

(Adopted December 21, 1990)(Amended January 4, 1991)(TBD)

**PROPOSED CONTROL OF ETHYLENE OXIDE AND
AMENDED CHLOROFLUOROCARBON EMISSIONS FROM
RULE 1405. ~~STERILIZATION PROCESSES OR FUMIGATION AND~~
RELATED OPERATIONS**

(a) Purpose

The purpose of this rule is to protect public health by reducing ~~eEthylene oXide~~ emissions from ~~sSterilization and related operations or fumigation operations in the South Coast Air Basin and to assess potential Ethylene Oxide emissions from Warehouses~~ and to fulfill state requirements. Pursuant to the requirements of Health and Safety Code Section 39650 (AB 1807 Tanner), the Air Resources Board (ARB) adopted an Air Toxic Control Measure for Ethylene Oxide Emissions from Sterilizers and Aerators in May, 1990. The District is required to enact equivalent or more stringent requirements than this measure. This rule requires recovery or reclamation of chlorofluorocarbons at certain commercial facilities and eliminates the use of certain chlorofluorocarbons as diluents in sterilization processes by 1997.

(b) Applicability

This rule shall apply to the owner or operator of any Facility performing is ~~applicable to persons that use eEthylene oXide for sSterilization or fumigation, any Post-Aeration Storage Facility, or any Warehouse storing materials Sterilized with Ethylene Oxide.~~ aerate products sterilized with ethylene oxide at another facility.

(c) Definitions

For purposes of this rule the following definitions shall apply:

- (1) AERATION is the process during which residual Ethylene Oxide ~~ethylene oxide~~ dissipates by forced air flow, or through natural or mechanically assisted convection, or other means, from Sterilized ~~previously sterilized~~ materials after the Sterilization Cycle ~~sterilization cycle~~ is completed. Aeration is completed when Products have been aerated for the minimum time specified in protocols, work orders, validation documents, or manufacturer's instructions, and have been removed from the Aerator or Combined Sterilizer/Aerator. ~~Aeration is completed when materials that~~

~~have previously undergone ethylene oxide sterilization can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.~~

- (2) ~~AERATION-ONLY FACILITY is any facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.~~
- (2) AERATOR is any equipment (excluding a Sterilizer or a Combined Sterilizer/Aerator), areospace, or room in which air is used to perform Aeration.~~remove residual ethylene oxide from sterilized materials.~~
- (3) BACK-DRAFT VALVE is a valve, hood, or rear chamber exhaust system for removal of ethylene oxide. Ethylene Oxide during unloading of ~~sterilized~~ Sterilized materials.
- (4) CHLOROFLUOROCARBON (CFC) DILUENT is any of the five chlorinated fluorinated carbon compounds (CFC-11, CFC-12, CFC-113, CFC-114, or CFC-115), or combinations of these compounds, used in sterilant gas. Sterilant Gas mixtures.
- (5) COMPONENT is any seal, gasket, or connection in Ethylene Oxide service at a Sterilizer, Sterilizer Exhaust Vacuum Pump, Combined Sterilizer/Aerator, Aerator, or Control System.
- (6) CONTINUOUS EMISSION MONITORING SYSTEM (CEMS) is the total combined equipment and systems required to continuously determine air contaminants and diluent gas concentrations and/or mass emission rate of a source effluent (as applicable). The CEMS consists of three major subsystems: sampling interface, analyzer, and data acquisition system. The CEMS is able to take and record a minimum of one measurement (e.g., concentration, mass emission, flow rate) every one (1) minute.
- (7) COMBINED STERILIZER/AERATOR is any chamber or related piece of equipment that performs the functions of a Sterilizer and an Aerator and where Aeration is completed within the chamber.
- (8) CONTROL SYSTEM is equipment and ducting installed for the purposes of collecting Exhaust Streams consisting of one or more adjoining air pollution control devices that reduces emissions of Ethylene Oxide and exhausts to a single stack.
- (9) DESIGNATED WAREHOUSE is any Warehouse, excluding a Large Warehouse or New Large Warehouse, that the Executive Officer has

- determined to be a potential source of Ethylene Oxide emissions and notified in writing of the determination by the Executive Officer.
- (10) ELEMENT is any drum, container, bin, or other vessel used to store Sterilant Gas or any Ethylene Oxide-contaminated liquids or solids.
- (6) ETHYLENE OXIDE (C₂H₄O) is a colorless, flammable gas that has been
- (11) identified as a suspected human carcinogen and a toxic air contaminant by the California Air Resources Board (CARB).
- (7) EXHAUST STREAM is the ethylene oxide Ethylene Oxide-contaminated
- (12) effluent, emitted from a sterilizer or aerator.
- (13) FACILITY is any source or group of sources or other air contaminant emitting activities which are located on one or more contiguous properties within the South Coast AQMD, in actual physical contact or separated solely by a public roadway or other public right-of-way, and are owned or operated by the same person (or by persons under common control), or an outer continental shelf (OCS) source as determined in 40 CFR Section 55.2. Such above-described groups, if noncontiguous, but connected only by land carrying a pipeline, shall not be considered one Facility.
- (14) LARGE FACILITY is any Facility performing Sterilization that is permitted to use more than or equal to 2,000 pounds (lbs) of Ethylene Oxide per calendar year.
- (15) LARGE WAREHOUSE is any Warehouse greater than or equal to 100,000 square feet of indoor floor area in a single building and reporting to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider.
- (16) LEAK is the detection of a concentration of Total Organic Compounds (TOC) above background, determined according to CARB Test Method 21.
- (17) LEEWARD WALL means the furthest exterior wall of a Permanent Total Enclosure that is opposite the Windward Wall.
- (18) MEDIUM FACILITY is any Facility performing Sterilization that is permitted to use more than 400 lbs and less than 2,000 lbs of Ethylene Oxide per calendar year.
- (19) NEW LARGE WAREHOUSE is a Large Warehouse starting operations after [Date of Amendment].
- (20) PALLETIZED UNIT is any pallet, skid, or other container with a collection of Products packaged in paper cartons, corrugated cardboard, or

