purchase any air pollution control equipment or services from providers within the South Coast AQMD jurisdiction. This is a hypothetical scenario in order to test the sensitivity of the previously discussed scenarios where the analyses rely on

REMI's embedded assumptions about how the capital and O&M spending would be distributed inside and outside the region. In reality, utilities expenditures are paid to local utilities producers. Moreover, increased construction jobs related to control installation are likely to be offered by the local construction companies. This worst-case scenario would result in an annual average of approximately 75 jobs foregone. The 75 jobs foregone represents less than 0.0006% of total jobs in the region.

Figure 2: Projected Regional Job Impact, 2023-2043

Competitiveness

The additional cost brought on by PAR 1405 would increase the cost of services rendered by the affected industries in the region. The magnitude of the impact depends on the size, diversification, and infrastructure in a local economy as well as interactions among industries. A large, diversified, and resourceful economy would absorb the impact described above with relative ease.

Changes in production/service costs would affect prices of goods produced locally. The relative delivered price of a good is based on its production cost and the transportation cost of delivering

the good to where it is consumed or used. The average price of a good at the place of use reflects prices of the good produced locally and imported elsewhere.

According to the REMI Model, PAR 1405 is projected to have a maximum single-year increase in the cost of production for the miscellaneous manufacturing industry by 0.015% and electromedical and electrotherapeutic apparatus manufacturing by 0.002% in the South Coast AQMD jurisdiction. The maximum increase in delivered prices for these sectors are projected to be 0.012% and 0.002%, respectively. The single-year maximum cost and price increases are expected to take place in 2026.

Overall, PAR 1405 is not expected to have a significant impact on the competitiveness of the affected industries in the region as these industries are regional businesses and could pass the costs to their end users. For example, due to the inelastic nature of demand for sterilized health products, the compliance cost incurred by sterilization facilities could potentially be passed on from sterilization facilities to downstream customers of medical and surgical supplies and to hospitals and end-use consumers.

Public Health Effects from Exposure to Ethylene Oxide

U.S. EPA recently published the Regulatory Impact Analysis (RIA) for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations (published in March 2023). According to this RIA report, the Department of Health and Human Services and the International Agency for Research on Cancer have classified EtO as a known human carcinogen. The U.S. EPA has also concluded that EtO is carcinogenic to humans by the inhalation route of exposure.

According to this report, the exposure to EtO increases the risk of lymphoid cancer (including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, for females, breast cancer (U.S. EPA 2016). Noncancer health effects from chronic exposure to EtO could include irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system.

In addition, there is some evidence linking EtO exposure to reproductive effects (U.S. EPA 2018). EtO has been considered as a mutagen, meaning that it acts directly on DNA and causes chromosome damage. Children may be particularly susceptible to the harmful effects of mutagenic substances (U.S. EPA 2005).

Overall, PAR 1405 is expected to reduce EtO concentrations, and therefore the adverse public health impacts described in this section will be reduced.

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