- other packaging, often secured with strapping, stretch wrap, shrink wrap, or other binding.
- (21) PERMANENT TOTAL ENCLOSURE (PTE) means 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, and has been evaluated to meet the design requirements set forth in U.S. Environmental Protection Agency (EPA) Method 204 except the term "Administrator" in provision 5.1 is revised to mean Executive Officer, as defined in Rule 102.
- (22) POST-AERATOR is any equipment, area, or room where Sterilized materials are stored, transferred, loaded, or unloaded after completing Aeration. Post-Aerator excludes:
- (A) Motor vehicles used during loading, unloading, and transport; or
- (B) Equipment, area, or room that is an Aerator or Combined Sterilizer/Aerator.
- (23) POST-AERATION STORAGE FACILITY is any Facility not performing Sterilization and used for the storage of Sterilized materials which have been Sterilized at another Facility.
- (24) PRODUCT is any material intended to be Sterilized by Ethylene Oxide, and may include primary packaging.
- (25) SEMI-CONTINUOUS EMISSION MONITORING SYSTEM (SCEMS) is the total combined equipment and systems to semi-continuously determine air contaminant and diluent gas concentrations and/or the mass emission rate in a source effluent (as applicable). The SCEMSsystem consists of three major subsystems: sampling interface, analyzer, and data acquisition system. This class of monitoring includes but is not limited to gas chromatography, integrated sensitized tape analyzer, other sample integration based technologies, and time-shared CEMS. The SCEMS is able to take and record a minimum of one measurement (e.g., concentration, mass emission, flow rate) every fifteen (15) minutes.
- (26) SMALL FACILITY is any Facility performing Sterilization that is permitted to use more than four (4) lbs and less than or equal to 400 lbs of Ethylene Oxide per calendar year.

- (27) STERILANT GAS is Ethylene Oxide, or any combination of Ethylene Oxide and other gases, used to perform Sterilization.
- (28) STERILANT GAS STORAGE AREA is any area used to store Sterilant Gas not in current use by a Sterilizer or Combined Sterilizer/Aerator.
- ~~(41)~~ STERILIZATION/FUMIGATION is the process where Sterilant Gas
(29) ethylene oxide or any combination of ethylene oxide and other gases are is used to destroy bacteria, viruses, fungi, and other unwanted organisms on materials. This includes fumigation processes using Sterilant Gas. These materials include, by way of illustration and not limitation, medical products, cosmetics, and foodstuffs.
- (30) STERILIZATION CYCLE is the process where Products and other materials are exposed to Sterilant Gas in a Sterilizer or a Combined Sterilizer/Aerator. A Sterilization Cycle is completed when Products are removed from the Sterilizer or Combined Sterilizer/Aerator.
- (31) STERILIZED is having undergone a Sterilization Cycle in a Sterilizer or a Combined Sterilizer/Aerator.
- ~~(42)~~ STERILIZER is any chamber or related piece of equipment (excluding a
(32) Combined Sterilizer/Aerator) that uses Sterilant Gas ethylene oxide or an ethylene oxide mixture in any sterilization Sterilization or fumigation process.
- ~~(43)~~ STERILIZER EXHAUST VACUUM PUMP is a device (including any
(33) associated heat exchanger) used to evacuate sterilant gas Sterilant Gas during the sterilizer cycle Sterilization Cycle, but is not a device used solely to evacuate a Sterilizer or Combined Sterilizer/Aerator sterilizer prior to the introduction of Sterilant Gas ethylene oxide.
- (34) WAREHOUSE is any building with the primary purpose of storing materials for later distribution to intermediaries or users of stored materials.
- (35) WASTE STORAGE AREA is any area used to store any Ethylene Oxide-contaminated liquids and solids produced as a byproduct of Sterilization and associated processes.
- (36) WINDWARD WALL means the exterior wall of a Permanent Total Enclosure which is most impacted by the wind in its most prevailing direction determined by a wind rose using data from the nearest meteorological station.

(d) Large Facility Requirements

(1) Stack Emission Requirements

Beginning December 31, 2024, the owner or operator of a Large Facility shall not perform Sterilization unless the following requirements are met:

(A) Install and maintain a Back-Draft Valve for each Sterilizer and operate the Back-Draft Valve when unloading the Sterilizer;

(B) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure to a Control System;

(C) For each Control System either:

(i) Demonstrate control of Ethylene Oxide emissions with 99.99% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m); or

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test that meets the requirements in subdivision (m);

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

(E) Conduct a source test that meets the requirements in subparagraphs (d)(1)(C) and (d)(1)(D) and pursuant to subdivision (m) for each Control System:

(i) No later than February 28, 2025 for an existing Control System installed or modified on or before December 31, 2024;

(ii) Within 60 days after initial operation of a Control System installed or modified after December 31, 2024; and

(iii) No later than 12 calendar months from the day of the most recent source test of the Control System.

(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, the owner or operator of a Large Facility shall not perform Sterilization unless the following requirements are met:

- (A) Monitor the Ethylene Oxide emissions from each exhaust stack from all Control Systems by operating a SCEMS or CEMS that meets the requirements in subdivision (j);
- (B) Demonstrate the sum of mass emission rates, averaged over a calendar day and measured at each exhaust stack, is 0.025 pounds per hour (lbs/hr) or less of Ethylene Oxide from all Control Systems averaged over each calendar day in operation, by a SCEMS or CEMS that meets the requirements in subdivision (j); and
- (C) For each Control System complying with clause (d)(1)(C)(ii), demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, averaged over each calendar day in operation, by a SCEMS or CEMS that meets the requirements in subdivision (j).

(3) Fugitive Emissions Requirements

Beginning December 31, 2024, the owner or operator of a Large Facility shall Facility shall not perform Sterilization unless the following requirements are met:

- (A) Maintain all Sterilizers, Combined Sterilizer/Aerators, Back-Draft Valves, Aerators, Post-Aerators, Elements in a Sterilant Gas Storage Area, and Elements in a Waste Storage Area within a Permanent Total Enclosure that meets the requirements in subdivision (k); and
- (B) Either operate a Control System within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor all Components up to the exhaust stack of the Control System by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n).

(4) Other Requirements

Beginning [3 Months After Date of Amendment], the owner or operator of a Large Facility shall:

- (A) Record the destinations of Sterilized Palletized Units shipped;
- (B) Place on a vertical surface on each Sterilized Palletized Unit at least one label, size 8.5 inches by 11 inches, with letters of sufficient size and contrast as to be readily visible and legible, reading:

STERILIZED WITH ETHYLENE OXIDE (EtO/EO) ON {Date
of Sterilization}

- (C) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure with:
 - (i) Type of equipment, area, or room;
 - (ii) Unit number or other identifier, if applicable; and
 - (iii) South Coast AQMD permit number, if applicable;
- (D) Label or write on each bill of lading, "STERILIZED WITH ETHYLENE OXIDE (EtO/EO)":
- (E) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area;
- (F) Prepare and submit an annual report in writing by electronic mail to Rule1405notifications@aqmd.gov each calendar year on or before January 30 regarding the preceding calendar year. The annual report shall contain at a minimum either:
 - (i) The number of Sterilization Cycles and the pounds of Sterilant Gas (measured or calculated) used per Sterilization Cycle for each Sterilizer and each Combined Sterilizer/Aerator each operating day; or
 - (ii) The total pounds of Sterilant Gas purchased and the total pounds of Sterilant Gas used per calendar month and calendar year, respectively; and
- (G) Prepare and submit a semi-annual report in writing by electronic mail to Rule1405notifications@aqmd.gov on or before January 30 of each calendar year for the preceding July-December semi-annual reporting period and on or before July 30 of each calendar year for the preceding January-June semi-annual reporting period. The semi-annual report shall contain at a minimum:
 - (i) Semi-Annual Summary Report pursuant to Appendix 1; and
 - (ii) Semi-Annual Excess Emission Report pursuant to Appendix 2, if the duration of excess emissions or parameter monitoring exceedances for the reporting period exceeds 1 percent of the reporting period or the total monitored downtime for the reporting period exceeds 5 percent of the reporting period.

(5) No later than December 31, 2023, the owner or operator of a Large Facility operating prior to [Date of Amendment] shall submit complete South Coast AQMD permit application(s) to modify existing permit conditions, modify existing equipment, or install new equipment to meet the requirements specified in paragraphs (d)(1) and (d)(3).

(e) Medium Facility Requirements

(1) Stack Emission Requirements

Beginning July 1, 2025, the owner or operator of a Medium Facility shall not perform Sterilization unless the following requirements are met:

(A) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator that immediately follow an Aerator or Combined Sterilizer/Aerator, and Permanent Total Enclosure to a Control System;

(B) For each Control System either:

(i) Demonstrate control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m); or

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test that meets the requirements in subdivision (m); and

(C) Conduct a source test that meets the requirements in subparagraph (e)(1)(B) and pursuant to subdivision (m) for each Control System:

(i) No later than September 1, 2025 for an existing Control System installed or modified on or before July 1, 2025;

(ii) Within 60 days after initial operation of a Control System installed or modified after July 1, 2025; and

(iii) No later than 12 calendar months from the day of the most recent source test of the Control System.

(2) Fugitive Emissions Requirements

Beginning July 1, 2025, the owner or operator of a Medium Facility shall not perform Sterilization unless all the following requirements are met:

(A) Operate each of the following within a Permanent Total Enclosure that meets the requirements in subdivision (k):

(i) Sterilizer, if applicable;

- (ii) Aerator, if applicable; and
 - (iii) Post-Aerator used to store Sterilized materials directly from an Aerator or Combined Sterilizer/Aerator; and
 - (B) Either maintain each of the following within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor each of the following by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n):
 - (i) Combined Sterilizer/Aerator, if applicable;
 - (ii) Back-Draft Valve, if applicable;
 - (iii) All Components up to the exhaust stack of the Control System;
 - (iv) All Elements in a Sterilant Gas Storage Area; and
 - (v) All Elements in a Waste Storage Area.
 - (3) Other Requirements

Beginning [3 Months After Date of Amendment], the owner or operator of a Medium Facility shall:

 - (A) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator subject to the requirements of clause (e)(2)(A)(iii), and Permanent Total Enclosure with:
 - (i) Type of equipment, area, or room;
 - (ii) Unit number or other identifier, if applicable; and
 - (iii) South Coast AQMD permit number, if applicable; and
 - (B) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator subject to the requirements of clause (e)(2)(A)(iii), Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area.
 - (4) No later than July 1, 2024, the owner or operator of a Medium Facility operating prior to [Date of Amendment] shall submit complete South Coast AQMD permit application(s) to modify existing permit conditions, modify existing equipment, or install new equipment to meet the requirements specified in paragraphs (e)(1) and (e)(2).
- (f) Small Facility Requirements
 - (1) Stack Emission Requirements

Beginning December 31, 2025, the owner or operator of a Small Facility shall not perform Sterilization unless the following requirements are met:

- (A) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, and Permanent Total Enclosure to a Control System;
- (B) For each Control System either:
 - (i) Demonstrate control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m); or
 - (ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test that meets the requirements in subdivision (m); and
- (C) Conduct a source test that meets the requirements in subparagraph (f)(1)(B) and pursuant to subdivision (m) for each Control System:
 - (i) No later than February 28, 2026 for an existing Control System installed or modified on or before December 31, 2025;
 - (ii) Within 60 days after initial operation of a Control System installed or modified after December 31, 2025; and
 - (iii) No later than 12 calendar months from the day of the most recent source test of the Control System.

(2) Fugitive Emission Requirements

Beginning December 31, 2025, the owner or operator of a Small Facility shall not perform Sterilization unless the following requirements are met:

- (A) Operate the following areas and processes within a Permanent Total Enclosure that meets the requirements of subdivision (k):
 - (i) Sterilizer, if applicable; and
 - (ii) Aerator, if applicable; and
- (B) Either maintain the following areas and processes within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor the following areas and processes by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n):
 - (i) Combined Sterilizer/Aerator, if applicable;
 - (ii) Back-Draft Valve, if applicable.

- (ii) All Components up to the exhaust stack of the Control System;
 - (iv) All Elements in a Sterilant Gas Storage Area; and
 - (v) All Elements in a Waste Storage Area.
 - (3) Other Requirements
Beginning [3 Months After Date of Amendment], the owner or operator of a Small Facility shall:
 - (A) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, and Aerator with:
 - (i) Type of equipment, area, or room;
 - (ii) Unit number or other identifier, if applicable; and
 - (iii) South Coast AQMD permit number, if applicable; and
 - (B) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area.
 - (4) No later than December 31, 2024, the owner or operator of a Small Facility operating prior to [Date of Amendment] shall submit complete South Coast AQMD permit application(s) to modify existing permit conditions, modify existing equipment, or install new equipment to meet the requirements specified in paragraphs (f)(1) and (f)(2).
- (g) Post-Aeration Storage Facility Requirements
Beginning [3 Months After Date of Amendment], the owner or operator of a Post-Aeration Storage Facility that vents the Exhaust Stream of a Post-Aerator to a Control System shall not receive Sterilized materials unless all the following requirements are met:
 - (1) For each Control System, demonstrate control of Ethylene Oxide emissions with 95% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m);
 - (2) Conduct a source test that meets the requirements in paragraph (g)(1) and pursuant to subdivision (m) for each Control System:
 - (A) No later than [5 Months After Date of Amendment] for an existing Control System installed or modified on or before [3 Months After Date of Amendment];

- (B) Within 60 days after initial operation of a Control System installed or modified after [3 Months After Date of Amendment]; and
 - (C) No later than 12 calendar months from the day of the most recent source test of the Control System;
 - (3) Either operate a Control System within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor all Components up to the exhaust stack of Control System by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n);
 - (4) Clearly label each Post-Aerator and Permanent Total Enclosure with:
 - (A) Type of equipment, area, or room, if applicable;
 - (B) Unit number or other identifier, if applicable; and
 - (C) South Coast AQMD permit number, if applicable; and
 - (5) Prepare and maintain onsite a Facility diagram that identifies each Post-Aerator and Permanent Total Enclosure.
- (h) Warehouse Reporting Requirements
- (1) The owner or operator of a Large Warehouse, New Large Warehouse, or Designated Warehouse shall record the number of Sterilized Palletized Units, excluding Sterilized Palletized Units received from other Warehouses, received each month according to the schedule specified in Table 1 – Warehouse Recording Schedule.

Table 1 – Warehouse Recording Schedule

<u>Type of Warehouse</u>	<u>Start Date to Record Number of Sterilized Palletized Units</u>	<u>End Date to Record Number of Sterilized Palletized Units</u>
<u>Large Warehouse</u>	<u>July 1, 2023</u>	<u>June 30, 2024</u>
<u>New Large Warehouse</u>	<u>30 days after starting operation</u>	<u>395 days after starting operation</u>
<u>Designated Warehouse</u>	<u>30 days after being designated</u>	<u>Per notification by Executive Officer</u>

- (2) The owner or operator of a Large Warehouse, New Large Warehouse, or Designated Warehouse shall submit an initial summary report to the Executive Officer to document the number of Sterilized Palletized Units, excluding Sterilized Palletized Units received from other Warehouses, in

the preceding twelve months pursuant to the schedule specified in Table 2 – Warehouse Initial Report Schedule that includes the following:

- (A) Name of Warehouse;
- (B) South Coast AQMD Facility ID, if applicable;
- (C) Address of Warehouse;
- (D) Contact information for Warehouse;
- (E) Total number of Sterilized Palletized Units received each month for the preceding 12-month period; and
- (F) Addresses of where Sterilized Palletized Units shipped from.

Table 2 – Warehouse Initial Report Schedule

<u>Type of Warehouse</u>	<u>Submittal of Initial Summary Report</u>
<u>Large Warehouse</u>	<u>No later than August 1, 2024</u>
<u>New Large Warehouse</u>	<u>No later 425 days after starting operation</u>
<u>Designated Warehouse</u>	<u>No later than 425 days after being designated by Executive Officer</u>

(i) Interim Requirements

- (1) ~~The following requirements shall be met by December 21, 1992 by~~ the owner of operator of a Facility performing Sterilization all persons who that uses a total of 400 poundslbs or less of eEthylene oOxide per calendar year:
 - (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of 99-percent% or more, by weight.
 - (B) If eEthylene oOxide emissions from aAeration are greater than four pounds per calendar year, the aAerator(s) shall be vented to control equipment with an efficiency of 95-percent% or more, by weight.
 - (C) If the eExhaust sStreams from the equipment identified in subparagraphs (i)(1)(A) and (i)(1)(B) are vented to the same control equipment, the combined efficiency must be 98.8-percent% or more, by weight.
- (2) ~~The following requirements shall be met by June 21, 1992 by~~ the owner of operator of a Facility performing Sterilization all persons who uses a total of more than 400 poundslbs and less than or equal to 4,000 pounds lbs of eEthylene oOxide per calendar year:

- (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of ~~99.9-percent%~~ 99.9% or more, by weight.
 - (B) Aerator(s) shall be vented to control equipment with an efficiency of ~~95-percent%~~ 95% or more, by weight.
 - (C) Back-~~d~~Draft ~~exhaust~~ ~~v~~Valve(s) shall be vented to control equipment with an efficiency of 95 percent or more, by weight.
 - (D) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (i)(2)(A), (i)(2)(B), and (i)(2)(C) are vented to the same control equipment, the combined efficiency must be 99.6 percent% or more, by weight.
- (3) ~~The following requirements shall be met by December 21, 1991 by t~~The owner or operator of a Facility performing Sterilization all persons who uses a total of more than 4,000 ~~pounds-lbs~~ of ~~e~~Ethylene ~~o~~Oxide per calendar year:
- (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of ~~99.9-percent%~~ 99.9% or more, by weight.
 - (B) Aerator(s) and ~~s~~Sterilizer door hood ~~e~~Exhaust ~~s~~Stream(s) shall be vented to control equipment with an efficiency of ~~99-percent%~~ 99% or more, by weight.
 - (C) Back-~~d~~Draft ~~exhaust~~ ~~v~~Valve(s) shall be vented to control equipment with an efficiency of ~~99-percent%~~ 99% or more, by weight.
 - (D) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (i)(3)(A), (i)(3)(B), and (i)(3)(C) are vented to the same control equipment, the combined efficiency must be 99.8 percent or more, by weight.
- (4) ~~Persons owning or operating aeration only facilities where more than four pounds of ethylene oxide are emitted per calendar year shall install control equipment with an efficiency of 95 percent or more, by weight, by June 21, 1992.~~
- (4) The owner or operator of a Facility that stores materials that are Sterilized with Sterilant Gas at another Facility and has as a permit to operate to control Ethylene Oxide emissions issued by South Coast AQMD prior to [Date of Amendment] shall vent to control equipment with an efficiency of 95% or more, by weight.

- (5) The owner or operator of a Facility subject to either paragraph (i)(1), (i)(2), (i)(3), or (i)(4) operating Sterilizers, Combined Sterilizer/Aerators, Aerators, control equipment, and emissions collection systems shall meet the following: ~~be leak free effective December 21, 1990. The maximum sterilant gas mass flow shall be less than 30 parts per million ethylene oxide for sterilant gas composed of 12 percent ethylene oxide/88 percent chlorofluorocarbon-12, by weight, and less than 10 parts per million ethylene oxide for other compositions of sterilant gas, as measured one (1) centimeter away from any portion of a sterilizer, aerator, or control equipment that could have an ethylene oxide leak. Leak tests shall be conducted during conditions of maximum sterilant gas mass flow. Leak tests shall be conducted every six months, as specified in paragraph (f), Test Methods.~~
- (A) The maximum Sterilant Gas mass flow shall be less than 10 parts per million Ethylene Oxide, as measured one (1) centimeter away from any portion of a Sterilizer, Combined Sterilizer/Aerator, Aerator, or Control System that could have an Ethylene Oxide leak;
- (B) Test during conditions of maximum Sterilant Gas mass flow; and
- (C) Test at least once every six months, as specified in paragraph (i)(8).
- (6) The owner or operator of a Facility subject to either paragraph (i)(1), (i)(2), (i)(3), or (i)(4) ~~All persons subject to this rule shall conduct source tests on control equipment within 60 days after the initial operation of the equipment to verify compliance with control efficiency requirements, as specified in paragraph (f)(7), Test Methods. Thereafter, annual source tests shall be conducted on catalytic oxidation, carbon, or solid bed control equipment at least once per calendar year. More frequent source tests, or source tests on other control equipment, may be required at the District's discretion.~~
- (7) ~~A person shall not discharge any sterilizer exhaust vacuum pump working fluid to the wastewater stream.~~
- (8) ~~By July 1, 1992, all persons who use more than 30,000 pounds of chlorofluorocarbons per calendar year for ethylene oxide sterilization, except at hospitals, shall vent the sterilizer exhaust to recovery or reclamation equipment with an efficiency of 70 percent or more, by weight.~~

- ~~(9) A person shall not use chlorofluorocarbon diluents in ethylene oxide sterilization, effective January 1, 1997.~~
- (7) Source tests shall be conducted according to CARB Test Method 431 or an acceptable source test method approved by CARB and the Executive Officer. In addition, the following requirements shall be met:

 - (A) Tests on control equipment shall be run with a typical load in the sterilizer or aerator.
 - (B) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.
 - (C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes and during normal operations. To measure the control efficiency of the control equipment on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.
- (8) Tests shall be conducted by CARB Test Method 21 using a portable flame ionization detector or a non-dispersive infrared analyzer calibrated with methane, or an acceptable alternative method or analytical instrument approved by the Executive Officer.
- (j) SCEMS, CEMS, or other Monitoring Requirements for Stack Emissions

 - (1) The owner or operator of a Facility required to monitor the emissions from a Control System shall install, operate, and maintain a SCEMS or CEMS for each Control System complying with applicable requirements in Rule 218 through Rule 218.3 and the following requirements:

 - (A) Measures the following parameters:

 - (i) Ethylene Oxide concentration, with a resolution of at least 0.01 ppm, by volume;
 - (ii) Oxygen concentration; and
 - (iii) Exhaust stack flow rate;

- (B) Measures at a location reviewed and approved by the Executive Officer during the SCEMS or CEMS certification process;
 - (C) Meets the performance specifications for certification and quality assurance of the SCEMS or CEMS established by South Coast AQMD; and
 - (D) Is equipped with a data acquisition system (DAS) that is capable of logging direct measurements and providing the date, time in local standard time, and applicable Ethylene Oxide performance standard.
- (2) The owner or operator of a Facility required to operate a SCEMS or CEMS shall calculate and record the sum of mass emission rates for all exhaust stacks, averaged over a calendar day and expressed in lbs/hr, no later than the next calendar day.
- (3) The owner or operator of a Facility required to operate a SCEMS or CEMS shall install and operate a backup battery that provides uninterruptible power supply to ensure operation of the SCEMS or CEMS.
- (4) The owner or operator of a Facility required to operate a SCEMS or CEMS shall maintain and calibrate each SCEMS or CEMS pursuant to manufacturer specification.
- (5) The owner or operator of a Large Facility operating a Control System containing an acid-water scrubber shall either:
 - (A) Sample the scrubber liquor at least once per calendar week and analyze and record the ethylene glycol concentration using American Society for Testing and Materials (ASTM) D 3695-88, Standard Test Method for Volatile Alcohols in Water by Direct Aqueous-Injection Gas Chromatography (1988); or
 - (B) Measure and record at least once per calendar week the level of the scrubber liquor in the recirculation tank and install, maintain, calibrate, and use a liquid level indicator to measure the scrubber liquor tank level.
- (6) The owner or operator of a Large Facility operating a Control System containing a catalytic oxidation unit or thermal oxidation unit shall continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using a temperature monitor:

- (A) Installed, calibrated, operated, and maintained to an accuracy within ± 5.6 degrees Celsius (± 10 degrees Fahrenheit); and
- (B) Verified for accuracy twice each calendar year with a reference temperature monitor traceable to National Institute of Standards and Technology (NIST) standard, or with an independent temperature measurement device dedicated for this purpose. During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.
- (7) The owner or operator of a Large Facility operating a Control System containing an air pollution control device other than an acid-water scrubber, catalytic oxidation unit, or thermal oxidation unit shall monitor specific parameters of the device as approved by the Executive Officer.

(k) Permanent Total Enclosure Requirements

The owner or operator of a Facility required to operate within a Permanent Total Enclosure shall:

- (1) Demonstrate the Permanent Total Enclosure is maintained at a negative pressure of at least 0.007 inches of water column averaged over one (1) minute;
- (2) Install, operate, and maintain a digital differential pressure monitoring system for each Permanent Total Enclosure as follows:
 - (A) A minimum of one digital differential pressure monitor at each of the following three walls in each Permanent Total Enclosure having a total ground surface area of 10,000 square feet or more:
 - (i) The Leeward Wall;
 - (ii) The Windward Wall; and
 - (iii) An exterior wall that:
 - (I) Connects the Leeward and Windward wall at a location defined by the intersection of a perpendicular line between a point on the connecting wall and a point on its furthest opposite exterior wall;
 - (II) Intersects within plus or minus ten (+/-10) meters of the midpoint of a straight line between the two other monitors specified in clauses (k)(2)(A)(i) and (k)(2)(A)(ii); and

- (III) Is not located on the same wall as either of the other two monitors described in clauses (k)(2)(A)(i) or (k)(2)(A)(ii);
- (B) A minimum of one building digital differential pressure monitor at the Leeward Wall of each Permanent Total Enclosure that has a total ground surface area of less than 10,000 square feet;
- (C) Certified by the manufacturer to be capable of measuring and displaying negative pressure in the range of 0.005 to 0.110 inches of water column with a minimum increment of measurement of plus or minus 0.0005 inches of water column;
- (D) Equipped with a continuous strip chart recorder or electronic recorder approved by the Executive Officer. If an electronic recorder is used, the recorder shall be capable of writing data on a medium that is secure and tamper-proof. The recorded data shall be readily accessible upon request by the Executive Officer. If software is required to access the recorded data that is not readily available to the Executive Officer, a copy of the software, and all subsequent revisions, shall be provided to the Executive Officer at no cost. If a device is required to retrieve and provide a copy of such recorded data, the device shall be maintained and operated at the Facility;
- (E) Calibrated pursuant to manufacturer's specifications at least once every 12 calendar months or more frequently if recommended by the manufacturer; and
- (F) Equipped with a backup, uninterruptible power supply to ensure operation of the monitoring system during a power outage.
- (3) Demonstrate an inward air velocity of at least 200 feet per minute (fpm) at each natural draft opening at least once per calendar month and pursuant to Appendix 3 - PTE Inward Face Air Velocity Measurement; and
- (4) In the event of a failure to meet the negative pressure performance standard specified in paragraph (k)(1) or if there are more than 24 consecutive hours of missing data, notify the Executive Officer within 24 hours in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG.
- (I) Record-~~K~~keeping

- (1) The owner or operator of any Facility performing Sterilization shall maintain records of, as applicable:
 - (A) The number of ~~sSterilization~~ ~~eCycles~~ and the pounds of Sterilant Gas ~~ethylene oxide~~ (measured or calculated) used per Sterilization ~~eCycle~~ for each ~~sSterilizer~~ and each Combined Sterilizer/Aerator each operating day; ~~or~~
 - (B) The total pounds of Sterilant Gas ~~ethylene oxide~~ purchased and the total pounds of Sterilant Gas used per calendar month and calendar year, respectively, ~~provided that monthly totals are also kept.~~
 - (C) Data collected from the SCEMS or CEMS pursuant to subdivision (j):
 - (D) Source test reports pursuant to subdivision (m):
 - (E) Measurements of inward face velocity pursuant to Appendix 3:
 - (F) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to subdivision (k):
 - (G) Plot-plan reports, daily check, and monthly inspections for LDAR programs pursuant to subdivision (n) ~~Documentation and results of leak tests; and either;~~
 - (H) The numbers of Sterilized Palletized Units shipped, grouped by destination, pursuant to subparagraph (d)(3)(A):
 - (I) Facility diagrams pursuant to subparagraph (d)(4)(E), (e)(3)(B), or (f)(3)(B):
 - (J) Annual reports pursuant to subparagraph (d)(3)(F):
 - (K) Semi-annual reports pursuant to subparagraph (d)(3)(G); and
 - (L) Protocols, work orders, validation documents, or manufacturer's instructions that specify the minimum time to complete Aeration for a Sterilization Cycle.
- (2) The owner or operator of a Post-Aeration Storage Facility subject to subdivision (g) shall maintain records of, as applicable:
 - (A) Source test reports pursuant to subdivision (m):
 - (B) Measurements of inward face velocity pursuant to subdivision (k):
 - (C) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to subdivision (k):
 - (D) Plot-plan reports, daily check, and monthly inspections for LDAR programs pursuant to subdivision (n); and
 - (E) Facility diagrams pursuant to paragraph (g)(6).

- (3) The owner or operator of any Facility subject to this rule shall provide all available onsite records to the Executive Officer upon request.
- (4) The owner or operator of any Facility~~Any person~~ subject to this rule shall ~~maintain~~ retain all applicable written records for at ~~minimum of~~ least five years with two years of records maintained onsite ~~and~~. ~~Records shall include:~~

(m) Source Test Requirements~~Test Methods~~

The owner or operator of a Facility required to conduct source test pursuant to either subdivision (d), (e), (f), or (g) shall:

- (1) Prior to conducting the initial source test that demonstrates compliance with subdivision (d), (e), (f), or (g) for the Control System, submit a source test protocol for approval to the Executive Officer that includes:
 - (A) Operating conditions of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System;
 - (B) Number of Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System; and
 - (C) Planned sampling parameters;
- (2) Prior to conducting any subsequent source test that demonstrates compliance with subdivision (d), (e), (f), or (g) for the Control System, submit a source test protocol that includes the conditions, numbers, and parameters referenced by subparagraphs (m)(1)(A) through (C) if there are any changes in the conditions, numbers, or parameters referenced by subparagraphs (m)(1)(A) through (C) in the most recently-approved source test protocol;
- (3) Report the source test schedule to the Executive Officer at least 10 days prior to the start of any source test in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG;
- (4) Report any changes to the source test schedule in writing or verbally 24 hours prior to the start of source testing or within one (1) hour of discovery of a change in the source testing schedule;
- (5) Conduct a source test:

- (A) Pursuant to the source test protocol approved by the Executive Officer;
- (B) With triplicate runs at either typical operating conditions or at maximum operating parameters, as specified in the source test protocol;
- (C) With each run being a minimum of 60 minutes;
- (D) Pursuant to CARB Method 431, U.S. EPA Method TO-15 or TO-15A, or an acceptable source testing method approved by the Executive Officer; and
- (E) Assessing the efficiency of controlling Ethylene Oxide emissions by:
 - (i) Measuring or determining the total inlet amount of Ethylene Oxide entering the Control System from any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System; and
 - (ii) Measuring the outlet amount of Ethylene Oxide exhausted from the Control System; and
- (6) Submit the source testing report to the South Coast AQMD within 60 days of completing source testing.
 - ~~(B) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.~~
 - ~~(C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control equipment on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.~~
- (n) Leak Detection and Repair (LDAR) Program Requirements

The owner or operator of a Facility required to implement an LDAR program shall:

- (1) Prepare and maintain onsite a plot-plan report that identifies all Components subject to the LDAR program;
- (2) Maintain clear labeling using tags or other means to physically identify all Components subject to the LDAR program;
- (3) Maintain all Components and Elements subject to the LDAR program free of Leaks greater than 2 ppm above background;
- (4) Conduct daily audio-visual checks for all applicable Components and Elements; and
- (5) Conduct monthly leak inspections of all applicable Components and Elements pursuant to CARB Test Method 21 using a portable photoionization detector calibrated with Ethylene Oxide or other calibrating gas, or an acceptable alternative method or analytical instrument approved by the Executive Officer. If other calibrating gases are used, the correction factor shall also be recorded and the measured readings shall be correlated to and also expressed as Ethylene Oxide.; and
- (6) Record results of daily audio-visual checks or monthly leak inspections at all Components and Elements.

(o) Prohibitions

- (1) The owner or operator of a Facility performing Sterilization A person shall not discharge any sSterilizer eExhaust vVacuum pPump working fluid to the wastewater stream.
- (2) The owner or operator of a Facility performing Sterilization A person shall not use eChlorofluorocarbon dDiluents in-ethylene oxide sSterilization; effective January 1, 1997.
- (3) The owner or operator of a Facility performing Sterilization shall not allow the release of uncontrolled emission of Ethylene Oxide to atmosphere from any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, or Permanent Total Enclosure at any time.
- (4) The owner or operator of a Facility performing Sterilization shall not remove any Sterilized materials from the Facility before completing Aeration.

(p) Reporting

- (1) The owner or operator of a Sterilization Facility shall notify the Executive Officer in the event of exceeding a limit of permitted use of Ethylene Oxide in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG within 30 days of exceeding the limit of permitted use.
- (2) The owner or operator of a Sterilization Facility shall notify the Executive Officer in the event of using more than the applicable amount of Ethylene Oxide in a calendar year as listed in Table 3 in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG within 30 days of exceeding the applicable amount.

Table 3

<u>Facility Type</u>	<u>Ethylene Oxide Usage per Calendar Year</u>
<u>Medium Facility</u>	<u>2,000 lbs</u>
<u>Small Facility</u>	<u>400 lbs</u>
<u>Other*</u>	<u>4 lbs</u>

*Any Facility other than a Large Facility, Medium Facility, or Small Facility

- (q) Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage
 - (1) No later than 24 months from the day of using 2,000 lbs or more of Ethylene Oxide within in a calendar year, the owner or operator of a Sterilization Facility, excluding a Large Facility, that uses more than 2,000 lbs of Ethylene Oxide in a calendar year shall meet the requirements specified in subparagraphs (d)(1)(A) through (d)(1)(E); (d)(2)(A) through (d)(2)(B); (d)(3)(A) through (d)(3)(B); and (d)(4)(C) through (d)(4)(E).
 - (2) No later than 24 months from the day of using more than 400 lbs of Ethylene Oxide within in a calendar year, the owner or operator of a Sterilization Facility, excluding a Large Facility or Medium Facility, that uses more than 400 lbs of Ethylene Oxide in a calendar year shall meet the requirements specified in subparagraphs (e)(1)(A)-(e)(1)(B), (e)(2)(A)-(e)(2)(C), and (e)(3)(A)-(e)(3)(B).
 - (3) No later than 24 months from the day of using more than 4 lbs of Ethylene Oxide within in a calendar year, the owner or operator of a Sterilization facility, excluding a Large Facility, Medium Facility, or Small Facility,

that uses more than 4 lbs of Ethylene Oxide in a calendar year shall meet the requirements specified in subparagraphs (f)(1)(A)-(f)(1)(B), (f)(2)(A)-(f)(2)(B), and (f)(3)(A)-(f)(3)(B).

(4) No later than 12 months from the day of exceeding the applicable Ethylene Oxide usage limit, the owner or operator of a Sterilization facility subject to the requirements of paragraphs (q)(1), (q)(2), or (q)(3) shall submit complete South Coast AQMD permit application(s) to modify existing permit conditions, modify existing equipment, or install new equipment to meet the requirements specified in paragraphs (q)(1), (q)(2), or (q)(3).

(r) Exemptions

~~The provisions of paragraph (d), "Requirements," of this rule shall not apply to any person who uses less than or equal to four pounds of ethylene oxide per calendar year.~~

(1) The requirements of subdivisions (i) and (o) do not apply to any owner or operator who is permitted to use four (4) pounds or less of Ethylene Oxide per calendar year.

(2) The requirements of subdivision (i) do not apply to any Facility subject to requirements of subdivision (d), (e), (f), or (g) pursuant to the schedule specified in Table 3 – Interim Requirements.

Table 3 – Interim Requirements

<u>Applicable Subdivision</u>	<u>Beginning Date of Exemption</u>
<u>(d)</u>	<u>December 31, 2024</u>
<u>(e)</u>	<u>July 1, 2025</u>
<u>(f)</u>	<u>December 31, 2025</u>
<u>(g)</u>	<u>[3 Months After Date of Amendment]</u>

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

(A) No Products or other materials are added or removed from Sterilizers, Combined Sterilizer/Aerators, Aerators, Post-Aerators, or Permanent Total Enclosures;

- (B) All natural draft openings (NDOs) are closed except for the purposes of exiting a Permanent Total Enclosure or restarting a Control System; and
- (C) Monitor and record the Ethylene Oxide concentration at all NDOs at least once every calendar day during the loss of power or other unplanned event outside of the control of the owner or operator using a portable photoionization detector calibrated with Ethylene Oxide or other calibrating gas, or an acceptable alternative method or analytical instrument approved by the Executive Officer. If other calibrating gases are used, the correction factor shall also be recorded and the measured readings shall be correlated to and also expressed as Ethylene Oxide.

Appendix 1 – Content of Semi-Annual Summary Reports

Semi-annual summary reports shall, at a minimum, contain the following information:

1. The company name and address of the source;
2. The date of the report, and the beginning and ending dates of the reporting period.
3. A brief description of the process units;
4. The emission and operating parameter limitations specified in the standard;
5. The monitoring equipment manufacturer(s) and model number(s);
6. The date of the latest monitoring system certification or audit;
7. The total operating time during the reporting period;
8. An emissions data summary, including the total duration of excess emissions during the reporting period (recorded in hours), the total duration of excess emissions expressed as a percent of the operating time during the reporting period, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control or monitoring equipment problems, process or process equipment problems, quality assurance, quality control calibrations, other known causes, and other unknown causes;
9. A monitoring system performance summary, including the total monitoring system downtime recorded in hours, the total duration of monitoring system downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total monitoring system downtime during the reporting period into periods that are due to monitoring equipment malfunctions, non-monitoring equipment malfunctions, quality assurance, quality control calibrations, other known causes, and other unknown causes;
10. A description of any changes in monitoring system, processes, or controls since the last reporting period; and
11. The name, title, and signature of who is certifying the accuracy of the report.

Appendix 2 – Content of Semi-Annual Excess Emission Reports

Semi-annual excess emission reports shall, at a minimum, contain the following information:

1. The name, title, and signature of who is certifying the accuracy of the report;
2. The date and time identifying each period during which the monitoring system was inoperative except for zero (low-level) and high-level checks;
3. The date and time the identifying each period during which the monitoring system was out of control;
4. The specific identification (i.e. the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, that occurs during periods other than startups, shutdowns, and malfunctions;
5. The specific identification (i.e. the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, that occurs during startups, shutdowns, and malfunctions;
6. The nature and cause of any malfunction if known;
7. The corrective action taken or preventive measures adopted;
8. The nature of the repairs or adjustments to the monitoring system that was inoperative or out of control; and
9. The total process operating time during the reporting period.

Appendix 3 – PTE Inward Face Air Velocity Measurement Procedures

1. Applicability

This method applies to an owner or operator of a Facility required to measure the inward face air velocity of each natural draft openings (NDO), defined in U.S. EPA Method 204 as “Any permanent opening in the enclosure that remains open during operation of the Facility and is not connected to a duct in which a fan is installed.”

2. Equipment – Anemometer

The anemometer shall be capable of measuring the inward face air velocity in feet per minute (fpm) within an appropriate velocity range with an accuracy within +/- 10% of full scale.

The anemometer shall be operated and calibrated per the manufacturer’s recommendations.

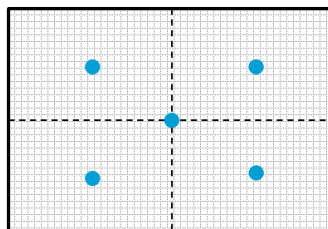
3. Test Conditions

The inward face air velocity measurement test shall be conducted while the Permanent Total Enclosure is in normal operation and under typical conditions representative of the Facility’s operations.

4. Procedure

The inward face velocity air measurements shall be taken at the plane of the NDO. The inward face air velocity measurement shall be conducted over a five-point grid pattern such as shown in the below example. For a NDO one square foot or less, the single center point may be used in lieu of the five-point grid:

Natural Draft Opening
Using a Five-Point Grid
Pattern



● = Measurement Point

The inward face velocity air measurements shall be taken at ~~the~~ the plane of the NDO.

5. Recordkeeping

The following information shall be recorded for each inward face air velocity measurement.

Anemometer Make and Model:

Anemometer Calibration Factor:

Anemometer Calibration Date:

Inward Face Air Velocity Measurements:

Natural Draft Opening Location: _____

Upper Left: _____ fpm

Upper Right: _____ fpm

Center: _____ fpm

Lower Left: _____ fpm

Lower Right: _____ fpm

Measurements Conducted by:

Measurement Date: